IP HIGH COURT DECISIONS

2023

International IP Law Research Center
of IP High Court of Korea

IP HIGH COURT DECISIONS

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FOREWORD

In today's world, knowledge and information have emerged as the most valuable assets. In the past, land, labor, and capital were the sources of wealth. Now, creative ideas, innovative technologies, and the intellectual property that protects and utilizes them have emerged as the core of new competitiveness. Intellectual property has also become a measure of national strength and serves as a source driving innovation on the global stage.

In such an era, the role of the IP High Court is becoming increasingly important in ensuring the fair and professional resolution of intellectual property disputes.

As part of its efforts to enhance international expertise, the IP High Court has hosted the International IP Court Conference annually, which celebrated its 10th anniversary in 2024. Furthermore, in April 2025, the IP High Court and WIPO co-hosted the WIPO Master Class on Intellectual Property Adjudication, where judges engaged in in-depth discussions on the latest IP issues, such as artificial intelligence and intellectual property rights. Most notably, on July 11, 2025, the IP High Court enacted the "Rules of Practice for Civil Appellate Trial before the IP High Court of Korea," which corresponds to the Patent Local Rules in the U.S. This provides a foundation for appellate proceedings to focus on grounds of appeal, thereby ensuring that trials proceed expeditiously, substantively, and predictably.

The International IP Law Research Center (hereinafter, the 'International Center'), established in 2017, has played a significant role in enhancing the IP High Court's capabilities. In particular, in 2025 the International Center was reorganized to expand its capacity, strengthen international research networks, and actively promote the IP High Court's expertise worldwide. The International Center officially launched its Advisory

Board in June 2025, consisting of prominent domestic and international figures, and in July 2025 hosted its own International Seminar, providing court members with opportunities to broaden their international perspectives. It also spearheaded the drafting and revision of the above-mentioned Rules of Practice.

In today's rapidly changing technological environment, intellectual property law is closely influenced by and interconnected with developments across borders. The 2023 IP High Court Decisions is a compilation of 13 major judgments rendered by the IP High Court in 2023, which have been translated into English. These include not only cases concerning the invalidation of patents, trademarks, and designs, but also significant rulings: a decision on the rejection of a patent application related to COVID-19 genetic vaccines; a ruling on the registrability of a trademark featuring a person's portrait; and a judgment that meticulously analyzes various contractual issues in intellectual property rights.

This casebook serves not only as a platform for sharing the IP High Court's accumulated expertise and balanced legal reasoning with the world, but also as an important cornerstone for the International Center in advancing as a world-class research institution.

The IP High Court will continue to seek legal standards befitting the changing times and further strengthen communication with the international community. I hope this casebook proves to be a valuable resource for those researching and studying intellectual property, and I extend my sincere gratitude to all the researchers of the International Center and everyone involved in its publication.

November 2025

HAN Kyu-Hyun
Chief General of the International IP Law Research Center
Chief Judge of the IP High Court of Korea

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IP HIGH COURT OF KOREA
THIRD DIVISION
DECISION

Case No.	2020Heo1212 Invalidation of Registration (Trademark)
Plaintiff	Corporation A CEO B Counsel for Plaintiff DR&AJU LCC Attorney in Charge Jongseon CHOI; DARAE Law & IP Group Patent Attorney in Charge Geumho LEE
Defendant	C Representative D Counsel for Defendant Attorney in Charge Minjeong PARK, Patent Attorney in Charge Hyeonju HONG
District Court's Decision	Seoul Central District Court 2017GaHap579373, Jul. 5, 2019
Date of Closing Argument	November 29, 2022
Decision Date	February 7, 2023

ORDER

1. The IPTAB Decision 2019Dang1273, decided on December 3, 2019, shall be revoked.

2. Costs shall be borne by the defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Background

A. Registered Trademark at Issue (Plaintiff's Exhibit 2)

1) **Registration number / Filing Date of Application / Date of Registration:** No. 1333843 / December 15, 2016 / February 23, 2018

2) **Trademark at Issue**: c o c o d'o r

3) **Designated goods**: Goods under Class 3 of the classification of the category of goods: Reed diffusers, diffuser-type air fresheners, refill products for non-electric indoor air freshener dispensers, indoor air fresheners, interior fragrances, aroma oils, automotive air fresheners, air-purifying fresheners, air fresheners for home, scented room sprays, pomanders (fragrance products), incense sticks, aromatic potpourris, and plant-based natural fragrances.

4) **Trademark right holder**: Plaintiff

B. Prior-registered Trademark (Plaintiff's Exhibit 3)

1) **Registration number / Filing Date of Application / Date of Registration / Renewal registration date:** No. 59639 / March 7, 1978 / January 17, 1979 / November 8, 2018

2) **Trademark**: COCO

3) **Designated goods**: Goods under Class 3 of the classification of the category of goods: Perfumes, perfume oils, eye shadows, eyebrow pencils, mascara, face powder, liquid makeup, general cosmetic toners, emulsions, skin lotions, cosmetic creams, eau de cologne, vanishing creams, cold creams, cleansing creams, foundation creams, lipsticks, blushes, pomades, hair oils, hair tonics, hair creams, powdery perfumes, nail polish enamels, and hair sprays.

4) **Trademark right holder**: Defendant

C. Procedural History

1) On April 23, 2019, the defendant filed a petition seeking invalidation of the registered trademark at issue (the "subject trademark") against the plaintiff, claiming: ① the subject trademark is similar to the prior-registered trademark in terms of the trademark and designated goods, thereby constituting a nullity ground falling under Article 34(1)(vii) of the Trademark Act; ② the subject trademark can cause misconception and confusion and further deceive consumers as to the source in relation with the prior-registered trademark of the defendant, which is conspicuously perceived among consumers, thereby constituting a nullity ground falling under the last part of Article 34(1)(xii) of the Trademark Act; and ③ the subject trademark constitutes a similar mark filed for the unfair purpose of taking advantage of the reputation of the prior-registered trademark to obtain undue profits, and therefore falls under the ground for invalidation under Article 34(1)(xiii) of the Trademark Act.

2) The Intellectual Property Trial and Appeal Board (the "IPTAB") reviewed the above petition by the defendant under Case No. 2019Dang1273 and rendered the decision to uphold the defendant's petition for trial on December 3, 2019, on the ground that as the "coco" portion constitutes an essential part of the subject trademark and when comparing the subject trademark with the prior-registered

trademark, the marks and the designated goods are similar, constituting a nullity ground falling under Article 34(1)(vii) of the Trademark Act (hereinafter, the "IPTAB Decision").

【Factual basis】 Undisputed facts, statements in Plaintiff's Exhibits 1 through 3, and the purport of the overall argument.

2. Parties' Arguments and Issues

A. Summary of Plaintiff's Arguments

The subject trademark does not fall within Article 34(1)(vii), Article 34(1)(xii), and Article 34(1)(xiii) of the Trademark Act for the following reasons:

1) Article 34(1)(vii) of the Trademark Act

The subject trademark shall be compared as a whole in its entirety as "cocod'or", and in this regard, the prior-registered trademark and the subject trademark are not identical or similar. Also, they do not have similar or identical designated goods.

2) Article 34(1)(xii) of the Trademark Act

As the subject trademark has a different mark and designated goods from the prior-registered trademark, it is not likely to deceive consumers.

3) Article 34(1)(xiii) of the Trademark Act

The subject trademark has a different mark and designated goods from the prior-registered trademark. At the time of its filing, the plaintiff did not have unjust purposes.

B. Summary of Defendant's Arguments

The registration of the subject mark shall be invalidated as it falls within Article 34(1)(vii), Article 34(1)(xii), and Article 34(1)(xiii) of the Trademark Act in relation to the prior-registered trademark for the

following reasons:

1) Article 34(1)(vii) of the Trademark Act

The "coco" portion of the subject trademark is identical to the defendant's prior-registered trademark, which is a well-known trademark, and thus leaves a strong impression on the general consumers and has a high distinctiveness while "d'or" portion lacks distinctiveness, as it is a French word meaning a "gold color," or "golden," and that directly expresses the color, the characteristics, and raw materials of the designated goods of the subject trademark, such as diffuser-type air fresheners, aroma oils, indoor air fresheners, etc. Therefore, in this subject trademark, the "coco" portion is relatively distinctive and well-known to the general consumers and shall be considered as an essential part. When comparing the "coco" portion, the subject trademark is similar to the prior-registered trademark. Also, air fresheners, etc., of the designated goods of the subject trademark are similar to those designated for the prior-registered trademark, which are perfumes, general cosmetic toners, skin lotions, etc.

2) Article 34(1)(xii) of the Trademark Act

The subject trademark has the "coco" portion as an essential part, which has distinctiveness, and is similar to the prior-registered trademark. The prior-registered trademark has acquired famousness by being used for a long time, and being acknowledged as the source of the defendant at the time when determining the registration of the subject trademark. In practice, the plaintiff's products on which the subject trademark is applied are creating misconception and confusion among the general consumers with the defendant's products. Hence, the subject trademark may cause misconception and confusion as to the source in relation to the prior-registered trademark and deceive consumers.

3) Article 34(1)(xiii) of the Trademark Act

The subject trademark was filed for unjust purpose of taking advantage of the reputation of the prior-registered trademark to obtain undue profits, and is similar to the prior-registered trademark of the defendant when it comes to the mark and the designated goods, which is conspicuously known among domestic consumers.

3. Whether the IPTAB Erred

A. Whether Article 34(1)(vii), Article 34(1)(xii), and Article 34(1)(xiii) of the Trademark Act can be applied

1) Issues

In order for the subject trademark to fall under Article 34(1)(vii), Article 34(1)(xii), and Article 34(1)(xiii) of the Trademark Act, the mark must be identical or similar to the prior registered trademark. Accordingly, the Court will first examine whether the two marks are similar.

2) Relevant Law

In principle, the similarity of the composite trademark consisting of two or more letters, or a letter and a figure, etc., can be determined by appearance, sound, and concept as a whole that constitute the trademark, and in some cases, the similarity of trademarks can be determined depending on the entirety of appearance, sound, and concept created by an essential part that distinguishes one's product from another's (Supreme Court Decision 2006Hu3502, decided March 29, 2007; Supreme Court Decision 2005Hu2977, decided May 15, 2008). Here, the question of whether some elements of a trademark can independently serve as an indicator that distinguishes them from those of others should be objectively determined by considering the

conception of the elements and their relations with the designated goods, as well as circumstances in the marketplace (Supreme Court Decision 2004Hu912, May 25, 2006; Supreme Court Decision 2005Hu1134, November 9, 2006).

3) Comparison of the essential part of the subject trademark

The subject trademark consists of a string of letters of the "coco" portion and the "d'or" portion. In light of the following circumstances, the "coco" portion of the subject trademark alone cannot be deemed to be an essential part that serves as an identifier of the source of the good itself.

a) The subject trademark is a writing of the same type of characters "coco" and "d'or" from left to right without the word spacing and therefore, the "coco" portion and the "d'or" portion are not visually separated.

b) The "d'or" portion is the combination of the French word "de", meaning "of," and "or", meaning "gold", and has the meaning of "something gold" overall. However, in light of the level of knowledge regarding French in Korea, general consumers will not be able to easily recognize such meanings. Hence, it is natural for the general consumers to recognize "cocod'or" as a whole rather than separately recognize the word "cocod'or" as the "coco" portion and the "d'or" portion, which is written without the word spacing and in the same character.

c) The sound of the subject trademark is just four syllables of "A" and among them, two syllables of the "coco" portion is not deemed to take a higher portion compared to the "d'or" portion, which has two syllables as well, and thus it is natural for the general consumers to sound the mark as "A."

d) It is also difficult to view that the "coco" portion has high distinctiveness compared to the "d'or" portion in the subject trademark

for the following reasons:

① According to the statements and videos in Defendant's Exhibits 1 through 14, the following facts are acknowledged: ⓐ the fact that the prior-registered trademark originated from "Coco C," a nickname of the founder E of the Defendant's company, and one of the representative newsmagazines F in the U.S., selected "Coco C" as one of "the 20th century's 100 most influential people" on April 3, 2012 and posted an article covering that the nickname "COCO" became globally famous, ⓑ the fact that the trademark "COCO" was registered in France in 1954, and applied to perfumes since 1984 and extended to various cosmetic products including body lotions, soaps, and lipsticks, etc., ⓒ the fact that cosmetic products using the prior-registered trademark are being sold in renowned domestic department stores, duty free shops, independent shops and the defendant has been actively running business through C LLC established in 1991 and the sales volume recorded 247 billon won from 2011 to 2015, ⓓ the fact that the defendant spent 56.2 billon won on advertisement from 2011 to 2015 through print advertisement, TV commercials, a standing signboard advertisement at a bus stop, etc. However, according to the evidence above, it is also recognized that the defendant's trade name "C" has been applied along with the prior-registered trademark to the advertisement and products of the defendant. Hence, the facts established above alone are not enough to conclude that the prior-registered trademark consisting only of "coco" without the mark "C," is widely recognized by consumers.

② The following facts are recognized that the letter "d'or" has been used as a part of the product names or a part of some products' color names for specific types of perfumes and cosmetic products and that the original solution of some air fresheners, perfume oils, and diffusers are a transparent yellow color. However, in light of the fact that the number of products that contain the letter "d'or" in their product names is only three, and thus it is hard to acknowledge that the letter "d'or" is commonly used in air fresheners and related

goods to present the "gold color," and that original solution of air fresheners, aroma oils, and diffusers are generally colored transparent yellow. In this regard and based on facts established above, it is not enough to view that the "d'or" portion applied to some of the designated goods of the subject trademark such as air fresheners, aroma oils, and diffusers, leads general consumers to instinctively believe that the goods with the "d'or" portion indicate the attribute (color), or raw materials, etc. In this regard, the "d'or" portion cannot be deemed to have little distinctiveness.

4) Comparison of the subject trademark and the prior-registered trademark

The subject trademark and the prior-registered trademark are not similar in appearance as they have a different composition of character strings and types, and the sounds are also different as the subject trademark sounds "A", while the prior-registered trademark is voiced "COCO", and their conception cannot be compared as they do not create special conception.

5) Summary of analysis

The subject trademark at issue is not similar to the prior-registered trademark.

B. Summary of Discussion

Since the subject trademark at issue is not similar to the prior-registered trademark, it is unnecessary to further examine the remaining issues. Accordingly, the registered trademark at issue does not fall under Article 34(1)(vii), Article 34(1)(xii), and Article 34(1)(xiii) of the Trademark Act. The IPTAB's decision is inconsistent with the above analysis. Therefore, it shall be revoked.

4. Conclusion

The plaintiff's claim requesting for revocation of the IPTAB's decision is meritorious and shall be granted.

Presiding	Judge	Hyounggeun LEE
	Judge	Eunhee PARK
	Judge	Jiyoon HAN

IP HIGH COURT OF KOREA
TWENTY-FIFTH-SECOND DIVISION
DECISION

Case No.	2021Na1039 Royalty, etc.
Plaintiff/Appellee	A Co., Ltd. Representative Director B
Plaintiff/Appellant	C Co., Ltd. Representative Director D Counsel for Plaintiffs Yulchon LLC Hyojun LEE, Sangtae JEONG Attorneys in Charge Madang Law Firm Jaecheol LEE
Defendant/Appellee/Appellant	E Co., Ltd. Representative Director F Counsel for Defendant Madang Law Firm Attorney in Charge Jaecheol LEE
District Court's Decision Date	Daegu District Court Decision 2018GaHap203887, December 17, 2020
Date of Closing Argument	May 11, 2023
Decision Date	August 24, 2023

ORDER

1. Including the claims expanded and added in the IP High Court of Korea (hereinafter 'this Court'), the district court's decision is

amended as follows:

A. The defendant shall pay to the Plaintiff A:

(1) the amount of KRW 195,344,450 together with interest thereon at the rate of 6% per annum from July 21, 2015 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made; and

(2) the amount of KRW 104,594,091, of which KRW 94,134,673 shall bear interest at the rate of 5% per annum from December 31, 2015 to December 17, 2020, and at the rate of 12% per annum from the following day until full payment is made, and of which KRW 10,459,418 shall bear interest at the rate of 5% per annum from December 31, 2015 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made; and

(3) the amount of KRW 82,600,435, of which KRW 74,340,385 shall bear interest at the rate of 5% per annum from November 10, 2016 to December 17, 2020, and at the rate of 12% per annum from the following day until full payment is made, and of which KRW 8,260,050 shall bear interest at the rate of 5% per annum from November 10, 2016 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made; and

(4) the amount of KRW 73,898,542, of which KRW 66,508,683 shall bear interest at the rate of 5% per annum from December 22, 2017 to December 17, 2020, and at the rate of 12% per annum from the following day until full payment is made, and of which KRW 7,389,859 shall bear interest at the rate of 5% per annum from December 22, 2017 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made; and

(5) the amount of KRW 47,806,207, of which KRW 43,025,582 shall bear interest at the rate of 5% per annum from October 26, 2018 to December 17, 2020, and at the rate of 12% per annum from the

following day until full payment is made, and of which KRW 4,780,625 shall bear interest at the rate of 5% per annum from October 26, 2018 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made; and

(6) the amount of KRW 102,196,024, of which KRW 38,128,305 shall bear interest at the rate of 5% per annum from December 31, 2019 to December 17, 2020, and at the rate of 12% per annum from the following day until full payment is made, and of which KRW 64,067,719 shall bear interest at the rate of 5% per annum from December 31, 2019 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made; and

(7) the amount of KRW 145,907,561, of which KRW 43,772,264 shall bear interest at the rate of 5% per annum from June 19, 2020 to December 17, 2020, and at the rate of 12% per annum from the following day until full payment is made, and of which KRW 102,135,297 shall bear interest at the rate of 5% per annum from June 19, 2020 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made; and

(8) the amount of KRW 18,649,871 together with interest thereon at the rate of 5% per annum from October 31, 2021 to August 24, 2023, and at the rate of 12% per annum from the following day until full payment is made.

B. The remainder of the claims of the Plaintiff A and the claims of the Plaintiff C are respectively dismissed.

2. Out of the total litigation costs, 10 percent of the portion arising between Plaintiff A and the defendant shall be borne by Plaintiff A, and the remainder shall be borne by the defendant; while the portion arising between Plaintiff C and the defendant shall be borne by Plaintiff C.

3. Provisional execution may be carried out with respect to Paragraph A of Article 1.

PLAINTIFF'S DEMAND and APPELLANT'S DEMAND

1. PLAINTIFF'S DEMAND

A. The Defendant shall pay Plaintiff A:

(1) the amount of KRW 287,681,531; plus the amount of money calculated by the rate of 6 percent per annum thereof from July 21, 2015 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 287,681,531 from December 18, 2020 until the date of payment in full; and

(2) the amount of KRW 104,594,091; plus the amount of money calculated by the rate of 5 percent per annum thereof from December 31, 2015 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 104,594,091 from December 18, 2020 until the date of payment in full; and

(3) the amount of KRW 82,600,435; plus the amount of money calculated by the rate of 5 percent per annum thereof from November 10, 2016 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 82,600,435 from December 18, 2020 until the date of payment in full; and

(4) the amount of KRW 73,898,542; plus the amount of money calculated by the rate of 5 percent per annum thereof from December 22, 2017 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 73,898,542 from December 18, 2020 until the date of payment in full; and

(5) the amount of KRW 47,806,207; plus the amount of money

calculated by the rate of 5 percent per annum thereof from October 26, 2018 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 47,806,207 from December 18, 2020 until the date of payment in full; and

(6) the amount of KRW 102,196,024; plus the amount of money calculated by the rate of 5 percent per annum thereof from December 31, 2019 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 102,196,024 from December 18, 2020 until the date of payment in full; and

(7) the amount of KRW 145,907,561; plus the amount of money calculated by the rate of 5 percent per annum thereof from June 19, 2020 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 145,907,561 from December 18, 2020 until the date of payment in full; and

(8) the amount of KRW 18,649,871; plus the amount of money calculated by the rate of 5 percent per annum thereof from October 31, 2021 to the decision date of the appellate judgment, and the amount of money calculated by the rate of 12 percent per annum for KRW 18,649,871 from the following date of the decision date until the date of payment in full.

2. The Defendant shall pay Plaintiff C the amount of KRW 456,223,325 plus the amount of money calculated by the rate of 6 percent per annum thereof from July 21, 2015 to December 17, 2020, and the amount of money calculated by the rate of 12 percent per annum for KRW 456,223,325 from December 18, 2020 until the date of payment in full.

[The plaintiffs expanded their demand in the decision by this Court, added violation of trade secret and the exclusive license for patents as the cause of action concerning the claim for damages after the termination of the agreement, and added the claim for penalty as the

selective cause of action.]

2. APPELLANT'S DEMAND

A. PLAINTIFFS

The judgment of the district court shall be modified as follows: The relief sought by the plaintiffs' shall be granted (In light of the amendment of the claims made before this Court as set forth above, demand of the plaintiffs in the appeal is also deemed to have been amended accordingly, which are concisely stated as above).

B. DEFENDANT

The portion of the judgment of the district court unfavorable to the defendant shall be reversed, and the plaintiff's corresponding claim shall be dismissed.

OPINION

1. Background

A. Status of the Parties

1) Plaintiff A Co., Ltd. (hereinafter, "Plaintiff A") is a company engaged in manufacturing and sales of industrial machinery and molds, and Plaintiff C Co., Ltd. (hereinafter, "Plaintiff C") is a company engaged in manufacture, processing, and sales of various secondary products for concrete. The defendant is a company engaged in manufacturing, processing and sales of various secondary products for concrete.

2) G is a person who engages in the business of manufacture and sales of concrete products under the trade name of "Takashimizu Concrete" and who also developed Sansoo block series as below and holds intellectual property rights thereto, including the patents, design rights, trademark rights, and technical know-how.

"Sansoo View" Products	"Sansoo Bank" Products	"Sansoo Step" Products
		

B. Execution of the License Agreement between G and Plaintiff A

1) In around April 2003, Plaintiff A executed an agreement on the license for technical guidance and know-how concerning artificial stone concrete blocks, metal forms, construction tools, and connecting rods (hereinafter, the "Initial License Agreement"). The main terms of the Initial License Agreement are as follows.

Article 1 (Purpose of the Agreement and the Matters to be Confirmed)

1. The licensor (referring to G, hereinafter the same) developed artificial stone concrete blocks, forms (metal molds), and connecting rods; holds valuable technical know-how thereof; and applied for and registered patent and design for such artificial stone concrete blocks and forms (metal molds) in Japan and the Republic of Korea. The licensee (referring to Plaintiff A, hereinafter the same) desires to obtain from the licensor a sublicense to sell the imitation concrete blocks, forms (metal molds), construction tools and connecting rods by using and based on the relevant patent rights, design rights and technical know-how (hereinafter, the "permitted methods") and

the licensor intends to grant such license to the licensee on the conditions set forth below. The licensor and the licensee hereby agree to set forth the terms of this agreement concerning technical guidance and know-how license.

2. The licensor and the licensee affirm that they will comply with the provisions set forth in this Agreement regardless of whether the patent and design concerning the permitted methods, filed by the licensor, are granted or recognized in the Republic of Korea.

Article 2 (Definitions)

1. The terms used in this Agreement are defined as follows.
(a) “Present Patent” refers to granted patents and pending patent applications in countries listed in Annexed Table A.
(b) “Present Design” refers to a granted design and pending design applications in countries listed in Annexed Table A.
(c) “Technical know-how” refers to the technical know-how held by the licensor.
(d) “Contract Products” collectively refer to Sansoo View products, forms (metal molds), Sansoo Bank products and each construction tool and connecting rods.

Article 3 (Permission)

1. The licensor authorizes the licensee to manufacture and sell Sansoo View products, molds (metal molds), Sansoo Bank products, construction tools, and connecting rod by using the patents, designs, and technical know-how thereof in the relevant region.

2. The licensor and the licensee confirm that the scope of the license under the preceding paragraph does not include the use of methods for manufacturing Sansoo Bank molds (metal molds) and the right to manufacture and sell them. However, the resale of Sansoo Bank molds (metal molds) in the licensed territory shall not be prohibited.

3. Pursuant to Article 9, the licensee has the right to sublicense the rights in Paragraph 1 in the relevant region.

Article 9 (Sublicense Agreement)

1. The licensee shall not authorize the permitted methods to a person other than the third party in the relevant region, who has entered into a sublicense agreement in accordance with the conditions in the following paragraph, and shall use its best efforts to conclude such sublicense agreement.

Article 10 (Response to Infringement)

1. Upon discovering a third party's infringement of a patent right, design right, or unfair competition in relation to the technical know-how, etc. in the region, the licensee shall notify such infringement to the licensor by providing obtained evidentiary materials without delay.

2. In relation to the preceding paragraph, the licensee shall seek necessary legal measures to eliminate such infringement under its own name and at its own expense.

Article 13 (Term of Agreement)

This Agreement shall take effect from the date of execution. Unless it is terminated by other provisions in this Agreement, it shall remain effective for 10 years, regardless of whether there is any pending and unfiled invention, or any future patent rights or design rights, irrespective of their status or changes over time.

Annexed Table A

(1) Patent No. 2881642 registered in Japan as of the date of this Agreement (Sansoo View)
(2) Patent No. 2562790 registered in Japan as of the date of this Agreement (Shape of color) (Sansoo View, Sansoo Bank, and Sansoo Step)
(3) Patent No. 3056699 registered in Japan as of the date of this Agreement (Sansoo Bank)
(4) Patent No. 3266876 registered in Japan as of the date of this Agreement (Sansoo Bank)
(5) Patent No. 3266877 registered in Japan as of the date of this Agreement (Sansoo Bank)

(6) ① Patent No. 2002-282552 registered in Japan as of the date of this Agreement

② Patent Application corresponding to the above ①, pending as of the date of this Agreement in the Republic of Korea

(Items ① and ②: Sansoo View)

(7) ① Japanese Design Application No. 2002-24804, pending as of the date of this agreement

② Korean Design Application corresponding to the above ①, pending as of the date of this Agreement

(Items ① and ②: Sansoo Bank)

2) Thereafter, with respect to the Initial License Agreement, Plaintiff A was granted by G additional permission for the manufacture and sale of Sansoo Step products and molds that were not included in the above Agreement.

3) When the Initial License Agreement expired on April 30, 2013, Plaintiff A signed an agreement with G on May 1, 2013, for the purport of extending the said Agreement for another ten (10) years (hereinafter, the "License Agreement at Issue"). The terms of the License Agreement at Issue are the same as the Initial License Agreement, except for the additions and modifications set forth below.

[Portions of the Initial License Agreement Added and Modified in the License Agreement at Issue]

Article 2 (Definitions)

1. The terms used in this Agreement are defined as follows.

(a) "Present Patent" refers to a granted patents and a pending patent application in countries listed in Annexed Table A.

(b) "Present Design" refers to a granted design and a pending design application in countries listed in Annexed Table A.

(c) "Technical know-how" refers to the technical know-how held by the licensor.

(d) "Contracted Products" collectively refer to Sansoo View products, Sansoo View forms (metal molds), Sansoo Bank products, Sansoo Bank forms (metal molds), Sansoo Step products, Sansoo Step forms (metal molds), and each construction tool and connecting rod.

Annexed Table A

(1) Patent No. 2881642 established in Japan as of the date of this Agreement (Sansoo View)
(2) Patent No. 2562790 established in Japan as of the date of this Agreement (Shape of color) (Sansoo View, Sansoo Bank, and Sansoo Step)
(3) Patent No. 3056699 established in Japan as of the date of this Agreement (Sansoo Bank)
(4) Patent No. 3266876 established in Japan as of the date of this Agreement (Sansoo Bank)
(5) Patent No. 3266877 established in Japan as of the date of this Agreement (Sansoo Bank)
(6) Patent No. 2652780 established in Japan as of the date of this Agreement (Sansoo Step)
(7) ① Patent No. 2002-282552 granted in Japan as of the date of this Agreement
② Patent No. 0583322 granted in the Republic of Korea as of the date of this Agreement
(Items ① and ②: Sansoo View)
(8) ① Design Application No. 2002-24804, pending in Japan as of the date of this Agreement
② Design No. 032449 granted in the Republic of Korea as of the date of this Agreement
(Items ① and ②: Sansoo Bank)
(9) ① Patent No. 4181433 granted in Japan as of the date of this Agreement
② Patent No. 0676449 granted in the Republic of Korea as of the date of this Agreement
(Items ① and ②: Sansoo Bank)
(10) ① Trademark No. 4162527 registered in Japan as of the date of this Agreement
② Trademark No. 0570468 registered in the Republic of Korea as of the date of this Agreement

C. Content of Sansoo Block-related Intellectual Property Rights Held by Plaintiff A, etc.

1) Exclusive license, etc. to the patent rights, etc. held by G

Pursuant to the Initial License Agreement and the License Agreement at Issue, the plaintiff A has acquired the exclusive license or exclusive right to use the patent on the "Formwork for Artificial Stone Concrete Blocks and Its Manufacturing Method" (Registration No. 0583322, hereinafter, the "Patent 322"), the patent on the "Concrete Blocks and Construction Tools Used for Shore Protection, etc." (Registration No. 0676449, hereinafter, "Patent 449"), the design on the "Blocks for Shore Protection" (Registration No. 0329449, hereinafter, "Design 449"), and the trademark  (Registration No. 0570468, hereinafter, the "Sansoo Trademark"). The specifics are as follows.

a) Patent 322
   (1) Title of invention: Formwork for Artificial Stone Concrete Blocks and Its Manufacturing Method
   (2) Application date / Registration date / Registration number: October 23, 2002 / May 18, 2006 / No. 0583322
   (3) Patentee / Exclusive licensee: G / Plaintiff A
   (4) Content of the exclusive license
      (a) Registration date of the exclusive license: July 29, 2013
      (b) Period: From July 20, 2013 to October 23, 2022
      (c) Region: Throughout the Republic of Korea
   (5) Claims

[Claim 1] A formwork consisting of an artificial stone formwork (5) and a lateral formwork (72) of a concrete block with an artificial stone (11) placed on the surface, wherein metal mesh (41) is laid on the bottom part (51) of the said artificial stone formwork (5), and a

reinforcing stake (43) of a metal rod is installed on the lateral part (54) of the said artificial stone formwork (5), a resin as a base material is mixed with a fiber made by shortening a monofilament to form a rough artificial stone formwork (5), the said resin as a base material is cut off from the said artificial stone formwork (5) to expose the said fiber to make it fluffy, a resin mixed with the fiber made by shortening the monofilament is applied as a thin layer on the lateral side (54) of the said artificial stone formwork (5), and the formwork on the lateral side (72) of a block-making device (7) is put into contact with the resin applied on the lateral side (54) of the said artificial stone formwork (5) to increase the degree of sealing of the two.

[Claim 2] Manufacturing method of the formwork stated in the above Claim 1 (The specifics omitted).

(6) Main drawings

Fig. 1

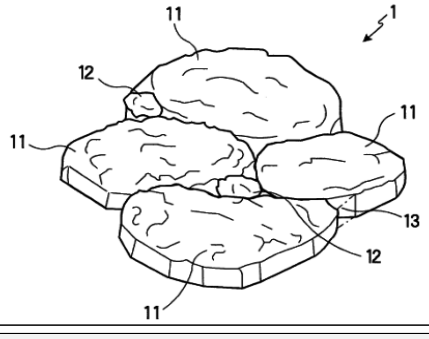


Fig. 6

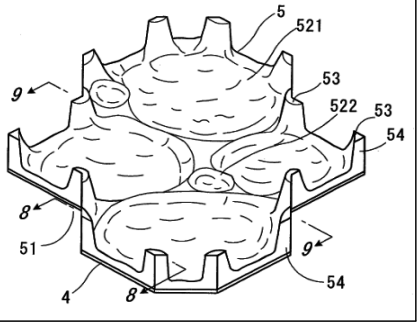


Fig. 4a

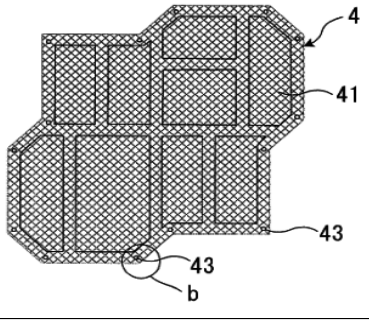
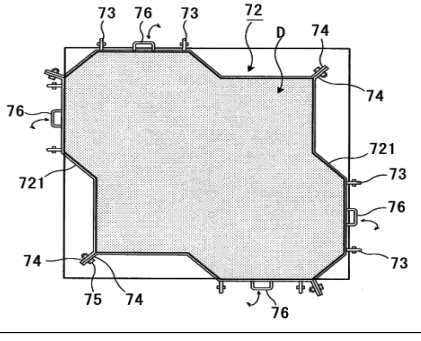


Fig. 10a



b) Patent 449

(1) Title of invention: Concrete Blocks and Construction Tools Used for Shore Protection, etc.

(2) Application date / Registration date / Registration number: September 23, 2003 / January 24, 2007 / No. 0676449

(3) Patentee / Exclusive licensee: G / Plaintiff A

(4) Content of the exclusive license
(a) Registration date of the exclusive license: July 29, 2013
(b) Period: From July 20, 2013 to September 23, 2023
(c) Region: Throughout the Republic of Korea

(5) Claims (This claim section was revised in accordance with the petition for correction on February 7, 2022. Underlined parts are the ones which were revised.)

[Claim 1] A concrete block, wherein a cast stone used for shore protection, etc. is laid, whose unit block is composed of the face part (2) and the base (3), which is a polygonal shape consisting of a straight line to enable continuous attachment construction in all directions by having the same exterior, the joint of the base part (3) of each block (1) of which is zigzag-shaped to form a rainwater channel, with each corner chamfered at 45 degrees, and wherein an embankment is installed between the perimeter of the said unit block and the said cast stone, with the top part of the said embankment being zigzag-shaped and the lateral part being wave-shaped, a through hole for a construction penetrating rod and also for anchoring the unit block is installed in the upper and lower directions around the two ends of the said unit block, with the said penetrating rod being installed in a straight line in the upper and lower directions when the said unit block is assembled, and a recessed part forming water-permeable cuts is

installed in the openings of the said penetrating rod.

[Claim 2] Omitted

(6) Main Drawings

Fig. 1	Fig. 2a

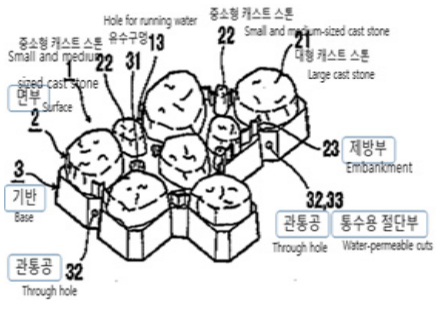
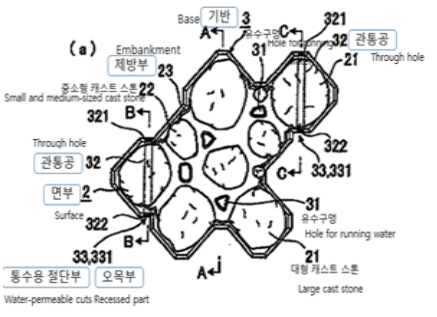
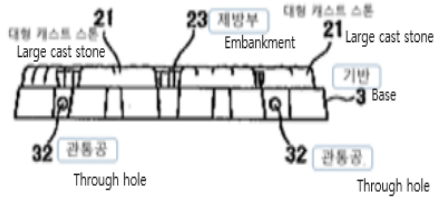
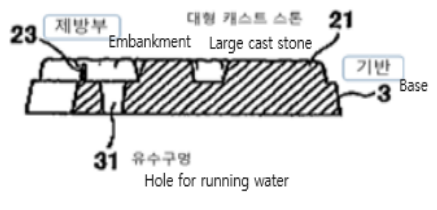

	

Fig. 3	**Fig.4 (Cross-sectional drawing along the A-A line in Fig. 2a)**
	

c) Design 449

(1) Article to which design is applied: blocks for shore protection

(2) Application date / Registration date / Registration number: October 22, 2002 / July 14, 2003 / No. 329449

(3) Patentee / Exclusive licensee: G / Plaintiff A

(4) Content of the exclusive license

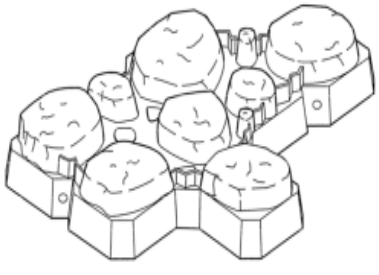
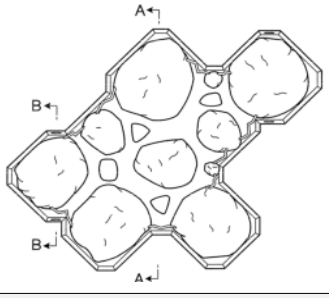
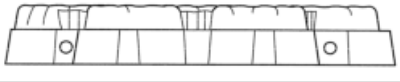
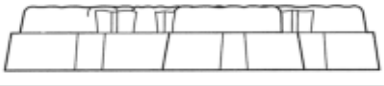
(a) Registration date of the exclusive license: July 30, 2013

(b) Period: From July 20, 2013 to July 14, 2018

(c) Region: Throughout the Republic of Korea

(5) Summary of the design creation: The combination of the shape and configuration of the "block for shore protection" is the focal point of the design creation.

(6) Main Drawings

Perspective View	Top View
	
Front View	**Left Side View**
	

d) Sansoo Trademark

(1) Application Date / Registration Date / Registration Date of Extension / Registration Number: October 22, 2002 / December 29, 2003 / June 21, 2013 / Registration No. 0570468

(2) Patentee / Exclusive Licensee: G / Plaintiff A

(3) Content of the Exclusive License

(a) Registration Date of the Exclusive License: July 30, 2013

(b) Period: From July 20, 2013 to December 31, 2023

(c) Region: Within the whole territory of the Republic of Korea

(4) Mark: 

(5) Designated Goods: Class 19 of artificial stone made of concrete, artificial stone blocks made of concrete, concrete blocks. Artificial stone made of cement mortar. Artificial stone blocks made of cement mortar.

2) Utility model rights of Plaintiff A, etc.

Plaintiff A holds the utility model for "blocks for vegetation shore protection" (Registration No. 0350401; hereinafter, "Utility Model 401") and the utility model for the "artificial stone manufacturing mold" (Registration No. 0376485, hereinafter, "Utility Model 485"), and the Representative Director B of Plaintiff A holds the utility model for "environment-friendly concrete blocks for shore protection construction" (Registration No. 0324531, hereinafter, "Utility Model 531) and the utility model for "terraced artificial stone blocks" (Registration No. 0327403, hereinafter, "Utility Model 403"), and the specifics are as in Appendix 1.

3) Technical know-how concerning the manufacture of Sansoo block products

Plaintiff A acquired the right to use the technical know-how concerning the manufacture of Sansoo block products under the Initial License Agreement and the License Agreement at Issue. The specifics of the technical know-how claimed by Plaintiff A are set forth in Appendix 2.

D. Execution of the Agreement between the Plaintiff A and the Defendant

On June 6, 2005, Plaintiff A executed an agreement with the defendant on technical guidance and know-how license concerning Sansoo View products, Sansoo Bank products, and Sansoo Step products (hereinafter,

collectively referred to as the "Sansoo block products"), regarding which Plaintiff A acquired from G the right to manufacture and sell the Sansu block products. Around June 16, 2008, Plaintiff A executed another agreement (hereinafter, the "Agreement at Issue") to amend the said agreement, such as adding a provision to grant Plaintiff C the right to deliver 20 percent of the defendant's orders. The main terms of the Agreement at Issue are as follows.

Technology provider: Plaintiff A
Technology adopter: Defendant

Article 1 (Purpose of the Agreement and the Matters to be Confirmed)

1. A (referring to Plaintiff A, hereinafter the same) was granted by a Japan-based company G, which developed artificial stone concrete blocks (hereinafter, "Sansoo blocks"), manufacturing metal molds and forms, construction tools and each connecting loop thereof, the right to transfer technology, patent rights, design rights, and utility model rights, and possesses valuable technical know-how thereabout, and applied for or registered the establishment of the relevant patent rights, utility model rights and designs in the Republic of Korea and Japan. B (referring to the defendant, hereinafter the same) desires to acquire from A the right to manufacture and sell Sansoo blocks and sell construction tools and connecting rods by using the relevant patent rights, design rights and technical know-how (hereinafter, the "permitted methods") in Gwangju and Jeollanam-do, Republic of Korea based on the relevant technical know-how, patent rights, and design rights, and A intends to grant a non-exclusive license (hereinafter, "non-exclusive license") to B in accordance with the conditions set forth below.

2. A and B affirm that they will comply with the provisions set forth in the Agreement regarding permitted methods regardless of whether each application of A's patents, utility models, and designs is recognized in the Republic of Korea.

Article 2 (Definitions)

The terms used in this Agreement are defined as follows.

(a) The present patent, utility model, and design refer to patent rights, utility model rights, design rights, and pending patent applications in the

Republic of Korea and Japan as stated in this Agreement.

(b) Technology refers to all technical information possessed by A.

(c) The contracted products collectively refer to Sansoo View products, Sansoo View metal molds, Sansoo Bank products, Sansoo Bank metal molds, Sansoo Step products, Sansoo Step metal molds, each construction tool, connecting rod, and subsidiary materials for Sansoo blocks.

Article 3 (Permission)

1. A grants to B a non-transferable right to use a non-exclusive right to the permitted methods based on such permitted methods with respect to the contracted products in order to manufacture and sell them in the relevant region.

3. In any case, B shall not have the authority to grant to a third party or for other products the re-execution of the permitted methods of the contracted products granted by A.

Article 4 (Provision of Technical Know-how and Technical Assistance)

1. During the effective period of this Agreement, A shall provide B with the technology necessary for using the permitted methods of the contracted products. Provided, this shall not apply to each metal mold, construction tool, connecting rod, and subsidiary materials for Sansoo blocks of the contracted products.

Article 6 (Royalty)

B shall pay A a technical fee (hereinafter, "royalty") for the grant of the non-exclusive license under this Agreement in the amount and manner described below.

A royalty on the net sales of the contracted products at the following rates:

① B shall pay A seven (7) percent of the net sales of Sansoo View products.

② B shall pay A five (5) percent of the net sales of Sansoo Bank products.

③ B shall pay A seven (7) percent of the net sales of Sansoo Step products.

④ B shall submit to A a notification stating the name of the store, the name of the construction at the construction site, the map of the delivery location, the quantity of sales, the amount of sales, and the amount of royalty for the contracted products manufactured and sold using the

permitted methods during the period specified in the [Manufacture and sales period] of this paragraph by the date specified in the [Notification and payment date] below, and shall pay A the royalty by transferring it to the bank account designated by A by the same due date.

[Manufacture and Sales Period]	[Notification and Payment Date]
(1) January 1 – June 30, each year	July 20 of the same year
(2) July 1 – December 31, each year	January 20 of the following year

⑤ B shall keep such books and records that are necessary for verifying the calculation of the royalties set forth in Article 6(1) and (2), and shall allow a certified public accountant designated by A to inspect and review such books and records at A's expense.

Article 7 (Technology Improvements and Mutual Use)

A shall promptly initiate and provide to B any and all improvements with regard to the permitted methods during the term of this Agreement.

Article 11 (Sales, Production, Supply, and Order of the Contracted Products)

1. The defendant C, an exclusive licensee to the patent rights of A, is allowed to engage in sales activities in B's contracted region to boost the sales of the contracted products.

2. A shall not grant a non-exclusive license to any other partner companies in the contracted region (Gwangju and South Jeolla Province) without the consent of B.

3. The defendant C, designated by A, shall have the right to produce and deliver 20% of the products ordered by B's business activities in the contracted region, and similarly, B shall have the right to produce and deliver 20% of the products ordered by the business activities of the defendant C, designated by A, in the contracted region.

5. A and B shall pay operating expenses for 20% of the total quantity of the products ordered by the other party pursuant to Paragraph 2. The operating expenses shall be actual expenses, and the amount not exceeding 10 percent of the delivery amount (total delivery amount after deducting value-added tax and freight) shall be paid to the other party that ordered the products. In such case, the royalty in Article 6 shall be paid to A based on the quantity of products produced and delivered by B.

Article 14 (Addition of Sansoo Series)

When B requests A to add items other than the contracted items of

Sansoo blocks in response to the market demand, the items may be added to the contracted items upon mutual consultation.

Article 16 (Duty of Confidentiality)

3. Upon the termination of this Agreement, regardless of the reason, B shall dispose of the confidential information received from A under A's instructions, such as by immediately returning or destroying it, and shall not use the permitted methods provided to B in connection with other products.

Article 17 (Disclaimer of Warranty)

1. A makes no representation or warranty that the use of the Permitted Methods provided to B under this Agreement will not infringe upon any third party's patent rights or design rights.

Article 18 (Term of Agreement)

1. This Agreement shall become effective on the date of the deposit of the contract amount and, unless terminated under other provisions hereof, shall remain effective for three (3) years from the effective date, regardless of any pending patents, the existence of the relevant invention, or any future patent or design rights, whether acquired, withdrawn, dismissed, or extinguished. B shall not be entitled to request any reduction of the royalty hereunder, and neither party shall have the right to terminate this Agreement.

B may extend this Agreement by giving a written notice to A at least three (3) months prior to the expiration of this Agreement and on terms agreed upon by both parties.

4. The duty of confidentiality under Article 16 shall survive the termination of this Agreement (including termination by expiration of the term).

Article 19 (Termination of the Agreement)

In any of the following cases, A may terminate this Agreement by giving a written notice to B stating the fact of the termination, the effective date of termination, and reasons therefor.

1. Where B delayed the payment or report required under this Agreement by 40 or more days;

2. Where B neglected to pay or report, or perform any other duty prescribed hereunder, and received a warning from A to correct such

negligence, but failed to correct it within 30 days from receiving the warning; and

3. Where B violated any order of distribution (engaging in sales activities in a region other than the contracted region, etc.) or price range with regard to the manufacture and sales of the contracted products

4. Upon termination hereof, B shall pay A the royalty prescribed in this Agreement for all the products manufactured after the termination regardless of whether such products were sold or not. As to the products manufactured but not settled or sold, the net sales shall be calculated based on the sales price of the same products of the preceding year.

Article 21 (Transfer and Succession)

1. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of both parties. However, any assignment of this Agreement by B, in whole or in part, shall not be effective unless and until A gives prior written consent. Nevertheless, this shall not apply to statutory transfers or effects as provided by law.

Article 22 (Force Majeure)

Neither party shall be held responsible for any loss or non-performance of this Agreement, occurring from natural disasters, fire, war, government regulations of the Republic of Korea or Japan), or any other causes that are beyond the parties' control.

E. Notification of the termination of the Agreement by Plaintiff A

On February 10, 2015, Plaintiff A sent a content-certified mail to the defendant, stating that Plaintiff A would terminate the Agreement at Issue on the grounds that the defendant had breached it by failing to pay the royalties stipulated therein properly.

F. Sales of Sansoo Block Products by the Defendant

The defendant manufactured and sold Sansoo block products as follows, from which the defendant generated unreported sales revenue totaling KRW 6,673,096,443 (including VAT) between June 6, 2005, and February 10, 2015, as shown in Table 1 of Appendix 3, and

KRW 6,714,307,116 (including VAT) between February 11, 2015 and October 30, 2021, as shown in Table 3 of Appendix 3.

Sansoo View products	Sansoo Bank products	Sansoo Step products
		

G. Confirmation of Invalidation of Registration of Patent Rights Concerning Sansoo Block Products, Etc.

1) On May 15, 2013, the Intellectual Property Trial and Appeal Board (IPTAB) issued an administrative decision to invalidate the registration of Utility Model 401 held by Plaintiff A. It further issued decisions to invalidate the registration of Utility Model 531 held by Plaintiff B on May 28, 2013, and Utility Model 403 on February 18, 2013. Each of the aforementioned invalidation decisions was confirmed around that time.

2) On April 19, 2022, the IPTAB issued an administrative decision to invalidate the registration of Claim 1 of Patent 449 held by G. G initiated a case requesting the revocation of the IPTAB decision with this Court. Nevertheless, the IP High Court of Korea issued a decision to dismiss the claim raised by G on March 10, 2023 (see IP High Court of Korea Decision 2022Heo3588, dated March 10, 2023).[1)]

1) G appealed the above decision made by the IP High Court of Korea, but the Supreme Court issued a decision on June 29, 2023, after the closing date of the arguments in this case, dismissing the appeal by discontinuing the trial, thus confirming the above decision of invalidation of registration of Claim 1 of the 499 Patent (2023Hu10330).

3) Upon expiration of its term of registration on December 11, 2014, Utility Model 485 held by Plaintiff A was expired.

【Factual basis】 Undisputed facts, statements in Plaintiff's Exhibits 1, 7, 8, 21, 22, 24-27, Defendant's Exhibits 1, 4-8 (including Exhibits with branching numbers, hereinafter the same), replies of fact-finding inquiries requested by this Court and the district court to the Administrator of Gwangju Regional Office of Public Procurement Service, and the purport of the overall argument.

2. Discussion on Royalty Claim Concerning Sales during the Term of the Agreement

A. Summary of Plaintiffs' Arguments

1) Plaintiff C's claim concerning its 20 percent delivery rights

Pursuant to Article 11(3) of the Agreement at Issue, the defendant is obligated to grant Plaintiff C 20 percent of the total number of deliveries received from its business activities. However, between June 16, 2008, when the defendant agreed to grant 20 percent delivery rights to Plaintiff C, and February 10, 2015, when the Agreement at Issue was terminated, the defendant received contracts for Sansoo block products worth a total of KRW 8,279,035,243 (including VAT), as shown in Table 2 of Appendix 3. Instead of allowing Plaintiff C to perform 20 percent of such deliveries, the defendant carried out all of them directly, in violation of Article 11(3) of the Agreement at Issue.

Accordingly, the defendant is obligated to pay Plaintiff C, as damages incurred from the breach of Article 11(3) of the Agreement at Issue, KRW 456,223,325, the profit that Plaintiff C would have earned if it had delivered 20% of the defendant's orders, that is, an amount equal to 20 percent of the sales as shown in Table 2 of Appendix 3, less

production costs, value-added tax, and operating expenses, plus liquidated damages arising from July 21, 2015 (or, alternatively, the defendant is obligated to return to Plaintiff C the amount of money gained by unjust enrichment equivalent to the aforementioned amount).

2) Plaintiff A's claim for royalties

a) Pursuant to Article 6 of the Agreement at Issue, the defendant is obligated to pay Plaintiff A royalties for the sales amount of Sansoo block products. Accordingly, the defendant is obligated to pay KRW 287,681,531 as royalties[2] for 80 percent of Sansoo block products received and delivered by the defendant between June 6, 2005, when the Initial Agreement was executed, and February 10, 2015, when the Agreement at Issue was terminated, plus liquidated damages arising from July 21, 2015, which is the day following the due date[3] for the payment of said royalties.

b) On the other hand, the reason why the plaintiff only claims royalties for 80 percent of Sansoo block products ordered and delivered by the defendant in Paragraph A is that Plaintiff claims for damages related to the delivery rights or amount of unjust enrichment, as described in Paragraph 1, for the remaining 20 percent. And if the damages or amount of unjust enrichment related to the 20 percent delivery rights in Paragraph 1 are not acknowledged, the plaintiff seeks payment of royalties for the above 20 percent of the deliveries preliminarily.[4] In other words, if the claim in Paragraph 1 is not acknowledged, the defendant is obligated to pay Plaintiff A KRW 6,066,451,316 (excluding VAT), i.e., the unreported net sales of Sansoo block products not declared to Plaintiff A, plus the royalty of

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2) Net sales, excluding VAT, to which the royalty rate for each Sansoo block product (7 percent for Sansoo View, 7 percent for Sansoo Step, and 5 percent for Sansoo Bank) is applied.

3) See Article 6(4) of the Agreement at Issue.

4) See page 8 of the plaintiffs' brief dated November 29, 2021.

KRW 389,000,513[5] to which royalty rate, established for each Sansoo block product in the Agreement at Issue, is applied, and liquidated damages on the royalty calculated from July 21, 2015.

B. Discussion on Plaintiff C's Claim Concerning Its 20 Percent Delivery Rights

1) Based on the aforementioned fact established and the purport of the overall argument, it can be acknowledged that Plaintiff C was entitled to the right to deliver 20 percent of the Sansoo block deliveries ordered by the defendant's sales activities (Article 11(3) of the Agreement at Issue), and that the defendant won the contract for the deliveries of Sansoo block products as listed in Table 1 of Appendix 3 during the term of the Agreement at Issue, but did not let Plaintiff C deliver 20 percent of them, and instead delivered all of them directly.

But Article 23 of the Agreement at Issue prescribes, "Neither party shall be held responsible for any loss or non-performance of this Agreement, occurring from natural disasters, fire, war, government regulations, or any other causes that are beyond the control of the parties." Taking into consideration the purport of the overall argument in accordance with the statements in Plaintiff's Exhibit 4, Defendant's Exhibit 23, and replies of fact-finding inquiries requested by this Court and the district court to the Administrator of Gwangju Regional Office of Public Procurement Service, it can be acknowledged that the defendant, as a small and medium-sized enterprise (SME), supplied Sansoo block products to public institutions such as the state and local governments by the order of the Administrator of the Office of Public Procurement Services. In the event where the head of a public institution signs a product procurement contract by means of competition among SMEs or signs a product procurement contract with an SME by means of a private contract pursuant to the proviso of

5) See Table 1 of Appendix 3 for the specific statement of calculations.

Article 7 of the Act on Contracts to which the State is a Party (hereinafter, the "State Contract Act"), the head of the public institution has to confirm whether the SME directly produces the products (see Article 9 of the Act on Facilitation of Purchase of Small and Medium Enterprise-Manufactured Products and Support for Development of their Markets), and if the SME that signed the product procurement contract, after being confirmed as meeting the direct production standards, delivers products in violation of the direct production standards, it may be subject to restrictions on the bidding qualifications of inappropriate business entities pursuant to Articles 27(1)1 and 27(1)9(b) of the State Contract Act and Article 76(2)2(a) of the Enforcement Decree of the State Contract Act. If this is the case, that the defendant, in executing the contract for delivery of Sansoo block products that it received, did not deliver the products produced directly by itself and let the defendant C deliver 20 percent of the volume of orders received is deemed to be a prohibited act in accordance with the government regulation, and thus, even if the defendant did not grant the 20 percent delivery rights to Plaintiff C is under the category of the violation of Article 12(3) of the Agreement at Issue, it is reasonable to consider that the defendant shall not be held responsible for damages pursuant to Article 23 of this Agreement at Issue.

Therefore, it is difficult to accept Plaintiff C's claim for damages concerning the 20 percent delivery rights based on the violation of Article 12(3) of the Agreement at Issue.

2) While Plaintiff C alternatively claims the return of the amount of unjust enrichment in relation to the 20 percent delivery rights, it is difficult to perceive that the profits that the defendant made from the delivery of Sansoo block products to the public institution under the Agreement at Issue were obtained without legal cause, and there is no evidence supporting that the defendant obtained profits without legal cause in relation to the 20 percent delivery rights. Therefore, Plaintiff C's claim for return of the amount of money gained by unjust

enrichment in relation to the 20 percent delivery rights is also unacceptable.

C. Discussion on Plaintiff A's Claim for Royalties

1) Incurrence of duty to pay royalties

Since the grounds for this Court's judgment is the same as "1) Incurrence of the duty to pay royalties" (From line 15 on page 11 to line 4 on page 15 of the district court's written judgment) on page 11 of the district court's written judgment, except that the "It is reasonable to deem that the object of the Agreement at Issue is ..." part on lines 16-19 on page 11 of the district court's written judgment is modified as follows, this Court accepts such statement pursuant to the body of Article 420 of the Civil Procedure Act.

"It is reasonable to deem that the object of the Agreement at Issue includes the sublicense right and technical know-how necessary for manufacturing Sansoo block products based on the non-exclusive license, to manufacture and sell Sansoo block products, that Plaintiff A acquired from G as well as the utility model rights[6], concerning Sansoo block products, held by Plaintiff A."

2) Judgment on the scope of duty of royalty payment

Since the grounds for this Court's judgment is the same as "2) Discussion on the scope of duty of royalty payment" (From line 6 on page 15 to line 12 on page 16 of the district court's written judgment) on page 16 of the district court's written decision, except that the part

6) Referring to Utility Model 401 and Utility Model 485 held by Plaintiff A. Since the Agreement at Issue is an agreement executed by and between Plaintiff A and the defendant, it is difficult to deem that Utility Model 531 and Utility Model 403 held by B became the object of the Agreement at Issue unless there is definite contractual provision. This is true even considering the fact that B is the Representative Director of Plaintiff A and that Utility Model 531 and Utility Model 403 appear to be related to *Sansoo* block products.

from line 3 from the bottom on page 15 to line 12 on page 16 of the district court's written judgment is modified as follows, this Court accepts such statement pursuant to Article 420 of the Civil Procedure Act.

"In accordance with the Agreement at Issue, the defendant is obligated to pay Plaintiff A royalties for Sansoo block products sold between June 6, 2005, and February 10, 2015, the period during which the Agreement at Issue was in effective. Since the Agreement at Issue sets forth that royalties shall be calculated as the amount of net sales, by deducting VAT from the total sales (although the defendant claims that freight shall be additionally deducted, there is no basis to deem that such additional deduction must be made under the Agreement at Issue), multiplied by a royalty rate for each product under the Agreement at Issue. Because the defendant sold Sansoo block products, as shown in Table 1 of Appendix 3, between June 6, 2005 and February 10, 2015, the defendant is obligated to pay Plaintiff A 389,000,513 KRW[7], i.e. the royalties calculated by multiplying the net sales, from selling the said Sansoo block products, and the royalty rate for each product, plus liquidated damages."

3) Judgement on the defendant's argument

Since the grounds for this Court's judgment is same as "3) Judgement on the defendant's argument" (From line 14 on page 16 to line 9 on page 19 of the district court's written judgment) on page 16 of the district court's written judgment, except that the "B) Judgement on defense concerning completion of extinctive prescription" part is modified as follows and the "C) Judgement on claiming amount reduction due to invalidation of utility model rights" part is added, this

7) Since the claim concerning 20 percent delivery rights was not accepted as shown in the "B. Discussion on Plaintiff C's Claim Concerning Its 20 Percent Delivery Rights" part, royalties were calculated for 100 percent of the deliveries in accordance with the preliminary claim by Plaintiff A.

Court accepts such statement pursuant to the body of Article 420 of the Civil Procedure Act.

b) Judgment on defense concerning completion of extinctive prescription

(1) The defendant counter-argues that royalties for the products delivered before May 8, 2013, the date when five years had elapsed counting backward from May 8, 2018, were extinguished by the completion of the five-year extinctive prescription.

In accordance with the aforementioned basic facts, since the Agreement at Issue is subject to a commercial act executed for business between merchants, the commercial extinctive prescription of 5 years applies to the royalty obligation under the Agreement at Issue. Furthermore, pursuant to Article 6 of the Agreement at Issue, the maturity date of royalties for products sold between January 1 and June 30 of each year falls on July 20 of the same year, and the maturity date of royalties for products sold between July 1 and December 31 of each year arrives on January 20 of the following year. According to the statements in Plaintiff's Exhibit 3, the fact that Plaintiff A's peremptory notification on November 16, 2017 to the defendant to perform the royalty obligation is acknowledged, and it is clear from the record that this case was initiated on May 8, 2018 before 6 months had elapsed therefrom. Therefore, it is clear that the extinctive prescription of the royalty obligation was suspended by the said notification dated November 16, 2017.

Accordingly, since the royalties whose maturity date arrived five (5) years before November 16, 2017, that is, the royalties for the products[8] sold before June 30, 2012 were extinguished by the completion of five (5)-year extinctive prescription, the defendant's defense concerning

8) The maturity date of the products sold before June 30, 2012, is July 20, 2012, or earlier. Since the maturity date of the products sold after July 1, 2012 is January 20, 2013 or later, the prescription was suspended by the peremptory notification dated November 16, 2017.

completion of extinctive prescription is reasonable within the scope of the above recognition.

(2) In response to it, Plaintiff A claims with the purport that the prescription of the royalty obligation was suspended since this case was initiated on May 8, 2018, before the lapse of six (6) months from the date of peremptory notification by certified mail after repeated peremptory notices of its obligations.

However, Article 174 of the Civil Act sets forth that in the event that peremptory notification, which is stipulated as the reason for suspension of prescription under the said Article, has been made several times, the effect of suspension does not occur at the time of initial peremptory notification, but rather, at the time of peremptory notification made within six (6) months retrospectively from the date of judicial claims, etc. (see Supreme Court Decision 83Daka437, dated July 12, 1983; Supreme Court Decision 2018Du56435 dated March 14, 2019). However, there is no evidence to prove that Plaintiff A notified the defendant's performance of its obligations before the completion of prescription of each royalty payment obligation other than the certified mail dated November 16, 2017. And as described above, since it is evident that the extinctive prescription of the products sold before June 30, 2012 was completed on July 20, 2017, the date when five (5) years have elapsed from the maturity date, which was July 20, 2012, the said peremptory notification by certified mail dated November 16, 2017 is merely a peremptory notification after the completion of prescription and does not have any effect of suspending the prescription. Therefore, the plaintiff's above argument is groundless.

(3) In addition, considering the facts that even though the defendant had to diligently submit a notification on the statement of manufacture and sales of Sansoo block products, the defendant submitted a notification omitting such statement, and that Plaintiff A could get a sense of the scale of sales of the defendant only after requesting a fact-finding inquiry to the Procurement Service Office

through this litigation, it is deemed that the defendant seriously interfered with Plaintiff A's exercise of rights or Plaintiff A's suspension of prescription, or the defendant made Plaintiff A's exercise of its rights or Plaintiff A's suspension of prescription impossible. Therefore, Plaintiff A claims that the defendant's argument about completion of extinctive prescription falls under the category of abuse of rights and shall not be permitted.

Since a debtor's exercise of the rights of defense based on extinctive prescription is controlled by the principle of due diligence and the principle against abuse of rights, which are the basic principles of the Civil Act of the Republic of Korea, in the event where a debtor makes it impossible or considerably difficult for a creditor to exercise its right or to suspend prescription before the completion of prescription; where a debtor engages in any act that led the creditor to believe that such measures are unnecessary; where there is an objective cause making the creditor unable to exercise its rights; where the debtor acted in a manner of not intending to invoke prescription upon the completion of prescription and led the rightholder to believe that way; where there is an exceptional circumstance, such as a creditor, requiring the more significant need for creditor protection and having same conditions, receives payment of debt, which makes it considerably unjust or unfair to recognize the refusal to pay the debt, the defendant's argument of completion of extinctive prescription is in violation of the principle of due diligence and thus cannot be permitted as abuse of rights (see Supreme Court Decision 98Da42929, dated December 7, 1999; Supreme Court Decision 2002Da32332 dated October 25, 2002).

However, according to the Agreement at Issue, although the defendant is obligated to notify Plaintiff A of the details of the delivery contract, if any, regarding Sansoo block products (Article 6(4) of the Agreement at Issue), Plaintiff A had the right to access and review the defendant's book records necessary for calculating royalties and was therefore able to check the exact details of the defendant's delivery despite the defendant's inadequate notification (Article 6(5) of the

Agreement at Issue). Therefore, even if the defendant was not acting in good faith in notifying the manufacturing and sales details, it cannot be said that such circumstance alone rendered it impossible or considerably difficult for Plaintiff A to claim royalties. In addition, there are no circumstances to indicate that the defendant acted in a manner that led Plaintiff A to believe that it was unnecessary to take action to suspend the prescription, or that the defendant would not invoke the prescription after the completion of extinctive prescription. Therefore, the circumstance alone claimed by Plaintiff A does not indicate that the defendant's defense concerning extinctive prescription falls under the category of abuse of rights, and Plaintiff A's above argument is groundless.

c) Judgment regarding claim on amount reduction due to invalidation of utility model rights

(1) Summary of the defendant's argument

In addition to the sublicense rights to the G's patents, etc., the object of the Agreement at Issue also includes the non-exclusive license to the utility model rights (Utility Model 401, Utility Model 531, and Utility Model 403) related to Plaintiff A's Sansoo block products. Since all of the above utility model rights have been invalidated and extinguished after execution of the Agreement at Issue, the royalties payable by the defendant shall be reduced by at least 50 percent.

Even though Article 18(1) of the Agreement at Issue stipulates that "... shall survive a pending patent, an invention of the relevant application, and any future patent rights or design rights of such application, whether or not acquired, withdrawn, dismissed, or extinguished. B shall not be entitled to any reduction of the royalty for such reason, and no mid-term rescission of the contract shall be authorized by either party," the above provision which does not allow a request for reduction of the amount even in the event where utility model rights, the object of the Agreement, are extinguished, constitutes

a legal act contrary to public policy. And therefore, it shall be deemed to be invalid as it violates Article 103 of the Civil Act.[9)]

(2) Whether Article 18(1) of the Agreement at issue is invalid

Since whether the defendant's above reduction claim is acknowledged or not depends on whether Article 18(1), prohibiting such request for reduction of the amount, of the Agreement at Issue in this case is invalid or not, this issue will be examined first.

(a) Relevant law

An act against social order invalid under Article 103 of the Civil Act is a comprehensive concept that includes the case where the content of rights and duties, the purpose of a legal act, is in violation of good social order or other social order, the case where the content of rights and duties itself is not against social order, but is of anti-social order nature since the law compels it or conditions of anti-social order or financial consideration is attached thereto, or the case where the motive, expressed or known to the other party, of a legal act is against social order. The case where a business entity, a party to legal action, is in a superior position due to a difference in

9) The defendant also argues that the above provision is invalid because it is subject to an unfair term, but since the defendant entered into the Agreement at Issue after conducting special negotiations on the Agreement at Issue on an equal footing with Plaintiff A, and there seems to have been a sufficient possibility of modifying certain provisions in the process, that it is reasonable to consider the provisions of the Agreement at Issue as an individual agreement to which the Regulation of Standardized Contracts Act does not apply is deemed to have already discussed on pages 16 and 17 of the district court's written judgment which this Court accepts, and this shall not be discussed as a separate argument. In addition, the defendant argues that Article 1(2) of the Agreement at Issue violates Article 103 of the Civil Act, which is unacceptable, and the defendant also argues that Articles 16(3) and 17(1) violates the said Article, but since that provision is not directly relevant to the defendant's claim for reduction of royalties, only the argument as to whether Article 18(1) of the Agreement at Issue violates Article 103 of the Civil Act will be examined here.

economic power and can use its position to gain an unfair advantage for itself and to impose an excessive counter payment or an unfair burden on the other party and where compelling it can be deemed to be not having social validity is the relevant example and also shall be invalidated (see Supreme Court Decision 94Da34432, dated April 26, 1996; Supreme Court Decision 2017Da229048, dated September 7, 2017).

However, the inclusion of a provision in a patent exploitation contract that provides for the continued existence thereof until the termination of the contract even when the patent right is extinguished due to patent invalidation, etc. and the continued payment of royalties stipulated in the exploitation contract until the termination of the contract after expiration or invalidation of the patent right may result in the patentee being able to receive royalties from the licensee even during the period[10] when the patentee is no longer able to perform the exploitation contract due to the extinguishment of the patent right, and this may be considered an unfair advantage to the patentee and an unfair burden on the licensee. In particular, the case where the patentee includes such provision in the patent exploitation contract by taking advantage of its superior trading position may violate the Monopoly Regulation and Fair Trade Act (hereinafter, "Fair Trade Act") unless it is acknowledged that there is a reasonable cause of inclusion of such provision,[11] and its legal validity as well may be

10) Unless it is impossible to practice a patented invention that is the purpose of the license contract regarding the patented invention, notwithstanding the retroactive effect of the invalidation of the patent, the license contract regarding the patented invention which was executed with respect to such patent cannot be regarded that it has been in the state of prima facie impossibility of performance from the time of entering into the contract, but the contract shall be deemed to fall into the state of impossibility of performance upon confirmation of the invalidation of the patent (see Supreme Court Decision 2012Da42666, dated November 13`, 2014 and Supreme Court Decision 2018Da287362, dated April 25, 2019)

11) The Fair Trade Act stipulates that an act of trading with the other party by

negated as a legal act in violation of good customs and other social order.[12)]

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unfairly taking advantage of its trading position, which may impede fair trade, is an unfair trade practice prohibited under the Act (Article 45(1)6 of the Fair Trade Act). In addition, the established rule no. 389 "Guidelines for Examination of Unfair Exercise of Intellectual Property Rights" of the Fair Trade Commission lists "unfairly charging royalties, including the period after the extinguishment of patent rights" as one of the acts that can be deemed to be beyond the scope of the legitimate exercise of patent rights.

12) Article 627(1) of the Civil Act stipulates, "If a part of the leased object cannot be used or profited from due to destruction or other reasons without negligence of the lessee, the lessee may claim a reduction of the rental fee in proportion to that part," and since the case where a part of the patent becomes extinguished by invalidation or other reasons during the term of the license contract of the patent right is similar to the reduction claim in the case where the part of the leased object cannot be used or profited from due to destruction or other reasons, it is not impossible to apply Article 652 (which stipulates that an agreement that violates the provisions of Article 627 of the Civil Code, etc. and is unfavorable to the lessee shall be invalid) to the patent license contract by analogy and to reason that an agreement that prevents the licensee from claiming reduction of royalties despite the extinguishment of the patent right is in violation of mandatory provisions and is thus invalid. However, the provisions of Article 652 of the Civil Act (mandatory provisions) relating to lease contracts are intended to protect the lessee, who is a socially disadvantaged person, and it is difficult to prescribe the relationship between the patentee and the licensee in a patent license contract as a relationship between a socially disadvantaged person and a strong person (for instance, it is easy to postulate a situation where a patent license contract is executed in a circumstance where a large company intends to use the patent rights held by a small and medium-sized company), it may be unreasonable to apply Articles 627 and 652 of the Civil Act, which are mandatory provisions for leases, to patent license contracts by analogy, and to view reduction prohibition provisions as uniformly invalid. Rather, it is judged that the following is the logic which can lead to a more reasonable conclusion regarding whether the provision prohibiting the request for reduction of amount in a patent license contract is invalid or not: After examining specific details and process of the negotiation regarding the patent license contract in a detailed way, if it falls under the category of unjust abuse of superior position by the patent holder, then it constitutes a violation of

However, whether the content of a legal act such as a contract is invalid as a juristic act contrary to good morals and other social order as set forth in Article 103 of the Civil Act shall not be judged by a uniform abstract standard, but instead shall be judged by examining the substance of the contract in a specific case (see Supreme Court Decision 2022Da287383, dated February 23, 2023). In particular, in the event that an exploitation contract is entered into regarding multiple patented inventions, or regarding other intellectual property rights such as trademarks, designs, know-how or trade secrets in addition to patent rights, and how to adjust the royalty when some of the multiple rights are extinguished can be decided within the reasonable scope of negotiation between the parties. And it cannot be deemed that imposing a uniform rule regarding the extinguishment of rights and the reduction of royalties while restricting the principle of freedom of contract of the parties always brings fair and reasonable results. Therefore, it should not be rashly concluded that a contract violates the Fair Trade Act or is absolutely invalid without examining the circumstances that led to such contract, solely because, in a patent license contract, no reduction of royalties was recognized after some rights were extinguished, resulting in the receipt of royalties even after the rights were extinguished.

Furthermore, the fact that the patentee has exclusive rights to the patented invention does not automatically lead to the conclusion that in the license contract the patentee has a superior position in the transaction. Rather, the nature and market share of the patent rights that are the purpose of the exploitation contract, the difference in the economic power of the patentee and the licensee, the circumstances under which such contract was executed, the content of the contract, and other relevant factors must be explicitly taken into account to

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the Fair Trade Act and it falls under the category of a juristic act which is contrary to good morals and other social order. Based on the aforementioned grounds, the judicial effect of the patent exploitation contract is to be denied.

determine whether the patentee has a superior position in the transaction.

(b) Analysis

In light of the relevant law, in this case, the subject matter of the Agreement at Issue encompasses various intellectual property rights, including patents, designs, trademarks, utility models, and technical know-how related to the *Sansoo* block products, and there is a possibility that improvement technologies based on Plaintiff A's technology development may be added as the subject matter of the license contract in the future (Article 7(1) of the Agreement), so it would not have been easy to allocate the royalty rates accurately, (7% for *Sansoo* View, 7% for *Sansoo* Step, and 5% for *Sansoo* Bank) set forth in the Agreement at Issue, for each individual intellectual property right at the time when the Agreement at Issue was executed.[13] Furthermore, since the term of the Agreement at Issue is relatively short (3 years) compared to the remaining period of existence of the object of the license contract, there is room for both parties to initiate negotiation anew regarding how much the extinguished rights etc. will be reflected in determining the royalty rates in a renewed contract when renewing the contract after the termination of the contract. And there is also a possibility that both parties may terminate the contract without renewing it. Thus, even if it seems rather disadvantageous to the defendant to maintain the initial royalty rates after the extinguishment of some rights pursuant to Article 18(1) of the Agreement at Issue in this case, the term during which the parties are bound by such Agreement does not seem unreasonably long. Taking these circumstances into account comprehensively, it is difficult to reach the conclusion that Article 18 of the Agreement at Issue is a considerably unreasonable provision, which stipulates that the Agreement shall continue to exist during the term of the Agreement regardless of whether any specific intellectual property rights have been extinguished or not, and that it is

13) Plaintiff A and the defendant did not even include the list of the specific content of intellectual property rights in the Agreement at Issue when executing it.

not permitted to request a reduction of royalties based on such reason.

In addition, since the market share of *Sansoo* block products, to which Plaintiff A has exclusive rights in the Republic of Korea under the license agreement with G, in the market for concrete retaining wall blocks is not on the record, there is no evidence that it is difficult to enter the concrete retaining wall block market without the exploitation of the exclusive license and utility model rights held by Plaintiff A, and there is no evidence that there is a difference in economic power between Plaintiff A and the defendant that makes it difficult for them to negotiate on an equal footing. Therefore, it is difficult to conclude that the inclusion of the above provision in the Agreement at Issue is the result of Plaintiff A's taking advantage of its position in the course of transaction.

Accordingly, the sole circumstance alleged by the defendant cannot render Article 18 of the Agreement at Issue invalid for violation of Article 103 of the Civil Act, and there is no evidence sufficient to acknowledge the defendant's argument.

(3) Possibility of royalty reduction according to the principle of good faith and the concept of equity

Whether royalty reduction may be acknowledged in accordance with the principle of good faith or equity, notwithstanding the validity of Article 18 of the Agreement at Issue, will be discussed.

(a) Relevant law

In principle, it is not permissible for a court to reduce a portion of payment when the creditor is seeking performance of the payment under a contract that was validly established (see Supreme Court Decision 2012Da64253, dated October 15, 2015). However, when a creditor's exercise of its rights is impermissible in light of the principle of good faith, negating it may be permitted exceptionally (see Supreme Court En Banc Decision 2016Da35833, dated May 17, 2018), but since restricting the validly established contractual responsibilities, based on general principles such as the principle of equity and the

principle of good faith may pose a serious threat to the principle of private autonomy or legal stability, permission to negate a creditor's exercise of his rights should be acknowledged only in extremely exceptional cases with utmost care (see Supreme Court Decision 2003Da45410, dated January 27, 2004; Supreme Court Decision 2011Da66252 dated July 12, 2013).

(b) Analysis

Taking into account the above relevant law, it is difficult to say that it is unacceptable not to permit the reduction of royalties in light of the following circumstances, even considering the fact that the utility model rights, the object of the Agreement at Issue, were extinguished due to invalidation or other reasons during the term of the Agreement, and there is no evidence to support exceptional circumstances that require the reduction of royalties based on the principle of due diligence.

① The object of the Agreement at Issue encompasses various intellectual property rights, including Utility Model 401 and Utility Model 531 owned by Plaintiff A, and Patent 322, Patent 449, Design 449, the Sansoo trademark, and technical know-how for manufacturing Sansoo blocks, and other related rights owned by G and to which Plaintiff A has the right to sublicense (The Utility Model 531 and Utility Model 403, confirmed to be invalidated, do not belong to the object of the Agreement at Issue since they belong to the utility models owned by B, not Plaintiff A).

② Although Utility Model 401 was declared invalid on May 15, 2013, during the term of the Agreement at Issue, the decision to invalidate Utility Model 401 (Defendant's Exhibit 2-3) shows that Utility Model 401 was invalidated for violation of the extended first-to-file rule on the grounds that it is substantially the same as the idea stated in the specification of G's Patent 449. If so, despite the invalidation of Utility Model 401, a third party may still be unable to exploit the technology which is within the scope of

protection of Utility Model 401 due to the proprietary and exclusive effect of G's Patent 449 covering all the technical scope of Utility Model 401, and thus, it seems that such invalidation does not make much difference in the substance of the non-exclusive license provided to the defendant under the Agreement at Issue.

③ Even though the IPTAB made a decision to invalidate the registration of Claim 1 of Patent 449 on April 19, 2022, the time when such decision was made is after February 10, 2015, which is after the termination of the Agreement at Issue, and thus, notwithstanding the decision to invalidate the registration, it can be deemed that the exploitation by a third party was practically prohibited during the term of the Agreement at Issue due to the proprietary and exclusive effect concerning Claim 1 of Patent 449. Accordingly, the said invalidation decision cannot be deemed to have made the Agreement at Issue fall into the state where performance is impossible (see Supreme Court Decision 2018Da287362, dated April 25, 2019, etc.).

④ On December 11, 2014, which was during the term of the Agreement at Issue, the Utility Model 485 was extinguished due to the expiration of the term. However, it is difficult to conclude that not acknowledging the reduction of royalties [calculated] from the expiration date of the duration of Utility Model 485 to the date of the termination of the Agreement is in violation of the principle of good faith in light of the [following] facts: that both parties could know the expiration date of the term of Utility Model 485 either at the time of signing the Initial Agreement on June 6, 2005, or at the time of execution of the Amended Agreement on June 16, 2008[14]; that when the parties executed the Amended Agreement on June 16, 2008, they agreed on three (3)-year term of the Agreement so that the agreed term of the Agreement terminates before the expiration of the term of

14) Therefore, the expiration of the duration of the 485 Utility Right cannot be deemed to be an unexpected change of circumstances.

Utility Model 485; that the defendant implicitly renewed the Agreement at Issue by continuing to manufacture and sell Sansoo block products after the expiration of the three-year contract duration, and did not claim a reduction in the royalty on the grounds of the expiration of the term of Utility Model 485 until the Agreement at Issue was terminated by the plaintiff's notice of termination due to the defendant's non-performance of the Agreement; that Utility Model 485 concerns the manufacturing mold of Sansoo Step, and that it is difficult to regard that a third party can freely manufacture and sell Sansoo Step even if the duration of Utility Model 485 has expired because various intellectual property rights, including technical know-how relating to the manufacturing of Sansoo Step, are included in the subject matters of the Agreement at Issue in this case.[15)]

(c) Summary of analysis

Accordingly, pursuant to Article 18 of the Agreement at Issue in this case, the defendant cannot seek a reduction on the grounds that the utility model right, the object of the Agreement at Issue, was extinguished, and it is difficult to regard that it would be a breach of the principle of good faith for Plaintiff A to continue to collect the royalties thereunder. Therefore, the defendant's claim for reduction of royalties is without merit.

4) Summary of conclusion

Therefore, the defendant is obligated to pay Plaintiff A KRW 195,344,450[16)], the total amount of royalties calculated by multiplying

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15) Considering that the defendant could at any time terminate the Agreement at Issue by giving notice of termination after the Agreement was implicitly renewed (application of Articles 639 and 635 of the Civil Act by analogy), it would not be against the principle of good faith for Plaintiff A to continue to charge the royalty as stipulated in the Agreement because the defendant continued to use the subject matters of the Agreement, such as Plaintiff A's intellectual property rights, etc., not casting off the constraint of the Agreement.

16) See Appendix 4 for the details of royalties relating to each product type.

the net sales of Sansoo block products sold from July 1, 2012 to February 10, 2015 by the royalty rate for each type of product, plus liquidated damages calculated by the rate of 6 percent per annum for the said amount as prescribed by the Commercial Act from July 21, 2015, the following day of the final maturity date sought by Plaintiff A, to August 24, 2023, the decision date, when the defendant is deemed to have substantial grounds to contest the existence or scope of the performance obligation, and liquidated damages calculated by the rate of 12 percent per annum for the said amount as prescribed by the Act on Special Cases concerning Expedition etc. of Legal Proceedings from August 25, 2023 until the date of payment in full.

Plaintiff A's claim regarding the abovementioned part is meritorious to the extent acknowledged, and the remainder of Plaintiff A's claims are without merit.

3. Discussion on Claim for Damages Concerning Sales After Termination of the Agreement at Issue

A. Summary of Plaintiff A's Arguments

1) Even after February 10, 2015 when the Agreement at Issue was terminated, the defendant continued to sell Sansoo block products, as shown in Table 3 of Appendix 3. Since the defendant's such act falls under the category of (1) infringement of trade secrets, (2) infringement of the exclusive license for Patent 322, (3) infringement of the exclusive license for Patent 449, (4) infringement of the exclusive license for Design 449, (5) infringement of the exclusive license for the Sansoo trademark, and (6) infringement of the sole non-exclusive license[17], the defendant is obligated to compensate Plaintiff A for such damage arising from the aforementioned infringements.

17) Referring to the obligation right, which the plaintiff acquired from G under the Agreement at Issue, to exclusively manufacture and sell *Sansoo* block products.

	Trade Secret	Patent 322	Patent 449	Utility Model 485[18]	Design 449	Sansoo Trade-mark	Sole License
Sansoo View	◯	◯[19]				◯[20]	◯
Sansoo Bank	◯		◯[21]		◯[22]	◯[23]	◯
Sansoo Step	◯					◯[24]	◯

2) Article 19(4) of the Agreement at Issue prescribes that regardless of whether all the products manufactured after the termination of the Agreement at Issue were sold or not, a penalty equivalent to the royalty as stipulated in the Agreement at Issue shall be paid. Therefore, the defendant, who was a party to the Agreement at Issue, is obligated to pay a penalty equivalent to the royalty, under Article 19(4) of the Agreement at Issue, for Sansoo block products manufactured and sold

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18) Plaintiff A, if the termination date of the Agreement at Issue is prior to February 10, 2015, preliminarily claims for damages for infringement of Utility Model 485 with regard to the sale of *Sansoo* Step products prior to December 11, 2014, when Utility Model 485 was extinguished by the expiration of the term. However, as discussed above, the Agreement at Issue was terminated on February 10, 2015, so preliminary claim will not be discussed here.

19) An act of selling *Sansoo* View products after July 29, 2013 when the exclusive license for Patent 322 was registered

20) An act of selling *Sansoo* View products after July 30, 2013 when the exclusive license for the *Sansoo* trademark was registered

21) An act of selling *Sansoo* Bank products after July 29, 2013 when the exclusive license for Patent 449 was registered

22) An act of selling *Sansoo* Bank products from July 30, 2013 when the exclusive license for Design 449 was registered until July 14, 2018 when the exclusive license for Design 449 was expired

23) An act of selling *Sansoo* Bank products after July 30, 2013 when the exclusive license for the *Sansoo* trademark was registered

24) An act of selling *Sansoo* Step products after July 30, 2013 when the exclusive license for the *Sansoo* trademark was registered

after the termination of the Agreement at Issue.

3) With respect to the claims for damages described in Paragraph 1, the joinder of the claims for damages for infringement of each right is subject to ordinary joinder, and the relation between the claim for damages described in Paragraph 1 and the claim for penalty equivalent to the royalties described in Paragraph 2 is subject to alternative joinder. The specific details of the claims against the defendant for damages relating to the sales after the termination of the Agreement at Issue are set forth in Appendix 5.

B. Discussion on Whether Trade Secrets Were Infringed

1) Plaintiff A alleges that the defendant has infringed upon Plaintiff A's technical know-how described in Appendix 2, that is, the trade secret regarding pigment formulation and mortar application methods, concrete molding and vibrating methods, mold release and coating methods, etc., which was granted through the sole non-exclusive license according to the license agreement in this case.

2) Pursuant to Subparagraph 2 of Article 2 of the former Unfair Competition Prevention Act (the former one which is prior to the amended Act, Act No. 13844 on January 27, 2016), the term "trade secret" is the one that is not publicly known and has independent economic value. And it denotes a production method, sales method, and other technical or managerial information useful for business activities which has been kept as secret through reasonable efforts. Here, "not publicly known" means that the information cannot be obtained if not through the information holder because there is no occasion that the information is published in a medium, such as publications, that the information is not known to unspecified persons (see Supreme Court Decision 2002Da60610, dated September 23, 2004). "Has independent economic value" means that the information holder may gain a competitive advantage over competitors through making use of it, or that the acquisition or development of the

information would require a considerable amount of costs or efforts (see Supreme Court Decision 2005Do6223, dated February 15, 2008). "Being kept in secret through reasonable efforts" means that it is in the state of being recognizable that the information is being kept and maintained in confidence, by mark or notification so that the information would be recognized as a secret, restricting personnel who can access the information or access methods, or imposing the duty of confidentiality on those who have gained access to the information. Whether such efforts for maintenance and management were reasonable shall be decided by comprehensively taking into account the specifics of preventive measures taken by the trade secret holder, the operational necessity to permit access to the relevant information, the trust relationship between the holder and the infringer, and the degree of such relationship, economic values of the trade secret, and the business scale and economic capacity of the trade secret holder (see Supreme Court Decision 2017Do13791, dated October 31, 2019).

3) First, when examining as to whether pigment formulation and mortar application methods, concrete molding and oscillating methods, mold release and coating methods, etc. contain any contents which belong to trade secrets, in light of the circumstances which can be figured out by comprehensively considering the purport of the testimony of witness Tae-Hwan PARK in the district court's decision and of the overall argument in the statements in Defendant's Exhibits 3, 21 and 22, there is not enough ground to conclude that the information which Plaintiff A alleges to be trade secret actually falls under the category of trade secret based on the statement in Plaintiff's Exhibit 15 alone, and there is no other supporting evidence for it to be acknowledged as a trade secret.

a) Plaintiff A argues that ① the mixing ratio of mortar using monochromatic pigment, silica sand, cement, water, etc., ② the type and application amount of release oil, ③ the prevention of loss of pigment using a shovel, etc., ④ the use of a high-frequency oscillator

and a rod oscillator in combination to control viscosity and remove blisters, and ⑤ the method of using the above technical know-how by appropriately modifying it according to changes in seasons and weather are not the information disclosed to the public, but instead are special technical know-how.

b) If the mixing ratio of mortar or the specific amount of application of release oil were specified in a specific numerical range, such information regarding numerical range would likely be recognized as a trade secret. However, in this case, Plaintiff A only argues that "the appropriate mixing ratio of mortar" and "the appropriate application amount of release oil" are important technical know-how, but does not argue that Plaintiff A provided detailed information to the defendant, such as the numerical range of the specific mixing ratio and the numerical range of the application amount and detailed types of release agent. Furthermore, there is no evidence to support that Plaintiff A provided detailed information beyond the scope of technical know-how that is generally used in the process of concrete production when giving a lecture on the production process of Sansoo block products to employees of Shinsung Concrete.

c) The technical know-how claimed by Plaintiff A does not contain any information beyond the information on how to mix pigments and cement "appropriately," which is a commonly used technique for making mortar of the desired color. Also, it is deemed that spraying "appropriate" release agent or using an oscillator "appropriately" to stabilize the concrete mix into place is no more than a commonly used technique in the concrete production process.

d) In light of the circumstances above, even if the technical know-how alleged by Plaintiff A has some economic value in relation to the manufacture of Sansoo blocks, it is difficult to judge that the information is not publicly known because it does not seem that the content of it is something which cannot be generally acquired if not through the information holder. In addition, considering the fact that

Plaintiff A included a comprehensive provision on duty of confidentiality in the Agreement at Issue in this case, objectively it is difficult to deem that the fact that the information is being kept and managed as a secret is recognizable.

4) Therefore, Plaintiff A's claim that the trade secrets were infringed on the premise that the technical know-how which Plaintiff A alleges falls under the category of trade secrets is without merit.

C. Discussion on Whether the Exclusive License for Patent 322 Was Infringed

1) Plaintiff A argues that the defendant's manufacturing and sales of Sansoo View products is an infringement of the exclusive license for Claim 1 of Patent 322 (hereinafter, the "Claim 1 of Patent 322") since the formwork of the defendant's Sansoo View products contains all elements of Claim 1 of Patent 322 as stated in Appendix 6. Plaintiff A also argues that Claim 2 of Patent 322 (hereinafter, "Claim 2 of Patent 322"), which is an invention relating to a method of manufacturing a formwork of the invention of Claim 1 of Patent 322, contains substantially the same content as the invention of Claim 1, differing only in the category of invention, and that therefore the defendant has infringed the exclusive license for Claim 2 of Patent 322 by manufacturing and selling Sansoo View products.

2) As examined, Plaintiff's Exhibit 20-2 shows the appraisal results that the formwork of Sansoo View products contains all the elements of Claim 1 of Patent 322,[25] but the appraisal above does not compare the formwork which is related to the defendant's Sansoo View products with the patented invention. But it is merely the result of comparing the formwork which is related to Plaintiff A's Sansoo View products, specifying the formwork as the invention in question, with

25) It is actually the same as the results of comparison of components listed in Appendix 7.

Patent 322. Plaintiff's Exhibit 20-2 uses the logic that "It is judged that if the cured concrete structure is the same, it must be that the formwork for manufacturing the cured concrete structure exists as the same structure"[26] as a medium in concluding that the formwork of Plaintiff A's Sansoo View products and the formwork of the defendant's Sansoo View products are the same structure as these products have substantially the same form. However, based on the statement in Defendant's Exhibit 19, it seems that it is possible to produce the same form of the Sansoo View product as the one produced by Plaintiff A by using a different metal mold (a formwork made of iron castings in which the entire mold that produces the artificial stone pattern is made of a single material)[27] which is not included in the scope of protection for Claim 1 invention because it does not include the "metal mold (Element 1-2)" or "reinforcing stakes of metal rods (Element 1-3)" of Claim 1 invention of Patent 322. If that is the case, in this case where the defendant argues that it uses a formwork different from that of Plaintiff A, it is insufficient to conclude that the defendant's Sansoo View formwork infringes upon Claim 1 of Patent 322 based only on the fact that the shape of the blocks, the final output, is the same. And there is no evidence to support that the formwork used by the defendant is the same as Plaintiff A's formwork or includes all the elements of Claim 1 of Patent 322.

3) Therefore, it is difficult to conclude that the defendant's manufacture and sales of Sansoo View products have infringed the exclusive license for Claim 1 invention of Patent 322, and for the same reason, it is difficult to conclude that the defendant infringed upon the Claim 2 invention, an invention related to the method of manufacturing a formwork. Therefore, Plaintiff A's claim of infringement of the exclusive license for Patent 322 is without merit.

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26) See pages 2 and 9 of Plaintiff's Exhibit 20.

27) See the description of the challenged invention in Defendant's Exhibit 19.

D. Discussion on Whether the Exclusive License for Patent 449 Was Infringed

1) While Plaintiff A argues that the defendant's Sansoo Bank products infringe upon claim 1 of Patent 449, the defendant argues in defense that, since it is obvious that the registration of the said claim will be invalidated, the exercise of rights based on that claim falls under the category of the abuse of rights.

2) Even before the court has come to the final decision on invalidation for the patented invention, in the event where it is obvious that the patent will be invalidated by a patent invalidation decision due to the denial of the inventive step of the patented invention, the claims for injunction or for damages based on the patent right are not allowed because they constitute abuse of rights unless there are special circumstances. Furthermore, since the court in charge of patent infringement litigation may also examine and determine whether the patented invention has inventive step not as a prerequisite for examining the claim of the patentee that such claim constitutes an abuse of rights (see Supreme Court En Banc Decision 2010Da95390, dated January 19, 2012), the defendant's defense argument will be discussed first for the sake of convenience of discussion.

3) According to Defendant's Exhibit 25, it can be acknowledged that the IP High Court of Korea, in its judgment on March 10, 2023, denied the inventive step of Claim 1 of Patent 449 on the grounds of a combination of Prior Art 1 (Japanese Patent Publication Special 2001-32289) and Prior Art 6 (Utility Model Publication 20-1975-892) (see IP High Court of Korea Decision 2021Na1022, dated March 10, 2023). Considering the grounds for the foregoing decision comprehensively, it appears obvious that the inventive step of Claim 1 of Patent 449 will be denied and that the patent will accordingly be invalidated.[28)]

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28) In fact, the above decision rendered by the IP High Court Korea was concluded on June 29, 2023, after the closing of the date for argument in this case, and

4) Thus, the claim for damages with the reason of infringement of the exclusive license for Claim 1 of Patent 449 is not permissible because it constitutes an abuse of rights. Therefore, the defendant's argument for defense on this point is well-grounded, and Plaintiff A's claim regarding this part is without merit.

E. Discussion on Whether the Exclusive License for Design 449 Was Infringed

1) Relevant law

Since the similarity of design depends on whether it gives viewers a distinct aesthetic impression when the overall appearance is observed and compared, rather than by separating and comparing each element that constitutes it individually, if their dominant features are alike, the designs should be deemed similar even if there are some differences in details (see Supreme Court Decision 2005Hu2274, dated September 8, 2006; Supreme Court Decision 2010Hu3240 dated February 24, 2011).

2) Analysis

In consideration of the totality of the purport of the overall argument and statements in the Plaintiff's Exhibit 20-1, since Design 449 and the design of the defendant's Sansoo Bank products have similar dominant features and give the viewers the same aesthetic impression, it is reasonable to conclude that the defendant's manufacture and sale of Sansoo Bank products infringed upon the exclusive license for the Plaintiff A's Design 449 unless there are special circumstances.

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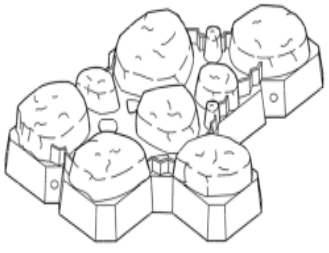
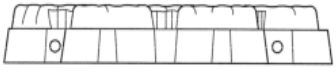
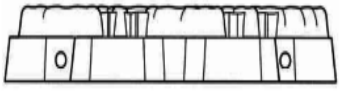
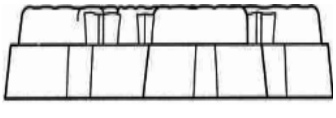
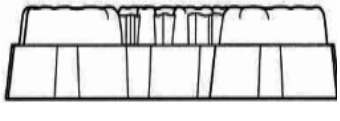
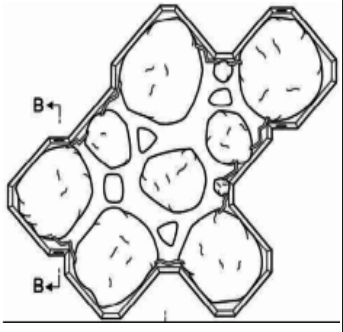
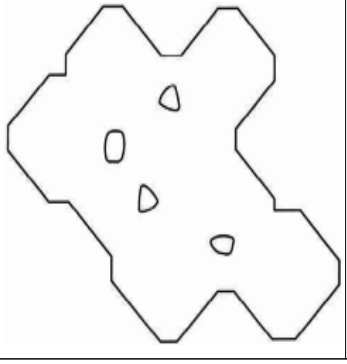
the decision to invalidate the registration of the 499 Patent claim 1 was also concluded.

	Design 449	Defendant's Sansoo Bank products [29]
Perspective view		
Front view		
Rear view		
Left side view		
Front view		

29) While the perspective view is based on the design of the defendant's *Sansoo* Bank products as published in the catalog, and the other drawings are identified as photographs of the design of plaintiff A's *Sansoo* Bank products (see footnote 2 of Plaintiff's Exhibit 20-1), there seems to be no dispute over that the front view, rear view, planar view, bottom view, left side view, and front view of the defendant's product are the same as the photographs shown in the table above.

	Design 449	Defendant's Sansoo Bank products
Planar view		
Bottom view		

3) Discussion on the defendant's argument

a) The defendant argues that Sansoo block products are practiced products of Utility Model 401, but since the said utility model was invalidated with retroactive effect, the exclusive license for Design 449 does not apply to the defendant. However, there is no basis to deem that the invalidation of Utility Model 401 renders Design 449 invalid or that the effect of Design 449 does not apply to the defendant. Therefore, the defendant's argument cannot be accepted.

b) Defendant also argues that Plaintiff A acquired an exclusive license for Design 449 from G not long after Utility Model 401 was declared invalid, which is illegal and unfair on the grounds that it results in overlapping rights to the same product and undermines the

invalidation of Utility Model 401. However, there is no reason to consider it inappropriate for the technical features of the same product to be protected by a utility model and the aesthetic features by a design right. Therefore, the defendant's argument above cannot be accepted.

c) Furthermore, the defendant argues that Sansoo Bank products are in the public domain and can be freely practiced by anyone. Even if the defendant's above argument is interpreted in a good way by considering it as a free design argument, there is no evidence to support that the defendant's Sansoo Bank product is similar to the prior design or can be easily created from the prior design. Therefore, the defendant's free design defense cannot be accepted.

F. Discussion on Whether the Exclusive License for Sansoo Trademark Was Infringed

1) Discussion on whether the defendant's use of catalogs is an infringement of the exclusive right to use

Plaintiff A alleges that the defendant's use of the following marks in the catalog of its Sansoo block products (Plaintiff's Exhibit 18) constitutes an infringement of Plaintiff A's exclusive right to use the Sansoo trademark: "山水 (Sansoo) view", "山水 (Sansoo) bank", "山水 (Sansoo) step."

The registration date of Plaintiff A's exclusive right to use Sansoo trademark is July 30, 2013, but since each catalog in Plaintiff's Exhibit 18 does not indicate the date of production or distribution of

the catalogs, the above evidence alone is insufficient to prove that the defendant produced and distributed the catalogs having the marks "山水 (Sansoo) view", "山水 (Sansoo) bank", and "山水 (Sansoo) step" after Plaintiff A's registration of the exclusive license for the Sansoo trademark, and there is no evidence to the contrary.

Therefore, the argument that the defendant's use of catalogs is an infringement of the exclusive right to use is without merit.

2) Whether the exclusive right to use is infringed by the marking of article name on the Korea ON-line e-Procurement System

a) Underlying facts

In consideration of the totality of the statement in Plaintiff's Exhibit 4 and the replies of fact-finding inquiries requested to the Commissioner of Gwangju Regional Office of Public Procurement Service by this Court and the district court, it is recognized that the defendant used "Sansoo View", "Sansoo Bank", and "Sansoo Step" (hereinafter, the "marks used by the defendant") as a source indicator of artificial stone made of concrete by displaying them on the advertisement of its concrete retaining wall block products posted on Korea ON-line e-Procurement System (KONEPS) operated by the Commissioner of Public Procurement Service during the period of July 30, 2013, when Plaintiff A received from G an exclusive right to use the Sansoo trademark, and October 31, 2021, when the defendant delivered last Sansoo block products through Public Procurement Service.

b) Whether the Sansoo trademark and the marks used by the defendant are similar

(1) Relevant Law

In principle, the similarity of a combined trademark consisting of a combination of two or more characters or shapes shall be judged based on the appearance, pronunciation, and concept of the mark as a whole, but if there is a prominent part of the trademark that gives general consumers an impression of that trademark or causes memory

or association, it is necessary to compare and judge the similarity of the trademark based on that prominent part in order to reach an appropriate overall conclusion. Since the prominent part of a trademark is subject to comparison when determining whether it is similar to another trademark due to its unique distinctiveness that is recognized by general consumers as prominent regardless of the other elements, if the prominent part of a trademark exists, it is possible to determine whether the trademarks are similar by comparing the prominent part alone without having to determine whether such part can be observed separately. In addition, whether an element of a trademark is a prominent part shall be determined by comprehensively considering factors such as whether the part is notable, prominent, or gives a strong impression to the general public, or whether it accounts for a large proportion of the entire trademark, as well as its relative level of distinctiveness compared to other elements, the state and degree of combination with them, the relationship with the designated goods, and the actual state of trade (see Supreme Court Decision 2015Hu1690, dated February 9, 2017).

(2) Analysis

While the Sansoo trademark () is an iconographic mark combining the Chinese characters 山 and 水, the marks used by the defendant are marks composed of three or four Korean characters, combining the words “Sansoo”, “View”, “Bank”, and “Step” in a plain typeface.

Sansoo trademark	Marks used by the defendant		
	Sansoo View	Sansoo Bank	Sansoo Step

In light of the statement in Plaintiff’s Exhibits 7 and 16, and the purport of the overall argument, it is recognized that from around April 2003, Plaintiff A acquired a license from G, and used the

Sansoo mark by displaying it as "山水 (Sansoo) view," "山水 (Sansoo) bank," and "山水 (Sansoo) step" as follows.

Taking into account the state of trade, it seems that general consumers may recognize the "Sansoo" part, in "Sansoo View," "Sansoo Bank," and "Sansoo Step" marks used by the defendant on KONEPS, as a prominent part having a feature of independent distinctiveness. Furthermore, while "Sansoo," the prominent part of the trademarks used by the defendant, and the Sansoo trademark  have different appearances, it is reasonable to deem them similar trademarks since they share similar pronunciation and concept.[30)]

c) Summary of Discussion

Therefore, the defendant infringed an exclusive right to use the Sansoo trademark by using the marks on KONEPS.

3) Discussion on the defendant's argument

(a) Defendant argues that it is contrary to the purport of the Agreement at Issue and a violation of the principle of good faith for Plaintiff A to claim that acquiring an exclusive right to use the Sansoo trademark and using the trademark is unlawful after entering into the Agreement at Issue, which includes a provision allowing the use of the Sansoo trademark.

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30) There is no dispute between the parties over the fact that the designated goods of the *Sansoo* trademark and the goods used by the defendant are the same, such as "concrete blocks".

However, even if the defendant could freely use the Sansoo trademark during the existence of the Agreement at Issue, the defendant is no longer able to use the Sansoo trademark as long as the Agreement at Issue was terminated, and it is difficult to deem that Plaintiff A's argument about infringement of an exclusive right to use the Sansoo trademark is a violation of the principle of due diligence. Therefore, the defendant's above argument is without merit.

(b) Defendant argues that its use of the Sansoo trademark on KONEPS constitutes a descriptive use rather than trademark use.

However, since it is difficult to deem that "Sansoo View," "Sansoo Bank," and "Sansoo Step" are descriptive expressions identifying generic titles or origin, quality, or raw materials of blocks made of concrete, the defendant's above argument is without merit.

G. Discussion on Whether the Sole Non-exclusive License Was Infringed

Since the grounds for this Court's judgment are the same as those from line 3 on page 20 to line 13 on page 21 of the district court's judicial decision, except that "(1) An illegal act of infringement of the license argued by Plaintiff A" on line 16 on page 20 of the district court's judicial decision is deleted, this Court adopts that portion pursuant to the body of Article 420 of the Civil Procedure Act.

H. Liability for Damages

1) Since the fact that the defendant's manufacture and sale of Sansoo block products by using the Sansoo trademark infringes Plaintiff A's exclusive license for Design 449 and the exclusive right to use the Sansoo trademark is the same as discussed above, a person who infringes upon the other person's design right and trademark right is presumed to be negligent in such act of infringement (see the main body of Article 116 (1) of the Design Protection Act and Supreme

Court Decision 2013Da21666, dated July 25, 2013).[31] An exclusive licensee of a design and trademark may claim damages suffered against the person who infringes, whether by intention or negligence, upon his/her exclusive license or right to use (see Article 115 (1) of the Design Protection Act and Article 109 of the Trademark Act). Therefore, the defendant is obligated to compensate Plaintiff A for losses arising from the infringement of the exclusive license and use right.

2) As discussed above, the defendant's manufacture and sale of Sansoo block products after the termination of the Agreement at Issue constitutes an illegal act infringing upon Plaintiff A's sole license, and therefore, the defendant is obligated to compensate Plaintiff A for losses arising from the aforementioned unlawful act.

<Summary of Infringements>

	Trade secret	**Patent 322**	**Patent 449**	**485 Utility Right**	**Design 449**	**Sansoo trademark**	**Sole non-exclusive license**
Sansoo View	×	×				◯[32]	◯
Sansoo bank	×		×		◯[33]	◯[34]	◯
Sansoo Step	×					◯[35]	◯

31) Defendant also appears to argue that it is not negligent with respect to the infringement of the *Sansoo* trademark, but since there is no evidence to reverse the presumption of negligence, the defendant's argument cannot be accepted.

32) An act of selling *Sansoo* View products after July 30, 2013 when the exclusive right to use the *Sansoo* trademark was registered

33) An act of selling *Sansoo* Bank products between July 30, 2013 when the exclusive license for Design 449 was registered and July 14, 2018 when the exclusive license was expired

34) An act of selling *Sansoo* Bank products after July 30, 2013 when the exclusive right to use the *Sansoo* trademark was registered

35) An act of selling *Sansoo* Step products after July 30, 2013 when the exclusive

I. Discussion on the Scope of Damages

1) The scope of damage caused by the infringement of exclusive license for Sansoo Trademark

a) Summary of Plaintiff A's argument

If the infringer of the exclusive right to use a trademark has profited from such infringement, the amount of profit can be estimated as the amount of damages received by the exclusive licensee (Article 110 (3) of the Trademark Act), and here, the amount of profit can be said to be marginal profits after deducting variable costs from sales, so the amount of damages for infringement of the exclusive right to use can be calculated by multiplying the defendant's sales by the profit margin ratio (45%).

Therefore, the defendant is obligated to pay Plaintiff A the sum of KRW 3,021,438,202, as shown in the sum of "468 Trademark Damages" in Appendix 5, plus liquidated damages, as damages for infringement of the exclusive right to use the Sansoo trademark, and Plaintiff A claims the sum of KRW 575,652,731, as shown in the sum of "① Amount claimed" in Appendix 5, plus liquidated damages, as a partial claim.

b) Whether the amount of damages can be calculated under Article 110(3) of the Trademark Act

(1) Relevant law

Article 110(3) of the Trademark Act stipulates that if a trademark holder or exclusive licensee claims against an infringer, who infringes upon his/her rights by intention or negligence, damages suffered by him/her, the amount of profits earned by the infringer shall be presumed to be the amount of damages suffered by the trademark holder or exclusive licensee, and in such case, "the amount of profits earned by the infringer" can be calculated as marginal profits after deducting the costs (variable

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right to use the *Sansoo* trademark was registered

costs) additionally spent for the manufacture and sale of the infringing product from the gross sales revenue of the infringing product.

(2) Analysis

The "ratio of variable costs to sales" according to the statistics in Plaintiff's Exhibit 29 cannot be viewed as the profit margin ratio for the infringing product as claimed by Plaintiff A, and it is difficult to objectively calculate the variable costs spent for producing the infringing product even according to Defendant's Exhibit 14. Therefore, since it is difficult to accurately calculate the defendant's sales and marginal profits from the production and sale of the infringing product in this case, it is difficult to calculate the amount of damages suffered by Plaintiff A according to the method stated in Article 110(3) of the Trademark Act.

c) Calculation of damages under Article 110(6) of the Trademark Act

In this case, it is recognized that damages have been incurred, but it is extremely difficult to reveal the facts necessary to prove the amount of damages. Therefore, it is necessary to determine reasonable damages based on the overall purport of the arguments and the results of the examination of evidence in accordance with Article 110(6) of the Trademark Act.

Considering the totality of established facts, the overall purport of the arguments, and the statements in Plaintiff's Exhibits 1, 3, 7, and 29, it appears that the reasonable damages under Article 110(6) of the Trademark Act exceed the amount set forth in "① Amount claimed" in Appendix 5.

(1) Under the License Agreement at Issue with G, Plaintiff A has the right to directly manufacture and sell Sansoo block products using the Sansoo trademark, as well as to sublicense them to third parties in Korea. Plaintiff A divided the country into nine regions and granted non-exclusive licenses to prospective licensees, including the defendant Sinsung Concrete, within a certain area, and if the defendant

Sinsung Concrete and other prospective licensees failed to produce and deliver Sansoo block products, Plaintiff A could supply the products to the licensees. That is, since Plaintiff A not only authorizes the exploitation of Sansoo block products, but also manufactures and sells them directly, it is likely that the sale of Sansoo block products by the defendant in violation of the exclusive right to use the Sansoo trademark has resulted in a decrease in sales equivalent to the number of units sold or a decrease in the royalty income.

(2) Although it is reasonable to calculate Plaintiff A's damages arising from a decrease in its sales by using marginal profits after deducting variable costs from the sales of Sansoo block products, the information in the Statistics on Business Management Analysis published by the Bank of Korea (Plaintiff's Exhibit 29) cannot be used directly to calculate the marginal profits of Sansoo block products. However, since the said statistical data are finalized statistics that were prepared based on the statistics of all profit-making corporations in Korea (based on corporate tax filings with the National Tax Service), except for a few exceptions such as non-operating holding companies, the reliability of the statistics cannot be regarded as unreliable, and that the part of the above statistics for <C233. Cement, lime, plaster and their products> concerns enterprises engaged in the manufacture of "cement, lime and plaster, concrete tiles, roof tiles, bricks and blocks, and other concrete products, etc." and appears to include the manufacture of concrete block products (Sansoo block products), which corresponds to Plaintiff A's business activities (see pages 123 and 124 of Plaintiff's Exhibit 29), it can be deemed that such statistics are worthy of being used as a reference.

(3) According to the statement in Plaintiff's Exhibit 29, the ratio of variable costs to sales[36] of <C233. Cement, lime, plaster and their products> was 54.84 percent in 2018, 55.45 percent in 2019,

36) Variable costs/amount of sales

and 54.48 percent in 2020, and the profit margin ratio[37] based on the said statistics is 45.16 percent, 44.55 percent, and 45.52 percent respectively. However, in the Agreement at Issue, if the licensee (defendant) is unable to produce and deliver the products smoothly and instead is delivered from Plaintiff A or an OEM manufacturer to match the supply and demand, the delivery unit price is "Sansoo View (colored): KRW 63,800 (Type A), Sansoo View (colorless): KRW 58,000 (Type A); Sansoo Bank (colored): KRW 36,500, Sansoo Bank (colorless): KRW 31,025; and Sansoo Step: KRW 47,850" (Article 11(7) of the Agreement at Issue), and the lowest price of the selling price is "Sansoo View (colored): KRW 131,000, Sansoo View (colorless): KRW 97,000; Sansoo Bank (colored): KRW 71,500, Sansoo Bank (colorless): KRW 58,500; and Sansoo Step: KRW 127,500" (Article 12 of the Agreement at Issue). Accordingly, the minimum marginal profits that the licensee can make by selling Sansoo block products in such OEM method as stipulated in the Agreement at Issue (when selling the products in the market at the lowest price) are as shown in the table below. In other words, the minimum marginal profits from selling Sansoo block products are calculated as 40-62 percent[38], which, on average, is not significantly less than the profit volume rate of 44-45 percent as in the above statistics.

	Lowest sales price	**OEM delivery unit price**	**Marginal profits**	**Profit volume ratio**
Sansoo View (colored)	KRW 131,000	KRW 63,800	KRW 67,200	51%

37) Profit volume ratio = marginal profits/amount of sales = (amount of sales – variable costs)/amount of sales = 1 – variable costs/amount of sales

38) This number is not an accurate marginal profit since additional variable costs, such as freights, can be deducted. But, considering that the price threshold set in Article 12 of the Agreement at Issue is the lowest price and the actual sales price may be higher, the marginal profit estimated as above does not seem to be far beyond the reasonable range.

	Lowest sales price	OEM delivery unit price	Marginal profits	Profit volume ratio
Sansoo View (colorless)	KRW 97,000	KRW 58,000	KRW 39,000	40%
Sansoo Bank (colored)	KRW 71,500	KRW 36,500	KRW 35,000	49%
Sansoo Bank (colorless)	KRW 58,500	KRW 31,025	KRW 27,475	47%
Sansoo Step	KRW 127,500	KRW 47,850	KRW 79,650	62%

(4) Furthermore, Plaintiff A's damages arising from a decrease in royalty are equivalent to the royalty amount stipulated in the Agreement at Issue, or, specifically, equivalent to 7 percent of the net sales of Sansoo View and Sansoo Step products, and 5 percent of the net sales of Sansoo Bank products.

(5) If the defendant did not sell Sansoo block products without authorization, it is likely that, without special circumstances, the consumers (most of whom are public institutions such as countries or local governments), who purchased Sansoo block products from the defendant during the infringement period, would have purchased Sansoo block products from Plaintiff A or a person licensed by Plaintiff A, but there is no data to identify the proportion of such customers.[39] But, for instance, if such proportion is 50 to 50, Plaintiff A's damages arising from the defendant's infringement can be estimated to be an amount equivalent to the sum of 1) (net sales of the infringing product × royalty rate[40]) × 50 percent[41] and 2) (net sales of the infringing

39) Although Article 11(2) of the Agreement at Issue stipulates that Plaintiff A shall not grant a non-exclusive right to other partner companies in the contracted area (Gwangju and South Jeolla Province) without the consent of the defendant, it cannot be ruled out that Plaintiff A may have granted a non-exclusive right to other suppliers in the areas of Gwangju and South Jeolla Province after the termination of the Agreement at Issue.

40) 5-7 percent

41) The profits that Plaintiff A could have made if the infringing products were

product × profit volume ratio per product[42]) × 50%.

(6) It may be the case that consumers purchased the defendant's products based on their special competitive edge, not the marking of the Sansoo trademark, and if the defendant did not sell Sansoo block products, there might have been a case where the consumers did not purchase those products. But the infringer shall claim and prove that there are exceptional circumstances in which the infringer has gained profits, unrelated to the infringement of trademark rights, from the excellence of the quality and technology of the infringer's products, the infringer's credit, sales skills, sales policy, and advertisement and promotion, and the extent to which the said factors contributed [See Supreme Court Decision 2005Da75002 dated March 27, 2008 and Supreme Court Decision 2020Da238639 dated June 1, 2013 (principal claim) and 238646 (counterclaim)], but in this case, the defendant has never claimed or proved such circumstances. Therefore, it is difficult to take such circumstances when calculating damages.

(7) In consideration of the totality of those circumstances, it seems obvious that Plaintiff A's damages arising from the infringement of the exclusive right to use in this case exceed the amount claimed by Plaintiff A (plaintiff A claims the net sales of the infringing products multiplied by the royalty rate as the amount of damages). Taking into account the fact that Plaintiff A is claiming three times the amount of net sales of the infringing products after applying the royalty rate for an act of infringement after July 9, 2019 when a provision, concerning the increased compensation, introduced in the Unfair Competition Prevention Act came into effect, but the proportion of the portion that seeks the tripled royalty is not greater than the proportion of the portion that seeks the general royalty, that the royalty rate is significantly higher than 5-7 percent (exceeding 21 percent, which is three times 7 percent) even if assuming the profit

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purchased from a person, granted a license, not from an infringer

42) 40-62 percent

volume ratio of the infringing products as low as 40-62 percent, and that the defendant intentionally infringed upon the exclusive right to use the Sansoo trademark even knowing that Plaintiff A has an exclusive right to use the Sansoo trademark in accordance with the Agreement at Issue, it is reasonable that the amount of damages determined by the Court exceeds the amount claimed by Plaintiff A.

(8) It is considered that as long as some of Plaintiff A's claims are recognized by the reasonable amount of damages determined by the court, it is not necessary to calculate the exact amount of damages in excess of this amount.[43)]

2) Sub-conclusion

Therefore, as shown in the table below, the defendant is obligated to pay Plaintiff A the amount of damages incurred between 2015 and 2021, and specifically, the defendant shall pay Plaintiff A KRW 104,594,091, the amount of damages arising from the infringement of the exclusive right to use the Sansoo trademark in 2015, plus liquidated damages at a rate of 5 percent per annum for KRW 94,134,673, the amount recognized in the district court's decision, from December 31, 2015, the final date of infringement of the exclusive right to use and the date claimed by the plaintiff, to December 17, 2020, the date of the district court's decision, and at a rate of 12 percent per annum therefor, as prescribed in the Act on Special Cases concerning Expedition, etc. of Legal Proceedings, from December 18, 2020 until it is paid in full[44)]; and at a rate of 5 percent

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43) There is not sufficient evidence to accurately calculate the amount of damages in excess.

44) Under the Act on Special Cases concerning Expedition etc. of Legal Proceedings, whether a dispute is reasonable shall be judged separately for each matter of a lawsuit, so the fact that the royalty claim was partially dismissed cannot be translated into that disputing over a claim for damages, which is a separate claim, is reasonable. Also, as shown below, even if the liquidated damages portion of the claim expanded in the trial on appeal with respect to the compensation for damages portion is without merit, it cannot be said that it is

per annum, as prescribed in the Civil Act, for KRW 10,459,418, the amount additionally recognized in accordance with the expansion of the purport of the claim in the trial on appeal, from December 31, 2015, to August 24, 2023, the decision date of this ruling and the date which is considered to be reasonable for the defendant to dispute the existence or scope of the performance obligation[45], and at a rate of 12 percent per annum therefor, as prescribed in the Act on Special Cases concerning Expedition etc. of Legal Proceedings, from August 25, 2023, until it is paid in full (As the amount of damages arising from the infringement of the exclusive right to use the Sansoo trademark is sufficient to satisfy Plaintiff A's claim for sales after the termination of the Agreement at Issue, the scope of damages arising from the infringement of the sole non-exclusive license, the scope of damages arising from the infringement of the exclusive license for Design 499, and Plaintiff A's selective claim for penalties under Article 19(4) of the Agreement at Issue will not be examined. However, Plaintiff A is also seeking liquidated damages, for the portion expanded in the trial on appeal, at a rate of 12 percent, as prescribed in the Act on Special Cases concerning Expedition etc. of Legal Proceedings, from the following day of the decision date of the district court's ruling until it is paid in full. But since an interest rate, under the said Act, for that portion cannot be calculated until the date of delivering the copy of Plaintiff A's application for change of the claim purport dated September 27, 2021, with the purport of expanding the liquidated damages,

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reasonable to dispute over the entire amount, accepted in the district court's decision, out of the portion accepted in the trial on appeal from the following day of the date of the district court's decision (see Supreme Court Decision 94Da56234, dated February 17, 1995 and Supreme Court Decision 2010Da85645 dated February 10, 2011).

45) As long as the part of the liquidated damages concerning the part of the claim expanded in the trial on appeal as below is partially dismissed, it seems reasonable to dispute over the existence or scope of the performance obligation in relation to the expanded claim.

Plaintiff A's claim for liquidated damages is without merit.

J. Summary of Discussion

This portion of Plaintiff A's claim against the defendant is meritorious within the acknowledged scope discussed above.

Year in which the damage occurred	Amount of damages (principal) [KRW]	Liquidated damages		
		Principal [KRW]	5%	12%
2015	104,594,091	94,134,673	Dec 31, 2015 ~ Dec 17, 2020	Following day ~ until the date of full payment
		10,459,418	Dec 31, 2015 ~ Aug 24, 2023	The same as above
2016	82,600,435	74,340,385	Nov 10, 2016 ~ Dec 17, 2020	The same as above
		8,260,050	Nov 10, 2016 ~ Aug 24, 2023	The same as above
2017	73,898,542	66,508,683	Dec 22, 2017 ~ Dec 17, 2020	The same as above
		7,389,859	Dec 22, 2017 ~ Aug 24, 2023	The same as above
2018	47,806,207	43,025,582	Oct 26, 2018 ~ Dec 17, 2020	The same as above
		4,780,625	Oct 26, 2018 ~ Aug 24, 2023	The same as above
2019	102,196,024	38,128,305	Dec 31, 2019 ~ Dec 17, 2020	The same as above
		64,067,719	Dec 31, 2019 ~ Aug 24, 2023	The same as above
2020	145,907,561	43,772,264	Jun 19, 2020 ~ Dec 17, 2020	The same as above
		102,135,297	Jun 19, 2020 ~ Aug 24, 2023	The same as above
2021	18,649,871	18,649,871	Oct 31, 2021 ~ Aug 24, 2023	The same as above

4. Conclusion

Therefore, Plaintiff A's claim is meritorious within the acknowledged scope as discussed above and shall be granted, and the remainder of the claims shall be dismissed as it is without merit. Plaintiff C's claim shall also be dismissed as it is without merit. Since the district court's decision is partially inconsistent with the conclusion above, the district court's decision shall be amended as above to the extent of the expansion and addition of the claims. It is so ordered.

Presiding Judge Sungyop WOO
Judge Youngwoo LIM
Judge Kisu KIM

[Appendix 1]

Utility Model Rights and Other Intellectual Property Held by the Plaintiff, Etc.

1. Utility Model 401

(1) Title of the utility model: Blocks for vegetation shore protection

(2) Application date / Registration date / Registration No.: February 25, 2004 / May 3, 2004 / No. 0350401

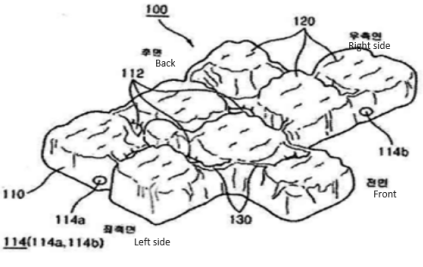
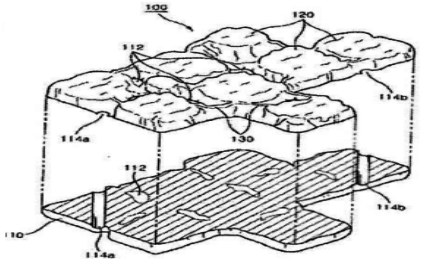
(3) Exclusive licensee: Plaintiff

(4) Claims

[Claim 1] Blocks for vegetation shore protection whose unit block structure used to protect embankments is installed continuously on the slopes of rivers and reservoirs, wherein the overall planar form is formed in a polygonal geometric shape and in a shape that can be combined with adjacent blocks, and wherein the base (110) where through holes (114) are formed at both sides; a natural stone patterned protrusions (120), having a predetermined height and area, is formed on top of said base (110); an embankment is formed on the upper surface of the base (110) between the said protrusions (120) to connect the said protrusions (120); multiple planting holes (112) are formed on the said base (110) for planting; and the connecting rod (140) is formed by being inserted inside the said through holes (114) to fasten the blocks.

[Claim 2] Omitted.

(5) Main drawings

Fig. 3	Fig. 4
	

2. Utility Model 485

(1) Title of the utility model: Artificial stone manufacturing mold

(2) Application date / Registration date / Registration number: December 10, 2004 / February 11, 2005 / No. 0376485

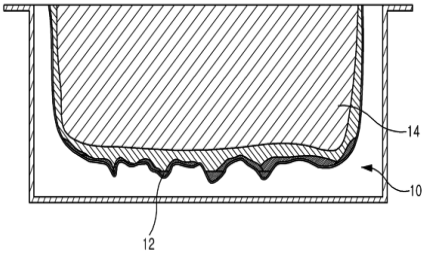
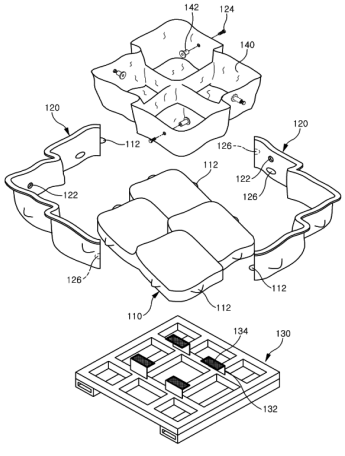
(3) Exclusive licensee: Plaintiff, C Concrete Co., Ltd.

(4) Claims

[Claim 1] An artificial stone manufacturing mold characterized by and comprising the bottom mold and the detachable sidewall molds that are formed alongside the perimeter of the said bottom mold and can be detached from the said bottom mold; and the inner mold made of flexible materials, supported by the inner surface of the bottom mold and the sidewall molds to which it is joined and formed in a shape covering the entire inner surface thereof and corresponding to the outer surface of said artificial stone.

[Claims 2-4] Omitted.

(5) Main Drawings

Fig. 1	Fig. 2
	

3. Utility Model 531

(1) Title of the utility model: Environment-friendly concrete blocks for shore protection construction

(2) Application date / Registration date / Registration number: April 25, 2003 / August 14, 2003 / No. 0324531

(3) Exclusive licensee: B

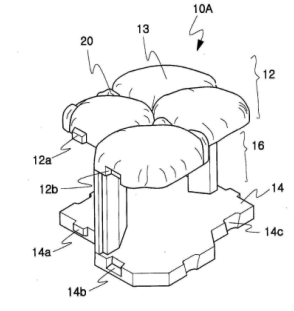
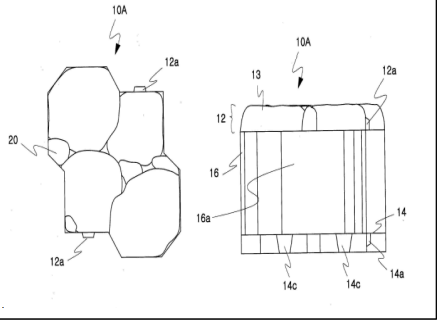
(4) Claims

[Claims 1-4] Deleted

[Claim 5] Environment-friendly concrete blocks for shore protection construction comprising the head part (12) wherein multiple natural stone-shaped artificial stones (13) having a flat bottom are arranged with at least two sides abutting on each other; the base part (14) having a polygonal shape identical or similar to the shape of the said head part (12) and grooves (14c) molded on both sides and formed in the shape of platelets at proper thickness; the column part (16),

wherein the horizontal opening (16a) is formed, connecting the said head part (12) and the base part (14) and having multiple columns; and wherein the longitudinal opening (17) is formed in the space between the said head part (12) and the base part (14) through the said horizontal opening (16a); tetrahedral-shaped convex grooves (12a, 14a) and concave grooves (12b, 14b), having a shape corresponding to the said grooves (12a, 14a), are formed on a certain part of the said head part (12) and the base part (14) so that the convex grooves (12a, 14a) and the concave grooves (12b, 14b) are constructed to be constructible by being combined in series in all directions with the same parts of other blocks (10A, 10B, 10C) having an identical or similar shape; and for concrete blocks used for shore protection where small artificial stones (20) are arranged in small spaces between multiple artificial stones (13) on the said head part (12), the said head part (12) is formed by multiple natural stone-shaped artificial stones (13) with at least two sides abutting on each other and with at least one side formed in a matching straight line, and at the same time, the said column part (16) has an integral barrier wall, with perforations (19a), formed from one column to the other column.

(5) Main drawings

Fig. 1	**Fig. 2**
	

4. Utility Model 403

(1) Title of the utility model: Terraced artificial stone blocks

(2) Application date / Registration date / Registration number: May 19, 2003 / September 9, 2003 / No. 0327403

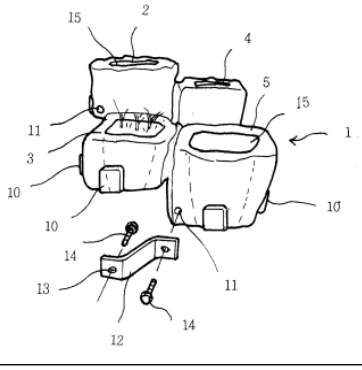
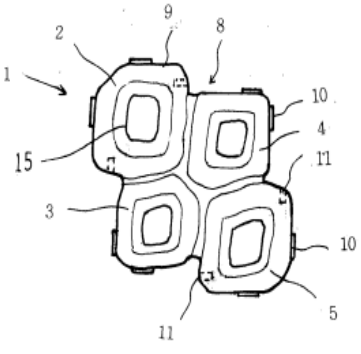
(3) Exclusive licensee: B

(4) Claims

[Claim 1] Terraced artificial stone blocks comprising a left upper staircase (2), a left lower staircase (3), a right upper staircase (4), and a right lower staircase (5), with vegetation holes (15), wider at the top and narrower to the bottom, arranged alternately in the perforated left and right staircases, and artificial stone staircase blocks (unit blocks) (1), whose bottom part is standardized by unit, having a slanted bottom and identically shaped depressions (8) and projections (9) and guide protrusions for pulling (10) and rectangular nuts (11) projected or recessed in all directions.

[Claims 2-5] Omitted

(5) Main drawings

Fig. 1	Fig. 2
	

[Appendix 2]

Technical Know-how Alleged by the Plaintiff

1. Pigment Formulation and Mortal Application Method

Related photos	Content (Plaintiff's argument)
3-2. Mortar formulation: White mortar formulation (white cement + silica sand)  Green mortar formulation (green+silica sand+cement)  Red mortar formulation (red+silica sand+cement)  Black mortar formulation (black+silica sand+cement) 	Formulate four colors of mortar (white, green, red, and black) by mixing five monochromatic pigments, silica sand, cement, and water in the proper proportions. Since the strength and adhesion of the mortar varies depending on the mixing ratio, the mixing ratio of the mortar is important technical know-how.
Application of release agent 	Apply release agents on a metal mold before applying the above mortar on the metal mold. Since the strength or the degree of blisters on the surface of the product differs according to the amount of a release agent applied (If too small amount of a release agent is applied on the metal mold, the product will not be not release from the mold, and if too much amount is applied, the surface

Related photos	Content (Plaintiff's argument)
	state of the product will be poor), the amount of application of a release agent is also subject to an important technical know-how.
Spraying white mortar at [*] and paintbrushing  Spraying green mortar at the 2nd[*]part 	Then, apply four colors of mortar on the metal mold in sequence. Apply the white mortar with a bone tile gun to the metal mold's recessed part, then use a paintbrush to push the mortar into the recessed part, and wipe off any excess white mortar. Apply a proper amount of green and red mortar in sequence by considering the product's outer design. Lastly, apply black mortar on the remaining part of the product to express the dark part of the appearance and to protect the white, green, and red color mortars already applied.

2. Concrete Molding and Oscillating Methods

Related photos	Content (Plaintiff's argument)
4-2. 1st concrete molding (pouring concrete) ※ Surface impact prevention and concrete dispersion when pouring concrete	First, mix concrete, pour the concrete into the above metal mold where the color is applied,

Related photos	Content (Plaintiff's argument)
 4-4. 1st concrete molding (portable oscillation and rebar placement) 	and place rods into concrete (1st molding). Here, using a wide shovel to slow down the falling speed of the concrete to minimize the impact of pigment and prevent loss of pigment is another technical know-how. Oscillate the concrete with an oscillator to reduce its viscosity, eliminate blisters, increase the adhesion of the concrete to the colored mortar, and pour the concrete without voids.
5-1 concrete molding (column-using a portable oscillator) 	Close the form, pour concrete again, and place rods into the concrete to manufacture the column and back parts of the product (2nd molding) Pour concrete into only one column first, since pouring concrete into both columns at the same time when molding columns will prevent the air layer at the bottom from escaping. When molding columns, pour concrete into only one column

Related photos	Content (Plaintiff's argument)
	first, as pouring concrete into both columns at the same time will prevent the air layer at the bottom from escaping. To fill concrete in the bottom and the other column, the viscosity of the concrete must be controlled and blisters must be effectively eliminated. Using both a high-frequency oscillator and a rod oscillator (inserted into the columns) to do so is important technical know-how.
5-2. 2nd concrete molding (using a rod oscillator) ※ Filling mortar from one column to the other column 	A high-frequency oscillator with 14,000RPM at the maximum for pigment protection since using a low-frequency oscillator causes pigment loss due to vibration. Also, use a rod oscillator for quick filling of the columns. Using both oscillators will prevent pigment loss and quickly eliminate blisters, resulting in the quick completion of concrete pouring.
6-2. Curing (steam curing chamber) 	When the 1st and 2nd concrete molding works are complete, trim the surface and cure the concrete properly. For the products in this case, curing the concrete until the hourly sum of the curing chamber temperature becomes 500 degrees is technical know-how.

3. Mold Release and Coating Methods

Related photos	Content (Plaintiff's argument)
7-3. Dismantle the mold and the mold release is ready 	After curing is complete, release the product from the metal mold using a steel pipe, a forklift, and a mold-releasing jig. First, open and dismantle the fixed clamp of the metal mold with a steel pipe, and then release the cured product from the mold by lifting it from the bottom to the top using a forklift fork.
7-7 Product flipping is complete 	Since the natural stone pattern of the product faces the floor immediately after the mold release, rotate the product 180 degrees up and down after attaching the mold releasing jig to prevent a forklift fork from damaging the product.
8-1. Coating on the product surface (anti-whitening and maintaining the surface condition) 	When the coating work is done on the surface to protect the pigment (anti-whitening) and maintain the surface condition, the product is finished.

[Appendix 3]

Quantity and Sales of the Defendant's Sansoo Block Products

(Same as the attachment)

[Appendix 4]

Particulars of Royalty Claims Accepted

(Same as the attachment)

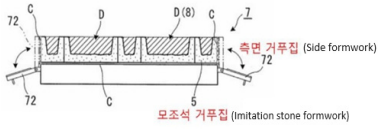
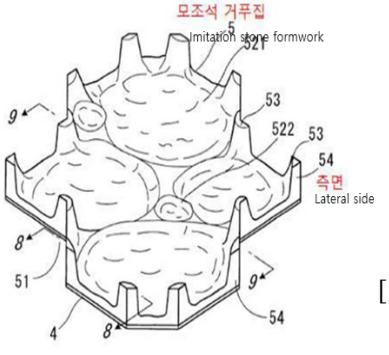
[Appendix 5]

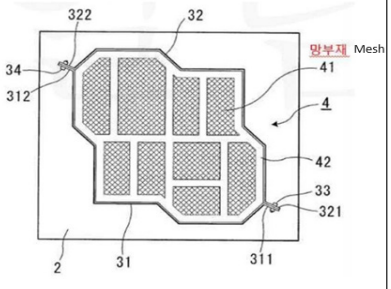
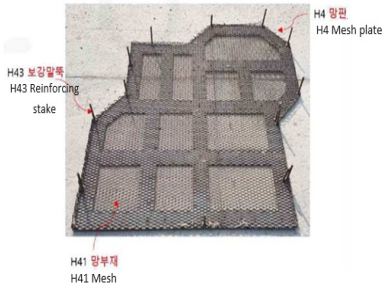
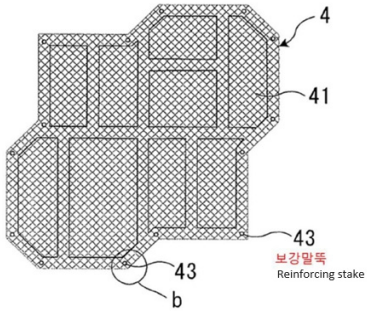
Plaintiff's Arguments Concerning the Manufacture and Sale of Products After the Termination of the Agreement

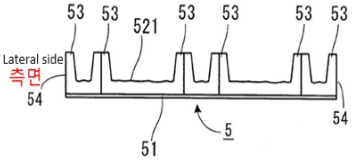
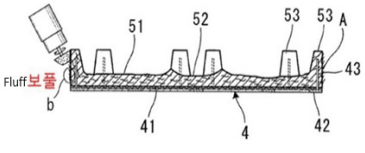
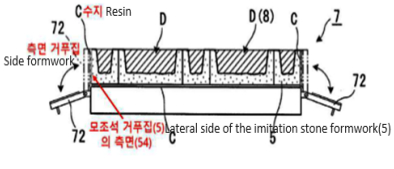
(Same as the attachment)

[Appendix 6]

Comparison between Elements of Claim 1 of Patent 322 and Sansoo View Formwork

Element	531 Patent Claim 1	Formwork of Sansoo View Products	Note
1-1	A formwork consisting of the artificial stone formwork (5) where an artificial stone (11) is placed and the side formwork (72)  [Sansoo View Patent Fig. 10b]  [Sansoo View Patent Fig. 2]	  Consisting of the artificial stone formwork (H5), made of concrete blocks, where an artificial stone is placed and the side formwork (H72)	Included
1-2	A metal mesh (41) is laid at the bottom part of the above artificial stone formwork (5)	A metal mesh (H41) is laid inside the bottom of the artificial stone formwork (H5)	Includ

Element	531 Patent Claim 1	Formwork of Sansoo View Products	Note
	 [Sansoo View Patent Fig. 5]		ed
1-3	A reinforcing stake (43) for a metal rod is installed at the lateral side (54) of the said artificial stone formwork.  [Sansoo View Patent Fig. 4b]	A reinforcing stake (H43) for a metal rod is at the side of the artificial stone formwork. 	Included
1-4	a resin as a base material is mixed with a fiber made by shortening a monofilament to form a rough artificial stone formwork (5), and the said resin as a base material is cut off from the lateral side (54) of the said artificial stone formwork (5) to expose the said fiber to make it fluffy	A shortened fiber made by shortening a monofilament is mixed as a base material of the artificial stone formwork, and the fiber at the lateral side is exposed to make it fluffy.	Included

Element	531 Patent Claim 1	Formwork of Sansoo View Products	Note
	 [Sansoo View Patent Fig. 7]  [Sansoo View Patent Fig. 9a]		
1-5	A formwork made of artificial stone concrete characterized by a resin mixed with the fiber made by shortening the monofilament is applied as a thin layer on the lateral side (54) of the said artificial stone formwork (5), and the formwork on the lateral side (72) of a block-making device (7) is put into contact with the resin applied on the lateral side (54) of the said artificial stone formwork (5) to increase the sealing of the two.  [산수유 특허 도 10b] [*Sansoo* view Patent Fig. 10b]	The lateral side (H54) of the artificial stone formwork (H5) is smooth immediately releasing the formwork from a block-making device, and it is made of resin. 	Included

IP HIGH COURT OF KOREA
TWENTY-FOURTH-FIRST DIVISION
DECISION

Case No.	2022Na1111 Damages (Infringement)
Plaintiff-Appellant-Appellee	A Counsel for Plaintiff Attorney Jeongsul KIM Lawfirm Yulwoo (Attorney in Charge Jeongsik LEE and Jaewook PARK)
Defendant-Appellee-Appellant	Corporation B CEO C Counsel for Defendant Attorney Hyeonjin JANG and Chunsu LEE
District Court's Decision	Seoul Central District Court 2019GaHap513063, decided Jan. 28, 2022
Date of Closing Argument	December 15, 2022
Decision Date	March 15, 2023

ORDER

1. Among the order of the district court's decision, the part of decision adverse to the Defendant shall be revoked, and the Plaintiff's corresponding claim is dismissed.

2. The Plaintiff's appeal is dismissed.

3. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND AND APPELLANT'S DEMAND

PLAINTIFF'S DEMAND

Primarily, the Defendant shall pay the Plaintiff KRW 4,834,736,594. Of this amount, for KRW 4,571,114,503, the Defendant shall pay interest thereon at the rate of 5% per annum from March 27, 2016 until the date of the pronouncement of the judgment of the district court, and at the rate of 12% per annum from the following day until payment in full. Additionally, the Defendant shall pay the Plaintiff interest at the rate of 10% per annum from April 1, 2015 on KRW 4,110,308; from April 1, 2016 on KRW 11,799,906; from April 1, 2017 on KRW 73,101,347; from April 1, 2018 on KRW 57,688,007; from April 1, 2019 on KRW 32,731,554; and from April 1, 2020 on KRW 84,190,969, until the date of the pronouncement of the judgment of the district court, and at the rate of 12% per annum from the following day until payment in full.

Alternatively, the Defendant shall pay the Plaintiff KRW 2,380,970,666. Of this amount, for KRW 2,117,348,575, the Defendant shall pay interest thereon at the rate of 5% per annum from March 27, 2016 until the date of the pronouncement of the judgment of the district court, and at the rate of 12% per annum from the following day until payment in full. Additionally, the Defendant shall pay the Plaintiff interest at the rate of 10% per annum from April 1, 2015 on KRW 4,110,308; from April 1, 2016 on KRW 11,799,906; from April 1, 2017 on KRW 73,101,347; from April 1, 2018 on KRW 57,688,007; from April 1, 2019 on KRW 32,731,554; and from April 1, 2020 on KRW 84,190,969, until the date of the pronouncement of the judgment of the district court, and at the rate of 12% per annum from the following day until payment in full.

APPELLANT'S DEMANDS

Plaintiff: The Plaintiff seeks modification of the district court's

decision in accordance with the Plaintiff's claims.

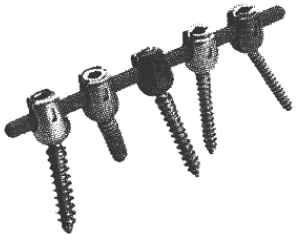
Defendant: The Defendant seeks the same relief as stated in the paragraph 1 of the Order.

OPINION

1. Basic Facts

A. Advisory Agreement

On November 1, 2001, the Plaintiff entered into a technical advisory agreement (hereinafter, "the Advisory Agreement") with the Defendant[1] regarding the spinal fixation apparatus (Spinal Instrument System, brand name "D," hereinafter, "**Product D**"), which was developed by the Plaintiff, and the agreement included the following provisions (hereinafter, the "Advisory Agreement at Issue").[2]



Excerpt from Plaintiff's Exhibit 35-2

Technical Advisory Agreement For the Development of Medical Devices

The Plaintiff, as an advisor providing technical advice on medical devices regarding the development of the subject item of this Agreement, the Spinal Instrument System, agrees that the Defendant shall have the exclusive license to use the subject item, and also provide continuous advisory services for its improvements, while the Defendant intends to obtain the said exclusive license and continuous technical advisory services.

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1) The Defendant previously operated under the trade name "Corporation E" and subsequently changed its name to "Corporation F" on March 31, 2022, and then to its current name "Corporation B," on June 30, 2022.

2) The Advisory Agreement at Issue (Plaintiff's Exhibit 1) states the Plaintiff as the "advisor" and the Defendant as the "company." For ease of understanding, the terms "advisor" and "company" in the agreement are replaced with "Plaintiff" and "Defendant" respectively, in the following text.

1. Definition of Terms

1) The term “Subject Item” refers to the spinal instrument system (brand name D, spinal fixation device), which has been developed through joint research by the Plaintiff, the Defendant, and the third parties since November 1, 2001.

2) The term “Improvement” refers to any technical information or modifications applicable to the Subject Item, either independently devised by the Plaintiff or jointly conceived by the Defendant and advisors.

4) The term “Technical Information” refers to all research and development information, patents, patent applications, non-patented inventions, know-how, trade secrets, and technical materials related to the Subject Item, which have been owned by the Plaintiff from the effective date of this Agreement, or for which the Plaintiff has provided advice during the term of this Agreement.

5) The term “Joint Advisors” includes G and H, who have entered into development agreements for the development of one of the existing Subject Items D (the Defendant’s brand, Pedicle screw and R system), as well as any additional individuals or entities that may subsequently be included.

7) The term “Agreement Term” commences on November 1, 2001 and shall expire upon the cessation of the production and sale of the Subject Item. However, the obligation to pay advisory fees shall remain in effect until the advisory fee has been paid in full.

2. Assignment of License

1) The Plaintiff grants the Defendant a global exclusive license to use the Technical Information for the manufacture, use, and sale of the Subject Item.

3. Consideration

1) As consideration for the grant of the license, the Defendant shall pay the Plaintiff an advisory fee equivalent to 2.5% of the net sales amount during the term of this Agreement. The Defendant shall submit to the Plaintiff, on an annual basis, the advisory fee amount for the preceding year, along with detailed supporting documentation regarding its calculation.

2) The advisory fee shall be calculated from November 1, 2001, and shall

be paid annually.

3) The advisory fee shall be paid on an annual basis, no later than March 31 of the year following the accrual of the advisory fee.

after the advisory fee accrues.

9. Obligations

1) The Plaintiff warrants that no agreement has been executed with any third party that would interfere with granting the license or providing advisory services to the Defendant. The Plaintiff shall not, during the term of this Agreement, assert any rights related to industrial property rights and intellectual property rights that may hinder the Defendant, Defendant's direct customers, and end-users from enjoying the rights to the Subject Item.

2) The Plaintiff warrants that, to the best of its knowledge, the Defendant's ownership, sale, and use of the Subject Item, as well as the sale, ownership, and use of the Subject Item by the Defendant's customers and end-users, shall not infringe upon any third party's industrial property rights and intellectual property rights. The Plaintiff shall make efforts to provide an appropriate defense against third party's claims regarding infringement of abovementioned rights against the Defendant, the Defendant's customers, or end-users, without additional costs to the Defendant, throughout the term of this Agreement.

10. Improvements

1) Any Improvement shall be subject to the granted license. In the event that the Defendant determines that additional domestic or international patent protection is necessary for the Subject Item or Improvement, the Plaintiff shall, at the Defendant's request, carry out the necessary documentation related to granting the legal status required for patent application as deemed necessary by the Defendant, with all associated costs borne by the Defendant.

2) The Plaintiff shall promptly disclose to the Defendant all information related to Improvement and shall ensure that the Defendant is always informed of the latest and significant information concerning the following matters owned by the Plaintiff.

① Possible design modifications and the Improvement related to the Subject Item

② Clinical trials, clinical research, and related information

③ The preparation of labels and packaging inserts for the Subject Item, as well as modifications and the Improvement to surgical techniques related to the Subject Item

3) The rights to additional development and the improvement related to the Subject Item shall be jointly owned by the Plaintiff and the aforementioned Joint Advisors.

13. Term

1) This Agreement shall remain in effect until the production and sale of the Subject Item are discontinued.

2) The commencement date of the technical advisory services shall be November 1, 2001, and such services shall remain valid until the termination of this Agreement as set forth in the preceding paragraph. Thereafter, this Agreement regarding advisory services shall be extended on an annual basis by mutual agreement of both parties.

B. Domestic and U.S. Patent Applications and Registrations

1) Domestic Patents

The Defendant applied for and registered the following domestic patents:

a) Patent 1

(1) Title of invention: Bone fixation apparatus

(2) Filed / Registered / Registration No.: October 31, 2001/ March 26, 2003/ 379194

(3) Patentee: Defendant

(4) Inventors: Plaintiff and three others[3)]

(5) Claims and main content of the invention: See Appendix 1.

b) Patent 2

(1) Title of invention: Bone fixation apparatus, assembly method, and surgical instrument

3) One of the inventors, I, served as the Defendant's CEO from August 22, 2000, to August 22, 2006, and from March 31, 2007, to March 31, 2022.

(2) Filed / Registered / Registration No.: November 25, 2002/ June 8, 2005/ 495876
(3) Patentee: Defendant
(4) Inventor: Plaintiff
(5) Claims and main content of the invention: See Appendix 2.

2) U.S. Patents

a) The Defendant filed a patent application in the United States on February 4, 2002, for an invention titled "BONE FIXATION APPARATUS" (inventors: Plaintiff and two others), disclosing the same technical subject matter as Patent 1, and the patent was granted on June 14, 2005 (Registration No.: US 6,905,500). This patent claimed priority from the filing date of Patent 1 (hereinafter, the "U.S. Registered Patent at Issue").

b) The Defendant filed a patent application in the United States on November 29, 2002, for an invention titled "BONE FIXATION APPARATUS, METHOD AND TOOL FOR ASSEMBLING THE SAME" (inventor: Plaintiff), disclosing the same technical subject matter as Patent 2. This application claimed priority from the filing date of Patent 2 (Publication No.: US 2004/0102781 A1, hereinafter, the "U.S. Patent Application at Issue"). However, the United States Patent and Trademark Office (USPTO) issued a final rejection on January 23, 2006, and the patent was no patent was issued.

C. D Lawsuit and Mediation Agreement

1) On August 9, 2006, the Plaintiff filed a lawsuit against the Defendant, who had been manufacturing and selling Product D, seeking a total of KRW 532,835,097, consisting of advisory fees under the Advisory Agreement at Issue and conference participation expenses (Seoul Central District Court, 2006Gahap68365, hereinafter, the "D

Lawsuit"). In response, the Defendant filed a counterclaim (Seoul Central District Court, 2007Gahap50170), arguing that Product D infringed the patent rights of Company J[4] in the United States, leading the Defendant to enter into a patent license agreement with Company J, and thus sought payment from the Plaintiff for the equivalent amount of the royalties that the Defendant had to bear. In the D Lawsuit, the court rendered a judgment on April 4, 2008, mostly ruling in favor of the Plaintiff, ordering the Defendant to pay KRW 532,806,223, while dismissing the Defendant's counterclaim.

2) The Defendant appealed the foregoing judgment on April 21, 2008 (Seoul High Court, 2008Na44537). While the appeal was pending, a settlement was reached on June 16, 2009, under which the Defendant agreed to pay the Plaintiff KRW 552,457,639. On the same day, separately from the above settlement, the Plaintiff and the Defendant entered into an agreement setting forth the following terms (hereinafter, the **"Mediation Agreement at Issue"**).

Mediation Agreement

1. Ownership of Patent Rights

A. The Defendant acknowledges that the Plaintiff is an inventor of Product D, as stated in Article C of this Agreement, and further acknowledges that the patent rights were registered solely under the Defendant's name in order to grant the Defendant an exclusive license.

B. The Plaintiff, for the purpose of promoting the sale of Product D and its improved products (hereinafter, the "Subject Item"), agrees to the patent registration under the Defendant's name for the duration of the Advisory Agreement at Issue, and grants the Defendant an exclusive license to the Subject Item.

C. The patent rights for which the Plaintiff has agreed to register under the Defendant's name are as follows:

4) J Medical Products, Inc.

(1) Domestic Patents

① Title of invention: Bone fixation apparatus/ Application Date: October 31, 2001/ Registration Date: March 26, 2003/ Registration No.: 379194/ Inventors: the Plaintiff and three other inventors (corresponding to Patent 1)

② Title of invention: Bone fixation apparatus, method and tool for assembling the same/ Application Date: November 25, 2002/ Registration Date: June 8, 2005/ Registration No.: 495876/ Inventor: Plaintiff (corresponding to Patent 2)

(2) U.S. Patents

③ BONE FIXATION APPARATUS, US 2003/0158552 A1, Inventors: Plaintiff, G, and I

④ BONE FIXATION APPARATUS (US 6,905,500 B2) Application date: June 14, 2005, Inventors: Plaintiff, G, and I (corresponding to the U.S. Registered Patent at Issue)

⑤ BONE FIXATION APPARATUS, METHOD AND TOOL FOR ASSEMBLING THE SAME, US 2004/0102781 A1, Inventor: Plaintiff (corresponding to the U.S. Patent Application at Issue)

2. Restrictions on Place of Production

A. The Defendant shall not manufacture the Subject Item outside of the Republic of Korea, nor allow a third party to do so, without obtaining prior written consent from the Plaintiff. The Plaintiff shall not unreasonably withhold consent for such a plan by the Defendant.

B. If the Defendant manufactures the Subject Item outside the Republic of Korea or permits any third party to do so without prior written consent from the Plaintiff, the Defendant shall pay the Plaintiff, in addition to the advisory fee, three times the highest annual advisory fee paid before the violation was discovered as liquidated damages.

C. If the Defendant manufactures the product overseas or allows a third party to do so with the Plaintiff's consent, the Defendant shall submit annual accounting records regarding production and sales performance to the Plaintiff.

3. Scope of the Subject Item and Defect Notification

A. The Defendant shall pay the Plaintiff the advisory fee for the Subject

Item in accordance with the percentage set forth in Article 4.

B. The Subject Item shall include the items listed in the Appendix as well as all spinal fixation apparatuses developed utilizing, in whole or in part, the patent rights to Product D in the future.

4. Payment of Advisory Fee

A. The Defendant shall pay the Plaintiff an advisory fee equivalent to 2.5% of the net sales amount of the Subject Item until 2008 and, from 2009 onward, 2.0% of the annual total sales revenue of the Subject Item as determined in accordance with the Korean Generally Accepted Accounting Principles (K-GAAP) as consideration for the assignment of patent rights to Product D, the grant of an exclusive license, and the provision of advisory services throughout the term of the Advisory Agreement at Issue.

B. The advisory fee shall be paid annually, no later than March 31 of the year following the sales. If the Defendant delays payment, the Defendant shall pay the Plaintiff not only the advisory fee, but also default interest at an annual rate of 10%, calculated from the day after the due date until the full payment is made.

C. The Defendant shall submit to the Plaintiff, immediately after each annual general meeting, the advisory fee for the preceding year, calculated based on the sales amount of the Subject Item, along with supporting documentation showing the basis of its calculation.

D. If the Defendant fails to pay the advisory fee for two or more consecutive years at any time from 2009 onward, the Plaintiff may terminate both the Advisory Agreement at Issue and the title trust of the patent rights.

8. Rights to Improvement

A. The rights to improvement related to the Subject Item shall be jointly owned by the Plaintiff and the Joint Advisors.

B. The Plaintiff shall promptly provide the Defendant with the following information learned during the surgical procedures involving the Subject Item.

(1) Possible design modifications and improvement related to the Subject Item

(2) Clinical trials, clinical research, and related information

(3) Improvement and modification of surgical techniques related to the Subject Item

C. Upon receiving the above information from the Plaintiff, the Defendant shall promptly incorporate it into improvement of the Subject Item and notify the Plaintiff of the results thereof.

D. The Defendant shall not modify or improve the size, shape, material, or performance of the Subject Item without obtaining prior written consent from the Plaintiff.

9. Return of Patent Rights Upon Termination

A. In the event that the assignment of the Patent Rights at Issue to the Defendant, the exclusive license, and the advisory agreement are all terminated, the patent rights and the exclusive license related to the Subject Item shall revert to its developer(s), and the Defendant shall carry out the necessary procedures for the transfer of registration of the said patent rights to the developer(s).

14. Transitional Provisions

A. Any provisions of the Advisory Agreement at Issue that conflict with the terms of this Mediation Agreement shall be deemed amended by this Mediation Agreement.

B. This Mediation Agreement shall take effect upon the preparation of the conciliation protocol in this case, notwithstanding the content of the conciliation protocol. End.

<Appendix>

1. Spinal Instrumentation System currently manufactured by the Defendant {brand name D; spinal fixation apparatus; pedicle screws, reduction hooks (R) and all related components, surgical instruments required for the procedure D, D ZS Transition Screw (OTS), and the Cannulated screw version of the D ZS Transition Screw}

2. All products in the Prima (P) product line currently manufactured by the Defendant

3. SIO100, SIO190, SIO210, SIO220, SIO230, SIO240, SIO250, SIS02와 SP0042, SPA6040C, SPA6045C, SPA6050C, SPA6540, SPA6045, SPA7040C, SPA7045C, SPA7050C, and other products currently manufactured by the Defendant under the Q-CAN product line. End.

D. The Defendant's Production and Sales of Products and the K Lawsuit

1) The Defendant manufactured and sold spinal fixation apparatuses with the same technical composition as those listed in Appendix 3 under the brand name "K (K)" (hereinafter, "K Products") from approximately 2009 to 2012, reaching a total sales amount of KRW 12,680,857,986. Additionally, the Defendant manufactured and sold spinal fixation apparatuses under the brand name "L" (hereinafter, "L Products") and spinal fixation apparatus-related products under the brand name "M" (hereinafter, "M Products") from approximately 2014 onward. Furthermore, the Defendant has supplied spinal fixation apparatus-related product lines (hereinafter, "O Product Line") to Company O in France from around 2009.

2) The Plaintiff filed a lawsuit against the Defendant on May 9, 2011, seeking payment of the advisory fee and other related amounts with respect to K Products (Seoul Central District Court, 2011 Gahap45502, hereinafter, the "K Lawsuit"),[5] and the court rendered a judgment partially in favor of the Plaintiff on October 12, 2012. Both the Plaintiff and the Defendant subsequently appealed (Seoul High Court, 2012Na90209), and the appellate court, on April 21, 2016,

5) In the K Lawsuit, the Plaintiff ① claimed that product K constituted an "Improved Product of Product D" as defined in the Mediation Agreement and demanded payment of advisory fees for the period from 2009 to 2011; ② demanded payment of advisory fees amounting to 2% of the royalties the Defendant received from Company O; and ③ claimed that the Defendant violated Article 2-A of the Mediation Agreement by manufacturing Product K overseas and demanded payment of damages.

issued a ruling ordering the Defendant to pay an advisory fee of KRW 262,193,455. Around August 2016, the appellate ruling was finalized following the Supreme Court's dismissal of the Defendant's appeal. The appellate ruling in the K Lawsuit was premised on the premise that the sales of K Products were subject to the advisory fee, and its primary reasoning was that K Products were identical to Product D in that "a flange with an outer diameter larger than the inner diameter of the screw portion is formed on the upper part of the cap, and the flange, together with the lower part of the screw portion, undergoes plastic deformation[6] and is inserted into the cap."

E. Expiration and Lapse of Patent Rights

1) Patent 1 lapsed on March 27, 2016 for failure to pay the maintenance fee and its extinguishment was officially registered on February 9, 2017. Patent 2 expired on November 25, 2022, upon the expiration of its term.

2) Meanwhile, after filing Patent 1, the Defendant registered multiple patents in Europe, Japan, and China, claiming the application date of Patent 1 at Issue as the priority date (hereinafter, the "Overseas Patents at Issue"), with registration numbers "JP 4002915," "EP 1 500 376," "EP 1 439 788," "CN 100400006," and "CN 100469328." However, all of the Overseas Patents at Issue expired between February 2016 and March 2017 due to the Defendant's failure to pay registration (maintenance) fees.

【Factual basis】 Undisputed facts, the statements in Plaintiff's Exhibits

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6) An elastic object changes its shape when force is applied and returns to its original state when the force is removed. However, many solid materials, such as metals, have a low elastic limit, and when subjected to a strong force, they undergo permanent deformation that does not revert to the original shape. The property that allows a material to change shape under force is called plasticity, and such permanent deformation is referred to as plastic deformation.

1, 2, 3, 11, 12, 13, 21, 32, 33, 34, 35, 36, 38, 60, and 219 (where there are Exhibits with branching numbers, such branching numbers are included, and unless otherwise specified, the same shall apply hereinafter), and the purport of the overall argument

2. Determination on the Claim for Advisory Fees

A. Plaintiff's Argument

At the time of the Mediation Agreement, the Defendant agreed to pay the Plaintiff an advisory fees equal to 2.0% of the sales revenue of the Subject Item from 2009 onward (Mediation Agreement, Articles 3-A and 4-A). However, certain products, including Product L, Product M, Product Line N, and Product Line O, qualify as "improved products" of Product D, just as Product K does, and therefore fall within the scope of the Subject Item, yet the advisory fees for these products remain unpaid. The unpaid advisory fees for the period from 2014 to 2019 amount to KRW 263,622,091, as calculated in the Appendix 4 Calculation Table. Accordingly, the Defendant is obligated to pay the Plaintiff that amount in advisory fees, along with delay damages.

B. Subject Item for Advisory Fee Payment

1) Issue

The Advisory Agreement at Issue defines the Subject Item as Product D, "spinal instrument system (brand name D) developed through joint research by the Plaintiff, the Defendant, and third parties" [Agreement, Article 1-1)]. However, the Mediation Agreement contains a transitional provision stating that "any provisions of the Advisory Agreement at Issue that conflict with the terms of this Mediation Agreement shall be deemed amended by this Mediation Agreement" (Mediation Agreement,

Article 14-A), thereby expanding the scope of the Subject Item to include not only Product D but also "improved products" (Mediation Agreement, Article 1-B). Accordingly, a key issue in this case is whether Products L, M, N, and O, as pointed out by the Plaintiff, fall under the "improved products" as defined in the Mediation Agreement.

2) Scope of "Improved Products"

a) If the authenticity of a dispositive document is established, the court shall, in principle, acknowledge the existence and content of the declaration of intent as stated in the document, unless there is clear and convincing evidence to the contrary. When a dispute arises between the parties regarding the interpretation of a contract and interpretation of the parties' intent expressed in the notice of disposition becomes an issue, the court shall reasonably interpret it based on logic and empirical rules, taking into comprehensive consideration the wording of the document, the motives and circumstances under which the agreement was made, the objectives intended to be achieved by the agreement, and the true intent of the parties (see Supreme Court Decisions 2000Da48265, dated February 26, 2002; 2004Da60065, dated May 27, 2005; and 2010Da58728, dated May 13, 2011).

b) At the time of the Mediation Agreement, the Plaintiff and Defendant agreed that "all spinal fixation apparatuses developed utilizing, in whole or in part, the patent rights to Product D in the future" would be included as Subject Item for advisory fee payment (Agreement, Article 3-B). In this context, "the patent rights to Product D" refer to patent rights of patents listed in Article 1-C of the Mediation Agreement (Domestic Patents ① and ②, and U.S. patents ③, ④, and ⑤), and there is no dispute between the Plaintiff and the Defendant on this point.[7] Furthermore, it is evident from the wording

7) Refer to the record for the first date for pleading and to the record for the

of the Mediation Agreement that Domestic Patents ① and ② correspond to Patent 1 and Patent 2, and U.S. Patents ④ and ⑤ correspond to the U.S. Registered Patent at Issue and the U.S. Patent Application at Issue.

On the other hand, regarding the entry for U.S. Patent ③ in Article 1-C of the Mediation Agreement, specifically "BONE FIXATION APPARATUS, US 2003/0158552 A1, Inventors: Plaintiffs G and I," it is difficult to interpret this as indicating that, in addition to the U.S. Registered Patent at Issue and the U.S. Patent Application at Issue, there exists a separate and distinct patent included in the patent rights of Product D. Based on the statements in Plaintiff's Exhibits 3-3, 3-17, and 219-1, as well as the purport of the overall argument, it is evident that the reference to "BONE FIXATION APPARATUS" pertains to the title of the U.S. Registered Patent at Issue, that "US 2003/0158552 A1" refers to the publication number of the U.S. Registered Patent at Issue, which was published on August 21, 2003, and that the listed inventors "Plaintiffs G and I," are the same as those of the U.S. Registered Patent at Issue. In summary, the reference in part to U.S. Patent ③ in the Mediation Agreement appears to have resulted from a misunderstanding that the patent gazette of the U.S. Registered Patent at Issue (Plaintiff's Exhibit 3-3) and the published gazette of the same patent (Plaintiff's Exhibits 34-17 and 219-1) pertain to separate patent inventions, when, in fact, both refer to the same patent.

Accordingly, at the time of the Mediation Agreement, it can be concluded that the Plaintiff and Defendant agreed that spinal fixation apparatuses developed utilizing, in whole or in part, the patent rights of Patent 1, Patent 2, and the U.S. Registered Patent at Issue and U.S. Patent Application at Issue, which share the same technical content, would be included as improved products and thus fall within the Subject Item. Ultimately, the scope of improved products is to be determined based on whether the technical content of Patent 1 or

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second date for pleading.

Patent 2 was utilized in whole or in part.

c) However, even if the use of "a part" of the technical content of Patent 1 and Patent 2 may qualify a product as an improved product, it is not reasonable to construe that any product qualifies as an improved product merely because it incorporates a part of the technical content included in Patent 1 and Patent 2, including the technical content which had already been publicly known at the time of their application date, in light of the following considerations:

(1) At the time of the Advisory Agreement at Issue, the Plaintiff and Defendant defined the term "Improvement" as "any technical information or modifications applicable to the Subject Item, either independently devised by the Plaintiff or jointly conceived by the Plaintiff, the Defendant, and others." [Agreement, Article 1-2)]. Here, the term "Technical Information" was defined as "all research and development information, patented inventions, non-patented inventions, know-how, trade secrets, and technical materials relating to the Subject Item, which are personally owned by the Plaintiff as of the effective date of this Agreement or which are advised by the Plaintiff during the term of this Agreement" [Agreement, Articles 1-4) and 1-7)]. Additionally, the Plaintiff, at the time, warranted that the Plaintiff would utilize the full extent of knowledge during the contract term to ensure that the sale and use of the Subject Item do not infringe on any third-party's industrial property rights or intellectual property rights [Agreement, Article 9-2)], and further agreed to promptly disclose all information related to improvements to the Defendant and to keep the Defendant informed of the latest updates regarding design modifications of the Subject Item [Agreement, Article 10-2)].

(2) At the time of the Mediation Agreement, the Plaintiff and Defendant agreed that, for the promotion of sales of the Subject Item, Patent 1, Patent 2, U.S. Registered Patent and U.S. Patent Application at Issue would be registered under the Defendant's name

for duration of the Advisory Agreement at Issue (Mediation Agreement, Articles 1-B and 1-C). Additionally, the Plaintiff agreed to promptly provide the Defendant with information regarding design modifications and other relevant information of the Subject Item learned during surgical procedures, and the Defendant agreed to reflect such information in the Improvement of the Subject Item and notify the Plaintiff of the results (Mediation Agreement, Articles 8-B and 8-C). Furthermore, the Defendant agreed to obtain the Plaintiff's prior written consent before making any changes to the size, shape, material, or performance of the Subject Item (Mediation Agreement, Articles 8-C and 8-D).

(3) Based on the above contractual provisions regarding design modifications and "Improvements," it is reasonable to determine that the Plaintiff and Defendant, in agreeing that all spinal fixation apparatuses developed using the technical content of Patent 1 and Patent 2 would be included as Subject Items, premised their agreement on the assumption that the technical content of Patent 1 and Patent 2 applied to the Subject Item contains improvements over publicly known technology, constituting its distinct technical characteristics. This conclusion is further supported by the fact that the Plaintiff "warranted that the sale and use of the Subject Item would not infringe on any third party's industrial property rights or intellectual property rights." Conversely, it is unreasonable to construe the agreement as stating that even if a portion of the technical content of Patent 1 and Patent 2 was utilized without any design modifications or improvements beyond publicly known technology, such a product would still qualify as an Improved Product and thus be included in the Subject Item.

d) Based on the above considerations, it should be interpreted that, at the time of the Mediation Agreement, the Plaintiff and Defendant included within the Subject Item as Improved Product only those products in which "at least a portion of the technical content of

Patent 1 and Patent 2 has been improved beyond publicly known technology which constitute their distinct technical characteristics." [According to the statements in Plaintiff's Exhibit 13-2, the appellate court in the K Lawsuit (Seoul High Court, 2012Na90209) also construed Improved Products as "products that incorporate all or part of the distinctive technology of Product D, which was recognized as an advance over prior technology and patented, thereby establishing a substantial technical relevance to Product D."]

C. Technical Characteristics of Patent 1 and Patent 2

1) Problems and Challenges to the Prior Art

a) The specifications of Patent 1 at Issue (Plaintiff's Exhibit 3-1) and Patent 2 (Plaintiff's Exhibit 38) include the following statements.

(1) As illustrated in Figure 1, Patent Publication No. 2000-48562 (hereinafter, "Prior Art 1")[8] discloses a bone fixation apparatus, comprising a bone screw(10) with a spherical head (12); a shrinkage collet (14) supporting the head (12) of the bone screw; a receiver component (18) having a central bore defining a tapered recess (16) for accommodating the shrinkage collet (14), a U-shaped channel passing through the recess (16) for receiving a

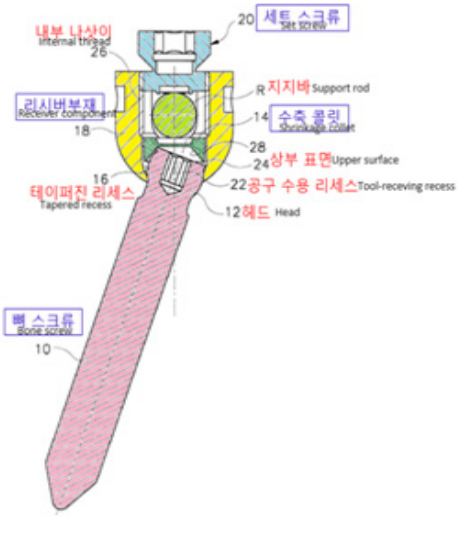


Fig 2. (Prior Art 1)

8) It refers to the invention titled "Multi-Axial Bone Screw Assembly" disclosed in the published Patent Gazette (Publication No. 2000-0048562, Defendant's Exhibit 13) published on July 25, 2000.

support rod (R); and a set screw (20) threadedly engaged with the internal thread of the receiver component (18) to secure the support rod (R). A tool-receiving recess (22) is formed in the head (12) of the bone screw to accommodate a tool, and the tool-receiving recess (22) is limited by a flat upper surface (24). The channel portion of the receiver component (18) is formed with internal threads (26) to allow threaded engagement with a set screw (20). The rear surface of the shrinkage collet (14) includes a recess (28) that conforms to and closely contacts the head (12). The lower portion of the shrinkage collet (14) and the recess (28) are provided with multiple slots to exert a certain level of compressive force on the head (12) of the bone screw. When the set screw (20) is tightened, the support rod (R) compresses the shrinkage collet (14), which is then pressed into the tapered recess (16) of the receiver component, thereby securing the bone screw (10) in a vertical portion or at a predetermined inclined angle.

(2) As illustrated as Figure 2, the U.S. patent No. 6280442 (hereinafter, "Prior Art 2")[9] discloses a structure in which multiple protruding bands (34) are formed on the head (32) of a bone screw (30), and a support ring (38) is fitted and coupled to the lower inner surface of the bore of a receiver component (36) so that the lower portion of the head (32) is retained. The upper portion of the head (32) is covered with a

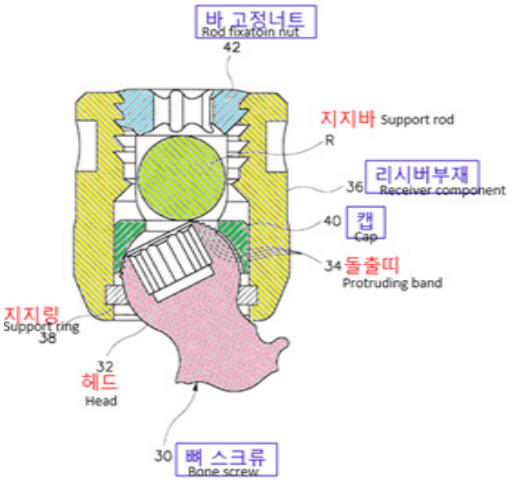


Fig 2. (Prior Art 2)

9) It is referred to the invention titled "Multi-Axial Bone Screw Assembly" disclosed in the U.S. Patent Gazette (Patent No. US 6280442, Defendant's Exhibit 14) published on August 28, 2001.

cap (40), and a support rod (R) is inserted into the channel of the receiver component (36) above the cap (40) and secured with a rod fixation nut (42). Additionally, the inner diameter of the section of the receiver component (36) where the cap (40) is inserted is larger than the inner diameter of the section where the rod fixation nut (42) is screwed, preventing the cap (40) from dislodging upward when the rod fixation nut (42) is loosened and the support rod (R) is removed. For assembly, the cap (40) is first inserted through the lower portion of the receiver component (36), and then the support ring (38) is externally fitted onto the lower end of the bone screw (30) and secured onto the lower inner surface of the bore of the receiver component (36). Additionally, an alternative structure is disclosed in which internal threads are formed throughout the interior of the receiver component, including the lower portion, so that the cap (40) can be threaded and prevented from dislodging.

(3) The bone fixation apparatus of Prior Art 1 has week support, causing the head (12), which is seated in the tapered recess (16), to move due to external disturbances, thereby failing to maintain its initial supporting state. Although Prior Art 2 was designed to improve the problems of Prior Art 1, it presented problems such as difficulty of assembling the support ring (38) and the inadequate support strength of the bone screw. Additionally, the structure in which the upper portion of the bone screw head is fixed by threading a cap downward not only required fully threading the cap to the lower portion but also failed to transmit the securing force of the rod fixation nut to the head, making assembly difficult and reducing the support strength of the bone screw. Against this backdrop, the present invention was devised to solve these problems, and its objective is to provide a bone fixation apparatus that not only enhances the support strength of the bone screw to prevent movement but also facilitates assembly and prevents the cap from dislodging.

b) According to the specifications, Patent 1 and Patent 2 at Issue

improve upon the bone fixation apparatuses of Prior Art 1 and Prior Art 2, which had weak support strength and were difficult to assemble, by enhancing the support strength of the bone screw to prevent movement, facilitating assembly, and preventing the cap from dislodging.

2) Technical Characteristics

a) The specification of Patent 1 (Plaintiff's Exhibit 3-1) includes the following statements:

(1) The bone fixation apparatus according to the present invention, designed to achieve the above objective, comprises a bone screw having a head, a cap that supports the upper side of the bone screw head, and a bore that is engaged with the head of the bone screw when the cap is accommodated, the receiver component with a U-type channel that receives a support rod and a rod fixation nut that secures the support rod threadedly. The lower inner surface of the bore is formed with multiple stepped portions to enhance the support strength of the head, ensuring line contact with the lower outer surface of the head.

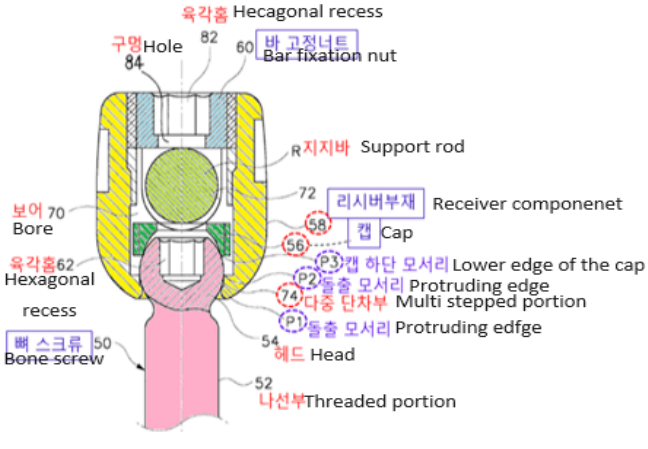


Fig. 3 (Cross-sectional view of bone fixation apparatus)

(2) The rear surface of the cap preferably has a recess formed to a predetermined depth, with the lower edge of the recess in line contact with the upper outer surface of the head. The threads of the screw portion are preferably trapezoidal to prevent deformation of the receiver component while optimizing force transmission, fastening strength, and loosening resistance.

b) The specification of Patent 2 (Plaintiff's Exhibit 38) includes the following statements:

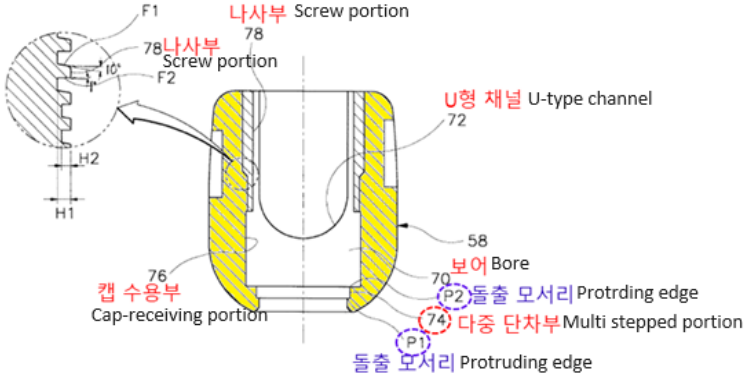


Fig. 5 (Cross-sectional view of receiver component in Fig. 3)

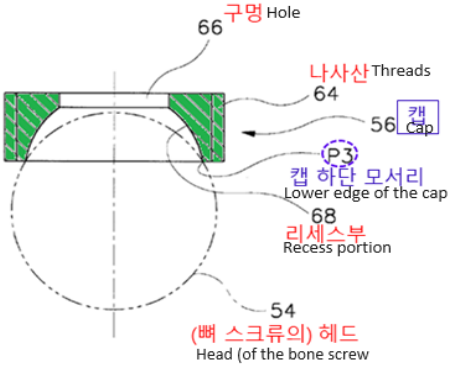


Fig. 6 (Cross-sectional view of cap in Fig. 3)

(1) The bone fixation apparatus according to the present invention, designed to achieve the above objective, comprises a bone screw having a head, a cap that supports the upper side of the bone screw head, a bore that is engaged with the head of the bone screw

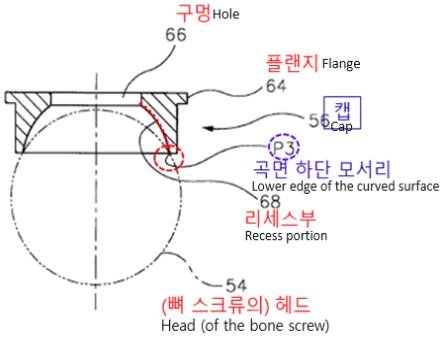


Fig. 6 (Cross-sectional view of the cap)

when the cap is accommodated, a receiver component with U-type channel that receives a support rod, and a rod fixation nut that secures the support rod threadedly to the receiver component. The bore consists of multiple stepped portions formed on the lower inner surface to enhance the support strength of the head by ensuring line contact with the upper outer surface of the head, a cap-receiving portion formed above the multiple stepped portions to accommodate the cap, and a screw portion formed with an inner diameter smaller than that of the cap-receiving portion to allow the rod fixation nut to be threadedly engaged. A flange with an outer diameter larger than the inner diameter of the screw portion is formed on the upper part of the cap, and the cap is inserted into the cap-receiving portion through plastic deformation of the flange together with the lower part of the screw portion.

(2) The outer surface of the bone screw head is formed with multiple groove bands at predetermined intervals to increase friction with the cap, and these groove bands are asymmetrically formed with respect to the axis of the bone screw so that the lower contact line of the cap crosses them regardless of the fixation angle of the bone screw. The receiver component has a jar shape, with the diameter of its central portion, through which the support rod passes, being larger than the diameters of its upper and lower portions.

c) Based on the statements in the above specification, the core technical concept adopted by Patent 1 and Patent 2 to address the aforementioned technical problems is that the bone fixation apparatus comprises a bone screw, a cap, a receiver component, and a rod fixation nut, and that ① to enhance the support strength of the bone

screw head, multiple stepped portions are formed on the lower inner surface of the receiver component, where the head is engaged (refer to Claim 1 of Patent 1 and Patent 2), and ② to prevent the cap from becoming dislodged while facilitating its assembly, a flange with an outer diameter larger than the inner diameter of the screw portion of the receiver component is formed on the upper part of the cap, so that the cap, together with the lower part of the screw portion, undergoes plastic deformation and is inserted into the cap-receiving portion (refer to Claim 1 of Patent 2 at Issue).

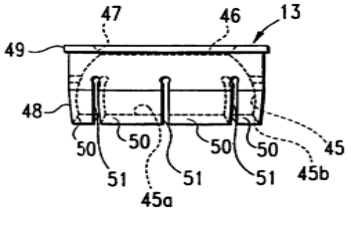
d) Combining the statements in the above specification with the circumstances set forth in the following subparagraphs (1) through (3), the aspects of Patent 1 and Patent 2 that directly implement the aforementioned technical concept or contribute as technical means, improved beyond the Prior Arts 1 and 2, which are publicly known technologies, to form their distinctive technical characteristics, can be identified as follows in the table below. (In this regard, there is no particular dispute between the Plaintiff and the Defendant.)[10)]

Component	Technical Characteristics	Relevant Claims
Receiver component	Multiple stepped portions are formed to enhance the support strength of the head	Claim 1 of Patent 1 and Patent 2
	The upper screw portion is a trapezoidal thread thread	Claim 5 of Patent 1
	The receiver component has a jar shape where the diameter of the central portion, through which the support rod passes, is larger than the diameter of the upper and lower portions	Claim 4 of Patent 2
Cap	A recess is formed at a predetermined depth on the rear surface of the cap, and the lower edge of the recess makes line contact with the upper outer surface of the head	Claim 2 of Patent 1

10) Refer to the records for the second trial date for this decision.

Component	Technical Characteristics	Relevant Claims
Cap insertion method	A flange with an outer diameter larger than the inner diameter of the screw portion is formed on the upper part of the cap, and the flange, together with the lower part of the screw portion, undergoes plastic deformation and is accommodated in the cap-receiving portion	Claims 1 and 5 of Patent 2

(1) Although Patent 1 and Patent 2 disclose a technical composition comprising a bone screw, a cap, a receiver component, and a rod fixation nut, this alone does not constitute a distinguishing feature, as previously examined, because multi-axial bone fixation apparatus of Prior Art 1 includes a bone screw, a shrinkage collet, a receiver component, and a set screw, while multi-axial bone fixation apparatus of Prior Art 2 comprises a bone screw, a cap, a receiver component, and a rod fixation nut, suggesting no significant difference between these structures. Accordingly, such relatively basic technical elements cannot be considered improvements over prior art that constitute the distinctive technical features of Patent 1 and Patent 2.

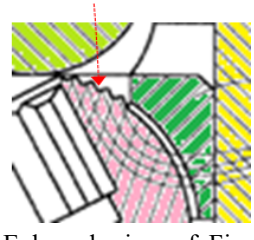


Drawing 7 of Prior Art 1

(2) Moreover, among the technical characteristics concerning the cap insertion method, the mere fact that a flange is formed on the upper part of the cap is already disclosed in Prior Art 1. Specifically, the specification of Prior Art 1 states “the shrinkage collet (13) includes a rim (49) at its upper end. The rim (49) of the shrinkage collet (13) has a diameter slightly smaller than that of the collet recess (36). The diameters of the collet recess (36) and the rim (49) of the shrinkage collet (13) are slightly larger than the inner diameter of the threaded portion (37) of the receiver component (12)” (Defendant’s Exhibit 13, page 5, lines 21-24). Based on this description, the rim

(49) formed at the upper end of the shrinkage collet in Prior Art 1 does not present any substantial technical difference from the flange formed on the upper part of the cap in Patent 2. Therefore, setting aside whether "the flange formed on the upper part of the cap undergoes plastic deformation together with the lower part of the screw portion and is accommodated in the cap-receiving portion," the technical content that merely states "a flange is formed on the upper part of the cap" cannot be considered an improvement beyond the prior art to constitute a technical characteristic of Patent 2.

(3) Meanwhile, Claim 2 of Patent 2 at Issue discloses the technical composition that "the outer surface of the bone screw head is formed with multiple groove bands at predetermined intervals to increase friction with the cap."[11] However, as previously examined, multiple protruding bands (groove bands) are also formed on the head of the bone screw in Prior Art 2. Therefore, the technical composition of forming multiple "groove bands" on the outer surface of the bone screw head in Patent 2 cannot be considered as an improvement beyond prior art that constitutes its distinctive technical characteristics.



Enlarged view of Fig. 2(Prior Art 2)

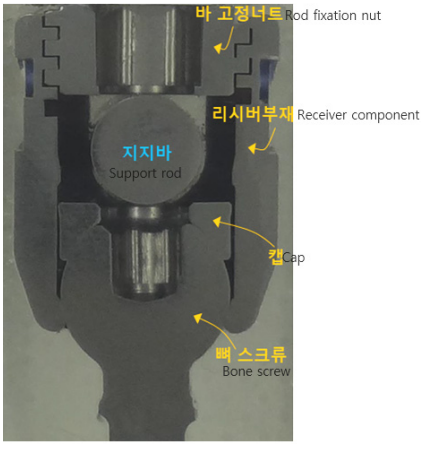
D. Whether Product L Qualifies as Improved Product

1) Overview of Product L

According to the statements and images in Defendant's Exhibits 29 (design drawings of Product L), 38 (cross-sectional photos of Product L), and 42 (cross-sectional sample photos of Product L), it is identified that Product L, as with the inventions of Patent 1 and Patent 2, fundamentally includes a bone screw, cap, receiver component, and bar

11) The district's court decision considered the above technical composition to be one of the elements constituting the technical characteristics of Patent 2.

fixation nut, and specifically incorporates the technical composition described in Appendix 5. [Meanwhile, the Plaintiff argues that the images in Defendant's Exhibits 38 and 42, submitted by the Defendant, do not show any indication of the Defendant's trade name, product name, or product number, and therefore cannot be deemed as actual evidence of Product L. However, based on the purport of the overall argument, these exhibits appear to have been taken and submitted by the Defendant as images of Product L, and this alone does not suffice to deny their evidentiary value. (Furthermore, no other materials have been submitted that provide a concrete understanding of technical composition of Product L.)]



Defendant's Exhibit 38 [Pic. 1]

2) Receiver Component

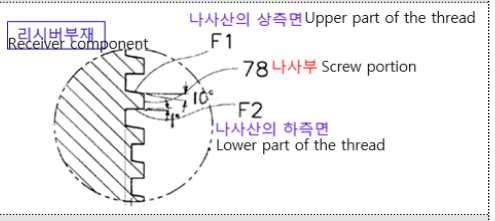
a) Shape of Screw

The invention of Patent 1 is characterized by the adoption of a trapezoidal thread at the upper part of the receiver component. However, Product L differs in that it adopts a square thread instead of a trapezoidal thread at the upper part of the receiver component.

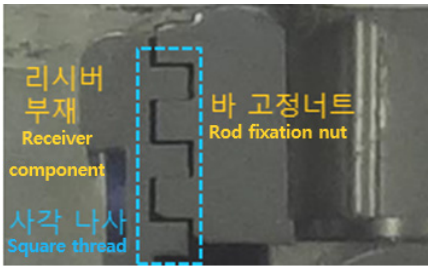
Regarding this, the Plaintiff argues that the trapezoidal thread and square thread are interchangeable in actual products depending on necessity, and therefore, the square thread used in Product L is substantially identical to the trapezoidal thread of the invention of Patent 1. However, the Plaintiff's argument is not accepted for the following reasons:

(1) The specification of Patent 1 states that "the thread of the screw portion (78) is designed to as a trapezoidal thread to prevent

Excerpt from Fig. 5 of Patent 1



Product L
(excerpt from Defendant's Exhibit 38)



deformation of the receiver component (58) while ensuring optimal performance in terms of force transmission, fastening force, and prevention of loosening. Specifically, in the case of a triangular thread, while the fastening force is excellent when the rod fixation nut (60) is tightened, the force transmission in the longitudinal direction is weak, and the receiver component expands radially after fastening, requiring an additional cap on the outer surface. Meanwhile, a square thread has excellent force transmission in the longitudinal direction but is prone to loosening after fastening. However, a trapezoidal thread maintains both fastening force and force transmission at optimal levels simultaneously and eliminates the need for an external cap on the receiver component" (Plaintiff's Exhibit 3-1, page 5, lines 15-20).

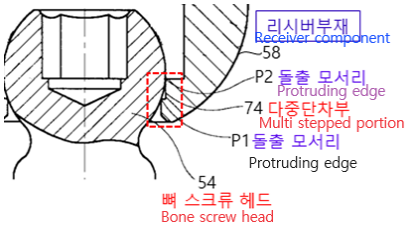
(2) According to the statements in the specification, the trapezoidal thread and the square thread exhibit different functional effects in terms of force transmission and fastening force. Therefore, it is difficult to conclude that the square thread used in Product L is substantially identical to the trapezoidal thread of the invention in Patent 1.

b) Contact Form Between Receiver Component and Bone Screw Head

(1) The inventions of Patent 1 and Patent 2 are characterized by the formation of multiple stepped portions on the lower inner surface of the receiver component, where the head of the

bone screw engages, enabling line contact between the receiver component and the bone screw head. However, Product L does not have multiple stepped portions on the lower inner surface of the receiver component, resulting in surface contact between the lower inner surface of the receiver component and the bone screw head. Thus, when compared to the inventions of Patent 1 and Patent 2, Product L differs in terms of the presence of multiple stepped portions and the contact form (line contact or surface contact).

Excerpt from Fig. 3 of Patent 1



Product L
(excerpt from Defendant's Exhibit 38)

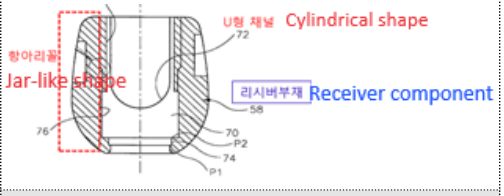
(2) Regarding this, the Plaintiff argues that the technical composition of surface contact adopted in Product L should qualify it as an Improved Product because the same technical composition was already used in K Product, which was recognized as an Improved Product in the appellate ruling of the K Lawsuit. Therefore, the Plaintiff contends that Product L should be deemed an Improved Product, regardless of the presence of multiple stepped portions. However, the Plaintiff's argument is not accepted for the following reasons:

(a) Whether Product L qualifies as an Improved Product shall be determined based on its technical composition, and the mere fact that a separate product pointed out by the Plaintiff was recognized as an Improved Product due to technical composition of surface contact does not justify concluding the Product L is an Improved Product without considering the presence of multiple stepped portions.

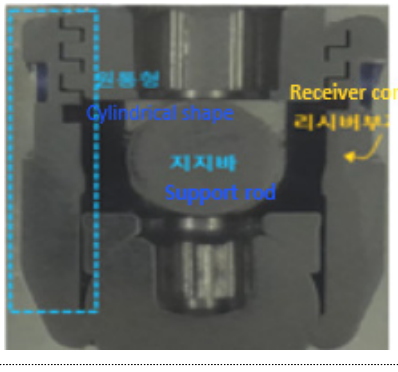
(b) Moreover, the specification of Patent 1 states that "the lower inner surface of the bore (70) is formed with a multi stepped portion (74) consisting of two steps to enhance the support strength of the head (54), and each protruding edge (P1) (P2) of the multi stepped portion makes line contact with the lower outer surface of the head (54). The multi stepped portion may be formed with three or four steps. The protruding edge (P2) located on the upper side of the multi stepped portion (74) has a larger inner diameter than the protruding edge (P1) located on the lower side, allowing the lower outer surface of the spherical head (54) to make line contact" (Plaintiff's Exhibit 3-1, page 5, lines 3-6).

(c) As seen in the statements in the specification, the multiple stepped portions formed on the lower inner surface of the receiver component serve to enhance the supporting force of the head through line contact and constitute a technical characteristic of the inventions of Patent 1 and Patent 2. However, Product L adopts a technical composition of surface contact, and thus does not incorporate the technical characteristic of the multiple stepped portions.

Excerpt from Fig. 5 of Patent 2



Product L
(excerpt from Defendant's Exhibit 38)



c) Shape of Receiver Component

The invention of Patent 2 is characterized by a receiver component in which the central portion through which the support rod passes has a larger diameter than the upper and lower portions, forming a jar-like shape. However, the receiver component of Product

L differs in that the central portion through which the support rod passes has a cylindrical shape with a diameter similar to that of the upper and lower portions.

Regarding this, the Plaintiff argues that the receiver component of Product L also has a jar-like shape, where the diameter of the central portion through which the support rod passes is larger than that of the upper and lower portions, just as in the invention of Patent 2. However, the statements and images in Plaintiff's Exhibits 184 and 185 alone are insufficient to overturn the statements and images in Defendant's Exhibits 29, 38, and 42, which indicate that the receiver component of Product L has the aforementioned cylindrical shape. Furthermore, there is no other evidence to support the claim that the diameter of the central portion is larger than that of the upper and lower portions. Therefore, the Plaintiff's argument is not accepted.

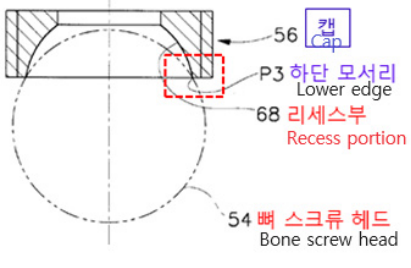
3) Cap

a) Contact Form between Cap and Bone Screw Head

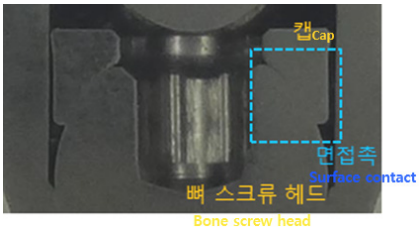
The invention of Patent 1 is characterized by the lower edge of the recess formed on the rear surface of the cap making line contact with the upper outer surface of the bone screw head. However, Product L differs in that the rear surface of the cap makes surface contact with the upper portion of the bone screw head.

Regarding this, the Plaintiff argues that, in the invention of Patent 1, the rear surface of the cap initially makes line contact with the bone screw head when

Fig. 6 of Patent 1



6 Product L
(excerpt from Defendan't Exhibit 38)



inserted into the receiving portion, but when the fixation nut is tightened to apply pressure, the rear surface of the cap and the bone screw head transition to surface contact. Based on this, the Plaintiff contends that there is no significant difference between Patent 1 at Issue and Product L. However, the Plaintiff's argument is not accepted for the following reasons:

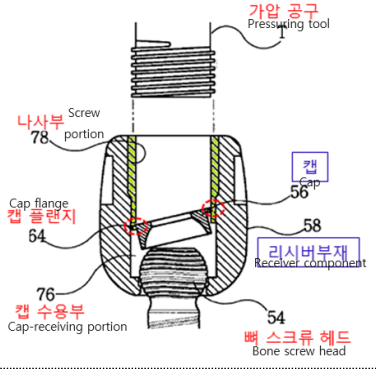
(1) The specification of Patent 1 states that "the fastening force of the rod fixation nut (60) is sequentially transmitted through the cap (56) of the support rod (R) to the head (54), where each protruding edge (P1) (P2) of the multi stepped portion (74) of the receiver component makes line contact with the lower outer surface of the head (54), and the lower edge (P3) of the cap (56) makes line contact with the upper outer surface of the head (54), thereby ensuring that the bone screw (50) is firmly fixed and supported without movement" (Plaintiff's Exhibit 3-1, page 6, lines 4-6). According to the specification, it is evident that Patent 1 adopts as its technical characteristic that when the rod fixation nut is tightened to apply pressure for securing the bone screw, the lower edge (P3) of the cap makes line contact with the upper outer surface of the head.

(2) Even if, as the Plaintiff asserts, the specific embodiment of Patent 1 allows for surface contact between the rear surface of the cap and the bone screw head during the process of tightening the fixation nut to apply pressure, this can only be understood as an additional surface contact following the initial line contact, which varies depending on the magnitude of the force applied by tightening the fixation nut. The mere fact that such an embodiment is possible does not negate the technical characteristic of Patent 1, namely that the lower edge of the recess makes line contact with the upper outer surface of the bone screw head. Nor does it justify concluding that Product L, which does not exhibit such line contact, has no significant technical difference from Patent 1.

b) Method of Cap Insertion

(1) As previously examined, the method of cap insertion in the invention of Patent 2 is characterized by a flange with an outer diameter larger than the inner diameter of the screw option being formed on the upper part of the cap, and the flange, together with the lower part of the screw portion, undergoing plastic deformation as it moves from the upper part to the lower part of the receiver component, thereby being accommodated in the cap-receiving portion. This is further supported by the following considerations.

Excerpt from Fig. 8 of Patent 2



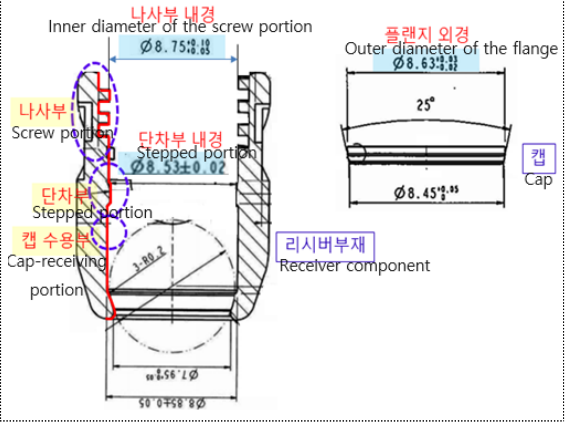
(a) The specification of Patent 2 states, regarding the cap insertion method of Product D, that "as illustrated in Fig. 8, the cap(56) insertion involves tilting the cap to first insert to onside of the flange (64) into the receiving portion (76) of the cap, then positioning the other side of the flange against the screw portion (78), and finally pressing the cap (56) with a pressing tool (T) so that the portion of the flange engaged with the screw portion (78) undergoes plastic deformation together with the lower part of the screw portion (78), thereby allowing the cap (56) to be inserted into the receiving portion (76). As a result, the cap (56) is prevented from becoming dislodged upward" (Plaintiff's Exhibit 38, page 5, lines 1-4).

(b) As shown in the statements and illustrations in the specification, the cap insertion method in the invention of Patent 2 involves tilting the cap to first insert one side of the flange into the receiving portion, then positioning the other side of the flange against the screw portion, and finally pressing the cap with a pressing tool so that the portion of the flange engaged with the screw portion

undergoes plastic deformation together with the lower part of the screw portion, thereby allowing the cap to be inserted into the receiving portion. As a result, the cap is prevented from becoming dislodged upward. That is, the cap insertion method of Patent 2 is characterized in that ① a flange with the outer diameter larger than the inner diameter of the screw portion shall be formed on the upper part of the cap, and ② the flange portion of the cap shall undergo plastic deformation together with the lower part of the screw portion.

(2) However, according to the statements and images in Defendant's Exhibits 29 and 38, Product L has a screw portion formed on the upper part of the receiver component and a stepped portion formed below the screw portion. Additionally, the outer diameter of the flange formed on the upper part of the cap (Φ 8.63) is smaller than the inner diameter of the screw portion of the receiver component (Φ 8.75) but larger than the inner diameter of the stepped portion (Φ8.53).

Product L (excerpt from Defendant's Exhibit 29)

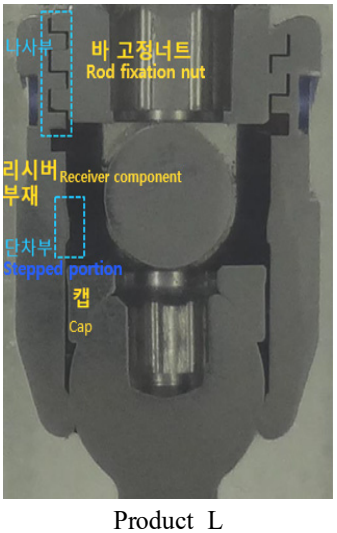


Accordingly, the cap insertion method of Product L appears to involve the cap moving from the upper part to the lower part of the receiver component without tilting or making contact between the flange of the cap and the screw portion, which has a relatively larger inner diameter, as it passes through the screw portion of the receiver component. The cap is then fitted into the stepped portion and subsequently accommodated in the receiving portion of the cap through compression. (The Defendant argues that as the cap flange of Product L moves from the upper part to the lower part of the receiver component, it

undergoes “elastic deformation” at the stepped portion and is accommodated in the receiving portion of the cap.)

(3) In summary, ① the outer diameter of the cap flange in Patent 2 is larger than the inner diameter of the screw portion, whereas in Product L, the outer diameter of the cap flange is smaller than the inner diameter of the screw portion, making a difference. ② Additionally, in Patent 2, the cap flange undergoes plastic deformation together with the lower part of the screw portion and is then accommodated in the receiving portion, whereas in Product L, the cap flange passes through without sufficient contact with the screw portion to cause plastic deformation, and after being fitted into the stepped portion, it is then accommodated in the receiving portion, highlighting another difference.

That is, the notable technical composition of Patent 2, namely that a flange with an outer diameter larger than the inner diameter of the screw portion is formed on the upper part of the cap, and the flange portion of the cap undergoes plastic deformation together with the lower part of the screw portion, has been modified in Product L such that the outer diameter of the cap flange is smaller than the inner diameter of the screw portion, and the flange portion of the cap passes through without contact with the screw portion before being fitted into the stepped portion for insertion.

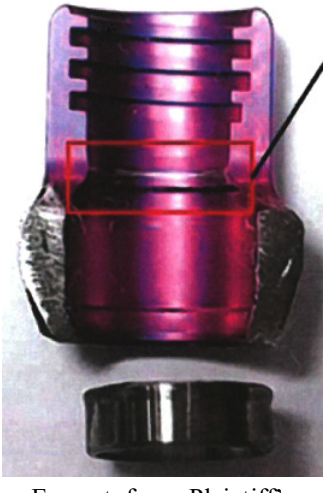


Product L
(excerpt from Defendant’s Exhibit 38)

(4) Regarding this, the Plaintiff argues that Product L is identical to the cap insertion method of Patent 2 at Issue because a deficiency in the screw thread was observed at the stepped portion on the lower part of the receiver component (Plaintiff’s Exhibit 162-3), and that this deficiency resulted from the plastic

deformation of the stepped portion, which occurred when the cap was inserted into the receiver component at an angle and then subjected to pressure.

However, the statements and images in Plaintiff's Exhibit 162-3 alone are insufficient to support the Plaintiff's assertion that a deficiency in the screw thread occurs at the stepped portion on the lower part of the receiver component in Product L or that plastic deformation occurs at the stepped portion together with the flange portion of the cap. Furthermore, no other evidence has been presented to substantiate such a conclusion.



Excerpt from Plaintiff's Exhibit 162-3

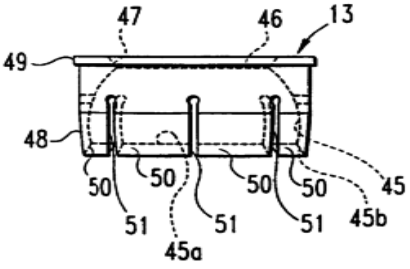
(5) As examined above, when comparing the cap insertion method of Product L with that of Patent 2, the relative size relationship between the outer diameter of the cap flange and the inner diameter of the screw portion is reversed, resulting in a distinctive modification of the technical composition. Consequently, this change affects the organic relation between the two technical compositions, in which the cap flange undergoes plastic deformation together with the lower part of the screw portion, altering it to a structure where the cap flange passes through without contact with the screw portion and is inserted after being fitted into the stepped portion.

Given these circumstances, it is difficult to conclude that the distinctive technical composition of the cap insertion method in Patent 2 at Issue has been fully retained and utilized in Product L while maintaining its integrity. (In contrast to Product L, the primary reason why Product K was recognized as an Improved Product in the appellate ruling of the K Lawsuit was, as previously examined, that Product K, like Product K, adopted a method in which a flange with an outer diameter larger than the inner diameter of the screw portion is formed on the upper part of the cap, and the flange undergoes

"plastic deformation" together with the lower part of the screw portion, allowing the cap to be inserted.)

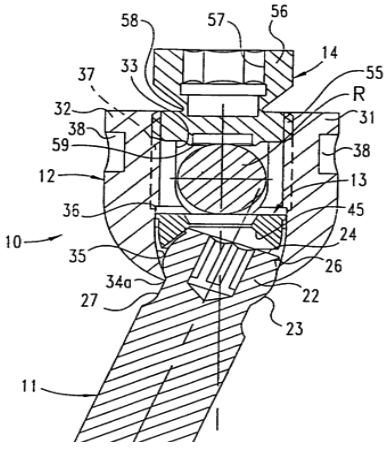
(6) Furthermore, in light of the following considerations, it is also difficult to conclude that the distinctive technical composition of the cap insertion method in Patent 2 has been equivalently utilized in Product L, given that the individual technical compositions have been modified, along with the organic relation of these technical compositions within the overall structure of the product.

(a) The specification of Prior Art 1 states that ① "the shrinkage collet (13) includes a rim (49) at its upper end, and the rim (49) of the shrinkage collet (13) has a diameter slightly smaller than the diameter of the collet recess (36). The diameters of the collet recess (36) and the rim (49) of the shrinkage collet (13) are slightly larger than the inner diameter of the threaded portion of the receiver component (12). … The rim (49) can be threadedly engaged through the threaded portion (37) of the receiver component (12) from the upper opening (33b) of the channel (33) until it is positioned within the collet recess (36)" (Defendant's Exhibit 13, page 5, lines 21-28); and ② "when the spine rod (R) is in place, the set screw (14) can be threadedly engaged with the threaded portion (37) of the receiver component (12). As the set screw (14) is further tightened to the receiver component (12), the tapered recess (35) of the receiver component (12) and the set screw (14) are pulled toward each other. As this process continues, the spine rod (R) is compressed against the upper surface of the shrinkage collet (R), and the shrinkage collet (13) pushes the collet (13) further into the tapered recess (35). As the collet advances into the tapered recess (35), the grasping fingers (50) are elastically compressed against the spherical surface (23) of the screw head (22). The set screw (14) is tightened



Drawing 7 of Prior Art 1

until the collet (13) and the fingers (50) are securely engaged between the screw head (22) and the tapered recess (35)" (Defendant's Exhibit 13, page 5, lines 16-22 from the bottom).



Excerpt from Fig. 2 of Prior Art 1

(b) As shown from the above statements and illustrations, Prior Art 1 discloses a technical composition in which ① the rim (49) of the shrinkage collet (13, corresponding to the "cap" in Patent 1 and Patent 2,) descends into the collet recess (36) through a threaded engagement with the threaded portion (37) of the receiver component (12) from the upper opening (33b), and ② as the set screw (14) is tightly fastened into the receiver component (12), the tapered recess (35) of the receiver component (12) and the set screw (14) are drawn toward each other, causing the shrinkage collet (13) to advance into the tapered recess (35) while the grasping fingers (50) elastically compress against the spherical surface (23) of the screw head (22), thereby securing the shrinkage collet (13) tightly between the screw head (22) and the tapered recess (35).

(c) However, as stated in the description of Prior Art 2 in the specification of Patent 2, Prior Art 2 differs from Prior Art 1, which positions the shrinkage collet (cap) by lowering it from the top. Instead, Prior Art 2 adopts a structure in which the cap (40) is inserted through the lower part of the receiver component (36), followed by the insertion of the bone screw (30), and then a separate technical means, the support ring (38), is fitted onto the lower side of the screw head (32) to secure it in place.

In other words, the specification of Patent 2 at Issue includes a statement regarding Prior Art 2, which describes "a structure which a

support ring (38) is fitted and coupled to the lower inner surface of the bore of the receiver component (36) so that the lower side of the head (32) is engaged, while the upper side of the head (32) is covered with a cap (40), and the upper side of the cap (40) has a support rod (R) inserted into the channel of the receiver component (36) and secured with a rod fixation nut (42). ··· For assembly, the cap (40) is inserted through the lower side of the receiver component (36), and finally the support ring (38) is externally fitted onto the lower end of the bone screw (30) and inserted into the lower inner surface of the bore of the receiver component (36).”

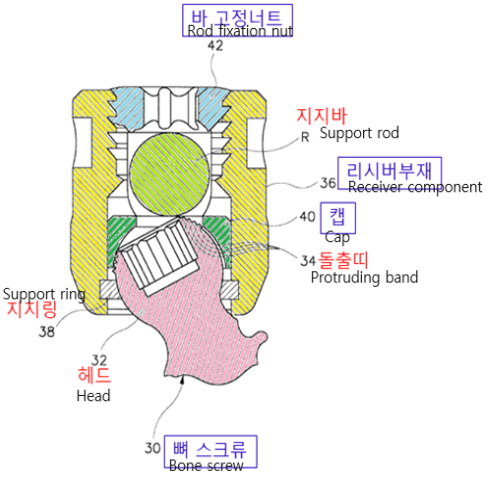


Fig. 2 from the specification of Patent 2 (Prior Art 2)

(d) Additionally, as previously examined, the specification of Patent 2 states that ① a structure in which a support ring (38) is fitted, as in Prior Art 2, presents a problem of being difficult to assemble; ② a structure in which the upper side of the head of the bone screw is secured by threadably engaging a cap, as in Prior Art 1, also has the problem that assembly becomes difficult when the cap is screwed down to the lower side; and ③ the purpose of the invention of Patent 2 is to provide a bone fixation apparatus that prevents the dislodging of the cap while ensuring ease of assembly.

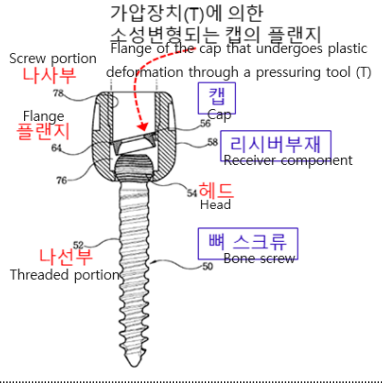
The concept of “preventing the cap from dislodged” is commonly recognized not only in the invention of Patent 2 but also in Prior Arts 1 and 2, as it is a fundamental objective that should naturally be achieved in bone fixation apparatuses. Therefore, it cannot be regarded as a distinctive feature unique to Patent 2. Rather, the ultimate objective of Patent 2 should be understood as achieving the distinctive

technical challenge of "ease of assembly" while simultaneously addressing the general objective of "preventing cap dislodging."

(e) Patent 2, in order to achieve the aforementioned ultimate objective, adopts the core technical concept in which a flange with an outer diameter larger than the inner diameter of the screw portion is formed at the upper end of the cap. This flange undergoes plastic deformation along with the lower part of the screw portion, thereby allowing the cap to be inserted and accommodated within the cap-receiving portion, as previously described.

More specifically, Patent 2, based on the aforementioned technical concept, deviates from the structure of Prior Art 2, where the bone screw head is inserted from the lower side of the receiver component, and a separate support ring is fitted and engaged beneath the bone screw head after inserting the cap above it. It also departs from the structure of Prior Art 1, where the upper portion of the bone screw head is fixed by being threadably engaged with the cap. Instead, it adopts a structure in which the bone screw head is inserted from the upper side of the receiver component, and the cap is inserted and accommodated within the cap-receiving portion without the need for a separate supporting means fitted beneath the bone screw head. This structure addresses the assembly inefficiency observed in the prior arts. Furthermore, to ensure that this insertion and accommodation structure is concretely realized within the organic relation of the entire invention, the patent adopts a technical feature in which the flange of the cap undergoes plastic deformation along with the lower part of the screw portion due to the occurrence of material loss, thereby functioning as a means to prevent the dislodging of the cap.

Excerpt from Fig. 8 of Patent no. 2 at Issue

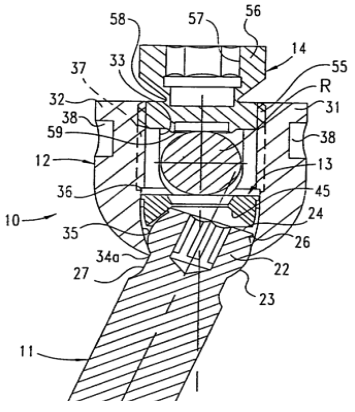


(f) However, Product L eliminates the structures of Prior Art 1 and 2 by allowing the bone screw head to be inserted from the upper side of the receiver component and enabling the cap to be inserted and accommodated in the cap-receiving portion without requiring any separate technical means that engages with and supports the lower side of the bone screw head. By doing so, it resolves the assembly inefficiency found in the prior arts. Although this does not differ significantly from Patent 2, the core technical concept of Patent 2 ensures that the above-described insertion and accommodation structure is concretely realized within the organic relation of the entire invention. Specifically, a flange with an outer diameter larger than the inner diameter of the screw portion is formed on the upper part of the cap and undergoes plastic deformation due to material loss together with the lower part of the screw portion. This technical content cannot be found at all in Product L.

(g) Instead, the technical content of the cap insertion method in Product L, which involves “the cap flange passing through without contacting the screw portion, then being fitted into a stepped portion with an inner diameter smaller than the outer diameter of the cap flange before being accommodated in the cap-receiving portion,” aligns with the technical content found in the cap insertion method of Prior Art 1 that “the shrinkage collet (cap) is tightly engaged and accommodated between the tapered recess and other components.” In this respect, the insertion and accommodation of the cap (shrinkage collet) also relies on being fitted (tightened) in relation to another component, making it conceptually similar to Prior Art 1 in terms of its underlying technical concept.

In other words, as examined previously, Prior Art 1 features a structure in which, when the set screw (14) is tightly fastened to the receiver component (12), the tapered recess (35) and the set screw (14) are pulled toward each other, causing the shrinkage collet (13, cap) to advance into the tapered recess (35). At the same time, the grasping finger (50) elastically compresses the spherical surface (23) of the screw

head (22), thereby securing and tightly fastening the shrinkage collet (13, cap) between the screw head (22) and the tapered recess (35). In this context, the tapered recess (35), in its relationship with the shrinkage collet (13, cap), can be seen as serving a function similar to the stepped portion in Product L, where the cap is fitted.



Excerpt from Fig. 2 of Prior Art 1

(h) In short, Product L does not embody the core technical concept of Patent 2 (where the cap flange undergoes plastic deformation due to material loss along with the lower portion of the screw portion), which ensures that the structure for the insertion and accommodation of the cap, aimed at solving the problem of assembly inefficiency, is concretely realized within the organic relation of the invention as a whole. Furthermore, there is no evidence suggesting that a person having ordinary skill in the technical field of Patent 2 would have readily conceived of modifying the characteristic technical configuration that directly implements this technical concept (forming a flange with an outer diameter larger than the inner diameter of the screw portion at the upper end of the cap) into the configuration seen in Product L, where the cap flange has an outer diameter smaller than the inner diameter of the screw portion and passes through without contact before being fitted into a stepped portion.

(i) Given the above circumstances, it is clear that Product L does not equivalently utilize the characteristic technical configuration of Patent 2 in any respect. Contrary to this, interpreting the characteristic technical configuration of Patent 2 as being equivalently utilized merely because the insertion of the cap is achieved through some form of physical deformation in relation to any technical means during the process of the cap flange being

accommodated in the receiving portion would result in an unjustifiable expansion of the technical scope or protection scope of Patent 2 beyond the extent to which it has contributed to technological advancement in comparison to prior art.

5) Summary of Findings

Based on the above considerations, Product L cannot be regarded as a product in which all or part of the technical content of Patent 1 and Patent 2, improved beyond publicly known technology and constituting their distinctive technical characteristics, has been utilized. Therefore, Product L does not belong to Improved Product for which the Defendant is obligated to pay advisory fees under the Mediation Agreement at Issue.

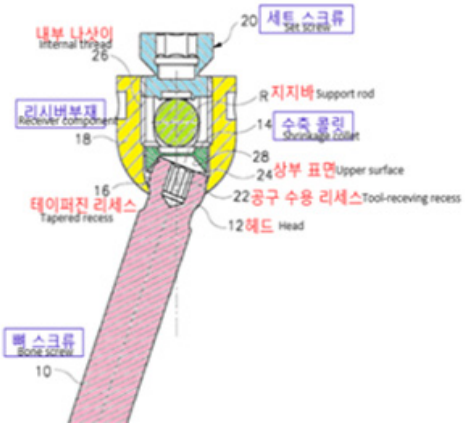
6) Determination on the Plaintiff's remaining arguments

a) Arguments regarding the cap

The Plaintiff argues that, in relation to Patent 1 and Patent 2 having a bone screw, a cap, a receiver component, and a rod fixation nut as their fundamental technical configuration, the shrinkage collet in Prior Art 1 and the cap in Prior Art 2 differ in form and functional effects from the cap in Patent 1 and Patent 2. Based on this, the Plaintiff asserts that the fundamental technical configuration of Patent 1 and Patent 2 constitutes an improved technical composition that was not disclosed in prior art. However, the Plaintiff's argument is not accepted for the following reasons:

(1) First of all, even by examining the previously reviewed statements and illustrations in the specifications of Patent 1 and Patent 2 regarding the "problems of prior art," it is evident that the bone fixation apparatuses in Prior Art 1 and Prior Art 2, like the inventions of Patent 1 and Patent 2, fundamentally comprise the technical components of a bone screw with a head, a cap (shrinkage collet) that supports the upper side of the bone screw head, a receiver component

with a U-type channel that accommodates the head, the cap, and the support rod, and a rod fixation nut (set screw) that secures the support rod from the upper side of the receiver component. (This point has already been examined in the section evaluating the technical characteristics of Patent 1 and Patent 2.)



Excerpt from Fig. 1 (Prior Art 1)

(2) In the inventions of Patent 1 and Patent 2, the "cap" has a cylindrical structure with a recess portion formed on its rear surface, functioning to support the upper side of the bone screw head (Plaintiff's Exhibit 3-1, page 4, first and fourth paragraphs from the bottom). According to the previously reviewed statements and illustrations in the specifications of Patent 1 and Patent 2 regarding the "problems of prior art," the "shrinkage collet" in Prior Art 1 and the "cap" in Prior Art 2 also have a cylindrical structure with a recess portion formed on their rear surface, pressing against the head so that the bone screw is securely fixed and supported within the receiver component. Therefore, it is evident that there is no substantial difference in the shape and functional effects between the "cap" in Patent 1 and Patent 2 and those in the prior art.

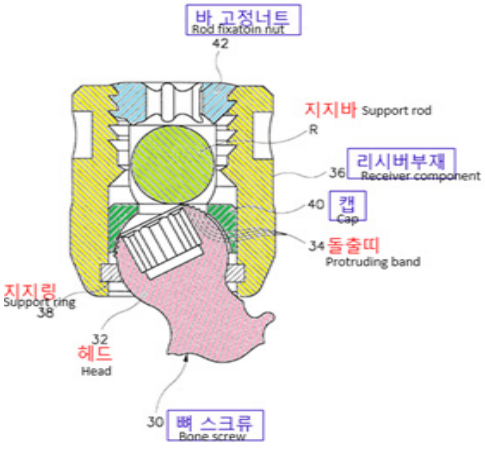


Fig 2. (Prior Art 2)

(3) Furthermore, according to the statements in Defendant's Exhibits 13, 14, and 20 through 24, 27, and 28, as well as the purport of the overall argument, it is evident that as of the application date of Patent 1 and Patent 2, multi-axial bone fixation apparatuses incorporating bone screws, caps, receiver components, and rod fixation nuts as basic components had already been disclosed in multiple prior art patent gazettes and other preceding documents.

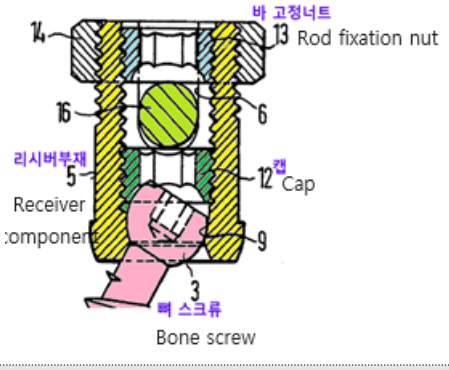


Fig. 2 of Defendant's Exhibit 21

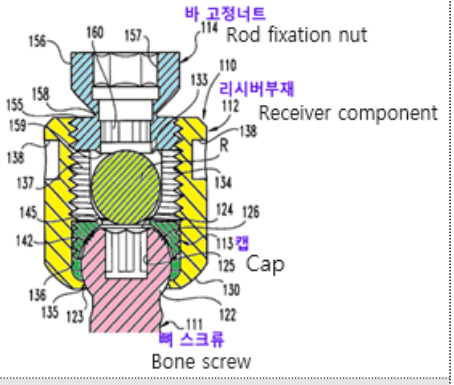


Fig. 8 of Defendant's Exhibit 24

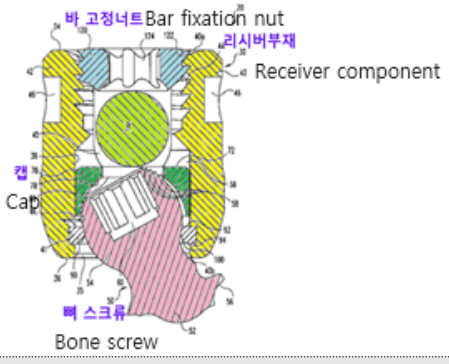


Fig. 7 of Defendant's Exhibit 14

b) Arguments regarding the expert opinion report

The Plaintiff also argues that, according to Plaintiff's Exhibit 67 (Expert Opinion Report), Product L should be considered an Improved Product that possesses the same components and operational effects as Patent 1 and Patent 2.

However, based on the statements in Plaintiff's Exhibit 67 (Expert Opinion Report), it can merely be identified that the expert opinion therein suggests that "since Product L includes fundamental technical components such as a bone screw, cap, receiver component, and rod fixation nut, just like Claim 1 of Patent 1, it may be considered an Improved Product." Moreover, the conclusion section of the report explicitly states that Product L does not include the technical configuration where "a multi-stepped portion is formed on the lower inner surface of the receiver component, ensuring line contact with the lower outer surface of the head." In light of these facts, the Plaintiff's argument cannot be accepted.

c) Arguments regarding surgical instruments

The Plaintiff further argues that the surgical instrument[12] of Product L corresponds to the surgical instrument for the bone fixation apparatus described in Claims 6 and 7 of Patent 2 and, therefore, should be considered an Improved Product for which the Defendant is obligated to pay advisory fees under the Mediation Agreement. However, the Plaintiff's argument is not accepted for the following reasons:

(1) Above all, based solely on the statements and images in Plaintiff's Exhibit 154-4, it is difficult to conclude that the aforementioned surgical instrument corresponds to the surgical tool for the bone fixation apparatus described in Claims 6 and 7 of Patent 2. Furthermore, there is no other evidence to support such a finding.

(2) Meanwhile, as previously examined, at the time of the Mediation Agreement, the Plaintiff and the Defendant agreed to include "surgical instruments (surgical tools) necessary for the procedure of Product D," which was "listed in the Appendix," as part of the Subject Item.

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12) The item numbers (item names) are SF0010 Poly screw driver, SP0040 FD Ratchet Handle, and SF0030 Anti Torque Device, as listed on pages 4, 5, and 12 of Plaintiff's Exhibit 154-4 (Product Manual).

However, Claims 6 and 7 of Patent 2 pertain to tools used when performing surgery with the bone fixation apparatus described in Claim 1, as indicated in the statements of the applicable Claims. As previously examined, Product L cannot be considered an Improved Product that incorporates any part of the technical content of the bone fixation apparatus of Patent 2 that has been improved beyond publicly known technology and constitutes its distinctive technical characteristics. Therefore, even if the surgical instruments identified by the Plaintiff are necessary for the procedure involving Product L, such a fact alone does not establish that they qualify as an Improved Product for which the Defendant is obligated to pay advisory fees under the Mediation Agreement.

E. Whether Product M and Product Lines N and O Qualify as Improved Products

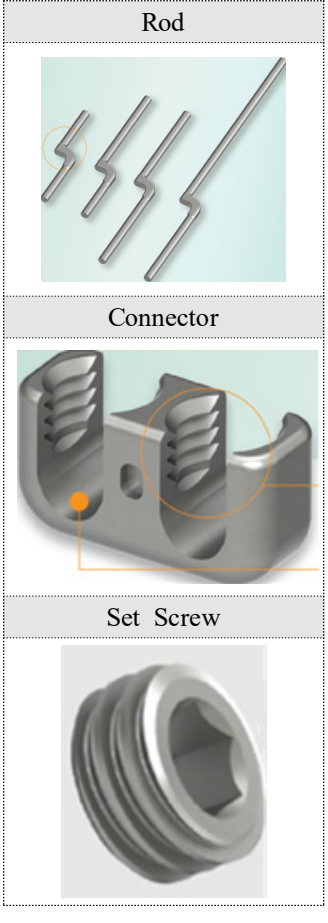
1) Product M

a) Established facts

Based on the statements and images in Plaintiff's Exhibits 13, 24, 138, and 159, as well as the purport of the overall argument, the following facts can be acknowledged:

(1) Product M is designed as a line extension device that allows for the expansion of the fixation area when additional complications are discovered without the need to remove previously implanted Product K or other bone fixation apparatuses, which consists of parts of a rod, connector, and set screw.

(2) The product description for Product M specifies the catalog numbers (Cat. No) for the parts that constitute Product



M, which the rods listed as "SE1608, SE1611, SE1614, SE1621," the connector as "SE1001," and the set screw as "SP3020." The Defendant's products, including models such as "K Spinal System Offset Connector SE1001" and "K Spinal System Extension Rod SE1608, SE1611, SE1614, SE1621," have been registered with the Ministry of Food and Drug Safety (MFDS), and the phrase "K™ M" is displayed on the Defendant's official website.

b) Discussion

(1) As examined above, it can only be determined that Product M consists of a rod, connector, and set screw. However, this alone is insufficient to conclude that Product M qualifies as an Improved Product, as there is no evidence to suggest that Product M incorporates any portion of the technical content of Patent 1 or Patent 2 that has been improved beyond publicly known technology and constitutes their distinctive technical characteristics. Furthermore, no other evidence has been presented to support such a conclusion.

(2) Furthermore, the catalog numbers listed in the product description for Product M match those found in the registered product model names with the MFDS and the bone fixation apparatus labeled as "K" in these product model or on the Defendant's official website corresponds to Product K, which was recognized as an Improved Product in the appellate ruling of the K Lawsuit. However, as previously examined, at the time of the Mediation Agreement, the Plaintiff and Defendant agreed to include "all spinal fixation apparatuses developed utilizing, in whole or in part, the patent rights to Product D," meaning "all spinal fixation apparatuses in which at least a portion of the technical content of Patent 1 and Patent 2 has been improved beyond publicly known technology and constitutes their distinct technical characteristics." The Plaintiff and Defendant did not agree to include all surgical instruments required for procedures involving such spinal fixation apparatus, even if some portion of the distinctive technical characteristics were utilized. Therefore, based

solely on these circumstances, Product M. which functions as a device for expanding the fixation area of a bone fixation apparatus, cannot be deemed as an Improved Product.

(3) Meanwhile, there is no dispute between the Plaintiff and Defendant that the set screw component with catalog number "SP3020" has been classified as sales related to Product D, for which advisory fees have been paid.[13] Given these circumstances, it is difficult to accept the Plaintiff's argument that, except for "SP3020," the remaining products qualify as Improved Products for which the Defendant is obligated to pay advisory fees under the Mediation Agreement, merely on the grounds that they are products in which the metal rods used in Product K have simply been bent and modified in shape.

2) Product Line N

a) The Plaintiff argues that Product Line N is either an Improved Product derived from Product K or a shared component of Products D and K, and thus qualifies as an Improved Product for which the Defendant is obligated to pay advisory fees under the Mediation Agreement. However, there is no available evidence specifying which special fixation-related apparatuses within Product Line N possess what kind of technical composition, nor is there any data indicating whether such technical compositions incorporate any portion of the technical content of Patent 1 or Patent 2 that has been improved beyond publicly known technology and constitutes their distinctive technical characteristics.

b) Furthermore, based on the statements in Plaintiff's Exhibits 24, 33, 40, 42, 59, 139, and 158, as well as the purport of the overall argument, the following facts can be recognized. In light of the circumstances described in Section (2) below, it cannot be conclusively

13) Refer to page 23 of Plaintiff's Secondary Preparatory Document dated November 30, 2022

determined that Product Line N has been undisputedly recognized between the Plaintiff and Defendant as an Improved Product subject to advisory fee payments under the Mediation Agreement, solely based on the product classification described in Section (1) below.

(1) Product Line N was categorized under Product Line "P" in the Defendant's annual advisory fee calculation table for 2013, under Product Lines "Q, K, R, and P" for 2014, and under Product Lines "P and N" for 2015, before being classified solely as Product Line "N" from 2016 onward. Additionally, in the Defendant's sales records for 2015, it was categorized alongside Product Lines "K, P, and Q," appearing as if it were subject to advisory fee payments.

(2) However, in the opposition lawsuit filed by the Defendant against the Plaintiff (Uijeongbu District Court, 2017Gadan129223), the Defendant's employee, S, testified as a witness on August 29, 2018, stating that the Defendant manufactured the products based on drawings provided by overseas Buyer N under an OEM production arrangement after receiving an OEM order from Buyer N. Therefore, the products sold to Buyer N were not manufactured using drawing created by the Defendant, and they they were not products for which the Defendant was required to pay advisory fees to the Plaintiff. He further testified that due to a mistake, these products were incorrectly classified as Product K in the advisory fee calculation table and sales records.

Meanwhile, Product Line N was listed in an export declaration certificate filed on March 19, 2014, with the Defendant recorded as both the export agent and manufacturer, Buyer N as the purchaser, and the model and specifications specified as "SG0001 AWL." While these model names and specifications appear in the product description for Product K, they actually refer to surgical instruments, not bone fixation apparatuses, as shown on the right. [The export declaration certificate itself also lists the product name as "SURGICAL INSTRUMENTS."]

c) Therefore, the Plaintiff's argument that the products in Product Line N qualify as Improved Products cannot be accepted under any circumstances.

Excerpt from Plaintiff's Exhibit 158-4

3) Product Line O

a) Based on the statements in Plaintiff's Exhibits 13, 33, 57, and 136, as well as the purport of the overall argument, the following facts can be acknowledged:

(1) Since around 2009, the Defendant has supplied Product K and a product named "T" to Company O in France, labeling them under Company O's brands "U" and "V," respectively. (Hereinafter, the former product is referred to as "Product U," and the latter as "Product V.")

(2) The Defendant classified Product U as Product K and has paid the Plaintiff advisory fees accordingly. (Meanwhile, from around September 2009 to December 2011, the Defendant provided Company O with technical information and other cooperation related to Product K and, in return, received a total of KRW 620,885,464 as royalty from Company O. As previously examined, the appellate ruling of the K Lawsuit determined that this royalty amount was considered part of the sales revenue of Product K, and that KRW 12,417,708, equivalent to 2% of that amount, shall be paid to the Plaintiff as advisory fees.)

(3) The Defendant's 2016 advisory fee calculation table indicates that, in addition to Product K, which was subject to advisory fee payments, the Defendant supplied products worth KRW 98,075,869 under the "OEM" category to Company O.

b) In light of the following circumstances, the Plaintiff's argument that Product V, in addition to Product U, which the Defendant classified as Product K and paid advisory fees for, qualifies

as an Improved Product, cannot be accepted.

(1) Above all, based on the above facts established, it is difficult to determine whether Product V incorporates any portion of the technical content of Patent 1 or Patent 2 that has been improved beyond publicly known technology and constitutes their distinctive technical characteristics. Furthermore, there is no evidence to support the conclusion that Product V qualifies as an Improved Product utilizing these technical characteristics. That is, while the Plaintiff argues that, in addition to Product U, there are additional Improved Products within Product Line O, such as Product V, a screw component, for which advisory fees shall be paid, the Plaintiff has failed to present any clear evidence demonstrating how such improvements were made.

(2) The Plaintiff argues that since the Defendant initially asserted that Product U was not an Improved Product but later acknowledged it during the K Lawsuit, where the Plaintiff sought advisory fees for Product K, it is reasonable to regard all products listed under the "OEM" category in the Defendant's 2016 advisory fee calculation table as Improved Products. However, as the advisory fee calculation table separately categorizes Product K, which is subject to advisory fee payments, in addition to the "OEM" category, it is difficult to conclude that the products listed under the "OEM" category qualify as Improved Products for which advisory fees shall be paid, in the same manner as Product K, solely based on this classification. [In response, the Defendant argues that the products listed under the "OEM" category are merely rods used as components in Company O's Product "W."]

F. Summary of Discussion

As examined above, Products L and M, as well as Product Lines N and O, cannot be regarded as Improved Products as defined in the Mediation Agreement. Therefore, the Plaintiff's claim for advisory

fees, which is based on a different premise, is without merit and requires no further review.

3. Determination on Primary Claim for Liquidated Damages

A. Plaintiff's Arguments

1) At the time of the Mediation Agreement, the Defendant agreed that if it "allows a third party to manufacture the Subject Item," the Defendant would pay the Plaintiff an amount equivalent to three times the highest annual advisory fee previously paid as liquidated damages (Mediation Agreement, Article 2-B; hereinafter, the "Liquidated Damages Commitment at Issue"). However, ① after the Mediation Agreement, the Defendant allowed overseas companies in Pakistan, China, and Germany to manufacture the Subject Item, thereby reducing Defendant's own sales of the Subject Item, and ② the Defendant failed to pay the registration fees for Patent 1 and the Overseas patents at Issue, resulting in the extinguishment of all these patent rights, which in turn enabled third parties to manufacture the Subject Item both domestically and internationally without any restrictions, making the Defendant's conduct equivalent to permitting third parties to manufacture the Subject Item.

2) Therefore, the Defendant is obligated to pay the Plaintiff the amount of KRW 4,571,114,503 equivalent to three times the highest annual advisory fee, as liquidated damages under the Liquidated Damages Commitment at Issue, along with delay damages, in accordance with the Plaintiff's primary arguments.[14)]

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14) ① At the first hearing of this court, the Plaintiff summarized the primary claim for liquidated damages as follows: The claim seeks liquidated damages stipulated in the Liquidated Damages Commitment at Issue as compensation for damages arising from the extinguishment of Patent 1 and the Overseas Patents at Issue due to the Defendant's breach of obligation. ② Meanwhile, the Plaintiff initially argued that

B. Analysis

1) Above all, the Plaintiff's argument that the Defendant, after the Mediation Agreement, caused a decrease in sales of the Subject Item by allowing overseas companies in Pakistan, China, and Germany to manufacture the Subject Item cannot be accepted for the following reasons:

a) The following facts concerning sales figures are either undisputed between the parties or can be established based on the statements in Plaintiff's Exhibits 11, 12, 13, 33, 214, and 218, and Defendant's Exhibits 4, 8, 9, and 36, as well as the purport of the overall argument. In other words, from 2009 to 2021, the Defendant paid advisory fees to the Plaintiff based on the sales figures of the Subject Item listed in the table below.

Year	Advisory Fee Payments (KRW)	Sales Revenue Used as the Basis for Advisory Fee Calculation (KRW)
2009	122,411,025	6,120,551,267
2010	145,323,462	7,266,173,126
2011	136,390,950	6,819,547,514
2012	130,586,717	6,529,335,890
2013	117,303,245	5,865,162,256
2014	126,691,269	6,334,563,470
2015	118,673,682	5,933,684,138
2016	63,818,041	3,337,763,573
2017	53,554,292	2,800,956,106
2018	57,500,798	3,152,456,031
2019	57,103,848	3,130,693,377
2020	27,851,283	1,526,934,159
2021	**31,814,749**	**1,744,229,953**

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i) the Defendant shall compensate for damages caused by patent infringement by third parties worldwide; ii) 2% of the sales losses resulting from the extinguishment of the patent rights and exclusive license constitutes the Plaintiff's damages; and iii) the Defendant shall pay up to twice the liquidated damages. However, at the first hearing of this court, the Plaintiff withdrew all of these arguments.

Examining the yearly trends of the advisory fee payments and the sales revenue used as the basis for advisory fee calculation, there is indeed a declining trend in both the annual advisory fee payments and the sales revenue used for calculation from around 2016. However, as evidenced by the calculation table in Appendix 4, which the Plaintiff presents, the Defendant has continuously manufactured (supplied) Products L and M, as well as Product Lines N and O during the same period, in addition to the Subject Item. Given this, there is room to interpret that the Defendant expanded its business by diversifying its product offerings beyond the Subject Item. Therefore, the mere decline in the sales revenue of the Subject Item, which serves as the basis for advisory fee calculation, does not, in itself, conclusively establish that the Defendant, after the execution of the Mediation Agreement at Issue, caused overseas companies to manufacture the Subject Item or that such conduct led to the decline in the Defendant's sales revenue of the Subject Item.

Year	Sales Revenue by Product	
	Product	Amount (Unit: KRW)
2016	Product N	111,473,512
	Product M	43,859,336
	Product L	3,401,658,277
	Product O	98,076,265
	Subtotal	3,655,067,390
2017	Product N	270,834,983
	Product M	50,274,938
	Product L	2,563,290,434
	Subtotal	2,884,400,355
2018	Product M	49,301,693
	Product L	1,587,276,017
	Subtotal	1,636,577,710
2019	Product M	52,860,312
	Product L	4,156,688,159
	Subtotal	4,209,548,471

Excerpt from calculation table of Appendix 4

b) Based on the statements in Plaintiff's Exhibits 13, 16, 19, 28, 30, 35, 36, 45, 46, 51, 53, 57, 59, 72 through 79, 84, 87, 89, 90, 92, 94 through 97, 115, 118 through 125, 131 through 134, 136, 153, 154, and 161, as well as the purport of the overall argument, the following facts can be acknowledged:

(1) Corporation X and others

(a) On January 11, 2016, Corporation X was established

with Y, who also served as a director of the Defendant, as its CEO. The company engages in the manufacturing of orthopedic and body correction apparatuses and has obtained approval from the Ministry of Food and Drug Safety (MFDS) as a medical device manufacturer and seller. In addition, it acquired ISO 13485 certification, which is required for medical device manufacturers.

(b) On October 12, 2019, Z Limited was established in China, and around that time, the Defendant, through an online news outlet called "News 114," publicly announced that it had "established a local subsidiary in China and that this entity would be responsible for the manufacturing and sale of spinal fixation apparatuses and other products in China."

(c) In around September 2019, the Defendant, in collaboration with AA University and other entities, formed a consortium and was selected as the domestic lead entity for a project titled "Development of a Smart Pedicle Screw System Using Raman Sensors," which was scheduled to run from October 2019 to September 2022. This project aimed to develop a new pedicle screw system that integrates Raman spectroscopy sensor technology, which detects components within the human body, with the Defendant's core product, the pedicle screw system, allowing for its application in MI S[15] spinal surgery. Meanwhile, following the final ruling in the K Lawsuit, which determined that the Defendant's product named "MIS" was included in the Subject Item, the Defendant has been paying advisory fees to the Plaintiff for this product.

(2) Company AB in Pakistan and others

(a) From around January 2013 to March 2015, the Defendant repeatedly imported components[16] from Company AB in

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15) Minimally Invasive Surgery

16) ① SG0009 D HOUSING HOLDER, ② SG0012 D ROD HOLDER, ③ SG0012 ROD HOLDER, ④ SG0015 D SPREADER(including SP0015-D), ⑤

Pakistan, which included the model name "D."

(b) From May 26, 2015, to October 14, 2016, the Defendant repeatedly imported "SP0040 FD Ratcheting Handle," a product with the model name "1ZS-SP0040" from Company AC in Germany, which is a "handle" component for surgical instruments.[17]

(c) On December 14, 2015, the Defendant imported multiple surgical instrument components from Company AD in China, with the product names "OS0170 Distraction Forceps, OS0180 Compression Forceps, OS0130 Rod bender, OS0240 Trial Rod, OS0140 Holding forceps for rod, and OS0120 Rod cutter."

(d) Around April 15, 2016, the Defendant imported multiple surgical instrument (medical device) components from Company AE in China, with the model names "Rod Templete Long, Rod Holder, Power Gripper(Derotator), Coronal Bender-Left, and Coronal Bender-Right."

(e) Around November 16, 2015, the Defendant imported multiple surgical instrument (medical device) components from Company AF in China, with the model names "SF0220 ROCKER, SFO0260 T-LINK HOLDER, SF0090 ROD HOLDER, and SN0009 HOUSING HOLDER."

SG0018 D AND GSFS DEROTATOR, ⑥ SH0012 D ROD HOLDER, ⑦ SH0019 D REDUCTION HOUSING CUTTER, ⑧ SH1060 PERSUADER FOR SPINAL R SYSTEM, ⑨ SH1080 CURVED R HOLDER FOR SPINAL R SYSTEM, ⑩ SH1100 D AND R ROCKER(HOLDER), ⑪ SO0170 D ROD HOLDER, ⑫ SP0015 D SPREADER, ⑬ SP0015-99 D SPREADER, ⑭ SP0016 D COMPRESSOR, ⑮ SP0019 D REDUCTION HOUSING CUTTER, ⑯ SP0019 REDUCTION HOUSING HOLDER and more

17) The import declaration certificate for the product (Plaintiff's Exhibit 76) lists the product name as "MEDICAL INSTRUMENTS PARTS," the trade name as "UNIVERSAL RACHETING HANDLE," and also states that it is classified as a "manual orthopedic surgical instrument handle, not subject to medical device registration."

(f) From around October 2015 to October 2016, the Defendant repeatedly imported medical device handle components from Companya AG in the United States.

(3) Company AH in India and others

(a) Around April 2020, the product "Relife Titanium Spine Pedical Screw" from Company AH in India and the product "Pedicle Screws" from Company AI in India were listed for sale on various internet platforms, and the images of these products were identical to those of Product D.

(b) Around the same time in Brazil, Company AJ was selling Product K under the brand name "NOVU-DYNAMO," Company AK was selling Product U, and Company AL was selling Product U under the brand name "PARAFUSOS PEDICULARES POLIAXIAIS."

c) The facts established in the preceding sections alone are insufficient to conclude that the Defendant, after the Mediation Agreement, caused third-party overseas companies to manufacture the Subject Item, and this is further supported by the following circumstances:

(1) Corporation X and others

(a) The Plaintiff argues that the Corporation X, by obtaining approval from the MFDS as described above, has established the conditions necessary to manufacture and sell Product D or its Improved Products. However, such circumstances alone do not suffice to conclude that the company actually manufactured the Subject Item at the direction of the Defendant.

(b) Furthermore, the mere facts that the Defendant promoted the establishment of Z Limited as well as the production and sale of its products, or that the Defendant, who was selected as the domestic lead entity, led the "Development of a Smart Pedicle Screw System Using Raman Sensors" project, which aimed to develop a screw system that had been deemed a Subject Item in the K Lawsuit,

do not, in themselves, conclusively establish that Z Limited or other third-party companies manufactured the Subject Item at the direction of the Defendant.

(2) Company AB in Pakistan and others

(a) The products imported from Company AB in Pakistan, including ROD HOLDER, SPREADER, PERSUADER, and HOUSING CUTTER, are components that cannot easily be regarded as embodiments of Patent 1 and Patent 2 at Issue. (The Defendant argues that they have ceased transactions with Company AB after 2015.) Additionally, the products imported from Company AC in Germany are handle components for surgical instruments. (According to the statements of Plaintiff's Exhibit 154-2, Company AC in Germany stated on its website around 2020 that it manufactures and sells surgical instruments used in orthopedic spinal surgery through an OEM method tailored to customer specifications.)

(b) As such, the Defendant appears to have imported components for Product D or its Improved Products from Company AB in Pakistan and Company AC in Germany to manufacture the Subject Item, and there is no basis to conclude that these companies themselves manufactured the Subject Item, such as Product D, at the direction of the Defendant. Furthermore, as is undisputed between the Plaintiff and Defendant, the Liquidated Damages Commitment at Issue was intended to prevent a decrease in the Defendant's sales revenue of the Subject Item, which serves as the basis for advisory fee calculation payable to the Plaintiff. If the Defendant had directly manufactured the Subject Item using components imported from Company AB or Company AC, such actions would not have resulted in a decrease in the Defendant's sales revenue of the Subject Item.

(c) Similarly, the products imported from Company AD, Company AE, and Company AF in China, as well as from Company AG in the United States, were components for Product D or its Improved Products. Therefore, there is no basis to conclude that these

companies manufactured Product D or other Subject Items at the direction of the Defendant. Furthermore, if the Defendant had directly manufactured the Subject Item using components imported from Company AD and others, such actions would not have resulted in a decrease in the Defendant's sales revenue of the Subject Item.

(d) Regarding this, the Plaintiff argues that the Defendant, in commissioning Company AD, Company AE, and Company AF in China to manufacture products, provided the complete product design for Product L, and thus, it shall be deemed that the Defendant effectively caused these companies to manufacture an Improved Product classified as a Subject Item. However, as previously established, Product L does not qualify as an Improved Product under the Mediation Agreement, and therefore, the Plaintiff's claim requires no further examination and cannot be accepted.

(3) Company AH in India and Others

It appears that around April 2020, Company AH and Company AI in India were selling Product D, and around the same time, Company AJ and Company AK in Brazil were selling Product U, which, as previously established, was classified as Product K.

However, such sales alone does not provide any basis to conclude that these companies manufactured Product D or its Improved Product, Product U, or that their production was carried out at the direction of the Defendant. (In other words, since Product D or Product U exported by the Defendant could have been sold in India or Brazil around the same time, the facts established above do not exclude the possibility, nor do they support the conclusion that these companies manufactured Product D or Product U at the direction of the Defendant.)

2) The Plaintiff's remaining claims that seek the payment of liquidated damages cannot be accepted for the following reasons.

Even if the Defendant caused the extinguishment of Patent 1 and the Overseas Patents at Issue, such circumstances alone do not establish

that third parties became able to manufacture the Subject Item without restriction or, based on this premise, that the Defendant's act of allowing the patent rights to extinguishment is effectively equivalent to enabling third parties to manufacture the Subject Item. Even if the patent rights had remained in force, third parties could have still manufactured the Subject Item, regardless of whether such manufacturing would constitute infringement of those patent rights. Likewise, the extinguishment of the patent rights does not directly lead to third parties manufacturing the Subject Item. Ultimately, whether the grounds specified in the Liquidated Damages Commitment at Issue have been satisfied shall be determined by assessing whether the Defendant actually caused third parties to manufacture the Subject Item. The remaining claims of the Plaintiff that disregard this requirement merely amount to a subjective assertion that lacks a logically inferred causal connection between the asserted cause and its resulting consequence.

3) As explained above, all of the Plaintiff's primary claims seeking the payment of liquidated damages under the Liquidated Damages Commitment at Issue against the Defendant shall be dismissed.

4. Determination on Alternative Claim for Liquidated Damages

A. Plaintiff's Arguments

1) Under the Mediation Agreement, the Defendant agreed to hold title to the patent rights to Product D in trust or to receive an exclusive license, complete patent registration under its own name, and in the event of termination of the Mediation Agreement at Issue, carry out the registration procedures of transfer of the patent rights to Product D, as well as patents registered or to be registered domestically and internationally using all or part of those rights. In this regard, the

Defendant was obligated to maintain and manage the patent rights, including Patent 1 and the Overseas Patents at Issue, which were filed using the priority claim based on the application of Patent 1. However, despite this duty, the Defendant, either intentionally or with gross negligence, failed to pay the registration fees, thereby causing the extinguishment of Patent 1 and the Overseas Patents at Issue.

2) Therefore, in accordance with the Plaintiff's alternative claim for liquidated damages, the Defendant is obligated to pay KRW 2,117,348,575 as reasonable royalties equivalent to the exchange value of the extinguished patent rights of Patent 1 and Overseas Patent Rights at Issue, based on breach of contract or tort liability, along with delay damages.[18)]

B. Analysis

1) The Mediation Agreement at Issue includes a provision stating that "in the event that the assignment of the Patent Rights at Issue to the Defendant, the exclusive license, and the advisory agreement are all terminated, the patent rights and the exclusive license regarding the Subject Item shall revert to its developer(s), and the Defendant shall carry out the necessary procedures for the registration of transfer of the said patent rights to the developer(s)" (Mediation Agreement, Article 9-A, hereinafter, the "Commitment to Transfer upon Termination at Issue"). Upon this provision, if the Advisory Agreement at Issue and the Mediation Agreement are terminated, the Defendant is obligated to transfer the Patent 1, which forms part of the patent rights to Product D, to its developer, the Plaintiff, and the Plaintiff has the right to demand the transfer of said patent rights from the Defendant under the

18) The Plaintiff clarified the alternative claim for liquidated damages during the first hearing of this court as follows. This claim seeks liquidated damages arising from the extinguishment of Patent 1 and Overseas Patents at Issue, based on breach of contract or tort liability, in the form of royalties equivalent to the exchange value of the patents.

same circumstances (Regarding this, the Plaintiff asserts that since Overseas Patents at Issue were registered claiming priority from Patent 1 and were obtained using all or part of its technical content, the Defendant is also obligated to transfer the patent rights of Overseas Patents at Issue, just as it is required to transfer Patent 1, under the Commitment to Transfer upon Termination at Issue).

2) The Commitment to Transfer upon Termination at Issue is subject to a suspensive condition, meaning that it takes effect from the moment the condition is fulfilled, which in this case is the termination of the Advisory Agreement at Issue and the Mediation Agreement (refer to Article 147 (1) of the Civil Act). However, as long as the fulfillment of this condition remains undetermined, the Defendant may not impair the Plaintiff's interests that would arise upon its fulfillment (refer to Article 148 of the Civil Act). Therefore, the Court finds that the Defendant is obligated to maintain and manage the patent rights as long as the Mediation Agreement remains in effect without being terminated (The Plaintiff's contention that the Defendant has held title to the patent rights to Product D in trust or has obtained an exclusive license and completed patent registration under its own name under the Mediation Agreement at Issue also supports the argument that the Defendant has an obligation to maintain and manage the patent rights). However, as previously established, the Defendant failed to pay the registration fees, resulting in the extinguishment of Patent 1 and Overseas Patents at Issue. Consequently, the Plaintiff's conditional right to demand the transfer of patent rights under the Commitment to Transfer upon Termination at Issue has effectively been nullified due to the destruction of its subject matter.

3) However, just as the Plaintiff's conditional right to demand the transfer of patent rights becomes a definitive right only upon the fulfillment of the condition, namely, the termination of the Advisory Agreement at Issue and the Mediation Agreement, the determination of whether the Plaintiff's interests have been infringed due to fulfillment

of the same condition also remains unsettled until the condition is fulfilled. In other words, the Plaintiff's right to claim damages for the infringement of the conditional right to demand the transfer of patent rights is itself a conditional right, and while it may be disposed of, inherited, preserved, or used as collateral under general provisions even while the fulfillment of the condition remains undetermined (refer to Article 149 of the Civil Act), it will not be definitively established until the condition is fulfilled.

4) Based on the aforementioned legal principles, even if the extinguishment of Patent 1 at Issue and Overseas Patents at Issue resulted from the Defendant's intentional act or gross negligence, as the Plaintiff asserts, there is no evidence that the Advisory Agreement at Issue and the Mediation Agreement have been terminated, thereby fulfilling the condition stipulated in the Commitment to Transfer upon Termination at Issue (There is no dispute between the parties regarding the fact that the Advisory Agreement at Issue and the Mediation Agreement "continue until the production and sale of the Subject Item cease," thereby remaining in effect without termination).[19)]

Given these circumstances, the Plaintiff's alternative claim seeking damages from the Defendant for the extinguishment of Patent 1 or Overseas Patents at Issue based on breach of contract or tort liability does not require further review and cannot be accepted.

5. Conclusion

The Plaintiff's claims against the Defendant are without merit and shall be dismissed. The district court's decision is inconsistent with the above analysis and is therefore erroneous. The Defendant's appeal is

19) Patent 1 at Issue, which was filed on October 31, 2001, would have expired on October 31, 2021, even if the Defendant had not failed to pay the registration fees.

upheld, and the portion of the district court's decision which ruled against the Defendant shall be revoked. The Plaintiff's corresponding claim shall be dismissed. The Plaintiff's appeal shall also be dismissed as it is without merit.

Presiding Judge	Sook Yeon LEE
Judge	Taeksoo JUNG
Judge	Jiyoung YI

[Appendix 1]

Patent 1

1. Claims

【Claim 1】 A bone fixation apparatus comprising: a bone screw having a head; a cap supporting an upper portion of the head of the bone screw; a receiver component having a bore that accommodates the cap while simultaneously engaging the head of the bone screw and including a U-type channel for receiving a support rod; and a rod fixation nut threadedly engaged with the receiver component to secure the support rod, wherein multi stepped portions are formed on the lower inner surface of the bore to enhance the support strength of the head and ensure line contact with the lower outer surface of the head.

【Claim 2】 The bone fixation apparatus of Claim 1, wherein a recess portion is formed on the rear surface of the cap at a predetermined depth, and the lower edge of the recess portion is in line contact with the upper outer surface of the head.

【Claim 3】 The bone fixation apparatus of Claim 1 or 2, wherein the bore comprises: the multi stepped portions; a cap-receiving portion formed above the multi stepped portions to accommodate the cap; and a screw portion allowing the cap to move by threading while the rod fixation nut is threadedly engaged, wherein the inner diameter of the cap-receiving portion is larger than that of the screw portion.

【Claim 4】 The bone fixation apparatus of Claim 3, wherein the screw portion is structured so that the cap passes through while the rod fixation nut engages from the upper side and is prevented from further movement, and wherein the thread depth at the upper part of the screw portion is greater than the thread depth at the lower part.

【Claim 5】 The bone fixation apparatus of Claim 4, wherein the threads of the screw portion are trapezoidal, preventing deformation of the receiver component and optimizing force transmission, fastening strength, and loosening resistance.

【Claim 6】 The bone fixation apparatus of Claim 5, wherein the trapezoidal threads are configured so that the inclination angle of the upper thread surface is greater than that of the lower thread surface, facilitating the assembly of the cap and rod fixation nut while preventing loosening.

【Claim 7】 The bone fixation apparatus of Claim 6, wherein the inclination angle of the upper thread surface is 10° and that of the lower thread surface is 1°.

2. Descriptions

Ⓐ **Technical Field and Prior Art of the Invention** (two paragraphs from the bottom of page 2 to six paragraphs from the top of page 3)

The present invention relates to a bone fixation apparatus designed to correct bones, such as the spine, to their normal state and immobilize it without movement.

Conventionally, bone fixation apparatuses for securing bones, such as the spine, include those disclosed in Korean Patent Publication No. 2000-48562 and U.S. Patent No. 6280442.

Korean Patent Publication No. 2000-48562 discloses, as illustrated in Fig. 1, a bone screw (10) with a spherical head (12), a shrinkage collet (14) that supports the head (12) of the bone screw, and a receiver component (18) that includes a bore defining a tapered recess (16) for accommodating the shrinkage collet (14), while also incorporating a U-type channel that allows a support rod (R) to pass through and be housed within. The apparatus further includes a set screw (20) threadedly engaged with the receiver component (18) to secure the support rod (R).

The head (12) of the bone screw includes a tool-receiving recess (22) for accommodating a tool, and the tool-receiving recess (22) is defined within a flat upper surface (24). Additionally, the channel section of the receiver component (18) is internally threaded (26) to allow the set screw (20) to be screwed in. The rear surface of the shrinkage collet (14) is formed with a recess (28) to snugly fit the head (12). Furthermore, multiple slots are formed on the lower portion of the shrinkage collet (14) and the recess (28) to apply a certain amount of compressive force to the head (12) of the bone screw.

When the set screw (20) is tightened, the support rod (R) compresses the shrinkage collet (14), and the shrinkage collet (14) is pressed into the tapered recess (16) of the receiver component, thereby securing the bone screw (10) in a vertical position or at a predetermined inclined angle.

U.S. Patent No. 6280442, as illustrated in Fig. 2, discloses a structure where multiple protruding ridges (34) are formed on the head (32) of the bone screw (30), and a support ring (38) is inserted and engaged with the lower inner surface of the bore in the receiver component (36), thereby securing the lower portion of the head (32). Additionally, a cap (40) is placed over the upper portion of the head (32), and a support rod (R) is inserted into the channel of the receiver component (36) above the cap (40), where it is secured using a rod fixation nut (42).

Furthermore, the inner diameter of the cap-receiving portion in the receiver component (36) is designed to be larger than the inner diameter of the section where the rod fixation nut (42) is threadedly engaged. As a result, when the rod fixation nut (42) is loosened and the support rod (R) is removed, the cap (40) does not become dislodged upward. For assembly, the cap (40) is first inserted from the lower portion of the receiver component (36), followed by the insertion of the head (32) of the bone screw (30) from the lower portion of the receiver component (36). Then, the support ring (38) is externally fitted around the lower end of the bone screw (30) and inserted into the lower inner surface of the bore in the receiver component (36).

Meanwhile, the interior of the receiver component is formed with internal threads extending to its lower portion, ensuring that the cap (40) remains secured through threaded engagement, thereby preventing dislodging.

Ⓑ **Technological Tasks to Achieve by the Invention** (7th to last paragraphs of page 3)

However, in the conventional bone fixation apparatus such as Korean Patent Publication No. 2000-48562, the support strength is weak, causing the head (12) seated in the tapered recess (16) to move due to external disturbances, thereby failing to maintain its initial support state.

While U.S. Patent No. 6280442 improves upon the problems of Korean Patent Publication No. 2000-48562, it still has issues that, specifically, the support ring (38) used for securing the bone screw is not easy to assemble, and the support strength of the bone screw remains unsatisfactory.

Additionally, in a structure where the upper portion of the bone screw

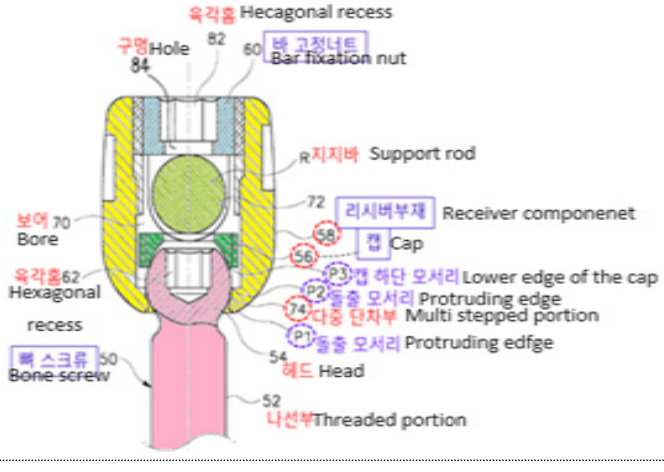
head is secured by threaded engagement with a cap, the cap should be fully screwed down to the lower side, and the fixation force of the rod fixation nut is not effectively transmitted to the head. As a result, assembly is not easy, and the support strength of the bone screw is weak.

Therefore, the present invention has been devised to solve these problems, with the objective of providing a bone fixation apparatus that not only increases the support strength of the bone screw to prevent movement but also facilitates easy assembly and prevents cap dislodging.

Ⓒ **Composition and Operation of the Invention** (1st to 6th paragraphs of page 4)

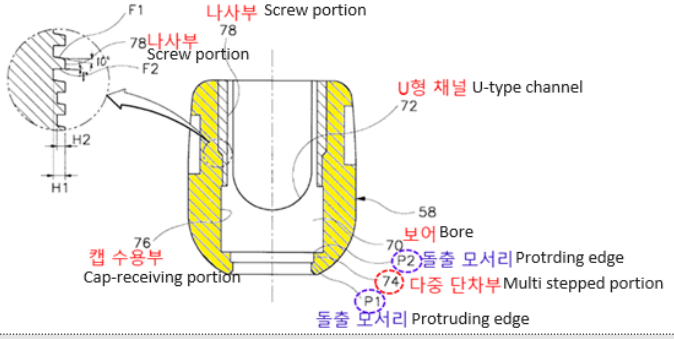
The bone fixation apparatus according to the present invention, designed to achieve the above objective, comprises a bone screw having a head, a cap that supports the upper side of the bone screw head, a receiver component that has a U-type channel to accommodate a support rod and a bore in which the cap is accommodated while the head of the bone screw is engaged, and a rod fixation nut that is threadedly engaged with the receiver component to secure the support rod, wherein a multi stepped portion is formed on the lower inner surface of the bore to increase the support strength of the head, ensuring line contact with the lower outer surface of the head.

[Fig. 3] Cross-sectional view of bone fixation apparatus

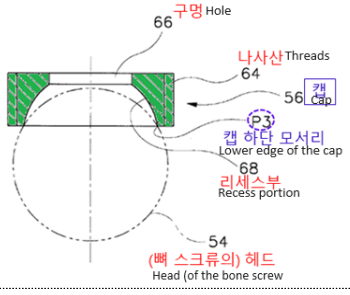


The rear surface of the cap is preferably formed with a recess portion of a predetermined depth, wherein the lower edge of the recess portion makes line contact with the upper outer surface of the head.

[Fig. 5] Crpss-sectional view of receiver component in Fig. 3



[Fig. 6] Cross-sectional view of cap in Fig. 3



The bore comprises a multi stepped portion, a cap-receiving portion formed above the multi stepped portion to accommodate the cap, and a threaded portion where the cap is threadably moved while the rod fixation nut is threadedly engaged, wherein the inner diameter of the cap-receiving portion is larger than the inner diameter of the threaded portion.

The threaded portion is structured so that the cap passes through it, while the rod fixation nut is prevented from moving further as it engages from the upper side, with the thread depth of the upper part of the threaded portion being deeper than that of the lower part. It is preferable that the threads of the threaded portion adopt a trapezoidal thread design, ensuring optimal conditions in terms of force transmission, fastening strength, and prevention of loosening, while also preventing deformation of the receiver component.

Ⓓ **Effectiveness of the Invention** (19th paragraph of page 10)

The bone fixation apparatus according to the present invention improves the support strength of the bone screw, preventing undesired movement, while also facilitating easy assembly, enhancing force transmission, and preventing loosening.

[Appendix 2]

Patent 2

1. Claims

【Claim 1】 A bone fixation apparatus comprising: a bone screw having a head; a cap supporting the upper side of the head of the bone screw; a receiver component having a U-type channel that accommodates a support rod and a bore that engages the head of the bone screw while accommodating the cap; and a rod fixation nut that is threadedly engaged with the receiver component to secure the support rod, wherein the bore comprises: a multi stepped portion formed on the lower inner surface and linearly contacting the upper outer surface of the head to enhance support strength; a cap-receiving portion formed above the multi stepped portion to accommodate the cap; and a threaded portion, which is formed with an inner diameter smaller than that of the cap-receiving portion and is configured for the threaded engagement of the rod fixation nut, wherein the upper end of the cap is formed with a flange having an outer diameter larger than the inner diameter of the threaded portion, wherein the cap is inserted into the cap-receiving portion by undergoing plastic deformation together with the lower end of the threaded portion.

【Claim 2】 The bone fixation apparatus of claim 1, wherein multiple groove bands are formed at predetermined intervals on the outer surface of the head of the bone screw to increase friction with the cap, and wherein the groove bands are asymmetrically formed with respect to the axis of the bone screw such that the lower contact line of the cap crosses the groove bands regardless of the fixation angle of the bone screw.

【Claim 3】 The bone fixation apparatus of claim 2, wherein the depth of the groove bands is between 0.01 mm and 0.03 mm.

【Claim 4】 The bone fixation apparatus of claim 1, wherein the receiver component has a jar shape such that the central portion through which the support rod passes has a larger diameter than the

upper and lower portions.

【Claim 5】 A method for assembling the bone fixation apparatus of claim 1, wherein the cap is tilted such that one side of the flange is first accommodated in the cap-receiving portion, and the other side of the flange is engaged with the threaded portion, and wherein a pressing tool is used to press the cap, thereby plastically deforming the flange portion engaged with the threaded portion along with the lower end of the threaded portion and inserting the cap into the cap-receiving portion.

【Claim 6】 A surgical instrument used in a procedure involving the bone fixation apparatus of claim 1, the tool comprising: an alignment rod having a protruding end that fits into the wrench insertion opening of the bone screw and a threaded portion that is threadedly engaged with the threaded portion of the receiver component to align the bone screw and the receiver component; and a handle coupled to the alignment rod to allow rotation of the alignment rod.

【Claim 7】 The surgical instrument of claim 6, wherein an outer pipe is coupled to the outer side of the alignment rod and is slidable in the longitudinal direction of the alignment rod, the outer pipe having a flange that is inserted into and engaged with the channel of the receiver component to increase the tightening and loosening forces of the bone screw and facilitate the retraction of the receiver component.

2. Descriptions

Ⓐ **Technical Field and Prior Art** (page 2 to 2nd paragraph of page 3)

The present invention relates to a bone fixation apparatus designed to correct bones, such as those in the spine, to a normal state and secure it in place without movement.

[The description is omitted as it is identical to Patent 1.]

Ⓑ **Technological Tasks** (3rd to 6th paragraphs of page 2)

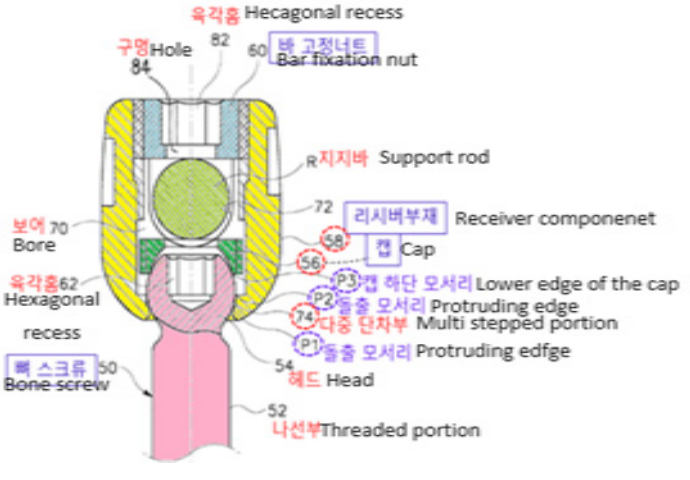
[The description is omitted as it is identical to Patent 1.]

Ⓒ **Composition and Operation of the Invention** (7th paragraph of page 2 to

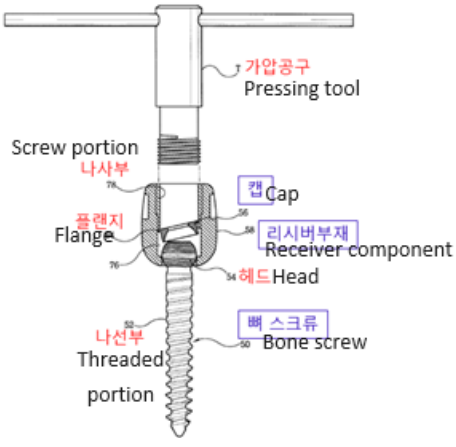
10th paragraph of page 3)

The bone fixation apparatus according to the present invention, designed to achieve the above objective, comprises a bone screw having a head, a cap that supports the upper side of the bone screw head, a receiver component with a U-type channel that accommodates a support rod and has a bore that engages the bone screw head while simultaneously receiving the cap, and a rod fixation nut that is threadedly engaged with the receiver component to secure the support rod. The bore comprises a multi stepped portion formed on its lower inner surface to enhance the support strength of the head by providing line contact with the upper outer surface of the head, a cap-receiving portion formed above the multi stepped portion to accommodate the cap, and a threaded portion having a smaller inner diameter than the cap-receiving portion to allow the cap to be threadedly inserted while enabling the rod fixation nut to be threadedly engaged. A flange with an outer diameter larger than the inner diameter of the threaded portion is formed at the upper part of the cap, and the cap is inserted into the cap-receiving portion by undergoing plastic deformation together with the lower part of the threaded portion, thereby ensuring secure assembly.

[Fig. 3] Cross-sectional view of bone fixation apparatus



[Fig. 8] Illustration of assembling the cap into bone fixation apparatus



The outer surface of the head of the bone screw is formed with multiple groove bands at predetermined intervals to increase friction with the cap. These groove bands are asymmetrically formed along the axis of the bone screw so that the lower contact line of the cap crosses them regardless of the fixation angle of the bone screw. Preferably, the depth of the groove bands ranges from 0.01 to 0.03 mm.

The receiver component has a jar-shaped structure, where the central portion, through which the support rod passes, has a larger diameter than the upper and lower portions.

For assembly, the cap is tilted so that one side of its flange is first accommodated in the cap-receiving portion, while the other side of the flange is engaged with the threaded portion. The cap is then pressed using a pressing tool, causing the engaged flange portion to undergo plastic deformation along with the lower part of the threaded portion, thereby allowing the cap to be inserted into the cap-receiving portion.

The surgical instrument used for the bone fixation apparatus includes an alignment rod, which has a terminal protrusion that fits into the wrench insertion slot of the bone screw and a threaded portion that engages with the threaded portion of the receiver component, thereby aligning the bone screw and the receiver component of the bone fixation apparatus. The instrument further comprises a handle coupled to the alignment rod to facilitate its rotation.

To enhance the clamping force and loosening resistance of the bone

screw and to facilitate the retraction of the receiver component, the outer side of the alignment rod is equipped with an outer pipe. This outer pipe has a flange that engages with the channel of the receiver component and is slidable along the longitudinal direction of the alignment rod. Preferably, the end of the outer pipe is formed with a handle portion to allow easy movement of the outer pipe.

Ⓓ **Effectiveness of the Invention** (1st paragraph of page 6)

According to the bone fixation apparatus of the present invention, it not only enhances the support strength of the bone screw to prevent movement but also facilitates assembly, improves force transmission, prevents loosening, and effectively prevents the dislodging of the cap.

[Appendix 3]

Product K

<Components>

A bone fixation apparatus comprising:

1) A bone screw (50) having a head (54),

2) A cap (56) that supports the upper side of the head of the bone screw,

3) A receiver component (58) having a U-type channel (72) that accommodates a support rod (R) and a bore (70) that receives the cap (56) while engaging the head (54) of the bone screw, wherein the bore (70) includes a protrusion (74) formed on the lower inner surface to support the head (54) of the bone screw; a cap-receiving portion formed above the protrusion (74) to accommodate the cap (56); and a threaded portion (52) formed with an inner diameter smaller than that of the cap-receiving portion, into which a rod fixation nut (60) is threadably engaged; and

4) A rod fixation nut (60) threadably engaged with the receiver component (58) to secure the support rod (R);

wherein at least a portion of the protrusion (74) formed on the lower inner surface of the bore (70) of the receiver component (58) has the same curvature radius as the corresponding portion of the head of the bone screw to ensure contact therebetween, and the upper end of the cap is formed with a flange having an outer diameter larger than the inner diameter of the threaded portion, such that the cap undergoes plastic deformation along with the lower portion of the threaded portion to be insesrted into the cap-receiving portion.

[Appendix 4]

Advisory Fee Calculation Table

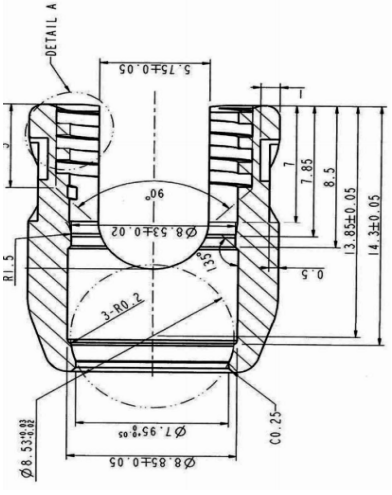
Year	Sales Revenue by Product		Advisory Fee (Unit: KRW)
	Product	Amount (Unit: KRW)	
2014	Product M	60,403,256	1,208,065
	Product L	145,112,159	2,902,243
	Subtotal	205,515,415	4,110,308
2015	Product N	238,804,834	4,776,096
	Product M	25,766,707	515,334
	Product L	325,423,799	6,508,475
	Subtotal	589,995,340	11,799,906
2016	Product N	111,473,512	2,229,470
	Product M	43,859,336	877,186
	Product L	3,401,658,277	68,033,165
	Product O	98,076,265	1,961,525
	Subtotal	3,655,067,390	73,101,347
2017	Product N	270,834,983	5,416,699
	Product M	50,274,938	1,005,498
	Product L	2,563,290,434	51,265,808
	Subtotal	2,884,400,355	57,688,007
2018	Product M	49,301,693	986,033
	Product L	1,587,276,017	31,745,520
	Subtotal	1,636,577,710	32,731,554
2019	Product M	52,860,312	1,057,206
	Product L	4,156,688,159	83,133,763
	Subtotal	4,209,548,471	84,190,969
Total		**13,181,104,681**	**263,622,091**

[Appendix 5]

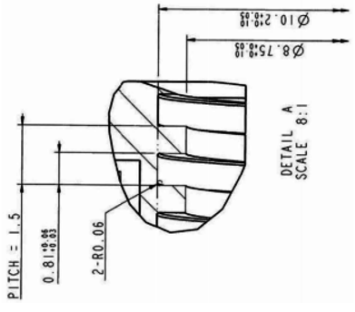
Product L

Design Drawings of Product L (Defendant's Exhibit 29)

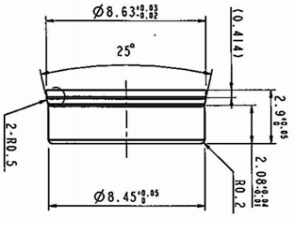
[Receiver component]



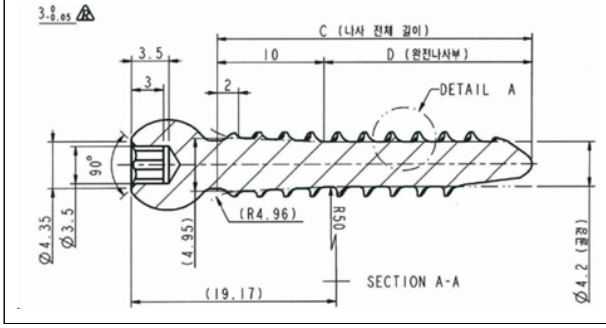
[Thread of the receiver component]

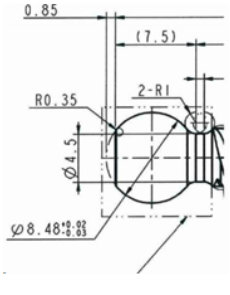


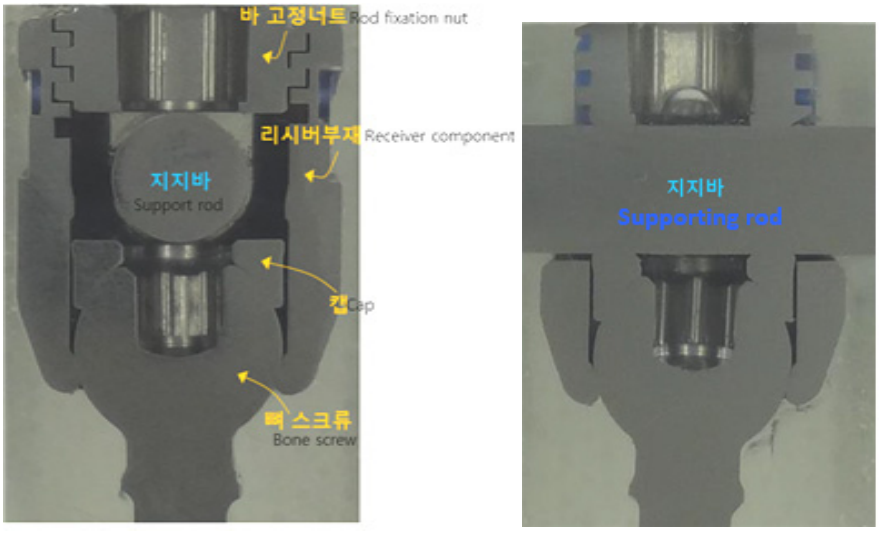
[Cap]



[Bone screw]





Cross-sectional images of Product L [X-axis and Y-axis] (Defendant's Exhibit 38)


IP HIGH COURT OF KOREA
FIRST DIVISION
DECISION

Case No.	2022Heo2530 Rejection (Patent)
Plaintiff	A Representative B Counsel for Plaintiff DAE-A Intellectual Property Consulting Patent Attorneys in Charge Jieun PARK and Sangjun LEE
Defendant	Commissioner of the Korean Intellectual Property Office Counsel for Defendant Byeongsook KIM
Date of Closing Argument	March 16, 2023
Decision Date	April 27, 2023

ORDER

1. The Plaintiff's claim is dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2021Won3203, decided February 24, 2022, shall be revoked.

OPINION

1. Background

A. Claimed Invention (Plaintiff's Exhibits 2, 6 and 18)

1) Title of invention: COVID-19 Antigenic Protein, DNA Fragment Coding the Same, and Gene Vaccines Including the Same

2) Filing date of the original application / Original application number / Filing date of the divisional application / Divisional application number: November 12, 2020 / No. 10-2020-0150689 / March 18, 2021 / No. 10-2021-0035382

3) Claims (as amended as of October 18, 2021)

【Claim 1】 (Deleted)[1)]

【Claim 2】 A DNA fragment consisting of gene sequence with the sequence number of 4 and for COVID-19 gene vaccines coding COVID-19 antigenic DNA,

wherein the COVID-19 antigenic protein is substituted with Y449A,[2)] N487A, Q493A, N501G, Y505G, R683G, R685G, R815G, K986P, and V987P;

the gene sequence is incorporated as a target antigen into a recombinant vector arranged in the order of CMV promoter, Kozak sequence, IgM signal peptide sequence, target antigen, BGH poly A tail, and two consecutive SV40 enhancers; and

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1) Before deletion, 【Claim 1】 was "A COVID-19 antigen protein characterized by comprising the amino acid sequence with the sequence number of 1."

2) This means that the 449th amino acid residue of the wild-type protein has been substituted from tyrosine (Y) to alanine (A). The three sets of four bases that make up DNA--adenine (A), guanine (G), cytosine (C), and thymine (T) [uracil (U) in RNA]--form an amino acid, which is referred to as a "codon." Each of the approximately 20 amino acids is specified by one or more codons. For example, alanine (A) is specified by the codons GCT, GCC, GCA, and GCG, and glycine (G) by the codons GGT, GGC, GGA, and GGG.

the recombinant vector constitutes a DNA fragment for a COVID-19 genetic vaccine characterized by being included in a composition for a COVID-19 genetic vaccine (hereinafter, "Claim 2").

【Claim 3】 A recombinant vector consisting of gene sequence with the sequence number of 4, and including a DNA fragment COVID-19 gene vaccines coding COVID-19 antigenic DNA,

wherein the COVID-19 antigenic protein is substituted by Y449A, N487A, Q493A, N501G, Y505G, R683G, R685G, R815G, K986P, and V987P

and the gene sequence is incorporated as a target antigen into a recombinant vector arranged in the order of, CMV promoter, Kozak sequence, IgM signal peptide sequence, target antigen, BGH poly A tail, and two consecutive SV40 enhancers.

【Claims 4 to 5】 (Each deleted)[3)]

【Claims 6 to 9】 (The description has been omitted since the case does not involve an examination of the claims.)

4) The main content of the claimed invention is detailed in [Appendix 1], while the information regarding the sequence number of 4 is described in [Appendix 2].

B. Prior Art

1) Prior Art 1 (Plaintiff's Exhibits 7, 10, 12, and 13 and Defendant's Exhibits 1, 6, 7, and 9)

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3) Before deletion, Claims 2 to 5 are as follows: 【Claim 2】 A DNA fragment comprising the gene sequence with the sequence number of 4, and encoding a COVID-19 antigen protein; 【Claim 3】 A recombinant vector comprising a DNA fragment consisting of the gene sequence with the sequence number of 4; 【Claim 4】 The recombinant vector according to Claim 3, wherein the gene sequence is arranged in the order of a target antigen, CMV promoter, target antigen, BGH poly(A) tail, and two consecutive SV40 enhancers; and 【Claim 5】 The recombinant vector according to Claim 4, comprising a Kozak sequence and an IgM signal peptide sequence between the CMV promoter and the target antigen.

Prior Art 1, published on August 14, 2020, is an article titled “DNA vaccine protection against SARS-CoV-2 in rhesus macaques.”[4] The main content is as described in [Appendix 3-1].

Prior Art 1 cites an article titled “Pre-fusion structure of a human coronavirus spike protein” published on March 2, 2016;[5] an article titled “Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen” published online on August 14, 2017;[6] and an article titled “Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation”[7] (The papers are cited in the order or their reference numbers in Prior Art 1 and hereinafter referred to as References 11, 12, and 13 respectively). The main content of each reference is detailed in [Appendix 3-2].

2) Prior Art 2 (Plaintiff’s Exhibit 8 and Defendant’s Exhibit 2)

Prior Art 2, published online on August 7, 2020, is an article titled “Effect of mutation on structure, function and dynamics of receptor binding domain of human SARS-CoV-2 with host cell receptor ACE2: a molecular dynamics simulations study”[8] and the main content is as described in [Appendix 4].

ACE2 (angiotensin-converting enzyme 2) is an enzyme-linked

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4) Jingyou Yu et al., “DNA vaccine protection against SARS-CoV-2 in rhesus macaques”, Science 369(6505), 806-811 (2020). Published online on May 20, 2020.

5) Robert N. Kirchdoerfer et al. “Pre-fusion structure of a human coronavirus spike protein”, Nature 531, 118-121 (2016).

6) Jesper Pallesen et al. “Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen”, PNAS 114(35), E7348-7357 (2017). Published on August 29, 2017.

7) Daniel Wrapp et al. “Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation”, Science 367(6438), 1260-1263 (2020).

8) Budheswar Dehury et al., “Effect of mutation on structure, function and dynamics of receptor binding domain of human SARS-CoV-2 with host cell receptor ACE2: a molecular dynamics simulations study”, Journal of Biomolecular Structure and Dynamics 39(18), 7231-7245 (2021).

receptor on the epithelial cells of the respiratory tract and various other tissues, which facilitates the binding of SARS-CoV-2 to the surface of host cells to enhance the virus's ability to penetrate the cells.

3) Prior Art 3 (Plaintiff's Exhibit 9 and Defendant's Exhibit 3)

Prior Art 3, published online on March 30, 2020, is an article titled "Structural basis of receptor recognition by SARS-CoV-2"[9] and the main content is as described in [Appendix 5].

C. Procedural History

1) The examiner of the Korean Intellectual Property Office (KIPO) issued a notice of grounds for rejection, stating, "Claims 1 to 9 of the claimed invention lack an inventive step under Article 29(2) of the Patent Act, as a person having ordinary skill in the art (hereinafter, "a skilled person") could easily conceive the invention by combining Prior Arts 1, 2, and 3, and therefore they are not patentable."

2) On July 22, 2021, the Plaintiff deleted Claim 1 and amended Claims 2 to 9. However, on September 17, 2021, the examiner rejected the application, stating that "Amended Claims 2 to 9 are denied of an inventive step by the combination of Prior Arts 1, 2, and 3, and thus the grounds for rejection have not been resolved."

3) On October 18, 2021, the Plaintiff requested reexamination after amending the claimed invention by limiting Claim 2 to cite the elements of pre-amended Claims 5 and 9; incorporating the elements of Claim 5 into Claim 3; and consequently deleting pre-amended Claims 4 and 5. However, on November 18, 2021, the KIPO examiner issued a rejection decision regarding Claims 2, 3, and 6 to 9, stating, "In the re-examination of the amended claims, they continue to be

9) Jian Shang et al., "Structural basis of receptor recognition by SARS-CoV-2", Nature 581, 221-224 (2020). Published on May 14, 2020.

denied of an inventive step by the combination of Prior Arts 1, 2, and 3, and therefore, the grounds for rejection remain unresolved."

4) On December 17, 2021, the Plaintiff requested an administrative trial against the above-mentioned rejection decision from the Intellectual Property Trial and Appeal Board (IPTAB) (Case No. 2021Won3203). On February 24, 2022, the IPTAB issued a decision which dismissed the Plaintiff's petition for administrative trial, stating that "the claimed invention lacks an inventive step as a skilled person could easily conceive the invention by combining Prior Arts 1, 2, and 3."

【Factual basis】 Undisputed facts; statements in Plaintiff's Exhibits 1 to 13 and 18 and Defendant's Exhibits 1, 2, 3, 6, 7, 9, and 27 (including Exhibits with branching numbers; hereinafter the same shall apply); and record as a whole

2. Summary of Parties' Arguments

A. Plaintiff

1) In Claim 2, the element specifying that "the COVID-19 antigenic protein is substituted by Y449A, N487A, Q493A, N501G, Y505G, R683G, R685G, R815G, K986P, and V987P" is neither described nor suggested in Prior Arts 1, 2, and 3. That is, Prior Arts 1, 2, and 3 do not describe or suggest the following elements: ① substituting glutamine (Q) at position 493 with alanine (A), and asparagine (N) at position 501 and tyrosine (Y) at position 505 with glycine (G) within the receptor-binding domain (RBD) of the spike protein; ② selectively substituting arginine (R) at positions 683 and 685 with glycine (G) at the S1/S2 furin cleavage site; and ③ substituting the residue at position 815 within the S2' cleavage site.

2) The statement in Claim 2, "(T)he gene sequence is incorporated as a target antigen into a recombinant vector arranged in the order of

CMV promoter, Kozak sequence, IgM signal peptide sequence, target antigen, BGH poly A tail, and two consecutive SV40 enhancers;
and the recombinant vector ... (is) characterized by being included in a composition for a COVID-19 genetic vaccine," constitutes a technical element of Claim 2. This element is neither described nor suggested in Prior Arts 1, 2, and 3, and it has already been recognized to have an inventive step, patented under Plaintiff's Patent No. 2216078 (Plaintiff's Exhibit 13; hereinafter, "Plaintiff's Related Patent").

3) Claim 2 cannot be easily conceived by a skilled person based on the combination of Prior Arts 1, 2, and 3, and it has a significant effect that cannot be predicted from the prior arts. Thus, its inventive step should not be denied.

B. Defendant

1) Claim 2 is related to a "DNA fragment," and the description regarding the recombinant vector including the fragment as a target antigen cannot be considered a technical element of the DNA fragment itself.

2) Prior Art 1 and its references disclose an element where arginine (R) is substituted with glycine (G) at the S1/S2 furin cleavage site (positions 682 to 686) and identify the location of the S' cleavage site (position 815). Prior Arts 2 and 3 disclose or suggest an element to substitute residues at positions 449, 487, 493, 501, and 505 within the RBD. Substituting amino acid residues at sites where mutations are deemed necessary with simple nonpolar amino acids such as alanine (A) or glycine (G) is considered a routine practice.

3) Also, it cannot be deemed that Claim 2 has a significant effect that cannot be predicted from the prior arts. Therefore, Claim 2 can be easily invented by a skilled person who combines Prior Arts 1, 2, and 3 and lacks an inventive step.

3. Whether IPTAB Erred

A. Relevant Law

When conducting an inventive step analysis of a claim of a patent comprised of multiple elements, courts should evaluate its inventive step based on the technical idea of the claim as an integrated whole considering the organic combination of all elements, rather than assessing each element in isolation. Therefore, when determining inventive step, it is not allowed only to examine, after breaking down multiple elements which are written in patent claims into each separate element, whether each separate element had been publicly known. Rather, the complexity of elements as an organically combined whole entity should be examined based on the unique solution principles. At the same time, the unique effect that the invention has, into which all the elements have been combined, should be considered together.

In determining the inventive step of a patented invention based on a combination of the elements disclosed in the multiple prior arts, its inventive step is denied if the references suggest or motivate the combination leading to the invention, or if it can be reasonably concluded that a skilled person could easily conceive the combination based on the level of the technology, technological common sense, basic problems to be solved in the field of the invention, development trends, and industry needs, etc. at the time of filing the patent application (see Supreme Court Decision 2005Hu3284, dated September 6, 2007).

B. Construction of Claim 2

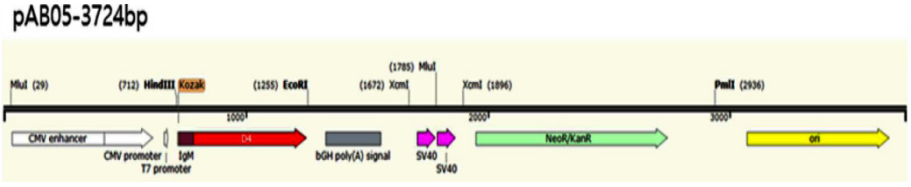
The Plaintiff argues that the recombinant vector is a technical element of Claim 2. However, based on the following facts inferred from the previously established facts, the aforementioned evidence, and the overall purport of the arguments, the recombinant vector cannot be considered a technical element of Claim 2.

1) The subject matter sought to be protected by Claim 2 is a "DNA fragment (for a COVID-19 genetic vaccine, comprising the gene sequence with the sequence number of 4)."

2) Here, a "vector" refers to a DNA molecule that is used to artificially transfer foreign genetic material and commonly includes plasmids, bacteriophages, and viruses (see Plaintiff's Related Patent, paragraph [0003, 0006]). A "recombinant vector" refers to a vector that has been produced through genetic recombination such as through transformation (see Plaintiff's Related Patent, paragraph [0042]). The vector as a carrier is different from the genetic material inserted into it for delivery (such as an antigen gene for a genetic vaccine).

3) The claims of Plaintiff's Related Patent include an "expression vector for delivering an antigen gene for a genetic vaccine, which comprises a sequentially arranged CMV promoter, Kozak sequence, IgM signal peptide sequence, target antigen, and BGH poly(A) tail sequence, along with one or two SV40 enhancer sequences, wherein the SV40 enhancer sequence is positioned either after the BGH poly(A) tail; two enhancers are positioned consecutively before the CMV promoter; two enhancers are positioned consecutively after the BGH poly(A) tail; or one enhancer is positioned before the CMV promoter and another after the BGH poly(A) tail" (Claim 1). Here, the "target antigen" may vary depending on the specific disease for which the vaccine is being developed. For instance, it can be a pathogenic antigen molecule. In Plaintiff's Related Patent, an example is provided where the vector contains the "anthrax D4 antigen" (see Plaintiff's Related Patent, paragraphs [0016, 0022, 0072]). [Figure 1] (the last figure of Drawing 3 in Plaintiff's Related Patent) is a schematic diagram illustrating where the target antigen is inserted within the recombinant vector (indicated by a red arrow labeled "D4").

[Figure 1] Insertion site of the recombinant vector for the target antigen (Plaintiff's Exhibit No. 13)



4) Claim 2 corresponds to the "DNA fragment" intended to be inserted in place of the "target antigen." Since the recombinant vector includes all the technical elements of Plaintiff's Related Patent, Claim 2 can be considered as utilizing Plaintiff's Related Patent. The only difference is that Claim 2 substitutes the gene sequence with the sequence number of 4 for the "anthrax D4 antigen" in the "target antigen" position of the schematic diagram. Plaintiff's Related Patent anticipated that different antigens could be inserted in the "target antigen" position. (However, the Plaintiff has separately claimed the "recombinant vector" incorporating the gene sequence with the sequence number of 4 as Claim 3.)

5) The recombinant vector part is merely described in the claim to illustrate how "the DNA fragment" claimed in Claim 2 can be used as a genetic vaccine. The Plaintiff argues that "the recombinant vector part describes a preparing method, which enhances the penetration efficiency of the DNA fragment." However, as the Plaintiff acknowledges, this does not constitute a preparing method for the "DNA fragment" itself and does not alter the structure of the "DNA fragment," that is, the gene sequence with the sequence number of 4. Therefore, the recombinant vector part cannot be considered a technical element that defines the "DNA fragment" itself, which is the subject of Claim 2 (Although not explicitly addressed by either the Plaintiff or the Defendant, the phrase "for COVID-19 gene vaccines coding COVID-19 antigenic DNA" in Claim 2 merely describes the use of the aforementioned "DNA fragment").

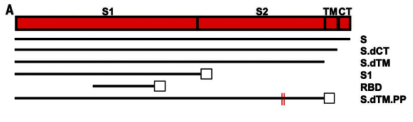
Thus, it is reasonable to interpret Claim 2 as "A DNA fragment (for

COVID-19 gene vaccines coding COVID-19 antigenic DNA), composed of the gene sequence with the sequence number of 4, substituted with Y449A, N487A, Q493A, N501G, Y505G, R683G, R685G, R815G, K986P, and V987P."

C. Element-by-Element Comparison

Claim 2 aims to provide a DNA fragment for a genetic vaccine that encodes an antigen protein by the substitution of amino acids in the SARS-CoV-2 (COVID-19)[10] spike protein [see the final specification of the claimed invention (hereinafter, "Final Specification"), paragraphs [0001, 0007, 0011]). Prior Art 1 is an article that develops six prototype DNA vaccine candidates with mutated SARS-CoV-2 spike proteins and evaluates their immunogenicity and protective efficacy through challenge studies in rhesus monkeys (page 806 of the article). Therefore, Claim 2 and Prior Art 1 share the same technical field and the object of the invention.

Based on the claim construction previously discussed, the following table compares the elements of Claim 2 with the corresponding elements in Prior Art 1.

Element	Claim 2	Prior Art 1
1	A DNA fragment consisting of gene sequence with the sequence number of 4 (for COVID-19 gene vaccines coding COVID-19 antigenic proteins)	Variants of SARS-CoV-2 spike proteins (Drawing 1.A) 
2	Substituted by Y449A, N487A, Q493A, N501G, Y505G, R683G, R685G, R815G, K986P, and V987P	S1/S2 furin cleavage site 682-685 substituted by GSAS, and residues 986 and 987 substituted by proline (P) (Reference 13)

10) COVID-19 is the name given by the World Health Organization (WHO) for the disease caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2).

D. Analysis of Commonalities and Differences

1) Commonalities

While Prior Art 1 does not disclose the complete gene sequence, Element 1 of Claim 2 explicitly describes the gene sequence of the DNA fragment as the one with the sequence number of 4. However, this merely involves the substitution of specific amino acids in the SARS-CoV-2 spike protein, as described in Element 2 (paragraphs [0043], [0049] of the Final Specification), and aside from the differences to be discussed later, the remaining sequence is identical (including the substitution by K986P and V987P[11]). The genetic sequence of SARS-CoV-2 was publicly disclosed around February 2020.[12] As widely known, scientists worldwide have since generated numerous research findings based on this sequence.

2) Difference 1

The substitution by Y449A, N487A, Q493A, N501G, and Y505G in Element 2 of Claim 2 is not disclosed in Prior Art 1 (hereinafter, “Difference 1”).

3) Difference 2

The mutant S.dTM.PP disclosed in Prior Art 1 differs in that it is characterized by a deletion of the furin cleavage site, while Reference 13 discloses substitutions at positions of 682 and 684, and the arginine (R) at positions 683 and 685 are replaced with serine (S), rather than glycine (G). (hereinafter, “Difference 2”).

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11) See Figure 1.A of Reference 12 and the “Supplementary Materials” section of Reference 13.

12) Roujian Lu et al., “Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding”, Lancet 395, 565-574 (2020), etc.

4) Difference 3

The substitution by R815G at the S2' cleavage site in Element 2 of Claim 2 is not disclosed in Prior Art 1 (hereinafter, "Difference 3").

E. Analysis of difference

1) Difference 1

Considering the following facts inferred from the previously recognized facts, the cited evidence, including Defendant's Exhibits 12, 13, and 21 to 24, and the overall purport of the arguments, Difference 1 can be easily overcome by a skilled person by combining Prior Arts 2 and 3 with Prior Art 1.

① Prior Art 2 is an article that provides structural information on SARS-CoV-2 receptor binding as foundational data to develop therapeutic agents against SARS-CoV-2. Prior Art 3 is an article that compares the ACE2 binding affinity among SARS-CoV-2, SARS-CoV, and RaTG13 to provide guidelines for intervention strategies targeting receptor recognition by SARS-CoV-2. These articles show that, at the viral entry stage mediated by spike proteins, mutations in the receptor-binding motif (RBM) within the RBD, the region that interacts with ACE2, can reduce ACE2 binding affinity. Prior Arts 2 and 3 share some commonalities with both Claim 2 and Prior Art 1 in terms of the technical field and object.

② Prior 2 discloses that substituting a part of RBM with Y449A, N487A, Y489A, N501A, and Y505A disrupts the ACE2's binding strength and that the position of 493 is involved in receptor binding.[13] Prior Art 3 discloses that the mutation into Q493N, Q493Y, and N501T results in a reduction in ACE2's binding affinity.

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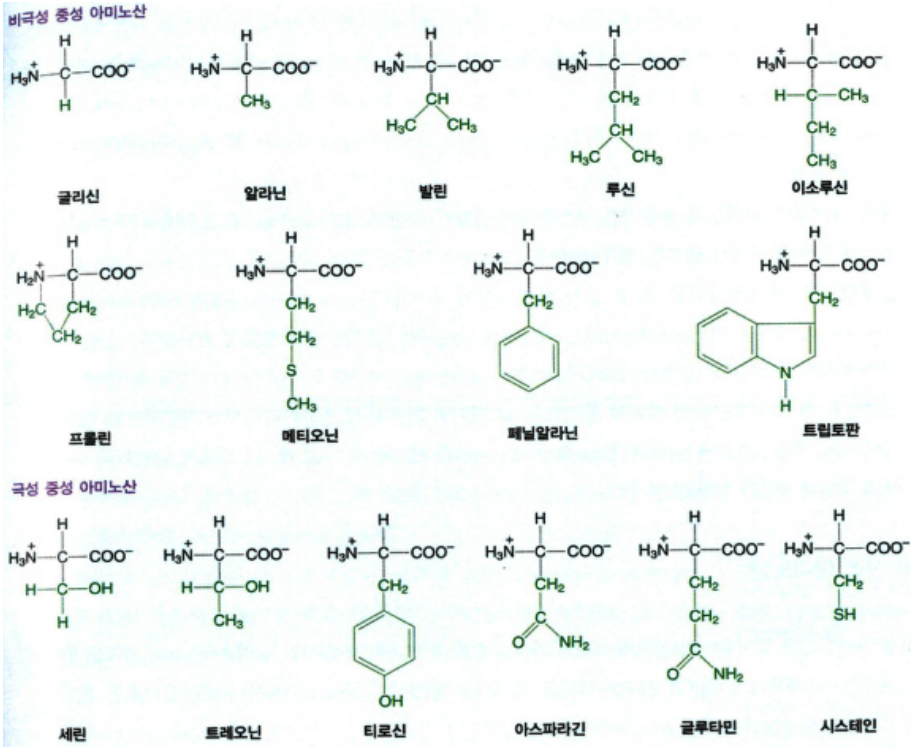
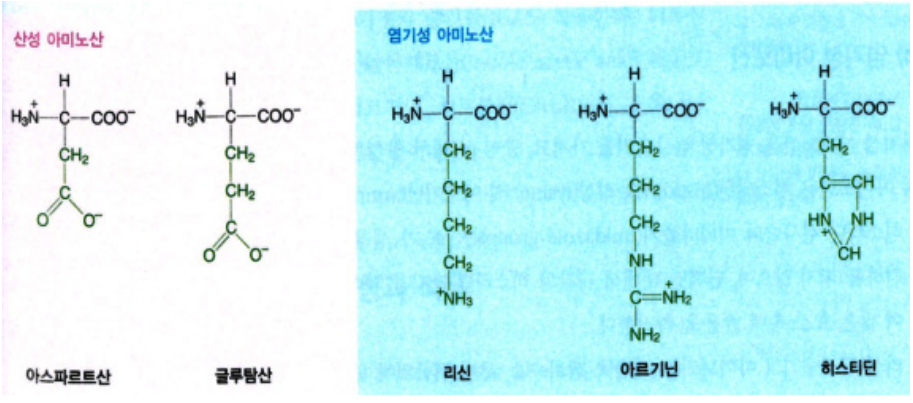
13) The "Q" marked with a star (★) below β9 in Figure 1.A on page 3 corresponds to 493 at position in the amino acid sequence. This is also explicitly indicated in Table 2 on page 9.

Y449A and N487A in Difference 1 are completely disclosed by Prior Art 2. With respect to the remaining Q493A, N501G, and Y505G, Prior Arts 2 and 3 disclose that the glutamine (Q) at position 493 is substituted with asparagine (N), tyrosine (Y) [rather than alanine (A)], and that the asparagine (N) and tyrosine (Y) at positions 501 and 505, respectively, are substituted with alanine (A), threonine (T) [rather than glycine (G)]. However, glycine (G) and alanine (A) adopted in Claim 2 are the nonpolar amino acids with the simplest structures among amino acids, and thus it makes them the most readily and intuitively selectable options for a skilled person (see [Figure 2]).[14)]

[Figure 2] Standard structure of an amino acid (Plaintiff's Exhibit No. 13)



14) The Plaintiff does not dispute that, in the relevant technical field of the present application, alanine (A) and glycine (G) are commonly used when substituting amino acids for the purpose of reducing binding affinity at specific amino acid positions (see Plaintiff's Brief dated September 26, 2022, page 8).



③ Before the original filing date of the claimed invention, alanine scanning, a method that induces mutations at specific amino acid positions by substituting them with alanine, was widely used in technical fields such as microbiology and molecular biology [see Defendant's Exhibit 12 (1997 paper) and Exhibit 21]. It was also known around 2012 that glycine could be introduced to provide a flexible linker without disrupting the function of each domain when forming a protein complex (see Defendant's Exhibits 22 and 23).

The Plaintiff asserts that there are 256 (i.e., 2^8) or more possible combinations when totally eight positions at 449, 487, 493, 501, 505, 683, 685, and 815, or more residues are substituted with either alanine (A) or glycine (G), and thus it is not easy to identify a superior single combination among them. However, it cannot be regarded that attempting substitutions using multiple combinations posed any particular difficulty when considering that alanine scanning and other methods for easily substituting amino acid residues were widely known at the time of the claimed invention.

④ Given that the position of RBM, which is known to closely interact with the SARS-CoV-2 receptor, a skilled person would naturally attempt replacements at these residues first,[15] and a skilled

15) Prior art 3 also discloses that the residues at position 493, 355, and 501 are involved in stabilizing 'hotspots' which is crucial for receptor recognition (see

person would be expected to first consider substitutions with alanine (A) or glycine (G). Accordingly, Difference 1 falls within the ordinary creative ability of a skilled person and does not involve any particular technical difficulty.

2) Difference 2

According to the following circumstances that can be inferred from the previously recognized facts, the cited evidence, and the overall purport of the arguments, Difference 2 can be easily overcome by a skilled person.

① Prior Art 1 describes that in the case of S.dTM.PP (a prefusion-stabilized, soluble extracellular domain with furin cleavage site deletion, two proline substitutions,[16] and a foldon trimerization tag),[17] it is presumed that proteolytic cleavage of the secreted protein did not occur due to the mutation at the furin cleavage site. It also suggests that such stabilization is crucial for a vaccine to function effectively. Reference 12 states that the ability to produce a prefusion-stabilized S protein extracellular domain is important since viruses can easily develop antibody-escape mutations in the RBD. An article published on September 28, 2020 (Defendant's Exhibit 24),[18] before the original filing date of the claimed invention, explains stabilizing substitutions, that is, the mutations in the furin cleavage site and the presence of two consecutive proline residues in the hinge

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page 224, Figure 2a).

16) As noted above, the K986P and V987P substitutions correspond to the portion indicated by two red lines in the middle of the S.dTM.PP sequence shown in the element comparison figure.

17) The term S.dTM.PP is an abbreviation for "prefusion-stabilized soluble ectodomain with deletion of the furin cleavage site, two proline mutations, and a foldon trimerization tag."

18) Rinke Bos et al., "Ad26 vector-based COVID-19 vaccine encoding a prefusion-stabilized SARS-CoV-2 Spike immunogen induces potent humoral and cellular immune responses", npj Vaccines 5, 91 (2020).

region of S2 enhance neutralizing antibody titers.

Reference 11 discloses an element to substitute RRKRR at positions 752 to 756 of the furin cleavage site with GGSGS;[19] Reference 12 includes an element to substitute RSVR at positions 748 to 751 of the furin cleavage site with ASVG, and Reference 13 discloses an element to substitute the amino acid residues at positions 682 to 685 of the furin cleavage site with GSAS. In other words, the references disclose the substitutions at positions 683 and 685, which was attempted by the Plaintiff.

② The Plaintiff argues that "positions 683 and 685 of the furin cleavage site were substituted because they were considered the most critical for ensuring antigen stability, and that Prior Art 1, etc. do not describe or suggest that certain positions are more important than others." However, the specification of the claimed invention at issue does not describe any indication that the substitution at positions 683 and 685 affects antigen stability, nor has any such effect been confirmed.

Therefore, substituting only some of the known candidate residues with glycine (G) falls within the scope of what a skilled person could easily attempt even without specific disclosure or suggestion.

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19) The Plaintiff points out that Reference 11 pertains to research conducted on COVID prior to the emergence of COVID-19 (see Plaintiff's Brief dated April 18, 2022, page 10). However, as the authors of Reference 11 has wrote "our study (on the HKU1 virus) may also be applicable to other Betacoronavirus, such as SARS-CoV and MERS-CoV" (see page 120, lower left), it is reasonable to conclude that a person skilled in the art could have sufficiently recognized the importance of the furin cleavage site based on Reference 11, given the high degree of homology among coronavirus of the same lineage. Reference 2 likewise states that "structural data reported over the past six months in the RCSB PDB (Protein Data Bank) support previous findings that the SARS-CoV-2 RBD and the SARS-CoV RBD share an almost identical binding interface" (see page 2, mid-left). See also Figure 5 comparing the spike proteins of SARS-CoV and SARS-CoV-2.

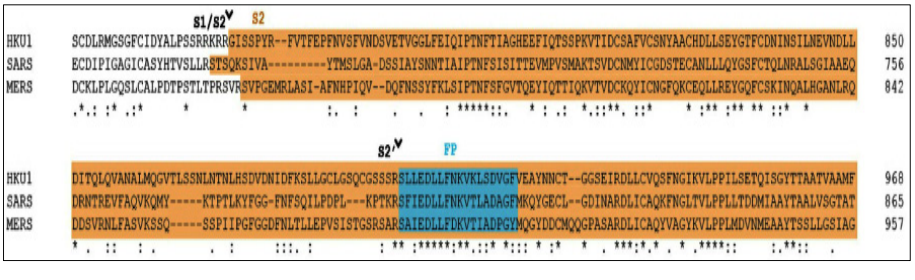
③ The Plaintiff also argues that none of the prior art references contain any disclosure or suggestion regarding the combination of substitutions in the RBM site with those at the furin cleavage site. However, as discussed above, it has already been disclosed that stabilization through furin cleavage site and proline substitutions is important as immune escape mutations can easily occur in the RBD. In addition, the lack of specific embodiments or experimental data in Prior Arts 2 and 3 does not mean that there is no motivation to combine them.

3) Difference 3

Considering the following circumstances inferred from the previously recognized facts, the cited evidence, Defendant's Exhibits 5, 10, 11, and 25, and the overall purport of the arguments, Difference 3 can be easily overcome by a skilled person.

① Reference 11 describes the S2' site, a secondary cleavage site adjacent to positions 901 to 918 in the HKU1 virus, and marks the corresponding positions for SARS-CoV and MERS-CoV in Drawing 6 [Figure 3].

[Figure 3] Reference 11, S2' cleavage site (Plaintiff's Exhibit No. 10; Defendant's Exhibit No. 6)

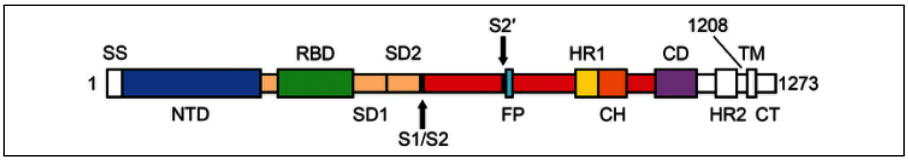


Drawing 1.A. [Figure 4] of Reference 13 and Drawing 3.A.B. [Figure 5] of an article published online on June 2, 2020 (Defendant's Exhibit 5)[20] prior to the original filing date of the claimed invention

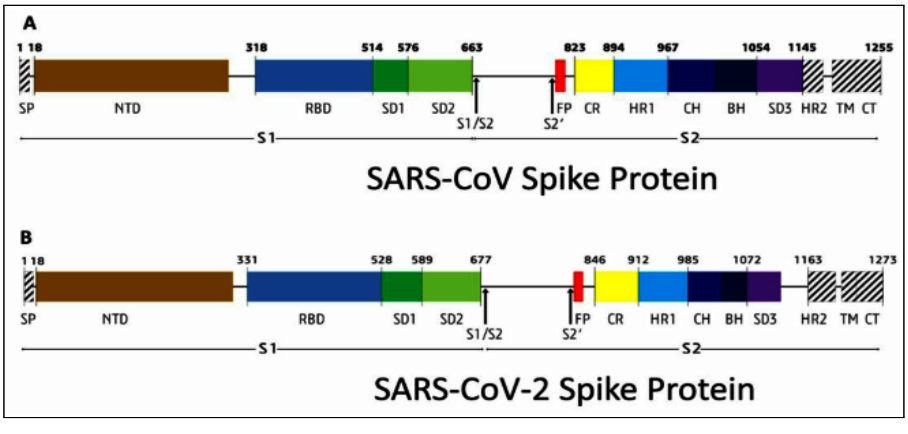
20) Syed Mohammad Lokman et al., "Exploring the genomic and proteomic variations

also mark the S2' cleavage site.

[Figure 4] Reference 13, S2' cleavage site (Plaintiff's Exhibit No. 12; Defendant's Exhibit No. 7)



[Figure 5] Lockman et al., S2' cleavage site (Defendant's Exhibit No. 5)



In addition, several documents published before the original filing date of the claimed invention had disclosed that when SARS-CoV-2 enters a cell, the "S2' cleavage (at position R815)" seems to occur after the S1/S2 cleavage, and that it may not occur until either host-receptor binding occurs at the plasma membrane or the virus is internalized through endocytosis (Defendant's Exhibits 6, 9, 10, and 11).[21] It was also known that combining a TMPRSS2 (transmembrane

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of SARS-CoV-2 spike glycoprotein: A computational biology approach", Infection, Genetics and Evolution (2020).

21) Donald J. Benton et al., "Receptor binding and priming of the spike protein of SARS-CoV-2 for membrane fusion," Nature 588, 327–330, published online on September 17, 2020 (Defendant's Exhibit No. 10); and Canrong Wu et al., "Furin: A potential therapeutic target for COVID-19," iScience 23, published online on October 5, 2020 (Defendant's Exhibit No. 11).

serine protease 2) inhibitor, which is involved in S2' cleavage, with the furin inhibitor MI-1851, which targets the S1/S2 cleavage, produces a stronger antiviral activity against SARS-CoV-2.[22)]

② Therefore, a skilled person would attempt substitutions at the S2' cleavage site along with the S1/S2 furin cleavage site, and as previously discussed, substitution with glycine (G) falls within his/her ordinary creative ability and does not present any technical difficulty.

③ In response, the Plaintiff argues that "Reference 12 suggests that substitution at the S2' cleavage site is either unnecessary or less important compared to the S1/S2 cleavage site."

As the basis for its argument, the Plaintiff cites Reference 12 stating "the reason that furin can access the S1/S2 cleavage site but not the S2' cleavage site during protein biosynthesis remains unclear. (...) In our structure, the peptide bond between R887 (Arg887) and S888 (Ser888) remains inaccessible to proteases, and this suggests that S2' cleavage cannot occur efficiently until S2 undergoes a change in the form during the fusion process" (p. 7351). However, the above finding merely indicates that S2' cleavage can occur efficiently only after a change in the form of the S2 has taken place — that is, the S2' cleavage occurs sequentially following the S1/S2 cleavage, as also described in other references. These findings cannot be interpreted to mean that substitution at the S2' cleavage site is little or unnecessary.

4) Ease of combination

As discussed earlier, Prior Arts 1, 2, and 3 share the same technical field and object as the claimed invention, and they provide disclosures or suggestions related to Differences 1, 2, and 3. Therefore, a skilled person could easily overcome these differences and derive an element that substitutes eight amino acid residues, as in Claim 2. Moreover,

22) Dorothea Bestle et al., "TMPRSS2 and furin are both essential for proteolytic activation of SARS-CoV-2 in human airway cells", Life Science Alliance 23 (2020) published online on July 23, 2020.

there are no negative teachings in the prior arts to discourage such a combination.

5) Comparison of effect

The Plaintiff argues that "Claim 2 has a significant effect that is unpredictable from Prior Arts 1, 2, and 3," and suggests comparative experiment results to indicate that "compared to the wild-type S protein, Claim 2 showed approximately a tenfold increase in antibody titers, maintained neutralizing activity up to a 1:2560 dilution, and demonstrated 95 to 100% cell survival up to a 1:40 dilution." It also contends that "the antibody titer of Claim 2 is 500 times higher than that of Prior Art 1."

However, considering the following circumstances inferred from the previously recognized facts, the cited evidence, Plaintiff's Exhibits 14 and 15, Defendant's Exhibit 4, and the purport of the overall arguments, the evidence submitted by the Plaintiff alone is not sufficient to establish that Claim 2 exhibits a significant effect that is unpredictable from the prior arts.

① In the Plaintiff's comparative experiment, the amino acid sequence of the wild-type protein (wtCoV) used as a control contains lysine (K) at position 986 and valine (V) at position 987.

Meanwhile, Reference 13 discloses the substitution of the amino acids at positions 986 and 987 with proline (P) as well as substitutions at the furin cleavage site, and multiple prior art documents disclose that such stabilization enhances neutralizing antibody formation. To prove that Claim 2 has a significant effect, the Plaintiff should have provided experimental results comparing Claim 2 with the prior art under identical conditions, at least concerning those disclosed in the prior art, including the proline substitutions. For instance, it must be demonstrated that its effect is better than that of S.dTM.PP in Prior Art 1.

② There is insufficient data to directly compare the effect of Claim 2 with Prior Art 1.

There is a difference in the experimental species used in Claim 2 and Prior Art 1. Claim 2 conducted experiments on golden hamsters, whereas experiment of Prior Art 1(drawing 1B, 2D) used rhesus monkeys as test subjects. Rhesus monkeys are classified as non-human primates and are considered an excellent model for research due to their similarities to humans (p. 83 of Defendant's Exhibit 4). Additionally, Prior Art 1 conducted experiments using a prototype DNA vaccine for rapid evaluation and used the pcDNA3.1+ vector as a carrier. Therefore, there is a difference in the construction of the recombinant vector between the experiment conducted for Claim 2 and the Prior Art 1. However, as previously discussed, the recombinant vector element cannot be considered a technical element of Claim 2, and therefore, in assessing whether the claimed invention has a significant effect, the comparison should be made under equivalent conditions with respect to the recombinant vector.

③ As a result, the exhibits submitted by the Plaintiff is not sufficient to determine whether Claim 2 has a significant effect compared to the prior arts.

F. Summary of Discussion

Claim 2 is denied of an inventive step and cannot be registered as a patent. Where a patent application includes two or more claims, the application as a whole must be rejected if one of the claims is found to be unpatentable. Accordingly, the present application cannot be granted a patent in its entirety, and there is no need to further examine the remaining claims.

4. Conclusion

The IPTAB Decision is consistent with the above analysis and shall be upheld. Accordingly, the Plaintiff's claim requesting the revocation of the IPTAB Decision is without merit. Therefore, it is dismissed.

Presiding Judge	Juhyung MOON
Judge	Bowon KWON
Judge	Jiyoon HAN

[Appendix 1]

Summary of Claimed Invention at Issue

A. Technical Field

[0001] The present invention pertains to a COVID-19 antigenic protein, a DNA fragment encoding the same, a recombinant vector containing the DNA fragment, a cell transformed with the recombinant vector, the method for preparing the recombinant vector, and a composition for a genetic vaccine comprising the recombinant vector.

B. Background Art

[0004] COVID-19 is a virus classified as a Betacoronavirus with an RNA genome of approximately 29kb in size that infect humans with high transmissibility. The key protein involved in the mechanism by which COVID-19 infiltrates the body and causes infection is the spike protein on the surface of the virus. This surface protein interacts with the angiotensin-converting enzyme 2 (ACE2) receptor, which is present on epithelial cells, such as those in the human respiratory and intestinal mucosa, enabling the virus to enter the cells. The spike protein can be broadly divided into two domains, S1 and S2, which are separated by the furin cleavage site. To enter the cell, the spike protein must undergo cleavage by furin. This results in a structural change and allows the protein to bind with the ACE2 receptor, enabling viral infection.

[0006] ... However, most of these approaches are focused on treatment after infection. A vaccine for the prevention of COVID-19 is still under development and has not yet been used in real-world cases. In China, an inactivated COVID-19 vaccine has been developed for prevention and is currently in clinical trials. In the past, genetic vaccines were attempted as next-generation vaccines for diseases such as Ebola and Zika virus, which caused numerous infections. Similarly, various attempts are currently underway, particularly by major global pharmaceutical companies, to develop vaccines that deliver DNA or RNA forms of genetic material into the body, and some of these are already in clinical trials.

[0007] In the present invention, an antigen was created by substituting

amino acids in the spike protein or Nucleocapsid protein of the COVID-19 virus, which was then developed into a genetic vaccine containing a recombinant vector for COVID-19 prevention. The invention was completed after confirming its effect against COVID-19.

C. Main Content of Invention

【Problem to be solved】

[0010] The object of the invention is to provide an antigenic protein for COVID-19.

[0011] Another object of the invention is to provide a DNA fragment to code the antigenic protein for COVID-19 above.

[0012] Another object of the invention is to provide a recombinant vector including the DNA fragment above.

[0013] Another object of the invention is to provide a cell transformed with the recombinant vector above.

[0014] Another object of the invention is to provide a preparing method for the recombinant vector above.

[0015] Another object of the invention is to provide a composition for a COVID-19 genetic vaccine including the recombinant vector above.

【Means for solving the problem】

[0019] To address the above problem, an aspect of the present invention provides a COVID-19 antigen protein comprising the amino acid sequence with the sequence number of 1.

[0020] According to another aspect of the present invention, a DNA fragment is provided, which is composed of the gene sequence of the sequence number of 4 and encodes a COVID-19 antigen protein.

[0021] According to another aspect of the present invention, a recombinant vector is provided, which includes a DNA fragment composed of the gene sequence with the sequence number of 4.

[0022] Additionally, the recombinant vector has the gene sequence serving as the target antigen and may be arranged in the order of the CMV promoter, target antigen, BGH poly(A) tail, and two consecutive SV40

enhancers.

[0023] Additionally, the recombinant vector may further include a Kozak sequence and IgM signal peptide sequence between the CMV promoter and the target antigen.

[0024] According to another aspect of the present invention, a cell transformed with the recombinant vector above is provided.

[0038] COVID-19 antigenic protein

[0039] The present invention provides a COVID-19 antigenic protein that includes one of the amino acid sequences selected from the group consisting of those with the sequence numbers of 1, 2, and 3.

[0040] The COVID-19 antigen protein of the present invention is produced by substituting some of the amino acids in the spike protein, one of the surface proteins of COVID-19, with other amino acids to facilitate the intracellular uptake of the antigen and helps maintain its stability so that it can be used as a vaccine. In other words, this protein minimizes the antigen protein's ability to bind with receptors on the cell surface to induce the generation of antibodies so that it can be used as a vaccine, where amino acids at the furin cleavage site are substituted to ensure that the spike protein remains structurally stable.

[0041] The full sequence of the COVID-19 spike protein may include both the S1 and S2 domains; only the S1 domain; or the S1 domain and the Nucleocapsid protein.

[0042] Drawing 1 illustrates the sites where amino acids are substituted of the COVID-19 antigenic protein of the present invention. Drawing 2 shows the modeling results from a three-dimensional structural simulation of the same antigen protein. The details are as follows.

[0043] Drawings 1a and 2a relate to the protein where amino acids 449, 487, and 493 are substituted with alanine, amino acids 501, 505, 683, 685, and 815 with glycine, and amino acids 986 and 987 with proline, between glutamine at position 14 on the N-terminus and proline at position 1213 on the C-terminus in the COVID-19 spike protein. This protein is referred to as "Antigen Co1V" or "Co1V" and is represented by the sequence number of 1.

[0047] A DNA fragment

[0048] The present invention provides a DNA fragment that codes COVID-19 antigenic proteins and is selected from the group consisting of the sequences with the sequence numbers of 4, 5, and 6.

[0049] The DNA fragment encoding Antigen Co1V of the present invention is indicated by the sequence number of 4, the DNA fragment encoding Antigen Co2V by the sequence number of 5, and the DNA fragment encoding Antigen Co3V by the sequence number of 6.

[0051] A recombinant vector

[0052] The present invention provides a recombinant vector including one or more of the genetic sequences selected from the group consisting of those with the sequence numbers of 4, 5, and 6.

[0053] The recombinant vector of the present invention is a plasmid vector used to deliver the COVID-19 antigen gene for use as a genetic vaccine. It enables effective in vivo delivery of the antigen sequence for gene vaccination, and is capable of inducing efficient expression and the formation of neutralizing antibodies.

[0054] The recombinant vector has may be arranged in the order of CMV promoter, target antigen, BGH poly(A) tail, and two consecutive SV40 enhancers. Arranging in the above order effectively delivers the target antigen in vivo, significantly increases the expression levels of the target antigen, and induces the formation of neutralizing antibodies to enhance the defensive effect against the target pathogen.

[0055] Additionally, the recombinant vector above may further include a Kozak sequence and IgM signal peptide sequence between the CMV promoter and the target antigen. The recombinant vector above may also include a kanamycin antibiotic marker.

[0056] As illustrated in Drawing 3, the recombinant vector above is preferably arranged in the order of CMV (Cytomegalovirus) promoter, Kozak sequence, IgM signal peptide sequence, target antigen, BGH (Bovine Growth Hormone) poly(A) tail, two consecutive SV40 enhancers, and kanamycin antibiotic marker.

[0066] A composition for a genetic vaccine

[0067] The present invention relates to a composition for a genetic vaccine including the recombinant vector above. In other words, the genetic vaccine composition of the present invention improves the defensive capability against the target pathogen by using the recombinant vector of the present invention to deliver the sequence of the genetic vaccine antigen into the body and inducing effective expression and the formation of neutralizing antibodies.

[0068] The composition above includes a recombinant vector and a carrier, and the recombinant vector above may be contained as the active ingredient.

D. Detailed description for implementing the invention

[0074] Embodiment 1: Preparing COVID-19 antigen

[**0075]** COVID-19 was acquired from the Korea Disease Control and Prevention Agency for experimental use. After analyzing the gene sequence and amino acid sequence of the spike protein and Nucleocapsid protein of COVID-19, the sequences of each domain were finalized, and the amino acids corresponding to the furin cleavage site and the ACE2 receptor-binding site were analyzed. After obtaining the three-dimensional structure of the protein to be transformed to an antigen from the RCSB (Research Collaboratory for Structural Bioinformatics) PDB (Protein DataBank), the positions of each amino acid were examined in three dimensions and analyzed using the Discovery Studio 4.5 protein modeling software. Based on the results, the amino acids for substitution were selected, and the suitable substitutions were made accordingly. The analysis was repeated, and using the homology modeling approach, the final vaccine candidate antigen was designed as Co3V.

[0076] As a result, Antigen Co1V was prepared by substituting amino acids 449, 487, and 493 with alanine, amino acids , 501, 505, 683, 685, and 815 with glycine, and amino acids , 986 and 987 with proline, between glutamine at position 14 on the N-terminus and proline at position 1213 on the C-terminus in the COVID-19 spike protein (Drawing 1a, the sequence number of 1);

[0077] Antigen Co2V was prepared by substituting amino acids 449, 487,

and 493 with alanine and amino acids 501, 505, and 683 with glycine between glutamine at position 14 on the N-terminus and alanine at position 684 on the C-terminus in the COVID-19 spike protein (Drawing 1b, the sequence number of 2);

[0078] and Antigen Co3V was prepared by substituting amino acids 449, 487, and 493 with alanine and amino acids 501 and 505 with glycine between the proline at position 337 on the N-terminus and the glutamic acid at position 516 on the C-terminus in the COVID-19 spike protein and by including the Nucleocapsid protein from amino acid 20 at the N-terminal to glutamine at position 409 at the C-terminal (Drawing 1c, the sequence number of 3).

[0080] Embodiment 2: Preparing a vector that includes the COVID-19 antigen

[0081] As illustrated in Drawing 3, the pVAX1 original vector was modified to create a recombinant vector that includes a CMV (cytomegalovirus) promoter, Kozak sequence, IgM signal peptide sequence, COVID-19 antigen (hereinafter referred to as Co1V, Co2V, and Co3V, with CoV1, CoV2, and CoV3 used interchangeably in the drawings), BGH (Bovine Growth Hormone) poly(A) tail, and two SV40 enhancer sequences in this order. The Kozak sequence and IgM signal peptide sequence were synthesized with the genes for COVID-19 antigens Co1V, Co2V, and Co3V prepared in Embodiment 1, which was then treated with Hind III and EcoR I restriction enzymes, and subsequently inserted into the vector to create the final three recombinant vectors.

[0083] Embodiment 3: Confirmation of expression of a vector that includes the COVID-19 antigen

[0087] Drawing 4a shows the Western blot results for Antigen Co1V expressed in cells transformed with the antigen, while Drawing 4b shows the Western blot results for Antigens Co2V and Co3V expressed in cells transformed with Antigen Co2V. Therefore, Drawings 4a and 4b confirm that Antigens Co1V, Co2V, and Co3V were expressed from the recombinant vectors containing these antigens.

[0089] Embodiment 4: Administration of a genetic vaccine containing a vector that includes the COVID-19 antigen

[0090] The three recombinant vectors prepared in Embodiment 2 were dissolved in PBS to prepared the genetic vaccine, and after anesthetizing male Syrian golden hamsters (6 to 8 weeks old) at a dose of 200 μg/head, the genetic vaccine was administered using the intradermal (ID) injection method. After administering the genetic vaccine, electroporation was performed using the BTX ECM-830 electroporator with 90V, 20 ms length, 3 pulses, and 100 ms interval.

[0091] The genetic vaccine was administered three times at 2-week intervals, and 2 weeks after the third dose, COVID-19 virus was administered intranasally at a dose of 6.4 x 10^4 PFU/head. After 5 days, lung damage and the virus in the tissues were quantified through necropsy. After the third immunization, blood was collected through the ophthalmic vein, and the serum was separated to measure antibody titer and assess neutralizing activity.

[0093] Embodiment 5: Measurement of antibody titer of a genetic vaccine containing a vector that includes the COVID-19 antigen

[0094] ELISA analysis was performed on the serum prepared in Embodiment 4 to measure the antibody titers generated in the hamsters that were administered the genetic vaccine.

[0097] As illustrated in Drawing 5, antibodies against Co1V, Co2V, and Co3V were formed in the hamsters that were administered the genetic vaccine in Embodiment 4. It was observed that subjects developed the highest antibody titers with Co1V, while the antibody titer for Co2V was slightly lower, measuring 1 × 10^4. However, Co3V showed almost no antibody titers.

[0099] Embodiment 6: Evaluation of neutralizing activity of a genetic vaccine containing a vector that includes the COVID-19 antigen

[0100] A Plaque Reduction Neutralization Test (PRNT) was performed on the serum prepared in Embodiment 4 to assess the neutralizing activity of the antibodies generated in the hamsters that were administered the genetic vaccines. Five hamsters were used for each vaccine, and tests were conducted separately to identify differences between individual subjects.

[0101] A total of 100 μl of the sample, consisting of hamster serum diluted

1:20 with DMEM medium containing 2% FBS, was prepared. As shown in Drawing 6, the serum was further diluted sequentially to 1:10, 1:20, 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280, and 1:2560 and was then prepared in 96-well plates. 50 μl of 200$TCID_{50}$ COVID-19 virus was added to each well of the prepared serum.

[0103] As illustrated in Drawing 6 in purple, live cells were observed that were not infected by the virus. Although there were differences between individuals, the serum from Co1V-vaccinated subjects provided protection up to a 1:2560 dilution in Drawing 6a, the serum for Co2V provided protection up to a 1:20 dilution in Drawing 6b, and the serum for Co3V showed almost no protection in Drawing 6c.

[0105] Embodiment 7: Assessment of cell viability in response to COVID-19 antibody

[0106] The serum from hamsters that received the genetic vaccine in Embodiment 4 was incubated with the virus, and the number of live cells that were not infected by the virus was measured based on the absorbance.

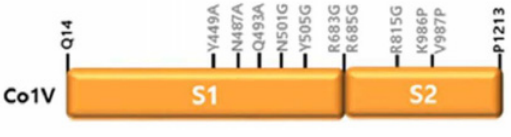
[0108] As shown in Drawing 7, Co1V demonstrated that more than 80% of the cells remained alive up to a 1:2560 dilution, Co2V showed excellent protective effects up to a 1:20 dilution, and Co3V displayed almost no protection.

[0110] Embodiment 8: Quantification of the viral load using real-time PCR

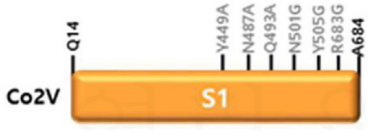
[0111] After infecting the hamsters that received the genetic vaccine of Embodiment 4 with the virus, the amount of virus remaining in the lungs of the hamsters was measured using real-time PCR.

[0113] According to Drawings 8a and 8b, in the case of Co1V, little to no residual virus was detected, whereas in case of Co2V and Co3V, a significant reduction in viral load was also observed compared to the group administered with the virus alone.

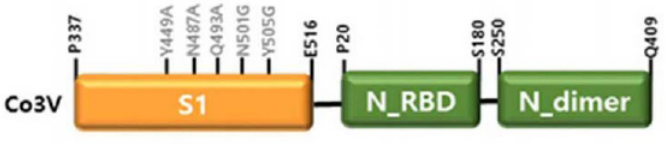
[Drawing 1a]



[Drawing 1b]



[Drawing 1c]



[Appendix 2]

The sequence number of 4

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[The end].

[Appendix 3-1]

Key Extracts from Prior Art 1

Abstract

The global coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has made the development of a vaccine a top biomedical priority. In this study, we developed a series of DNA vaccine candidates expressing different forms of the SARS-CoV-2 spike (S) protein and evaluated them in 35 rhesus macaques. Vaccinated animals developed humoral and cellular immune responses, including neutralizing antibody titers at levels comparable to those found in convalescent humans and macaques infected with SARS-CoV-2. After vaccination, all animals were challenged with SARS-CoV-2, and the vaccine encoding the full-length S protein resulted in >3.1 and >3.7 $\log_{10}$ reductions in median viral loads in bronchoalveolar lavage and nasal mucosa, respectively, as compared with viral loads in sham controls. Vaccine-elicited neutralizing antibody titers correlated with protective efficacy, suggesting an immune correlate of protection. These data demonstrate vaccine protection against SARS-CoV-2 in nonhuman primates.

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In the present study, we constructed a set of prototype DNA vaccines expressing various forms of the SARS-CoV-2 spike (S) protein and assessed their immunogenicity and protective efficacy against SARS-CoV-2 viral challenge in rhesus macaques.

Construction and immunogenicity of DNA vaccine candidates

We produced a series of prototype DNA vaccines expressing six variants of the SARS-CoV-2 S protein: (i) full length (S), (ii) deletion of the cytoplasmic tail (S.dCT) (10), (iii) deletion of the transmembrane domain and cytoplasmic tail reflecting the soluble ectodomain (S.dTM) (10), (iv) S1 domain with a foldon trimerization tag (S1), (v) receptor-binding domain with a foldon trimerization tag (RBD), and (vi) a prefusion- stabilized soluble ectodomain with deletion of the furin cleavage site, two proline mutations, and a foldon trimerization tag (S.dTM.PP) (Fig. 1A). Western blot analyses confirmed expression in cell lysates for all constructs and in culture supernatants for the soluble S.dTM and S.dTM.PP constructs (Fig.

1, B and C). Proteolytic cleavage of the secreted protein was observed in S.dTM, but not in S.dTM.PP, which is likely attributable to the mutation at the furin cleavage site in S.dTM.PP.

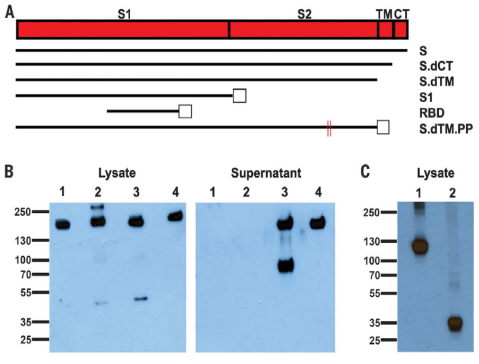


Fig. 1. Construction of candidate DNA vaccines against SARS-CoV-2. (**A**) Six DNA vaccines were produced expressing different SARS-CoV-2 spike (S) variants: (i) full length (S), (ii) deletion of the cytoplasmic tail (S.dCT), (iii) deletion of the transmembrane (TM) domain and cytoplasmic tail (CT) reflecting the soluble ectodomain (S.dTM), (iv) S1 domain with a foldon trimerization tag (S1), (v) receptor-binding domain with a foldon trimerization tag (RBD), and (vi) prefusion-stabilized soluble ectodomain with deletion of the furin cleavage site, two proline mutations, and a foldon trimerization tag (S.dTM.PP). Open squares depict foldon trimerization tags; red lines depict proline mutations. (**B**) Western blot analyses for expression from DNA vaccines encoding S (lane 1), S.dCT (lane 2), S.dTM (lane 3), and S.dTM. PP (lane 4) in cell lysates and culture supernatants using an anti-SARS polyclonal antibody (BEI Resources). (**C**) Western blot analyses for expression from DNA vaccines encoding S1 (lane 1) and RBD (lane 2) in cell lysates using an anti–SARS-CoV-2 RBD polyclonal antibody (Sino Biological).

We immunized 35 adult rhesus macaques (6 to 12 years old) with DNA vaccines in the following groups: S (N = 4), S.dCT (N = 4), S.dTM (N = 4), S1 (N = 4), RBD (N = 4), S.dTM.PP (N = 5), and sham controls (N = 10). Animals received 5-mg DNA vaccines by the intramuscular route without adjuvant at weeks 0 and 3. After the boost immunization at week 5, we observed S-specific binding antibodies by enzyme-linked immunosorbent assay (ELISA) (Fig. 2A) and neutralizing antibodies (NAbs) by both a pseudovirus neutralization assay (Fig. 2B) and a live virus neutralization assay (Fig. 2C). As determined by ELISA, two animals had binding antibodies at baseline, which might reflect cross-reactivity of other natural primate coronaviruses. NAb titers measured by the pseudovirus neutralization assay correlated with NAb titers measured by the live virus neutralization assay ($P < 0.0001$, $R = 0.8052$, two-sided Spearman rank-correlation test; fig. S1). Moreover, NAb titers in the vaccinated macaques (median titer = 74; median titer in the S and S.dCT groups = 170) were comparable in magnitude to NAb titers in a cohort of 9 convalescent macaques (median titer = 106) and a cohort of 27 convalescent humans (median titer = 93) who had recovered from SARS-CoV-2 infection (Fig. 2D).

S-specific and RBD-specific antibodies in the vaccinated macaques included diverse subclasses and effector functions, including antibody- dependent neutrophil phagocytosis (ADNP), antibody-dependent complement deposition (ADCD), antibody-dependent monocyte cellular phagocytosis (ADCP), and antibody-dependent natural killer (NK) cell activation [interferon-ɣ (IFN-ɣ) secretion, CD107a degranulation, and MIP-1β expression] (Fig. 2E). A

trend toward higher ADCD responses was observed in the S and S.dCT groups, whereas higher NK cell activation was observed in the RBD and S.dTM.PP groups. A principal components analysis of the functional and biophysical antibody features showed overlap of the different vaccine groups, with more distinct profiles in the S and RBD groups (Fig. 2E).

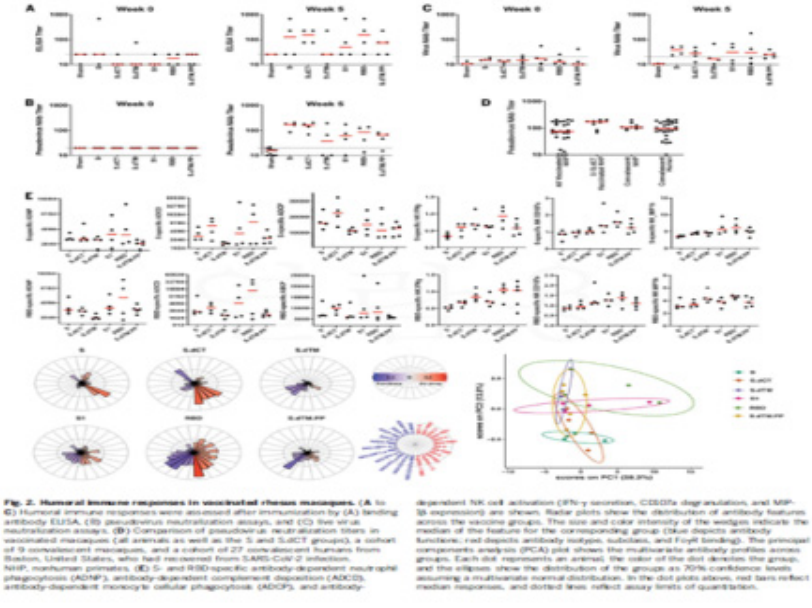
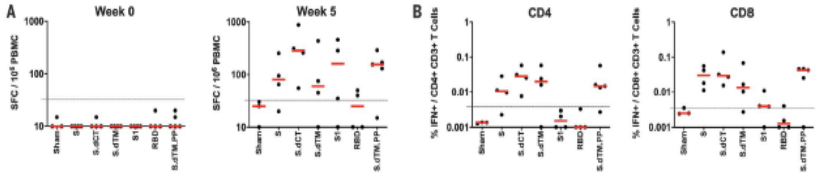


Fig. 2. Humoral immune responses in vaccinated rhesus macaques. (**A** to **C**) Humoral immune responses were assessed after immunization by (A) binding antibody ELISA, (B) pseudovirus neutralization assays, and (C) live virus neutralization assays. (**D**) Comparison of pseudovirus neutralization titers in vaccinated macaques (all animals as well as the S and S.dCT groups), a cohort of 9 convalescent macaques, and a cohort of 27 convalescent humans from Boston, United States, who had recovered from SARS-CoV-2 infection. NHP, nonhuman primates. (**E**) S- and RBD-specific antibody-dependent neutrophil phagocytosis (ADNP), antibody-dependent complement deposition (ADCD), antibody-dependent monocyte cellular phagocytosis (ADCP), and antibody-dependent NK cell activation (IFN-γ secretion, CD107a degranulation, and MIP-1β expression) are shown. Radar plots show the distribution of antibody features across the vaccine groups. The size and color intensity of the wedges indicate the median of the feature for the corresponding group (blue depicts antibody functions; red depicts antibody isotype, subclass, and FcγR binding). The principal components analysis (PCA) plot shows the multivariate antibody profiles across groups. Each dot represents an animal; the color of the dot denotes the group, and the ellipses show the distribution of the groups as 70% confidence levels assuming a multivariate normal distribution. In the dot plots above, red bars reflect median responses, and dotted lines reflect assay limits of quantitation.

We also observed cellular immune responses to pooled S peptides in most vaccinated animals by IFN-γ enzyme-linked immunosorbent spot (ELISPOT) assays at week 5 (Fig. 3A). Intracellular cytokine staining assays at week 5 demonstrated induction of S-specific IFN-γ+ CD4+ and CD8+ T cell responses, with lower responses induced by the shorter S1 and RBD immunogens (Fig. 3B). S-specific IL-4+ CD4+ and CD8+ T cell responses were marginal (Fig. 3C), suggesting induction of T helper 1 (TH1)–biased cellular immune responses.



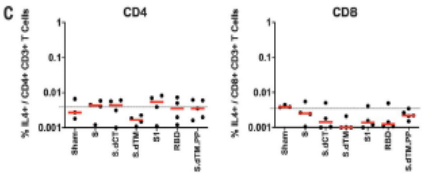


Fig. 3. Cellular immune responses in vaccinated rhesus macaques. At week 5 after immunization, cellular immune responses were assessed by (**A**) IFN-γ ELISPOT assays and (**B**) IFN-γ+ and (**C**) IL-4+ intracellular cytokine staining assays for CD4+ and CD8+ T cells in response to pooled S peptides. Red bars reflect median responses; dotted lines reflect assay limits of quantitation.

Protective efficacy against SARS-CoV-2 challenge

At week 6, which was 3 weeks after the boost immunization, all animals were challenged with 1.2 × 108 virus particles (VPs) [1.1 × 104 plaque-forming units (PFUs)] of SARS-CoV-2, administered as 1ml by the intranasal route and 1ml by the intratracheal route. After challenge, we assessed viral RNA levels by reverse transcription polymerase chain reaction in bronchoalveolar lavage (BAL) and nasal swabs (NS). Viral RNA was negative in plasma, and animals exhibited only mild clinical symptoms. High levels of viral RNA were observed in the sham controls, with a median peak of 6.46 (range = 4.81 to 7.99) $\log_{10}$ RNA copies/ml in BAL and a median peak of 6.82 (range = 5.96 to 7.96) log10 RNA copies/swab in NS (Fig. S2). Lower levels of viral RNA were observed in the vaccine groups (Figs. S3 and S4), including 1.92 and 2.16 $\log_{10}$ reductions of median peak viral RNA in BAL and NS, respectively, in S-vaccinated animals compared with sham controls (P = 0.02 and 0.04, two-sided Mann-Whitney tests) (Fig. S5). Viral RNA assays were confirmed by PFU assays, which similarly showed lower infectious virus titers in S-vaccinated animals compared with sham controls (P = 0.04, two-sided Mann-Whitney test) (Fig. S5).

We speculated that a substantial fraction of viral RNA in BAL and NS after challenge represented input challenge virus. Therefore, we also assessed levels of subgenomic mRNA (sgmRNA), which are believed to reflect viral replication cellular intermediates that are not packaged into virions, and thus putative replicating virus in cells. High levels of sgmRNA were observed in the sham controls (Fig. 4A) with a median peak of 5.35 (range = 3.97 to 6.95) $\log_{10}$ sgmRNA copies/ml in BAL and 6.40 (range = 4.91 to 7.01) $\log_{10}$ sgmRNA copies per swab in NS. Peak viral loads occurred variably on days 1 to 4 after challenge. Markedly lower levels of sgmRNA were observed in the vaccine groups (Fig. 4, B and C), including >3.1 and >3.7 $\log_{10}$ decreases of median peak sgmRNA in BAL and NS, respectively, in S-vaccinated animals compared with sham controls (P =

0.03 and 0.01, two-sided Mann-Whitney tests) (Fig. 4D). Reduced levels of sgmRNA were also observed in other vaccine groups, including S.dCT, S1, RBD, and S.dTM.PP, although minimal to no protection was seen in the S.dTM group, confirming the importance of prefusion ectodomain stabilization, as reported previously.

Discussion

A safe and effective SARS-CoV-2 vaccine may be required to end the global COVID-19 pandemic. Several vaccine candidates have initiated clinical testing, and many others are in preclinical development. However, very little is currently known about immune correlates of protection and protective efficacy of candidate SARS-CoV-2 vaccines in animal models. In this study, we generated a series of prototype DNA vaccines expressing various S immunogens and assessed protective efficacy against intranasal and intratracheal SARS-CoV-2 challenge in rhesus macaques. We demonstrated vaccine protection with substantial >3.1 and >3.7 $\log_{10}$ reductions in median viral loads in BAL and NS, respectively, in S-immunized animals compared with sham controls. Protection was likely not sterilizing but instead appeared to be mediated by rapid immunologic control after challenge. ... In summary, we demonstrate effective vaccine protection against SARS-CoV-2 in rhesus macaques and define NAb titers as an immune correlate of protection, which will accelerate the development of SARS-CoV-2 vaccines for humans.

[Appendix 3-2]

Key Extracts from References 11, 12, and 13

1. Reference 11

(Fourth paragraph on the left side of page 119) Processing of coronavirus S proteins by host proteases plays a critical role in the entry process. HKU1 S is cleaved by furin into S1 and S2 subunits during protein biosynthesis. Though mutated in the protein construct used here and disordered in the density map, the HKU1 S furin-cleavage site at the S1/S2 junction lies in a loop of SD-2 (Fig. 3 and Extended Data Fig. 6). Furin cleavage would leave a single S2 β-strand participating in the SD-2 β -sheets (Fig. 2d). Coronavirus S proteins also have a secondary cleavage site, termed S2' (Arg900), adjacent to the viral fusion peptide (amino acids 901−918)17 (Fig. 3b and Extended Data Fig. 6). This is similar to the multiple endoproteolytic cleavage events that occur in the fusion proteins of respiratory syncytial virus (RSV) and Ebola virus. Protease cleavage at S2' likely follows S1/S2 cleavage and may not occur until host-receptor engagement at the plasma membrane or viral endocytosis.

(Methods on page 112) A mammalian-codon-optimized gene encoding HKU1 S (isolate N5, NCBI accession Q0ZME7) residues 1−1276 with a C-terminal T4 fibritin trimerization domain, a HRV3C cleavage site, and a 6xHis-tag was synthesized and subcloned into the eukaryotic expression vector pVRC8400. The S1/S2 furin-recognition site 752-RRKRR-756 was mutated to GGSGS to generate the uncleaved construct used for cryoEM studies.

2. Reference 12

(Abstract) Here we use structure-based design to develop a generalizable strategy for retaining coronavirus S proteins in the antigenically optimal prefusion conformation and demonstrate that our engineered immunogen is able to elicit high neutralizing antibody titers against MERS-CoV. . . . Our studies suggest a potential mechanism for fusion initiation through sequential receptor-binding events and provide a foundation for the structure-based design of coronavirus vaccines.

(Second paragraph on the left side of E7349) As the primary glycoprotein on the surface of the viral envelope, S proteins are the major target of

neutralizing antibodies elicited by natural infection and are key antigens in experimental vaccine candidates. However, the S protein ectodomain from MERS-CoV is less stable and more difficult to produce than other S proteins, and soluble constructs of the RBD have been the main focus of structural studies, antibody isolation efforts, and subunit vaccine development. A drawback of this approach is that coronaviruses can readily generate antibody-escape mutations in the RBD. Thus, the use of a mixture of antibodies, including some directed against non-RBD epitopes, is a preferred strategy and has been used successfully for the treatment of Ebola virus disease. However, due to the difficulty in producing prefusion-stabilized MERS-CoV S proteins, few non-RBD antibodies have been described, and less is known about their epitopes. Antibodies against the prefusion conformation of the S2 stem are particularly attractive because the stem is more conserved than the S1 cap. Therefore, the ability to produce prefusion-stabilized S protein ectodomains from highly pathogenic coronaviruses, combined with the structural characterization of non-RBD epitopes that are recognized by potent neutralizing antibodies, would greatly facilitate the development of broadly protective interventions for current and emerging coronaviruses. . . . In this study, we rationally designed a general strategy to retain Betacoronavirus S proteins in the prefusion conformation. The prefusion-stabilized MERS-CoV S protein (MERS S-2P) retained high-affinity binding to its dimeric receptor DPP4 and a panel of neutralizing antibodies, and elicited high titers of neutralizing antibodies in mice. ... Collectively, these results advance our understanding of MERS-CoV entry and antibody-mediated neutralization and provide a foundation for the structure-based design of vaccine antigens for highly pathogenic coronaviruses, including those expected to emerge in the future.

(Left side on E7350) Engineering of Coronavirus S Proteins That Retain the Prefusion Conformation . . . Introduction of single proline substitutions into a similar region in the MERS-CoV S2 subunit dramatically increased expression levels of the ectodomains, and two consecutive proline substitutions at residues V1060 and L1061 (hereafter referred to as “2P”) resulted in a >50-fold improvement in yield (Fig. 1C and Fig. S1A). As evidenced by negative-stain EM, the 2P variant maintained prototypic prefusion morphology (Fig. 1D). Homologous substitutions in the S proteins from SARS-CoV (Fig. 1 C and D and Fig. S1B) and HCoV-HKU1 (Fig. S1 B and C) also increased the expression levels of the

ectodomains and improved conformational homogeneity. Thus, the introduction of two consecutive proline residues at the beginning of the central helix seems to be a general strategy for retaining Betacoronavirus S proteins in the prototypical prefusion conformation. . . . Collectively, these data demonstrate that the 2P substitutions prevent fusion from occurring but do not alter the conformation of the S protein.

(Fourth paragraph on the right side of E7350) For efficient infection of target cells, the MERS-CoV S protein requires a two-step, protease-mediated activation to facilitate membrane fusion. Furin cleavage at the S1/S2 junction occurs in the virus-producing cell, whereas cleavage at the S2′ site, upstream of the fusion peptide, occurs during viral entry at the cell surface or in endosomes and can be mediated by several proteases, including furin, TMPRSS2, and cathepsin L. However, it has not been understood why furin can access the S1/S2 site but not the S2′ site during protein biosynthesis. The S1/S2 furin site (RSVR), which remains uncleaved in our construct due to mutagenesis (ASVG), is located on an accessible solvent-exposed loop that is disordered in our structures (Fig. 4B). In contrast, the S2′ site (RSAR) is less exposed, particularly Arg887 at the P1 position, which interacts with Asp892 and Phe895 in the fusion peptide (Fig. 4C). In our structure, the peptide bond between Arg887 and Ser888 remains inaccessible to proteases, suggesting that S2′ cannot be efficiently cleaved until a conformational change occurs in S2 during the fusion process. Refolding of HR1 following DPP4 binding and S1 shedding would cause such a change and link the final proteolytic activation step to host-cell attachment, thus ensuring that irreversible refolding of S2 occurs at the proper time and place. Indeed, incubation of MERS-CoV virions with soluble DPP4 receptor increases the efficiency of furin cleavage at the S2′ site.

(Second paragraph on the left side of E7354) Engineering class-I viral fusion proteins in the prefusion conformation can significantly improve immunogenicity through preservation of neutralization-sensitive conformational and quaternary epitopes. This is exemplified by the failure of postfusion RSV F glycoprotein vaccine antigens and the promise of prefusion-stabilized RSV F glycoproteins. Recently, the MERS-CoV S1 monomer has been shown to elicit RBD-specific neutralizing antibodies in mice and protect rhesus macaques from MERS-CoV–induced pneumonia, but protection was improved in animals primed with full-length S antigens

that induced neutralizing antibodies directed to non-RBD sites. These data, together with the observation that the RBD has positional variability, suggest that the virus has evolved multiple mechanisms to evade neutralization by RBD-specific antibodies. The RBD sequence variability is compounded by the positional variability that allows conformational masking and transient exposure of quaternary surfaces and neutralization-sensitive sites. Our demonstration here that the prefusion-stabilized MERS-CoV S trimer (S-2P) elicits more robust neutralizing antibody responses in mice than S1 monomer or S WT suggests that MERS S-2P is a preferred antigen for vaccine development and is made more attractive due to inclusion of non-RBD epitopes and favorable manufacturing characteristics.

2. Reference 13

(Second paragraph on the left side of page 1260) 2019-nCoV makes use of a densely glycosylated spike (S) protein to gain entry into host cells. The S protein is a trimeric class I fusion protein that exists in a metastable prefusion conformation that undergoes a substantial structural rearrangement to fuse the viral membrane with the host cell membrane. This process is triggered when the S1 subunit binds to a host cell receptor. Receptor binding destabilizes the prefusion trimer, resulting in shedding of the S1 subunit and transition of the S2 subunit to a stable postfusion conformation. To engage a host cell receptor, the receptor- binding domain (RBD) of S1 undergoes hinge-like conformational movements that transiently hide or expose the determinants of receptor binding. These two states are referred to as the “down” conformation and the “up” conformation, where down corresponds to the receptor- inaccessible state and up corresponds to the receptor-accessible state, which is thought to be less stable. Because of the indispensable function of the S protein, it represents a target for antibody-mediated neutralization, and characterization of the prefusion S structure would provide atomic-level information to guide vaccine design and development.

(Second paragraph on the right side of page 1260) Based on the first reported genome sequence of 2019-nCoV, we expressed ectodomain residues 1 to 1208 of 2019-nCoV S, adding two stabilizing proline mutations in the C-terminal S2 fusion machinery using a previous stabilization strategy that proved effective for other Betacoronavirus S

proteins.

(Third paragraph on the left side of page 1263) The rapid global spread of 2019-nCoV, which prompted the PHEIC declaration by WHO, signals the urgent need for coronavirus vaccines and therapeutics. Knowing the atomic-level structure of the 2019-nCoV spike will allow for additional protein-engineering efforts that could improve antigenicity and protein expression for vaccine development. The structural data will also facilitate the evaluation of 2019-nCoV spike mutations that will occur as the virus undergoes genetic drift and help to define whether those residues have surface exposure and map to sites of known antibody epitopes for other coronavirus spike proteins. In addition, the structure provides assurance that the protein produced by this construct is homogeneous and in the prefusion conformation, which should maintain the most neutralization-sensitive epitopes when used as candidate vaccine antigens or B cell probes for isolating neutralizing human mAbs. Furthermore, the atomic-level detail will enable the design and screening of small molecules with fusion-inhibiting potential. This information will support precision vaccine design and the discovery of antiviral therapeutics, accelerating medical countermeasure development.

(Protein expression and purification of Materials and Methods in Supplementary Materials) To express the prefusion S ectodomain, a gene encoding residues 1-1208 of 2019-nCoV S (GenBank: MN908947) with proline substitutions at residues 986 and 987, a “GSAS” substitution at the furin cleavage site (residues 682-685), a C-terminal T4 fibritin trimerization motif, an HRV3C protease cleavage site, a TwinStrepTag and an 8XHisTag was synthesized and cloned into the mammalian expression vector pαH.

[Appendix 4]

Key Extracts from Prior Art 2

Abstract

Recent studies have pointed the role of angiotensin-converting enzyme-II (ACE2) in mediating the entry of SARS-CoV-2 to the host cell by binding to the receptor-binding domain (RBD) of viral spike protein, and successive priming by cellular proteases initiates the infection. SARS-CoV replication rate and disease severity is controlled by the binding affinity of RBD with ACE2. To understand, how mutations in the conserved residues of RBD affect the molecular interaction with ACE2, we generated five alanine mutants i.e. Y449A, N487A, Y489A, N501A and Y505A in the receptor binding motif (RBM) of the ACE2-RBD SARS- CoV-2 complex (PDB: 6M0J). Computational site directed mutagenesis induced dynamics in wild-type and mutant complexes were extensively studied through all-atoms molecular dynamics (MD) simulations of 150 ns. In silico mutational analysis revealed loss of important intermolecular hydrogen bonds and other non-bonded contacts, critical for molecular recognition of SARS-CoV-2 RBD to ACE2, which is well supported by saturation mutagenesis study of binding interface residues. MD simulations results showed that RBM motif is flexible, where mutant residues are relatively more mobile than corresponding wild-type residues. Global motion analysis through principal component studies revealed that RBD exhibits protuberant in-ward motion towards the human ACE2 binding interface which may be crucial for molecular interaction. Conclusively, the present finding are in congruence with previous experimental reports and provides detailed information on the structural basis of receptor binding by human SARS-CoV-2, which will crucial for the development of novel inhibitors or drugs to combat against SARS-CoV-2.

(From the second paragraph on page 1)

Coronaviruses are positive-sense single stranded RNA viruses with the largest genome among all RNA viruses, ranging from 26 to 32 Kilobases in length (Malik et al., 2020). The viral genome is packed inside a helical capsid made up of Nucleocapsid protein and further surrounded by an envelope which is formed of three major structural proteins, namely spike protein, small envelope protein, and membrane protein (Li et al., 2020). These four important glycoproteins majorly contribute to the structure of all

coronaviruses and play vital roles in pathogenesis. Particularly, the spike protein mediates coronavirus entry into the host cells by binding to host cell receptor which triggers a cascade of events leading to fusion of both viral and host membranes (Li, 2016). Additionally, the spike protein is a critical determinant of wide host range and viral tissue tropism.

Electron microscopy studies have revealed the three domain (i.e. N-terminal large ectodomain, middle transmembrane domain and C-terminal short intracellular tail) architecture of the spike protein of coronavirus. The ectodomain is comprised of two functional subunits i.e. S1-subunit having a receptor binding domain (RBD) and a membrane-fusion S2-subunit. The spike protein mediates viral genome to enter into host cell by first binding to a host receptor through the RBD domain in the S1 subunit and subsequently fusing the host and viral membranes with the help of the S2 subunit (Li et al., 2005; Liu et al., 2004; Tai et al., 2020). . . . A recent report on the structure of SARS-CoV-2 spike showed that the RBD domain of spike protein binds to the peptidase domain of ACE2 (Wrapp et al., 2020). It has been also observed that host susceptibility to SARS-CoV infection is primarily determined by the affinity between the viral RBD domain of spike protein and the host receptor ACE2, and there are some specific amino acid residues that are potentially involved in the interaction and viral binding (Huentelman et al., 2004; Wan et al., 2020; Zhang et al., 2005).

(From the bottom of the left side on page 2)

The highly conserved receptor binding motif of RBD of SARS CoV-2 is crucial for mediating interactions with host cellular receptor ACE2. However, how mutation in these conserved residues of RBD influence the molecular recognition and the underlying effect of these mutations on the structure, dynamics and interactions with ACE2 is not well understood. Molecular dynamics simulations have been a pivotal approach to investigate mutation-induced changes in protein structure, function and molecular interaction at atomic scale (Dehury et al., 2015, 2017; Pan et al., 2019, Dehury et al., 2014). Using the experimental ACE2-RBD complex (PDB: 6M0J), we combined site-directed computational mutagenesis along with all-atoms molecular dynamics simulation to provide more insights into the structure of the SARS-CoV-2 spike RBD and ACE2 complex. The key non-bonded interactions mediated by RBD of SARS-CoV-2 with ACE2 interactions have been explored comprehensively, and enlightened how

mutation in the receptor binding motif affects the dynamics of recognition. The results from our study provides depth understanding of the stability and flexibility of RBD spike protein binding to host receptor at atomistic level which could be useful for structure-based design of potent drugs or inhibitors to combat novel coronavirus SARS-CoV-2 infection.

Materials and Methods

[System preparation]
In SARS-CoV-2, viral entry mediated by the trimeric spike protein is most important step in its lifecycle and represents an attractive therapeutic intervention point by blocking the virus-cell membrane fusion event or the co-receptor interactions. SARS-CoV-2 and other human coronaviruses have similar infection mechanisms which share the same human ACE2 receptor crucial for viral entry. Therefore, the experimental crystal structure of ACE-RBD complex (PDB ID: 6M0J) was used as the reference structure for our study. ... In this study five mutations were introduced in three conserved and two variable sites of RBD of SARS CoV-2 randomly.

Results and Discussion

[Sequence-structure similarities of RBDs]
. . . Sequence-structure analysis of the residues at the ACE2-RBD interface for SARS-CoV-2 and SARS-CoV were found to be conserved with least variation (Figure 1(A)), and particularly, the hydrophobic residues known to be indispensable for interactions were highly conserved (Lan et al., 2020; Li et al., 2005). The binding site residues responsible for interactions in both the RBDs are labelled in stars (Blue: SARS-CoV and Green: SARS-CoV-2) where majority of the amino acids are either are highly conserved or share similar side chain. The receptor-binding motif (RBM) of RBD prefers to binds to the external surface of the claw-like structure of ACE2 (Figure 1(C)) and share similar side chain properties with those in the SARS-CoV RBD. A number of natural mutations occur near RBM region of RBD spike protein widely termed as ‘hot spots’ as it is mainly responsible for viral-host binding, are presumed to determine the host range of SARS-CoV. In SARS-CoV several amino acids i.e. Asp442, Leu472, Asn479, Asp480, and Thr487 underwent natural selections, which are found to be critical for host receptor recognition, cell entry, and host range of SARS-CoV (Li, 2008; Wu et al., 2012). Therefore, it is crucial to understand how mutation affects the strength of affinity of these complexes which will provide structural basis

mediating SARS-Cov-2 entry into human cells.

Here, based on the experimental structure of ACE2-RBD complex from SARS-CoV-2, the conserved residues of the RBM was mutated to alanine followed by molecular dynamics simulations experiments (Figures 2 and S1) to gauge the stability of ACE2-RBD residual interactions.

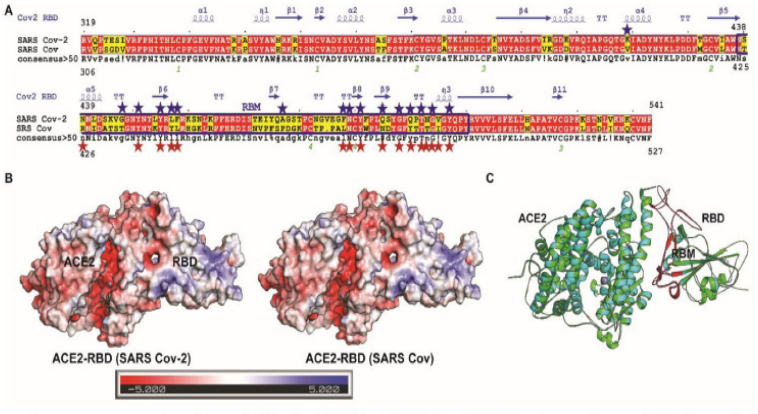


Figure 1. Sequence-structure comparison of receptor binding domain (RBD) from SARS CoV-2 and SARS CoV and structural features of ACE2-RBD complex (6M0J: ACE2-RBD complex of SARS CoV-2 and 2AJF:ACE2-RBD complex of SARS CoV. (A) Pair-wise sequence structure alignment of RBD from of SARS Cov-2 and SARS CoV (B). Electrostatic properties of ACE2-RBD complexes using the experimental structure 6M0J and 2AJF (Blue, red, and white colors represent positively charged, negatively charged, and neutral surfaces, respectively). (C) Structural superimposed view of ACE2-RBD complexes displaying the receptor binding motif marked in pink (green: 6M0J; SARS-CoV-2 and cyan: 2AJF; SARS-CoV).

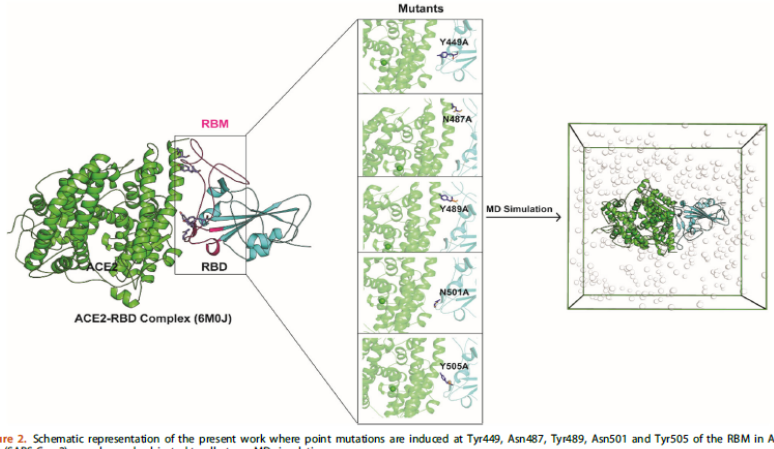


Figure 2. Schematic representation of the present work where point mutations are induced at Tyr449, Asn487, Tyr489, Asn501 and Tyr505 of the RBM in ACE2-RBD (SARS Cov-2) complex and subjected to all-atoms MD simulation.

[Molecular dynamics]

... The Wild type and Y505A system of the ACE2-RBD complex displayed lowest RMSD of 0.25 ± 0.03 nm and 0.25 ± 0.03 respectively, followed by Y449A, N487A, Y489 and N501A mutant systems. Among the mutants systems, N501A displayed higher RMSD of 0.33 ± 0.09 nm as compared to

the other complex systems. Overall most of the systems deviate to a quite similar small extent from their starting structures resulting in a backbone RMSD of $\sim 0.27 \pm 0.05$ nm during 150 ns time scale of molecular dynamics simulations. The above data indicates that all of the systems reached equilibrium after few ns of equilibration. Comparing to the wild type 6M0J complex (solved at 2.45 Å resolution), the Cα-RMSD of representative structure of each systems were found to be 1.87, 1.68, 1.66, 2.66, 1.77 and 2.28 Å respectively for Wild type, Y449A, N487A, Y489A, N501A and Y505A systems indicates that complex systems maintained their structural integrity throughout MD simulation.

[Evolution of secondary structure elements during MD]

To further confirm the stability of the complex systems, we also monitored the changes in secondary structure during MD simulations using DSSP algorithm (Figure S3). . . . [This] signifies that all systems retained the structural integrity and maintain the same fold with minor changes in the RBM of SARS-Cov-2.

[Dynamics of inter-molecular hydrogen bonds]

. . . In wild type system, the hydrogen bonds were found to be maintained during the MD simulations, while, in mutant displayed decline in the H-bonds with least number in N487A, and Y489A systems. A number of crucial bonds are found to be broken during MD simulation of mutant systems, which signifies that replacement of the conserved amino acids with alanine results in unfavourable interaction at the RBD-human ACE2 interface thereby affects the stability of inter-molecular H-bonds.

[Inter-molecular contact analysis]

. . . Our results show that mutation caused a significant decrease in binding interactions for five residues of the interface corresponding to RBM segment. This was corroborated by the binding affinity of the residues with receptor as calculated by PRODIGY, where mutation decreased the binding affinity of the vital residues. . . . Though Y449A system displayed a greater number of non-bonded contacts which may be attributed due to mutations, on the other hand it has lost few crucial H-bonds crucial for stability of the ACE2-RBD complex. Further a previous study by Wan et al. (2020), showed residue N501 in SARS-CoV-2 (corresponding to residue 487 in SARS-CoV) enhances viral binding to receptor ACE2 and plays a vital role

in human to human transmission. We observed the same interaction in the simulated complex also but mutating the residue501 led to loss of favourable interaction which signifies that it has important implications for the pathogenesis, tropism and transmission of SARS-CoV-2.

The complete interaction between wild type and mutant SARS-CoV-2 RBD-ACE2 systems have been illustrated in Figure 8. Though significant difference between the binding affinity for the SARS-CoV2 and SARS-CoV RBD for ACE2 has been observed experimentally, it is unlikely that binding affinity alone explain the unusual transmissibility of SARS-CoV-2. It is noteworthy to mention here that other critical factors including furin cleavage site located that at the S1/S2 periphery of the spike protein also might be playing a crucial role in expediting the swift human-to-human transmission. Moreover, recent studies have also shown that viral entry also depends on TMPRSS2 protease activity and cathepsin B/L activity may be able to substitute for TMPRSS (Sungnak et al., 2020).

Conclusion

Recent studies after the outbreak of COVID-19 have revealed that SARS-CoV-2 is highly homologous to human SARS-CoV (2005) and attributes to the human host cells through the binding of the spike protein to the angiotensin-converting enzyme II (ACE2) (Zhou et al., 2020). However, the molecular mechanisms of recognition and role of conserved amino acids at the RBM of RBD from SARS-CoV-2 binding to human ACE2 are under explored. In this study, we have comprehensively explored the wild type ACE2-RBD complex as well as five randomly selected mutants complexes (located in the conserved and variable sites of RBM of SARS-CoV-2) through all-atoms MD simulations.

Pair-wise sequence-structure alignment and structural superposition of ACE2-RBD complex from SARS-CoV-2 and SARS-CoV portrayed that ACE2 binds in the same fashion to the conserved receptor binding motif and share significant similarity in the side chain conformation, buried surface area of interacting residues, and other number of non-bonded contact networks with minor changes both in and outside the RBM (Fig. 9).

Most of the systems reached equilibrium after 10 to 20 ns of equilibration and maintained their structural integrity like the experimental ACE2-RBD (SARS-CoV-2) complex till 150 ns. The RBM of spike protein of SARS-CoV-2 exhibits high degree of flexibility and most importantly

induced mutations in these regions affects the mobility of RBM towards the ACE2 binding interface.

Principal component analysis suggested that RBD induces an inward motion towards the binding interface of host receptor ACE2, which is speculated to play a crucial role in the molecular recognition process besides other mechanisms behind the molecular interaction. The strength of binding depends on the perfect super-positioning side chains of both the interacting protein pairs at the binding interface mostly driven by the conserved binding residues located at RBM, where mutation tends to affect the binding affinity.

Site-directed mutagenesis and computational binding affinity studies showed that that mutation in the conserved RBM affects the structural-dynamics of the complex, affects the charge distribution and disturbs the inter-molecular non-bonded contacts thereby perturbs the strength of binding to host cell receptor ACE2. Recently a study has pointed out that SARS-CoV-2 may be more stable and can endure at higher temperature than SARS-CoV which points to the bat origin of SARS-CoV-2, as bats possess higher body-temperature as compared to humans (Chin et al., 2020; Qi et al., 2020). Hence, further studies are needed to understand the ACE2-RBD complex interactions at different temperature, which can provide crucial link of its infection ability at different temperature zones across the globe to formulate intervention therapeutic strategies for preventing and controlling SARS-CoV-2 in near future.

Overall, our results have shown encouraging findings in viral-host mediated receptor-interactions which can be very useful of development of novel inhibitors to combat against SARS-CoV-2. We strongly believe that our conclusions provide a suitable starting point for further development in understanding the highly contagious aetiology of SARS-CoV-2 infection in human.

[Appendix 5]

Key Extracts from Prior Art 3

Abstract

A novel severe acute respiratory syndrome (SARS)-like coronavirus (SARS-CoV-2) recently emerged and is rapidly spreading in humans, causing COVID-19. A key to tackling this pandemic is to understand the receptor recognition mechanism of the virus, which regulates its infectivity, pathogenesis and host range. SARS-CoV-2 and SARS-CoV recognize the same receptor—angiotensin-converting enzyme 2 (ACE2)—in humans. Here we determined the crystal structure of the receptor-binding domain (RBD) of the spike protein of SARS-CoV-2 (engineered to facilitate crystallization) in complex with ACE2. In comparison with the SARS-CoV RBD, an ACE2-binding ridge in SARS-CoV-2 RBD has a more compact conformation; moreover, several residue changes in the SARS-CoV-2 RBD stabilize two virus-binding hotspots at the RBD–ACE2 interface. These structural features of SARS-CoV-2 RBD increase its ACE2-binding affinity. Additionally, we show that RaTG13, a bat coronavirus that is closely related to SARS-CoV-2, also uses human ACE2 as its receptor. The differences among SARS-CoV-2, SARS-CoV and RaTG13 in ACE2 recognition shed light on the potential animal-to-human transmission of SARS-CoV-2. This study provides guidance for intervention strategies that target receptor recognition by SARS-CoV-2.

(First paragraph on the left side of page 221) The sudden emergence and rapid spread of SARS-CoV-2 is endangering global health and economy. SARS-CoV-2 has caused many more infections, deaths and economic disruptions than SARS-CoV in 2002–2003. The origin of SARS-CoV-2 remains unclear. Bats are considered the original source of SARS-CoV-2 because a closely related coronavirus, RaTG13, has been isolated from bats. However, the molecular events that led to the possible bat-to-human transmission of SARS-CoV-2 are unknown. Clinically approved vaccines or drugs that specifically target SARS-CoV-2 are also lacking. Receptor recognition by coronaviruses is an important determinant of viral infectivity, pathogenesis and host range. It presents a major target for vaccination and antiviral strategies.

(Third paragraph on the left side of page 221) Because of the sequence

similarity between the spike proteins of SARS-CoV and SARS-CoV-2, it was recently predicted that SARS-CoV-2 also uses ACE2 as its receptor, which has been validated by other studies. Here we determined the structural basis of receptor recognition by SARS-CoV-2 and compared the ACE2-binding affinity among SARS-CoV-2, SARS-CoV and RaTG13. Our findings identify the molecular and structural features of the SARS-CoV-2 RBM that result in tight ACE2 binding. They provide insights into the animal origin of SARS-CoV-2, and can help to guide intervention strategies that target SARS-CoV-2–ACE2 interactions.

(From the second paragraph on the right side of page 222) In comparison to the SARS-CoV RBM–ACE2 interface, subtle yet functionally important structural changes take place near the two virus-binding hotspots at the SARS-CoV-2 RBM–ACE2 interface (Fig. 2a, b). At the SARS-CoV–ACE2 interface, two virus-binding hotspots were previously identified: hotspot Lys31 (that is, hotspot 31) consists of a salt bridge between Lys31 and Glu35, and hotspot Lys353 (that is, hotspot 353) consists of a salt bridge between Lys353 and Asp38. Both salt bridges are weak, as judged by the relatively long distance of these interactions. Burial of these weak salt bridges in hydrophobic environments on virus binding would enhance their energy, owing to a reduction in the dielectric constant. This process is facilitated by interactions between the hotspots and nearby RBD residues. First, at the SARS-CoV RBM–ACE2 interface, hotspot 31 requires support from Tyr442 of the SARS-CoV RBM (Fig. 2b). In comparison, at the SARS-CoV-2 RBM–ACE2 interface, Leu455 of the SARS-CoV-2 RBM (corresponding to Tyr442 of the SARS-CoV RBM) has a less bulky side chain, providing less support to Lys31 of ACE2. As a result, the structure of hotspot 31 has rearranged: the salt bridge between Lys31 and Glu35 breaks apart, and each of the residues forms a hydrogen bond with Gln493 of the SARS-CoV-2 RBM (Fig. 2a). Second, at the SARS-CoV RBM–ACE2 interface, hotspot 353 requires support from the side-chain methyl group of Thr487 of the SARS-CoV RBM, whereas the side-chain hydroxyl group of Thr487 forms a hydrogen bond with the RBM main chain (which fixes the conformation of the Thr487 side chain) (Fig. 2b). In comparison, at the SARS-CoV-2 RBM–ACE2 interface, Asn501 of the SARS-CoV-2 RBM also has its conformation fixed through a hydrogen bond between its side chain and the RBM main chain; correspondingly, its side chain provides less support to hotspot 353 than the corresponding Thr487 of the SARS-CoV RBM does (Fig. 2a). Consequently, Lys353 of ACE2 takes a

slightly different conformation, forming a hydrogen bond with the main chain of the SARS-CoV-2 RBM while maintaining the salt bridge with Asp38 of ACE2 (Fig. 2a). Thus, both hotspots have adjusted to the reduced support from nearby RBD residues, yet still become well-stabilized at the SARS-CoV-2 RBM−ACE2 interface.

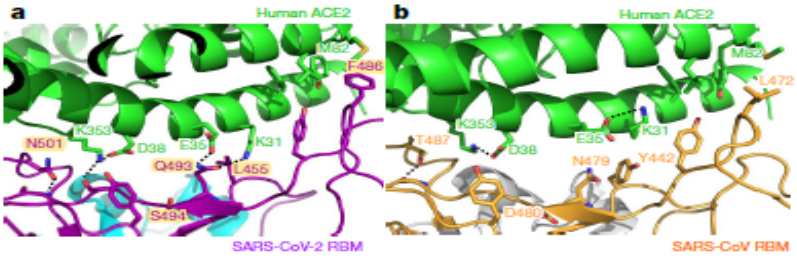


Fig. 2 | Structural details at the interface between the SARS-CoV-2 RBM and ACE2. a, The interface between the SARS-CoV-2 RBM and ACE2. **b**, The interface between SARS-CoV RBM and ACE2.

To corroborate the structural observations, we characterized ACE2-binding affinities of the SARS-CoV-2 spike that contains mutations in critical ACE2-interacting residues. To this end, protein pull-down assays were performed, with purified recombinant ACE2 as the bait and cell-associated SARS-CoV-2 spike as the target (Fig. 3a). For cross-validation, we used ACE2 with two different tags, His6 and Fc. The SARS-CoV-2 spike contained one of the following RBM changes: 481−487 (481-NGVEGFN-487 in SARS-CoV-2 were mutated to TPPALN as in SARS-CoV), Q493N (Gln493 in SARS-CoV-2 was mutated to an asparagine as in human SARS-CoV), Q493Y (Gln493 in SARS-CoV-2 was mutated to a tyrosine as in bat RaTG13) and N501T (Asn501 in SARS-CoV-2 was mutated to a threonine as in human SARS-CoV). The results showed that all of these introduced mutations reduced the ACE2-binding affinity of the SARS-CoV-2 spike. They confirm that the structural features of the SARS-CoV-2 RBM, including the ACE2-binding ridge and the hotspots- stabilizing residues, all contribute to the high ACE2-binding affinity of SARS-CoV-2.

(Second paragraph on the left side of page 224) Finally, this study helps to inform intervention strategies. First, neutralizing monoclonal antibodies that target the SARS-CoV-2 RBM can prevent the virus from binding to ACE2, and are therefore promising antiviral drugs. Our structure has laid out all of the functionally important epitopes in the SARS-CoV-2 RBM that can potentially be targeted by neutralizing antibody drugs. Thus, this study can

help to guide the development and optimization of these antibody drugs. Second, the RBD itself can function as a subunit vaccine. The functionally important epitopes in the SARS-CoV-2 RBM that were identified in this study can guide structure-based design of highly efficacious RBD vaccines. Such a structure-based strategy for subunit vaccine design has previously been developed. This strategy may be helpful in designing SARS-CoV-2 RBD vaccines. Overall, this study can help to inform structure-based intervention strategies that target receptor recognition by SARS-CoV-2.

IP HIGH COURT OF KOREA
FIRST DIVISION
DECISION

Case No.	2022Heo5522 Invalidation (Patent)
Plaintiff	A Co., Ltd. CEO B and C Counsel for Plaintiff Shin & Kim LLC Attorney in Charge Yongho MUN, Hyojin CHA, Chorong JIN, Jinhee LEE Subcounsel for Plaintiff Patent Attorney in Charge Taeyeong LEE
Defendant	D Co., Ltd. Representative Executive Officer E Counsel for Defendant Patent Attorney in Charge Jonghyeok PARK, Hwajin GONG, Jiho PARK
Date of Closing Argument	May 25, 2023
Decision Date	July 6, 2023

ORDER

1. The Plaintiff's claim is dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2021Dang2952, rendered on September 5, 2022, shall be revoked.

OPINION

1. Background

A. Defendant's Patented Invention at Issue (Plaintiff's Exhibit 3)

1) Title of Invention: A Method for Producing Sustained Release Tablets Containing Levodropropizine

2) Application date/ Registration date/ Registration number: February 12, 2019/ April 23, 2021/ No. 2246066

3) Claims (as corrected by the petition for correction dated December 24, 2021, and the underlined parts indicate the claims after correction)[1)]

【Claim 1】 A method of producing sustained-release bilayer tablets containing levodropropizine comprising: a step for producing an immediate-release layer (hereinafter, "IR layer") granules containing levodropropizine, a disintegrant and a lubricant (S1); a step for producing a sustained release layer (hereinafter, "SR layer") granules containing levodropropizine, a release-controlling polymer, a binder and a lubricant (S2); and a step for tableting the IR and SR layers granules to have a hardness ranging from 8 to 15kg/cm² (S3), wherein the amount of levodropropizine contained in the IR layer granules in S1 ranges between 30 and 50mg while the amount contained in the SR layer granules in S2 ranges between 35 and 60mg; the release-controlling polymer in the SR layer granules is at least one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and carbomer, wherein the release-controlling polymer takes up 30 to 60% in the entire weight of SR granules; the ratio in weight between the IR layer granules and the SR layer granules is between 1.5:1 and 2.5:1; the

1) In the said trial, there is no dispute between the parties on the lawfulness of the petition for correction filed on December 24, 2021, and there is no ground to conclude that the above correction is unlawful, and therefore, corrected claims will be judged.

bilayer tablet composed of the IR layer granules and the SR layer granules has a total weight of 250 to 350mg; in S3, the IR layer granules are first transferred into the tablet press and then compressed into the formulation of the IR layer, followed by the transfer of the SR layer granules into the tablet press and then tableting, wherein the turret speed of the tablet press runs at 12 to 28rpm, at the lower main pressure position of 7mm to 12mm. (hereinafter, "Claim 1"; the same shall apply to the remaining claims.)

【Claim 2】 Deleted

【Claim 3, 4】 Deleted by the petition for correction.

【Claim 5】 In Claim 1, a method for producing SR bilayer tablets containing levodropropizine, wherein a disintegrant of the IR layer granules is one or more selected from the group consisting of sodium starch glycolate,[2] croscarmellose sodium, pregelatinized starch, microcrystalline cellulose, and crospovidone.

【Claim 6】 In Claim 1, a method for producing SR bilayer tablets containing levodropropizine, wherein a lubricant is one or more selected from the group consisting of magnesium stearate, colloidal anhydrous silica, talc, and sodium stearyl fumarate.

【Claim 7】 In Claim 1, a method for producing SR bilayer tablets containing levodropropizine, wherein a binder is selected from one or more of the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinyl acetate, copovidone, and ethyl cellulose.

【Claim 8】 to **【Claim 10】** Deleted by the petition for correction.

【Claim 11】 to **【Claim 13】** Deleted

【Claim 14】 An SR bilayer tablet containing levodropropizine prepared by the method of Claim 1, comprising: a disintegrant including one or more selected from the group consisting of sodium starch glycolate,

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2) In Korean, the original term is "전분글리콜산나트륨," which refers to Sodium Starch Glycolate, and the prior art sets force "소듐 스타치 글리콜레이트" in Korean, reflecting the pronounciation of the ingredient.

croscarmellose sodium, pregelatinized starch, microcrystalline cellulose, and crospovidone; a lubricant one or more selected from the group consisting of magnesium stearate, colloidal anhydrous silica, talc, and sodium stearyl fumarate; a binder including one or more selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinyl acetate, copovidone, and ethyl cellulose; and a release-controlling polymer including one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and carbomer.

4) Main Content and Drawing

[1] Technical Field

[0001] This invention relates to a method for producing a sustained-release tablet containing levodropropizine, which comprises a sustained-release layer providing delayed release and an immediate-release layer, each containing levodropropizine.

[2] Background Art

[0008] Levodropropizine formulations now released in the market successfully provide quick initiation of therapeutic effects as they dissolve and absorb immediately upon oral administration. However, there is a growing need for a new sustained-release formulation of levodropropizine that can maintain effective blood concentrations for extended periods, thereby reducing blood concentration fluctuations and related side effects that occur with frequent administration of conventional formulations, improving patient compliance by reducing the number of doses needed to treat patient, and eliminating any inconvenience posed by three-times-daily dosing.

[0012] For a sustained-release formulation of levodropropizine, it is crucial to achieve rapid initial dissolution rates up to a specific time point, and subsequently maintain consistent and effective blood concentrations of the tablet (active ingredient) for an extended period, for up to 12 hours in the form of bilayer, double-layer, or multi-layer tablets (consisting of an immediate-release layer and a sustained-release layer), which can achieve both rapid initial onset of pharmacological activity and prolonged efficacy of the tablets.

[0018] However, in the case of multi-layer tablets including sustained-release tablets consisting of immediate-release and sustained-release layers, they may have reduced physical properties such as higher friability compared to a single-layered formulation, and delamination may occur during their storage and transportation. As a result, there is a need for a novel manufacturing technique for sustained-release bilayer tablets containing levodropropizine that enables mass production and improved stability during distribution, for example, long-term storage and transportation.

3 Problems to be Solved

[0020] This invention relates to a method for producing bilayer tablets, comprising an immediate-release layer containing levodropropizine and a sustained-release layer comprising levodropropizine and a release-controlling polymer, and more particularly, it provides a novel production method for sustained-release bilayer tablets containing levodropropizine with improved stability during the distribution process.

4 Means to Solve the Problem

[0021] To achieve the purpose—according to the present invention—the method for producing a levodropropizine-containing sustained-release bilayer tablet comprises the following steps:

[0022] a step for preparing immediate-release layer granules containing levodropropizine, a disintegrant, and a lubricant (s1);

[0023] a step for preparing sustained-release layer granules containing levodropropizine, a release-controlling polymer, a binder, and a lubricant (s2);

[0024] a step for compressing the sustained-release layer granules and immediate-release layer granules using a tablet press to achieve a hardness of 5 to 18kg/cm² (s3).

[0026] Notably, if the hardness is less than 5kg/cm², it may be impossible to produce a tablet, or a formulation may collapse during storage. Meanwhile, if the hardness exceeds 18kg/cm², dissolution may be delayed, failing to obtain the optimal dissolution profile.

[0028] To produce tablets within the above hardness range, it is preferable to perform tableting at the lower main pressure position ranging from 7 to 12mm. If the lower main pressure position is less than 7mm, this condition results in extremely hard tablets, delaying drug dissolution and thereby limiting the rapid onset of pharmacological activity upon oral

administration. On the other hand, if the position exceeds 12mm, friability increases, thus hampering the stability during storage of the formulation, which is undesirable.

[0030] According to the present invention, the content of levodropropizine in the immediate-release layer granules is preferably 10 to 70mg and more preferably 30 to 50mg. The content of levodropropizine in the sustained-release layer granules is preferably 20 to 80mg and more preferably 35 to 60mg.

[0038] Additionally, the sustained-release layer granules may include a release-controlling polymer that enables the controlled extended release of drugs. The release-controlling polymer may be one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and carbomer.

[0040] The sustained-release layer granules may comprise 30 to 60% by weight of the release-controlling polymer.

[0042] The total weight of the levodropropizine-containing sustained-release bilayer tablet produced by compressing the immediate-release layer granules and sustained-release layer granules, may be 250 to 350mg, and more preferably 270 to 320mg.

[0044] In this tablet, the weight of the immediate-release layer granules is relatively heavier than that of the sustained-release layer granules, and the tablet is characterized by a ratio in weight between the immediate-release layer granules and the sustained-release layer granules ranging between 1.5:1 and 2.5:1.

[0046] Meanwhile, in s3, the turret speed of the tablet press is preferably 12 to 28rpm, more preferably 15 to 25rpm, and most preferably 21 to 25rpm.

[0048] Also, in s3 of producing the bilayer tablet by compressing the immediate-release layer granules and sustained-release layer granules, it is preferable to transfer immediate-release layer granules into the tablet press, forming the initial immediate-release layer and then add the second layer of sustained-release layer granules, compressing on top of the first one, to produce a tablet with two layers, resulting in smooth tablet production.

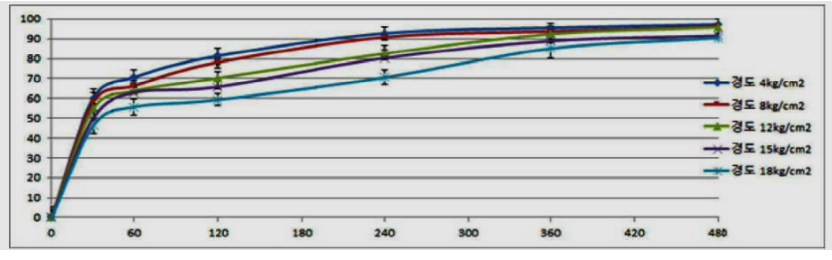
5 Effects of the Invention

[0049] The sustained-release bilayer tablet containing levodropropizine manufactured by the production method in the present invention has excellent resistance to friability and is characterized by high stability when stored in the prescription bottle bundle and then distributed.

6 Brief Description of the Drawings

[0050] Figure 1 shows the hardness and the dissolution rate of a preferred embodiment of a bilayer tablet manufactured by a bilayer tablet press, wherein the sustained-release layer is formed first, followed by the immediate-release layer. Figure 2 shows the hardness and the dissolution rate of a preferred embodiment of a bilayer tablet manufactured by a bilayer tablet press, wherein the immediate-release layer is initially formed, followed by the sustained-release layer.

[Figure 2]



7 Detailed Description of the Invention

[0055] The term "the lower main pressure position" in the specification of the present application refers to the distance between the die into which the raw material is added and the lower punch of the tablet press that performs compression during the main compression for tableting. For example, if "tableting is performed at the lower main pressure position of 5mm," it means that the action occurs when the distance between the die and the lower punch of the tablet press is 5mm. In the present invention, the hardness of the tablet during manufacturing can be controlled by adjusting the lower main pressure position.

[0063] To produce the sustained-release bilayer tablet containing levodropropizine according to the present invention, the immediate-release layer granules and sustained-release layer granules containing levodropropizine are prepared separately. The order of preparing the immediate-release layer granules and sustained-release layer granules is not critical.

[0065] The immediate-release layer granules contain levodropropizine, a disintegrant, and a lubricant; and the content of levodropropizine of the immediate-release layer granules can preferably be 10 to 70mg and more preferably 30 to 50mg.

[0067] Meanwhile, the sustained-release layer granules include levodropropizine, a release-controlling polymer, a binder, and a lubricant, and enable extended

release in a sustained manner due to the release- controlling polymer and other excipients. The active ingredient—levodropropizine—included in the sustained-release layer granules may be equal to or greater than that in the immediate-release layer, specifically from 20 to 80mg.

[0075] In particular, the sustained-release layer granules may include a release-controlling polymer to control sustained drug release. The release-controlling polymer can be one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and carbomer. Among these, using hydroxypropyl methylcellulose and/or Kollidon SR is preferable. Most preferably, hydroxypropyl methylcellulose with a viscosity value of 100,000cps, recognized as high viscosity, is used, which can be replaced with the same amount of Kollidon SR (BASF).

[0077] The most preferred is to include the release-controlling polymer between 30 to 60% by weight of the sustained-release layer granules' total weight. If it is included less than 30% by weight, the tablet will take effect too quickly, resulting in a short-lasting effect if the weight exceeds 60%, the pharmacological effect dramatically decreases within a few hours after oral administration. In conclusion, if the polymer is included in an amount falling outside the above range, it is highly unlikely to have an improved effect compared to those of traditional formulations.

[0080] It is preferable to perform tableting at the lower main pressure position of 7 to 12mm: if the lower main pressure position is less than 7mm, the compression pressure will become too high, which may cause the tablet to fail during manufacturing and contribute to tablet hardening to the extreme, exceeding 18kg/cm², thereby delaying the dissolution of the drug and preventing rapid pharmacological effects. If the lower main pressure position exceeds 12mm, the stability of the tablet is reduced due to an increase in friability and hard to maintain therapeutic drug blood concentration over a prolonged period.

[0082] The compression sequence can either start from the immediate-release layer granules and then the sustained-release layer granules or vice versa. However, tests show that forming the initial layer using the immediate-release layer granules and then adding the sustained-release layer granules and compressing atop the first one to produce a bilayer tablet, resulted in enhanced dissolution rates and therefore preferable.

[0084] The total weight of the sustained-release bilayer tablet containing levodropropizine produced by compressing the immediate-release layer granules and sustained-release layer granules can be 250 to 350mg and

preferably 270 to 320mg. If the weight falls outside this range and is less than 270mg, stability can be hampered; cracks may occur in the tablet during the tableting process, or delamination may occur after the tableting process. Also, if the weight exceeds 350mg, it not only negatively affects the dissolution rate but also results in tablets large in size, lowering the convenience of taking the medication.

[0086] In this tablet, the weight of the immediate-release layer granules is relatively heavier than that of the sustained-release layer granules and the preferred ratio in weight between the immediate-release layer granules and the sustained-release layer granules is preferably between 1.5:1 and 2.5:1. This ratio is the optimal ratio in weight considering the tabletability and dissolution characteristics of the tablet. If it falls outside this ratio, cracks may occur in the tablet, or it may show poor dissolution characteristics after the tablet production.

[0088] Meanwhile, in s3, the turret speed of the tablet press is preferably 12 to 28rpm, and more preferably 15 to 25rpm, and most preferably 21 to 25rpm. If the turret speed exceeds 25rpm, the granules of the tablet may not be sufficiently filled into the tablet press, which may reduce the hardness, increase friability, and lower the uniformity of formulations, which is inappropriate. In contrast, if the turret speed is less than 12rpm, the speed of the production process slows down, thereby failing to achieve production efficiency.

[0091] Regarding the above-producing method, the hardness of the sustained-release bilayer tablet containing levodropropizine can be 5 to 18kg/cm² and more preferably 8 to 15kg/cm². If the hardness is below this range, the stability during storage and transportation decreases. If the hardness exceeds this range, dissolution can become inconsistent, reducing the pharmacological effect. Specifically, if the hardness is too low, for example, less than 5kg/cm², the tablet may not form at all or may easily crumble, and friability may become unacceptable. On the other hand, if the hardness is too high, for instance, exceeding 18kg/cm², the dissolution of the tablet slows down, resulting in a dissolution rate outside the optimal range, thereby failing to meet the target dissolution acceptance criteria.

[0095] Preparation of immediate-release layer granules and sustained-release layer granules.

First, immediate-release layer granules and sustained-release layer granules were prepared according to the composition of the present invention. The detailed composition is shown in Table 1 below.

[0099]

[Table 1]

Classification	Application	Element	Content (mg)
Sustained-release layer granules	Active ingredient	Levodropropizine	45.0
	Excipient	Microcrystalline cellulose	6.8
	Release-controlling polymer	HPMC 2208 (Viscosity 100,000cps)	50.0
	Binder	PVP K-90	2.7
	Lubricant	Magnesium stearate	1.7
Immediate-release layer granules	Active ingredient	Levodropropizine	45.0
	Excipient	Lactose monohydrate	67.0
	Excipient	Microcrystalline cellulose	67.0
	Disintegrant	Sodium Starch Glycolate	7.5
	Lubricant	Magnesium stearate	1.9
Total weight	-	-	294.6

[0105] According to Comparable Embodiments 4 and 5 that show acceptable friability, six tablets were produced from each and were tested for dissolution, using 900mL of water as a dissolution medium. Applying the dissolution test method 2 of the general tests in the Korean Pharmacopoeia, a sinker at 50rpm was used and the dissolution test results are shown in Table 3 below.

[0107]

[Table 3]

Time(min)	Comparable Embodiment 4		Comparable Embodiment 5	
	Dissolution rate(%)	Deviation	Dissolution rate(%)	Deviation
0	0	0	0	0
30	45.7	1.9	42.8	2.7
60	55.3	3.2	53.9	2.5
120	59.6	3.3	58.7	4.6
240	80.3	5.2	75.8	1.8
360	90.6	4.1	84.3	3.7
480	93.1	3.9	90.1	2.5
Evaluation	Unacceptable		Unacceptable	

[0110] Formulation tests according to the sequence of tableting (forming the immediate-release layer first and then the sustained-release layer)

[0112] Next, the immediate-release layer granules, prepared according to the composition in Table 1, were transferred and compressed in the bilayer

tablet press. Then, the sustained-release layer granules were added and compressed on top of the first layer to produce a bilayer tablet. As shown in Table 4 below, all tablets were produced at different lower main pressure positions, and their hardness and friability were measured. (Tablet friability was considered acceptable if it was 1% or less after 40 test tablets were rolled 100 times.

[0114]

[Table 4]

Classification	Lower Main Pressure Position(mm)	Hardness(kg/cm^2)	Friability
Comparative Embodiment 6	13.26	4	Unacceptable
Embodiment 1	11.26	8	Acceptable
Embodiment 2	9.26	12	Acceptable
Embodiment 3	7.26	15	Acceptable
Comparative Embodiment 7	5.26	18	Acceptable

[0115] According to Embodiments 1 to 3 and Comparable Embodiment 7 showing acceptable friability, six tablets were produced from each and were tested for dissolution, using 900mL of water as a dissolution medium. Applying the dissolution test method 2 of the general tests in the Korean Pharmacopoeia, a sinker at 50rpm was used and the dissolution test results are shown in Table 5 below.

[0117]

[Table 5]

Time (min)	Embodiment 1		Embodiment 2		Embodiment 3		Comparative Embodiment 7	
	Dissolution rate(%)	Deviation	Dissolution rate(%)	Deviation	Dissolution rate(%)	Deviation	Dissolution rate(%)	Deviation
0	0	0	0	0	0	0	0	0
30	58.4	4.4	54.9	3.7	50.1	1.8	46.3	2.3
60	66.3	2.3	63.7	2.5	62.9	3.1	55.7	3.9
120	78.1	3.1	70.2	1.9	65.8	3.6	59.3	4.1
240	90.8	1.5	82.5	3.3	80.3	2.8	70.5	2.9
360	93.7	2.6	92.4	4.2	88.9	4.1	85.1	3.6
480	96.1	3.6	95.7	2.7	91.5	1.9	90.4	4.8
Evaluation	Acceptable		Acceptable		Acceptable		Unacceptable	

[0120] Formulation tests at a different turret speed.

[0123] Based on the test results of Embodiments 1 to 3, friability and content uniformity of tablets were tested by varying turret speeds of the tablet press at the lower main pressure position of 9.26mm, where the best effect was shown. As shown in Table 6 below, the immediate-release layer was formed first within the turret speed ranging from 15 to 35rpm and then the sustained-release layer granules were added and formulated into the bilayer tablet. The produced tablets were tested for friability and content uniformity.

[0125]

[Table 6]

Classification	Turret speed (rpm)	Friability	Formulation Uniformity Test
Embodiment 4	15	Acceptable	Acceptable
Embodiment 2	21	Acceptable	Acceptable (Excellent)
Embodiment 5	25	Acceptable	Acceptable (Excellent)
Comparative Embodiment 8	31	Acceptable	Unacceptable
Comparative Embodiment 9	35	Unacceptable	-

[0126] As shown in Table 6 above, Embodiments 2, 4, and 5 with turret speeds of 15 to 25rpm showed acceptable friability and high content uniformity. In particular, Embodiments 2 and 5 with turret speeds of 21 to 25rpm showed even higher content uniformity.

B. Prior Art (Plaintiff's Exhibit 5)

Prior Art, disclosed in the Public Patent Gazette No.1811700 on December 22, 2017, relates to "The Sustained-release Tablet Containing Levodropropizine, Comprising the Immediate-release Layer Including Levodropropizine and the Sustained-release Layer Including Levodropropizine and the Release-controlling Polymer and Its Producing Method Thereof" and its main contents are summarized as follows.

1 Problem to be Solved

[0010] Therefore, the purpose of the present invention is to provide a sustained-release tablet containing levodropropizine, characterized by a multilayer tablet comprising an immediate-release layer and a sustained-release layer, both containing levodropropizine as the active ingredient. This formulation allows 60 mg of levodropropizine to be administered twice daily instead of three times daily, and, most importantly, enables the rapid attainment and maintenance of therapeutic plasma drug concentration from the early stage after administration, thereby improving therapeutic efficacy and enhancing patient convenience and compliance by simplifying the dosing regimen.

2 Means to Solve the Problem

[0011] To achieve the above objective, the present invention provides a sustained-release tablet containing levodropropizine, consisting of an immediate-release layer containing levodropropizine and a sustained-release layer containing levodropropizine together with a release-controlling polymer.

3 Effects of the Invention

[0012] The sustained-release tablet of levodropropizine, consisting of the immediate-release layer and the sustained-release layer according to the present invention, is advantageous in that it not only provides an immediate antitussive and expectorant effect when administered orally but also maintains a constant plasma drug concentration for a considerable time, thereby reducing the frequency of administration and leading to improved patient compliance.

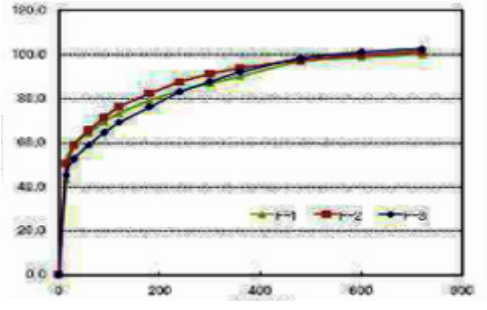
4 Brief Description of Drawings

[0014] Figure 1 shows the dissolution test results of the immediate- release layer containing levodropropizine according to the present invention. Figure 2 shows the dissolution test results of the sustained-release layer containing levodropropizine according to the present invention. Figure 3 shows the dissolution test results of the sustained-release characteristics of levodropropizine according to the present invention. Figures 4 and 5 show the comparative dissolution test results of the sustained-release tablet containing levodropropizine of the present invention and a comparative formulation.

[Figure 3]

Comparative dissolution test of levodropropizine (Final)

Dissolution rate (%)

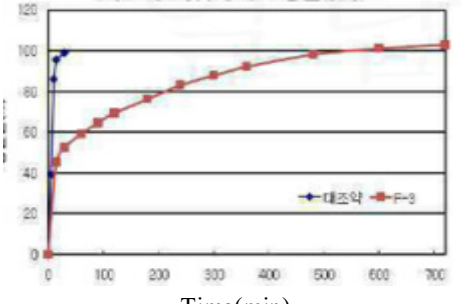


Time(min)

[Figure 4]

Comparative dissolution test of Reference formulation-Test formulation(%)

Dissolution rate (%)

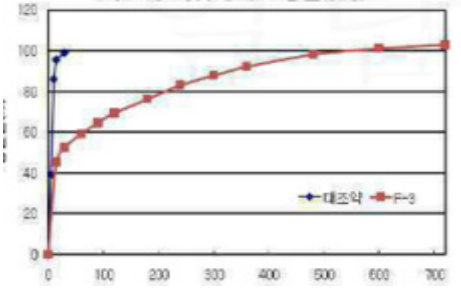


Time(min)

[Figure 5]

Comparative dissolution test of Reference formulation-Test formulation(%)

Release(mg)



Time(min)

5 Detailed Description for Implementing the Invention

[0016] The present invention provides a sustained-release tablet of levodropropizine consisting of the immediate-release layer containing levodropropizine and the sustained-release layer containing levodropropizine and a release-controlling polymer.

[0018] According to a preferred embodiment of the present invention, the immediate-release layer contains 10 to 70mg of levodropropizine, and the sustained-release layer contains 20 to 80mg. More preferably, the immediate-release layer contains 30 to 60 mg, and the sustained-release layer contains 30 to 60 mg.

[0020] The sustained-release layer of the sustained-release tablet containing levodropropizine of the present invention includes a release-controlling polymer. Any pharmaceutically acceptable polymer can be used as a release-controlling polymer and may be one or more selected from the group consisting of cellulose derivatives including hydroxypropyl methylcellulose, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose; propylene oxide and its derivatives; polymers including polyvinylpyrrolidone (the molecular weight is 90, and the trade name is Povidone K-90), polyethylene glycol, polyvinyl alcohol, polyvinyl acetate, polyvinyl acetate phthalate, polymethacrylate, and polymethacrylate (commercially referred to as Eudragit); derivatives of polyacrylic acid and polymethacrylate (prime example is carbomer); and glycerol monostearate and poloxamer. Preferably, one or more selected from the group consisting of hydroxypropyl methylcellulose, carbomer, hydroxypropyl cellulose, methylcellulose, polyvinylpyrrolidone, and polyvinyl alcohol can be used.

[0021] According to a preferred embodiment of the present invention, the content of a release-controlling polymer included in the sustained- release tablet containing levodropropizine is 10 to 80% by weight, based on the total weight of the sustained-release tablet containing levodropropizine. More preferably, the content of the release-controlling polymer is 10 to 60% by weight.

[0026] The immediate-release layer and the sustained-release layer of the sustained-release tablet containing levodropropizine of the present invention may include various excipients used in pharmaceutical compositions in the tablet manufacturing in addition to levodropropizine and a release-controlling polymer, respectively. For instance, it may additionally include one or more excipients selected from the group consisting of disintegrants, lubricants, water-soluble additives, fast-acting excipients, fillers, and binders commonly used to manufacture pharmaceutical compositions.

[0030] The weight of the disintegrant may range from 10 to 60% of the total weight of the immediate-release layer or the sustained-release layer.

[0040] Also, this invention provides a method for producing a sustained -release tablet of levodropropizine, comprising: a) a step of preparing dry or wet granulation for sustained-release formulation, by mixing levodropropizine, a release-controlling polymer, and additives; and

[0041] b) a step of mixing a lubricant with the sustained-release granules of step a) and with a mixture containing levodropropizine, respectively, and then compressing.

[0045] As a representative example, when manufacturing a bilayer tablet of levodropropizine with an immediate-release layer and a sustained- release layer, the sustained-release layer may be compressed first, followed by the immediate-release layer. Alternatively, the immediate- release layer may be compressed first, with the sustained-release layer added and compressed thereafter. It is also possible to load both layers in either order and compress them simultaneously.

[0064] 2) Formulation development of the immediate-release layer

[0065] <Method for testing>

[0066] Optimized formulation of the immediate-release layer was developed through various testing—fluidity testing, hardness testing, friability testing, disintegration testing, and dissolution testing—using the compressed mixture of levodropropizine and each excipient as shown in Table 2 below.

[0068] Friability: 1% or less after 40 test tablets were rolled 100 times

[0069] Fluidity: Angle of repose below 40°

[0070] Hardness: 4-5kg/cm²

[0071] Disintegration: Visually confirmed; all 6 samples disintegrated within 5 minutes

[0072] Dissolution: 80% within 30minutes.

[Table 2 (Partially Excerpted)]

Formulation 14a	Levodropropizine (45mg) Flowlac (67mg) MCC pH102 (67mg) Sodium Starch Glycolate (10mg) Magnesium stearate (1.9mg)	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

[0081] 3) Formulation development of the sustained-release layer

[0082] <Method of testing>

[0083] Optimized formulation of the sustained-release layer is developed through various testing—fluidity testing, hardness testing, and dissolution testing with a bilayer tablet consisting of the immediate-release layer mixed as formulation 14a and the sustained-release layer prepared by wet granulation as shown in Table 3 below.

[0085] Fluidity: Angle of repose below 40°

[0086] Hardness: 4-5kg/cm²

[0087] Dissolution: at 30min: 40~60%; at 180min: 60~80%; at 720min: over 85%

[0089]

[Table 3 (Partially Excerpted)]

Formu lation 19b	Levodropropizine (45mg) Flowlac (67mg) MCC pH102 (67mg) Sodium Starch Glycolate (10mg) Magnesium stearate (1.9mg)	Levodropropizine (45mg) MCC pH101 (7mg) PVP K-90 (3mg) HPMC2208(100,000 cps) (50mg) Magnesium stearate (1.7mg)	Acceptable	Acceptable	Acceptable

[0095] 4) Final formulation development

[0097] Through the above tests, the immediate-release layer was identified as formulation 14a, and the sustained-release layer as formulation 19b. However, since formulation 19b was close to both the upper and lower limits of the dissolution criteria, the final formulation was prepared with excipients as shown in Table 4 below, followed by dissolution testing.

[Table 4]

	Final Formulation	Embodiment 1	Embodiment 2	Embodiment 3
Sustained-release layer	Levodropropizine	45.0	45.0	45.0
	*MCC 101	7.0	6.8	6.8
	*HPMC 2208	50.0	50.0	50.0
	*PVP K-90	3.0	2.7	2.7
	*s-Mg	1.7	1.7	1.7
	Final weight(mg)	106.7	106.2	106.2
Immediate-release layer	Levodropropizine	45.0	45.0	45.0
	Flowlac	67.0	67.0	67.0
	MCC pH102	67.0	67.0	67.0

	Final Formulation	Embodiment 1	Embodiment 2	Embodiment 3
	Sodium Starch Glycolate	10.0	10.0	7.5
	s-Mg	1.9	1.9	1.9
	Final weight(mg)	190.9	190.9	188.4
Total weight (mg)		297.6	297.1	294.6

[0105] As shown in Figure 3, according to the dissolution testing results, the optimal formulation that meets the dissolution criteria is that of <Embodiment 3> as shown in Table 4.

[0107] 2. Non-linical Study: Pharmacokinetic evaluation following a single oral administration in beagle dogs

[0108] Dropizin tablets from Kolon Pharmaceutical Co., Ltd. were used as the comparator, and "UI04LDP090CT"—the formulation of <Embodiment 3>—from Pharmaceutical A Co., Ltd. was used as the test formulation. Beagle dogs received oral administration of three tablets of the comparator and two tablets of the test formulation repeatedly for 24 hours. The concentration of levodropropizine in the blood over time after oral administration is shown in Figure 6.

[0109] The average AUCt of the two groups of the comparator Dropizin group and the test formulation UI04LDP090CT group recorded 5318.39 and 5722.13hr*ng/mL, respectively, Cmax recorded 1205.72 and 1295.53ng/mL, respectively, Tmax recorded 1.08 and 0.83hr, respectively, and t1/2 was 2.43 and 1.89hr, respectively.

[0110] When calculating the ratio of the test formulation group to the comparator group from the above values, AUCt was 92.9% and Cmax was 93.1%, indicating that the change in dosage from the difference in content between the test formulation and the comparator had little influence in AUCt and Cmax. Due to the characteristics of the formulation, the initial blood concentration was higher in the comparator group than in the test formulation group during the first 1.5 hours after administration, but thereafter, the test formulation group maintained higher levels compared to the comparator group. Therefore, it was confirmed that the test formulation, which is a sustained-release formulation, also shows a sustained-release effect in vivo.

6 Claims

Claim 1. A sustained-release bilayer tablet of levodropropizine, consisting

of an immediate-release layer containing levodropropizine and a sustained-release layer containing levodropropizine and a release-controlling polymer, characterized in that sustained-release layer includes 45.0mg of levodropropizine, 6.8mg of microcrystalline cellulose (MCC), 50.0mg of hydroxypropyl methylcellulose (HPMC) with a viscosity of 100,000cps, 2.7mg of polyvinylpyrrolidone (PVP), and 1.7mg of magnesium stearate (s-Mg) and the immediate-release layer includes 45.0mg of levodropropizine, 67.0mg of lactose, 67.0mg of microcrystalline cellulose (MCC), 7.5mg of sodium starch glycolate, and 1.9mg of magnesium stearate (s-Mg).

C. Procedural History

1) On October 1, 2021, the Defendant filed a petition for invalidation of the patented invention (hereinafter, the "subject invention") before the Intellectual Property Trial and Appeal Board (IPTAB), against the Plaintiff, asserting that the subject invention should be invalidated for lack of inventive step in view of prior art (Case No. 2021Dang2952). On December 24, 2021, the Plaintiff filed a petition for correction of the claims of the subject invention during the trial proceedings.

2) On September 5, 2022, the IPTAB upheld the petition for correction and rendered its decision granting the Defendant's petition for an invalidation trial on the ground of lack of inventive step in view of prior art (hereinafter, the "IPTAB Decision").

【Factual basis】 Based on the undisputed facts, the statements in Plaintiff's Exhibits 1 to 5, and the purport of the entire pleadings.

2. Summary of Plaintiff's Arguments

A. Plaintiff

1) The meaning of "the lower main pressure position" is clearly defined in the specification of the subject invention, and thus the subject invention does not violate the definiteness requirement.

2) The subject invention is supported by the description of the invention, as the content corresponding to the claims is described in the detailed description.

3) The description of the subject invention is sufficiently detailed in such a manner that a person skilled in the art (hereinafter, a "skilled person") can readily carry out the invention.

4) For the following reasons, the inventive step of Claim 1 is not denied by the combination of the prior art and well-known or commonly used art. Given that the inventive step of Claim 1 is not denied, the inventive step of Dependent Claims 5, 6, 7, and 14 is likewise not denied.

a) Claim 1 and the prior art address different technical problems to be solved.

b) Elements 1 and 2 define the dose range of levodropropizine and the weight ratio of a release-controlling polymer that enables mass production while ensuring stability. In contrast, since the corresponding elements in the prior art merely disclose specific compositions, the elements in the subject invention and those in the prior art are not identical.

c) The prior art does not disclose the hardness, the compression sequence, the lower main pressure position, the turret speed, or their organic combination as recited in Claim 1.

d) Claim 1 produces significant effects that could not have been predicted by a skilled person.

B. Defendant

The subject invention has the following grounds for nullity; therefore, the IPTAB Decision reaching the same conclusion shall be upheld.

1) The meaning of "the lower main pressure position of 7 to 12mm" included in the claims of the subject invention is not clearly

described.

2) Regarding "the lower main pressure position," the type of tablet press, the composition of the filling materials, the upper main pressure position, the volume or shape of the die, or the amount of granules filled in the die are not clearly detailed in the specification of the subject invention in such manner that a skilled person cannot easily execute the invention.

3) The subject invention is not supported by the description of the invention as the specification does not specify the type of a tablet press, the composition of the filling materials, the upper main pressure position, and the volume or shape of the die, etc.

4) Claim 1 and the prior art differ only in the tablet hardness, the lower main pressure position, and the turret speed. However, the inventive step of Claim 1 is denied by the combination of the prior art and well-known or commonly used art as the act of adjusting the lower main pressure position and the turret speed properly to obtain the optimal tablet hardness is considered as well-known or commonly used art.

5) The elements added as limitations additionally specified in Claims 5, 6, 7, and 14 are denied inventive step by the combination of the prior art and well-known or commonly used art.

3. Whether the IPTAB Erred

A. Whether "the lower main pressure position" in the claims violates the requirement of definiteness

Article 42(4)(ii) of the Patent Act stipulates that the invention shall be clearly and concisely described in claims. Also, Article 97 of the same Act stipulates that the scope of protection of a patented invention shall be determined by the descriptions of the claims. Therefore, in

principle, claims shall be stated clearly, and ambiguous terms stating the constitution of the invention shall not be allowed. (Supreme Court Decision 2003Hu2072, decided November 24, 2006; Supreme Court Decision 2012Hu1613, decided July 24, 2014, etc.) In addition, in determining whether a patent is written sufficiently clear, a judge or an examiner is not to uniformly make a judgment based only on the terms used in the claims but rather to make individual judgment by examining whether a skilled person can clearly understand the invention that is sought to be patented for the features described in the claims, taking the detailed explanation of the invention, drawings, and technological common sense at the time of the application into account. (Supreme Court Decision 2014Hu1563, decided April 7, 2017)

As seen below, the specification (i.e. detailed description of the invention) of the subject invention states that "the lower main pressure position" means "the distance between the die of a tablet press, into which the granules are fed, and the lower punch of the tablet press that applies pressure when providing main pressure for tablet compression" and presents examples. (Identification Number [0055])

The Specification of the Subject Invention (Plaintiff's Exhibit 2)
Throughout this specification, the term "the lower main pressure position" refers to the distance between the die of a tablet press into which the granules are fed and the lower punch of the tablet press that applies pressure when providing main pressure for tablet compression. For example, in the case of "performing compression at the lower main pressure position of 5mm," it means that compression is provided when the distance between the die and the lower punch of the tablet press is 5mm. In the present invention, it is possible to control the hardness of a tablet during compression by adjusting the lower main pressure position.

It appears that a skilled person could easily understand the specific meaning of "the lower main pressure position" in the claims of Claim 1, based on technological common sense in the pharmaceutical field and the contents defined in the specification of the subject invention.

Therefore, the claims of Claim 1 are deemed to be clearly defined.

Hence, the Plaintiff's arguments in this regard are without merit.

B. Whether Claim 1 lacks an inventive step

1) Legal principle

In the case of a patented invention where the scope of the elements is defined by specific numerical values for an invention already known to public at the time of filing, if the difference lies only in the numerical limitation while the purpose and effects of the patented invention are consistent with those of the prior art, and the limited numerical range does not produce any substantial difference in effect, the patented invention lacks an inventive step, since it is merely a numerical limitation that a person skilled in the art could readily conceive through routine and repeated experimentation. However, the inventive step of a patented invention shall not be denied merely because the numerical limitation itself lacks critical significance, if the invention includes another additional element from which inventiveness can be recognized and the numerical limitation is merely supplementary; or even when the elements other than the numerical limitation are identical to those of the prior art, if the numerical limitation has significance as a technical means for solving the problem to be addressed, distinct from the prior art, and produces qualitatively different effects. (Supreme Court Decision 2008Hu4998, decided August 19, 2010). Also, unless there are special circumstances, it is difficult to recognize that a numerical range produces a qualitatively different effect if the patented invention addresses the same problem as the prior art and differs only in the numerical limitation, and if the specification does not describe any significant effect resulting from adopting such numerical limitation. (Supreme Court Decision 2007Hu1299, decided November 16, 2007; Supreme Court Decisions 2012Hu238 and 2012Hu245, decided May 16, 2014).

2) Comparison of elements

Element	Claim 1 (Plaintiff's Exhibit 2)	Prior art (Plaintiff's Exhibit 5)
1	A step for preparing the immediate-release layer ("IR layer") granules containing levodropropizine, a disintegrant, and a lubricant (s1); wherein the amount of levodropropizine contained in the IR layer granules therein ranges between 30 to 50mg.	Prepares the immediate-release layer ("IR layer") granules containing levodropropizine, sodium starch glycolate, and magnesium stearate (Identification Number [0064] to [0079], Embodiment 3 in Table 4). The levodropropizine content of the IR layer granules is 45.0mg (Embodiment 3 in Table 4).
2	A step for preparing the sustained-release layer ("SR layer") granules containing levodropropizine, a release-controlling polymer, a binder and a lubricant (s2); wherein the amount of levodropropizine contained in the SR layer granules of s2 is 35mg to 60mg; the release-controlling polymer of the SR layer granules is one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and carbomer; and the release- controlling polymer is included 30 to 60% by weight of the total weight of SR granules.	Prepares the sustained-release layer ("SR layer") granules containing levodropropizine and hydroxypropyl methylcellulose (HPMC), polyvinylpyrrolidone (PVP), and magnesium stearate (Identification Number [0082] to [0093] and Embodiment 3 in Table 4). The levodropropizine content of the SR layer granules is 45.0mg, the hydroxypropyl methylcellulose content is 50.0mg, and the total weight of the SR layer is 106.2mg (Embodiment 3 in Table 4).
3	A step for compressing the IR layer and SR layer granules to have a hardness ranging	Produces a bilayer tablet with the IR layer and the SR layer (Identification Number [0083]).

Element	Claim 1 (Plaintiff's Exhibit 2)	Prior art (Plaintiff's Exhibit 5)
	from 8 to 15kg/cm² (s3); wherein the IR layer granules are transferred into the tablet press first to form the IR layer, and the SR layer granules are then added to the tablet press and then compressed, wherein the turret speed of the tablet press runs at 12 to 28rpm, at the lower main pressure position of 7 to 12mm.	The hardness criterion for a bilayer tablet is 4-5kg/cm² (Identification Number [0086]). As a representative example of the present invention, if a bilayer tablet containing levodropropizine consisting of the IR layer and the SR layer is produced, a multi-layer tablet can be made by compressing the SR layer first and then adding and compressing the second SR layer on top of the first one. At this time, it is not necessary to compress the SR layer before the IR layer. It is also possible to compress the IR layer first and then add and compress the granules of the SR layer atop the first one. It is also possible to transfer the IR layer and the SR layer in either sequential or reverse order and then compress them together at once. (Identification Number [0045]).
4	The ratio in weight between the IR layer granules and the SR layer granules is between 1.5:1 and 2.5:1, and the bilayer tablet consisting of the IR layer granules and the SR layer granules has a total weight of 250 to 350mg.	The weight of the IR layer granules is 188.4mg, and that of the SR layer granules is 106.2mg, and the total weight of the bilayer tablet consisting of the IR layer granules and the SR layer granules is 294.6mg (Embodiment 3 in Table 4).
5	A method of producing SR bilayer tablets containing levodropropizine.	A method of producing SR bilayer tablets containing levodropropizine.

3) Commonalities and differences

a) Element 1

Element 1 is a step for preparing the IR layer granules containing levodropropizine, a disintegrant, and a lubricant, wherein the content of levodropropizine is limited to 30 to 50mg. The corresponding element of the prior art is the IR layer containing levodropropizine, sodium starch glycolate, and magnesium stearate, wherein the content of levodropropizine is 45.0mg.

It is obvious to a skilled person that sodium starch glycolate is used as a disintegrant and magnesium stearate as a lubricant. Although Element 1 uses specific numerical values to express the content of levodropropizine, the specification of the subject invention does not describe significant effects resulting from adopting the limited numerical values, and thus any special effect or critical significance due to the numerical limitation cannot be recognized. Hence, both elements can be deemed to be substantially the same.

b) Element 2

Element 2 is a step for preparing the SR layer granules containing levodropropizine, a release-controlling polymer, a binder, and a lubricant, wherein the content of levodropropizine in the SR layer granules is limited to 35 to 60mg, and the release-controlling polymer is one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and carbomer, and is limited to 30 to 60% by weight relative to the total weight of the SR layer granules. The corresponding element of the prior art is the SR layer containing levodropropizine, hydroxypropyl methylcellulose, polyvinylpyrrolidone, and magnesium stearate, wherein the content of levodropropizine is 45.0mg, that of hydroxypropyl methylcellulose is 50.0mg, and the total weight of the SR layer is 106.2mg.}

It is obvious to a skilled person that hydroxypropyl methylcellulose is used as a release-controlling polymer, polyvinylpyrrolidone as a binder, and magnesium stearate as a lubricant. The weight ratio of the

release-controlling polymer disclosed in the corresponding element of the prior art to the total weight of the SR layer is approximately 47% by weight (=50.0mg hydroxypropyl methylcellulose/ the total weight of the SR layer of 106.2mg) (Embodiment 3 in Table 4 from Plaintiff's Exhibit 5). Although Element 2 uses specific numerical values to express the content of levodropropizine and the weight ratio of the release-controlling polymer, the specification of the subject invention does not describe significant effects resulting from adopting the numerical limitations, and thus no special effect or critical significance can be acknowledged. Therefore, the compositions of both elements can be regarded as substantially the same.

In response, the Plaintiff argues that corresponding elements of Claim 1 and the prior art are different in that Claim 1 presents a range of weight ratios in which each combined element organically affects the physical properties of the bilayer tablet—enabling mass production, securing stability during storage and distribution, and providing optimal compression and dissolution characteristics, while the prior art merely discloses a specific composition of the SR bilayer tablets containing levodropropizine. The prior art states that "the specific composition (Embodiment 3 in Table 4) is the most appropriate for the dissolution criteria," and includes the results of comparison with a reference material and a commercially available formulation in its specification. (Identification Numbers [0105], [0107], [0108], [0112], [0113] of Plaintiff's Exhibit 5). Meanwhile, the specification of the subject invention does not include a description of the technological meaning or critical significance of the numerical limitation. Therefore, it is reasonable to deem that each weight ratio is substantially the same as long as the specific weight ratio disclosed in the prior art is in the limited numerical range of weight ratios of the subject invention. In this regard, the Plaintiff's argument is without merit.

c) Element 3

Element 3 and the prior art are different in that Element 3 specifies

the sequence of tableting—compressing the IR layer granules first and then the SR layer granules are added and compressed, while the prior art does not specify the sequence of tableting, as shown in "a step of compressing the SR layer first followed by the compression of the IR layer or in the reverse order". (hereinafter, **"Difference 1"**). Also, Element 3 limits the hardness of the tablet to 8 to 15kg/㎠, the turret speed of the tablet press to 12 to 28rpm, and the lower main pressure position to 7 to 12mm while the prior art merely discloses the hardness of the tablet to be 4~5kg/㎠ but does not include the turret speed and the lower main pressure position. (hereinafter, the differences related to the hardness as **"Difference 2,"** the differences related to the turret speed as **"Difference 3,"** and the difference related to the lower main pressure position are **"Difference 4"**).

d) Element 4

Element 4 limits the ratio in weight between the IR layer granules and the SR layer granules of the bilayer tablet to be between 1.5:1 and 2.5:1, and its total weight to be 250 to 350mg. The corresponding element of the prior art limits the total weight of the IR layer to be 188.4mg, that of the SR layer to be 106.2mg, and that of the bilayer tablet to be 294.6mg, resulting in a ratio in weight between the IR layer and the SR layer comprised approximately 1.8:1 (=188.4mg:106.2mg). Although Element 1 uses numerical values to express the content of levodropropizine, the subject invention does not describe a substantial difference in its specification after adopting the limited numerical values, and thus it is hard to recognize special effects or critical significance within the boundary of the numerical limitation. Therefore, the compositions of both elements can be deemed as substantially the same.

e) Element 5

Element 5 and the corresponding element of the prior art are identical in that both relate to a "method for producing SR bilayer tablets containing levodropropizine."

4) Analysis of differences

a) Difference 1

It would be reasonable to decide that a skilled person could easily overcome Difference 1 based on the prior art in light of the following reasons:

① There are only the following cases in the tableting sequence of an SR bilayer tablet; transferring the IR layer granules and then the SR layer granules in sequence or in reverse order followed by simultaneous compression of both granules; or compressing twice in the order of the IR layer granules and the SR layer granules; or compressing twice in reverse order. Therefore, it can be deemed that a skilled person would not have difficulty in selecting an appropriate tableting sequence.

② The specification of the subject invention describes that "at this time, the tableting sequence can either start from the IR layer granules or the SR layer granules, but the test results show that it was preferable to compress the IR layer granules first and then add the SR layer granules and compress atop the first one to produce a bilayer tablet, which led to a better dissolution rate." (Identification Number [0082] of Plaintiff's Exhibit 2) According to the above statement, it does not appear that the subject invention endows the limitation of the tableting sequence with andy special technical significance.

③ Regarding this, the Plaintiff argues that the tableting sequence of Claim 1 has inherent technical significance considering the following fact: the testing results show that when tableting in the specific order of Claim 1 (starting from the IR layer followed by the SR layer), both friability and dissolution rates were "acceptable," whereas reversing the order of the layer sequence (starting from the SR layer followed by the IR layer) led to "unacceptable" friability or dissolution rates. (Identification Number [0105], [0109] of Plaintiff's Exhibit 2) However, because the specification of the invention in

Claim 1 of this case does not disclose the criteria for determining whether the dissolution rate is "acceptable" or "unacceptable," specific details are hard to obtain. Also, the testing results mentioned by the Plaintiff relate to one specific embodiment within the numerically limited range of the lower main pressure position, the hardness, and the turret speed in Claim 1, and thus it cannot be concluded that the result can uniformly be applied to the whole scope of Claim 1, which includes all the above numerical values. Rather, as examined above, it is reasonable to view that the order of layer sequence does not have inherent technical significance in light of the description in the specification of the subject invention that "the tableting sequence can either be the IR granules first, followed by SR layer granules or vice versa," Therefore, the Plaintiff's argument in this regard is without merit.

b) Difference 2

It is reasonable to determine that a skilled person can easily overcome Difference 2 by combining the prior art and well-known or commonly used art for the following reasons:

① Prior to the filing of the subject invention, a textbook in the field of pharmaceutical preparations that became publicly available had the following statement: "Tablet formulations should be made durable for their handling and use, and have the ideal hardness for the manufacturing process. However, if the hardness is excessively high, it may cause a performance decline due to problems such as disintegration or dissolution. Hence, it is important to control the hardness to be just right." (Defendant's Exhibits 8 and 9). According to the above statement, it seems clear that a skilled person is motivated to achieve the ideal hardness when it comes to tablet formulation.

(Defendant's Exhibit 8)
1. Tablet Strength The mechanical strength of tablets is an important property and plays

an important role in the development of formulation and the management of production. (Omitted) Tablet hardness depends on the components of the formulation, the process of making the formulation, and the process of forming compressed tablets. How resistant a tablet is to chipping, scratching, or breaking depends on the tablet's strength. Tablet hardness is used as a means to control the manufacturing process, and for this purpose, the hardness is commonly measured throughout the tablet manufacturing lot. If the tablet hardness changes, a tablet press can be adjusted so that the change in the tablet hardness remains within the acceptable range. The tablet hardness should be high enough to show a satisfactory appearance and withstand the following steps of tablet production, but not too high so that the formulation would not fail to meet the performance criteria such as disintegration or dissolution behaviors. (refer to page 589).

(Defendant's Exhibit 9)

3. 4. 7. 4 Tablet Thickness

(Omitted) The degree of compression force greatly affects not only the thickness of the tablet but also the hardness of the tablet, and the hardness is considered to be a very important evaluation criterion as it significantly impacts disintegration and dissolution. While the thickness of the tablet is mainly affected by the size of the die and the volume of the filling materials rather than the compression itself, the hardness of the tablet is mainly controlled by the compression force. Therefore, in order to produce tablets with uniform thickness and hardness, it is very important to transfer the same amount of filling materials into the die and, in particular, to equally control the compression force.

3. 4. 7. 5. Tablet Hardness and Friability

Tablet presses can usually compress from as little as 1,300kg to as much as 18,000kg. The hardness of the tablet is related to the characteristics of the granulation process, and generally, the higher the compression force, the higher the hardness. Tablets such as troches or buccal tablets, designed to dissolve slowly, are intentionally produced to have a high hardness while tablets that need rapid drug release are to have low hardness. In general, the hardness of tablets should be such that they withstand basic tasks from product packaging to transportation and not be damaged, but at the same time, they should disintegrate properly and dissolve quickly after administration, and if needed, allowing tablets to be split in half using hands. The hardness of a tablet

is measured as the force needed to fracture the tablet in units such as kilogram force (kg) or pound (lb). Industrially, the tablet hardness of about 4kg is considered to be satisfactory. (pages 162, 163)

② The textbook states that "Industrially, the tablet hardness of about 4kg is considered to be satisfactory." (Defendant's Exhibit 9), and "Tablets generally have a hardness range of 4 to 10kg/㎠, but SR tablets can be adjusted to have higher hardness (10~20kg/㎠)." (Defendant's Exhibit 10). Therefore, it is reasonable to view that a skilled person can easily determine the hardness of tablets with acceptable friability and dissolution rates through common and repetitive experiments even if prior literature does not have a detailed hardness range for SR bilayer tablets.

(Defendant's Exhibit 10)

<Hardness or Crushing Strength>
(Omitted) The amount of kilogram force needed to fracture the tablet is measured, and a force of about 4kg is considered the minimum requirement for a satisfactory tablet. Oral tablets typically have a hardness of 4 to 10kg, but subcutaneous tablets and chewable tablets typically have lower hardness (3kg), and some SR tablets have stronger hardness. (10 to 20kg) (see page 583)

③ The specification of the subject invention merely states that "the hardness less than 5kg/㎠ may prevent tablet formation or result in the formulation that is prone to collapse during storage, while the hardness that exceeds 18kg/㎠ may lead to delayed dissolution, failing to meet an optimal dissolution profile," and "the hardness of the SR bilayer tablet containing levodropropizine may be 5 to 18kg/㎠, and more preferably 8 to 15kg/㎠." (Identification Numbers [0026], [0091] of Plaintiff's Exhibit 2), and no description acknowledges the technical significance of numerically limited tablet hardness or critical significance of the hardness range.

c) Difference 3

It is reasonable to determine that a skilled person can easily

overcome Difference 3 based on the prior art and well-known or commonly used art for the following reasons:

① According to the following description in the textbook used in the field of pharmaceutical preparation, published prior to the filing of the subject invention, adjusting the turret speed properly for quality control during the tablet production process is merely a well-known or commonly used art at the time when the subject invention was applied.

(Defendant's Exhibit 11)

Typical feeders are designed to work via gravity, in filling raw materials into the die. However, if the speed is too high for tableting, the raw materials may not be sufficiently and smoothly supplied from the feeder to the die, resulting in high weight variations in the tablets. Therefore, in the case of high-speed tableting, a forced feeding with a vibratory mixing technique to fill raw materials into the tablet press is needed. This feeder enables the advantages of high-speed tableting presses to be fully realized by quickly transferring raw materials as it forcefully directs the materials into the die of the tablet press compared to the typical feeding speed. In addition, high-speed tableting may lead to lamination and capping as there is insufficient time for compacting raw materials and fusing them. These problems can be solved by reducing the speed of production or using multi-stage compression, which repeatedly compresses the granules, instead of completing the compression at once. (see page 156)

② Controlling the turret speed is necessary operation process, which is common and ordinary, for the production of tablets. Therefore, it is reasonable to view that a skilled person can easily conceive a turret speed for acceptable friability and dissolution rates through normal and repetitive experiments.

③ The specification of the subject invention merely includes a description that "Meanwhile, in s3, the turret speed of the tablet press is preferably 12 to 28rpm, and more preferably 15 to 25rpm and the most preferred is 21 to 25rpm. If the turret speed exceeds 25rpm, the granules of the tablet may not be sufficiently

transferred into the tablet press, which may reduce the hardness or friability, which is inappropriate, leading to the inconsistency of formulations. In contrast, if the turret speed is less than 12rpm, the speed of the production process slows down, thereby failing to achieve production efficiency," and embodiments in which friability and uniformity of formulations are measured by setting the turret speed of the tablet press to 15, 21, 25, 31, and 35rpm (Identification Numbers [0088], [0129] of Plaintiff's Exhibit 2). Since the specific test results obtained for different friability values (as well as the criteria for friability determination) cannot be obtained from the specification of the subject invention, it cannot be deemed that there is significant effect. Therefore, neither the critical significance nor technological meaning of the numerical limitation of the turret speed can be acknowledged.

d) Difference 4

It is reasonable to determine that a skilled person can easily overcome Difference 4 by combining the prior art and well-known or commonly used art for the following reasons:

① According to the following description in the textbook used in the field of pharmaceutical preparation, published prior to the filing of the subject invention, accurately managing the compression force to produce tablets with acceptable hardness is merely a well-known or commonly used art in the pertinent technical field. Compression force refers to a force applied when the upper and lower punches of the tablet press compress raw materials filled in the die, and thus it constitutes technological common sense that the shorter the lower main pressure position, the higher the compression force, and the higher the hardness. [the specification of the subject invention also describes the testing results of the hardness, the friability, and the dissolution rate by adjusting the lower main pressure position. (Identification Numbers [0105], [0117] of Plaintiff's Exhibit 2)]

(Defendant's Exhibit 9)

3. 4. 7. 4 Tablet Thickness

(Omitted) The degree of compression force greatly affects not only the thickness of the tablet but also the hardness of the tablet, and the hardness is considered to be a very important evaluation criterion as it significantly impacts disintegration and dissolution. While the thickness of the tablet is mainly affected by the size of the die and the volume of the filling materials rather than the compression itself, the hardness of the tablet is mainly controlled by the compression force. Therefore, in order to produce tablets with uniform thickness and hardness, it is very important to transfer the same amount of filling materials into the die and, in particular, to equally control the compression force.

3. 4. 7. 5. Tablet Hardness and Friability

Tablet presses can usually compress from as little as 1,300kg to as much as 18,000kg. The hardness of the tablet is related to the characteristics of the granulation process, and generally, the higher the compression force, the higher the hardness. Tablets such as troches or buccal tablets, designed to dissolve slowly, are intentionally produced to have a high hardness while tablets that need rapid drug release are to have low hardness. (Omitted)

② It seems reasonable to conclude that a skilled person can easily conceive the appropriate lower main pressure position for the desirable hardness, friability, and dissolution rates through normal and repetitive experiments even if the prior art does not disclose specific figures.

③ The specification of the subject invention discloses that "it is preferable to perform tableting at the lower main pressure position of 7 to 12mm. If the lower main pressure position is less than 7mm, it results in extremely hard tablets, delaying drug dissolution, thereby limiting the rapid onset of pharmacological action upon oral administration. On the other hand, if the position exceeds 12mm, friability increases, hampering the stability during storage of formulations, which is inappropriate," and includes embodiments in which the hardness and friability are measured by setting the lower main pressure position at 13.26, 11.26, 9.26, 7.26, and 5.26mm

(Identification Numbers [0028], [0104], [0114] of Plaintiff's Exhibit 2). As the specification of the subject invention does not disclose the specific testing results obtained for different friability values (as well as the criteria for friability determination), and it is deemed that there is no significant effect in the dissolution rates in cases where the lower main pressure position is at 7.26mm and 5.26mm, respectively, neither critical significance nor technological meaning of the numerical limitation of the lower main pressure position can be acknowledged.

5) Effects of Claim 1

It is difficult to acknowledge that Claim 1 has a significant effect that a skilled person cannot predict for the following reasons:

a) As the specification of the subject invention does not describe dissolution acceptance criteria, the specific details of the effect on dissolution according to the subject invention cannot be obtained.

b) The specification of the prior art discloses the results of dissolution testing of a tablet consisting of the IR layer containing levodropropizine, sodium starch glycolate (a disintegrant), and magnesium stearate (a lubricant) and the SR layer containing levodropropizine, hydroxypropyl methylcellulose (a release-controlling polymer), polyvinylpyrrolidone (a binder), and magnesium stearate (a lubricant), wherein levodropropizine is contained in an amount of 45mg in the IR and SR layers, respectively, and the weight of the IR layer is set to be 188.4mg, the weight of the SR layer to be 106.2mg, and the total weight to be 294.6mg. (Embodiment 3 in Table 4 of Plaintiff's Exhibit 5)

Prior Art (Plaintiff's Exhibit 5)

[0066] As shown in Table 2 below, levodropropizine and each of the excipients were mixed and then tableted to conduct fluidity testing, hardness testing, friability testing, disintegration testing, and dissolution testing to develop an acceptable immediate-release layer composition.
[0072] Dissolution: 30min-80% or more
[0074]

[Table 2] (Immediate-Release Layer)

Formulation 14a	Levodropropizine (45mg) Flowlac (67mg) MCC pH102 (67mg) Sodium Starch Glycolate (10mg) Magnesium stearate (1.9mg)	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

[0083] An acceptable sustained-release layer composition was developed through fluidity testing, hardness testing, and dissolution testing of the bilayer tablet consisting of the immediate-release layer mixed as in formulation 14a and a sustained-release layer prepared via wet granulation of the formulation as shown in Table 3 below.

[0087] Dissolution: 30min-40~60%, 180min-60~80%, 720min-85% or more

[0089]

[Table 3] (Sustained-Release Layer)

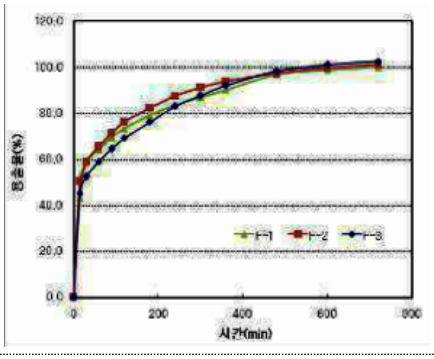
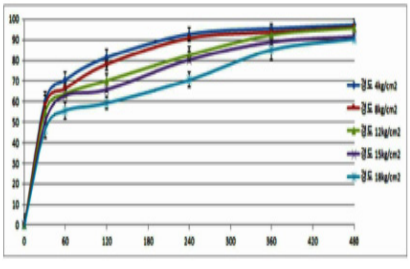
Formulation 19b	Levodropropizine (45mg) Flowlac (67mg) MCC pH102 (67mg) Sodium Starch Glycolate (10mg) Magnesium stearate (1.9mg)	Levodropropizine (45mg) MCC pH101 (7mg) PVP K-90 (3mg) HPMC2208(100,000 cps) (50mg) Magnesium stearate (1.7mg)	Acceptable	Acceptable	Acceptable

[0097] Through the above testing, the immediate-release layer was determined to be formulation 14a, and the sustained-release layer to be formulation 19b. However, as formulation 19b was close to the upper and lower dissolution acceptance criteria, the final formulation was prepared to include excipients as shown in Table 4 below, and then dissolution testing was conducted.

[Table 4]

	Final Formulation	Embodiment 1	Embodiment 2	Embodiment 3
Sustained-release layer	Levodropropizine	45.0	45.0	45.0
	*MCC 101	7.0	6.8	6.8
	*HPMC 2208	50.0	50.0	50.0
	*PVP K-90	3.0	2.7	2.7
	*s-Mg	1.7	1.7	1.7
	Final weight(mg)	106.7	106.2	106.2
Immediate-release layer	Levodropropizine	45.0	45.0	45.0
	Flowlac	67.0	67.0	67.0
	MCC pH102	67.0	67.0	67.0
	Sodium Starch Glycolate	10.0	10.0	7.5
	s-Mg	1.9	1.9	1.9
	Final weight(mg)	190.9	190.9	188.4
Total weight (mg)		297.6	297.1	294.6

The above embodiment is substantially identical in composition (ingredients and content) of the SR bilayer tablet of Claim 1 in that its IR layer contains levodropropizine, a disintegrant, and a lubricant, and the SR layer contains levodropropizine, a release-controlling polymer, a binder, and a lubricant, and the weight ratio of the IR layer to the SR layer is approximately 1.7:1 (= 188.4mg/106.2mg). Further, when comparing the dissolution rate of the above embodiment (Figure 3 of Plaintiff's Exhibit 5) with the dissolution rate of the bilayer tablet produced according to the preferred embodiment of the subject invention (Figure 2 of Plaintiff's Exhibit 2), it cannot be deemed that there is a conspicuous difference. Therefore, it is difficult to conclude that an "excellent dissolution rate" is an inherent effect of the subject invention.

Prior Art (Figure 3 of Plaintiff's Exhibit 5)[3]	The Subject Invention (Figure 2 of Plaintiff's Exhibit 2)[4]
	

c) As seen from above, setting physical properties such as friability and hardness by adjusting the sequence of tableting, the turret speed, and the lower main pressure position is merely a well-known or commonly used art, and the set points can be easily conceived by normal and repetitive tests. The adjustment of the sequence of tableting, the turret speed, and the lower main pressure position is merely a simple change in the physical environment, and since there is no chemical action involved during the process, the effects thereof are deemed to be in the predictable range that a skilled person can extrapolate.

6) Determination of the Plaintiff's remaining claims

a) The Plaintiff argues that the problem to be solved in the prior art and the problem to be solved in the subject invention are different, in that the problem to be solved in Claim 1 is to provide a production method that enables "mass production while maintaining tablet stability and drug efficacy." However, Claim 1 and the prior art partially share common problems to be solved as they both seek to improve drug efficacy by achieving the optimal dissolution rate.

3) See the blue graph (Embodiment 3)

4) The red graph corresponds to the embodiment with a hardness of 8kg/㎠.

Although the specification of the prior art does not explicitly disclose the problem to be solved—a method of mass production while maintaining optimal friability and hardness—it is reasonable to deem that the prior art inherently presumes securing and maintaining acceptable hardness and friability during mass tablet production as a prerequisite, because this requirement is essential in the field of formulations [the Korean Pharmacopoeia (Ministry of Food and Drug Safety Notice No. 2018-68) stipulating the standards and specifications of pharmaceuticals, discloses the friability testing method, the uniformity testing method for formulations, etc. (Defendant's Exhibits 13 and 14)]. Therefore, it cannot be deemed that the problem to be solved by Claim 1 is different from that of the prior art. Hence, the Plaintiff's argument stated above is without merit.

b) The Plaintiff argues that the subject invention achieved the significant effect of providing the SR bilayer tablet containing levodropropizine with optimal dissolution characteristics while ensuring stability for mass tablet production by organically combining various elements such as the hardness, the turret speed, the lower main pressure position, and the sequence of tableting and by offering the numerical limitation of the amount of levodropropizine contained in the IR and SR layers, the weight ratio of the release-controlling polymer, the weight ratio of the IR and SR layers, and the total weight of tablet. Therefore, the inventive step should not be determined based solely on whether each element is disclosed in the prior art by dissecting the subject invention into each element.

However, as seen above, the prior art already discloses an embodiment wherein the levodropropizine content in the IR and SR layers, the weight ratio of the release-controlling polymer, the weight ratio of the IR and SR layers, and the total weight of tablet falls into specific numerical values of the subject invention. The specification of the subject invention does not have any description regarding the critical significance of the above numerical limitation. Hence, the

elements of the subject invention related to the composition are substantially identical to those of the prior art.

Further, although the hardness, the turret speed, the lower main pressure position, and the sequence of tableting may have some influence on the physical properties determined by the chemical composition, it seems that this influence is merely a physical change to slightly enhance physical properties or to prevent degradation thereof, and thus the change in physical properties will not be significant. The testing results shown in the specification of the subject invention were obtained by selecting the same composition as Embodiment 3 in Table 4 of the prior art (Table 1 of Plaintiff's Exhibit 2) and then evaluating the hardness, the friability, and the dissolution rate by changing the tableting sequence and the lower main pressure position (Table 2 of Plaintiff's Exhibit 2), and then again evaluating the friability and the uniformity of formulations by changing the turret speed with the best mode or preferred embodiments. (Table 3 of Plaintiff's Exhibit 2). In this regard, in light of the fact that the composition was selected first, it seems that the physical properties are basically determined by the composition, and then adjusted through the sequence of tableting, and the setting of the lower main pressure position.

Moreover, the sequence of tableting, the lower main pressure position, the turret speed are the elements that must be selected in order to produce SR bilayer tablets containing levodropropizine set forth in the prior art, which falls into the well-known and commonly used art applied in the tablet formulation. The range is merely a simple numerical limitation that a skilled person can properly select through normal and repetitive tests.

In summary, even though Claim 1 involves elements such as the content of levodropropizine, the weight ratio of the release-controlling polymer, the weight ratio of the IR and SR layers, the total weight ranges of the tablet, the hardness, the turret speed, the lower main pressure position, and the sequence of tableting, compared to the prior

art, it cannot be deemed that it has achieved a significant effect that a skilled person could not have conceived. Therefore, the Plaintiff's argument above is without merit.

7) Summary of analysis

Since a skilled person can easily overcome Differences 1 to 4 by combining the prior art and well-known or commonly used art and it cannot be deemed that Claim 1 has a significant effect that a skilled person could not have conceived, the inventive step of Claim 1 is denied by the prior art.

C. Whether the Inventive Step of Claims 5 to 7 Is Denied

Claims 5 to 7 are all dependent claims of Claim 1, which further adds or limits the following features: the disintegrant in Claim 5 to be one or more selected from the group consisting of sodium starch glycolate, croscarmellose sodium, pregelatinized starch, microcrystalline cellulose, and crospovidone; the lubricant in Claim 6 to be one or more selected from the group consisting of magnesium stearate, light anhydrous silicic acid, talc, and sodium stearyl fumarate; and the binder in Claim 7 to be one or more selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinyl acetate, copovidone, and ethyl cellulose. However, regarding the production of the SR bilayer tablets containing levodropropizine, the composition of using sodium starch glycolate as a disintegrant, magnesium stearate as a lubricant, and polyvinylpyrrolidone as a binder is already disclosed in the prior art, and since it is technical common knowledge that the other elements not disclosed in the prior art can be used as disintegrants, binders, or lubricants, a skilled person can properly select and use them as needed. Therefore, the inventive step of Claims 5 to 7 is also denied by the prior art.

D. Whether the Inventive Step of Claim 14 Is Denied

1) Article 2(3) of the Patent Act divides the types of inventions as an "invention of a thing," an "invention of process," and an "invention of a process of manufacturing a thing," and in case of a claim for product invention that describes its manufacturing process (hereinafter, a "product invention describing its manufacturing process"), even if the manufacturing process is described, the subject of the invention is not the manufacturing process but the final product itself, and therefore, it falls under the category of an "invention of a thing" among the aforementioned types of inventions. Since the claims of the invention of a thing shall be described in a manner that specifies the composition of a product that is the subject of the invention, the manufacturing process set forth in the claims of the invention of a thing has significance only as a means of specifying the structure or properties, etc., of a final product. Therefore, in determining the patentability of a product invention describing its manufacturing process, the technical composition should not be examined only by the manufacturing process itself, but as a product having the structure, properties, etc., specified by all the descriptions of the claims including the description of the manufacturing process, and be determined if there is a novelty, inventive step, etc., by comparing it with the prior art already publicly known at the time of application. (Supreme Court Decision 2011Hu927, en banc decision, January 22, 2015)

2) Claim 14 is the SR bilayer tablet containing levodropropizine produced according to Claim 1—an invention of a process—that adds and limits the types of a disintegrant, a lubricant, a binder, and a release-controlling polymer. Although the claims of Claim 14 include the manufacturing process according to Claim 1, the manufacturing process has significance only as a means of specifying the structure or characteristics of the "SR bilayer tablet containing levodropropizine" as the final product and therefore, it is reasonable to view that the composition of the SR bilayer tablet that can be specified by Claim 1

constitutes the elements of Claim 14.

3) Accordingly, when comparing the elements of Claim 14 with the prior art, it is as follows:

Element	Claim 14 (Plaintiff's Exhibit 2)	Prior Art (Plaintiff's Exhibit 5)
1	Immediate-release layer granules containing levodropropizine, a disintegrant, and a lubricant, wherein the immediate-release layer granules contain levodropropizine 30 to 50mg.	Producing the immediate-release layer granules containing levodropropizine, sodium starch glycolate, and magnesium stearate. (Identification Numbers [0064] to [0079], Embodiment 3 in Table 4) The immediate-release layer granules contain levodropropizine 45.0mg (Identification Numbers [0064] to [0079], Embodiment 3 in Table 4)
2	The sustained-release layer granules containing levodropropizine, a release-controlling polymer, a binder, and a lubricant, wherein the content of levodropropizine is 35 to 60mg, and the release-controlling polymer is one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and carbomer, wherein the release-controlling polymer is included 30 to 60% by weight relative to the total weight of the sustained-release layer granules.	Producing the sustained-release layer granules containing levodropropizine, hydroxypropyl methylcellulose(HPMC), polyvinylpyrrolidone(PVP), and magnesium stearate (Identification Numbers [0082] to [0093] and Table 4). The sustained-release layer granules contain levodropropizine 45.0mg, the hydroxypropyl methylcellulose 50.0mg, and the total weight of the sustained-release layer is 106.2mg (Embodiment 3 in Table 4)
3	The weight ratio of the immediate-release layer granules and the sustained-release layer granules is 1.5:1 to 2.5:1.	The immediate-release layer granules and the sustained-release layer granules contain levodropropizine 45.0mg, respectively. (Identification Numbers [0064] to [0079], Embodiment 3 in Table 4)

Element	Claim 14 (Plaintiff's Exhibit 2)	Prior Art (Plaintiff's Exhibit 5)
4	The total weight of the bilayer tablet consisting of the immediate-release and sustained-release granules is 250-350mg.	The total weight of the bilayer tablet consisting of the immediate-release and sustained-release granules is 294.6mg. (Embodiment 3 in Table 4)
5	The tablet hardness of the sustained-release and immediate-release granules is 8-15kg/cm^2.	The hardness standard for the bilayer tablet is 4-5kg/cm^2. (Identification Number [0086])
6	As a disintegrant, one or more selected from the group consisting of sodium starch glycolate, croscarmellose sodium, pregelatinized starch, microcrystalline cellulose, and crospovidone;	As a disintegrant, sodium starch glycolate is used.
7	As a lubricant, one or more selected from the group consisting of magnesium stearate, light anhydrous silicic acid, talc, and sodium stearyl fumarate;	As a lubricant, magnesium stearate is used.
8	As a binder, one or more selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinyl acetate, copovidone, and ethyl cellulose;	As a binder, polyvinylpyrrolidone (PVP) K-90 is used.
9	As a release-controlling polymer, one or more selected from the group consisting of hydroxypropyl methylcellulose, Kollidon SR, and Carbomer.	As a release-controlling polymer, hydroxypropyl methylcellulose (HPMC) is used.
9	The sustained-release bilayer tablet containing levodropropizine.	The sustained-release bilayer tablet containing levodropropizine.

4) Elements 1 to 3 are identical to the corresponding elements of the prior art, and the difference in Element 4 can be easily overcome

by combining the prior art and well-known or commonly used art as seen above. The remaining elements are substantially identical to the corresponding elements of the prior art. Since a skilled person can easily conceive Claim 14 with the prior art and well-known and commonly used art, it lacks an inventive step.

E. Summary of Findings

Claims 1, 5, 6, 7, and 14 lack an inventive step, and thus the patent should be invalidated without further examining the remaining arguments. The IPTAB Decision is consistent with the above analysis and shall be upheld.

4. Conclusion

The Plaintiff's claim seeking revocation of the IPTAB Decision is without merit. Therefore, it is dismissed.

Presiding Judge Juhyung MOON
Judge Bowon KWON
Judge Jiyoon HAN

IP HIGH COURT OF KOREA
SECOND DIVISION
DECISION

Case No.	2022Heo6228 Scope of Rights Confirmation (Patent)
Plaintiff	A Corp. Representative Director B Counsel for Plaintiff Patent Attorneys Jonghyuk PARK and Hwajin GONG
Defendant	C Representative D Counsels for Defendant Attorney Gyungtae GANG Patent Attorneys Seunghyun OH and Jiyoung KIM
Date of Closing Argument	May 24, 2023
Decision Date	June 2, 2023

ORDER

1. The IPTAB Decision 2022Dang603, decided November 30, 2022, shall be revoked.

2. Costs shall be borne by the Defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Background

A. Patented Invention[1)]

1) **Title of invention:** Solid Form of Selective CDK4/6 Inhibitor

2) **Divisional application date / International application date / Original application's translation submission date / Date of claimed priority / Registration date / Registration number:** August 7, 2017 / February 8, 2014 / August 20, 2015 / February 21, 2013 / May 10, 2018 / No. 10-1858913

3) **Claims**

【Claim 1】 The particle of crystalline form A of the free base[2)] of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8 H-pyrido[2,3-d]pyrimidin-7-one[3)] with a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2, and 11.5 ± 0.2 and with a D[4,3] value ranging from 15 μm ± 20% to 30 μm ± 20% (hereinafter, "Claim 1"; the same shall apply hereinafter).

【Claim 2】 The particle of crystalline form A of the free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8 H-pyrido[2,3-d]pyrimidin-7-one with a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2,

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1) In principle, the claims and contents of the patented invention and the prior art are presented as stated in the specification, without considering spelling or spacing issues.

2) This is an active pharmaceutical ingredient (API), also known as "palbociclib" or "PD-0332991" (paragraph [0004] of Plaintiff's Exhibit 2).

3) The term "free" is used to distinguish the form of the API that exists as the original compound itself, rather than in its salt form. Since the API in the patented invention, palbociclib, is a basic compound, the compound itself that did not form a salt is referred to as the "free base."

and 11.5 ± 0.2 and with a D_{90} value ranging from 30 μm ± 20% to 65 μm ± 20%.

【Claim 3】 The particle of crystalline form A of the free base according to Claim 1 or Claim 2, having a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2, 10.3 ± 0.2, and 11.5 ± 0.2.

【Claim 4】 The particle of crystalline form A of the free base according to Claim 1 or Claim 2, having a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 5.1 ± 0.2, 8.0 ± 0.2, 10.1 ± 0.2, 10.3 ± 0.2, 11.5 ± 0.2, 14.0 ± 0.2, 15.1 ± 0.2, 16.0 ± 0.2, 17.1 ± 0.2, 18.7 ± 0.2, 19.7 ± 0.2, 20.2 ± 0.2, 21.2 ± 0.2, 22.5 ± 0.2, and 23.0 ± 0.2.

【Claim 8】 A pharmaceutical composition for the treatment of cancer, comprising the particle of crystalline form A of the free base according to Claim 1 or Claim 2, and one or more pharmaceutically acceptable carriers, diluents, or excipients.

【Claims 5 to 7 and 9 to 17】 (Omitted as they are not relevant to the issue)

4) Summary of Invention

The patented invention relates to the particles of crystalline form A of the palbociclib free base and provides palbociclib free base particles with a specific particle size distribution. Refer to [Appendix 1] for main content of the patented invention.

B. Invention Subject to Confirmation of Scope (hereinafter, the "Challenged Invention")

The Challenged Invention concerns the crystalline form particles of the palbociclib free base, and the specific details are as described in [Appendix 2].

C. Procedural History

1) The Plaintiff, on March 3, 2022, filed a request for defensive confirmation trial for the scope of rights with the Intellectual Property Trial and Appeal Board (hereinafter, the "IPTAB") against the Defendant, the patent holder, claiming that "the Challenged Invention does not fall within the scope of the claims of Claims 1 to 4 and 8," and sought confirmation (hereinafter, the "Petition for Trial").

2) The IPTAB reviewed the Petition for Trial under the case numbered 2022dang603 and, on November 30, 2022, rendered a decision (hereinafter, the "IPTAB Decision") dismissing the Plaintiff's request, stating that "the Challenged Invention does not fall within the literal scope of Claims 1 to 4 and 8, but has an equivalent structure to Claims 1 to 4 and 18, and therefore falls within the scope of rights."

【Factual basis】 Undisputed facts, statements in Plaintiff's Exhibits 1 through 11 and Defendant's Exhibits 1, and 4 through 12, and the purport of the overall arguments

2. Summary of Parties' Arguments

A. The Plaintiff

The patented invention identifies the necessary particle size for crystalline form A particles of the palbociclib free base to improve physicochemical properties and manufacturability, compared to particles obtained by the conventional salt break process. The technical feature distinguishing this invention from publicly known art is that it limits the particle size of the palbociclib free base crystalline form A to a specific numerical range. Therefore, since the core technical idea of the patented invention is not directly embodied in the Challenged Invention and the solution principle and effects are different, the Challenged Invention does not fall within the scope of rights of the

patented invention.

B. The Defendant

The solution principle (means) of the patent invention should be considered as providing a palbociclib free base with a primary particle size that is "larger" than that provided by the conventional salt break process. Therefore, the Challenged Invention has the identical problem-solving principle and effects as Claims 1 to 4 and 8, and it would be easy for a person having ordinary skills in the art (hereinafter, the "PHOSITA") to modify the particle size of the Challenged Invention to that of the patented invention. Thus, the Challenged Invention falls within the scope of rights of the claims as an equivalent.

3. Whether IPTAB Decision Erred

A. Whether the Challenged Invention Falls within the Scope of Claims 1 and 2 of the Subject Invention

1) Relevant law

In order for the challenged invention to fall within the scope of rights of the patented invention, each of the elements specified in the claims of the patented invention and the organic relationship between those elements must be directly included in the Challenged Invention. Even if the Challenged Invention includes changes to the elements described in the claims of the patented invention, if the solution principle of the challenged invention is the same as that of the patented invention, and such changes result in substantially the same effects as those of the patented invention, and if such changes are something that a person having ordinary skill in the art could easily think of, the Challenged Invention should still be considered as equivalent to the elements described in the claims of the patented

invention and fall within the scope of rights of the patented invention, unless there are special circumstances, such as the challenged invention being the same as publicly known art at the time of the patent application or being easily inventable by a person having ordinary skill in the art from publicly known art, or the changed elements of the challenged invention being consciously excluded from the claims during the application process. When determining whether the two inventions have the same solution principle, one should not merely extract part of the elements described in the claims. Instead, one should consider the detailed description of the invention in the specification and the publicly known art at the time of application to compare it with the prior art and practically explore and determine what is the core of the technical idea underlying the solution means distinctive of the patented invention (see the Supreme Court Decisions 2010Da65818, dated September 29, 2011, and 2013Da14361, dated July 24, 2014 etc.). What the substantive value of a patented invention that the patent law intends to protect lies in the fact that the patented invention solves a technical problem that was not addressed by the prior art and contributes to technological development. Therefore, whether the elements changed in an infringing product are equivalent to the corresponding components of the patented invention should be determined considering the solution principle unique to the patented invention. When identifying the solution principle of a patented invention, it is important to consider not only the detailed description of the invention but also the publicly known art at the time of application in order to objectively assess the substantive value of the patented invention based on its contribution to technological development in relation to the entire prior art to provide appropriate protection. Therefore, it is necessary to determine how broadly or narrowly the solution principle of the patent invention should be identified, based on the extent to which the patent invention has contributed to technological development considering the prior art (see Supreme Court Decision 2016Ma5698, dated January 31, 2019).

In addition, when the claims of a patent invention define a certain range of values as one of the elements, the Challenged Invention, which includes a value outside the limited range, does not fall within the scope of rights of the patent invention in principle, unless there are special circumstances, such as the value outside the range being considered equivalent (see Supreme Court Decision 99Hu2372, dated August 21, 2001).

2) Element-by-element comparison[4)]

Element (Claims 1 and 2)		Patented Invention	Challenged Invention
1		with a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2, and 11.5 ± 0.2	with a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 7.9341, 8.4852, 10.0533, 10.2140, and 11.4848
2	Claim 1	with a D[4,3] value ranging from 15 μm ± 20% to 30 μm ± 20%	with a D[4,3] value under 10 μm
	Claim 2	with a D_{90} value ranging from 30 μm ± 20% to 65 μm ± 20%	with a D_{90} value under 20 μm
3		The particle of crystalline form A of the free base of 6-acetyl-8-cyclopentyl -5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7- one	The particle of crystalline form of the free base of 6-acetyl-8-cyclopentyl-5-methyl -2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido-[2,3-d]pyrimidin-7-one

4) Claims 1 and 2 are composed as independent elements, but they are compared together as the only difference lies in the numerical range of Element 2.

3) Commonalities and Differences

Elements 1 and 3 of Claims 1 and 2 define the compound forming the particles as the palbociclib free base and limit it to crystalline form A based on the "powder X-ray diffraction pattern." Similarly, the elements of the Challenged Invention consist of the palbociclib free base as the compound forming the particle, with a powder X-ray diffraction pattern identical to the pattern of Element 1, which corresponds to crystalline form A. Therefore, the Challenged Invention includes the same elements as Elements 1 and 3 of Claims 1 and 2 (there is no dispute between the parties on this matter).

On the other hand, Element 2 of Claims 1 and 2 defines the particle size distribution of the particles with a D[4,3][5] value ranging from 15 μm ± 20% to 30 μm ± 20% (12 to 36 μm) and a D90 value ranging from 30 μm ± 20% to 65 μm ± 20% (24 to 78 μm). In contrast, the Challenged Invention has a D[4,3] value of 10 μm or less and a D90 value of 20 μm or less. This indicates that the corresponding particle size distribution range values are different (hereinafter, the "Difference").

Therefore, since the Challenged Invention does not have the same element as Element 2 of Claims 1 and 2, it does not fall within the literal scope of rights of Claim 1.

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5) The patent invention defines the term D[4,3] in the specification as "the volume mean or mass moment mean." Meanwhile, D90 is described as the "distribution width may also be characterized by citing one, two or preferably three values on the x-axis, typically some combination of the D10, D50, and D90. The D50, the median, has been defined above as the diameter where half of the population lies below this value. Similarly, 90 percent of the distribution lies below the D90, and 10 percent of the population lies below the D10." (paragraphs [0125] and [0126] of Plaintiff's Exhibit 2). In other words, the D90 value refers to the diameter of the particle corresponding to the cumulative 90% of the total particles when arranged in ascending order of size.

4) Analysis of Differences: Whether the two inventions are considered equivalent

A) Whether the two inventions share the same problem-solving principle

The two inventions are based on different problem-solving principles since the core of the technical idea underlying the distinctive solution means of Claims 1 and 2 and the Challenged Invention cannot be considered the same for the following reasons.

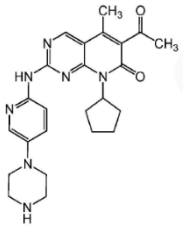
(1) Considering the description of the specification of this patent invention, the publicly known art at the time of the priority date, and the level of skill of a person having ordinary skill in the art, it is reasonable to conclude that the distinctive solution means of the Challenged Invention and the core of the technical idea underlying the means is to provide palbociclib particles with physicochemical properties improved by making the palbociclib free base obtained through recrystallization from a conventional salt break method have a particle size with a D[4,3] value of "15 μm ± 20% to 30 μm ± 20% and a D90 value of 30 μm ± 20% to 65 μm ± 20%."

(A) The patented invention relates to "particles of crystalline form A of the palbociclib free base," and when considering the specification of the patent invention and the prior art, the fact the palbociclib free base exists in crystalline form A was publicly known before the priority date (paragraphs [0004], [0008], and [0101] of the specification; paragraph [0010] of Plaintiff's Exhibit 4). Therefore, Claims 1 and 2 differ from the prior art in that the claims specify the D[4,3] and D90 values related to particle size within numerical ranges.

Specification of the patented invention (Plaintiff's Exhibit 2)

[0004] The compound **6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one** (also referred to herein as "**compound 1**"), may be represented by the structure and is also known as **palbociclib or PD-0332991:**

[0005] [Chemical Formula 1]

[0006] 

[0008] Compound 1 and pharmaceutically acceptable salts thereof are disclosed in International Publication No. WO 2003/062236 and U.S. Pat. Nos. 6,936,612, 7,208,489 and 7,456,168, which describe the preparation of compound 1 as its hydrochloride salt. International Publication No. WO 2005/005426 and U.S. Pat. Nos. 7,345,171 and 7,863,278 describe the preparation of **the free base** and various mono- and di-acid addition salts of **compound 1**, including polymorphic forms of the isethionate salt. A process for the preparation of compound 1 as a mono-isethionate salt is described in International Publication No. WO 2008/032157 and U.S. Pat. No. 7,781,583. The contents of each of the foregoing references are incorporated herein by reference in their entirety.

[0101] U.S. Pat. No. 7,345,171 reported that the free base of compound 1, prepared by a traditional salt break procedure, had poor water solubility (9 μg/mL) at pH 7.9 and exhibited low bioavailability in animal studies. The free base was reported to be in its most stable crystal phase according to slurry experiments (i.e., Form A). FIG. 17 of U.S. Pat. No. 7,345,171 provided the water adsorption/desorption isotherms for the free base of **Form A**. As noted previously, this material corresponds to the small particle size free base of compound 1 described herein.[6)]

Prior Art 1 (Plaintiff's Exhibit 4)

[0010] The '059 Application discloses a particularly potent and selective CDK4 inhibitor, 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one:
Chemical Formula 1

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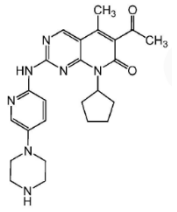
6) The prior art documents cited in the specification of the patent invention, namely WO 2005/005426 and its corresponding U.S. Pat. Nos. 7,345,171 and 7,863,278, correspond to the Korean Patent Publication KR 2006-0054300 (Plaintiff's Exhibit 4). The paragraph above states that "the small particle size free base of compound 1" in the patent invention corresponds to the small particle size of palbociclib free base disclosed in U.S. Pat. No. 7,345,171.

[0011] 

[0057] The data in Table 4 indicates that the water solubility of the mono-isethionate salt (at pH 5.4) is more than 20,000-fold higher than the freebase (at pH 7.9). This large disparity in water solubility cannot be explained by the relatively modest difference in pH of the saturated[7] solutions of the freebase and the mono-isethionate salt. Indeed, the theoretical water solubility of the freebase is only 0.62 mgA/mL at pH 5.4 by Henderson-Hasselbalch calculation (using free base solubility 0.0092 mg/mL at pH 7.9 and pKas 7.3 and 4.1).[8] Seeding an aqueous solution of the mono-isethionate salt prepared at 117 mgA/mL, pH 5.4 (supersaturated with respect to free base) **with crystals of the freebase** did not cause precipitation. Instead, the seeds dissolved, indicating some ability of the isethionate ion to solubilize the freebase in water.

(b) Considering ① to ③ below, the patent invention aims to provide palbociclib free base crystalline form A particles with a specific particle size that has improved physicochemical properties and manufacturability by selecting an appropriate recrystallization solvent system. It is reasonable to conclude that the patent invention contributed to technological development compared to the prior art in that it provides specific particle size ranges for the D[4,3] value and D90 value that achieve the aforementioned goal.

① Palbociclib is a substance known in the prior art disclosed before the priority date of the patent invention. The prior art already discloses that palbociclib can exist in various salt forms and

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However, Plaintiff's Exhibit 4 does not directly mention the small particle size of palbociclib free base.

7) It appears that it has been mistakenly written as "포화" in Korean.

8) It is the unit of solubility based on the active pharmaceutical ingredient (Milligrams of Active Ingredient per Milliliter of solution).

can also exist in a crystalline form and that the palbociclib free base shows the most stable crystalline form (paragraph [0056], Example 4 and Drawing 17 of Plaintiff's Exhibit 4; paragraph [0159] and Claims 7 to 9 of Plaintiff's Exhibit 5; and Example of Plaintiff's Exhibit 6).

② This patented invention recognizes the problem that when the previously known crystalline form A of the palbociclib free base is obtained by a conventional salt break process, small primary particle sizes are obtained, and such small particle sizes lead to poor pharmaceutical properties such as punch sticking and large aggregates. Since punch sticking is related to the API surface area, the invention aims to provide "larger free base particles of Compound 1" that demonstrate improved physicochemical properties and manufacturability by controlling the API particle size (paragraphs [0009], [0101], and [0102]). Accordingly, the patented invention uses a recrystallization process as the solution to identify an appropriate solvent system and then recrystallize the palbociclib free base with a small primary particle size obtained by a conventional salt break process to prepare larger primary particles (paragraphs [0103], [0104], and [0116], Example 6, etc.); confirms through the experiment that the larger particles within the specified range that are obtained by the recrystallization above show reduced stickiness, do not form aggregates, and are not static (paragraphs [0116], [0117], and [0242] and Fig. 7); and specifies the particle size of crystalline form A of the palbociclib free base as an element in the claims. That is, the patented invention was claimed not for the technical characteristic of the "specific crystalline form of palbociclib," but for the one of "limiting the particle size of palbociclib to a specific numerical range," and the claims include the "particle size distribution limited to a specific numerical range" as an essential element.

Specification of the Patented Invention (Plaintiff's Exhibit 2)
[0009] While compound 1 is a potent and selective CDK4/CDK6 inhibitor, its use as a free base presented challenges for pharmaceutical development.

The free base provided by traditional salt break procedures, e.g., as in Example 4 of WO 2005/005426, was highly static prone and formed small primary particles, which agglomerated into large, hard agglomerates that were difficult to disperse by sieving and were unsuitable for further development. The present invention **provides compound 1 free base having larger primary particle size that demonstrates improved physicochemical and manufacturability properties**.

[0101] U.S. Pat. No. 7,345,171 reported that the free base of compound 1, prepared by a traditional salt break procedure, had poor water solubility (9 μg/mL) at pH 7.9 and exhibited low bioavailability in animal studies. The free base was reported to be in its most stable crystal phase according to slurry experiments (i.e., Form A). FIG. 17 of U.S. Pat. No. 7,345,171 provided the water adsorption/desorption isotherms for the free base of **Form A**. As previously mentioned, **this substance corresponds to the small particle size free base of Compound 1 described herein**.

[0102] The free base of compound 1 (Form A) has a high propensity for punch sticking in the drug particle manufacturing process. As punch sticking is related to API surface area, **API particle size control is critical for minimizing sticking during drug product manufacturing**. In addition to issues with punch sticking, compound 1 free base isolated directly from a standard salt break process was found to be highly static prone and found to form large (approximately 500 μg) hard agglomerates that were not dispersed by sieving. Free base API with similarly poor physical properties was produced by free basing of the existing isethionate salt API or by neutralization of the in situ salt formed in the final step of the API synthesis. In either process, small API primary particles were produced due to the rapid crystallization caused by the dramatic change in solubility with adjustment of the pH. **In all cases the free base was isolated as the more stable polymorph of Form A**.

[0103] (Omitted) As the process for producing free base resulted in the isolation of API with poor physical properties, work was undertaken to identify a recrystallization process that could improve the API physical properties.

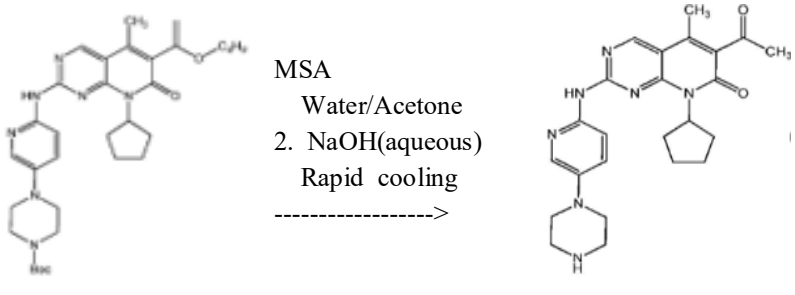
[0104] **Early crystallization screening experiments** for compound 1 free base **were completed to identify a solvent system that allows for the isolation of particles with improved physical properties**. A combination of solubility screening and small-scale recrystallization studies examined multiple potential solvent systems.

[0116] Based on these screening studies, a mixture of 40% n-butanol and anisole was selected as the crystallization solvent system for further work, in view of the relatively high solubility, chemical stability of the API, and particle properties of the recrystallized compound 1 API. **This solvent system was used in subsequent production to provide larger primary particle size API that had reduced sticking, was not static prone, and was free of agglomerates**.

[0117] Using this solvent mixture, compound 1 was dissolved with 40 mL/g of solvent (concentration of 25 mg/mL) by heating to 95-100 °C., before being crystallized using a controlled cooling profile and seeding to induce nucleation. FIG. 9 is a PLM[9] image of a lab-scale lot of compound 1 recrystallized using this recrystallization procedure, while **FIG. 7 displays a particle size distribution for three lots of recrystallized API**. **This recrystallization process results in the isolation of compound 1 API particles with a larger primary particle size, which leads to a decrease in the sticking tendency in the drug product manufacturing process. This recrystallized compound 1 API does not form agglomerates and also has the positive attribute of not being static prone**.

[0213] Example 5. Preparation of Small Particle Size Free Base of Compound 1 by Salt Break Method

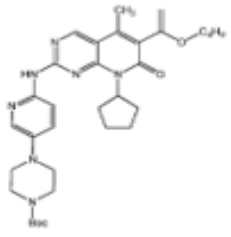
[0214]



[0217] **This method generated the small primary particle size free base of compound 1, which was equivalent to the material prepared from treatment of the compound 1 hydrochloride salt with aqueous NaOH in Example 4 of WO 2005/005426**.

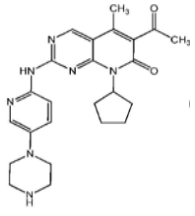
[0220] Example 6. Conversion of Small Particle Size Free Base to Lame Particle Size Free Base of Compound 1

[0221]



1. HCl
   Water/n-BuOH
2. Anisole
   NaOH(aqueous)

70℃
(75%)



[0222] To a reactor was added compound 1 free base (20 g, 44.69 mmol, 1.0 eq.), prepared according to Example 5, followed by 1-butanol (320 ml, 16 ml/g) and anisole (480 ml, 24 ml/g). The yellow slurry was warmed to between 95 °C and 100 °C to achieve dissolution. The reactor was cooled to 80 °C. To the solution in the reactor, 1-butanol (320 ml, 16 ml/g) and anisole (480 ml, 24 ml/g) were added. The yellow slurry was heated to 95 to 100°C to dissolve. The reactor was cooled to 80°C. To the solution in the reactor, **a seed slurry containing** compound 1 **free base (Form A) seed crystals (0.1 g, 0.2 mmol, 0.005 eq.**) suspended in 1-butanol (5 mL, 0.25 mL/g of starting material) **was charged to induce crystallization**. The resulting slurry was stirred at 80 °C for 3 hours. The slurry was cooled to 10 °C at 0.2 °C/min over 350 minutes, granulated, and filtered. The cake was washed with anisole followed by heptane, and dried under vacuum.

[0223] This method generated the large primary particle size crystals of the free base of compound 1, which were equivalent to the free base prepared using the one-pot method described in Example 7 below.

③ Furthermore, since API powders are typically groups of particles with different sizes, it is not possible to define their size by the size of a single particle alone, and thus, it is common to express particle size-related characteristics probabilistically and statistically to distinguish it from other powders and particle sizes. As in the description below, the patented invention has limited the particle size within a numerical range obtained by analyzing D90 and D[4,3] values, which are commonly used for particle distribution in the technical field, to differentiate it from particles with small primary sizes.

9) Polarized Light Microscopy

Specification of the Patented Invention (Plaintiff's Exhibit 2)

[0011] The present invention provides the crystalline free base of compound 1 having larger primary particle size, greatly reduced specific surface area, and lower surface energy measurements than the free base provided by traditional salt break methods described in the art. The large particle size compound 1 free base disclosed herein is distinguishable by a variety of methods.

[0016] In some embodiments described herein, the compound 1 free base of the invention is distinguished by particle size analysis. In some such embodiments, the crystalline free base has a primary particle size of from about 5 μm to about 150 μm, preferably from about 10 μm to about 100 μm, or more preferably from about 15 μm to about 80 μm. In other such embodiments, the crystalline free base has a primary particle size distribution characterized by: (i) a D10 value of from about 5 μm to about 10 μm; (ii) a D50 value of from about 10 m to about 45 μm; or **(iii) a D90 value of from about 30 μm to about 125 μm**; or a combination of (i), (ii) and (iii). In additional embodiments, the crystalline free base has a primary particle size distribution ratio of (D90-D10)/D50 of from about 2 to about 3. In further embodiments, **the crystalline free base has a volume mean diameter (D[4,3]) of from about 15 μm to about 125 μm**.

[0041] The present invention provides compound 1 free base having larger primary particle size, greatly reduced specific surface area, and lower surface energy measurements than the free base provided by traditional salt break methods. For convenience, **the compound 1 free base provided by the invention may sometimes be referred to herein as the "large (primary) particle size" free base. This is in contrast to the free base of compound 1 prepared through traditional salt break methods, which is sometimes referred to as the "small (primary) particle size" free base**. It will be understood by those of skill in the art that the reference to "small particle size" in this case refers to the particle size of individual API crystals, and does not take into account the propensity of the "small" particles to form large agglomerates.

[0046] In some embodiments described herein, the crystalline free base of compound 1 is **distinguished** by particle size analysis. (Omitted)

[0047] In other such embodiments, the free base has a primary particle size distribution characterized by: (i) a D10 value of from about 5 μm to about 10 μm; (ii) a D50 value of from about 10 μm to about 45 μm; or (iii) a D90 value of from about 30 μm to about 125 μm; or a combination of (i),

(ii) and (iii). In additional embodiments, the free base has a primary particle size distribution ratio of (D90－D10)/D50 of from about 2 to about 3. In further embodiments, the free base has a volume mean diameter (D[4,3]) of from about 15 μm to about 125 μm.

[0050] In another aspect, the invention provides a crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a primary particle size distribution having at least one of:

[0051] (a) a D10 value of from about 5 μm to about 10 μm;

[0052] (b) a D50 value of from about 10 μm to about 45 μm; and

[0053] a D90 value of from about 30 μm to about 125 μm.

[0062] In still other embodiments, the free base has a primary particle size distribution having a D90 value of: from about 30 μm to about 175 μm; from about 30 μm to about 160 μm; from about 30 μm to about 150 μm; from about 30 μm to about 140 μm; from about 30 μm to about 130 μm; from about 30 μm to about 125 μm; from about 30 μm to about 120 μm; from about 30 μm to about 115 μm; from about 30 μm to about 110 μm; from about 30 μm to about 100 μm; from about 30 μm to about 75 μm; from about 30 μm to about 70 μm; from about 30 μm to about 65 μm; from about 30 μm to about 60 μm; from about 30 μm to about 55 μm; from about 30 μm to about 50 μm; or from about 30 μm to about 45 μm.

[0066] In yet another aspect, the invention provides a crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino) -8H -pyrido[2,3-d]pyrimidin-7-one, having a volume mean diameter (D[4,3]) of from about 15 μm to about 125 μm. In some embodiments, the free base has a D[4,3] of from about 50 μm to about 100 μm. In other embodiments, the free base has a D[4,3] of from about 15 μm to about 30 μm.

[0067] In still other embodiments, the free base has a D[4,3] of: from about 15 μm to about 100 μm; from about 15 μm to about 90 μm; from about 15 μm to about 80 μm; from about 15 μm to about 70 μm; from about 15 μm to about 60 μm; from about 15 μm to about 50 μm; from about 15 μm to about 40 μm; from about 25 μm to about 120 μm; from about 25 μm to about 100 μm; from about 25 μm to about 90 μm; from about 25 μm to about 80 μm; from about 25 μm to about 70 μm; from about 25 μm to about 60 μm; from about 25 μm to about 50 μm; from about 25 μm to about 40 μm; about 25 μm; about 30 μm; about 35 μm; about 40 μm; about 45 μm; about 50 μm; about 55 μm; about 60 μm;

about 65 μm; about 70 μm; about 75 μm; to about 80 μm; about 90 μm; about 100 μm; about 105 μm; about 110 μm; about 115 μm; or about 120 μm.

[0078] (Omitted) In other such embodiments, the free base has a primary particle size distribution characterized by: (i) a D10 value of from about 5 μm to about 10 μm; (ii) a D50 value of from about 10 μm to about 45 μm; or (iii) a D90 value of from about 30 μm to about 125 μm; or a combination of (i), (ii) and (iii). In additional embodiments, the free base has a primary particle size distribution ratio of (D90－D10)/D50 of from about 2 to about 3. In further embodiments, the free base has a volume mean diameter (D[4,3]) of from about 15 μm to about 125 μm.

[0238] Particle Size Analysis

[0240] Results

[0241] Comparative data for four batches of API are provided in Table 11 below, using either the Vibri or Aspiros devices to disperse the sample. Batch No. 4 had a D90 of around 75 μm, whereas Batch Nos. 1 and 2 both had a D90 of approximately 45 μm. The laser diffraction particle size data confirms the SEM observations for these batches.

[0242] Table 11. Comparative Size Distribution Data

Summary of PSD data		Particle size (μm)			
Batch No.	Disp. Method.	D[v, 0.1]	D[v, 0.5]	**D[v, 0.9]**	**D[4,3]**
1	0.2 bar ASPIROS	5.21	17.00	**43.59**	**21.33**
2	0.2 bar ASPIROS	6.20	20.83	**46.15**	**23.87**
3	0.2 bar ASPIROS	11.64	46.08	**130.26**	**59.07**
	0.5 Bar VIBRI	9.96	41.23	**116.43**	**53.02**
4	0.2 bar ASPIROS	7.41	24.97	**76.56**	**35.06**
	0.5 Bar VIBRI	6.33	23.19	**69.20**	**32.16**

(c) The Defendant argues that the core of the technical idea of the patented invention is “to produce larger particles than the palbociclib free base particles of small primary sizes obtained by the traditional salt break method to provide pharmaceutically manufacturable particles,” and that the numerical ranges in the claims are not of critical significance. Based on these, the Defendant argues that even if the Challenged Invention falls outside of these numerical ranges, it still shares the same problem-solving principle as the patented invention. However, based on ① to ⑦ below, which are recognized by the

descriptions of Plaintiff's Exhibits 2, 4, 6, and 11 and the overall purport of the arguments, it is reasonable to conclude that the numerical range limited in the claims of the patented invention indicates "a numerical range that leads to the effect intended by the patented invention" or "a numerical range that can predict whether such an effect will be achieved."

① In the field of pharmaceutics where the patented invention belongs, it is a widely known fact and is even included in pharmaceutics textbooks that very small particles generally have strong adhesiveness, and the smaller the particle size of the API, the more likely it is to form aggregates and negatively affect powder flow due to stickiness (Plaintiff's Exhibit 11, etc.). As mentioned above, particle size is an important process parameter in pharmaceutical production that affects the physicochemical and biopharmaceutical properties of the API, and issues of stickiness and aggregation can be resolved by making particles slightly larger than fine particles that have adhesiveness. Thus, finding the optimal particle size range for the API that can be prepared without stickiness or aggregation is a common technical problem in the field of the patented invention. Consequently, simply providing "particles larger than those with stickiness" cannot be regarded as the problem-solving principle unique to this patented invention.

② The recrystallization process adopted as the technical means in the patented invention to increase the particle size is a widely used technology in pharmaceutical production processes to control particle size. The description in Plaintiff's Exhibit 4 also supports this fact by indicating that palbociclib free base and salt compounds can be administered as crystalline products, and that favorable (for example, larger and more uniform) crystals can be obtained through seeding.[10)]

10) Here, it is presented using the Korean term "씨딩" while the specification of the patented invention uses the Korean term "시딩." The meaning remains the

Prior Art 1 (Plaintiff's Exhibit 4)

[0063] In another method, the free base (Formula 1) is dispersed (slurried) in a first solvent and is **seeded** with a crystalline isethionate salt form. (Omitted) Compared to the previously described process, this method often results in improved yields and **better (e.g., larger, more uniform) crystals**. **[0071]** **The disclosed compounds (Formula 1** and salts) may be administered as crystalline or amorphous products. They may be obtained, for example, as solid plugs, powders, or films by methods **such as precipitation, crystallization,** freeze-drying, spray drying, or evaporative drying. (Omitted)

③ However, the specification of the patent invention only describes that the free base provided by the conventional salt break process forms small primary particles (paragraphs [0009], [0021], [0041], [0101], [0102], and [0103] and Example 5 of Plaintiff's Exhibit 2) and does not disclose values in detail of the "small primary particle size." The comparison of the sizes of small primary particles (Batch 5) obtained through conventional salt break and larger particles (Batches 6 to 8) obtained through recrystallization only describes surface area data (Table 12 below). Surface area values depend not only on the size of the particles but also on their shape and surface irregularities, so the difference in surface area alone cannot conclusively confirm the difference in primary particle size.

Plaintiff's Exhibit 2 (The Specification of the Patented Invention)

[0272] Table 12 provides BET-N_2 SSA for four batches of compound 1 free base API, one comprising the small primary particle size API prepared by the traditional salt break method (batch 5), and three batches comprising the large particle size API prepared according to the present invention. Batch 5 contained compound 1 free base having small primary particles and large agglomerates, which was very static-prone and sticky. Batch 6 was

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same.

The term "seeding" used herein refers to the act of adding crystals to a crystallization system for the purpose of initiating or enhancing nucleation or acting as a substance for further crystallization (paragraph [0037] of Plaintiff's Exhibit 2).

prepared using temperature cycling and had a typical particle size distribution (PSD) for the large particle size free base of compound 1, with a VMD of approximately 17 μm. (Omitted)

[0273] Table 12. BET SSA by N_2

Batch No.	BET SSA by N2
5	6.6
6	0.62
7	0.69
8	0.67

④ Moreover, the specification of the patented invention states, “In either process, small API primary particles were produced due to the rapid crystallization caused by the dramatic change in solubility with adjustment of the pH” (paragraph [0102] of Plaintiff’s Exhibit 2). However, the fact that the size of the crystals varies with the cooling rate is a technological common sense in the technical field where the patented invention belongs, and in fact, before the priority date of this patented invention, in addition to the “rapid cooling” method of palbociclib free base through the traditional salt break method, a “slow cooling” method was also disclosed, where triethylamine, a base, is gradually added to palbociclib isethionate to form a palbociclib free base solution at a slow rate and polymorphic seeds were added to obtain the palbociclib free base (Example 6 of Plaintiff’s Exhibit 6). Although specific particle size analysis values are not provided, it can be assumed that the size of the primary particles of the palbociclib free base obtained through the conventional salt break method can vary significantly depending on the process conditions.

⑤ Since the patented invention also manufactures large palbociclib free base particles through a recrystallization process, the particle size will similarly vary depending on the conditions of the recrystallization process, which is supported by Table 11 below where the D90 values for each batch number vary among 43.59 μm, 46.15 μm,

130.26 μm, and 76.56 μm.

Summary of PSD data		Particle size (μm)			
Batch No.	Disp. Method.	D[v, 0.1]	D[v, 0.5]	**D[v, 0.9]**	**D[4,3]**
1	0.2 bar ASPIROS	5.21	17.00	**43.59**	**21.33**
2	0.2 bar ASPIROS	6.20	20.83	**46.15**	**23.87**
3	0.2 bar ASPIROS	11.64	46.08	**130.26**	**59.07**
	0.5 Bar VIBRI	9.96	41.23	**116.43**	**53.02**
4	0.2 bar ASPIROS	7.41	24.97	**76.56**	**35.06**
	0.5 Bar VIBRI	6.33	23.19	**69.20**	**32.16**

Furthermore, according to Defendant's Exhibit 11, crystallization includes nucleation and growth processes, and the nucleation and growth rates vary depending on the relative supersaturation and the resulting different particle sizes, and thus, even the same solvent system of "n-butanol/anisole" as in the patented invention can result in particles of different sizes. Therefore, the "traditional salt break method" will also result in different primary particle sizes depending on whether it is slowly cooled or rapidly cooled, how fast the base was added, or how much the base was ultimately added (which can be expressed by pH). The latter two factors can influence the supersaturation.

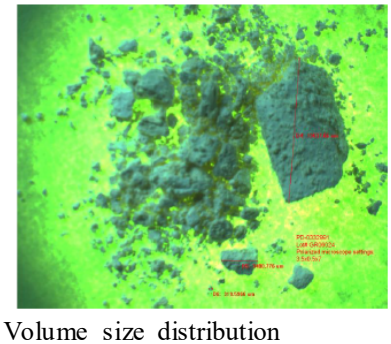
⑥ Furthermore, the "primary particle size obtained by the traditional salt break method" can vary depending on the process conditions, and even considering the evidence submitted by the Defendant, the size range of the "small primary particles of palbociclib free base obtained by the traditional salt break method," which the Defendant claims to be different from the patented invention, is not specifically defined.

ⓐ First, we examine Defendant's Exhibits 4 and 5 submitted by the Defendant as evidence supporting the claim that the "small primary particle size obtained by the traditional salt break method" can be verified.

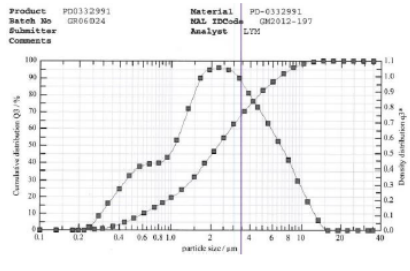
Defendant's Exhibits 4 and 5 (Plaintiff's Exhibits 7 and 8)[11)]

Experiment Title	Particle size assessment of Batch No. GR06024 of Pd-0332991
Type of Work	API
Category of Work	Release
Purpose of Work	Clinical Release Test
Purpose	Particle size assessment of Batch No. GR06024 of Pd-0332991 for information
Results	The samples were observed under a polarizing microscope. The unmilled samples exhibited sizes ranging from ~0.3mm to 13mm. The data is for informational purposes.

편광 현미경 사진(을 4)



레이저 회절 입자 분석 데이터(을 5)



Volume size distribution

D10=	0.61㎛	D50=	2.32㎛	D90=	6.77㎛	D95=
D16=	0.85㎛	D84=	5.47㎛	D[4,3]=	3.09㎛	

Volume size distribution

D10=	0.62㎛	D50=	2.29㎛	D90=	6.62㎛	D95=
D16=	0.85㎛	D84=	5.33㎛	D[4,3]=	3.04㎛	

Volume size distribution

D10=	0.62㎛	D50=	2.31㎛	D90=	6.75㎛	D95=
D16=	0.86㎛	D84=	5.43㎛	D[4,3]=	3.09㎛	

Defendant's Exhibits 4 and 5 above are internal experimental data from the Defendant, and it is confirmed that the compound being

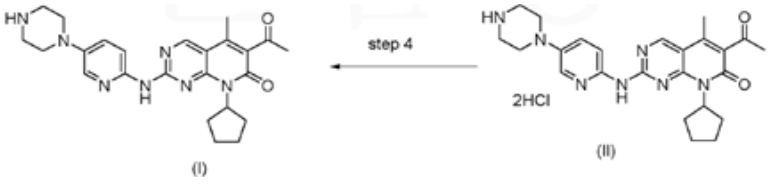
11) These are the documents submitted by the Defendant as Defendant's Exhibits 2 and 3 during the trial stage.

analyzed is PD-0332991, which indicates that the data pertains to the analysis of the particle size of Palbociclib. However, the descriptions do not specifically mention the preparing method, and thus, it is unclear whether they were obtained through a traditional salt break method. Even if the particles were obtained through a traditional salt break method as the Defendant argues, the specific conditions of the traditional salt break method used to obtain the particles are not described. The data is merely recorded under batch No. GR06024, and Defendant's Exhibit 4 describes the size of the "unmilled sample," and thus, there is a possibility that the analyzed D[4,3] values (3.04 μm, 3.09 μm) and D90 values (6.62 μm, 6.77 μm, 6.75 μm) were obtained by analyzing the size of the milled (ground) samples. Therefore, it is difficult to conclude that the above data clearly demonstrates the size range of the primary particles obtained through a traditional salt break method.

ⓑ Additionally, according to Defendant's Exhibit 7,[12] the primary particles of Palbociclib are obtained through a traditional salt break method, and the particle size distribution specifically observed in the examples shows a D90 value of 7.69 μm and accordingly, the range for the D90 value described as "about 7 μm to about 15 μm." This contrasts with the particle size distribution in Defendant's Exhibit 5, which has a different particle size range.

Defendant's Exhibit 7

[Scheme I of p. 9]



12) This is WO 2018/073574 A1 (April 26, 2018) published after the priority date of the patented invention. However, the "particle size obtained through the traditional salt break method" is a scientific fact that is independent of its public disclosure date, and therefore, it can be referenced when reviewing the particle size.

[Paragraph 3 on page 11]

On one hand, as shown in step (4) of Scheme I, the present invention involves separating compound (I) from compound (II) using a suitable solvent under basic conditions. (Omitted)

The basic conditions can be achieved by **slowly adjusting the pH of the reaction mixture to 8-8.5** using a 5% sodium hydroxide aqueous solution. During the forming process, compound (I) is preferably isolated and further dried at a temperature in the range of about 55°C to about 65°C, preferably for about 8 to about 10 hours.

[From paragraph 6 on page 14]

Suitable bases include organic bases such as methylamine, dimethylamine, triethylamine, etc. and inorganic bases such as sodium hydroxide, potassium hydroxide, sodium carbonate, potassium carbonate, sodium bicarbonate, potassium bicarbonate, sodium methoxide, and potassium methoxide.

The process involves isolating and drying crystalline form A of palbociclib free base in its solid form. Any suitable technique known in the art may be used, for example, filtration followed by drying under vacuum.

In one embodiment, the present invention has a surface area of 2 m^2/g or more, preferably in the range of about 5 to about 8 m^2/g, and a particle size distribution (PSD) that is at least one of the following:

(i) a D10 value in the range of about 1 µm to about 5 µm, preferably in the range of about 1 µm to about 3 µm; and/or

(ii) a D50 value in the range of about 2 µm to about 7 µm, preferably in the range of about 3 µm to about 5 µm; and/or

(iii) a **D90 value in the range of about 7 µm to about 15 µm, preferably in the range of about 8 µm to about 13 µm**.

[Paragraph 2 on page 16]

[Page 24]

Example 4: Preparation of crystalline free base form A of palbociclib with a surface area of 2 m^2/g or more (I).

Added to 10 volumes of water and 10 volumes of methanol were 100 gm of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino) -8H-pyrido[2,3-d]pyrimidin-7-one.2HCl (II). The substance was heated to 35-45°C and stirred for 20 minutes. The pH of the solution was **slowly** adjusted to 8-8.5 at 35-45°C using a 5% NaOH aqueous solution and the mixture was stirred for 180 minutes at 35-45°C. The obtained product was filtered and washed with 3 volumes of hot water. The solid was further

dried under vacuum at 50-60°C for 8 hours to obtain 74 gm of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one (I).
Surface area (m^2/g) by BET: 5.575 m^2/g
Particle size distribution (PSD): D10 (μm): 0.811 μm; D50 (μm): 2.26 μm; D90 (μm): 7.69 μm.
Example 5 Preparation of crystalline free base form A of palbociclib with a surface area of 2 m^2/g or more (I).
Added to 18 volumes of water and 4 volumes of methanol were 100 gm of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino) -8H-pyrido[2,3-d]pyrimidin-7-one.2HCl (II). The substance was heated to 35-45°C and stirred for 20 minutes, then further filtered through a high-flow bed and washed with methanol. The pH of the solution was **slowly** adjusted to 8-8.5 at 35-45°C using a 5% NaOH aqueous solution and the mixture was stirred for 180 minutes at 35-45°C. The obtained product was filtered and washed with 3 volumes of hot water. The solid was further dried under vacuum at 50-60°C for 8 hours to obtain 74 gm of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3- i]pyrimidin-7-one (I).
Surface area (m^2/g) by BET: 6.5358 m^2/g

However, the rate of adding the base and the final pH are different between the preparing method of Defendant's Exhibit 7 and Example 5 of the specification of the patented invention in this case. Due to these differences, it is likely that the relative supersaturation of the final reaction mixture will vary. Additionally, since the cooling rates are different, the rate of change in supersaturation of the reaction mixtures will also differ, which will result in varying nucleation rates and crystal growth rates in the two reaction mixtures.

	Plaintiff's Exhibit 2	Defendant's Exhibit 7
API Form	Palbociclib mesylate	Palbociclib maleate
Base	NaOH solution at **35°C** >pH 9	Slowly adjusted to **pH 8-8.5** using a NaOH solution at **35-45°C, and stirred for 180 minutes**
Cooling, etc.	**Cooled to 20 to 25°C (rapid cooling)**. Granulation, filtration	Filtration of the product

Additionally, Plaintiff's Exhibit 6 uses the weak base triethylamine in a traditional salt break method. Using that weak base and the strong base sodium hydroxide would result in different acid-base reaction rates. Accordingly, the rate at which the palbociclib free base is isolated would also differ and so does the rate of supersaturation.

As such, the size of the "small primary particles obtained through the traditional salt break method" is likely to vary significantly depending on the reaction conditions, and thus, a size value cannot be defined specifally.

⑦ The claims of the patented invention include "± 20%" within the numerical range, whereas the description of the invention does not include such a description for the numerical range and simply specifies the range for D90 as "from about 30 μm to about 175 μm; from about 30 μm to about 160 μm; from about 30 μm to about 150 μm; from about 30 μm to about 140 μm; from about 30 μm to about 130 μm; from about 30 μm to about 125 μm; from about 30 μm to about 120 μm; from about 30 μm to about 115 μm; from about 30 μm to about 110 μm; from about 30 μm to about 100 μm; from about 30 μm to about 75 μm; from about 30 μm to about 70 μm; from about 30 μm to about 65 μm; from about 30 μm to about 60 μm; from about 30 μm to about 55 μm; from about 30 μm to about 50 μm; or from about 30 μm to about 45 μm" (paragraph [0062] of Plaintiff's Exhibit 2). The Defendant, as the patent holder, would

argue that it has specified the matter it seeks to protect as the range of "30 μm ± 20% to 65 μm ± 20%," and it is reasonable to interpret the "± 20%" as reflecting a statistically meaningful range for the term "about," meaning "typically within 20% of the presented value or range" (paragraph [0027] of Plaintiff's Exhibit 2).

2) As the Challenged Invention, which has different D[4,3] and D90 values from the numerically limited elements that form the core of the technical idea underlying the problem-solving principle of Claims 1 and 2 of the patented invention, cannot be considered as having the same solution principle as the patented invention, it cannot be deemed to fall within the scope of rights of the patented invention.

b) Whether the two inventions have the same effects

(1) The patented invention provides palbociclib crystalline form A with a specific particle size range to achieve improved physicochemical properties, and its effect is that it reduces adhesion to the punch and prevents the formation of agglomerates, which makes subsequent preparation possible. As previously examined, the Challenged Invention has a different solution principle from the patented invention, so the two inventions do not have the same effects.

(2) Meanwhile, the Defendant argues that since Defendant's Exhibit 6 discloses the particle size of palbociclib with improved manufacturability, and the disclosed particle size has a D90 value ranging from 5 to 50 μm, which includes the Challenged Invention with a D90 value of 20 μm or less, the Challenged Invention has substantially the same effects as the patented invention. [13)]

However, the patented invention is characterized by providing particles with specific numerical ranges for the particle size assessment

13) The Defendant argued as stated above in the response dated March 24, 2023. However, in the written statement dated May 16, 2023, the Defendant claimed that Defendant's Exhibit 6 was submitted not to demonstrate the "identity of the effects" as a requirement for establishing equivalence, but to prove the "ease of modification."

parameters, D[4,3] and D90 values for improved physical properties, achieved by adopting a suitable recrystallization solvent system to obtain primary particles of small size that do not have adhesiveness and can be prepared. However, the palbociclib free base particles disclosed in Exhibit 6 are obtained by crushing agglomerates produced through a traditional salt break method using a 0.8 mm mesh sieve. Therefore, this is simply the result of a different technical approach, applying a different method from the patented invention, which addresses issues such as adhesiveness caused by the fine size of the API and prepares the product. Therefore, it cannot be concluded that the Challenged Invention has substantially the same effects as the patented inventions of Claims 1 and 2, merely based on the particle size disclosed in Defendant's Exhibit 6.[14)]

Defendant's Exhibit 6 (Plaintiff's Exhibit 9)[15)]

[0009] The present invention relates to a pharmaceutical granular composition comprising a therapeutically effective amount of crystalline palbociclib and one or more pharmaceutically acceptable excipients, where **the palbociclib crystals are needle-shaped with a surface area of 6 to 10 m²/g and a particle size distribution d(0.9) of 5 to 50 μm**.

[0023] The palbociclib of the present invention has a large surface area and **a small particle size**. These characteristics may lead to the production of formulations with high solubility, which may not be biologically equivalent to the marketed product. This issue can be resolved by adding one or more dissolution modifiers to the composition.

Example 1. Preparation of Palbociclib Free Base

[0094] 3.4 kg of palbociclib was mixed with 3.68 kg of water to form a suspension. The mixture was combined with 17 kg of water, and 0.86 kg of HCl (35-39%, w/w) was added to the mixture. The mixture was heated

14) The Defendant also acknowledged in the preparatory document dated May 16, 2023, that it "did not claim that all D90 values within the range of 5 to 50 μm of Defendant's Exhibit 6 necessarily have the same effect as the patented invention."

15) This is the document submitted by the Defendant as Defendant's Exhibit 4 during the trial stage.

to 40°C to dissolve the palbociclib, and the pH of the solution was adjusted to 3 to 4 using HCl. Subsequently, the **palbociclib.HCl** solution was filtered.

[0095] The **NaOH** solution was prepared by dissolving 0.37 kg of NaOH in 5 kg of water. The solution was added to the palbociclib.HCl solution over 60-80 minutes until the final **pH reached 11-12.5.** A yellow solid of **palbociclib free base precipitated** from the mixture.

[0096] The separated solid was isolated by filtration and washed with 9.1 kg of water and 2.5 kg of acetone. The obtained solid was dried on the filter for at least 12 hours. The solid was then dried at room temperature for more than 10 hours. **The solid was ground through a 0.8 mm mesh sieve.** The ground product was dried at 28-30°C for at least 4 hours.

[0097] **Palbociclib** in a needle shape with a surface area of 6.9 m^2/g and **a D90 of 11.5 μm** was obtained.

Similarly, based on the details provided in Defendant's Exhibit 7 presented by the Defendant, it is difficult to acknowledge that the Challenged Invention in this case has the same effects as Claims 1 and 2, and there is no other evidence to support this.

c) Summary of analysis

The Challenged Invention does not share the same problem-solving principle or effects as the inventions of Claims 1 and 2 in this case. Therefore, the Challenged Invention is not considered equivalent to Claims 1 and 2 and there is no need to examine it further.

5) Summary

The Challenged Invention does not fall within the scope of rights of Claims 1 and 2 of the Subject Invention.

B. Whether the Challenged Invention Falls within the Scope of Claims 3, 4, and 8 of the Subject Invention

Claims 3 and 4 cite Claims 1 or 2 and further limit the characteristics of crystalline form A particles by the XRD diffraction pattern. Claim

8 relates to the pharmaceutical use of the crystalline form A particles of the free base according to Claims 1 or 2 and includes the technological characteristic of Claims 1 or 2 while further limiting other characteristics. Therefore, as previously examined, since the Challenged Invention cannot be considered within the scope of the rights of Claims 1 or 2, it also cannot be considered within that of Claims 3, 4, and 8.

[The Defendant argues that the Challenged Invention is unlawful because it includes multiple examples with different scopes of rights and features an invention that cannot be practiced, and requests the resumption of the proceedings. However, for the following reasons, the Defendant's argument cannot be accepted. As previously discussed, the solution principle of the patented invention is "to provide palbociclib particles with physicochemical properties improved by making the palbociclib free base obtained through recrystallization from a conventional salt break method have a particle size with a D[4,3] value of 15 μm ± 20% to 30 μm ± 20% and a D90 value of 30 μm ± 20% to 65 μm ± 20%." Therefore, the Challenged Invention with D90 and D[4,3] values specified as below the aforementioned numerical ranges, does not change the scope of rights when compared to the patented invention. Additionally, the Defendant argues that the Challenged Invention is a "crystalline particle" but does not define a lower limit for the D90 value and includes "0," and therefore, the Challenged Invention is unclear and includes an invention that cannot be practiced. However, the Challenged Invention relates to "crystalline particles of the palbociclib free base," and the term "particle" refers to a small-sized object that constitutes the material. Since a particle with a D90 value of "0" cannot exist scientifically, it is reasonable to interpret that the technical meaning of "particles with a D90 value of 20 μm or less" does not include particles that are impossible to classify as crystalline particles, as they have a D90 value of 0 μm or are extremely close to 0 μm. Therefore, the Defendant's claim that the Challenged Invention includes an unclear or unpracticable invention is

also without merit.

4. Conclusion

The IPTAB Decision is inconsistent with the above analysis. Therefore, the Plaintiff's claim requesting the revocation of the decision is meritorious and shall be granted. It is so ordered.

Presiding Judge Jaheun KU
Judge Hyejin LEE
Judge Young Gi KIM

[Appendix 1]

Main Content of the Patented Invention

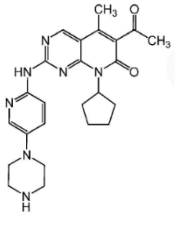
Technical field

[001] This invention relates to the free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one having improved physicochemical properties. (Omitted)

Prior art

[0004] The compound 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one (also referred to herein as "compound 1"), may be represented by the structure and is also known as palbociclib or PD-0332991:

[0005] [Formula 1]

[0006] 

[0008] (Omitted) International Publication No. WO 2005/005426 and U.S. Pat. Nos. 7,345,171 and 7,863,278 describe preparation of the free base and various mono- and di-acid addition salts of compound 1, including polymorphic forms of the isethionate salt. A process for the preparation of compound 1 as a mono-isethionate salt is described in International Publication No. WO 2008/032157 and U.S. Pat. No. 7,781,583. The contents of each of the foregoing references are incorporated herein by reference in their entirety.

[0009] While compound 1 is a potent and selective CDK4/CDK6 inhibitor, its use as a free base presented challenges for pharmaceutical development. The free base provided by traditional salt break procedures, e.g., as in Example 4 of WO 2005/005426, was highly static prone and formed small primary particles, which agglomerated into large, hard agglomerates that were difficult to disperse by sieving and were unsuitable for further development. The present invention provides compound 1 free base having larger primary particle size that demonstrates improved physicochemical and

manufacturability properties.

Summary of the Invention

[0011] The present invention provides the crystalline free base of compound 1 having larger primary particle size, greatly reduced specific surface area, and lower surface energy measurements than the free base provided by traditional salt break methods described in the art. The large particle size compound 1 free base disclosed herein is distinguishable by a variety of methods.

[0012] The polymorphic and solid forms of the invention can be distinguished by powder X-ray diffractometry (PXRD), solid state NMR (ssNMR), differential scanning calorimetry (DSC), vibrational spectroscopy (e.g., IR and Raman spectroscopy), polarized light microscopy (PLM), scanning electron microscopy (SEM), hot stage optical microscopy, electron crystallography, single crystal X-ray diffractometry, quantitative analysis, particle size analysis (PSA) (e.g., particle size, particle size distribution (PSD), and particle shape), specific surface area (SSA) analysis, surface energy analysis (e.g., inverse gas chromatography or IGC), by solubility studies and dissolution studies, or a combination of these techniques.

[0014] In preferred embodiments, the crystalline free base of compound 1 is a polymorph Form A of the free base. In some such embodiments, the crystalline free base has a PXRD pattern comprising a peak at diffraction angle (2θ) of 10.1±0.2. (Omitted) In still other embodiments, the crystalline free base has a PXRD pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2, and 11.5±0.2. (Omitted)

[0016] In some embodiments described herein, the compound 1 free base of the invention is distinguished by particle size analysis. In some such embodiments, the crystalline free base has a primary particle size of from about 5 μm to about 150 μm, preferably from about 10 μm to about 100 μm, or more preferably from about 15 μm to about 80 μm. In other such embodiments, the crystalline free base has a primary particle size distribution characterized by: (i) a D10 value of from about 5 μm to about 10 μm; (ii) a D50 value of from about 10 μm to about 45 μm; or (iii) a D90 value of from about 30 μm to about 125 μm; or a combination of (i), (ii) and (iii). In additional embodiments, the crystalline free base has a primary particle size distribution ratio of (D90－D10)/D50 of from about 2 to about 3. In further embodiments, the crystalline free base has a volume mean diameter (D[4,3]) of from about 15 μm to about 125 μm.

[0027] As used herein, the term “about” means within a statistically

meaningful range of a value, such as a stated concentration range, time frame, molecular weight, particle size, temperature or pH. Such a range can be within an order of magnitude, typically within 20%, more typically within 10%, and even more typically within 5% of the indicated value or range. (Omitted)

[0039] As used herein, the term "primary particles" refers to individual API crystals.

[0040] As used herein, the term "agglomerates" refers to tightly bound API crystals that are difficult to disperse into primary particles during processing and particle size analysis.

[0041] The present invention provides compound 1 free base having larger primary particle size, greatly reduced specific surface area, and lower surface energy measurements than the free base provided by traditional salt break methods. For convenience, the compound 1 free base provided by the invention may sometimes be referred to herein as the "large (primary) particle size" free base. This is in contrast to the free base of compound 1 prepared through traditional salt break methods, which is sometimes referred to as the "small (primary) particle size" free base. It will be understood by those of skill in the art that the reference to "small particle size" in this case refers to the particle size of individual API crystals, and does not take into account the propensity of the "small" particles to form large agglomerates.

[0046] In some embodiments described herein, the crystalline free base of compound 1 is distinguished by particle size analysis. (Omitted)

[0047] In other such embodiments, the free base has a primary particle size distribution characterized by: (i) a D10 value of from about 5 μm to about 10 μm; (ii) a D50 value of from about 10 μm to about 45 μm; or (iii) a D90 value of from about 30 μm to about 125 μm; or a combination of (i), (ii) and (iii). In additional embodiments, the free base has a primary particle size distribution ratio of (D90－D10)/D50 of from about 2 to about 3. In further embodiments, the free base has a volume mean diameter (D[4,3]) of from about 15 μm to about 125 μm.

[0050] In another aspect, the invention provides a crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a primary particle size distribution having at least one of:

[0051] (a) a D10 value of from about 5 μm to about 10 μm;

[0052] (b) a D50 value of from about 10 μm to about 45 μm; and

[0053] a D90 value of from about 30 μm to about 125 μm.

[0062] In still other embodiments, the free base has a primary particle size distribution having a D90 value of: from about 30 μm to about 175 μm; from about 30 μm to about 160 μm; from about 30 μm to about 150 μm; from about 30 μm to about 140 μm; from about 30 μm to about 130 μm; from about 30 μm to about 125 μm; from about 30 μm to about 120 μm; from about 30 μm to about 115 μm; from about 30 μm to about 110 μm; from about 30 μm to about 100 μm; from about 30 μm to about 75 μm; from about 30 μm to about 70 μm; from about 30 μm to about 65 μm; from about 30 μm to about 60 μm; from about 30 μm to about 55 μm; from about 30 μm to about 50 μm; or from about 30 μm to about 45 μm.

[0066] In yet another aspect, the invention provides a crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)- 8H-pyrido[2,3-d]pyrimidin-7-one, having a volume mean diameter (D[4,3]) of from about 15 μm to about 125 μm. In some embodiments, the free base has a D[4,3] of from about 50 μm to about 100 μm. In other embodiments, the free base has a D[4,3] of from about 15 μm to about 30 μm.

[0101] U.S. Pat. No. 7,345,171 reported that the free base of compound 1, prepared by a traditional salt break procedure, had poor water solubility (9 μg/mL) at pH 7.9 and exhibited low bioavailability in animal studies. The free base was reported to be in its most stable crystal phase according to slurry experiments (i.e., Form A). FIG. 17 of U.S. Pat. No. 7,345,171 provided the water adsorption/desorption isotherms for the free base of Form A. As noted previously, this material corresponds to the small particle size free base of compound 1 described herein.

[0102] The free base of compound 1 (Form A) has a high propensity for punch sticking in the drug particle manufacturing process. As punch sticking is related to API surface area, API particle size control is critical for minimizing sticking during drug product manufacturing. In addition to issues with punch sticking, compound 1 free base isolated directly from a standard salt break process was found to be highly static prone and found to form large (approximately 500 μg) hard agglomerates that were not dispersed by sieving. Free base API with similarly poor physical properties was produced by free basing of the existing isethionate salt API or by neutralization of the in situ salt formed in the final step of the API synthesis. In either process, small API primary particles were produced due to the rapid crystallization

caused by the dramatic change in solubility with adjustment of the pH. In all cases, the free base is isolated as the more stable polymorph of form A.

[0103] FIG. 6 shows a scanning electron microscopy (SEM) image of typical small primary particles formed by the free basing and neutralization experiments described above. The particle size distribution measurement for a batch of compound 1 (Form A) produced by this free base isolation process is provided in FIG. 8. The second mode in the particle size distribution was caused by the presence of large agglomerates, which are also seen in the SEM image in FIG. 6. Attempts to modify the free basing process were not successful in improving the physical properties of the API produced. As the process for producing free base resulted in the isolation of API with poor physical properties, work was undertaken to identify a recrystallization process that could improve the API physical properties.

FIG. 6

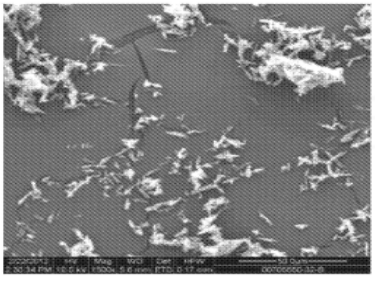
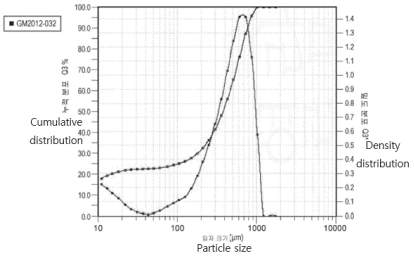


FIG. 8



[**0104**] Early crystallization screening experiments for compound 1 free base were completed to identify a solvent system that allows for the isolation of particles with improved physical properties. A combination of solubility screening and small-scale recrystallization studies examined multiple potential solvent systems.

[0105] Small-Scale Crystallization Studies

[0106] A series of small-scale crystallization experiments was run to identify a potential recrystallization solvent system as well as to assess the impact of solvent on the shape of the free base primary particles isolated. An initial set of 14 screening studies were run on a 10 mg scale using sealed vials and an external heat source to warm the 50 mg/mL samples up to reflux temperature. Visual observation identified the samples that went into solution, and photomicroscopy was used to characterize the particles produced. The results of these initial crystallization screening experiments are summarized in Table 5.

[0107] Table 5. Summary of results from preliminary small scale crystallization studies

Solvent System	Results of recrystallization
Cyclopentylmethyl ether	did not dissolve
n-Butyl Acetate	did not dissolve
n-Butanol	did not dissolve
Trifluorotoluene	did not dissolve
Toluene	did not dissolve
Chlorobenzene	small irregular shaped particles
DMF	small needle shaped particles
NMP	small irregular shaped particles
Propylene glycol	small irregular shaped particles
Anisole	large particles (lathes or tomahawk shape)
Pyridine	small lathe shaped particles
Sulfolane	small irregular shaped particles
m-Xylene	small/medium tomahawk shaped particles
Mesitylene	small needle shaped particles

[0108] Based on these small-scale crystallization studies, anisole became the focus of additional crystallization and solubility studies as the particles produced were large and as anisole is an ICH Class III solvent. This screening study also identified pyridine, m-xylene, and mesitylene as potential solvent systems based on the particles produced, although none of these solvents also have the ICH class III listing similar to anisole.

[0109] The following solvents have also been used for recrystallization of the solid: isopropanol, isobutanol, ethanol, ethyl acetate, toluene, tetrahydrofuran, and dioxane. Each of the solvents generated the polymorph Form A crystalline solid of compound 1 which was the same as the original crystalline form obtained from dichloromethane.

[0110] Solubility Studies:

[0111] In parallel with the initial small-scale crystallization studies, a series of solubility studies were conducted on the free base of compound 1 to identify a possible recrystallization system. In an initial room temperature solubility screening study, a total of 23 solvents were screened. This study indicated that the compound 1 free-base has low solubility in a range of organic solvents, with only methylene chloride displaying a solubility greater than 1 mg/mL (3.0 mg/mL). Subsequent targeted higher temperature solubility studies were conducted. In a follow-up study, a set of 16 solvent

systems were examined at a fixed concentration of 25 mg/mL, and the dissolution temperature was measured using a kinetic solubility method up to a maximum temperature of 110°C.

[0112] Synergistic solubility behavior predicted by a COSMOtherm solubility model of compound 1 was used to select the binary and ternary solvent systems included in this screening study. The results of these studies are listed in Table 6. For experiments listed as >110°C in the table, compound 1 did not dissolve in the solvent upon heating to 110°C, indicating that the solubility is less than 25 mg/mL at 110°C in this solvent.

[0113] TABLE 6. Kinetic solubility measurements for 25 mg/mL compound 1 free

Experiment #	Solvent	Dissolution Temp. (°C)
1	n-BuOH	>110°C
2	DMF	>110°C
3	NMP	97.9°C
4	DMSO	>110°C
5	DMAc	>110°C
6	n-Butyl Acetate	>110°C
7	Anisole	>110°C
8	10% n-BuOH/Anisole (v/v)	>110°C
9	20% n-BuOH/Anisole (v/v)	109.7°C
10	40% n-BuOH/Anisole (v/v)	101.4°C
11	10% n-BuOH/NMP (v/v)	103.7°C
12	25% n-BuOH/NMP (v/v)	>110°C
13	10% 1,4-butanediol/anisole (v/v)	109.8°C
14	25% 1,4-butanediol/anisole (v/v)	104.8°C
15	1:1:8 propylene glycol/n-BuOH/anisole (v/v)	91.2°C
16	2:1:7 propylene glycol/n-BuOH/anisole (v/v)	84.1°C

[0116] Based on these screening studies, a mixture of 40% n-butanol and anisole was selected as the crystallization solvent system for further work, in view of the relatively high solubility, chemical stability of the API, and particle properties of the recrystallized compound 1 API. This solvent system was used in subsequent production to provide larger primary particle size API that had reduced sticking, was not static prone, and was free of agglomerates.

[0117] Using this solvent mixture, compound 1 was dissolved with 40mL/g of solvent (concentration of 25 mg/mL) by heating to 95-100 °C., before being

crystallized using a controlled cooling profile and seeding to induce nucleation. FIG. 9 is a PLM image of a lab-scale lot of compound 1 recrystallized using this recrystallization procedure, while FIG. 7 displays a particle size distribution for three lots of recrystallized API. This recrystallization process results in the isolation of compound 1 API particles with a larger primary particle size, which leads to a decrease in the sticking tendency in the drug product manufacturing process. This recrystallized compound 1 API does not form agglomerates and also has the positive attribute of not being static prone.

FIG. 9

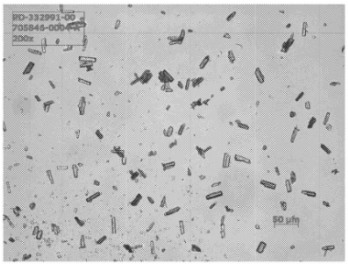
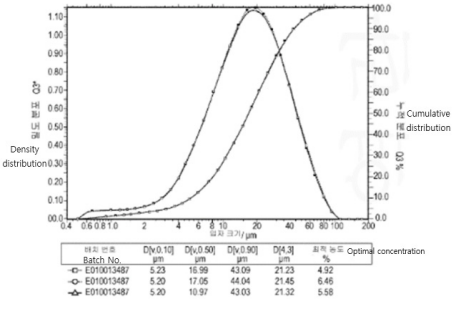


FIG. 7



[0118] The combination of solubility screening and small-scale recrystallization studies examined multiple potential solvent systems for the recrystallization of compound 1 free base. Based on the results from these screening studies, a mixture of 40% n-butanol/anisole was selected as the preferred crystallization solvent system based on the relatively high solubility, chemical stability of the API, and particle properties of the recrystallized compound 1. The larger particle size and improved particle properties of the API isolated from this recrystallization process facilitated the development of a drug product manufacturing process for compound 1 free base.

[0119] Particle Size Assessment

[0120] Particle sizes for the recrystallized materials were assessed using laser diffraction methods. Laser diffraction is recognized by standards and guidance agencies including ISO and ASTM and is widely used to determine particle size distributions. (Omitted)

[0122] In particle size determinations, the median value is defined as the value where half of the population resides above this point, and half resides below this point. For particle size distributions the median is called the D50. The D50 is the size in microns that splits the distribution with half above

and half below this diameter. The expression Dv50 or D[v,0.5] is sometimes used for the median of a volume distribution.

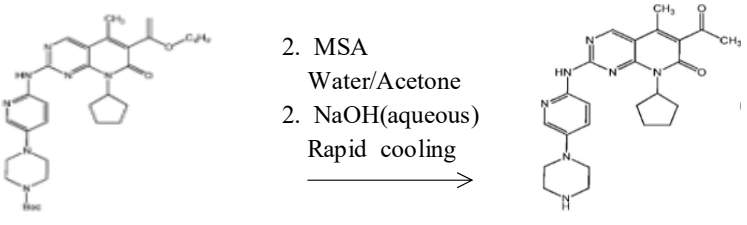
[0125] The distribution width may also be characterized by citing one, two or preferably three values on the x-axis, typically some combination of the D10, D50, and D90. The D50, the median, has been defined above as the diameter where half of the population lies below this value. Similarly, 90 percent of the distribution lies below the D90, and 10 percent of the population lies below the D10.

[0126] The term D[4,3] refers to the volume mean or mass moment mean. Laser diffraction results are reported on a volume basis and the volume mean can be used to define the central point of the distribution. The D[4,3] value is sensitive to the presence of large particles in the distribution.

[0162] Example

[0213] Example 5. Preparation of Small Particle Size Free Base of Compound 1 by Salt Break Method

[0214]



[0215] To a reactor was added 4-{6-[6-(1-butoxyl-vinyl)-8-cyclopentyl-5-methyl-7-oxo-7,8-dihydropyrido[2,3-d]pyrimidin-2-ylamino]-pyridin-3-yl}- piperazine-1-carboxylic acid tert-butyl ester (2.70 kg, 4.47 mol, 1.0 equiv.) followed by a mixture of water (27.00 L, 10 L/kg) and acetone (13.50 L, 5 L/kg). The yellow slurry was warmed to between 95 °C and 55 °C. A solution of methanesulfonic acid (2.15 kg, 22.36 mol, 5.0 eq.) diluted with water (5.40 L, 2 L/kg of starting material) and acetone (5.40 L, 2 L/kg of starting material) was added to the reactor over approximately 10 minutes. The reaction mixture was kept between 45 °C. and 55 °C. for at least 12 hours. A clear yellow solution was achieved during the reaction.

[0216] The reaction mixture was cooled to 35 °C., and a mixture of 5 wt % sodium hydroxide solution was added in portions to the reactor to raise the reaction mixture to a pH>9. The reactor was cooled to between 20 °C. and 25 °C., granulated, and filtered. The cake was washed with water followed by

acetone and dried under vacuum.

[0217] This method generated the small primary particle size free base of compound 1, which was equivalent to the material prepared from treatment of the compound 1 hydrochloride salt with aqueous NaOH in Example 4 of WO 2005/005426.

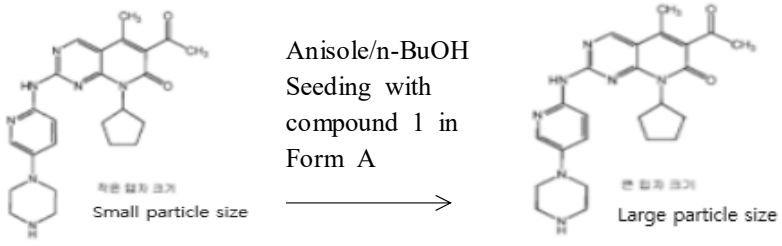
[0218] In addition to the representative procedure provided above (corresponding to Experiment S in Table 10), a range of acids and aqueous solvent systems were screened to determine the impact on the reaction and subsequent quench and isolation of free base of compound 1. Lab-scale screening experiments were run to identify reaction conditions for converting the intermediate vinyl ether to the free base compound 1. The results of these reaction screening experiments are summarized in Table 10, indicating the generality of the method.

[0219] TABLE 10. Summary of results from reaction screening experiments

Experiment	Acid	Solvent System	Yield	Purity
A	Isethionic acid	water	99	99.93
B	Isethionic acid	16% THF/water	>100	98.77
C	Isethionic acid	28% THF/water	95	97.95
D	HCI	water	>100	99.59
E	H_2SO_4	water	98	98.6
F	MSA	water	98	99.42
G	MSA	16% THF/water	>100	97.86
H	Isethionic acid	15% NMP/water	88	97.7
I	Isethionic acid	15% DMF/water	90	98.94
J	TFA (8 eq.)	water	100	99.14
K	Isethionic acid	15% CH_3CN/water	>100	99.56
L	Isethionic acid	15% acetone/water	92	99.54
M	Isethionic acid	15% DMAC/water	>100	98.91
N	Isethionic acid	15% sulfolane/water	92	98.67
O	MSA	15% CH_3CN/water	100	99.52
P	MSA	15% acetone/water	97	99.54
Q	CF_3SO_3H (incomplete)	water	N/A	N/A
R	MSA	33% CH_3CN/water	99	99.7
S	MSA	33% acetone/water	98	99.74
T	MSA	33% MeOH/water	98	99.74
U	MSA	33% THF/water	96	99.76

[0220] Example 6. Conversion of Small Particle Size Free Base to Lame Particle Size Free Base of Compound 1

[0221]

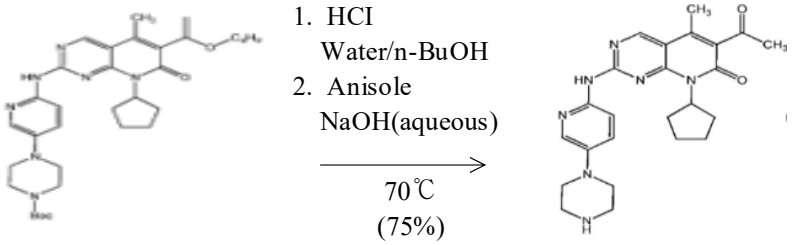


[0222] To a reactor was added compound 1 free base (20g, 44.69 mmol, 1.0 eq.), prepared according to Example 5, followed by 1-butanol (320 ml, 16 ml/g) and anisole (480 ml, 24 ml/g). The yellow slurry was warmed to between 95°C and 100°C to achieve dissolution. The reactor was cooled to 80°C. To the solution in the reactor, 1-butanol (320 ml, 16 ml/g) and anisole (480 ml, 24 ml/g) were added. The yellow slurry was warmed to between 95°C and 100°C to achieve dissolution. The reactor was cooled to 80°C. To the solution in the reactor, a seed slurry containing compound 1 free base (Form A) seed crystals (0.1 g, 0.2 mmol, 0.005 eq.) suspended in 1-butanol (5 mL, 0.25 mL/g of starting material) was charged to induce crystallization. The resulting slurry was stirred at 80°C for 3 hours. The slurry was cooled to 10°C at 0.2°C/min over 350 minutes, granulated, and filtered. The cake was washed with anisole followed by heptane, and dried under vacuum.

[0223] This method generated the large primary particle size crystals of the free base of compound 1, which were equivalent to the free base prepared using the one-pot method described in Example 7 below.

[0224] Example 7. One-Pot Method for Preparation of the Large Particle Size Free Base of Compound 1

[0225]



[0226] To a reactor was added water (200 mL, 10 mL/g) and 4-{6-[6-(1-butoxyl-vinyl)-8-cyclopentyl-5-methyl-7-oxo-7,8-dihydropyrido[2,3-d]pyrimidin-2-ylamino]-pyridin-3-yl}-piperazine-1-carboxylic acid tert-butyl ester (20 g, 33.1 mmol, 1.0 equiv.) followed by 1-BuOH (232 mL, 11.6 mL/g) to rinse any solids down into reactor. The yellow slurry was warmed to 70 °C. A two-liquid phase mixture formed. Concentrated HCl solution (16.3 g, 165.5 mmol, 5.0 eq.) was added to the reactor over approximately 10 minutes. The reaction mixture was kept at 70°C for 4 to 6 hours. A clear yellow biphasic solution was achieved after 3 hours.

[0227] To the reaction mixture was added anisole (356 mL, 17.8 mL/g). While maintaining the mixture at 70°C, a solution of aq. NaOH (17.2 g, 172.1 mmol, 5.2 eq.) (40 wt % solution) was added to the reactor over 20 minutes to raise the reaction mixture to a pH>10. The two-phase mixture was stirred for 30 minutes after the NaOH addition was complete.

[0228] The phases were separated and the organic phase was washed with water twice. The batch was then heated to 80°C and speck-free filtered into the crystallizing vessel, rinsing the filter with butanol. The batch was then distilled to remove water and achieve a temperature of 120°C. The batch was then cooled to 80°C and seeded with a seed slurry of compound 1 free base (Form A) seed crystals (0.015 g, 0.033 mmol, 0.1 wt.% compound 1) and 1-BuOH (10 mL, 0.5 mL/g). The batch was then cooled to 30°C at 0.2°C /min and then ripened with three cycles where the temperature was stepped down by 10°C each time. On the final cycle, the batch was cooled to 10°C, granulated and filtered. The cake was washed with twice with heptane and dried under vacuum. After drying, the sample was confirmed to be a single crystalline polymorph Form A.

[0230] Comparative PSA, SSA and surface energy data for the small primary particle size and large primary particle size formulations of the free base of compound 1 are provided below. In all cases, the free base was isolated as polymorph Form A.

[0238] Particle Size Analysis

[0240] Results

[0241] Comparative data for four batches of API are provided in Table 11 below, using either the Vibri or Aspiros devices to disperse the sample. Batch No. 4 had a D90 of around 75 μm, whereas Batch Nos. 1 and 2 both had a D90 of approximately 45 μm. The laser diffraction particle size data confirms the SEM observations for these batches.

[0242] Table 11. Comparative Size Distribution Data

Summary of PSD data		Particle size (μm)			
Batch No.	Disp. Method.	D[v, 0.1]	D[v, 0.5]	**D[v, 0.9]**	**D[4,3]**
1	0.2 Bar ASPIROS	5.21	17.00	**43.59**	**21.33**
2	0.2 bar ASPIROS	6.20	20.83	**46.15**	**23.87**
3	0.2 bar ASPIROS	11.64	46.08	**130.26**	**59.07**
	0.5 Bar VIBRI	9.96	41.23	**116.43**	**53.02**
4	0.2 bar ASPIROS	7.41	24.97	**76.56**	**35.06**
	0.5 Bar VIBRI	6.33	23.19	**69.20**	**32.16**

[0245] Sticking Analysis

[0246] The MASS (Material Adhesion Screen for Sticking) Punch was developed in-house to quantitatively assess the sticking propensity of tablet formulations by weighing the amount of adhered powder on removable punch tip after a series of compressions. This test enables preparers to objectively and quickly evaluate the risk of punch sticking during drug product development and troubleshoot sticking observed during clinical tablet manufacturing.

[0248] The MASS Punch profile for compound 1 free base mixed in the standard blend showed a positive response. Photos of the punch tips at the end of the compression runs confirmed that powder adhered to the tips (data not shown). For reference, a control sample of the standard blend is not sticky and would have less than 10 μm powders adhered. The test method was found to rank the sticking propensity of new API lots relative to those of known materials.

[0249] Specific Surface Area (SSA) Measurement (BET Nitrogen)

[0271] Results

[0272] Table 12 provides BET-N2 SSA for four batches of compound 1 free base API, one comprising the small primary particle size API prepared by the traditional salt break method (batch 5), and three batches comprising the large particle size API prepared according to the present invention. Batch 5 contained compound 1 free base having small primary particles and large agglomerates, which was very static-prone and sticky. Batch 6 was prepared using temperature cycling and had a typical particle size distribution (PSD) for the large particle size free base of compound 1, with a VMD of approximately 17 μm. Batch 7 demonstrated a similar PSD to batch 6. Batch 8 is a representative ICH batch of the large particle size free base of compound 1, also prepared by temperature cycling. The same batches were used in the surface energy determinations below.

[0273] Table 12. BET SSA by N2

Batch No.	BET SSA by N_2
5	6.6
6	0.62
7	0.69
8	0.67

End.

[Appendix 2]

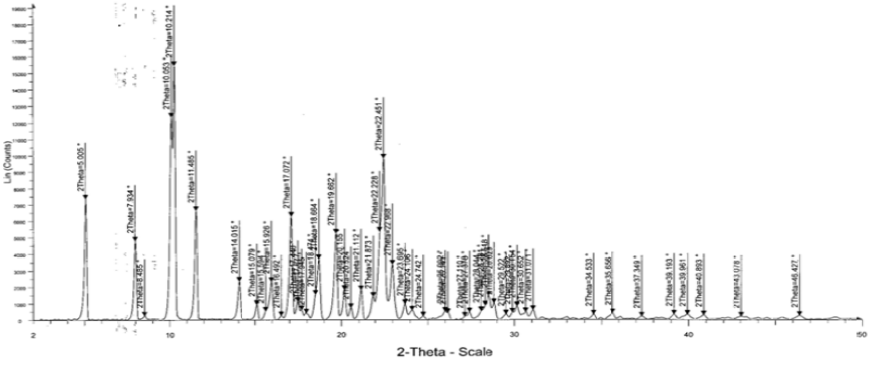
Description of Challenged Invention

Title of the Challenged Invention

Crystalline particles of palbociclib free base

Configuration of the Challenged Invention

Having the following powder X-ray diffraction pattern,



with a D[4,3] value of 10 μm or less and a D90 value of 20 μm or less, crystalline particles of the free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one

Description of the Challenged Invention

(1) The Challenged Invention is used as the active ingredient in a pharmaceutical for the treatment of cancer, such as 「for the treatment of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, either "in combination with an aromatase inhibitor as a first-line endocrine therapy for postmenopausal women" or "in combination with fulvestrant for women in whom the disease has progressed after endocrine therapy."」

(2) The Challenged Invention can be prepared into tablet or capsule forms with one or more pharmaceutically acceptable carriers, diluents, or excipients.

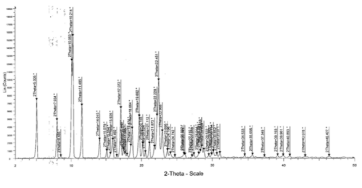
(3) The X-ray powder diffraction measurement of the Challenged Invention was conducted using a Bruker D8 diffractometer equipped with a copper X-ray source, a fixed slit, and a scintillation counter detector, with Copper $K\alpha_2$ used as the X-ray source.

No.	2θ value	Relative intensity (intensity/maximum intensity)	No.	2θ value	Relative intensity (intensity/maximum intensity)
1	5.0050	47.5	26	23.6951	5.9
2	7.9341	30.7	27	24.1059	3.5
3	8.4852	1.4	28	24.7424	1.2
4	10.0533	79.5	29	25.9919	3.0
5	10.2140	100.0	30	26.1407	2.5
6	11.4848	42.7	31	27.1102	1.1
7	14.0154	14.9	32	27.3775	2.8
8	15.0786	5.7	33	28.0438	3.3
9	15.5939	3.1	34	28.2815	5.4
10	15.9256	14.8	35	28.5183	9.2
11	16.4921	1.4	36	28.8288	6.3
12	17.0715	40.4	37	29.5222	1.9
13	17.4477	6.9	38	29.8916	2.7
14	17.6769	3.7	39	30.1539	5.1
15	17.9451	2.4	40	30.6520	2.8
16	18.4741	9.6	41	31.0709	3.6
17	18.6640	23.6	42	34.5332	1.9
18	19.6620	33.6	43	35.6560	2.3
19	20.1545	11.6	44	37.3494	1.1
20	20.5244	4.5	45	39.1925	1.9
21	21.1122	11.5	46	39.9612	1.8
22	21.8730	8.8	47	40.8934	1.6
23	22.2282	34.4	48	43.0777	1.1
24	22.4507	63.4	49	46.4272	1.4
25	22.9679	21.6			

The 2θ values listed in the X-ray diffraction pattern graph are as follows: (4) The particle size of the Challenged Invention was measured using a Malvern particle size analyzer (Malvern Mastersizer 3000), and the D[4,3] value and D_{90} of the Challenged Invention were measured based on volume.

Comparison Table between Patent Claims and the Challenged Invention

Same as the table below.

Claims	Patented Invention	Challenged Invention
1	The particle of crystalline form A of the free base of 6-acetyl -8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7- one with a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2, and 11.5 ± 0.2 and with a D[4.3] value ranging from 15 μm ± 20% to 30 μm ± 20%.	Having the following powder X-ray diffraction pattern,  with a D[4,3] value of 10 μm or less and a D90 value of 20 μm or less, crystalline particles of the free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d] pyrimidin-7-one.
2	The particle of crystalline form A of the free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino) -8H-pyrido[2,3-d]pyrimidin-7-one with a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2, and 11.5 ± 0.2 and with a D_{90} value ranging from 30 μm ± 20% to 65 μm ± 20%.	
3	The particle of crystalline form A of the free base according to Claim 1 or Claim 2, having a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2, 10.3 ± 0.2, and 11.5 ± 0.2.	
4	The particle of crystalline form A of the free base according to Claim 1 or Claim 2, having a powder X-ray diffraction pattern including peaks at diffraction angles (2θ) of 5.1 ± 0.2, 8.0 ± 0.2, 10.1 ± 0.2, 10.3 ± 0.2, 11.5 ± 0.2, 14.0 ± 0.2, 15.1 ± 0.2,	

Claims	Patented Invention	Challenged Invention
	16.0 ± 0.2, 17.1 ± 0.2, 18.7 ± 0.2, 19.7 ± 0.2, 20.2 ± 0.2, 21.2 ± 0.2, 22.5 ± 0.2, and 23.0 ± 0.2.	
8	A pharmaceutical composition for the treatment of cancer, comprising the particle of crystalline form A of the free base according to Claim 1 or Claim 2, and one or more pharmaceutically acceptable carriers, diluents, or excipients.	The crystalline form of the specified free base in the Invention in Question is used as the active ingredient in a pharmaceutical composition for the treatment of cancer, which includes one or more pharmaceutically acceptable carriers, diluents, or excipients.

End.

IP HIGH COURT OF KOREA
THIRD DIVISION
DECISION

Case No.	2021Heo4778 Invalidation of Registration (Patent)
Plaintiff	A Representative B Counsel for Plaintiff Law Firm Lee & Ko Attorneys in Charge Geumnang PARK and Gyeongjin KIM Subcounsel for Plaintiff Patent Law Firm Lee & Ko Patent Attorneys in Charge Mi SON and Seunghoon CHO
Defendant	C Representative D Counsel for Defendant Attorneys Gyeongtae KANG, GIyun NAM, and Bogyeong CHOI Patent Attorneys in Charge Seongwan KIM and Hyejin HAN
Date of Closing Argument	August 25, 2022
Decision Date	October 13, 2022

ORDER

1. The Plaintiff's claims are dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2018Dang2990, decided May 31, 2021, shall be revoked.

OPINION

1. Background

A. Patented Invention at Issue

1) Title of invention: Food Products Comprising a Slowly Digestible or Digestion Resistant Carbohydrate Composition

2) Date of claimed priority / International application date / Registration date / Registration number: January 25, 2006, September 15, 2006, and December 14, 2006 / January 24, 2007 / March 4, 2015 / No. 1500939

3) Claims (as amended as of July 6, 2020)[1)]

【Claim 1】 A method for producing dextrose oligomers, comprising the following steps (hereinafter, "Element 1"): (a) a step to heat an aqueous feed composition, comprising dextrose, linear dextrose oligomers, a combination thereof, or a combination of any of the aforementioned with non-linear dextrose oligomers, with a solids concentration of at least 90% by weight based on dry solids, to at least 149°C and (b) a step to contact the feed composition with at least one acid catalyst, which accelerates the rate of cleavage or formation of glucosyl bonds within a pH range of 1.0 to 2.5, while maintaining a solids concentration of at least 90% by weight and a temperature of at least 149°C for 0.1 to 15 minutes in order to form non-linear dextrose oligomers, (hereinafter, "Element 2"), wherein the resulting composition

1) Corrected parts are underlined.

from (a) heating and (b) contact contains non-linear dextrose oligomers at a concentration at least twice that of linear dextrose oligomers; the resulting composition contains, based on dry solids weight, non-linear dextrose oligomers with a degree of polymerization of at least 3 at a minimum concentration of 50%; this resulting composition is essentially digestion-resistant or digested at a significantly slower rate (hereinafter, "Element 3") and the acid used is characterized as hydrochloric acid, sulfuric acid, phosphoric acid, or a combination thereof (hereinafter, "Element 4"); the dextrose oligomers have a degree of polymerization ranging from 2 to 30 (hereinafter, "Element 5") (hereinafter, the "corrected Claim 1," the same applies to the remaining claims).

【Claim 2】 The method according to Claim 1, wherein the aqueous feed composition characterized by consisting of dextrose, linear dextrose oligomers, and non-linear dextrose oligomers, based on dry solids.

【Claims 3 to 6】 (Each deleted)

【Claim 7】 The method according to Claim 1, wherein the acid is selected from the group consisting of hydrochloric acid, sulfuric acid, phosphoric acid, and combinations of hydrochloric acid with either sulfuric acid or phosphoric acid.

【Claim 8 to 10】 (Each deleted by the trial for correction dated July 6, 2020)

【Claim 11】 The method according to claim 1, wherein the acid is characterized as a combination of phosphoric acid and hydrochloric acid.

【Claims 12 to 15】 (Each deleted by the trial for correction dated July 6, 2020)

【Claim 16】 The method according to claim 1, wherein the resulting composition contains trace amounts of residual dextrose, characterized by further comprising a step of removing at least a portion of the residual dextrose from the resulting composition by membrane filtration, chromatographic fractionation, or digestion through fermentation.

【Claim 17】 (Deleted)

【Claims 18 to 21】(Each abandoned)

【Claims 22 to 31 and 33】(Each deleted)

【Claims 32 to 31 and 33】(Each deleted by the trial for correction dated July 6, 2020)

【Claims 37 to 43】(Each abandoned)

【Claim 44】(Deleted)

4) Summary of invention

A. Technical Field

[0001] The food product contains an oligosaccharide composition that is digestion-resistant or slowly digested. (Omitted) Alternatively, the oligosaccharide composition can be produced through a process comprising the following steps: a step to heat an aqueous feed composition containing at least one monosaccharide or linear saccharide oligomer, with a solids concentration of at least 70% by weight, to at least 40°C; a step to contact the feed composition with at least one catalyst that accelerates the rate of cleavage or formation of glucosyl bonds for a time enough to form non-linear saccharide oligomers, wherein a resulting composition contains a concentration of non-linear saccharide oligomers higher than that of linear ones.

B. Background Art

[0003] There is growing interest in developing non-digestible or only partially digestible components that are suitable for use in food products to enhance dietary fiber content or reduce caloric content in the products. These modifications offer specific health benefits.

C. Summary of Invention

[0010] Another aspect of the present invention is a process of producing saccharide oligomers. The saccharide oligomer compositions produced by some embodiments of the process are inherently digestion-resistant. In others, they are inherently slowly digested. The process uses an aqueous feed composition containing at least one monosaccharide or linear saccharide oligomer with a solid concentration of at least 70% by weight. The feed composition above is heated to at least 40°C and contacts at least one catalyst that accelerates the rate of cleavage or formation of glucosyl bonds

for a duration enough to form non-linear saccharide oligomers. As a result, a composition is produced containing a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers.

[0011] In one embodiment of the process, at least one catalyst is an enzyme that accelerates the rate of cleavage or formation of glucosyl bonds. In some embodiments of the process, an acid and an enzyme can be used sequentially, where the feed composition is first treated with the enzyme and then with the acid, or vice versa.

D. Detailed Description of Invention

[0036] In this specification, "oligosaccharide" and "saccharide oligomer" refer to saccharides comprising at least two saccharide units, for example, saccharides with a degree of polymerization (DP) of about 2 to 30. For example, a disaccharide has a DP of 2.

[0037] In some embodiments of the present invention, the aqueous feed composition contains at least one monosaccharide and at least one linear saccharide oligomer, and may contain multiple of each. In many cases, monosaccharides and oligosaccharides together constitute at least 70% of the feed composition on a dry solids basis by weight.

[0038] Practical examples of suitable starting materials include but are not limited to syrups produced by the hydrolysis of starch, such as dextrose greens syrup (i.e., the recycle stream of mother liquor from dextrose monohydrate crystallization), other dextrose syrups, corn syrups, and maltodextrin solutions.

[0040] The feed composition contacts at least one catalyst for a variable duration. In some cases, the contact duration is at least 5 hours. In some embodiments of the present invention, the feed composition contacts at least one catalyst for approximately 15 to 100 hours. In other embodiments, the composition may contact catalyst(s) at higher temperatures for shorter times, in some cases less than 1 hour.

[0043] The resulting composition contains non-linear oligosaccharides such as isomaltose at high concentrations. The composition contains a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers. In some cases, the concentration of non-linear saccharide oligomers in the final composition is at least twice that of linear saccharide oligomers.

[0046] Another embodiment of the present invention is a process that involves the acid reversion of monosaccharides. It uses starting materials the

same as those previously described in relation to the enzyme version of this process. Various acids, such as hydrochloric acid, sulfuric acid, phosphoric acid, or combinations thereof, can be used. In some embodiments of the process, the acid is added to the feed composition in an amount sufficient to lower its pH to around 4 or below, or in some cases, to a pH range of around 1.0 to 2.5, or 1.5 to 2.0.

[0048] In another specific embodiment, the feed composition has a solids concentration of approximately 90 to 100% by weight and, after contact with the acid, is maintained at a temperature of at least 149°C (300°F) for approximately 0.1 to 15 minutes.

[0049] To date, the most abundant glycosidic linkage in starch is the alpha-1,4 linkage, which is broken most commonly during the acid hydrolysis of starch. However, acid-catalyzed reversion (condensation) can occur between two random hydroxyl groups, and given the wide variety of combinations and bond geometries, it is relatively unlikely that alpha-1,4 linkage is formed. The human digestive system includes alpha-amylase, which easily digests the alpha-1,4 linkages in starch and corn syrup. The human digestive system contains alpha-amylase, which easily digests the alpha-1,4 linkages in starch and corn syrup.

[0055] The resulting composition produced through treatment with acid, enzymes, or both contains an increased concentration of non-linear saccharide oligomers on a dry solids basis. In some cases, the concentration of non-linear saccharide oligomers with a degree of polymerization of at least 3 (DP3+) in the resulting composition is at least 20%, 25%, 30%, or 50% by weight on a dry solids basis. In some embodiments, the concentration of non-linear saccharide oligomers in the resulting composition is at least twice that of linear saccharide oligomers.

E. Embodiment

[0113] Embodiment 1

[0114] Raffinate syrup was purchased from a plant that processes corn starch into high-fructose corn syrup. Raffinate is produced through chromatographic separation and is primarily composed of fructose and dextrose. The raffinate above was nanofiltered using a Desal DK1812C-31D nanofiltration cartridge under a pressure of about 500 psi and a temperature of 40 to 60°C. The retentate obtained from the nanofiltration was decolorized using activated carbon and then evaporated into approximately

80% dry solids. The saccharide analysis of this dry product was performed using HPAE-PAD chromatography, and the results are shown in Table 1.

<Table 1>

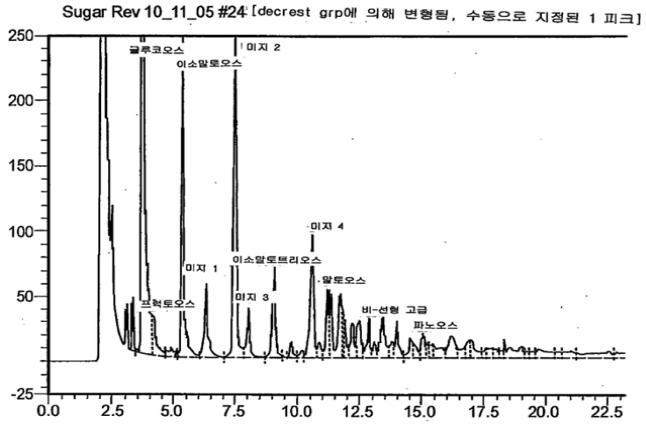
Component	wt% d.s.b.
Dextrose	38.9%
Fructose	6.1%
Isomaltose	14.3%
Maltose	10.5%
Maltotriose	0.3%
Panose	9.5%
Linear higher saccharides	0.0%
Non-linear higher saccharides	20.4%

[0123] Embodiment 3 - Production of Non-linear Oligomers from Dextrose Using Enzymes

[0127] The concentrations of various sugar types were determined using High-Performance Anion Exchange Chromatography with Pulsed Amperometric Detection (HPAE-PAD). DX500, a Dionex ion chromatograph, equipped with an electrochemical detector and a gradient pump was used for analysis.

[0154] Embodiment 6 - Acid-Catalyzed Reconstruction of Corn Syrup to Form Non-linear Oligomers

[Figure 14] Chromatographic Analysis Results of Acid-Treated Syrup in Embodiment 6



국문	영문	국문	영문
Decrest grp에 의해 변형됨, 수동으로 지정된 1피크	Modified by Decrest grp, manually assigned 1 peak	이지 2	Easy 2
		이소알로브리오스	Isoalobiose
		이지 3	Easy 3
		이지 4	Easy 4
글루코오스	Glucose	알로오스	Allose
프럭토오스	Fructose	비-선형 고급	Non-linear higher
이소말로오스	Isomalose	파노오스	Panose
이지 1	Easy 1		

[0156] Staley 1300 syrup was heated to approximately 60°C in 50 mL screw-cap centrifuge tubes in a shaking water bath. A predetermined amount of acid required to reach the target pH was added to the syrup above. The syrup tubes were shaken hard to evenly disperse the acid. The tubes were returned to the water bath, and when needed, the temperature of the bath was adjusted. The treatment was performed at temperatures of 60, 70, and 80°C, and at pH levels of 1.2, 1.8, and 2.3. To monitor the progress of the reaction, a portion of the syrup was transferred from the tubes and the tubes were added with a caustic solution to be neutralized.

[0165] The ion chromatography separation of the sugars was performed using a Dionex CarboPac PA200 column. Figure 14 illustrates the chromatographic trace of the acid-treated syrup which was broken down by the column. This clearly shows four components in the range of DP 2 to 3 that elute independently of maltose, isomaltose, maltotriose, and panose (all of which elute before maltose). It also shows multiple peaks regarding unidentified higher oligomers.

[0744] Embodiment 54

[0745] Sweetose 300 corn syrup (81% ds) was evaporated to a moisture content of 6% or less by passing it through a hot oil jacketed paddle mixer at a rate of 77 kg/h. The paddle mfixer's shaft speed was typically set to 300 to 600 rpm, and the oil jacket temperature varied within the range of 150 to 205°C. In some tests, phosphoric acid was added at a rate the same as that of providing the corn syrup solids with 0.1 to 0.4% phosphoric acid solids. In some tests, hydrochloric acid was added at 25 ppm, either instead of or in addition to phosphoric acid.

샘플 명칭	Temp °C	$\%H_3PO_4$	HCl ppm	섬유 %
run 1	194	0.2%		43
run 2	195	0.2%	25	52
run 3	193	0.4%	25	62
run 4	203	0.4%	25	68
run 5	180	0.2%		27
run 6	181	0.4%		37
run 7	181	0.4%	25	33
폴리덱스트로스 대조				82

국문	영문
샘플 명칭	Sample name
섬유 %	Fiber %
폴리덱스트로스 대조	Polydextrose control

[0746 to 0748] The product recovered from these tests (25 mg) was dissolved in 4 mL of pH 4.0 buffer and cultured with 100 mL of 10 mg/mL amyloglucosidase enzyme (Amyloglucosidase, Sigma Catalog #A-7255) at 45°C for 2 hours. The mixture obtained from the culture was treated with a small amount of ion exchange resin and filtered (0.45 microns) before saccharide distribution analysis by liquid chromatography. The weight percentage of carbohydrates that were found to be present in the analysisas higher saccharides, such as trisaccharides or larger, was quantified as digestion-resistant carbohydrates and is shown in the table below as Fiber %. A laboratory sample of polydextrose was used as a control for this test with a fiber level of approximately 82%.

B. Prior Art (Plaintiff's Exhibit 4-1)[2)]

The prior art relates to a "Method for Producing Non-Digestible Food Additives" published in British Patent No. 1490415, released on November 2, 1977, and below is its summary.

A. Summary of Invention

(Page 1, Lines 19 to 33) It is well known that starch can be modified by heat and/or reaction with small amounts of inorganic acids, alkalis, or salts.

2) It is the same as Prior Art 7 submitted in the IPTAB Decision.

The products of such process are known as British gum, Ganary dextrins, etc., some of which are partially non-digestible. Also, starch can be hydrolyzed in aqueous solution using acids and/or amylolytic enzymes to influence hydrolysis, forming partially or fully hydrolyzed products, all of which are fully digestible. It is also known to produce partial esters of starch using dicarboxylic acids such as maleic acid, fumaric acid, and succinic acid.

(Page 1, Lines 34 to 39) The inventors found that substantially non-digestible products can be produced from starch or partially hydrolyzed starch by heating starch or starch hydrolysates under specific conditions in the presence of edible di- or tri-carboxylic acids.

(Page 1, Lines 40 to 57) Therefore, according to the present invention, a method to produce a non-digestible food additive includes heating a mixture of starch or starch hydrolysate and an edible di-, or desirably tri-basic carboxylic acid (or its anhydride) under reduced pressure at a temperature of 140 to 220°C for a time enough to form a non-digestible product, as determined by its resistance to the action of amylolytic enzymes. The mixture contains less than 5% by weight of water both before and during heating, based on the total weight of the mixture before heating at the temperature above, and includes 1 to 25% by weight of an edible acid (or an equivalent amount of its anhydride).
(Page 1, Lines 58 to 71) Starch hydrolysates mean partial acidic or enzymatic hydrolysis products of starch, including products variously known as low-viscosity starch, corn syrup solids, white dextrins, and amylase dextrins. These products have a dextrose equivalent ranging from around 1 to 70 and consistently contain a certain proportion of oligosaccharides as well as the monomer glucose and the disaccharide maltose. One particularly advantageous form of starch hydrolysate that can be used in the present invention is one produced through partial hydrolysis in the presence of the acid the same as that incorporated into the mixture.

(Page 1, Lines 72 to 82) For instance, it is expected that starch and starch hydrolysates can be used as starting materials that have been chemically modified or slightly oxidized to introduce small amounts of etherified or esterified hydroxyl groups, by reacting with alkylene oxides to form ethers or with organic or inorganic acids to form esters. Their use is included in the present invention, as are physically modified starches such as pre-gelatinized starch.

(Page 1, Line 83 to Page 2, Line 9) Edible di- and tri-basic carboxylic acids that can be used include maleic acid, fumaric acid, succinic acid, adipic acid, malic acid, tartaric acid, citric acid, and isocitric acid. Among them, the desirable acid is citric acid.

(Page 2, Lines 10 to 14) It is important that the moisture content of the mixture remains low not only before but also during heating to implement the present invention. The mixture should always contain less than 5%, desirably less than 2% water.

(Page 2, Lines 55 to 102) The duration of heating depends on the characteristics of the starting materials, the proportion of edible acid, the type of equipment used during the heating stage, the characteristic needed for the product, and the actual heating temperature. (omitted) The duration required to provide a non-digestible product also varies depending on the present proportion of edible acid. A lower proportion of acid requires more time. (omitted) Generally, a higher dextrose equivalent of the starch hydrolysate decreases the duration required to provide a non-digestible product, but increases the duration needed to reduce the product's solubility or moisture absorption to the desired level. The temperature used surely has a direct impact on decreasing the duration required to provide a non-digestible product as well as the duration needed to reduce the product's solubility or moisture absorption to the desired level. A higher temperature clearly decreases the duration.

B. Embodiment

(Page 3, Line 113) Embodiment 1

(Page 3, Line 114 to Page 4, Line 14) Raw corn starch powder, which contains approximately 10% moisture and having an average particle size of about 25 microns, is dried in a 60°C oven to reduce the moisture content to 1% by weight. Then, the dried powder (170 g) is blended with anhydrous citric acid powder (30 g), which contains an average particle size of approximately 150 microns in a conventional blending apparatus to obtain a homogeneous mixture. The mixture is then heated in a glass flask in an oil bath at 180°C for 3 hours under a pressure of 50 mm of mercury (maintained using a vacuum pump). Samples taken at intervals during the heating period show that the proportion of products hydrolyzable by α -amylase decreases gradually until the end of the period to as low as 4%. The proportion of water-soluble substances also gradually decreases to 10%.

After cooled down to room temperature, the product (180 g) is suspended in water (820 mL) twice, filtered, and re-suspended in water (820 mL). Subsequently, the product was added with a 72 mL solution of 10% sodium chlorate for bleaching and then with 10% aqueous sodium carbonate to neutralize to pH 6. The mixture is then filtered, washed with water, and dried to obtain 160 g of a pale cream-colored product only 1% of which can be hydrolyzed by α-amylase and which is insoluble in water.

C. Procedural History and IPTAB Decision

1) On September 12, 2018, the Defendant filed a petition seeking invalidation against the Plaintiff in the Intellectual Property Trial and Appeal Board (IPTAB), arguing that "the patented intention is not described in enough detail for a person having ordinary skill in the art (hereinafter, a "skilled person") to easily invent it, is not supported by its description, and is not clearly disclosed. The invention lacks novelty and an inventive step as it can be easily derived by a skilled person considering each of or combinations of Prior Arts 1 to 7 and well-known and commonly used art."

2) During the invalidation trial procedure, on July 6, 2020, the Plaintiff requested correction (hereinafter, "the Petition for Correction") to amend the claims of the patented invention as in Section 1.A.3).

3) The IPTAB reviewed the Plaintiff's petition above under the case numbered 2018Dang2990, and rendered a decision accepting the Plaintiff's petition for correction on May 31, 2021 (hereinafter, the "IPTAB Decision"), stating that "the Petition for Correction is legitimate and shall be accepted. However, the patented invention after correction is not described in a way that can be easily implemented by a skilled person, is not supported by the description, and is not clearly disclosed. The corrected Claims 1, 2, 7, 11, and 16 is denied an inventive step as it can be easily invented by a skilled person based on Prior Art 7."

【Factual basis】 Undisputed facts, the descriptions on Plaintiff's Exhibits 1 through 4 (including Exhibits with branching numbers), and the purport of the overall arguments

2. Parties' Arguments

A. Plaintiff

1) The Petition for Correction meets the requirements for correction and is therefore lawful.

2) The patented invention is not denied an inventive step by the prior art for the following reasons.

a) The corrected Claim 1 is different from the prior art in both the starting materials and resulting composition; its starting materials and resulting compositions are composed solely of dextrose residues, while the prior art uses starch hydrolysates with etherified or esterified hydroxyl groups as starting materials and uses organic acids as acid catalysts, leading the resulting compositions to include cross-linked ester bonds.

b) The corrected Claim 1 includes a preheating step to heat the starting material prior to contact with the acid, whereas the prior art does not include such a step.

c) The corrected Claim 1 uses an inorganic acid to conduct the reaction at a low pH and high temperature for a short contact time, while the prior art only discloses that it uses an organic acid without specifying acid reaction conditions such as the pH range.

d) In the corrected Claim 1, the resulting composition contains non-linear dextrose oligomers at a concentration at least twice that of linear dextrose oligomers and with a degree of polymerization of at least 3 at a minimum concentration of 50% based on dry solids weight. In contrast, the prior art does not disclose the specific

components or composition of the resulting product.

e) The corrected Claims 2, 7, 11, and 16 as well are not denied an inventive step by the prior art.

3) The description of the patented invention in this case is described in enough detail so that it can be easily implemented, is supported by the specification, and is clearly disclosed.

4) The IPTAB's decision, concluding to the contrary, is unlawful.

B. Defendant

1) The Petition for Correction is unlawful as it introduces new matters beyond the scope of what is disclosed in the specification or drawings of the patented invention.

2) Even if the Petition for Correction is deemed lawful, the patented invention is denied an inventive step by the prior art for the following reasons.

a) The resulting composition and its characteristics of the corrected Claim 1 are either disclosed in the prior art or can be easily derived by a skilled person based on the prior art and common general knowledge in the relevant technical field. The effects can also be easily predicted.

b) The corrected Claims 2, 7, 11, and 16 as well are denied an inventive step by the prior art.

3) The description of the patented invention in this case is not described in enough detail so that it can be easily implemented, is not supported by the specification, and is not clearly disclosed for the following reasons.

a) To clearly understand and implement the patented invention, it shall be confirmed by experiments that the resulting composition contains non-linear dextrose oligomers at a concentration at least twice that of linear dextrose oligomers and with a degree of polymerization

of at least 3 at a minimum concentration of 50% based on dry solids weight.

b) "HPAE-PAD" is an analytical technique used for analyzing compositions with the same type of bonds, and it is not suitable for analyzing compositions containing various types of bonds, such as the resulting composition of the patented invention.

c) It is not easy to clearly understand and implement the patented invention using the "HPAE-PAD" described in the specification. The specification does not include the results of analyzing the composition in the embodiments using "HPAE-PAD."

4) The IPTAB's decision consistent with the above is well-grounded.

3. Whether IPTAB's Decision is Unlawful

A. Whether IPTAB's Decision on Petition for Correction Erred

1) Relevant law

Articles 133-2 and 136(3) of the Patent Act is to allow a patentee, who becomes the Defendant in an invalidation trial, to request corrections within the trial procedure without filing a separate correction trial while not permitting expansion or alteration of the claims but allowing for corrections to reduce the scope of the claims or correct errors to fix flaws and resolve the lack of written description, provided that such corrections do not risk infringing on the rights of third parties.

Whether a correction request for a patented invention constitutes a substantial expansion or alteration of the claims should be determined not only by the formal wording of the claims themselves but also by comparing the substantive content of the claims as understood from the entire specification and drawings, including the description of the invention. If the correction of the claims is a reduction in their scope,

does not result in any changes to the purpose or effect, and merely reflects the content described in the specification and drawings without causing unforeseen harm to third parties, it does not constitute a substantive alteration of the claims (See Supreme Court Decisions 2016Hu830, dated April 12, 2018, and 2016Hu403, dated February 28, 2019).

The specification or drawings of a patented invention shall be corrected within the scope of the features described therein (Article 136(3) of the Patent Act). Here, "features described therein" refers not only to what is explicitly stated therein but also to those features that, although not explicitly described, can be clearly understood by a skilled person as being equivalent to disclosing such features based on technical common sense at the time of filing. However, it is not permitted to amend the specification or drawings of a patented invention by adding new features beyond this scope (See Supreme Court Decision 2012Hu3404, dated February 27, 2014).

2) Correction

A comparison of the claims before and after the correction is as follows (Corrected parts are underlined).

Element	Claim 1 before Correction	Claim 1 after Correction
1	A method for producing saccharide oligomers, comprising the following steps:	A method for producing dextrose oligomers, comprising the following steps (hereinafter, **"Correction 1"**):
	a step to heat an aqueous feed composition to at least 40℃, wherein the composition contains at least one monosaccharide or linear saccharide oligomer with a solid concentration of at least 70% by weight;	(a) a step to heat an aqueous feed composition, comprising dextrose, linear dextrose oligomers, a combination thereof, or a combination of any of the aforementioned with non-linear dextrose oligomers based on dry solids,(**"Correction 2"**) with a solids concentration of at least 90% by weight, to at least 149°C (**"Correction 3"**);

Element	Claim 1 before Correction	Claim 1 after Correction
	a step to contact the feed composition with at least one acid catalyst that accelerates the rate of cleavage or formation of glucosyl bonds for a duration enough to form non-linear saccharide oligomers,	(b) a step to contact the feed composition with at least one acid catalyst that accelerates the rate of cleavage or formation of glucosyl bonds to form non-linear dextrose oligomers, within a pH range of 1.0 to 2.5, while maintaining a solids concentration of at least 90% by weight and a temperature of at least 149°C for 0.1 to 15 minutes (**"Correction 4"**),
3	The resulting composition contains a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers, and this composition includes non-linear saccharide oligomers with a degree of polymerization of at least 3 at a concentration of at least 20% based on dry solids weight.	The resulting composition obtained through (a) heating and (b) contacting has a concentration of non-linear dextrose oligomers at least twice that of linear dextrose oligomers (**"Correction 5"**), contains non-linear dextrose oligomers with a degree of polymerization of at least 3 at a concentration of at least 50% based on dry solids weight (**"Correction 5"**), and is inherently digestion-resistant or inherently slowly digestible (**"Correction 6"**).
4		The acid above is characterized as hydrochloric acid, sulfuric acid, phosphoric acid, or a combination thereof (**"Correction 7"**).
5		The dextrose oligomers have a degree of polymerization ranging from 2 to 30 (**"Correction 6"**).

3) Discussion

The Defendant disputes only Corrections 3 through 7 of the Petition for Correction. The remaining corrections, excluding the ones above,

are considered to meet all the requirements for correction in the invalidation trial procedure as they either reduce the scope of the claims or clarify features that were not clearly described. Therefore, the following discussion will focus solely on whether Corrections 3 through 7 are lawful.

Corrections 3 through 7 cannot be considered to expand or alter the scope of the claims for the following reasons.

① Correction 3 corrects "with a solid concentration of at least 70% by weight" and "to at least 40°C" in the scope of claims before correction to "with a solids concentration of at least 90% by weight" and "to at least 149°C," respectively. The specification of the patented invention discloses "a step to heat an aqueous feed composition with a solids concentration of at least 70% by weight to at least 40°C" and "The process uses an aqueous feed composition (omitted) with a solid concentration of at least 70% by weight. The feed composition above is heated to at least 40°C" (Plaintiff's Exhibit 2, paragraphs [0001] and [0010]) while it does not describe "with a solids concentration of at least 90% by weight" and "to at least 149°C." However, since "with a solids concentration of at least 90% by weight" falls within the scope of "with a solid concentration of at least 70% by weight" and "to at least 149°C" within the scope of "to at least 40°C," Correction 3 constitutes a reduction in the prima facie scope of the claims. There are no circumstances to suggest that the correction results in any differences in its purpose or effects.

② Correction 4 corrects "saccharide oligomers" into "dextrose oligomers" and "a step to contact" into "a step to contact (omitted) within a pH range of 1.0 to 2.5, while maintaining a solids concentration of at least 90% by weight and a temperature of at least 149°C for 0.1 to 15 minutes." The specification of the patented invention mentions dextrose syrup as an example of starting materials and states that the materials are not limited thereto (Plaintiff's Exhibit 2, paragraph [0038]). It also describes, "Another embodiment of the

present invention is a process that involves the acid reversion of monosaccharides. In some embodiments of the process, the acid is added to the feed composition in an amount sufficient to lower its pH to around 4 or below, or in some cases, to a pH range of around 1.0 to 2.5, or 1.5 to 2.0. Another specific embodiment states that "the feed composition has a solids concentration of approximately 90 to 100% by weight and, after contact with the acid, is maintained at a temperature of at least 149°C (300°F) for approximately 0.1 to 15 minutes" (Plaintiff's Exhibit 2, paragraphs [0046] and [0048]). Therefore, Correction 4 specifies the subject matter and process conditions based on the description in the specification of the patented invention to narrow the scope of the claims.

③ Correction 5 corrects "The resulting composition contains a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers" into "The resulting composition obtained through (a) heating and (b) contacting has a concentration of non-linear dextrose oligomers at least twice that of linear dextrose oligomers" and "non-linear saccharide oligomers with a degree of polymerization of at least 3 at a concentration of at least 20%" into "non-linear dextrose oligomers with a degree of polymerization of at least 3 at a concentration of at least 50%." The specification of the patented invention discloses, "The resulting composition produced through treatment with acid, enzymes, or both contains an increased concentration of non-linear saccharide oligomers on a dry solids basis. In some cases, the concentration of non-linear saccharide oligomers with a degree of polymerization of at least 3 (DP3+) in the resulting composition is at least 20%, 25%, 30%, or 50% by weight on a dry solids basis. In some embodiments, the concentration of non-linear saccharide oligomers in the resulting composition is at least twice that of linear saccharide oligomers" (Plaintiff's Exhibit 2, paragraph [0055]). Claim 14 before correction discloses "the method according to Claim 1, wherein the resulting composition contains non-linear saccharide oligomers with a degree of polymerization of at least 3 at a

concentration of at least 50% by weight on a dry solid basis" and Claim 15 before correction states that "the method according to Claim 1, wherein the resulting composition contains the concentration of non-linear saccharide oligomers at least twice that of linear saccharide oligomers." Therefore, Correction 5 is deemed to narrow the scope of the claims by merging the descriptions in the specification above and the claims before correction.

④ Correction 6 adds the features that "[the resulting composition] is inherently digestion-resistant or inherently slowly digestible" and "The dextrose oligomers have a degree of polymerization ranging from 2 to 30" to define the characteristics of the resulting composition and the polymerization range of the oligomers. The specification discloses "the oligosaccharide composition (resulting composition) is digestion-resistant or slowly digested" (Plaintiff's Exhibit 2, paragraphs [0001] and [0006]) and "oligosaccharide and saccharide oligomer refer to saccharides comprising at least two saccharide units, for example, saccharides with a degree of polymerization of about 2 to 30" (Plaintiff's Exhibit 2, paragraph [0036]). As it is common technical knowledge that dextrose oligomers are a type of oligosaccharide composition, Correction 6 is deemed to reflect the description in the specification and reduce the scope of the claims.

⑤ Correction 7 adds the scope of claims before correction with "The acid above is characterized as hydrochloric acid, sulfuric acid, phosphoric acid, or a combination thereof" to specify the type of the acid. Since the specification of the patented invention states, "Various acids, such as hydrochloric acid, sulfuric acid, phosphoric acid, or combinations thereof, can be used" (Plaintiff's Exhibit 2, paragraph [0046]), Correction 7 is deemed to reflect the description in the specification and reduce the scope of the claims.

4) Discussion on the Defendant's argument

The Defendant argues that the manufacturing method combining

Corrections 3 through 7 is not disclosed in the specification or embodiments of the patented invention and therefore, that Corrections 3 through 7 exceed the scope of what is described in the specification of the patented invention, which is discussed as follows.

Corrections 3 through 7 relate to subject matters or process conditions in the heating and contacting steps that a skilled person could choose or not considering the description in the specification of the patented invention, and each correction falls within the scope disclosed in the specification of the patented invention as previously discussed. Additionally, there are no circumstances to suggest that limiting the subject matters and process conditions as in Corrections 3 through 7 significantly changes the characteristics of the resulting composition or effects. Therefore, it cannot be concluded that the Petition for Correction exceeds the scope of the descriptions in the specification of the patented invention. This part of the Defendant's argument is not accepted.

5) Summary of analysis

The Petition for Correction is lawful.

B. Whether the Patented Invention at Issue Lacks an Inventive Step

1) Whether Claim 1 is denied an inventive step

a) Element-by-element comparison

Element	The amended Claim 1	Prior Art
1	A method for producing dextrose oligomers, comprising the following steps:	o A method for producing a non-digestible food additive, which is a heating product of a mixture of starch or starch hydrolysates and edible di- or tri-basic carboxylic acids (Claim 1). o The starch hydrolysates have

Element	The amended Claim 1	Prior Art
		various dextrose equivalents ranging from around 1 to 70 and always contain a certain proportion of oligosaccharides, as well as the monomer glucose and the disaccharide maltose (Page 1, Lines 58 to 67, Claim 2).
2	(a) a step to heat an aqueous feed composition, comprising dextrose, linear dextrose oligomers, a combination thereof, or a combination of any of the aforementioned with non-linear dextrose oligomers, with a solids concentration of at least 90% by weight based on dry solids, to at least 149°C; and (b) a step to contact the feed composition with at least one acid catalyst that accelerates the rate of cleavage or formation of glucosyl bonds to form non-linear dextrose oligomers, within a pH range of 1.0 to 2.5, while maintaining a solids concentration of at least 90% by weight and a temperature of at least 149°C for 0.1 to 15 minutes	o A method for producing a non-digestible food additive, comprising heating a mixture of starch or starch hydrolysates and edible di- or tri-basic carboxylic acids under reduced pressure at a temperature range of 140 to 220°C for a time enough to form a non-digestible product as determined by resistance to the action of amylolytic enzymes, wherein the mixture contains less than 5% by weight of water before or during heating based on the total weight of the mixture before heating and includes 1 to 25% by weight of an edible acid (Page 1, Lines 40 to 57, Claim 1). o Starch hydrolysates mean partial acidic or enzymatic hydrolysis products of starch, including products variously known as low-viscosity starch, corn syrup solids, white dextrins, and amylase dextrins. Such products have various dextrose equivalents ranging from around 1 to 70 and always contain a certain proportion of

Element	The amended Claim 1	Prior Art
		oligosaccharides, as well as the monomer glucose and the disaccharide maltose (Page 1, Lines 58 to 67, Claim 2). o It is important that the moisture content of the mixture remains low not only before but also during heating to implement the present invention. The mixture should always contain less than 5%, desirably less than 2% water (Page 2, Lines 10 to 14). o The duration of heating depends on the characteristics of the starting materials, the proportion of edible acid, the type of equipment used during the heating stage, the characteristics needed for the product, and the actual heating temperature. (omitted) Here, producing a non-digestible product may require only a few minutes of residence time. (omitted) Generally, a higher dextrose equivalent decreases the time required to provide a non-digestible product. The temperature used surely and directly affects both the time needed to provide the non-digestible product and the duration required to reduce its solubility or moisture absorption to the desired level. A higher temperature clearly decreases the duration (Page 2, Lines 55 to 102).

Element	The amended Claim 1	Prior Art
3	The resulting composition obtained through (a) heating and (b) contacting has a concentration of non-linear dextrose oligomers at least twice that of linear dextrose oligomers, contains non-linear dextrose oligomers with a degree of polymerization of at least 3 at a concentration of at least 50% based on dry solids weight, and is inherently digestion-resistant or inherently slowly digestible.	o Substantially non-digestible products can be produced from starch or partially hydrolyzed starch by heating starch or starch hydrolysates under specific conditions in the presence of edible di- or tri-carboxylic acids (Page 1, Lines 34 to 39, Claim 1). o The proportion of products hydrolyzable by α-amylase decreases gradually until the end of the period to as low as 4% (Embodiment 1).
4	The acid above is characterized as hydrochloric acid, sulfuric acid, phosphoric acid, or a combination there of.	o Edible di- or tri-basic carboxylic acids (or their anhydrides) (Claim 1). o The edible acid is citric acid (Claim 4, Embodiment 1).
5	The dextrose oligomers have a degree of polymerization ranging from 2 to 30.	o No description on the degree of polymerization.

b) Commonalities and differences

(1) Elements 1 and 5

Element 1 of the corrected Claim 1 relates to a method for producing dextrose oligomers, while Element 5 discloses the feature that the dextrose oligomers, the resulting composition, have a degree of polymerization ranging from 2 to 30. The corresponding element of the prior art relates to a method for producing non-digestible food additives by heating a mixture of starch hydrolysates, which have various dextrose equivalents ranging from 1 to 70 and contain a certain proportion of oligosaccharides, monomeric glucose, and the disaccharide maltose, with edible di- or tri-basic carboxylic acids.

Elements 1 and 5 of the corrected Claim 1 and the corresponding

element of the prior art are different in that the former specifies the components and their degree of polymerization in the resulting composition, but the latter does not (hereinafter, "Difference 1").

(2) Elements 2 and 4

Element 2 of the corrected Claim 1 and the corresponding element in the prior art are identical in that both involve contacting an aqueous feed composition [starch or starch hydrolysates] with an acid at high temperature.

The aqueous feed composition in Element 2 of the corrected Claim 1 consists of dextrose, linear dextrose oligomers, a combination thereof, or a combination of any of them with non-linear dextrose oligomers. The "starch hydrolysate" in the corresponding element of the prior art is a substance obtained by hydrolyzing starch [a polysaccharide formed by the condensation of D-glucose (dextrose) molecules into long chains], which has various dextrose equivalents ranging from 1 to 70 and always contains a certain proportion of oligosaccharides, monomeric glucose, and the disaccharide maltose. Therefore, it is substantially the same as Element 1 of the corrected Claim 1 in that it corresponds to dextrose, linear dextrose oligomers, a combination thereof, or a combination of any of them with non-linear dextrose oligomers.

Additionally, Element 2 of the corrected Claim 1 involves maintaining the aqueous feed composition and the acid catalyst during the acid contact step at a temperature of at least 149°C and a solids concentration of at least 90% by weight. However, the specification of the patented invention does not describe the technical significance of the minimum temperature and weight ratio above, and therefore, they are merely numerical limitations. Therefore, this is substantially identical to the corresponding element of the prior art, which involves heating a mixture of starch hydrolysates and an acid catalyst to a temperature range of 140 to 220°C, with the mixture containing less than 5% by weight of water before or during heating.

Element 2 includes "heating" the aqueous feed composition to at least 149°C, but the prior art does not disclose any details regarding "heating" (hereinafter, "Difference 2"). In addition, Element 2 and the corresponding element in the prior art are different in that the former discloses the type of acid as inorganic acids, such as hydrochloric acid, sulfuric acid, phosphoric acid, or combinations thereof with acidity levels in the range of pH 1.0 to 2.5 and a duration of 0.1 to 15 minutes while the latter specifies the type of acid as organic acids, such as edible di- or tri-basic carboxylic acids, but does not disclose any details regarding acidity (pH) or duration (hereinafter, "Difference 3").

(3) Element 3

Element 3 of the corrected Claim 1 and the corresponding element in the prior art are the same in that their resulting compositions are digestion-resistant or slowly digested.

However, the resulting composition in Element 3 of the corrected Claim 1 is characterized by having a concentration of non-linear dextrose oligomers at least twice that of linear dextrose oligomers and including non-linear dextrose oligomers with a degree of polymerization of at least 3 at a minimum concentration of 50% based on dry solids weight, whereas the corresponding element of the prior art does not disclose the concentration or degree of polymerization of non-linear dextrose oligomers (hereinafter, "Difference 4").

c) Analysis of differences

The following discussion first reviews Differences 2 and 3, which relates to the method to produce the resulting composition, and then Differences 1 and 4, which relate to the components and characteristics of the resulting composition.

(1) Whether it is easy to overcome Difference 2

Difference 2 can be easily overcome by a skilled person due to the following reasons.

(a) Related to the heating phase, the specification of the corrected Claim 1 only discloses "a step to heat an aqueous feed composition (omitted) to at least 40°C" and "was evaporated to a moisture content of 6% or less by passing it through a hot oil jacketed paddle mixer," but does not describe the technical significance or effects of an element to heat the aqueous feed itself or to set the lower limit of the heating temperature to 149°C. According to the specification, heating the aqueous feed composition to at least 149°C in the corrected Claim 1 appears to be a conventional preliminary step to activate the reaction and to not have any special technical significance.

(b)

- **(paragraph [0010])** Another aspect of the present invention is a process for producing saccharide oligomers. (omitted) The process uses an aqueous feed composition containing at least one monosaccharide or linear saccharide oligomer with a solid concentration of at least 70% by weight. The feed composition above is heated to at least 40°C and contacts at least one catalyst that accelerates the rate of cleavage or formation of glucosyl bonds for a duration enough to form non-linear saccharide oligomers. As a result, a composition is pepared containing a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers.
- **(paragraph [0744] and [0745])** Embodiment 54
  Sweetose 300 corn syrup (81% ds) was evaporated to a moisture content of 6% or less by passing it through a hot oil jacketed paddle mixer at a rate of 77 kg/h. The paddle mfixer's shaft speed was typically set to 300 to 600 rpm, and the oil jacket temperature varied within the range of 150 to 205°C. In some tests, phosphoric acid was added at a rate the same as that of providing the corn syrup solids with 0.1 to 0.4% phosphoric acid solids. In some tests, hydrochloric acid was added at 25 ppm, either instead of or in addition to phosphoric acid.

(c) The specification of the prior art discloses, "It is important that the moisture content of the mixture remains low not only before but also during heating to implement the present invention.

The mixture should always contain less than 5%, desirably less than 2% water," while Embodiment 1 describes a process of drying corn starch powder containing approximately 10% moisture in a heated oven to reduce the moisture content to 1% by weight and then mixing it with acid (Plaintiff's Exhibit 4, Pages 1 to 2, Lines 10 to 14; Page 3, Line 113 to Page 4, Line 14). It is reasonable to conclude that a skilled person would fully recognize from the above descriptions and embodiments that the starting material should be heated to a certain temperature before contact with the acid to reduce its moisture content in order to activate the reaction.

(d) Heating the aqueous nutritional composition to at least 149°C prior to contact with the acid catalyst in the corrected Claim 1 is merely a common preliminary step to activate the reaction and is just an option that a skilled person would choose or not based on the prior art.

(2) Whether it is easy to overcome Difference 3

Difference 3 is deemed to be easily overcome by a skilled person for the following reasons.

(a) The purpose and technological characteristic of the patented invention and the prior art

① According to the following descriptions in the specification of the patented invention, the technological problem of the corrected Claim 1 is to provide non-digestible or only partially digestible components that are suitable for use in food products to enhance dietary fiber content or reduce caloric content, and to solve this, it adopts an element to heat an aqueous feed composition containing monosaccharides or linear saccharide oligomers and contacting it with one or more acids to produce saccharide oligomers.

o **(paragraph [0002])** Various carbohydrates, such as different sugars and starches, are used in food products. Many of these types of carbohydrates are digested in the human stomach and small intestine. On the contrary, dietary fiber in food products is generally not digested in the stomach or small intestine but can potentially be fermented by microorganisms in the colon.

o **(paragraph [0003])** There is growing interest in developing non- digestible or only partially digestible components that are suitable for use in food products to enhance dietary fiber content or reduce caloric content in the products. These modifications offer specific health benefits.

o **(paragraph [0004])** There is a demand for edible materials with reduced levels of easily digestible carbohydrates that can be used in food products either as a substitute for or in addition to conventional carbohydrate products.

o **(paragraph [0010])** Another aspect of the present invention is a process of producing saccharide oligomers. The saccharide oligomer compositions prepared by some embodiments of the process are inherently digestion-resistant. In others, they are inherently slowly digested. The process uses an aqueous feed composition containing at least one monosaccharide or linear saccharide oligomer, with a solid concentration of at least 70% by weight. The feed composition above is heated to at least 40°C and contacts at least one catalyst that accelerates the rate of cleavage or formation of glucosyl bonds for a duration enough to form non-linear saccharide oligomers. As a result, a composition is produced containing a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers.

② The following descriptions in the specification of the prior art indicate that the technical problem of the prior art is to provide non-digestible products, and to solve the problem, it adopts an element to heat a mixture of starch or starch hydrolysates with an acid for a time sufficient to form non-digestible products.

o **(Page 1, Lines 34 to 39)** The inventors found that substantially non-digestible products can be produced from starch or partially hydrolyzed starch by heating starch or starch hydrolysates under specific conditions in the presence of edible di- or tri-carboxylic acids.

o **(Page 1, Lines 40 to 57)** Therefore, according to the present invention, a method to produce a non-digestible food additive includes heating a mixture of starch or starch hydrolysate and an edible di-, or desirably tri-basic carboxylic acid (or its anhydride) under reduced pressure at a temperature of 140 to 220°C for a time enough to form a non-digestible product as determined by its resistance to the action of amylolytic enzymes.

③ The corrected Claim 1 and the prior art share the same technical problem, which is to provide digestion-resistant or slowly digestible products. Both inventions also have the same solution in that they involve contacting an aqueous feed composition (starch hydrolysates) with an acid at high temperatures for a time enough to form a non-digestible product.

(b) Choice of acid

① Element 4 of the corrected Claim 1 limits the type of acid acting as a catalyst to inorganic acids, such as hydrochloric acid, sulfuric acid, phosphoric acid, or combinations thereof. However, the specification of the patented invention only states that "the acid facilitates the hydrolysis of starch and acid-catalyzed reversion (condensation) to produce a resulting composition containing an increased concentration of non-linear saccharide oligomers" but does not describe the technical significance or effects of limiting the type of acid.

o **(paragraph [0046])** Another embodiment of the present invention is a process that involves the acid reversion of monosaccharides. It uses starting materials the same as those previously described in relation to the enzyme version of this process. Various acids, such as hydrochloric acid, sulfuric acid, phosphoric acid, or combinations thereof, can be used. In some embodiments of the process, the acid is added to the feed composition in an amount sufficient to lower its pH to around 4 or below, or in some cases, to a pH range of around 1.0 to 2.5, or 1.5 to 2.0.

o **(paragraph [0049])** To date, the most abundant glycosidic linkage in

starch is the alpha-1,4 linkage, which is broken most commonly during the acid hydrolysis of starch. However, acid-catalyzed reversion (condensation) can occur between two random hydroxyl groups, and given the wide variety of combinations and bond geometries, it is relatively unlikely that alpha-1,4 linkage is formed.

o **(paragraph [0055])** The resulting composition produced through treatment with acid, enzymes, or both contains an increased concentration of non-linear saccharide oligomers on a dry solids basis.

② As below, the specification of the prior art discloses that "it is well known that starch can be partially modified into non-digestible products through reactions involving heat and/or inorganic acids" and that "it was found that heating starch or starch hydrolysates with edible di- or tri-carboxylic acids could produce non-digestible products." Therefore, a skilled person who read such descriptions would easily recognize that besides in "edible di- or tri-basic carboxylic acids" inorganic acids can be used to produce non-digestible products from starch or starch hydrolysates.

o **(Page 1, Lines 19 to 25)** It is well known that starch can be modified by heat and/or reaction with small amounts of inorganic acids, alkalis, or salts. The products of such process are known as British gum, Ganary dextrins, etc., some of which are partially non-digestible.

o **(Page 1, Lines 34 to 39)** The inventors found that substantially non-digestible products can be produced from starch or partially hydrolyzed starch by heating starch or starch hydrolysates under specific conditions in the presence of edible di- or tri-carboxylic acids.

③ According to the descriptions in Plaintiff's Exhibit 8 and Defendant's Exhibits 11, 14, and 16, the technology to produce poorly digestible, low-calorie polysaccharides from glucose or other starch hydrolysates using either inorganic or organic acids was already widely used at the time of filing the patented invention.

Defendant's Exhibit 16 (published on September 27, 1955)
o **(Page 2, Column 4, Lines 26 to 34)** An aqueous solution containing 50% by weight of D-glucose (dextrose), 49% by weight of water, and 1% by weight of concentrated hydrochloric acid was evaporated in a vacuum drum dryer for 2 to 6 minutes at a pressure of 10 to 15 mmHg and a temperature of 80 to 100°C to produce a glass-like brittle polymer. This polymer was found to be easily soluble in water except for a very small fraction with an extremely high molecular weight. o **(Page 2, Column 4, Lines 39 to 43)** A portion of the non-linear polyglucose obtained from the drum drying process above was dissolved in water containing a sufficient amount of sodium bicarbonate to neutralize the hydrochloric acid blocked by the glass-like solid polymer.
Plaintiff's Exhibit 8 (published on October 16, 1973)
o **(Page 2, Column 4, Lines 29 to 31)** Non-edible acids are chemically suitable for the process but are not for producing edible polyglucose or polymaltose. Therefore, the selected acid catalyst must be non-toxic to humans. o **(Page 2, Column 4, Lines 43 to 55)** The polycarboxylic acid used is largely, but not completely, esterified with polyglucose or polymaltose during the polymerization process, forming acid polyglucose esters or acid polymaltose esters. The introduction of acid residues into polyglucose or polymaltose does not affect their suitability for human consumption.
Defendant's Exhibit 11 (published on September 24, 1998)
o **(Page 5, Lines 13 to 21)** The above and other objectives are achieved by the present invention that provides a method for producing highly branched polysaccharides, wherein saccharides such as maltose, glucose, or other simple sugars, or glucose-containing materials such as hydrolyzed starch, are reacted typically at a polyol level of about 5% to about 20% by weight, in the presence of polyols such as sorbitol, glycerol, erythritol, xylitol, mannitol, galactitol, or mixtures thereof and in the presence of sufficient amounts of one or more inorganic acid catalysts or a mixture of inorganic and organic acid catalysts to form polysaccharides suitable for

food use (i.e., showing low coloration and low levels of off-flavors).

o **(Page 5, Line 24 to Page 6, Line 2)** In Embodiment 1, the method of the present invention uses a catalyst including one or more inorganic acids selected from hydrochloric acid, sulfuric acid, sulfurous acid, thiosulfuric acid, dithionic acid, pyrosulfuric acid, selenic acid, selenious acid, phosphoric acid, hypophosphoric acid, pyrophosphoric acid, polyphosphoric acid, hypophosphoric acid, boric acid, perchloric acid, hypochlorous acid, hydrobromic acid, hydroiodic acid, and silicic acid; acidic alkali metal or alkaline earth metal salts of the acids above, such as sodium bisulfate or sodium bisulfite; or mixtures of these acids (and/or acidic alkali or alkaline earth metal salts) with phosphoric acid as a catalyst.

Defendant's Exhibit 14 (published on June 22, 1990)

o **(Page 1, Right Column, Lines 15 to 16)** The present invention relates to a method for producing so-called low-calorie polysaccharides that are difficult to digest in the human body.

o **(Page 2, Right Column, Lines 8 to 13)** Elements of the present invention are characterized by heating glucose, maltose, or other starch hydrolysates in the presence of sugar alcohols and inorganic acids, desirably under anhydrous conditions to conduct polymerization reaction, and subsequently removing bitter-tasting substances and digestible materials contained therein to obtain indigestible low-calorie polysaccharides.

o **(Page 3, Bottom Left Column, Lines 4 to 15)** Furthermore, the acid used as a catalyst in the present invention is a weak inorganic acid but non-volatile and mildly acidic phosphoric acid is desirable, which is used by the amount of 0.1 to 1% by weight of the reactants and is typically used by around 0.3 to 0.5% by weight.

④ Considering the descriptions in the specification of the patented invention, the prior art, and the level of technology at the time of the application as discussed above, the choice of the acid type for producing indigestible products (particularly whether to use organic or inorganic acids) is just what a skilled person can make as needed.

(c) Acidity and heating time

① The corrected Claim 1 limits the pH range to "1.0 to 2.5" and the heating duration to "0.1 to 15 minutes." However, the specification of the patented invention only discloses that "the acid is added to the nutritional composition in an amount sufficient to achieve a pH of around 4 or lower, or in some cases of approximately 1.0 to 2.5 or 1.5 to 2.0" and that "[i]n another specific embodiment, the feed composition has a solids concentration of approximately 90 to 100% by weight and, after contact with the acid, is maintained at a temperature of at least 149°C (300°F) for approximately 0.1 to 15 minutes," but does not describe the technical significance or effects of the numerical limitations. A skilled person could simply select through simple routine experimentation the limitation of the pH range to "1.0 to 2.5" and the heating duration to "0.1 to 15 minutes" in the corrected Claim 1, which is a mere numerical limitation without critical significance.

② The specification of the prior art includes, "The heating duration should be appropriately selected based on the characteristics of the starting material, the proportion of acid, the type of heating apparatus, etc." Thus, a skilled person who read the descriptions of the prior art would recognize that the composition and characteristics of the starting material should be considered in selecting the appropriate process conditions such as the acid type and content, pH range, heating temperature, heating duration, etc. Therefore, it is deemed that a skilled person could, based on the prior art, appropriately select such process conditions through routine experimentation.

o **(Page 2, Lines 55 to 102)** The duration of heating depends on the characteristics of the starting materials, the proportion of edible acid, the type of equipment used during the heating stage, the characteristics needed for the product, and the actual heating temperature. (omitted) Here, producing a non-digestible product may require only a few minutes of residence time. (omitted) The duration required to provide a non-digestible

product also varies depending on the present proportion of edible acid. A lower proportion of acid requires more time. (omitted) Generally, a higher dextrose equivalent of the starch hydrolysate decreases the duration required to provide a non-digestible product, but increases the duration needed to reduce the product's solubility or moisture absorption to the desired level. The temperature used surely has a direct impact on decreasing the duration required to provide a non-digestible product as well as the duration needed to reduce the product's solubility or moisture absorption to the desired level. A higher temperature clearly decreases the duration. (omitted) It is desirable to maintain the minimum reaction time and temperature necessary to form the desired product, which can be easily determined through experiments.

(3) Whether it is easy to overcome Differences 1 and 4

Differences 1 and 4 can be easily overcome by a skilled person due to the following reasons.

(A) According to the following description in the specification of the subject patent, the resulting composition of the corrected Claim 1 is a substance generated by contacting an aqueous feed composition with at least one monosaccharide or linear saccharide oligomer with acid at a high temperature, and contains a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers. The "ratio of concentrations of linear and non-linear dextrose oligomers and the range of degrees of polymerization of non-linear dextrose oligomers" specified in the corrected Claim 1 can be considered characteristics of the resulting composition obtained through the producing method described in the claim. As the specification of the patent in question does not describe the technical significance or effects of such numerical limitations, such as the range of the degree of polymerization or the ratio of linear to non-linear dextrose oligomer concentrations, it cannot be deemed that the limitations have partiuclar technical significance.

o **(paragraph [0010])** Another aspect of the present invention is a process of producing saccharide oligomers. The saccharide oligomer compositions produced by some embodiments of the process are inherently digestion-resistant. In others, they are inherently slowly digested. The process uses an aqueous feed composition containing at least one monosaccharide or linear saccharide oligomer with a solid concentration of at least 70% by weight. The feed composition above is heated to at least 40°C and contacts at least one catalyst that accelerates the rate of cleavage or formation of glucosyl bonds for a duration enough to form non-linear saccharide oligomers. As a result, a composition is produced containing a concentration of non-linear saccharide oligomers higher than that of linear saccharide oligomers.

o **(paragraph [0036]) In this specification, "oligosaccharide" and "saccharide oligomer" refer to saccharides comprising at least two saccharide units, for example, saccharides with a degree of polymerization (DP) of about 2 to 30.** For example, a disaccharide has a DP of 2.

o **(paragraph [0049])** To date, the most abundant glycosidic linkage in starch is the alpha-1,4 linkage, which is broken most commonly during the acid hydrolysis of starch. However, acid-catalyzed reversion (condensation) can occur between two random hydroxyl groups, and given the wide variety of combinations and bond geometries, it is relatively unlikely that alpha-1,4 linkage is formed.

o **(paragraph [0055])** The resulting composition produced through treatment with acid, enzymes, or both contains an increased concentration of non-linear saccharide oligomers on a dry solids basis. In some cases, the concentration of non-linear saccharide oligomers with a degree of polymerization of at least 3 (DP3+) in the resulting composition is at least 20%, 25%, 30%, or 50% by weight on a dry solids basis. In some embodiments, the concentration of non-linear saccharide oligomers in the resulting composition is at least twice that of linear saccharide oligomers.

(B) The following description of the prior art indicates that the resulting composition of the prior art is a substance obtained by heating and contacting starch or hydrolyzed starch with acid, where the composition contains 15% or less, or 5% or less of the components that can be hydrolyzed by α-amylase enzyme. However, it is common

technical knowledge in the field that α-amylase enzyme acts only on the α-1,4 linkages of glucose (i.e., linear saccharides), and thus, a skilled person can easily recognize that the resulting composition of the prior art has a concentration of non-linear saccharide oligomers at least twice that of linear saccharide oligomers. Also, since a condensation reaction follows the hydrolysis process when starch or starch hydrolysates come into contact with acid and are heated, a skilled person can readily recognize that the resulting composition would include non-linear dextrose oligomers with a degree of polymerization of at least 3 without any particular difficulty.

- **(Page 1, Lines 34 to 39)** The inventors found that substantially non-digestible products can be produced from starch or partially hydrolyzed starch by heating starch or starch hydrolysates under specific conditions in the presence of edible di- or tri-carboxylic acids.
- **(Page 1, Lines 40 to 57)** Therefore, according to the present invention, the method for producing a non-digestible food additive involves heating a mixture of starch hydrolysates and edible di- or tri-basic carboxylic acids for a time enough to form non-digestible products.
- (Page 3, Line 113 to Page 4, Line 14) Embodiment 1
  Raw corn starch powder, which contains approximately 10% moisture and having an average particle size of about 25 microns, is dried in a 60°C oven to reduce the moisture content to 1% by weight. Then, the dried powder (170 g) is blended with anhydrous citric acid powder (30 g), which contains an average particle size of approximately 150 microns in a conventional blending apparatus to obtain a homogeneous mixture. The mixture is then heated in a glass flask in an oil bath at 180°C for 3 hours under a pressure of 50 mm of mercury (maintained using a vacuum pump). Samples taken at intervals during the heating period show that the proportion of products hydrolyzable by α-amylase decreases gradually until the end of the period to as low as 4%.
- **(Page 10, Lines 6 to 12) [Claims 19]** A non-digestible food additive comprising the reaction product of starch or starch hydrolysates and edible di- or tri-carboxylic acids (or anhydrides thereof), wherein 15% or less of the product is hydrolyzed by amylolytic enzymes.
- **(Page 10, Lines 13 to 15) [Claim 20]** The product according to Claim 19, wherein 5% or less is hydrolyzable by amylolytic enzymes.

(C) Therefore, the characteristics of the resulting compositions regarding the "ratio of concentrations of linear and non-linear dextrose oligomers and the range of degrees of polymerization of non-linear dextrose oligomers" in Element 3 of the corrected Claim 1 can be easily predicted by a skilled person considering the starting material's components, characteristics, and reaction conditions described in the prior art.

d) Discussion on the Plaintiff's Remaining argument

(1) Whether the two inventions have different starting material

The Plaintiff argues that the two inventions have different starting materials since the aqueous feed composition of the corrected Claim 1 is entirely composed of dextrose residues, whereas the prior art uses a starting material consisting of starch hydrolysates containing etherified or esterified hydroxyl groups.

The corrected Claim 1 discloses "an aqueous feed composition, comprising dextrose, linear dextrose oligomers, a combination thereof, or a combination of any of the aforementioned with non-linear dextrose oligomers" as starting material. The specification of the prior art discloses that "a mixture of starch or starch hydrolysates and edible di- or tri-carboxylic acids is heated to produce non-digestible products" and the starting materials include white dextrin and amylase dextrin (Plaintiff's Exhibit 4-1, Page 1, Lines 40 to 57). However, the white dextrin, which is a hydrolyzed starch product, contains dextrose, a combination of linear and non-linear dextrose oligomers, or any one of the above with non-linear dextrose oligomers, and the "edible di- or tri-basic carboxylic acid" used in the prior art acts merely as a catalyst. Thus, the two inventions share the same starting material. The specification of the prior art states that "starch and starch hydrolysates can be used as starting materials that have been chemically modified or slightly oxidized to introduce small amounts of etherified or esterified hydroxyl groups," (Plaintiff's Exhibit 4-1, Page 1, Lines 72

to 80), but such description merely provides an example of "starch hydrolysates," one of the starting materials. The description alone does not imply that the starting materials are limited to "starch hydrolysates containing etherified or esterified hydroxyl groups." Even if the Plaintiff's argument is understood as "the prior art's starting materials include esters generated by the reaction of organic acids with starch and starch hydrolysates," since the US Patent No. 3,766,165 titled "Polysaccharides and Production Thereof" registered on October 16, 1973, states, "The polycarboxylic acid used is largely, but not completely, esterified with polyglucose or polymaltose during the polymerization process, forming acid polyglucose esters or acid. The introduction of acid residues into polyglucose or polymaltose does not affect their suitability for human consumption" (Plaintiff's Exhibit 8, Column 4, Lines 43 to 55), it is not deemed that by-products cause a difference in the effects of the invention.

This part of the Plaintiff's argument is not accepted.

(2) Whether the two inventions have different resulting compositions

The Plaintiff contends that since the corrected Claim 1 and the prior art have different resulting compositions, the corrected Claim 1 cannot be easily derived by the prior art for the following reason: the resulting compositions of the corrected Claim 1 are all composed of dextrose residues, whereas the prior art uses organic acids with the resulting compositions including cross-linked ester bonds.

The specification of the prior art states, "It is well known that starch can be modified by heat and/or reaction with small amounts of inorganic acids, alkalis, or salts. The products of such process are known as British gum, Ganary dextrins, etc., some of which are partially non-digestible" and "It is also known to produce partial esters of starch using dicarboxylic acids such as maleic acid, fumaric acid, and succinic acid" (Plaintiff's Exhibit 4-1, Page 1, Lines 19 to 25 and 30 to 33).

In addition, the US Patent No. 3,766,165 titled "Polysaccharides and Production Thereof" registered on October 16, 1973, states, "Non-edible acids are chemically suitable for the process but are not for producing edible polyglucose or polymaltose. Therefore, the selected acid catalyst must be non-toxic to humans" and "The polycarboxylic acid used is largely, but not completely, esterified with polyglucose or polymaltose during the polymerization process, forming acid polyglucose esters or acid polymaltose esters. The introduction of acid residues into polyglucose or polymaltose does not affect their suitability for human consumption" (Plaintiff's Exhibit 8, Column 4, Lines 29 to 31 and 43 to 55).

Therefore, it is reasonable to conclude that a skilled person who is aware of the prior art could selectively use either organic or inorganic acids to produce non-digestible products from starch or starch hydrolysates and would be able to predict that using organic acids may result in byproducts such as partial esters of starch in the resulting composition and that replacing the organic acids with inorganic ones could reduce such byproducts.

Further, the specification of the corrected Claim 1 merely states the mechanism of action where "the acid facilitates the hydrolysis of starch and acid-catalyzed reversion (condensation) to produce a resulting composition containing an increased concentration of non-linear saccharide oligomers" (Plaintiff's Exhibit 2, paragraphs [0046] an [0049]), but does not describe the technical significance or effects of limiting the type of acid catalyst to inorganic acids. Thus, it is difficult to conclude that adopting inorganic instead of organic acids results in a significant difference in effects from the prior art.

Therefore, it is deemed that a skilled person could easily derive the corrected Claim 1 from the prior art.

This part of the Plaintiff's argument is also not accepted.

e) Summary of analysis

Therefore, the corrected Claim 1 can be easily derived by a skilled

person based on the prior art and thus is denied an inventive step.

2) Whether the corrected Claims 2, 7, 11, and 16 are denied an inventive step

a) The corrected Claim 2 is a dependent claim citing the corrected Claim 1, stating "the aqueous feed composition characterized by consisting of dextrose, linear dextrose oligomers, and non-linear dextrose oligomers, based on dry solids." But as described above, the starting material in the prior art includes those where "[t]he starch hydrolysates have various dextrose equivalents ranging from around 1 to 70 and always contain a certain proportion of oligosaccharides, as well as the monomer glucose and the disaccharide maltose (Plaintiff's Exhibit 4-1, Page 1, Lines 58 to 67)," and thus, the starting material of the corrected Claim 2 and that of the prior art are not substantially different. Therefore, as long as a skilled person can easily derive the corrected Claim 1 from the prior art, the corrected Claim 2 can also be easily derived.

b) The corrected Claims 7 and 11 of the present invention are dependent on the corrected Claim 1 and states that "the acid is selected from the group consisting of hydrochloric acid, sulfuric acid, phosphoric acid, and combinations of hydrochloric acid with either sulfuric acid or phosphoric acid" and "the acid is (omitted) a combination of phosphoric acid and hydrochloric acid," respectively. However, the specification of the patented invention does not disclose the technical significance or effects of limiting the type of acid, and considering the descriptions in the specification of the prior art (Plaintiff's Exhibit 4-1, Page 1, Lines 19 to 25 and 34 to 39) and the level of technology at the time of the application (Plaintiff's Exhibit 8 and Defendant's Exhibits 11, 14, and 16), a skilled person can appropriately choose the type of the acid as needed. Therefore, as long as a skilled person can easily derive the corrected Claim 1 from the prior art, the corrected Claim 7 and 11 can also be easily derived.

b) The corrected Claim 16 is a dependent claim of the corrected Claim 1 and describes, “The method according to claim 1, wherein the resulting composition contains trace amounts of residual dextrose, characterized by further comprising a step of removing at least a portion of the residual dextrose from the resulting composition by membrane filtration, chromatographic fractionation, or digestion through fermentation.” However, the above element is a post-treatment process commonly performed in the relevant technical field to remove residual dextrose from the resulting composition. Therefore, it is not deemed to have any special technical significance. Therefore, as long as a skilled person can easily derive the corrected Claim 1 from the prior art, the corrected Claim 16 can also be easily derived.

3) Summary of discussion

As the corrected Claims 1, 2, 7, 11, and 16 are denied an inventive step by the prior art, the patent registration shall be invalidated without further examining whether there are grounds for lack of sufficient descriptions. The IPTAB Decision in line with this conclusion is legitimate.

4. Conclusion

The Plaintiff’s petition to revoke the IPTAB Decision is without merit. Therefore, it is dismissed.

Presiding Judge Hyounggeun LEE
Judge Eunhee PARK
Judge Jiyoon HAN

IP HIGH COURT OF KOREA
FIFTH-THIRD DIVISION
DECISION

Case No.	2021Heo5914 Invalidation of Registration (Design)
Plaintiff	A Counsel for Plaintiff Attorney Junhee KIM, Wuwon HA Subcounsel for Plaintiff Attorney Junsung KIM, Minwha BAEK
Defendant	B Corp. CEO C and D Counsel for Defendant AJU Kim Chang & Lee Patent Attorney Changhun LEE
Date of Closing Argument	October 6, 2022
Decision Date	November 3, 2022

ORDER

1. The Plaintiff's claim is dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The Intellectual Property Trial and Appeal Board (hereinafter, the "IPTAB") Decision 2021Dang789, decided October 5, 2021, shall be revoked.

OPINION

1. Background

A. Plaintiff's Registered Design at Issue (hereinafter, the "subject design")

1) Filing date of application / Date of registration / Application number: February 19, 2020 / December 22, 2020 / No. 1088710

2) Article on which design is expressed: Vehicle Air Freshener Container

3) Drawings: As in [Appendix 1]

B. Prior Designs

1) Prior Design 1

Prior design 1 relates to "Air Freshener Container" and was filed an application on October 31, 2016, and described in the Design Registration Gazette of the Korean Intellectual Property Office (hereinafter, the "KIPO") on April 27, 2017. The drawings are as illustrated in images in "A" in [Appendix 2].

2) Prior Design 2

Prior Design 2 relates to "Air Freshener Container B" posted on Blog E (https://blog.E.com/F/221238849002) on March 28th, 2018, as illustrated in the drawings in "B" in [Appendix 2].

C. Procedural History

1) On March 16, 2021, the Defendant filed against the Plaintiff, who is the right-holder of the subject design, a petition for trial to invalidate the subject design to the IPTAB on the ground that the subject design falls under Article 33(1) and 33(2) of Design Protection

ACT.

2) The IPTAB heard the petition for trial as 2021Dang789 and, on October 5, 2021, rendered its decision as ordered since the Defendant's petition for trial has grounds in seeking "the subject design is similar to the Prior Designs 1 and 2 and falls under Article 33(1) of the Design Protection ACT and therefore, the registration shall be invalidated without further examining whether the subject design falls under Article 33(2) of the Design Protection Act. (hereinafter, the "IPTAB Decision")

【Factual basis】 Undisputed facts, the Plaintiff's Exhibits 1, 2 and 3 (including Exhibits with branching numbers, and the same shall apply to the following), individual statements or video clips of the Defendant's Exhibit 14, and the purport of the overall argument.

2. The Summary of Parties' Argument

A. Plaintiff

The subject design and the prior designs show significant differences in detailed shapes in the front and the back and therefore create different aesthetic senses, leading to the conclusion that they are not similar in general. In addition, the subject design cannot be easily created from the prior designs. Hence, the IPTAB Decision is unlawful and shall be revoked.

B. Defendant

The subject design and the prior designs can be deemed to be similar in terms of the overall shape and composition and some detailed differences between them are so small that they cannot affect the overall aesthetic impressions. Even if the subject design and the prior designs are seen as different, the subject design can be easily

created from the prior designs and thus, the IPTAB Decision is lawful.

3. Whether IPTAB Erred

A. Similarity Between the Subject Design and Prior Designs

1) Relevant law

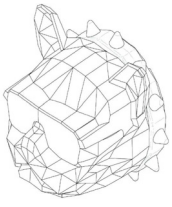
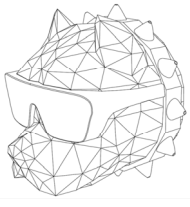
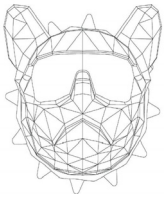
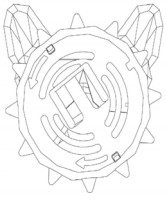
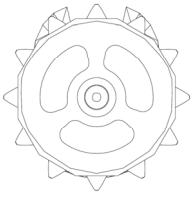
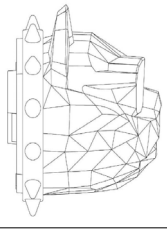
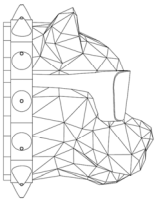
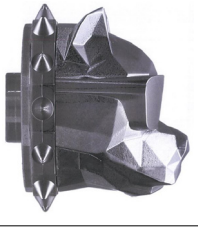
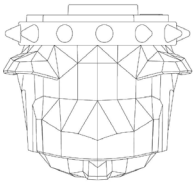
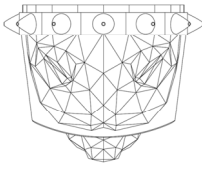
In determining the question of similarity of the designs in contention, a judge or an examiner is not to compare individual features that comprise the designs separately, but rather consider whether an ordinary observer is able to identify differing aesthetic features by comparing and contrasting each design's overall appearance, and if the dominant features of both designs are deemed to be similar, they shall be considered similar even though the two designs provide differences in detail. (See Supreme Court Decision, 2016Hu1710, dated September 3, 2020, etc.)

2) Determining identity/similarity of the articles on which the design is applied

Considering the evidence examined above, the article on which the subject design is applied is a "vehicle air freshener container" and the article on which the prior designs are applied is recognized as an "air freshener container" that can be placed inside a vehicle and thus, in light of the function and the use of each article, both are deemed to be identical.

3) Similarity of designs

a) Comparison of the overall shape and composition of the subject design and prior designs are shown in the table below.

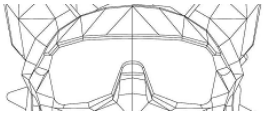
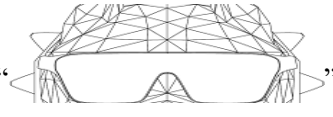
Classification	Subject Design	Prior Art 1	Prior Art 2
Perspective View			
Front View			
Rear View			
Left Side View			
Plane View			

b) Commonalities

① The subject design and the prior designs are common in that they embodied the face and head of a “bulldog”, ② the bulldog wears goggles like sunglasses, ③ at the back, the bulldog

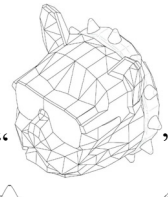
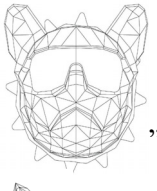
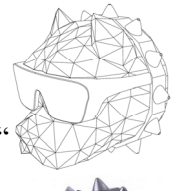
wears a lead around its neck on which multiple conic projections protrude extending out all directions from the center at regular distances, ④ the bulldog's head and face are polygonal, and ⑤ twelve cornic projections are attached to the lead and the lead itself is a dodecagon.

c) Differences

On the other hand, when it comes to the shape of ears (Ⓐ), the subject design shows that it has pricked ears—the upper front edge is soaring upward and curving outward as illustrated in "  ", while prior designs "  " and "  " have relatively smaller ears and the upper front edge curves inward. Concerning a bulldog's forehead (Ⓑ), the subject design's forehead is relatively short because most of the forehead is covered by wide goggles as illustrated in "  " while prior arts feature relatively longer foreheads due to the shape of goggles where the frame is narrower both at the top and bottom that covers merely eyes as shown in "  " and "  ". When it comes to the protruded shape of a mouth (Ⓒ), the subject design is vertical from around the nose to all the way down to the mouth like "  ", while the prior designs feature a protruded nose compared to the mouth and the jaw as shown in the images

“  ”, and “  ”. For the back (Ⓓ), the subject design has a connection to which a vehicle’s air vent shaped like Korean alphabet character “ㄷ” at the center of a circle as well as counterclockwise arrow onto the large circle like “  ”, while the prior designs do not have such shapes as shown in “  ”, and “  ”.

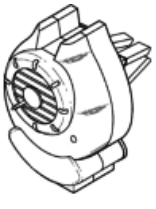
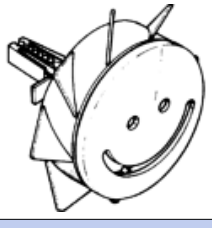
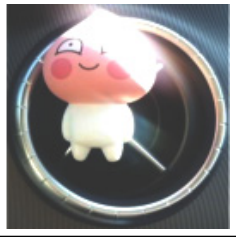
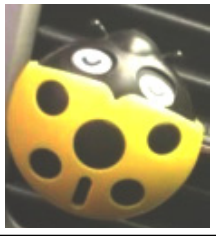
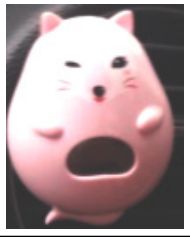
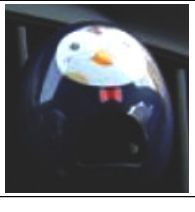
d) Analysis of commonalities and differences

(1) As recognized above, when comparing the subject design and the prior designs from the perspective views and the front views that particularly well illustrates the overall shape and composition of the designs as shown in the images of the subject design “  ”, “  ”, and those of Prior Design 1 “  ”, “  ” and Prior design 2 “  ”, “  ”, they have in common in the following points: they are all bulldog-shaped that give an impression of aggressive

aesthetic; they are wearing goggles like sunglasses; they are wearing the leads with conic projections; the bulldog's head and face are polygonal. In this regard, the subject design and the prior designs have identical creative motives or the subject matter.

In addition, the aforementioned creative motive, etc., is determined to be newly emerged since the application of prior designs as shown in the table below. It seems that in the field of vehicle air freshener device that relates to a container of a vehicle air freshener, such designs were not commonly adopted before the application of prior designs, considering the detailed shapes of the design and its progress of air freshener container for a vehicle, which can be recognized based on each statement or video clip of the Defendant's Exhibits 15 to 24 as well as the overall purport of the argument.

[Table]

Defendant's Exhibit 16	Defendant's Exhibit 17	Defendant's Exhibit 18
		
Defendant's Exhibit 19	Defendant's Exhibit 20-1	Defendant's Exhibit 21
		
Defendant's Exhibit 22	Defendant's Exhibit 23	Defendant's Exhibit 24
		

In addition, both designs are deemed to create similar aesthetic impressions in the observers' minds, as they have commonalities in terms of their dominant features since the commonalities of both designs from ① to ⑤ provide dominant features of the overall appearance of the designs and can be recognized as the essential parts that can attract the observers' attention.

(2) Meanwhile, as the differences between both designs Ⓐ and Ⓑ relate to the shape of the ears and the forehead, which are deemed to be easily modified from the prior designs by enlarging the size of the ears of the subject design and then narrowing the forehead, such difference is considered to be of a low creative level and its aesthetic value is also considered not to be high overall. Also, the difference Ⓒ wherein the nose and the mouth are vertically embodied in the subject design is so small that it can only be perceived from the side views—simplified the shape of around the mouth of the prior designs—and thus cannot be deemed to be a feature that draws the observers' attention. The difference Ⓓ that illustrates the variation in the back part of designs can hardly be seen as the point that creates a dominant aesthetic impression to the consumers at the time of use when considering how the article on which both designs are expressed is commonly used, for example, the placement on the ventilation system of a vehicle. (Hence, the Plaintiff's argument that "the back part of the subject design is obviously perceived by the observers when considering how a vehicle air freshener container is used by the consumers in general and the difference of the shape of the back of the subject design and the prior designs can be deemed to create a meaningful difference in terms of aesthetic senses, and therefore, the subject design and prior designs are not similar" cannot be accepted.)

(3) In consideration of all the above circumstances, despite the aforementioned differences between the subject design and the prior designs, the dissimilarity in light of detailed shapes and the degree, does not rise to the degree that offsets the similarity brought

by the commonalities from ① to ⑤, which represent the dominant features of the designs so as to display distinct aesthetic senses as a whole, in addition to the differences that the Plaintiff argues at the court.

e) Summary of analysis

According to the above findings, the subject design is deemed to create similar aesthetic senses to observers even if there are small differences when compared and contrasted with prior designs in terms of the overall appearance, considering the submitted evidence and the circumstances of all the arguments by the Plaintiff. Therefore, the subject design is similar to prior designs as it does not create different aesthetic senses from those of prior designs.

4) Discussion of the Plaintiff's argument

a) The Plaintiff contends that "the subject design is different from the prior designs in that it is the design that embodies "pit bull terriers," which are totally different from "bulldogs" that prior designs have expressed and this creates obviously different aesthetic senses and thus, the subject design is distinctive."

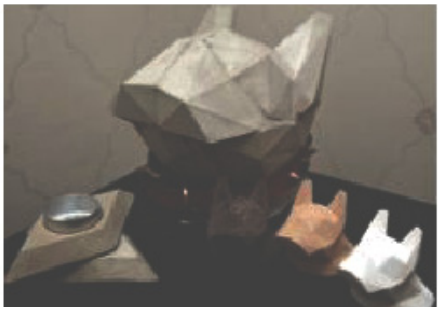
Upon consideration, even if the subject design embodies a different type of dog from those of the prior arts, when determining the similarity of the subject design and prior designs, the question of similarity shall depend on whether the overall comparison of those features provides any aesthetic difference with the observers, rather than comparing individual features comprising the designs which are different due to the types of dogs as the Plaintiff argues. Considering all the aforementioned circumstances, the subject design and prior designs are deemed to provide similar aesthetic senses to the observers who compare and observe the overall appearances of the designs as they have similar dominant shapes, etc. Along with this circumstance, according to the overall purport of the argument stated in the Defendant's Exhibit 10, consumers can hardly differentiate the types of

dogs embodied in each design. In considering all of these circumstances, the Plaintiff's claim shall not be granted.

b) The Plaintiff argues that "the features that the Defendant claims to be characteristic of prior designs—a dog of a bulldog family wearing sunglasses and a spiked lead and the face and head of a dog expressed polygonal—are publicly known or widely used design techniques, and importance thereof should be assessed in limited degree."

The fact that [Polygon-shaped plaster air freshener] or [Bluetooth speaker] as in the images below were released in the market before the application of the prior designs can be recognized based on the undisputed facts between the parties or the statements or video clips of the Plantiff's Exhibits 4 and 5 in addition to the overall purport of the arguments.

[Polygon-shaped plaster air freshener]



[Bluetooth speaker][1)]

Considering, however, each statement of the Defendant Exhibits 15 to 24, submitted to the Court by the Plaintiff, it is insufficient to recognize that the designs aforementioned—Polygon shape plaster air freshener or Bluetooth speaker—are publicly known for a vehicle air freshener container or a widely used design technique and there is no evidence to recognize otherwise. In addition, the polygon-shaped plaster air freshener and the prior designs are differentiated in terms of

1) Product G

the shape of faces, the disposition and the shapes of eyes, noses, and mouths, and the polygon shape plaster air freshener is without sunglasses. Moreover, the bluetooth speaker is different from the prior arts in that the articles to which the designs are applied are not the same and the composition is also different. Also, the speaker is recognized to be designed polygonal on the entire surface except the glasses compared to the prior designs and there is an evident difference in relation to the existence of the spike lead, etc. As a result, regarding all the aforementioned differences and the differences examined in "D) Analysis of Commonalities and Differences", the Plaintiff's claim in this part has no merit.

B. Summary of Discussion

According to the above findings, the subject design shall be invalidated as it is similar to the prior arts. The IPTAB's decision is consistent with the above analysis and shall be upheld and there is no error of law as argued in the Plaintiff's claims. [Even if the subject design is considered to be dissimilar to the prior designs, in consideration of all the above circumstances, the subject design and the prior designs are deemed to have adopted the identical creative motif in general, and the differences from Ⓐ to Ⓓ that differentiate the subject design from the prior designs are merely a commercial and functional modification without any other recognized aesthetic value overall or falls into the expression that requires a low creative level for a person with ordinary knowledge in the design industry (hereinafter, a person having ordinary design knowledge) to create such partially modified designs based on aforementioned differences. Therefore, the subject design is determined to be the design that a person having ordinary design knowledge can easily create based on prior designs and therefore its design registration should be invalidated.

4. Conclusion

The Plaintiff's claim requesting the revocation of the IPTAB's decision is without merit and therefore dismissed.

Presiding	Judge	Sungyop WOO
	Judge	Youngwoo LIM
	Judge	Donggyu KIM

[Appendix 1]

The Registered Design at Issue (or the Subject Design)

【Article to Which Design Is Applied】

Vehicle air freshener container

【Description of Design】

1. This design of a vehicle air freshener shall be made of synthetic resin.

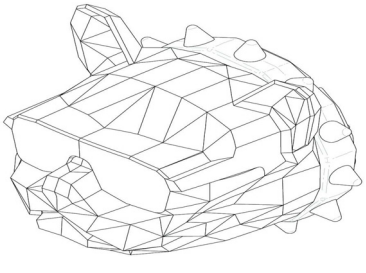
2. This article to which the design is applied wherein air freshener is filled adheres to various locations of an automobile.

3. Drawing 1.1 describes the overall shape of the design, Drawing 1.2 is a front view of this design, Drawing 1.3 is a back view of this design, Drawing 1.4 is a left side view of this design, a right side view is omitted as symmetry of Drawing 1.4, Drawing 1.5 is a plane view of the design, and Drawing 1.6 is a bottom view of this design.

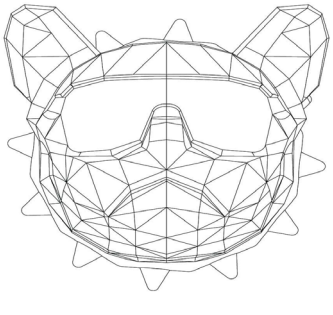
【Summary of Design's Creative Content】

The essence of the creation of this design is the combination of an image and the shape of a "vehicle air freshener container."

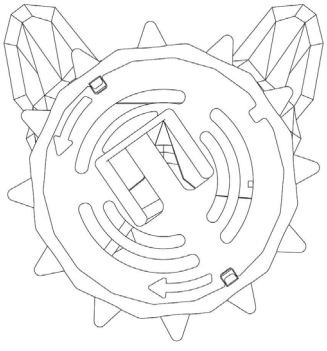
[Drawing 1.1]



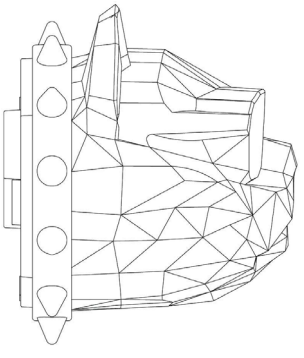
[Drawing 1.2]



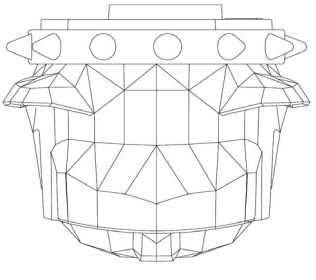
[Drawing 1.3]



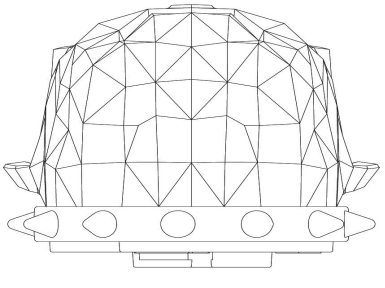
[Drawing 1.4]



[Drawing 1.5]



[Drawing 1.6]



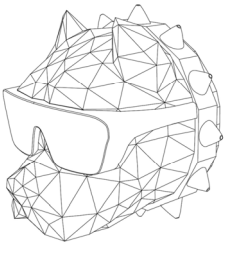
End.

[Appendix 2]

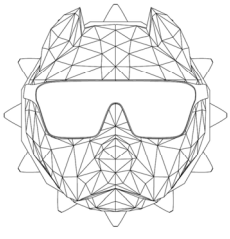
Prior Designs

A. Prior Design 1

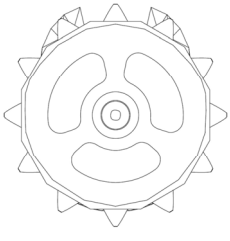
[Drawing 1.1]



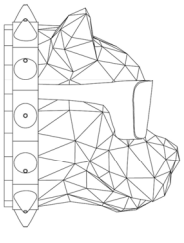
[Drawing 1.2]



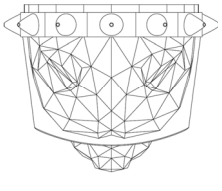
[Drawing 1.3]



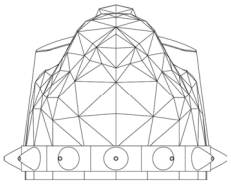
[Drawing 1.4]



[Drawing 1.5]



[Drawing 1.6]



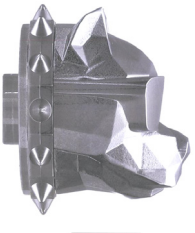
B. Prior Design 2

[Drawing 1.1]

[Drawing 1.2]

[Drawing 1.3]

[Drawing 1.4]



[Drawing 1.5]

[Drawing 1.6]

[Reference Picture]

End.

IP HIGH COURT OF KOREA
THIRD DIVISION
DECISION

Case No.	2022Heo1216 Invalidation of Registration (Trademark)
Plaintiff	A Co. Ltd. CEO B Counsel for Lawfirm Hanrim Attorney in Charge Jingyeong SONG, Beom YANG, Jeongyeon, YUN, Seho JANG, and Jangwoo HYEONG Subagent Patent Attorney in Charge Jaeyeon JU
Defendant	C Counsel for Defendant Major Patent and Saw Firm Patent Attorney in Charge Sugyeong HA
Date of Closing Argument	September 29, 2022
Decision Date	December 15, 2022

ORDER

1. The IPTAB Decision 2020Dang3497, decided December 21, 2021, shall be revoked.

2. Costs shall be borne by the Defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Background

A. Registered Service Mark at Issue (Plaintiff's Exhibit 2)

1) Registration number/Filing date of application/Registration date: No. 1592311/June 7, 2019/April 1, 2019

2) Mark at issue: JBC 종로서적 북카페

3) Designated services

Classification of Services, Class 43: Book café services; salad bar services; brunch café services; franchise café services; self-service restaurant services; patisserie café services; coffee shop services; cafeteria services; study café operation services; snack bar services; guesthouse operation services; snack bar operation services; beverage dispenser rental services; venue rental services for gatherings, conferences, conventions, exhibitions, seminars, and meetings; and study space provision services.

B. A's Operations and Closure

1) A was the first modern bookstore in Korea, opened in 1907 on D Street in Seoul, and operated for approximately 95 years before closing in 2002. (A was initially established by E but was later acquired and operated by the late F and others. Subsequently, it was managed by A Co., Ltd., established by the late F and others. Hereinafter, regardless of the entity operating it, it will be referred to simply as "Former A.")

2) The Plaintiff, established on October 26, 2016, is a company engaged in book sales (wholesale and retail), consignment, and bookstore operation. Since the end of the same year, the Plaintiff has been operating a bookstore under the trade name "A" (hereinafter,

"New A").

C. Prior-used Service Mark and Prior-registered Service Mark

1) Prior-used service mark

a) Mark at issue: A

b) Services where the mark used: Publishing business, book retail sales, and book wholesale

c) Users: Former A and the Plaintiff (however, the Plaintiff used the character string "A" in a blue font, as shown in " 종로서적 ")

2) Prior-registered service mark 1 (Plaintiff's Exhibit 3)

a) Registration number / Filing date of application / Registration date: No. 1351822 / June 27, 2017 / April 18, 2018

b) Mark at issue: 

c) Designated services: Classification of Services, Class 35: Marketing, market research, and market analysis services; business management, administration, and office administration processing services; internet comprehensive shopping mall services; telecommunication -based intermediary services for online sales; publication advertising services; distribution of advertisements and advertising materials (leaflets, brochures, printed materials, and samples); advertising agency services; advertising material publishing services; intermediary services for subscriptions to books, reviews, newspapers, or comic books; intermediary services for subscriptions to publications; intermediary services for the distribution of educational materials; wholesale of books; wholesale of downloadable digital books; retail of books;

agency services for book sales; agency services for publication sales; intermediary services for book sales; intermediary services for publication sales; agency services for book purchases; and agency services for publication purchases

d) Right holder: Plaintiff

3) Prior-registered service mark 2 (Plaintiff's Exhibit 4)

a) Registration number / Filing date of application / Registration date: No. 1351823 / June 27, 2017 / April 18, 2018

b) Mark at issue: 

c) Designated services: Classification of Services, Class 35: Marketing, market research, and market analysis services; business management, administration, and office administration processing services; internet comprehensive shopping mall services; telecommunication-based intermediary services for online sales; publication advertising services; distribution of advertisements and advertising materials (leaflets, brochures, printed materials, and samples); advertising agency services; advertising material publishing services; intermediary services for subscriptions to books, reviews, newspapers, or comic books; intermediary services for subscriptions to publications; intermediary services for the distribution of educational materials; wholesale of books; wholesale of downloadable digital books; retail of books; agency services for book sales; agency services for publication sales; intermediary services for book sales; intermediary services for publication sales; agency services for book purchases; and agency services for publication purchases

d) Right holder: Plaintiff

D. Procedural History

1) The Plaintiff, on November 22, 2020, filed an administrative trialfor invalidation of registration of the registered service mark at issue with the Korean Intellectual Property Trial and Appeal Board (IPTAB) against the Defendant, claiming that the registered service mark at issue should be invalidated as it falls under Article 34(1)12 or 13 of the Trademark Act.

2) The IPTAB reviewed the case under Case No. 2020Dang3497 and, on December 21, 2021, dismissed the Plaintiff's request, issuing a decision (hereinafter, the "IPTAB Decision") on the grounds that the registered service mark at issue does not fall under Article 34(1)12 or 13 of the Trademark Act.

【Factual basis】 Undisputed facts, Plaintiff's Exhibits 1 through 9, and purport of the overall argument

2. Summary of Parties' Arguments

A. Plaintiff's Argument

The registered service mark at issue falls under Article 34(1)12 or 13 of the Trademark Act for the following reasons and should therefore be invalidated. The IPTAB Decision, which reached a different conclusion, is erroneous and should be revoked.

1) The registered service mark at issue evokes "Former A" or "New A" in general consumers, raising concerns about misleading them regarding its quality. Thus, it falls under the former part of Article 34(1)12 of the Trademark Act.

2) The registered service mark at issue was similar in its mark and designated goods to the prior-used service marks and prior-registered service marks which are known to domestic traders as indicating the

source of goods of a specific party prior to its registration decision date. As a result, it may lead to deceiving consumers and causing confusion about the source of goods. Accordingly, the registered service mark at issue falls under the latter part of Article 34(1)12 of the Trademark Act.

3) The registered service mark at issue is identical or similar to the prior-used marks and prior-registered service marks. The Defendant filed the application for the registered service mark at issue with an improper intent to unfairly benefit from the goodwill or reputation embodied in the prior-used service marks and prior-registered service marks. Therefore, the registered service mark at issue falls under Article 34(1)13 of the Trademark Act.

B. Defendant

The registered service mark at issue does not fall under Article 34(1)12 and 13 of the Trademark Act for the following reasons. The IPTAB Decision is consistent with the above analysis and shall be upheld.

1) Consumers can recognize from the “book café” portion of the registered service mark at issue that it pertains to a book café rather than a bookstore. Therefore, the registered service mark at issue does not raise concerns about misleading consumers regarding its quality. Consequently, the registered service mark does not fall under the former part of Article 34(1)12 of the Trademark Act.

2) Even if the prior-used service mark is known to domestic consumers as the service mark of Former A, the Plaintiff was established only after the closure of Former A. Therefore, the reputation of the prior-used service mark acquired by Former A cannot be considered to have been succeeded by the Plaintiff. Furthermore, the prior-used service marks and prior-registered service marks cannot be regarded as having become known to domestic consumers to the extent that they

are recognized as the Plaintiff's service marks. Therefore, the registered service mark at issue does not fall under the latter part of Article 34(1)12 and 13 of the Trademark Act.

3. Whether IPTAB Erred

A. Whether the Registered Service Mark at Issue Falls Under Article 34(1)13 of the Trademark Act[1)]

1) Relevant Law

For a registered service mark to fall under Article 34(1)13 of the Trademark Act, at the time of application, the prior-used trademark must be recognized by domestic or foreign consumers as indicating the goods or services of a specific party, and the applicant for the registered trademark must have used a mark identical or similar to the prior-used trademark with improper intent (refer to Supreme Court Decision 2013Hu2460 on February 13, 2014).

Whether the prior-used service mark is recognized among domestic or foreign consumers as the trademark of a specific party should be determined based on factors such as the period, method, manner, and scope of its use, as well as whether it has been objectively well-known to a significant extent in light of transactional circumstances or social norms (See Supreme Court Decisions 2017Hu752 on August 14, 2019; 2011Hu3896 on May 9, 2013; and 2012Hu672 on June 28, 2012). Recognition of a prior-used trademark as indicating the goods or services of a specific party refers to an objective state acknowledged under transactional circumstances, with general consumers as the standard. It is not necessary for the name of the rights holder of the prior-used trademark to be specifically known; it suffices if the source

1) For the convenience of discussion, the invalidation grounds under Article 34(1)13 of the Trademark Act are examined first.

can be consistently perceived as an identical source, even if the identity of the rights holder is unknown (See Supreme Court Decision 2020Hu11431 on December 30, 2021).

Whether the applicant of the registered trademark had improper intent must be determined based on a comprehensive consideration of the following factors as of the time of the trademark application: the degree of recognition or originality of the specific party's trademark; the degree of similarity or identity between the specific party's trademark and the applicant's trademark; the existence and details of negotiations over the trademark between the applicant and the specific party; other relationships between the parties; whether the applicant had specifically prepared a business utilizing the registered trademark; the identity or similarity of the goods or services, or the existence of an economic connection; and transactional circumstances (See Supreme Court Decisions 2017Hu752 on August 14, 2019; 2013Hu1108 on August 20, 2014; and 2012Hu672 on June 28, 2012).

2) The degree of how the prior-used service mark is well known

a) Established facts

Based on the statements of Plaintiff's Exhibits 10 and 13 (including Exhibits with branching numbers, hereinafter applies the same) and the purport of the overall arguments, the following facts can be acknowledged:

(1) Former A, established in 1907 in Seoul's D area, was the first modern bookstore in South Korea. It operated for approximately 95 years until its bankruptcy and closure in 2002.

(2) After the closure of Former A, there were opinions advocating for the revival of the bookstore that had a 95-year history. A proposal was made on a "Preparatory Committee for the Re-establishment of Former A," which included publishing industry officials, G Museum director, professors, and others.

(3) After the Plaintiff's establishment on October 26, 2016, numerous domestic media articles were published with content such as "A has been revived." Excerpts from these articles regarding former A are as follows:

Date and Source	Excerpts
January 20, 2017, H (Plaintiff's Exhibit 13-3)	"A," a meeting place for university students in the 1980s and a symbol of the bookstore district in Jongno, has returned after 14 years. Back in a time without smartphones or even mobile phones, there was an implicit agreement to wait at "A" when hanging out together. To rekindle that nostalgia among younger generations, "A" has been reborn as a "place to meet." Along with I and J, which opened in the 1980s, "A" was a symbol of Jongno.
January 8, 2017, K (Plaintiff's Exhibit 13-4)	Established in 1907 in Seoul's R area, "A" was a cultural and historical legacy that survived a century, making Jongno the top bookstore district, until it closed in 2002.
January 18, 2022, L (Plaintiff's Exhibit 13-7)	Quietly disappearing amidst the excitement of Korea's semifinal advancement in the 2002 World Cup, "A" returns. Originally opening as the small wooden Christian bookstore "E" in 1907 in R area, it grew into Korea's largest bookstore, becoming a cultural space and a popular meeting spot. With its limited space stacked with an overwhelming number of books, "A" was once a destination for middle- and high-school student field trips. It pioneered "conversations with readers" programs, developed its own book brand, opened a branch in Daehakro, and launched Korea's first online bookstore, playing a significant role in transforming local bookstores into modern enterprises. Nearby I is also known to have received substantial early support from people associated with "A." However, with increasing competition from local and online bookstores and declining readership, "A:" ultimately went bankrupt in 2002.

Date and Source	Excerpts
January 18, 2022, M (Plaintiff's Exhibit 13-12)	Established in 1907 in Seoul's R area, "Former A" served as a landmark, symbolizing "books and meetings" for nearly a century in Jongno. Before the advent of mobile phones and the internet, it grew into Korea's largest bookstore, beloved as both a cultural space and a meeting place. However, intensified competition in the 2000s with online bookstores led to its closure in 2002.
December 22, 2016, N (Plaintiff's Exhibit 13-13)	Originally opened by E in 1907 in R area, "A" closed in 2002 due to the emergence of J and I since the 1980s and the advent of online bookstores. Thanks to efforts in the publishing industry, the 95-year-old "A" has been revived as a cultural space and meeting place.
December 25, 2016, O (Plaintif's Exhibit 13-14)	◆ Beloved by writers, "A" was a "spiritual buoy for youth." ◆ Although its location and owner have changed, the nostalgia evoked by the name "A" alone revives memories. Opened by E in 1907, "Former A" was the longest -standing bookstore and the first to implement fixed book pricing. It was a representative meeting place for youth and Korea's first bookstore, standing in R area for 95 years. Even after other historic bookstores like "P" and "Q" that led the literary golden age closed, "A" endured as a literary beacon of D. However, it failed to adapt to the advent of online bookstores and changes in the industry, leading to its bankruptcy and disappearance into history.
December 23, 2016, S (Plaintiff's Exhibit 13-15)	After opening in 1907 in R area, "A" became a symbol of Jongno alongside I and J, which opened in the 1980s. However, it struggled in competition with online and other large bookstores, ultimately closing in 2002. Since then, calls to revive "A" have persisted in the publishing industry.

b) Analysis

The prior-used service mark consists of the character string "종로 (Jongno)" combined with the character string "서적 (Bookstore)," where "종로" is a geographical name and "서적" intuitively suggests publishing and book sales. Therefore, the mark "A" itself in the prior-used service mark is not considered distinctive. However, considering the duration and continuity of its use, domestic media articles, and the publishing industry's reaction to the closure of Former A, it is reasonable to conclude that the prior-used service mark was widely recognized by domestic consumers as indicating the business of a specific entity with respect to its use by 2016, when New A opened, and continuing through 2019, when the registered service mark at issue was filed (this fact is undisputed between the parties).

c) Analysis on the Defendant's arguments

In this regard, the Defendant argues that under Article 34(1)13 of the Trademark Act, as for "a trademark recognized as indicating the goods of a specific person", the specific person must refer exclusively to the rights holder or user of the trademark. The Defendant contends based on this premise that even thought the prior-used service mark was recognized by domestic consumers as the service mark of Former A, the Plaintiff was established only after the closure of Former A and did not succeed to the reputation of the prior-used service mark acquired by Former A. Additionally, the prior-used service mark is not recognized as indicating the Plaintiff's services. Consequently, the Defendant claims that the prior-used service mark does not constitute to "a trademark recognized as indicating the goods of a specific person" to domestic consumers. However, under Article 34(1)13 of the Trademark Act, "a trademark recognized as indicating the goods of a specific person" is sufficiently established if it can be perceived as indicating a "consistent and identical source," and it is not necessary for the name of the rights holder or user to be specifically known. Therefore, as long as the prior-used service mark is recognized by

domestic consumers as the service mark of the consistent and identical source "Former A," it qualifies as "a trademark recognized as indicating the goods of a specific person" under Article 34(1)(13) of the Trademark Act. The Defendant's argument on this cannot be accepted.

3) Whether the mark is similar

a) Primary part of the registered service mark at issue

Considering the following facts or circumstances, the '종로서적' portion of the registered service mark at issue serves as the distinctive part, i.e., the primary part, by creating an impression, memory, or association in the minds of general consumers and independently performing the source identification of the trademark:

(1) The registered service mark at issue consists of a combination of three elements: a graphicized portion representing the English letters "JBC," " JBC ," the character string "A" forming the "종로서적" portion, and the string "북카페 (Bookcafé)" forming the "북카페" portion.

(2) In the composition of the registered service mark at issue, the " JBC "' portion can only be perceived as representing the English initials of A 북카페 (A Bookcafé) that follow it, and thus lacks or has weak distinctiveness.

(3) The "북카페" portion intuitively conveys the nature of the designated services, such as book café services, franchise café services, and patisserie café services, and therefore lacks or has weak distinctiveness.

(4) As previously explained, the "종로서적" portion is widely recognized by domestic consumers as the service mark of a specific party, demonstrating strong distinctiveness. Furthermore, the "종로서적" portion cannot be considered inseparably combined with the remaining string to the extent that observing it separately would seem unnatural in commercial transactions.

b) Analysis on the similarity of the two marks

The primary part of the registered service mark at issue is "A." When compared to the prior-used service mark based on this primary part, the two marks are identical in appearance, name, and concept, making them similar.

4) Whether the improper intent is recognized

Considering the facts previously acknowledged, the evidence mentioned earlier, and statements of Plaintiff's Exhibits 46 through 50, Defendant's Exhibits 2, 6, and 28 (including Exhibits with branching numbers, if any) and the purport of overall arguments, as well as the following facts and circumstances, it can be concluded that the Plaintiff had an improper intent at the time of filing the application for the registered service mark at issue, specifically indenting to imitate the prior-used service mark, which was known among domestic consumers as indicating the source of goods of a specific party, thereby seeking to unjustly benefit from the business reputation embodied in the prior-used service mark.

(1) As previously explained, the registered service mark at issue is highly similar to the prior-used service mark, which was widely recognized by domestic consumers at the time of the application.

(2) A "book café" typically operates as a space within a bookstore where food and beverages are sold in a café-style setting.

Therefore, when the registered service mark at issue is used for its designated services, such as "book café services," it is highly similar in form and style to the book sales services where the prior-used service mark was used.

(3) Considering the following facts in overall, it appears that the Defendant, at the time of filing the application for the registered service mark at issue, could easily have obtained extensive information about Former A and New A established by the Plaintiff. Accordingly, it aligns with common experience to conclude that the registered service mark at issue imitated the prior-used service mark in its process of application.

(a) The Defendant, on April 10, 2016, entered into a contract with B and others, under which the Defendant was entrusted with the exclusive rights for the development of New A and its lifestyle store. The Defendant was to carry out store development tasks and receive a commission equivalent to 2% of annual sales as compensation. In accordance with this contract, the Defendant performed tasks such as store development for the "New A" stores opened by the Plaintiff.

(b) The Defendant was appointed as an internal director of the Plaintiff on November 22, 2018, and served in this position until October 15, 2020. On June 7, 2019, when the Defendant served its duty, the Defendant filed the application for the registered service mark at issue under his/her own name.

(c) The Plaintiff's CEO B emphasized in promotional activities that "New A" represented the restoration of "Former A," and such content was shared with the Defendant through emails and other communications.

(d) Around the time the Plaintiff opened "New A" in late 2016, numerous media articles were published reporting that "Former A" had been revived or that "New A" was succeeding "former A."

(e) Around November 2019, when the Defendant was serving as its CEO, A D&C Co., Ltd., entered into contracts with T Co., Ltd., to grant the rights to operate "A Book Café" stores and receive a portion of net sales as a licensing fee, as a franchise business for "A Book Café."

5) Summary of Discussion

The registered trademark at issue is a mark similar to the prior-used service mark, which was recognized by domestic consumers at the time of application as indicating the goods of a specific party, leading to the conclusion that the registered trademark at issue is a mark used with improper intent to unjustly benefit from the business reputation embodied in the prior-used service mark. Accordingly, the registered trademark at issue falls under the invalidation grounds stipulated in Article 34(1)13 of the Trademark Act.

B. Whether the Registered Trademark at Issue Falls Under the Former Part of Article 34(1)12 of the Trademark Act

1) As explained above, the prior-used service mark was recognized by domestic consumers at the time of the application for the registered service mark at issue as indicating the business of a specific party. Against this backdrop, it can be reasonably inferred that, as of the registration decision date for the registered service mark at issue, the prior-used service mark was still sufficiently known among domestic consumers to be recognized as indicating the business of a specific party.

2) Furthermore, the registered service mark at issue, at the time of its registration decision, was similar in its mark to the prior-used service mark, which was recognized among domestic consumers and traders as indicating the services of "Former A" in connection with "book café services" and similar businesses. The designated services of the registered service mark were also similar to, or economically

connected with, the services of the prior-used service mark, leading to circumstances in which it could be mistaken as being used by "Former A," the user of the prior-used service mark.

3) Accordingly, the registered service mark at issue is a service mark likely to deceive consumers by causing confusion regarding the source. It falls under the invalidation grounds stipulated in the latter part of Article 34(1)12 of the Trademark Act.

C. Summary of Discussion

Therefore, the registered service mark at issue falls under the latter part of Article 34(1)12 and Article 34(1)13 of the Trademark Act in relation to the prior-used service mark, and therefore its registration must be invalidated (having acknowledged the invalidation grounds under the latter part of Article 34(1)12 and Article 34(1)13 of the Trademark Act, it is unnecessary to further examine the invalidation grounds under the former part of Article 34(1)(12), which is in an selective relationship).

4. Conclusion

Therefore, the Plaintiff's claim requesting the revocation of the IPTAB Decision is meritorious and shall be granted.

Presiding Judge	Hyounggeun LEE
Judge	Eunhee PARK
Judge	Jiyoon HAN

IP HIGH COURT OF KOREA
FOURTH-SECOND DIVISION
DECISION

Case No.	2022Heo1827 Rejection (Patent)
Plaintiff	A Foundation Corp. Representative Head of the Foundation B Counsel for Plaintiff Tae Woong IP Law Firm Patent Attorney in Charge Gyungchan KANG
Defendant	Commissioner of the Korean Intellectual Property Office Counsel for Defendant Byeongsook KIM
Date of Closing Argument	January 26, 2023
Decision Date	February 15, 2023

ORDER

1. The Plaintiff's claims are dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2021Won1847, decided January 25, 2022, shall be revoked.

OPINION

1. Background

A. Plaintiff's Claimed Invention (Plaintiff's Exhibits 8 and 10)

1) Title of invention: Composition for Inhibiting Angiogenesis Using Extracts of *Zizania latifolia*

2) Filing date of application (Divisional) / Filing No.: April 14, 2020 / No. 2020-45169

3) Claims (As Finally Amended on October 15, 2020)

【Claim 1】 A composition for inhibiting angiogenesis, comprising extracts of *Zizania latifolia* as an active ingredient, wherein the extract is obtained using a mixed solvent of water and ethanol (hereinafter referred to as "Claim 1").

【Claim 2】 to 【Claim 5】: It is the same as the corresponding section in Appendix 1.[1)]

4) Summary of invention

The main content of the invention is as follows, and the detailed description for implementing the invention corresponds to the description provided in the relevant section of Appendix 1.

> **1 Background Technology**
>
> **[0004]** The formation of angiogenesis is known to date to be promoted by more than 20 angiogenic factors, among which vascular endothelial growth factor (VEGF) is secreted by various types of tumor cells and mast cells. VEGF is also recognized as the most potent angiogenic factor. VEGF, also known as vascular permeability factor, is believed to bind to its receptors VEGFR-1 (Flt-1) and VEGFR-2 (Flk-1/KDR), inducing endothelial cell proliferation and increasing vascular permeability, contributing to the growth and metastasis of tumors and mast cells (Leung DW et al., Science

1) Errors in the specification, such as typos, are recorded as is.

246:1306-1309, 1989; Ferrara N & Davis-Smyth T Endocr. Rev. 18:4-25,1997; Liping Liu & Meydani Mohsen Nutrition Review, 61(11):384-387, 2003; Jaap G et al., The FASEB Journal 10.1096/fj.03-1101fje. 2004; Hausman GJ & Tichardson RL, J. anim. Sci., 82:925-934, 2004). Additionally, enzymes such as matrix metalloproteinases (MMPs), which degrade the vascular basement membrane, play an importan role in angiogenesis (Haas TL et al., Am J Physiol Heart Circ Physiol. 2000 Oct;279(4):H1540-7.).

[0005] In a normal physiological state, factors that promote and inhibit angiogenesis interact to strictly regulate and participate in processes such as growth, development, and regeneration. However, when these factors fail to properly regulate angiogenesis, diseases can occur; Excessive angiogenesis has been reported in various conditions, including cancer, arthritis, diabetic retinopathy, retinopathy of prematurity, neovascular glaucoma, corneal diseases caused by angiogenesis, retinal degeneration, corneal graft rejection, posterior capsular fibrosis, granular conjunctivitis, psoriasis, telangiectasia, pyogenic granulomas, seborrheic dermatitis, and acne (Nature, 407:249, 2000; Ophthalmol 102:1261-1262, 1995; J Am Acad Derm 34(3):486-497, 1996; Circultion 93(4):632-682, 1996; Cell 86:353-364, 1996).

[0006] Also, angiogenesis plays a critical role in the growth and metastasis of tumors. Tumors can grow up to a size of approximately 1-3 mm on their own, but further growth requires nutrients from external sources, and this is when the continuous growth of capillaries is stimulated. When new capillaries are formed, they integrate into the tumor, providing pathways for the supply of oxygen and nutrients, enabling the tumor to grow and metastasize to other organs through these blood vessels (McDougall SR et al., JTheor Biol. 2006 Aug 7;241(3):564-89, Grant MB et al.,Expert Opin Investig Drugs. 2004 Oct;13(10):1275-93.;Tarzami ST and Singh JP., Expert Opin Investig Drugs. 2004 Oct;13(10):1319-26.;Bandello F et al., Acta Diabetol. 2013 Feb;50(1):1-20).

2 Problem to be solved

[0011] The present invention aims to provide a composition for inhibiting angiogenesis using extracts of *Zizania latifolia*.

3 Means for solving the problem

[0013] The inventors have confirmed, as demonstrated in the following

embodiments and experimental examples, that extracts of *Zizania latifolia* inhibit the proliferation, adhesion, and migration of human umbilical vein endothelial cells. Additionally, the extract increases the expression of p27, a known cell cycle inhibitor (Cell, 1996, 85(5): 733-44; Trends Cell Biol. 2003, 13(2):65-70), while suppressing the expression of cyclin E and cdk2, which are involved in the transition from the G1 phase to the S phase of the cycle (Cell. 1992, 70: 993-1006;Cell Cycle. 2010, 9: 4900-4907). The extract was also found to inhibit the activity of MMP-2/9, a critical factor for new capillary formation along with VEGF (Curr. Opin. Hematol. 2003 10(2):136-141).

[0015] In this specification, "extracts of *Zizania latifolia*" refer to (i) extracts obtained by extracting parts of Zizania latifoli, such as stems, leaves, fruits, flowers, roots, or the whole plant, using a solvent such as water, methanol, ethanol, butanol or other C1−C4 lower alcohols, methylene chloride, ethylene, acetone, hexane, ether, chloroform, ethyl acetate, butyl acetate, N,N-dimethylformamide (DMF), dimethyl sulfoxide (DMSO), 1,3-butylene glycol, propylene glycol, or their mixed solvents; (ii) extracts obtained using supercritical fluid extraction solvents such as carbon dioxide or pentane; or (iii) fractions obtained by fractionating the extract. Depending on the polarity of the active substances, the degree of extraction, and the extent of preservation, various extraction methods can be employed, including cold steeping, reflux, heating, ultrasonic radiation, or supercritical fluid extraction. Fractionated extracts include (i) fractions obtained by suspending the crude extract in a specific solvent before mixing and settling with a solvent of differing polarity and (ii) fractions obtained by adsorbing the crude extract onto a column packed with silica gel, etc. and using a hydrophobic solvent, a hydrophilic solvent, or their mixed solvents as the mobile phase. Additionally, the extracts above refer to concentrated liquid extracts or solid extracts obtained by removing the extraction solvent using methods such as freeze-drying, vacuum drying, hot air drying, or spray drying. The extracts desirably refer to extracts obtained using water, ethanol, or a mixed solvent of these as the solvent, or more desirably extracts obtained using a mixed solvent of water and ethanol as the extraction solvent.

4 Effect of the invention

[0044] As described above, the present invention provides a composition for inhibiting angiogenesis using *Zizania latifolia* extracts.

[0045] The composition for inhibiting angiogenesis according to the present invention can be commercialized as pharmaceuticals, foods, etc. for purposes such as improving angiogenesis-related diseases.

5 Detailed description for implementing the invention

[0051] <Embodiment 2> Example of preparing *Zizania latifolia* extract 2

[0052] The *Zizania latifolia* extract (G56 80%) was prepared in the same way as in <Embodiment 1>, except that 80% ethanol was used as the extraction solvent.

[0053] <Experimental Example> Evaluation of angiogenesis inhibitory activity

[0069] <2> Experiment results

[0071] When the effect of *Zizania latifolia* extract on the proliferation of vascular endothelial cells was examined, both the 70% (Embodiment 1) and the 80% ethanol extracts (Embodiment 2) exhibited cell proliferation inhibitory activity, but the 80% one demonstrated better activity (See Figure 1). The 80% ethanol extract was treated at different concentrations (25, 50, and 100 mg/mL) to compare the expression levels of cell cycle-related proteins. The results showed that G56 80% increased the expression of p27, a cell cycle inhibitor, while decreasing the expression of cyclin E and cdk2, which are involved in the transition from the G1 phase to the S phase of the cell cycle (See Figure 2). When the effect of the extract on vascular endothelial cell adhesion was examined using a cell adhesion assay, both the 70% and the 80% ethanol extracts showed adhesion inhibitory activity dependent on concentration (See Figure 3). The effects of the extracts on vascular endothelial cell migration were assessed using in vitro wound healing assay and in vitro transwell migration assay, and the results showed that the 80% ethanol extract exhibited stronger migration inhibitory activity than the 70% one (see Figures 4 and 5). Zymography revealed that the activity of MMP2/9, which is involved in cell migration, was inhibited at 100 mg/mL of the 80% ethanol extract (See Figure 6). These results indicate that the 80% ethanol extract regulates migration of vascular endothelial cell by moderating the activity of MMP2/9.

B. Prior Art[2] (Plaintiff's Exhibit 9 and Defendant's Exhibit 1)[3]

The prior invention relates to "Physiological Activities and Anticancer Effects of Ethanol Extracts of Euonymi Ramuli Suberalatum and *Zizania latifolia*" published in the doctoral dissertation submitted and successfully defended by D to the Department of Complementary and Alternative Medicine at C University Graduate School in April 2014. The main content is detailed in Appendix 2.

C. Procedural History

1) On June 17, 2020, the patent examiner of Korean Intellectual Property Office (hereinafter, the "KIPO") sent a notice of grounds for rejection regarding the subject invention, stating that "The claims are unclear and not supported by the description of the invention, and the specification does not provide sufficient information to enable a person having ordinary skill in the art (hereinafter, a "skilled person") to easily invent it. Therefore, the invention fails to meet the requirements of Articles 42(3)1, 42(4)1, and 42(4)2 of the Patent Act. Claims 1 to 4 are denied of novelty by Cited Art 1[4], and lack an inventive step as a skilled person could easily derive it from Cited Art 1."

2) In response, the Plaintiff submitted amendments to the specification along with written opinions on October 15, 2020, and January 25, 2021, but the KIPO examiner issued a rejection on June 16, 2021, stating that the reasons for rejection that "the invention lacks novelty and an inventive step" had not been resolved.

3) The Plaintiff filed a petition in the Intellectual Property Trial and Appeal Board (hereinafter, the "IPTAB") on July 19, 2021, for an

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2) Strictly speaking, it is "prior literature," but for the convenience of comparison with the subject invention, it will be referred to as "prior art."

3) The prior art in this case is identical to the comparable invention referenced during the trial stage of this case.

4) It is the same as the prior art in this case.

administrative trial against the rejection above under IPTAB 2021Won1847, and submitted amendments to the specification and written opinions on August 25, 2021, November 15, 2021, and January 18, 2022. The IPTAB dismissed the Plaintiff's petition on May 19, 2017, (hereinafter, the "IPTAB Decision") on the grounds that "Claim 1 of the present invention can be easily invented based on the cited invention, thereby lacking an inventive step, and is not patentable under Article 29(2) of the Patent Act. If any claim in an invention contains grounds for rejection, the entire patent application shall be rejected."

【Factual basis】 Undisputed facts, the descriptions on Plaintiff's Exhibits 1 through 10, the description and images of Defendant's Exhibit 1, and the purport of the overall arguments

2. Summary of Parties' Arguments

A. Plaintiff

As Claim 1 is acknowledged to possess an inventive step, the IPTAB Decision that reached a different conclusion is erroneous and shall be overturned.

1) The pharmaceutical use of Claim 1 in this case is the "inhibition of angiogenesis" itself, with its pharmacological mechanism being the suppression of endothelial cell proliferation, adhesion, migration, and the expression of angiogenic inducers (hereinafter, "endothelial cell proliferation, etc."). Since its pharmaceutical use and pharmacological mechanism are different from the anticancer effect disclosed in the prior art (cytotoxicity against cancer cells), it has an inventive step.

2) The prior art merely experimented on the cytotoxicity of *Zizania latifolia* extract against cancer cells, and a skilled person would not be able to confirm from this invention that the suppression

of endothelial cell proliferation, etc. inhibits angiogenesis. Therefore, it cannot be concluded that Claim 1 is easily derivable from the prior art.

B. Defendant

Claim 1 lacks an inventive step due to the following reasons based on the prior art. Therefore, the IPTAB Decision consistent with this conclusion is well-grounded.

1) Claim 1 and the prior art share the same active ingredients, comprising a mixed solvent of Zizania latifoli, water, and ethanol (hereinafter, "*Zizania latifolia* extract"), and as angiogenesis is closely related to cancer, the inhibition of angiogenesis inherently encompasses the concept of cancer treatment. Therefore, the pharmaceutical use disclosed in Claim 1 and the prior art is substantially identical.

2) A skilled person could identify the pharmacological mechanism of the prior art by confirming its anti-angiogenic effects through experiments. Thus, the anti-angiogenic use of the invention in Claim 1 can be easily derived.

3) The pharmacological data presented in the specification of the present invention merely confirm the inhibitory effects on "angiogenesis" through experimentation, which is already known to be closely associated with cancer occurrence and metastasis. Simply verifying this effect does not demonstrate that Claim 1 exhibits remarkable or qualitatively distinct effects that a skilled person could not have predicted from the prior art.

3. Whether IPTAB Erred

A. Claim Construction Regarding the Pharmaceutical Use of Claim 1

1) Relevant law

In an invention of pharmaceutical use, the invention is constituted by

a specific substance and its pharmaceutical use (See Supreme Court Decision 2006Hu3564, dated January 30, 2009). The pharmacological mechanism is merely an inherent property inseparably tied to the substance and serves only as a means to derive the connection between the substance and its pharmaceutical use. Therefore, the pharmacological mechanism described in the claims of an invention of pharmaceutical use is meaningful as a constituent element of the invention only to the extent that it specifies the pharmacological use of the particular substance. The pharmacological mechanism itself should not be regarded as an element that limits the scope of the claims (See Supreme Court's 2012Hu3664 decision, dated May 16, 2014). Therefore, in case the pharmaceutical use of a specific substance is already known for a particular disease or therapeutic effect, identifying the pharmacological mechanism and including it in the claims does not make the mechanism an element of the invention. Thus, it cannot serve as a basis for acknowledging its inventive step.

When evaluating the inventive step of a patented invention by referencing multiple prior art documents, if the prior art provides suggestions or motivations, or even if this is not the case, if it can be acknowledged that a skilled person could easily achieve such combination based on the level of technology, technical common knowledge, fundamental challenges in the field, development trends, industry demands, etc. at the time of filing the patent application, the inventive step of the invention is denied. In the case of inventions of pharmaceutical use, if a skilled person can easily predict the therapeutic effect of a specific substance for a specific disease based on prior inventions, the inventive step is denied (See Supreme Court's 2016Hu502 decision, dated January 31, 2019).

2) Discussion

Considering the following facts and circumstances recognized based on the descriptions of Plaintiff's Exhibit 2 and Defendant's Exhibits 2, 3, and 6, as well as the purport of the overall arguments, it is reasonable

to interpret "inhibiting angiogenesis" in Claim 1 as including "prevention, inhibition, or delay of the onset of a disease caused by angiogenesis, such as cancer, etc. (hereinafter, the "treatment")" "Inhibiting angiogenesis" can be an element of the invention only to the extent that it specifies such a pharmaceutical use, and it is difficult to consider it to be an element that by itself limits the scope of the claims.[5)]

a) The specification of the present invention defines "angiogenesis inhibition" as including the prevention, suppression, or delay of diseases[6)] such as cancer, arthritis, and diabetic retinopathy, as described below.

Specification of the Claimed Invention (Plaintiff's Exhibit 8)
[0017] Also, in this specification, "angiogenesis inhibition" includes the improvement (alleviation of symptoms), treatment, prevention, suppression, or delay of diseases caused by angiogenesis, as defined below.
[0018] Furthermore, in this specification, "diseases caused by angiogenesis" include all diseases related to angiogenesis. To be specific, it encompasses the aforementioned cancer, arthritis, diabetic retinopathy, (omitted) inflammatory diseases, and neurodegenerative diseases.

b) The documents published before the filing of the present invention describes that cancer cells stimulates angiogenesis to obtain a blood supply, and thus cancer can be treated by inhibiting angiogenesis. Therefore, it is deemed that angiogenesis inhibition is recognized as

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5) After the conclusion of arguments in this case, the Plaintiff submitted several Patent Publications as reference materials, with the titles of the inventions ending in "composition for inhibiting angiogenesis." However, it is reasonable to conclude that each of these inventions specifies its pharmaceutical use by their claims or specifications, such as the treatment or prevention of particular diseases.

6) The specification of the subject invention states that "excessive angiogenesis has been reported in diseases such as cancer, arthritis, diabetic retinopathy, retinopathy of prematurity, neovascular glaucoma, corneal diseases caused by angiogenesis, retinal degeneration, corneal graft rejection, posterior capsular fibrosis, granular conjunctivitis, psoriasis, telangiectasia, pyogenic granuloma, seborrheic dermatitis, and acne" ([0005]).

one of the various pharmacological mechanisms for treating cancer, which was widely known at the time of filing the application.

▸ Defendant's Exhibit 2 (p. 846, Hard Tissue and Oral Biochemistry, Molecular Cell Biology, published January 1, 2013)

In 2000, Hanahan D and Weinberg RA suggested 6 **fundamental capabilities of malignant tumors**: (i) to produce their own growth signals bypassing the need for external growth factors; (ii) to evade external anti-growth signals; (iii) to evade apoptosis; (iv) to avoid aging and achieve essentially infinite growth; **(v) to stimulate sustained angiogenesis;** and (vi) to invade surrounding tissues and form distinct tumors.

▸ Defendant's Exhibit 3 (p. 3 to 4, Trends in Cancer Vaccine Development, published around October 2005)

C. Characteristics of Cancer Cells

○ The transformation of normal cells into cancer cells through mutations alters cellular characteristics and leads to the development of tumors. Additional mutations cause benign tumors to progress into malignant ones, which acquire new characteristics in the process. Cancer cells secrete substances to **promote the growth of surrounding blood vessels, stimulating angiogenesis and being provided with blood, which enables the cancer cells to metastasize to other tissues.**

▸ Defendant's Exhibit 6 (p. 542 to 543, Journal of the Korean Medical Association, published around 2003)

Most anticancer drugs currently used in clinical practice exhibit cytotoxic effects by targeting the chromosomes or microtubules of cancer cells. However, as these drugs also damage normal cells, leading to side effects, there is a growing demand for anticancer drugs that target substances or mechanisms specific to cancer cells without harming normal cells. As a result, the development of such targeted drugs has become inevitable, and some of these drugs have already been commercialized and are currently used in clinical practice. Most newly developed drugs with advances in molecular biology are designed to target molecules unique to cancer cells, thereby demonstrating efficacy. **Drugs or anticancer drugs used in molecular targeted therapies** are designed to act on various targets, including signal transduction pathways, **angiogenesis,** matrix, cell cycle regulators, and **apoptosis**.

c) Considering the specification of the subject invention and the publicly disclosed literature prior to the filing, it is clear that the pharmaceutical use of Claim 1 includes the treatment of cancer through an angiogenesis inhibition mechanism. Thus, it is reasonable to interpret the scope of Claim 1 as including the therapeutic use of *Zizania latifolia* extract for the treatment of cancer, etc.

3) Discussion on the Plaintiff's argument

a) The Plaintiff argues that "inhibition of angiogenesis" itself can be recognized as a pharmaceutical use, and that "inhibition of proliferation, adhesion, and migration of vascular endothelial cells" and "inhibition of expression of angiogenesis-inducing factors" are its pharmaceutical mechanism, based on Supreme Court Decision 2003Hu1550, decided December 23, 2004, which held that the claims are described clearly even though the claims refer to "inhibition of vasculogenesis," not the treatment of a specific disease, as a pharmaceutical use.

b) However, the Supreme Court decision above only determines whether the "inhibition of vasculogenesis" is percieved by a skilled person as a specific pharmaceutical effect and is clearly an expression of a pharmaceutical use considering the requirement of definiteness of the patent claims [Article 42(4)2 of the old Patent Act (before amended by Act No. 8197 of January 3, 2007; the same shall apply hereinafter)] and the requirement of practicability of the patent specification [Article 42(3) of the old Patent Act], and does not conclude that "inhibition of vasculogenesis" itself is an element that limits the scope of the claims. Furthermore, as previously examined, angiogenesis is one of the key mechanisms driving cancer progression, and while cancer may not be the only condition treated through angiogenesis inhibition, it undeniably falls within the category of diseases that can be treated by inhibiting angiogenesis. Moreover, it cannot be argued that "inhibition of angiogenesis" does not inherently

encompass the treatment of diseases such as cancer. Considering these, the Plaintiff's argument, which is based on the assumption that the therapeutic use of Claim 1 does not include the treatment of cancer and similar conditions, cannot be accepted.

Meanwhile, the pharmacological mechanisms claimed by the Plaintiff for Claim 1, that is, "inhibition of endothelial cell proliferation, adhesion, and migration" and "suppression of the expression of angiogenesis-inducing factors," can be regarded as individual and specific sub-mechanisms of the broader pharmacological mechanism of "angiogenesis inhibition." So, even if it is a higher-level pharmacological mechanism encompassing these subordinate mechanisms, that alone does not suffice to constitute a medical use on its own [Even if viewed differently, considering the description in the specification of the subject invention, the "inhibition of angiogenesis" in Claim 1 should be understood as an "efficacy" aimed at treating specific diseases such as cancer. Therefore, it is reasonable to interpret the pharmaceutical use of Claim 1 as "the treatment of cancer, etc. (through angiogenesis inhibition)."]

B. Comparison Between Claim 1 and Prior Art

1) Element-by-element comparison

Element	Claim 1 (Plaintiff's Exhibit 8)	Prior Art (Defendant's Exhibit 1)
1	Including *Zizania latifolia* extract as an active ingredient, wherein the extract is characterized as being obtained using a mixed solvent of water and ethanol.	After grinding *Zizania latifolia* and obtaining sample through extraction with 80% ethanol (See 2. Sample Extraction on page 7)
2	Composition for angiogenesis inhibition	The anticancer effect of *Zizania latifolia* extract was evaluated against four types of cancer cells. - When *Zizania latifolia* extract was treated for 24 hours, the survival rates of cervical cancer

Element	Claim 1 (Plaintiff's Exhibit 8)	Prior Art (Defendant's Exhibit 1)
		cells, liver cancer cells, and breast cancer cells decreased (second paragraph on page 17). - When *Zizania latifolia* extract was treated for 48 hours, the survival rate of liver cancer cells decreased, and a minimal anticancer effect was observed for breast cancer cells (second paragraph on page 19). - When *Zizania latifolia* extract was treated for 72 hours, a low anticancer effect was observed for gastric cancer cells and a weak anticancer effect for breast cancer cells (second paragraph on page 21).

2) Commonalities and differences

a) Element 1

Element 1 and the corresponding component of the prior art are substantially identical in that both are *Zizania latifolia* extracts, and there is no dispute between the parties regarding this.

b) Element 2

Element 2 and the corresponding element in the prior art are different in that the former is limited the use to "angiogenesis inhibition," whereas the latter is an anticancer effect (reduction effect in cancer cell survival rate) "through apoptosis" (hereinafter, referred to as the "Difference").[7)]

7) However, as previously discussed, if Claim 1 is considered to include the therapeutic use for cancer, it can be deemed substantially the same.

C. Analysis of difference

1) Pharmaceutical use of Claim 1

The scope of Claim 1 includes therapeutic uses such as the treatment of cancer, and "angiogenesis inhibition" shall be considered an element of the invention only to the extent that it specifies this pharmaceutical use, as previously discussed.

2) Whether the element can be easily derived

The prior art discloses experimental results showing a reduction in the survival rate of cancer cells treated with *Zizania latifolia* extract (apoptosis). The close correlation between angiogenesis and cancer (Defendant's Exhibits 2 and 3) and the fact that various targets, such as angiogenesis and apoptosis (or programmed cell death), are utilized in cancer treatment (Defendant's Exhibit 6) were well-known in the relevant field at the time of the application.

Therefore, a skilled person could easily derive a use for cancer treatment from the prior art disclosing the results of tests showing that extracts of *Zizania latifolia* reduce cancer cell survival rates, and reviewing "inhibition of angiogenesis" is only an optional step in the process of reviewing the anticancer effects. Thus, Claim 1 has no difficulty in its configuration, and the difference in this case can be easily overcome.

It is true that the prior art discloses the experimental results showing that compared to *Euonymus alatus* extract, the anticancer effect of *Zizania latifolia* extract is weak, and that it exhibits little to no effect on certain types of cancer cells. However, it is difficult to conclude that the prior art includes negative teachings regarding the anticancer effects of *Zizania latifolia* extract for the following reasons: (i) While the experimental results indicate that the anticancer effect of *Zizania latifolia* extract is relatively lower than *Euonymus alatus* extract or decreases over time, it is not recognized that *Zizania latifolia* extract completely lacks anticancer effects and (ii) As the prior art infers that

the efficacy of *Euonymus alatus* is attributed to the content of polyphenol and flavonoid, and it is disclosed that *Zizania latifolia* extract, though in a smaller amount compared to *Euonymus alatus* extract, also includes them, a skilled person would have sufficient motivation to investigate whether *Zizania latifolia* extract has anticancer effects through angiogenesis inhibition.

3) Analysis of effect in Claim 1

The active ingredient described in both Claim 1 and the prior art is *Zizania latifolia* extract, and they share the common characteristic of having anticancer effects. The only difference lies in their pharmacological mechanisms.

Claim 1 merely confirms anticancer activity through experiments, and simply verifying such effects through experiments does not establish that Claim 1 possesses remarkable or unexpected effects that could not have been predicted by a skilled person.

D. Summary of discussion

Therefore, Claim 1 can be easily derived by a skilled person based on the prior art and thus is denied of an inventive step. Meanwhile, in a patent application consisting of two or more claims, if even one claim has grounds for rejection, the entire application must be rejected (See Supreme Court's 2007Hu3820 decision, dated December 10, 2009). Since the inventive step of Claim 1 is denied and it cannot be granted a patent, the subject application cannot be granted a patent and there is no need to further examine the remaining claims. Thus, the IPTAB's decision in line with this conclusion is lawful.

4. Conclusion

Therefore, the Plaintiff's petition seeking the revocation of the IPTAB Decision is without merit, and accordingly, the decision is rendered as ordered.

Presiding Judge	Taeksoo JUNG
Judge	Sook Yeon LEE
Judge	Jiyoung YI

[Appendix 1]

Claims and Detailed Description of Subject Invention

【Claim 2】According to Claim 1,

the *Zizania latifolia* whole plant extract above is a composition for angiogenesis inhibition, characterized by being a 70% or an 80% ethanol extract.

【Claim 3】According to Claim 1 or Claim 2,

the composition above is a composition for angiogenesis inhibition, characterized by being a pharmaceutical composition.

【Claim 4】While including *Zizania latifolia* extract as an active ingredient,

the *Zizania latifolia* extract above is a food composition for inhibiting angiogenesis, characterized by being a mixed solvent extract of water and ethanol.

【Claim 5】According to Claim 4,

the *Zizania latifolia* whole plant extract above is a food composition for angiogenesis inhibition, characterized by being a 70% or an 80% ethanol extract.

Detailed description for implementing the invention

[0048] <Embodiment> Preparation of *Zizania latifolia* extract

[0049] <Embodiment 1> Example of preparing *Zizania latifolia* extract 2

[0050] 100 g of dried and ground *Zizania latifolia* (whoe plant) was mixed with 1 L of 70% ethanol and underwent one repeated extraction at room temperature for 24 hours before being filtered with filter paper. The obtained 70% ethanol filtrate was vacuum-concentrated and then freeze-dried to produce the *Zizania latifolia* extract (G56 70%).

[0051] <Embodiment 2> Example of preparing *Zizania latifolia* extract 2

[0052] The *Zizania latifolia* extract (G56 80%) was prepared in the same way as in <Embodiment 1>, except that 80% ethanol was used as the extraction solvent.

[0053] <Experimental Example> Evaluation of angiogenesis inhibitory activity

[0054] <1> Experiment method

[0055] Cell culture

[0056] Human Umbilical Vein Endothelial Cells (HUVECs) were purchased from Lonza (Walkersville, MD, USA) and cultured in EGM-2 MV BulletKit (Lonza) medium. Only endothelial cells between passages 4 and 6 were used for the experiments. The medium was replaced every two days during the culture period.

[0057] Cell proliferation assay (Cell proliferation)

[0058] Endothelial cells were plated in 6-well plates (100,000 cells/well) and synchronized to the G1/G0 phase using serum-free basic EBM-2 medium. Then, the cells were treated with the extract in EGM-2 MV BulletKit medium (growth media) under the defined conditions to observe the inhibitory effect of the extract on cell proliferation. The inhibitory effect on cell proliferation was assessed using the tryphan blue exclusion assay (Curr Protoc Immunol. 2001 May; Appendix 3: Appendix 3B).

[0059] Cell adhesion assay (Cell adhesion)

[0060] The cultured endothelial cells were detached using trypsin/EDTA treatment and reacted in EGM-2 MV BulletKit medium for 1 hour to normalize cell surface and activity (recovery). Then, the medium was replaced with basic EBM-2 medium. The extract was applied in EGM-2 MV BulletKit medium (growth media) under experimental conditions, and the cells were cultured in a 96-well plate (15,000 cells/well) for 2 hours. Non-adherent cells were removed by washing with phosphate-buffered saline (PBS, pH 7.4), and the remaining ones were stained with Giemsa stain solution. The extent of cell adhesion was measured by manually counting the stained cells using a microscope (Hemacytometer, counter, chemidoc, and 37°C shaking incubator).

[0061] In vitro wound-healing assay (Cell migration)

[0062] The monolayer wound healing assay was performed through the following process: endothelial cells were cultured as a confluent monolayer (40,000 cells/well) in a 48-well plate, and the layer was scratched using a 200 μl pipette tip; the cells were then synchronized to the G1/G0 phase by incubating them in serum-free basic EBM-2 medium for 2 hours; and the extract was applied in EGM-2 MV BulletKit medium (growth media) under experimental conditions, and changes in cell migration were observed based on the extract concentration and time (12 to 15 hours). The cells were stained using Giemsa stain solution, and the cell migration distance was measured.

[0063] In vitro transwell migration assay (Cell migration)

[0064] Endothelial cells cultured in basic EBM-2 medium for 2 hours were plated at 100 μl (4×10^4 cells/mL) in a transwell insert (Costar, 6.5 mm diameter insert). The lower wells were filled with 600 μl of either basic EBM-2 medium or EGM-2 MV BulletKit medium. The extract was applied under experimental conditions, and after 18 hours, the insert was fixed with methanol. Unmigrated cells on the upper surface of the insert were removed using a cotton-tipped swab. The cells were stained with Giemsa stain solution, and six different parts were observed under a microscope (×200) to manually count migrated cells using microscopy.

[0065] Zymography (MMPs enzyme activity)

[0066] Endothelial cells were plated in 6-well plates (100,000 cells/well) and synchronized to the G1/G0 phase using serum-free basic EBM-2 medium. Then, the extract was applied under experimental conditions (alternatively, the medium from the lower wells could be used as the sample after the transwell migration experiment), and the culture medium was mixed with a non-denaturing loading buffer and incubated at 37°C for 30 minutes. A 10% SDS-PAGE gel containing 0.1% gelatin as the substrate was then performed.

After the electrophoresis, the gel was washed with 2.5% Triton X-100 solution at room temperature for an hour to remove SDS. The gel was then reacted in developing buffer (50 mM Tris, pH 7.5, 10 mM $CaCl_2$, and 150 mM NaCl) at 37°C for 15 to 18 hours. After the reaction, the gel was stained for 2 hours with a staining solution containing 0.5% Coomassie Brilliant Blue (30% methanol-10% acetic acid). The gel was then destained using a destaining solution (30% methanol-10% acetic acid).

[0067] Western blot

[0068] Endothelial cells were cultured in a culture dish (100×104 cells/well) and synchronized to the G1/G0 phase using serum-free basic EBM-2 medium. Then, the extract was applied under experimental conditions, and the cells were then lysed using lysis buffer (50 mM Tris-HCl, [pH 7.4], 150 mM NaCl, 10% glycerol, 1% nonidet P-40, 1 mM EDTA, 100μg/ml 4-(2aminoethyl)benzenesulfonyl fluoride, 10μg/ml aprotinin, 1μg/ml pepstatin A, 0.5μg/ml leupeptin, 80mM β-glycerophosphate, 25mM NaF, and 1mM sodium orthovanadate) to be centrifuged to obtain the cell extract. The expression and activity changes of various enzyme proteins were observed using immunoblot analysis.

[Appendix 2]

Prior Art

1 Introduction

(Page 5)

This study explored potential therapeutic agents for gastric cancer, one of the major cancers in Korea and identified that *Euonymus alatus* and *Zizania latifolia* are widely used in traditional remedies. To evaluate their effects, it aims to investigate the antioxidant and anticancer properties of ethanol extracts from *Euonymus alatus* and *Zizania latifolia*, as well as their mechanisms of action in order to provide foundational data for developing new drugs. To this end, the study analyzed total polyphenol content, total flavonoid content, DPPH (2,2-diphenyl-1-picrylhydrazyl) radical scavenging activity, and ABTS (2,2'-azino-bis-3-ethylbenzothiazoline- 6-sulfonic acid) radical scavenging activity to evaluate the antioxidant properties. Then, to assess anticancer efficacy, it treated four cancer cell lines: gastric cancer cells (AGS), cervical cancer cells (HeLa), liver cancer cells (HepG2), and breast cancer cells (MCF-7) with *Euonymus alatus* and *Zizania latifolia* extracts to measure cell viability (MTT assay), perform Western blot analysis, and observe cells using fluorescence microscopy. Also, to determine whether the activation of caspases induces apoptosis, it studied the effects of *Euonymus alatus* and *Zizania latifolia* extracts on the expression of Bcl-2, Bax, and caspases-3 in cancer cells.

2 Materials and Methods

(Page 7)

2. Sample Extraction

Zizania latifolia and *Euonymus alatus* for use were dried and ground to a 25-mesh size. Each 5 g sample was immersed in 80% ethanol and extracted at room temperature for 3 hours while agitated at 150 rpm using an orbital shaker (VS-201D, Vision Scientific Co.). The extract was filtered using Whatman paper No. 2 and vacuum-concentrated using a rotary vacuum evaporator (N-1000S-W, Tokyo Rikakikai Co.) to evaporate ethanol. Each sample was placed in a 50 mL conical tube, frozen for 24 hours in an ultra-low temperature freezer (MDF-794, Sanyo Electric Co.), and then

lyophilized into powder using a freeze-dryer (PVTFD10R, Ilshin Lab Co.). The weight of each sample was measured, and the extraction yield (%) was calculated (28). The resulting extracts were then used as samples for later experiments.

(Page 9)

7. Cell Culture

In this study, the AGS, MCF-7, and Vero cell lines were cultured in RPMI-1640 medium, while the HeLa and HepG2 cell lines were cultured in Minimum Essential Medium (MEM). The culture media were added with 10% FBS and 1% antibiotic-antimycotic reagent and incubated at 37°C in a 5% CO_2 incubator. For the experiments, cells were subcultured and seeded at a concentration of 1×10^5 cells/mL.

3 Results

(Page 17)

6. Anticancer Efficacy of Extracts After 24-Hour Treatment

To evaluate the anticancer efficacy of *Zizania latifolia* and *Euonymus alatus* extracts on gastric cancer cells (AGS), cervical cancer cells (HeLa), liver cancer cells (HepG2), and breast cancer cells (MCF-7), the extracts were treated at varying concentrations (10, 50, and 100 μg/mL) for 24 hours, and anticancer activity was measured using the MTT assay (Fig. 4). Also, to evaluate the cytotoxicity of the extracts on normal cells, Vero, kidney cells, were treated with the same concentrations, and assessed for the extracts' cytotoxicity.

In gastric cancer cells (AGS), *Zizania latifolia* extract showed no anticancer efficacy, but when treated with the *Euonymus alatus* extract at 50 μg/mL, cell viability of AGS was decreased to 21.8% and at 100 μg/mL to 8.4% (Fig. 4A). When treated with *Zizania latifolia* extract, cervical cancer cells (HeLa) showed cell viabilities of 101.0%, 78.1%, and 67.8% at the extract's concentrations of 10, 50, and 100 μg/mL, respectively. When treated with *Euonymus alatus* extract, cell viabilities fell to 85.3%, 11.7%, and 10.0% at the same concentrations (Fig. 4B). When treated with *Zizania latifolia* extract, liver cancer cells (HepG2), decreased in cell viability to 96.8%, 96.7%, and 83.7% at concentrations of 10, 50, and 100 μg/mL, respectively, and when treated with *Euonymus alatus* extract, they showed

cell viabilities of 73.9%, 59.7%, and 48.3% at the same concentrations, showing lower anticancer efficacy in HepG2 cells compared to that in gastric cancer and cervical cancer cells (Fig. 4C). *Zizania latifolia* extract decreased cell viability in breast cancer cells (MCF-7) to 94.2%, 88.1%, and 84.1%, while *Euonymus alatus* extract to 99.5%, 99.1%, and 76.1% at the same concentrations. Among the cancer cell lines tested, the lowest anticancer efficacy was observed in breast cancer cells, while the highest was in gastric cancer and cervical cancer cells (Fig. 4D). In normal kidney cells (Vero), both *Zizania latifolia* and *Euonymus alatus* extracts were confirmed to have no cytotoxicity (Fig. 4E).

(Page 19)

7. Anticancer Efficacy of Extracts After 48-Hour Treatment

Cells were treated with *Zizania latifolia* and *Euonymus alatus* extracts at varying concentrations (10, 50, and 100 μg/mL) for 48 hours, and the anticancer activity of the extracts were measured using the MTT assay (Fig. 5). Kidney cells (Vero) were also treated with the extracts at the same concentrations to evaluate their cytotoxicity.

The *Zizania latifolia* extract showed no anticancer inhibitory effect on gastric cancer cells, while the *Euonymus alatus* extract exhibited remarkable efficacy, with cancer cell viabilities of 63.7%, 10.8%, and 6.7% at concentrations of 10, 50, and 100 μg/mL, respectively (Fig. 5A). The *Zizania latifolia* extract did not have anticancer efficacy in cervical cancer cells, which indicates that drug resistance have developed after 24 hours. In contrast, *Euonymus alatus* extract showed sustained anticancer efficacy, with cervical cancer cell viabilities of 86.2%, 7.2%, and 6.0% (Fig. 5B). The anticancer efficacy of the *Zizania latifolia* extract in liver cancer cells was minimal, with a cell viability of 79.2% at a concentration of 100 μg/mL. In contrast, the *Euonymus alatus* extract exhibited concentration- proportional efficacy, with cell viabilities decreasing to 68.0%, 46.3%, and 38.6% at concentrations of 10, 50, and 100 μg/mL, respectively (Fig. 5C). In breast cancer cells, both *Zizania latifolia* and *Euonymus alatus* extracts exhibited only a little anticancer efficacy, but the *Euonymus alatus* extract demonstrated slightly higher anticancer efficacy (Fig. 5D). Both were found to have no cytotoxicity in normal kidney cells (Fig. 5E).

(Page 21)

8. Anticancer Efficacy of Extracts After 72-Hour Treatment

Cells were treated with *Zizania latifolia* and *Euonymus alatus* extracts at varying concentrations (10, 50, and 100 μg/mL) for 72 hours to measure cell viability using the MTT assay (Fig. 6). Vero or normal kidney cells were also treated with the same concentrations for the same duration to evaluate the extracts' cytotoxicity for normal cells.

When gastric cancer cells were treated with the *Zizania latifolia* extract, there was little change in cell viability, indicating that *Zizania latifolia* has low anticancer efficacy. However, when treated with *Euonymus alatus* extract at concentrations of 10, 50, and 100 μg/mL, gastric cancer cell viabilities were 66.7%, 18.7%, and 7.5%, respectively. This means that even with prolonged treatment, the extract consistently inhibited cancer cell proliferation, demonstrating the remarkable efficacy (Fig. 6A). The *Zizania latifolia* extract did not affect the cell viability of cervical cancer cells, and prolonged treatment beyond 24 hours appeared to result in resistance, as cell viability was similar to that of the untreated control group. On the contrary, the *Euonymus alatus* extract significantly reduced cervical cancer cell viability, with viabilities of 91.2%, 5.2%, and 7.0% at the extract's concentrations of 10, 50, and 100 μg/mL, respectively (Fig. 6B). Liver cancer cells exhibited resistance to the *Zizania latifolia* extract and their cell proliferation significantly increased. Their cell viability was even higher than the untreated control group. In contrast, the *Euonymus alatus* extract demonstrated sustained anticancer efficacy, with liver cancer cell viabilities of 96.4%, 20.7%, and 18.9% at concentrations of 10, 50, and 100 μg/mL, respectively (Fig. 6C). The *Zizania latifolia* extract had weak anticancer efficacy against breast cancer cells, while the *Euonymus alatus* extract showed concentration-dependent anticancer efficacy, decreasing breast cancer cell viabilities to 90.9%, 62.8%, and 33.9% at concentrations of 10, 50, and 100 μg/mL, respectively (Fig. 6D). Both *Zizania latifolia* and *Euonymus alatus* showed slight cytotoxicity in normal kidney cells (Fig. 6E).

Table 2 presents the inhibitory concentration 50% (IC50) values of *Zizania latifolia* and *Euonymus alatus* extracts, indicating the concentrations required to inhibit cancer cell growth by 50% over various durations, which were measured using the MTT assay.

Table 2. The half maximal inhibitory concentration(IC50) values of the extracts at different time periods

(unit: μg/mL)

Extracts	Time	AGS	HeLa	HepG2	MCF-7
Zizania latifolia	24 hr	324.3 ± 4.7	215.0 ± 3.0	288.9 ± 4.4	411.7 ± 4.5
	48 hr	338.7 ± 1.7	267.2 ± 0.5	264.6 ± 4.9	315.6 ± 2.8
	72 hr	263.3 ± 2.0	297.7 ± 2.9	364.9 ± 2.7	264.3 ± 1.8
Euonymus alatus	24 hr	32.2 ± 1.0	29.2 ± 0.4	92.7 ± 6.7	260.0 ± 9.6
	48 hr	20.2 ± 2.0	28.3 ± 0.3	42.8 ± 2.1	202.5 ± 7.3
	72 hr	23.9 ± 0.4	29.1 ± 0.6	34.5 ± 0.4	72.1 ± 1.3

IP HIGH COURT OF KOREA
FIFTH-SECOND DIVISION
DECISION

Case No.	2022Heo3809 Invalidation of Registration (Patent)
Plaintiff	A Corp. CEO B Counsel for Plaintiff PLUS INTERNATIONAL IP LAW FIRM Patent Attorney in Charge Changhee PARK
Defendant	C Representative D Counsel for Defendant KOREANA PATENT FIRM Patent Attorney in Charge Suyeon SONG and Donghwan KIM
Date of Closing Argument	April 20, 2023
Decision Date	May 25, 2023

ORDER

1. The Plaintiff's claims are dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2020Dang3238, decided May 20, 2022, shall

be revoked.

OPINION

1. Background

A. Plaintiff's Claimed Invention (Plaintiff's Exhibit 2)

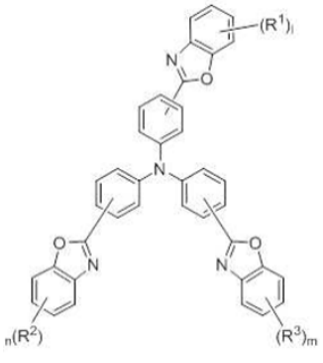
1) Title of invention: Tribenzazole Amine Derivatives and Organic Electroluminescent Device Including the Same

2) Filing date of application / Date of registration / Registration No.: December 12, 2018 / December 26, 2019 / No. 2059550

3) Claims

【Claim 1】 A tribenzazole amine derivative for use as a capping layer in an organic electroluminescent device, represented by the chemical formula below.

[Chemical Formula 1]

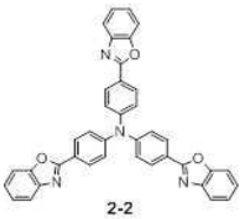


In Chemical Formula 1, R^1, R^2, and R^3 are identical or different, each independently being hydrogen; a C1-C10 alkyl group; and l, n, and m are integers ranging from 0 to 4 (hereinafter, "Claim 1," the same applies to the remaining claims).

【Claim 2】 The tribenzazole amine derivative for use as a capping layer in an organic electroluminescent device according to Claim 1,

wherein Chemical Formula 1 is selected from compounds represented by Chemical Formula 2.

[Chemical Formula 2]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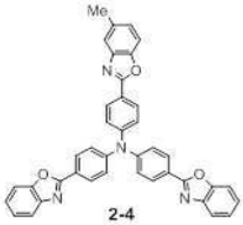
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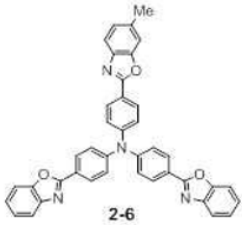
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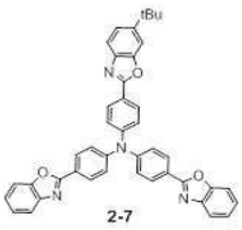
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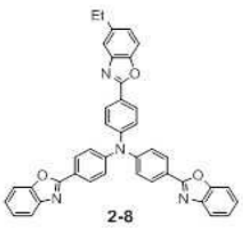
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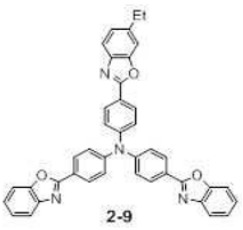
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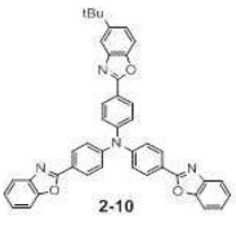
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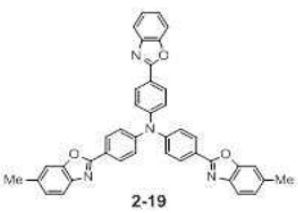
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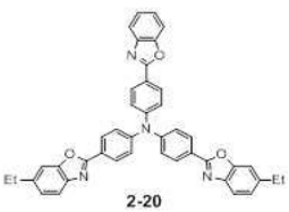
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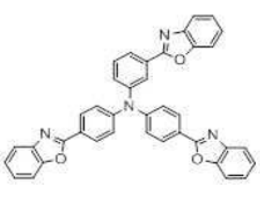
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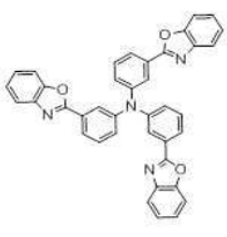
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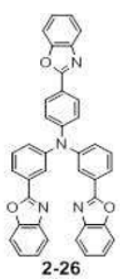
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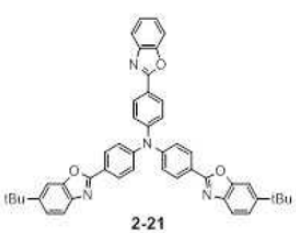
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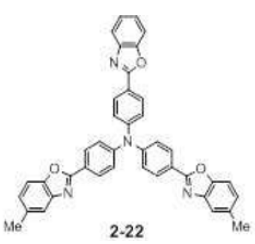
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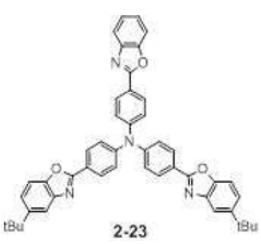

2-23

【Claim 3】 An organic light-emitting device comprising:
a first electrode; an organic layer comprising a plurality of organic material layers disposed on the first electrode; a second electrode disposed on the organic layer; and a capping layer disposed on the second electrode, wherein the capping layer includes a tribenzazole amine derivative according to any one of Claims 1 or 2.

【Claim 4】 An organic electroluminescent device wherein the organic layer includes a hole injection layer; a hole transport layer; an emitting layer; an electron transport layer; and an electron injection layer, according to Claim 3.

4) Summary of invention

The present invention aims to provide a capping layer material designed to enhance the luminous efficiency, lifespan, and viewing angle characteristics of an organic electroluminescent device (OLED)[1], offering a tribenzazole amine derivative with a defined structure. Refer to Appendix 1 for main content of the present invention.

B. Prior Art (Plaintiff's Exhibit 4)[2]

This invention, filed on December 21, 2017, and published internationally on June 27, 2019 in Korean Laid-open Patent Publication No. 10-2020-0086747, under the title "Organic Electroluminescence Device and Manufacturing Method Thereof," discloses an amine

1) Organic Light Emitting Diodes: It is also referred to as an organic electroluminescent device, organic light-emitting device, or organic EL device.

2) The prior art is the Korean translation of WO 2019/124550, which was claimed priority based on Japanese Patent Application No. 2017-244969, filed on December 21, 2017, and was filed internationally on December 21, 2018, and published internationally on June 27, 2019. Since the prior art was applied for registration before the filing date of the subject patent application but published after the date, it qualifies as prior art in relation to the applicability of the expanded first-to-file rule under Article 29(3) of the Patent Act.

compound with a benzoazole ring structure suitable for use as a capping layer material in organic electroluminescent devices. Refer to Appendix 2 for main content of the prior art.

C. Procedural History

1) The Defendant filed a petition on October 29, 2020, seeking invalidation against the Plaintiff in the Korean Intellectual Property Trial and Appeal Board (IPTAB), reasoning, "Claims 1 to 4 at issue all violate the extended first-to-file rule in Article 29(3) of the Patent Act."

2) The IPTAB reviewed the case under Case No. 2020Dang3238, and issued an administrative decision to invalidate the patented invention, stating "the present invention violates the extended first-to-file rule based on the prior art."

【Factual basis】 Undisputed facts, the descriptions on Plaintiff's Exhibits 1 through 6, the purport of the overall arguments

2. Summary of Parties' Arguments and Questions Presented

A. Plaintiff

The subject invention does not violate the extended first-to-file rule due to the following reasons, and the IPTAB decision concluding otherwise is erroneous.

1) Even if the prior art documents disclose the name or chemical structure of a compound, the compound cannot be considered disclosed in the prior art if they fail to provide information on how to prepare the compound, and a person having ordinary skill in the art (hereinafter, a "skilled person") cannot prepare it without undue effort.

2) Although the prior art mentions "compound (27)," corresponding

to [Chemical Formula 1] in Claim 1, it does not disclose a method for preparing compound (27), and the preparation method for compound (10), an existing embodiment, cannot be extended to compound (27). Without extensive experimentation, a skilled person would be unable to prepare compound (27). Therefore, compound (27) cannot be considered disclosed in the prior art.

3) Thus, Claim 1 does not violate the extended first-to-file rule based on the prior art. Claims 2 to 4 also do not violate the extended first-to-file rule based on the prior art for the same reasons.

B. Defendant

The subject invention violates the extended first-to-file rule due to the following reasons, and the IPTAB decision is lawful as it is consistent with this conclusion.

1) Whether the prior art discloses a compound shall be determined based on whether a skilled person can directly perceive the presence of the compound from the prior art, based on its specification and the technological common knowledge at the time of the application.

2) The prior art provides a specific description of compound (27), which corresponds to [Chemical Formula 1] in Claim 1. As a result, a skilled person can directly perceive the presence of the compound. Therefore, compound (27) shall be considered disclosed in the prior art.

3) Furthermore, regarding the enablement of compound (27), even if the preparation method for compound (27) is not explicitly disclosed in the prior art, a skilled person could readily synthesize and use compound (27) based on the preparation example of compound (10) and the technological common knowledge at the time of the application.

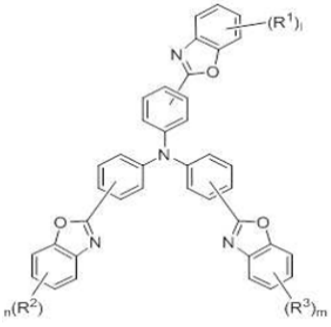
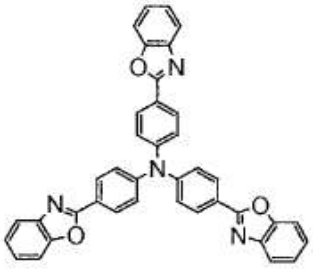
4) Thus, Claim 1 violates the extended first-to-file rule based on

the prior art. Claims 2 to 4 also violate the extended first-to-file rule based on the prior art for the same reasons.

3. Whether IPTAB Erred

A. Whether Claim 1 Violates the Extended First-to-File Rule

1) Comparison between Claim 1 and the prior art

Claim 1	Prior Art
A tribenzazole amine derivative for use as a capping layer in an organic electroluminescent device, represented by the chemical formula below. [Chemical Formula 1]  In Chemical Formula 1, R^1, R^2, and R^3 are identical or different, each independently being hydrogen; a C1-C10 alkyl group; and l, n, and m are integers ranging from 0 to 4.	 (27) (Paragraph [0142])

2) Analysis on whether the two inventions are substantially identical

"The compound (27)" described in the prior art in a literal sense is equivalent to the tribenzazole amine derivative in [Chemical Formula 1] where R^1 to R^3 are hydrogen atoms, and there is no dispute between the parties regarding this.

Eventually, regarding whether Claim 1 is equivalent to the invention shown in the specification or the drawing of the prior art and thus violates the extended first-to-file rule in Article 29(3) of the Patent Act, the question is whether the compound (27) in the prior art can be deemed to be an invention disclosed in the prior art. The analysis is provided below.

3) Whether compound (27) is an invention disclosed in the prior art

a) Relevant law

(1) To conclude that the prior art discloses a specific compound, it is insufficient for the compound to be merely encompassed in principle within the chemical formula of a Markush structure or within the range of its substituents. Instead, the compound must be explicitly described in the prior art, or a skilled person in the art must directly recognize the existence of the compound from the prior art, based on its descriptions and the common technical knowledge available at the time of the application (See Supreme Court Decision 2008Hu736,743, dated October 15, 2009).

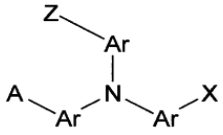
(2) Meanwhile, even if the specific compound is described in the prior art in a literal sense or a skilled person can directly recognize its existence, in case the compound is inexecutable--such as the person cannot prepare the compound based on the description of the prior art and common technical knowledge at the time of the application--the compound is not deemed to be disclosed in the prior art in determining whether the invention lacks novelty or violates the extended first-to-file rule.

b) Analysis

(1) Detailed description in the compound (27) of the prior art, etc.

(a) The prior art is an invention that aims to provide an organic EL element[3] with good luminous and power efficiency (paragraph [0015]), disclosing amine compounds with capping layer

material of organic EL element and a benzoxazole ring structure in General Formula (A-1) (paragraphs [0016] to [0022] and [0097]).



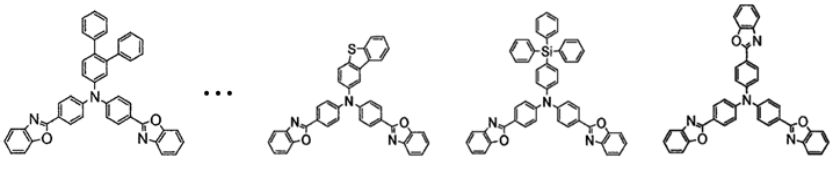
(A-1)

(In General Formula (A-1), A and X may be the same or different, and each represents a monovalent group with one bonding site selected from R_1 to R_6 in General Formula (B-1) below. Z represents a monovalent group with one bonding site selected from R_1 to R_6 in General Formula (B-1), a substituted or unsubstituted aromatic hydrocarbon group, a substituted or unsubstituted aromatic heterocyclic group, or a substituted or unsubstituted fused polycyclic aromatic group. Ar represents a bivalent group or a single bond, which may be the same or different from one another, selected from substituted or unsubstituted aromatic hydrocarbon groups, substituted or unsubstituted aromatic heterocyclic groups, or substituted or unsubstituted fused polycyclic aromatic groups.)

(b) The prior art discloses 85 compounds as examples of a desirable amine compound in General Formula (A-1), and among them is compound (27).

[0137] Among the compounds represented by General Formula (A-1) or (A-2), which are suitably used in the organic EL device of the present invention, compounds represented by formulas (1) to (85) are presented below as specific examples of desirable compounds.

(The description of the compounds in formulas (1) through (9), (11) through (24), and (28) through (85) is omitted.)



(10) (25) (26) (27)

3) It is an abbreviation for organic electroluminescent device.

(c) Therefore, the prior art is deemed to explicitly and thoroughly describe the presence of compound (27). Based on this description, a skilled person could directly recognize compound (27) as a useful material for the capping layer of an organic EL element.

(2) Whether the compound (27) can be executed

(a) Though the prior art does not directly describe a preparation example of compound (27), it shall be deemed that a skilled person could prepare compound (27) from the prior art based on its description and common technical knowledge at the time of the application due to the following reasons.

① According to the description in the specification of the prior art below, the prior art discloses that compounds corresponding to General Formula (A-1), including compound (27), can be prepared using various well-known preparation methods.

o **(paragraph [0014])** (non-patent literature 0001) pp. 55-61 of Preview of the 9th Lecture Session of the Korean Physics Society (2001), (non-patent literature 0002) Appl. Phys. Let., 78, 544 (2001), (non-patent literature 0003) Appl. Phys. Let., 82, 466 (2003), (non-patent literature 0004) J. Org. Chem., 71, 1802 (2006), (non-patent literature 0005) J. Org. Chcm., 60, 7508 (1995), (non-patent literature 0006) Synth. Commun., 11, 513 (1981), (non-patent literature 0007) Appl. Phys. Lett., 98, 083302 (2011)

o **(paragraph [0163])** Amine compounds with a benzoazole ring structure, represented by General Formulas (A-1) and (A-2), can be prepared using the methods described below.

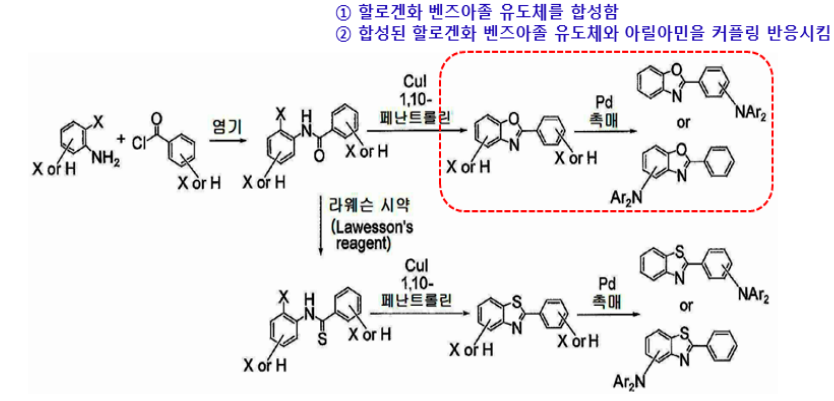
o **(paragraph [0164])** First, to form the benzoazole ring structure represented by Formula (B-1) or (B-8), which serve as the main framework of the compounds represented by General Formulas (A-1) and (A-2), a halogenated benzoazole derivative is prepared as the starting material. Halogenated benzoazole derivatives with structures corresponding to the benzoazole ring structure represented by Formula (B-1) or (B-8) can be prepared, for example, using publicly-known methods as described below (See, for instance, non-patent literature 4).

o **(paragraph [0165])** Additionally, the synthesized halogenated benzoazole

derivative and an arylamine undergo a coupling reaction using a copper catalyst, palladium catalyst, or similar catalysts. Now, the amine compounds with a benzoazole ring structure represented by General Formula (A-1) or (A-2) of the present invention can be synthesized.

o **(paragraph [0166])** Also, by subjecting halogenated arylamines and boronic acid derivatives or boronic acid ester derivatives, instead of halogenated benzoazole derivatives, to a coupling reaction, the amine compounds with a benzoazole ring structure represented by General Formulas (A-1) or (A-2) of the present invention can be synthesized (See, for instance, non-patent literature 5 and 6).

o **(paragraph [0167])** [Chemical Formula 16]



국문	영문
할로겐화 벤즈아졸 유도체를 합성함	Synthesis of halogenated benzazole derivatives
합성된 할로겐화 벤즈아졸 유도체와 아릴아민을 커플링 반응시킴	Coupling reaction between synthesized halogenated benzazole derivatives and arylamines
염기	Base
CuI 1,10-페난트롤린	CuI 1,10-phenanthroline
Pd 촉매	Pd catalyst
CuI 1,10-페난트롤린	CuI 1,10-phenanthroline
Pd 촉매	Pd catalyst

② In addition, the prior art describes a specific preparation method for compound (10), one of the desirable compounds represented by General Formula (A-1).

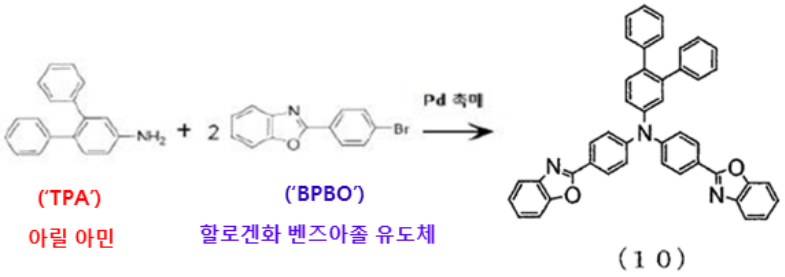
o **(paragraph [0224])** 「Embodiment 1」

o **(paragraph [0225])** Synthesis of the compound <Bis-{4-(benzoxazol-2-yl)phenyl}-([1,1',2',1"]terphenyl-4'-yl)-amine> represented by Formula (10)

o **(paragraph [0226])** A reaction vessel was charged with 5.6 g of ([1,1',2',1"]terphenyl-4'-yl)-amine, 14.4 g of 2-(4-bromophenyl)benzoxazole, 4.4 g of sodium t-butoxide, and 60 mL of toluene, followed by ultrasonic irradiation for 30 minutes under a nitrogen gas purge. Additionally, 0.1 g of palladium acetate and 0.4 mL of a 50% (w/v) toluene solution of tri-(t-butyl)phosphine were added to the vessel, and the mixture was stirred overnight under reflux heating. After allowing the vessel to cool down, methanol was added, and the precipitated solid was collected to obtain a crude product. The crude product was purified through recrystallization using a toluene/acetone mixed solvent, and the precipitated solid was collected to obtain 11.0 g of a yellow powder of bis-{4-(benzoxazol-2-yl)phenyl}-([1,1',2',1"]terphenyl-4'-yl)-amine (the compound represented by formula (10) above) with a yield of 76.4%.

③ The prior art describes the preparation method for halogenated benzoazole derivatives and states that "the synthesized halogenated benzoazole derivative and an arylamine undergo a coupling reaction using a copper catalyst, palladium catalyst, or similar catalysts. Now, the amine compounds with a benzoazole ring structure represented by General Formulas (A-1) or (A-2) of the present invention can be synthesized." Thus, it proposes a coupling reaction between halogenated benzoazole derivatives and arylamines as a process for preparing various amine compounds represented by General Formula (A-1). Furthermore, Embodiment 1 of the prior art demonstrates the synthesis of compound (10) by performing a coupling reaction between a halogenated benzoazole derivative {BPBO (2-(4-bromophenyl)benzoxazole)} and an arylamine {TPA ([1,1',2',1"]terphenyl-4'-yl)amine)} under a palladium catalyst (See Chemical Equation 1 below).

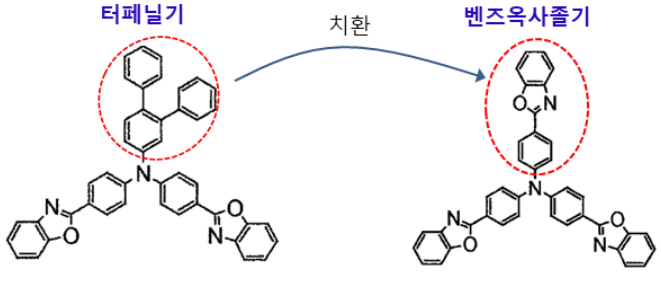
Chemical Equation 1



(10)

국문	영문
아릴 아민	Arylamines
할로겐화 벤즈아졸 유도체	Halogenated benzazole derivatives
Pd 촉매	Pd catalyst

④ However, when comparing compound (27), which is presented as a desirable compound of General Formula (A-1), with compound (10), the only difference lies in the substituent bonded to the central nitrogen atom. In compound (27), the substituent is replaced with a benzoxazole group instead of the terphenyl group in compound (10).

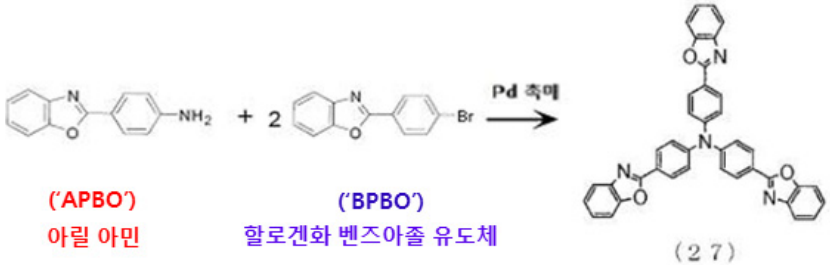


(10) (27)

국문	영문
터페닐기	Terphenyl group
치환	Substitution
벤즈옥사졸기	Benzoxazole group

⑤ Therefore, a skilled person would easily understand that, based on the preparation process described in the prior art mentioned above, simply altering the substituents bonded to the central nitrogen atom of the reactant would enable the production of various amine compounds of General Formula (A-1), including compound (27). In other words, it can be easily understood that compound (27) can be prepared through the same reaction process as in Embodiment 1 of the prior art, simply by substituting "TPA," the reactant in Embodiment 1 of the prior art, with "APBO (2-(4-aminophenyl) benzoxazole)," as shown in Chemical Equation 2 below.

Chemical Equation 2



국문	영문
아릴 아민	Arylamines
할로겐화 벤즈아졸 유도체	Halogenated benzazole derivatives
Pd 촉매	Pd catalyst

⑥ Furthermore, the synthesis method for "BPBO" (a halogenated benzoxazole derivative), one of the reactants used in the preparation process of compound (27), is described in the prior art ([Chemical Formula 16] of paragraphs [0164] and [0167]). Also, the structure and various synthesis methods of "APBO," another reactant, were widely disclosed in multiple references prior to the date of claimed priority of the prior art (December 21, 2017). Therefore, it would not be reasonable to consider that it is difficult to synthesize or acquire "APBO" before the date.

(b) Regarding this, the Plaintiff argues that since "APBO," the starting material in Chemical Equation 2 preparing compound (27), is not commercially common enough to be acquired easily and preparing "APBO" requires finding bibliographic items through meticulous search in paid professional chemical database and finding the source again to check if it is preparable, preparing the material exceeds the level of effort of a skilled person that does not require excessive experiment.

However, considering the level of technological development at the time of the application, that is, the fact that a person can access any time the database about the relevant technical information due to the commercialization of the internet and the development of search engines; can easily look for literature about a specific compound published around the world with the name or the structural formula of the compound without extra time and effort; and can quickly and easily order and receive reagents online from various foreign suppliers, a skilled person does not have to conduct excessive experiment to check if "APBO" can be prepared or acquired based on Defendant's Exhibits 1 to 5 and prepare the material. Therefore, the Plaintiff's argument cannot be accepted.

(3) Summary of analysis

In summary, based on the analysis above, compound (27) is deemed to be specifically disclosed as an invention in the prior art.

4) Summary of discussion

Thus, Claim 1 violates the extended first-to-file rule based on the prior art.

B. Whether Claims 2 to 4 Violate the Extended First-to-File Rule

1) Claim 2

Claim 2 is a dependent claim referencing Claim 1, and involves

selecting a tribenzazole amine derivative of Chemical Formula 1 from compounds such as compound (2-2), where compound (2-2) is identical to compound (27) disclosed in the prior art above.

2) Claim 3

Claim 3 relates to an organic light-emitting device comprising: a first electrode; an organic layer comprising a plurality of organic material layers disposed on the first electrode; a second electrode disposed on the organic layer; and a capping layer disposed on the second electrode, wherein the capping layer includes a tribenzazole amine derivative according to any one of Claims 1 or 2. However, the prior art discloses "an organic EL device comprising an organic layer including a light-emitting layer between a first and a second electrode, with a capping layer laminated on the surface opposite the organic layer of the first electrode, where the capping layer contains an amine compound with a benzoxazole ring structure represented by General Formula (A-1) or (A-2) [specific example: compound (27)] (paragraphs [0101], [0119], [0122], [0018] through [0093], and [0142]). Accordingly, the structures of the organic electroluminescent devices (organic EL devices) in both inventions are identical.

3) Claim 4

Claim 4 is a dependent claim referencing Claim 3, and it relates to "an organic electroluminescent device wherein the organic layer includes a hole injection layer; a hole transport layer; an emitting layer; an electron transport layer; and an electron injection layer." The prior art also discloses "an organic EL device wherein the organic layer includes a hole injection layer; a hole transport layer; a light-emitting layer; an electron transport layer; and an electron injection layer" (paragraphs [0105] and [0106]). Therefore, the structures of the organic EL devices in both inventions are identical.

4) Summary of discussion

As outlined above, Claims 2 to 4 violate the extended first-to-file rule due to the prior art.

C. Summary of Analysis

In summary, since Claims 1 to 4 violate the extended first-to-file rule due to the prior art, its patent registration should be invalidated. The IPTAB decision consistent with the above shall be upheld, as it is without an error justifying revocation as argued by the Plaintiff.

4. Conclusion

Therefore, the Plaintiff's petition seeking the revocation of the IPTAB Decision is without merit, and accordingly, the decision is rendered as ordered.

Presiding Judge Sungyop WOO
Judge Youngwoo LIM
Judge Kisu KIM

[Appendix 1]

Summary of Invention at Issue

A. Technical Field

[0001] The present invention relates to tribenzazole amine derivatives and organic electroluminescent devices including the same. Specifically, it aims to enable the capping layer of an organic electroluminescent device to simultaneously exhibit high refractive index properties and ultraviolet absorption properties through the use of the tribenzazole amine derivatives above.

B. Background Art

[0010] With the commercialization of organic electroluminescent devices, the demand for properties beyond the devices' intrinsic light-emitting characteristics has emerged. Organic electroluminescent devices are often exposed to external light sources for extended periods, which results in prolonged exposure to ultraviolet light with high energy, having a lasting impact on the organic materials that make up the devices. Applying a capping layer with ultraviolet absorption properties can prevent exposure to such high-energy light sources.

[0011,0012] Additionally, while it is generally known that organic electroluminescent devices have wide viewing angles, the light source spectrum defers significantly depending on the viewing angle. This is due to the discrepancies between the overall refractive index of components such as the glass substrate, organic materials, and electrode materials that constitute the organic electroluminescent device and the appropriate refractive index values corresponding to the emission wavelength of the device. In general, the required refractive index is higher for blue light, and as the wavelength increases, the required refractive index decreases. Accordingly, it is necessary to develop a material for the capping layer that simultaneously has the aforementioned ultraviolet absorption properties and the appropriate refractive index.

C. Problem To Be Solved

[0016] The present invention aims to provide a capping layer material for organic electroluminescent devices that enhances light-emission efficiency and lifespan while simultaneously contributing to improvements in viewing

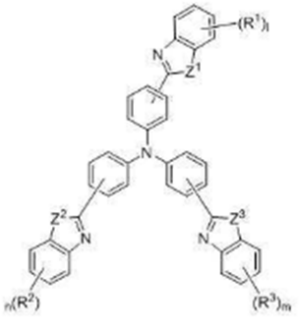
angle.

[0017] The present invention also aims to provide an organic electroluminescent device with an applied capping layer to improve its characteristics.

D. Means for Solving the Problem

[0018] One embodiment of the present invention comprises: a first electrode; an organic layer disposed on the first electrode; a second electrode disposed on the organic layer; and a capping layer disposed on the second electrode, and the organic layer provides an organic electroluminescent device including a tribenzazole amine derivative represented by Chemical Formula 1.

[0019] [Chemical Formula 1]



[0021 to 0023] In Chemical Formula 1, Z^1, Z^2 and Z^3 are each independently O, S, or NR^4 (where R^4 is phenyl), and R^1, R^2, and R^3 are the same or different and are each independently from hydrogen; deuterium; substituted or unsubstituted alkyl groups; substituted or unsubstituted cycloalkyl groups; substituted or unsubstituted alkoxy groups; substituted or unsubstituted aryloxy groups; substituted or unsubstituted aralkyl groups; substituted or unsubstituted alkylaryl groups; substituted or unsubstituted allyl groups; or substituted or unsubstituted heteroaryl groups. l, n, and m are integers from 0 to 4.

[0024] The organic layer of the organic electroluminescent device above may include a hole transport region, a light-emitting layer disposed on the hole transport region, and an electron transport region disposed on the light-emitting layer. The capping layer may include a tribenzazole amine derivative represented by Chemical Formula 1.

[0025] In addition, the present invention provides tribenzazole amine

derivatives represented by Chemical Formula 1 above.

E. Detailed Description for Implementing the Invention

[0041] Referring to Figure 1, the organic electroluminescent device according to one embodiment may include a first electrode (110), a hole injection layer (210), a hole transport layer (215), a light-emitting layer (220), an electron transport layer (230), an electron injection layer (235), a second electrode (120), and a capping layer (300) stacked on a substrate (100) in this order.

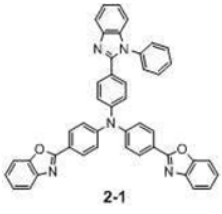
[Figure 1] Schematic Diagram of Organic Electroluminescent Device

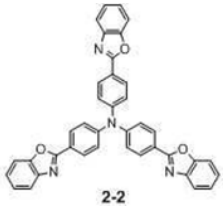
국문	영문
캡핑층	Capping layer
제2 전극	Second electrode
전자주입층	Electron injection layer
전자수송층	Electron transport layer
발광층	Emitting layer
정공수송층	Hole transport layer
정공주입층	Hole injection layer
제1 전극	First electrode
기판	Substrate
유기물층	Organic layer

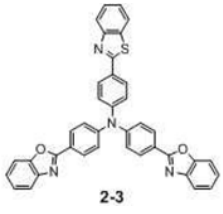
[0043] Meanwhile, the capping layer (300) presented in the present invention is a functional layer deposited on the second electrode (120) and includes an organic material according to Chemical Formula 1 of the present invention.

[0099] The tribenzazole amine derivative represented by Chemical Formula 1 of the present invention may be any one of the compounds selected from those represented by Chemical Formula 2. However, it is not limited thereto.

[0100] [Chemical Formula 2]

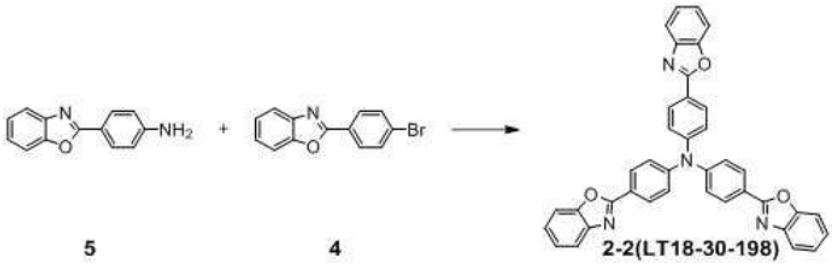

2-1


2-2


2-3

(The description of compounds 2-4 to 2-80 is omitted.)

[0244] Embodiment 2: Synthesis of compound 2-2 (LT18-30-198)



[0246] To a 250 mL single-neck flask, 1.8 g (8.56 mmol) of intermediate (5), 5.9 g (21.40 mmol) of intermediate (4), and 85.6 mL of xylene were added and stirred at 50°C. Then, 0.5 g (0.86 mmol) of $Pd(dba)_2$, 4.9 g (51.40 mmol) of sodium tert-butoxide, and 0.69 g (1.71 mmol) of tri-tert-butylphosphine (50 wt% in toluene) were added, and the mixture was stirred for an entire day at 125 to 130°C. After the reaction was complete, the mixture was cooled to room temperature, and the reaction product was passed through a celite pad using $CHCl_3$. Subsequently, the solvent was removed using vacuum distillation. The obtained compound was solidified using hexane to yield a yellow solid, which was dissolved in 800 mL of $CHCl_3$ under heating, and charcoal was added before stirring for 30 minutes. The mixture was passed through a celite and SiO_2 pad using (Hot CHCl3:EA=20:1), and then the solvent was removed by vacuum distillation. The obtained compound was purified using SiO_2 column chromatography (EA:CHCl3:HEX=1:1:5). The compound was slurried with DCM and hexane, yielding 3.0 g of yellow solid compound 2-2 (LT18-30-198) (yield: 59.1%).

[0340,0341] The properties of the optical characteristic samples prepared in the above Comparative Test Example and Test Examples 1 to 23 are shown in Table 1. Table 1 shows the refractive index constants at wavelengths of 420 nm and 620 nm, as well as the absorption coefficient constant at a wavelength of 380 nm.

(The description of Test Examples 4 to 23 is omitted.)

[0356] The electroluminescent properties of the organic electroluminescent devices prepared in the above Comparative Test Example and Test Examples 1 to 23 are shown in Table 2.

[Table 1]

		(Refractive index constant)	(Absorption coefficient constant)
Classification	Compound	N (450nm, 620nm)	K (380nm)
Comparative example	REF01	2.138, 1.971	0.274
Test Example 1	2-1 (LT18-30-267)	2.227, 1.980	0.634
Test Example 2	2-2 (LT18-30-198)	2.326, 2.081	0.679
Test Example 3	2-3 (LT18-30-238)	2.263, 1.997	0.598

[Table 2]

Classification	Compound	Driving voltage [V]	Efficiency [cd/A]	Lifespan (%)
Comparative Embodiment 01	REF01	6.60	5.10	88.92
Embodiment 1	2-1 (LT18-30-267)	4.62	6.70	98.87
Embodiment 2	2-2 (LT18-30-198)	3.93	6.07	105.43
Embodiment 3	2-3 (LT18-30-238)	3.81	5.65	98.79

(The description of Embodiments 4 to 23 is omitted.)

F. Effect

[0026] The organic electroluminescent device including the capping layer according to the present invention exhibits ultraviolet absorption properties, minimizing damage to the organic materials within the device caused by external light sources, which helps maintain the inherent efficiency and lifespan of the device as much as possible. Furthermore, the organic electroluminescent device of the present invention, through the use of a capping layer, improves light efficiency, reduces the full width at half maximum of the emission spectrum, and enhances viewing angle. As a result, it meets the diverse performance requirements of currently commercialized organic electroluminescent devices.

[Appendix 2]

Main Content of Prior Art

A. Technical Field

[0001] The present invention relates to an organic electroluminescent device (hereinafter, "organic EL device") and a method for preparing the same.

B. Background Art

[0012] Improving the device characteristics of organic EL devices particularly requires absorbing light with a wavelength of 400 to 410 nm from sunlight while preventing any impact on the materials inside the device. Additionally, to significantly improve light extraction efficiency, materials for the capping layer are required to have a high absorption coefficient, high refractive index, and excellent thin-film stability and durability.

C. Problem To Be Solved

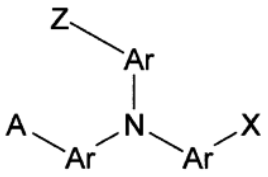
[0015] The present invention has been devised in consideration of the above circumstances, and aims to provide an organic EL device with high brightness, high luminous efficiency, high power efficiency, and long lifespan, along with a method for preparing the same.

D. Means for Solving the Problem

[0018] In other words, the following organic EL device is provided according to the present invention.

[0019] 1) The organic EL device comprising at least an anode electrode, a hole transport layer, a light-emitting layer, an electron transport layer, a cathode electrode, and a capping layer in this order, wherein the capping layer contains an amine compound having a benzoxazole ring structure represented by General Formula (A-1) below.

[0020] [Chemical Formula 1]

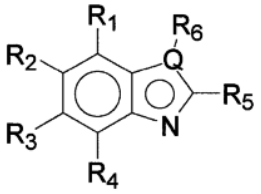


(A－1)

[0022] (In Formula (A-1), A and X may be the same or different, and each represents a monovalent group with one bonding site selected from R_1 to R_6 in General Formula (B-1) below. Z represents a monovalent group with

one bonding site selected from R_1 to R_6 in General Formula (B-1), a substituted or unsubstituted aromatic hydrocarbon group, a substituted or unsubstituted aromatic heterocyclic group, or a substituted or unsubstituted fused polycyclic aromatic group. Ar represents a bivalent group or a single bond, which may be the same or different from one another, selected from substituted or unsubstituted aromatic hydrocarbon groups, substituted or unsubstituted aromatic heterocyclic groups, or substituted or unsubstituted fused polycyclic aromatic groups.)

[0023] [Chemical Formula 2]



(B－1)

[0025] (In Formula (B-1), R_1 to R_6 may be the same or different and represent a linking group as a bonding site, a hydrogen atom, a deuterium atom, a fluorine atom, a chlorine atom, a cyano group, a nitro group, or a straight-chain or branched alkyl group with 1 to 6 carbon atoms that may have substituents, [omitted] and Q represents a nitrogen atom, an oxygen atom, or a sulfur atom. However, when Q is an oxygen atom or a sulfur atom, Q does not have R_6.)

[0049] 19) The organic EL device according to the above 5), wherein A, X, and Z in General Formula (A-1) are the same and the device contains an amine compound having a benzoxazole ring structure.

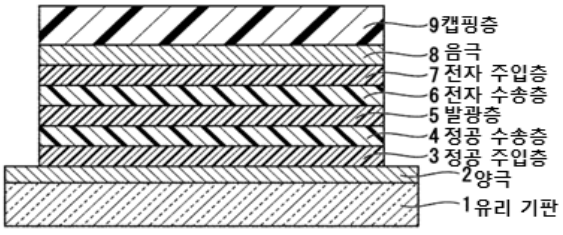
E. Detailed Description for Implementing the Invention

[0097] The present invention is to improve the device characteristics of organic EL devices. It particularly aims to absorb sunlight with wavelengths of 400 nm to 410 nm while preventing any impact on the materials inside the device, and to significantly improves light extraction efficiency. Furthermore, its objective is to provide an organic EL device equipped with a capping layer which is composed of a material that (1) has a high absorption coefficient, (2) has a high refractive index, (3) exhibits good thin-film stability, (4) possesses excellent durability, (5) has superior light resistance, and (6) does not exhibit absorption in the wavelength regions of

blue, green, and red light.

[0100] 「Organic EL Device」

[Figure 1] Example of Organic EL Device



국문	영문	국문	영문
캡핑층	Capping layer	정공 수송층	Hole transport layer
음극	Cathode	정공 주입층	Hole injection layer
전자 주입층	Electron injection layer	양극	Anode
전자 수송층	Electron transport layer	유리 기판	Glass substrate
발광층	Emitting layer		

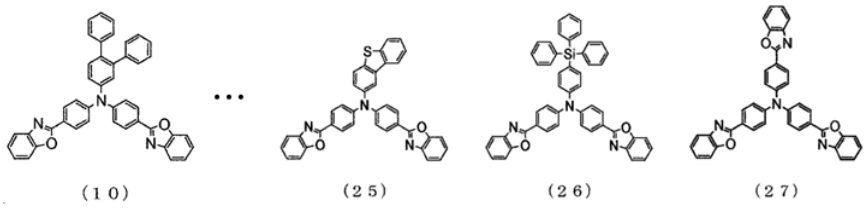
[0106] Figure 1 is a schematic cross-sectional view illustrating an example of the organic EL device according to the present embodiment. The organic EL device shown in Figure 1 has a top-emission structure, with an anode (2), a hole injection layer (3), a hole transport layer (4), a light-emitting layer (5), an electron transport layer (6), an electron injection layer (7), a cathode (8), and a capping layer (9) stacked on a glass substrate (1) in this order.

[0109] 「Capping Layer」

[0119] The capping layer of the organic EL device according to the present invention contains an amine compound having a benzoxazole ring structure represented by General Formula (A-1) or (A-2).

[0127] In the organic EL device of the present invention, Ar in General Formulas (A-1) and (A-2) is desirably a divalent or single bond of a substituted or unsubstituted aromatic hydrocarbon group, and more desirably, a divalent group of a substituted or unsubstituted phenyl group.

[0137] Among the compounds represented by General Formula (A-1) or (A-2), which are suitably used in the organic EL device of the present invention, compounds represented by formulas (1) to (85) are presented below as specific examples of desirable compounds.



(10) (25) (26) (27)

(The descriptions of the compounds in formulas (1) through (9), (11) through (24), and (28) through (85) are omitted.)

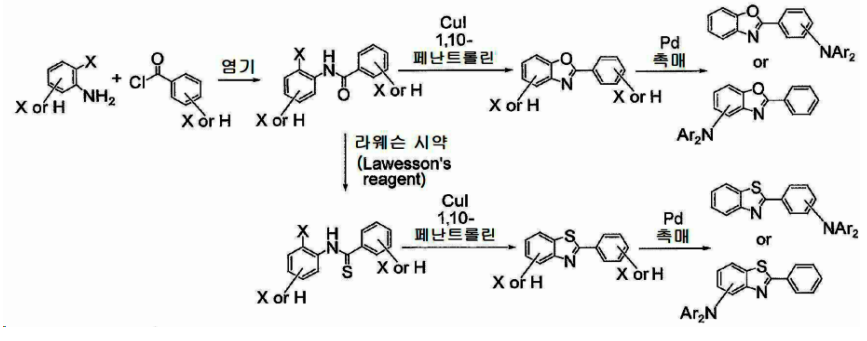
[0162] 「Method for Preparing Compounds Represented by General Formulas (A-1) and (A-2)」

[0163] Amine compounds with a benzoazole ring structure, represented by General Formulas (A-1) and (A-2), can be prepared using the methods described below.

[0164] First, to form the benzoazole ring structure represented by Formula (B-1) or (B-8), which serve as the main framework of the compounds represented by General Formulas (A-1) and (A-2), a halogenated benzoazole derivative is prepared as the starting material. Halogenated benzoazole derivatives with structures corresponding to the benzoazole ring structure represented by Formula (B-1) or (B-8) can be prepared, for example, using publicly-known methods as described below (See, for instance, non-patent literature 4).

[0165] Additionally, the synthesized halogenated benzoazole derivative and an arylamine undergo a coupling reaction using a copper catalyst, palladium catalyst, or similar catalysts. Now, the amine compounds with a benzoazole ring structure represented by General Formula (A-1) or (A-2) of the present invention can be synthesized.

[0167] [Chemical Formula 16]



국문	영문	국문	영문
염기	Base	CuI 1,10-페난트롤린	CuI 1,10-phenanthroline
CuI 1,10-페난트롤린	CuI 1,10-phenanthroline	Pd 촉매	Pd catalyst
Pd 촉매	Pd catalyst		

[0224] 「Embodiment 1」

[0225] Synthesis of the compound <Bis-{4-(benzoxazol-2-yl)phenyl} -([1,1',2',1"]terphenyl-4'-yl)-amine> represented by Formula (10)

[0226] A reaction vessel was charged with 5.6 g of ([1,1',2',1"]terphenyl -4'-yl)-amine, 14.4 g of 2-(4-bromophenyl)benzoxazole, 4.4 g of sodium t-butoxide, and 60 mL of toluene, followed by ultrasonic irradiation for 30 minutes under a nitrogen gas purge. Additionally, 0.1 g of palladium acetate and 0.4 mL of a 50% (w/v) toluene solution of tri-(t-butyl) phosphine were added to the vessel, and the mixture was stirred overnight under reflux heating. After allowing the vessel to cool down, methanol was added, and the precipitated solid was collected to obtain a crude product. The crude product was purified through recrystallization using a toluene/acetone mixed solvent, and the precipitated solid was collected to obtain 11.0 g of a yellow powder of bis-{4-(benzoxazol-2-yl) phenyl}-([1,1',2',1"]terphenyl-4'-yl)-amine (the compound represented by formula (10) above) with a yield of 76.4%.

[0304] (Measurement of peak wavelength, absorbance, and absorption coefficient of the compound)

[Table 1]

	Peak wavelength (λmax)	Absorbance (λ:400nm)	Absorbance (λ:410nm)	Absorption coefficient
Compound 10	387 nm	0.94	0.29	130367
Comparative compound (2-1)	358 nm	0.07	0.02	48856
Alq3	394 nm	0.07	0.06	7518

[0316] (Measurement of refractive index and extinction coefficient of thin films)

[Table 2]

	Refractive Index n (λ:400nm)	Refractive Index n (λ:410nm)	Extinction Coefficient k (λ:400nm)	Extinction Coefficient k (λ:410nm)
Compound 10	2.37	2.47	0.66	0.44
Comparative compound (2-1)	2.13	2.10	0.15	0.06
Alq3	1.86	1.89	0.16	0.14

[0364] (Measurement of device lifespan)

[Table 3]

Capping layer	Voltage [V] ($10mA/cm^2$)	Luminance [cd/m^2] ($10mA/cm^2$)	Luminous efficiency [cd/A] ($10mA/cm^2$)	Power efficiency [lm/W] ($10mA/cm^2$)	Lifespan of device 95% degradation
Compound 10	3.65	702	7.02	6.04	157 hours
Comparative compound (2-1)	3.69	668	6.68	5.68	121 hours
Alq3	3.67	647	6.47	5.54	106 hours

E. Effect

[0094] The organic EL device of the present invention exhibits high brightness, high luminous efficiency, high power efficiency, and a long lifespan.

IP HIGH COURT OF KOREA
SECOND DIVISION
DECISION

Case No.	2022Heo5881 Invalidation of Registration (Trademark)
Plaintiff	A CEO B Counsel for Plaintiff AJU INTERNATIONAL & PATENT GROUP Patent Attorney in Charge Changchoon LEE Subagent Patent Attorney in Charge Hyerin Lee
Defendant	C Co. Ltd. CEO D and E Counsel for Defendant SHIN & KIM LLC Patent Attorney in Charge Jongwoo LEE Subagent Patent Attorney in Charge Jeongsik Kim and Seoungmin Lee
Date of Closing Argument	June 21, 2023
Decision Date	July 14, 2023

ORDER

1. The Plaintiff's claim is dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2020Dang3136, decided September 28, 2022, shall be revoked.

OPINION

1. Background

A. Defendant's Registered Trademark (Plaintiff's Exhibit 1)

1) Registration number / Filing date of application / Registration decision date / Registration date: No. 1607108 / May 17, 2019 / March 30, 2020 / May 19, 2020

2) Mark: Hyundai Connect

3) Designated goods: As per Appendix 1.

B. Plaintiff's Prior-registered Trademark (Plaintiff's Exhibit 4)

1) Registration number / Filing date of application / Registration date: No. 244689 / November 12, 1990 / July 24, 1992

2) Mark: HYUNDAI

3) Designated goods: As per Appendix 2.

C. Procedural History

1) The Plaintiff filed an administrative trial to invalidate the trademark registration of the Defendant's registered trademark (hereinafter the Registered Trademark at Issue) with the Korean Intellectual Property Trial and Appeal Board (IPTAB) on October 19, 2020 claiming that "the Registered Trademark at Issue falls under

Article 34(1)7 of the Trademark Act in relation to the Plaintiff's prior-registered trademarks (hereinafter, "the Prior-registered Trademark"[1]) and should therefore be invalidated."

2) Accordingly, the IPTAB, after examining the case under Case No. 2020Dang3136, issued its decision on September 28, 2022, dismissing the Plaintiff's petition on the grounds that "the Registered Trademark at Issue is not similar to the Prior-registered Trademarks and therefore does not fall under Article 34(1)(7) of the Trademark Act."

【Factual basis】 Undisputed facts, statements in Plaintiff's Exhibits 1 to 4 and videos, and purport of the overall argument

2. Summary of Parties' Arguments

A. Plaintiff

The Prior-registered Trademarks are well-known and widely recognized, and the "Hyundai" portion of the Registered Trademark at Issue should be regarded as the distinctive part. Since the distinctive part of the Registered Trademark at Issue is identical or similar to the appearance, name, and concept of the Prior-registered Trademarks, and the designated goods of the both marks are also identical or similar, the Registered Trademark at Issue should be invalidated under Article 34(1)(7) of the Trademark Act.

B. Defendant

While the "HYUNDAI" mark itself is considered as well-known and widely recognized, such a mark is commonly understood by the

1) While the Plaintiff argued during the issuance of administrative decision that other prior-registered trademarks, in addition to the above prior-registered trademarks, were similar trademarks, in the present case, the Plaintiff is claiming similarity only with the above prior-registered trademarks.

general public as referring to “F” and is associated with numerous trade names and trademarks of various companies that include this mark. Consequently, general consumers typically perceive such trademarks as a whole to identify its source among the numerous “Hyundai+[suffix]” trademarks. Therefore, the Trademark at Issue and the Prio-registered Trademarks are not similar in terms of appearance, name, or concept and do not fall under Article 34(1)(7) of the Trademark Act.

3. Whether IPTAB Erred

A. Whether the Registered Trademark at Issue falls under Article 34(1)7- of the Trademark Act

1) Stand of Decision

For a trademark to fall under Article 34(1)7 of the Trademark Act, the “similarity” between trademarks means that, even though the two trademarks are not identical, they are proximate in terms of appearance, name, or concept, leading to ordinary consumers or traders to mistakenly believe, according to trade norms, that the goods originate from the same source when the trademarks are used for identical or similar goods. Furthermore, the determination of similarity between trademarks is a normative judgment made in terms of the Trademark Act, such as for deciding whether a trademark registration is permissible, as well as a legal evaluation that considers the essential function of a trademark,which is preventing “confusion about the source.” Thus, the similarity should not be determined merely by comparing the trademarks’ appearance, name, and concept , but by the consideration on whether there is a likelihood of confusion regarding the source of goods among general consumers or traders.

2) Method for Determining the Identity or Similarity Between the

Registered Trademark at Issue and the Prior-Registered Trademarks

a) Established Facts

Based on the entirety of the statements of Plaintiff's Exhibit 2 and 4, Defendant's Exhibits 1, 2, 4, 5, 14 through 16, and 31, and 32 (including Exhibits with branching numbers, if any), in addition to the purport of the overall argument, the following facts can be acknowledged:

(1) The so-called "former F" was a corporate group formed based on company "G" established around April 1946, and company "H" established around May 1947, becoming a large-scale corporate group that ranked first in domestic asset size among the corporate groups in Korea from 1977 to 2000. From 1999 to 2002, the former F underwent a process of separating its affiliated companies, resulting in I Co., Ltd., J Co., Ltd., K Co., Ltd., L Co., Ltd., M Co., Ltd., N Co., Ltd., and related affiliated companies being separated from the former F. Subsequently, these companies formed large-scale corporate groups centered around themselves, referred to as the so-called "pan-F," which includes the L Group, I Group, J Group, K Group, and N Insurance Group.

(2) From 2001 to 2022, in the asset rankings of public disclosure corporate groups announced by the Korea Fair Trade Commission, the I Group and L Group consistently ranked within the top 10, while the K Group and J Group consistently ranked within the 20th to 30th range. As of 2020, the total number of the affiliates belonging to these groups amounted to 136.

(3) As of May 2022, among the "pan-F" corporate groups, approximately 73 affiliates use marks that include the "Hyundai" group mark, and there are around 3,600 registered trademarks incorporating the "Hyundai" group mark. These registered trademarks are individually owned and used by 47 companies. Among these "Hyundai" group trademarks, approximately 500 are registered for goods in the categories of computer software and telecommunication devices.

(4) The Defendant, the holder of the Registered Trademark at Issue, is the holding company of the L Group. The Prior-registered Trademark was registered on July 24, 1992, by O Co., Ltd., a company affiliated with the former F. After O Co., Ltd. ceased its monitor business, some personnel from the monitor division established P Co., Ltd. (now Q Co., Ltd.) and acquired the rights to the Prior -registered Trademark for certain designated goods. Subsequently, on January 18, 2019, the Plaintiff acquired those rights. The Plaintiff currently has no affiliation with the former F or the "pan-F" corporate groups.

b) Decision on This Case

Considering the facts acknowledged above in conjunction with the following circumstances, it is reasonable in this case to compare the entirety of the Defendant's registered trademark at issue with the prior-registered trademark when determining whether it constitutes a "similar trademark" as stipulated under Article 34(1)(7) of the Trademark Act. Conversely, it is difficult to justify the necessity of determining the similarity of the marks solely based on the "Hyundai" portion of the Registered Trademark at Issue as an appropriate conclusion of an overall observation.

(1) As of March 30, 2020, the registration decision date of the Trademark at Issue, the marks "현대," "HYUNDAI," or "Hyundai" had been used as group marks of the pan-F group for over 70 years. Therefore, it is reasonable to consider that these marks were widely recognized among general consumers as names referring to the pan-F group and its affiliates.

(2) Ordinary consumers and traders typically distinguish and recognize names such as Samsung, Hyundai, and LG as names or group marks for large-scale corporate groups. While such group marks are collectively used by dozens or even hundreds of companies, the companies within a large-scale corporate group often exhibit distinct business characteristics from one another. Consequently, while group

marks strongly convey information about the corporate group as a whole, they are less persuasive in conveying information about the specific supplier of goods, i.e., the individual company responsible for the ultimate and specific source of the goods. Therefore, it is common for ordinary consumers and traders to recognize the trade names and trademarks of companies within a large-scale corporate group as marks that combine the corporate group name with a designation indicating the specific business area of the individual company, which is reasonable when viewed in light of the source identification of trademarks.

(3) In this litigation, numerous companies affiliated with the pan-F group currently use trademarks combining "현대," "HYUNDAI," or "Hyundai" with designations indicating their specific business sectors, such as "L," "I," and "R," in various industries including automobiles, IT, food, and machinery. Under these transactional circumstances, it is typical for general consumers to recognize the source of trademarks that include the corporate group name "현대," "HYUNDAI," or "Hyundai" from the entire trademark as a whole.

(4) Furthermore, considering the existence of numerous trademarks that include the "Hyundai" group mark and are registered for goods in the categories of computer software and telecommunication devices, which overlap with the designated goods of the Registered Trademark at Issue, it is difficult to conclude that general consumers would perceive both the Registered Trademark at Issue and the Prior-registered Trademark as indicating the same source solely based on the "Hyundai" portion.

(5) Meanwhile, from the functional perspective of a trademark's capability to identify goods, even when observing a trademark as a whole, if a particular part is especially easy to draw the attention of consumers and independently serves to indicate the source of goods, such a part is referred to as the "primary part" that leads to the development of the legal doctrine to determine the

similarity of trademarks based on this primary part. The legal doctrine of observing the primary part applies, when a specific mark has attained such a degree of recognition as a source identifier among general consumers or traders of the designated goods, that even trademarks that slightly modify the primary part or include relatively minor addition of distinctive characters or figures can be deemed similar through primary part observation. This aims to protect the trademark holder who has built treputation around the widely recognized and well-known mark, as well as to protect the interests of general consumers or traders in relation to the reputation embodied in the mark. However, the trademark holder of the Prior-registered Trademark is a company completely unrelated to the Hyundai group. Moreover, it does not engage in business activities that have reputation associated with the "HYUNDAI" or "Hyundai" marks as recognized by general consumers or traders. Under such circumstances, directly applying the legal doctrine of primary part observation does not align with the underlying reasons for adopting this doctrine, as described above.

(6) The Plaintiff, citing Supreme Court Decision 2015Hu1690, argues that the "Hyundai" portion of the Registered Trademark at Issue is widely recognized and well-known, and therefore, the legal doctrine of primary part observation should be applied directly, comparing only the "Hyundai" portion of the registered trademark with the Plaintiff's prior-registered trademark. However, the Supreme Court decision referenced by the Plaintiff also declares that the principle of overall observation takes precedence in determining trademark similarity, and the legal doctrine of primary part observation may only be adopted when necessary to guide an appropriate conclusion of overall observation. Moreover, the decision explicitly states that in determining whether a specific component of a trademark constitutes the primary part, not only the recognition and prominence of the particular component but also transactional circumstances must be comprehensively considered. Thus, the Plaintiff's argument cannot be accepted. (Additionally,

the Trademark Act provides grounds for rejecting or invalidating trademark registrations beyond Article 34(1)7, including Articles 34(1)11 through 13, thereby establishing provisions to pursue the fundamental purposes of the Trademark Act, such as maintaining the buisness reputation of trademark users and protecting the interests of consumers in connection with marks related to large-scale corporate groups.)

3) Whether the Registered Trademark at Issue is similar to the Prior-registered Trademark

a) When observing the similarity between the Registered Trademark at Issue and the Prior-registered Trademark as a whole, the Registered Trademark at Issue consists of the English letters "Hyundai Connect," while the Prior-registered Trademark consists of the uppercase letters "HYUNDAI," with the letter "H" partially stylized as "  ." Due to the differences in the composition of the letters and the combination with design elements, the visual appearances of the two marks differ.

b) In terms of name, the Registered Trademark at Issue is pronounced as "Hyundai Connect," whereas the Prior-Registered Trademark is pronounced as "Hyundai," concluding that the pronunciations of the two trademarks cannot be considered identical.

c) Regarding concept, while the Registered Trademark at Issue and the Prior-registered Trademark both include "Hyundai," the Registered Trademark at Issue is combined with the word "Connect," unlike the Prior-registered trademark. Thus, it is difficult to conclude that the two trademarks share the same or similar conceptual meaning.

B. Summary of Discussion

The Registered Trademark at Issue is not similar to the Prior-registered Trademark in terms of its mark, and therefore, it cannot be considered

to cause misunderstanding or confusion regarding the source of goods. Consequently, there is no need to further examine other requirements, such as the similarity of the designated goods, as the trademark does not fall under Article 34(1)7 of the Trademark Act. Accordingly, the IPTAB Decision is consistent with the above analysis and shall be upheld.

4. Conclusion

The Plaintiff's petition requesting the revocation of the IPTAB Decision is without merit. Therefore, it is dismissed. It is so ordered.

Presiding Judge Jaheun KU
Judge Hyejin LEE
Judge Young Gi KIM

[Appendix 1]

List

Classification of Goods, Class 9: Computer software; computer software for ships; computer programs and software for marine telematics; computer software for construction equipment (for the remote control, maintenance, and management of construction equipment and for collecting and transmitting information on construction equipment and construction sites); communication apparatus and instruments for ships; data communication devices; communication devices connecting ships and land; devices for recording, transmitting, processing, and reproducing sound, images, or data; telemetry control apparatus and instruments for ships; telecommunication devices for construction equipment; remote control devices; remote monitoring devices; ship motion simulators; navigation apparatus for ships; black boxes for ships; information processing devices; equipment for connecting to computer communication networks; computer programs for remote access to computers or computer networks; and central processing units for processing information, data, sound, or images.

Classification of Goods, Class 42: Computer programming services for marine telematics; configuration of computer systems and networks for the remote control, maintenance, and management of construction equipment and for collecting and transmitting information on construction equipment and construction sites; configuration of computer systems and networks for the remote control, maintenance, and management of ships; configuration of computer systems and networks for collecting and transmitting information on ports and port equipment; development and maintenance of computer software for ships; online computer services for the remote control, maintenance, and management of ships; online computer services for the remote control, maintenance, and management of construction equipment;

computer system monitoring services via remote access; design of communication apparatus and equipment; design of computer hardware; technical consulting services related to electronics and telecommunications equipment; consulting services in office and workplace automation; design of computer systems for controlling ship mechanisms; consulting services in shipbuilding engineering technology; chart updating services; and research services related to construction machinery. End.

[Appendix 2]

List

Classification of Goods, Class 39: Industrial X-ray machinery and equipment; seismic exploration machinery and equipment; ultrasonic detection devices; electronic calculators; electron microscopes; electronic copiers; robotic controllers; closed-circuit systems; electronic gaming devices; electronic typewriters; workstations; monitors; integrated circuits; tapes, diskettes, and disks containing computer programs; electronically operated vending machines; electronic anti-theft devices; vacuum tubes; diodes; and transistors. End.

IP HIGH COURT OF KOREA
SECOND DIVISION
DECISION

Case No.	2023Heo10361 Rejection (Trademark)
Plaintiff	A Counsel for Plaintiff Intellectual Property Law Firm ERUUM & LEEON Patent Attorney in Charge Hyeokseong KWON and Seongjun PARK
Defendant	Commissioner of the Korean Intellectual Property Office Counsel for Defendant Yulgeon SHIN
Date of Closing Argument	September 20, 2023
Decision Date	October 27, 2023

ORDER

1. The Plaintiff's claims are dismissed.

2. Costs shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2021Won2107, decided December 28, 2022, shall be revoked.

OPINION

1. Background

A. Claimed Trademark at Issue

1) Filing date of application / Application number: September 3, 2021 / No. 40-2021-0024052

2) Mark: 

3) Designated goods:

- Classification 16: Stationery, office supplies (excluding furniture), school supplies, paper advertisement boards for wall decoration, calendars, printed photographs, developed photographs, stickers, double-sided stickers, memo pads, albums, printed materials (excluding books and periodicals), books, publications, posters, periodicals, ballpoint pens, printed pictures, comic-printed materials, comic books, serialized comics, file folders

- Classification 35: Online marketplace services, promotion/ advertising services, online advertising and marketing services, promotion and marketing services related to products and services accessible online, marketing services via the Internet, product and service promotional agency services via the Internet, wholesale of clothing, retail of clothing, wholesale of cosmetics, retail of cosmetics, organizing and conducting commercial exhibitions and shows, promotion through issuing prize coupons, advertising/ marketing and promotional services, advertising in the tourism and travel sector, magazine advertising services, advertising related to cultural projects,

advertising related to the entertainment business, promotion and marketing related to cultural projects, promotion and marketing related to the entertainment business, convenience store operations, supermarket operations, wholesale of fresh vegetables, wholesale of processed grains, retail of fresh vegetables, retail of processed grains, wholesale of stationery, retail of stationery, Internet advertising services, commercial information services via the Internet, wholesale of bedding (excluding linen), wholesale of mattress covers (bedding), retail of bedding (excluding linen), retail of mattress covers (bedding), wholesale of hats, retail of hats

B. Procedural History

1) The Plaintiff applied for the registration of the trademark at issue on February 3, 2021, but the examiner of the Korean Intellectual Property Office (hereinafter, the "KIPO") issued a notice of grounds for rejection on April 21, 2021, stating, "The claimed trademark falls under Articles 33(1)7 and 38(1) of the Trademark Act.

2) In response, the Plaintiff submitted written argument on May 10, 2021. On July 15, 2021, the KIPO examiner issued a decision to reject the application stating, "While the grounds for rejection based on Article 38(1) were resolved, the trademark still falls under Article 33(1)7."

3) Regarding the rejection, the Plaintiff filed an administrative appeal on August 13, 2021 with the Intellectual Property Trial and Appeal Board (hereinafter, the "IPTAB") as Case No. 2021Won2107. The IPTAB issued an administrative decision to dismiss the Plaintiff's appeal on December 28, 2022, concluding that "the claimed trademark falls under Article 33(1)7."

【Factual basis】 Undisputed facts, the descriptions and images on Plaintiff's Exhibits 1 through 5, the purport of the overall arguments

2. Summary of Parties' Arguments

A. Plaintiff

The claimed trademark does not fall under Article 33(1)7 due to the following reasons. Therefore, the administrative decision ruling otherwise is erroneous and should be revoked.

1) Since the Plaintiff is a well-known and famous public figure, recognized as a politician, lecturer, broadcaster, and celebrity, the claimed trademark--a portrait--is widely recognizable among the general public in Korea. The portrait possesses inherent distinctiveness due to its association with the Plaintiff. Furthermore, the Plaintiff's consistent use of the depicted hairstyle and red tie over an extended period reinforces the portrait as a well-established representation of the Plaintiff. Unlike a typical identification photograph, this portrait demonstrates a high degree of distinctiveness.

2) The portrait in question qualifies for protection as a trademark since the design and the trademark are not mutually exclusive; even the portrait of a prominent individual may be registered as a trademark, provided the individual depicted consents, as stipulated under Article 34(1)6 of the Trademark Act; and the publicity rights of celebrities are safeguarded under Article 2(1)(l) of the Unfair Competition Prevention and Trade Secret Protection Act.

3) Also, considering the numerous instances in which pictures are utilized as trademarks in the marketplace, the claimed trademark functions as a distinctive indicator through which consumers associate the product with the individual whose work the trademark represents. Therefore, it does not fall within the scope of Article 33(1)7 of the Trademark Act.

4) Even if the claimed trademark is not inherently distinctive, it has been used for various products and has acquired distinctiveness through such use.

B. Defendant

The claimed mark depicts only the upper body of a middle-aged man dressed in a black suit and red tie. In connection with products and services such as stationery, online marketplace services, wholesale and retail of cosmetics, convenience store operations, printed photographs, wholesale and retail of clothing, office supplies, school supplies, calendars, developed photographs, books, publications, posters, and promotional/advertising services, ordinary consumers are unlikely to recognize the image as a portrait of a specific individual. Consequently, the mark does not fall under Article 33(1)7 of the Trademark Act, as it fails to function as a distinctive indicator to differentiate the applicant's products or services from those of others. The acquired distinctiveness of the claimed trademark concerning the designated products listed above is not established either. Therefore, the IPTAB decision to uphold the rejection of the claimed trademark is justified.

3. Whether the Claimed Trademark Falls under Article 33(1)7 of the Trademark Act

A. Relevant Law

1) Article 33(1)7 of the Trademark Act stipulates that a trademark cannot be registered if, "other than the trademarks falling under Articles 33(1)1 to 33(1)6, consumers cannot identify whose work the product with the mark is associated with." This provision indicates that even if a trademark does not fall under the specific prohibitions outlined in Articles 33(1)1 to 33(1)6, it is not eligible for registration when it fails to function as an indicator to differentiate the applicant's goods or services from those of others. Whether a trademark lacks distinctiveness must be determined objectively, considering the mark's concept, its relationship with the designated goods, and its use in the course of

trade. A trademark is deemed non-distinctive if, under social norms, it is found that the mark does not distinguish the applicant's products from those of others or if granting exclusive rights to a specific individual would be deemed inappropriate for the public interest (See Supreme Court Decisions 91Hu455, dated December 24, 1991, 2012Hu2951, dated December 27, 2012, etc.).

2) If the claimed mark fails to meet the registration requirements for certain designated goods, the application shall be rejected in its entirety with respect to all designated goods (See Supreme Court Decision 93Hu1360, dated December 21, 1993, etc.).

3) The determination of whether the claimed mark falls under each paragraph of Article 33(1) of the Trademark Act is, in principle, made at the time of determining its registration and of the administrative decision in cases where an administrative trial against rejection is conducted (See Supreme Court Decision 2011Hu1142, dated April 13, 2012, etc.).

B. Established Facts

Based on the descriptions and videos provided in Plaintiff's Exhibits 6 through 10, 12, 16, 18, 20, and 21, as well as the overall purport of the argument, the following facts are acknowledged.

1) The Plaintiff first participated in an election in 1991, running in a local election. By December 2022, shortly before the administrative decision at issue, he had run in three presidential elections, two local elections, two National Assembly elections, and one Seoul mayoral by-election. In the Seoul mayoral by-election, he ranked third with 1.07% of the vote, and in the most recent 20th presidential election, he received 289,000 votes, accounting for 0.83% of the total.

2) The Plaintiff also operates several YouTube channels, including "A Lecture," "A Short Lecture," "A TV," and "Mr. A Studio."

3) In 2009, a music album released by the Plaintiff ranked first among background music on website B. Additionally, from at least February 9, 2022, or August 26, 2022, a picture resembling the claimed trademark has been used as the official profile picture in the "Figures" section on search engines such as NAVER, DAUM, and Nate.

C. Whether the Claimed Trademark is Distinctive

1) Legal principle

a) It is understood that the provisions of the Trademark Act (Article 2(1)2 and the proviso of Article 34(1)6) imply that a portrait can be utilized as a trademark. Therefore, the mere fact that the mark is a portrait photograph does not render it ineligible for trademark registration (eligibility for registration). However, the Act also specifies that a trademark cannot be registered if it lacks the "istinctiveness necessary to differentiate its products from those of others" (Article 33(1)). Thus, the distinctiveness of a portrait photograph must be evaluated comprehensively, considering not only its appearance, name, and concept but also its relationship with the designated goods, the course of trade, and the perception of ordinary consumers and traders, similar to the evaluation of other types of marks.

b) The reason Article 33(1)7 requires distinctiveness as a condition for registration is that a trademark must enable the recipient of specific goods or services to distinguish them, without confusion, from goods or services of the same source and quality, which is a fundamental function of a trademark. However, because human faces share similar basic composition and shape, a portrait photograph cannot be presumed to have distinctiveness for all designated goods uniformly. The distinctiveness of a portrait photograph, when used in connection with specific designated goods, must be assessed on a case-by-case basis.

c) If a portrait photograph of a specific individual is inherently very unique, or if the individual is a well-known and famous figure in certain fields and the primary consumers or customers are people related to those fields, then the photograph can possess distinctiveness as a trademark. However, even in such cases, if the photograph does not reasonably indicate the source of the specific designated goods, it cannot be considered to possess distinctiveness with respect to those goods. In other words, if ordinary consumers require education or additional explanations to recognize that the mark indicates a specific source (a particular person), the mark cannot be considered inherently distinctive.

d) Article 33(1)7 of the Trademark Act serves as a supplementary provision to prevent the registration of marks that, in light of the purposes of Articles 33(1)1 through 33(1)6, are deemed unsuitable for registration (See Supreme Court Decision 93Hu1018, dated December 28, 1993). The reason Article 33(1) prohibits the registration of marks lacking distinctiveness is to serve the public interest by protecting consumers and preventing market confusion that could arise from the registration of such marks. Additionally, under the Korean legal system, a trademark may be registered for all the designated goods specified by the applicant, regardless of whether the mark has been used or the form in which it is used for specific designated goods, unless the registration is based on distinctiveness acquired through use. In summary, even if a mark is recognized as an indicator of source to consumers in certain specific modalities of use, it should not be registered for the corresponding designated goods if it lacks distinctiveness in general modalities of use.

2) Discussion

Considering the following circumstances derived from the facts above, in light of the legal principles and evaluation criteria outlined, it can be concluded that the claimed trademark lacks distinctiveness in

distinguishing the applicant's products from those of others concerning its relationship with "some of the designated products" under social norms at the time of the administrative decision in question.

a) First, the claimed trademark is a portrait photograph, specifically an ID picture, and therefore lacks any distinctive features. In other words, the mark in question does not have any unique features that distinguish it from other ID pictures, whether in terms of the person's appearance, posture, clothing, or the photograph's appearance, such as composition or background. Therefore, ordinary consumers who are unfamiliar with the Plaintiff or unable to recognize the subject of the photograph as the Plaintiff would perceive or think the trademark simply as "a photograph of the upper body of a middle-aged man wearing a black suit and red tie."

b) Moreover, as detailed below, the evidence submitted by the Plaintiff does not establish that the claimed trademark has exclusive distinctiveness with respect to all the designated goods.

(1) In the case of stationery, school supplies, and retail of stationery, while adults may not be entirely excluded as ultimate consumers who frequent such places or purchase products, minors constitute the primary consumer group for these goods.[1] Based on the acknowledged facts, it is evident that the Plaintiff has gained public recognition and attention by running elections many times, with the primary audience for the Plaintiff's YouTube channels appearing to consist predominantly of his political supporters.[2] However, the evidence submitted by the Plaintiff alone is insufficient to establish

1) The claimed trademark also includes "official supplies" as additional designated goods, in addition to the goods and services mentioned above.

2) The Plaintiff further argues that his lecture encompasses the fields of science, politics, history, economics, humanities, society, philosophy, and religion, and that through these lectures, he conveys his political views, address social issues, and share insights on humanities, religion, and philosophy. He asserts that his primary audience consists of unspecified individuals, including his supporters and fans (see preparatory document dated August 17, 2023).

that the audience for his YouTube lectures includes people of all age groups, and there is no additional evidence to support this claim. Therefore, it cannot be concluded that the Plaintiff is well-known not only among voters but also among students who are minors. Since the consumers of the designated goods mentioned above perceive the claimed mark merely as "a photograph of the upper body of a middle-aged man wearing a black suit and red tie," its use on those goods cannot be regarded as having distinctiveness sufficient to differentiate the applicant's products from those of others, particularly in relation to trademarks featuring images of other middle-aged men.

(2) For the remaining designated goods, even if the Plaintiff is widely recognized by their consumers and customers, and those consumers and customers can easily distinguish the Plaintiff's picture from those of others, when the claimed trademark is applied to items such as books, publications, posters, periodicals, printed photographs, developed photographs, and albums, a portrait photograph like the claimed trademark cannot reasonably be expected to function as an "indicator of source." In this case, ordinary consumers are highly likely to perceive the photograph as that of a person who authored something related to the goods or as an image intended to explain, promote, or represent the goods. In connection with the designated goods mentioned above, even if the claimed trademark does not lead consumers to instinctively think of the uses of the designated goods prescribed in Article 33(1)3 of the Trademark Act, it incorporates content that is highly related to the designated goods. As a result, consumers are generally unable to associate the goods represented by the mark with any specific source (See the legal basis of Supreme Court Decision 2000Hu1696, dated December 12, 2000). Accordingly, the claimed trademark cannot be considered to possess distinctiveness in relation to the designated goods above.

(3) The same conclusion applies when considering the course of trade for "printed photographs" and "developed photographs" among the designated goods of the claimed mark. These types of designated

goods are commonly traded as "merch" featuring the actual image of a person or celebrity printed on them (Plaintiff's Exhibits 23 and 24). In such cases, ordinary consumers are likely to perceive the image as merely a promotional element, etc. rather than as a distinctive indicator to differentiate the goods from those of others. This is because, in general, the picture on such goods does not serve to indicate the "source" of the goods and consumers who purchase "merch" featuring a particular celebrity typically do not view the picture as an indicator of source but rather as a decorative element reflecting their personal preference.

Mug	Tissue Box Cover	Figurine	Commemorative Stamp	Photograph Card
				

3) Discussion on the Plaintiff's argument

a) Citing the "Trademark Perception Survey" (Plaintiff's Exhibit 49) submitted as evidence, the Plaintiff argues that when portraits are used on items such as photographs, posters, etc., general consumers perceive the portrait as both the image of an advertisement model and an indicator of the source of the goods. The Plaintiff further contends that design elements and trademarks are not mutually exclusive. Therefore, even a shape or form typically considered a design can function as a trademark if it performs the essential function of a trademark. Based on this reasoning, the Plaintiff asserts that the claimed mark should be considered distinctive, regardless of its designated goods.

According to Plaintiff's Exhibit 49, it is acknowledged that C Corp. conducted a survey of 500 adult men and women, aged 20 to 59, from across the country between June 12 and June 18, 2023. However, it is difficult to accept the survey results for the reasons outlined below.

Furthermore, even if some of the results are deemed reliable and it is assumed that ordinary consumers perceive the portrait not only as an image of an advertisement model but also as an indicator of source, the claimed trademark cannot be regarded as an indicator of source concerning certain designated products, as seen above. Therefore, this part of the Plaintiff's argument is unfounded.

(1) The Plaintiff contends that consumers perceive a portrait (or portrait photograph) as an indicator of source, citing survey results where 62.6% of respondents selected option ② (portrait trademark part) in Q2, and 55.4% selected option ③ (portrait trademark part) in Q3. However, as the two questions state, "Please assume that you have purchased other products produced or sold by the producer or seller of the product listed below," respondents were required to speculate arbitrarily, as they lacked information about the appearance or characteristics of the "other products" and the commonalities they might share with the product, among the options provided in the questions.

Q2. Please assume that you have purchased other products produced or sold by the producer or seller of the product listed below. What aspects of the product listed below led you to believe that the product(s) you previously purchased were produced or sold by the same entity responsible for the product listed below? Please select all that apply. [Choose all that apply]	Q3. Please assume that you have purchased other products produced or made by the producer or maker of the product listed below. What aspects of the product listed below led you to believe that the product(s) you previously purchased were produced or sold by the same entity responsible for the product listed below? Please select all that apply. [Choose all that apply]
 1) ① 2) ② 3) ③ 4) ④	 1) ① 2) ② 3) ③ 4) ④

(2) The Plaintiff further asserts that, as 80.2% of the respondents identified one or both of the two images in Q6 as an indicator of source, portrait photographs should be considered trademarks. However, in this case, the issue is whether the claimed trademark demonstrates distinctiveness. Option ② of the survey referenced above presents a portrait photograph accompanied by the "TM" symbol as supplementary characters on the side, signifying its intended function as a trademark. Therefore, unless it can be established that the respondents perceived portrait photographs as trademarks solely based on the photographs themselves, as with the claimed trademark, the survey questions are inadequate, and the results are unreliable. Option ① "  " of Q7 also includes the terms "Book Publisher" and "TM" written on the side, emphasizing the unreliability of the survey results.

Q6. The following are two mugs featuring celebrity A's picture. Which of the two appears to function as a trademark, indicating the product's source? [Choose one]

① 

② 

1) ①
2) ②
3) 둘 다 출처표시로 보임
4) 둘 다 출처표시로 보이지 않음

(3) The Plaintiff argues that, since 87.2% of the respondents answered “yes” to the question “Do you think portrait photographs can also serve as an indicator of source?” in Q8, portrait photographs are perceived as trademarks by ordinary consumers. However, this response appears to have been influenced by the preceding questions, Q6 and Q7, which displayed portrait photographs with “TM” written on the side, leading respondents to perceive the photographs as being used as trademarks.

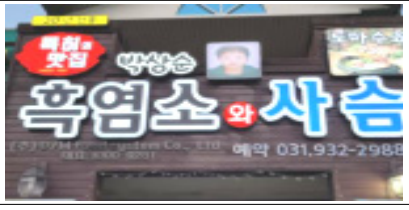
b) The Plaintiff contends that numerous portrait photograph trademarks exist in other countries for designated goods such as stationery, photographs, and posters, serving as evidence to demonstrate that portrait photographs possess inherent distinctiveness.

Based on the descriptions of Plaintiff’s Exhibits 30, 45, and 46, it is acknowledged that portrait photographs have indeed been registered as trademarks in jurisdictions such as the United States, the European Union (EU), and Japan for designated goods or services, including photographs, printed materials, stationery, and promotional/advertising services. However, while practical examples from other countries can serve as references, the decision to approve the registration of a claimed trademark must be made independently based on the Korean trademark law and should not be bound by examples from other jurisdictions. Therefore, the Plaintiff’s argument above is denied.

c) The Plaintiff argues that portrait photographs are frequently used as identifiers on signage, packaging, advertisements, and similar contexts, as illustrated in the photographs provided in Plaintiff’s Exhibit 31. Therefore, the Plaintiff asserts that the claimed trademark also possesses distinctiveness. However, the images below consist of portrait photographs accompanied by registration numbers or characters indicating the name of the person in the picture, and they were not used independently as the claimed trademark is. Thus, these examples cannot serve as evidence to demonstrate that the claimed trademark possesses distinctiveness across all the designated goods. Therefore, the Plaintiff’s argument above is denied.


설악추어


마복림
떡볶이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Hangover Solution
808
DAWN
숙취해소에 조은차


백종원의
홍콩반점 0410


장동민의
Crowd
The center of playground
PC
PREMIUM PC + RESTAURA
MD COOK


통등심 돈까스
Delicious loin Pork Cutlet


이승윤의
쿼스
치킨피자

4) The Plaintiff contends that while trademarks primarily function as indicators of association for consumers, this is merely one aspect of their broader functions, such as "advertisement and promotion." Consequently, the Plaintiff asserts that portrait photographs possess inherent distinctiveness, and the claimed mark should therefore be recognized as distinctive. In cases where portrait photographs are recognized as distinctive and registered as trademarks, such trademarks can serve an advertising and promotional function for the designated goods as one of their functions. However, the reverse does not hold true—that is, the ability of a portrait photograph to function in advertising and promotion does not guarantee that it possesses distinctiveness for all designated goods or meets the requirements for registration. Thus, as discussed above, the distinctiveness of a trademark must be assessed on a case-by-case basis for each designated good. Therefore, the Plaintiff's argument above is denied.

D. Whether the Claimed Trademark Has Acquired Distinctiveness Through Use

1) The Plaintiff argues that the claimed trademark has been used across various categories of goods, thereby acquiring distinctiveness through such use.

2) Article 33(1)7 of the Trademark Act simply stipulates that even if a mark does not fall under Articles 33(1)1 to 6, it cannot be registered if it fails to distinguish the applicant's products from those of others. Thus, even if certain trademarks may initially appear to lack distinctiveness based on their concepts or their relationship with the designated goods when evaluated objectively without considering their usage, if, through the applicant's use of the mark, consumers or traders can identify whose work the goods are associated with, the mark would not be considered non-distinctive under Article 33(1)7 for the goods it is used with, unless special circumstances exist. Consequently, there would be no obstacle to the mark being

registered. This interpretation is not altered merely because Article 33(2) does not explicitly reference Article 33(1)7 (See Supreme Court Decisions 2001Hu2863, dated July 11, 2003, and 2005Hu339, dated May 12, 2006). However, trademarks can only acquire distinctiveness for goods that are substantially identical to those on which the mark is used. Therefore, the mark cannot be registered for other goods or similar goods within the same classification.

3) In this case, based on the descriptions and images provided in Plaintiff's Exhibits 25 and 50, it is acknowledged that the claimed trademark has been used on vacuum flasks, key holders, and similar items, but the timing of such use remains unclear. Furthermore, after reviewing all the evidence submitted by the Plaintiff, including the aforementioned exhibits, it is insufficient to establish that the Plaintiff used the mark for all the designated goods that were previously deemed non-distinctive and that consumers have come to recognize the mark as an indicator of source. Additionally, no other evidence has been provided to support such a claim. Therefore, the Plaintiff's argument above is groundless with no need to further examine it.

E. Summary of discussion

The claimed trademark lacks distinctiveness for certain designated goods and, therefore, falls under Article 33(1)7 of the Trademark Act. As a result, it cannot be registered for all designated goods, and acquired distinctiveness through use cannot be recognized.

4. Conclusion

Therefore, the IPTAB Decision, which aligns with this conclusion, is legitimate. The Plaintiff's petition seeking the revocation of the decision is without merit. Accordingly, it is dismissed. The decision is rendered as ordered.

Presiding	Judge	Jaheun KU
	Judge	Hyejin LEE
	Judge	Young Gi KIM