PATENT COURT DECISIONS

2017

International IP Law Research Center

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FOREWORD

Since its establishment in 1998 as the first court specializing in intellectual property matters in Asia, the Patent Court of Korea has come a long way through continued reform and innovation. The year 2017 was particularly full of meaningful changes. The National Assembly passed the bill to amend the Court Organization Act to establish the International Chamber, the initial steps were taken to launch the International Association of IP Judges, and the court's International IP Law Research Center took off.

With the number of global IP disputes on the rise, the court has diligently put efforts towards the establishment of the International Chamber to allow parties to argue their cases in languages other than Korean. In December 2017, the efforts came to fruition and the National Assembly passed the bill to amend the Court Organization Act, which will take into force in June 2018 and open a new chapter for the Korean patent litigation system.

The Patent Court also hosts the International IP Court Conference every fall to promote communication and cooperation among judges specializing in IP across the world. At the Third International IP Court Conference in September 2017, many judges joined forces to discuss the current issues in global patent litigation and the foundation of the International Association of IP Judges.

Furthermore, the International IP Law Research Center was established to carry out comparative legal research and promote systematic international communication. On its first year alone, the center published the Korean-English/English-Korean IP Law Dictionary and a research paper titled "the Comparative Research on Damages Calculation

in Patent Infringement Litigation," hosted a symposium celebrating its establishment under the theme of "the New Direction of IP Law in the Era of Technological Innovation and Fair Competition," and signed MOUs with major IP research institutes such as the Seoul National University Law Research Institute. The 2017 Patent Court Decisions and the 2017 IP Law Journal are also important parts of the center's work.

The 2017 Patent Court Decision includes twelve major decisions rendered by the Patent Court in 2017. It is aimed to help you better understand the court's position in adjudicating matters such as inventiveness of pharmaceutical invention, the scope of doctrine of equivalents, similarity of marks, and dilution of distinctiveness or reputation of a mark. I humbly hope that the book will be a helpful source to those who are interested in Korean IP law.

I would like to extend my deepest gratitude to those at the center and everyone involved in publishing the book for their hard work.

December 2017
Director of the International IP Law Research Center
Chief Judge of the Patent Court of Korea
Daekyeong Lee

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1. Patent Court Decision, 2016Heo4733, decided May 12, 2017 (Sorafenib Tosylate Case) ····· ***1***

Claim 1 in this case and Prior Art 1 were activators which were common in the fact that they were pharmaceutical compositions to treat overgrowth disorders including cancer which included refined insulin containing sorafenib tosylate acid but they differed in the sense that Claim 1 in this case designated inclusion of at least 55% sorafenib tosylate in terms of weight composition while Prior Art 1 did not designate the content of sorafenib tosylate in 50mg tablet which made it impossible to determine the weight ratio of sorafenib tosylate in the entire composition.

But such designation of value above for Claim 1 in this case can be easily conceived from prior arts by a person with ordinary skills and the significance of such effect cannot be recognized which denies the inventiveness for Claim 1 in this case.

2. Patent Court Decision, 2016Heo7695, decided August 17, 2017 (Light Control Film Case) ····· ***30***

The grounds argued by the Commissioner of the Korean Intellectual Property Office in the procedure for revocation action of administrative decision for dismissal of trial against rejection can be based on the trial decision limited to when the grounds for rejection which was given an opportunity to submit arguments and the primary purpose correspond which makes it just an amendment of previously notified grounds for rejection. In order for the newly argued grounds in the litigation procedures to correspond with the grounds for rejection and primary purpose which were given an opportunity to submit arguments during examination or trial stage, each element of the claimed invention must be identical to the preceding technical documents being suggested based on publication and be consistent throughout the critical parts

of the premises necessary for the process of determining inventiveness of claimed invention from the preceding technical documents (level of technology at the time of application, technical knowledge, basic tasks of corresponding field of technology, etc.), elements as key factors of judgement, and details of judgement (problem to be solved, technical method necessary for resolution, purpose/suggestion of combination or obstacles, etc.) as well as congruent with the opinion documents expected from the applicant to resolve the grounds for rejection or the direction for attempted amendment by the applicant which makes it seem that the practical opportunities for submission of opinion documents and amendment were given to the applicant regarding the newly argued grounds. Even if the newly argued grounds in the litigation procedure is a simple argument for difference in combination or relationship of combination with preceding invention which was suggested as the basis for denial of inventiveness in the examination or trial stage, the premises necessary in the process of determining inventiveness, elements as key factors of judgement, and details of judgement may change and this change may make the applicant unable to submit opinion documents or make amendments during the examination or trial stage regarding the combination of preceding inventions that was newly suggested which makes it new grounds for rejection that does not correspond with the grounds for rejection and primary purpose given opportunities to submit arguments during examination or trial stage thus making it unpermitted.

3. Patent Court Decision, 2015Heo7889, decided February 3, 2016 (Tadalafil Formulation Case) ····· 65

It is determined that inventiveness is not denied if a specific administration method or dosage maintains the medicinal effect while minimizing toxicity and side effects yet has advantageous effect that came from the specific administration method or dosage without any special circumstances which is out of scope of predictability that a person with ordinary skills would not conceive from preceding invention or publicly known inventions as optimizing the dosage, administration cycle, and administration method within the scope

of no toxicity and side effect for desirable treatment effect to solve the task of medicinal effect increase and reduction of side effect for publicly known drugs belongs within the scope of creative ability of a person with ordinary skills by principle.

4. ***Patent Court Decision, 2016Heo4498, decided March 16, 2017 (Overactive Bladder Remedy Patent Term Extension Case)*** ····· ***111***

Article 89(2) of the Patent Act excludes the period which has elapsed for reasons attributable to the patentee, etc. from the period during which the subject invention would not have been practiced. In this case, "the period which has elapsed for reasons attributable to the patentee" means the period during which approval under the Pharmaceutical Affairs Act, etc. was delayed for reasons attributable to the patentee, i.e., the period during which a considerable causal relationship is recognized between the reason attributable to the patentee and the delay of the approval under the Pharmaceutical Affairs Act.

In light of the process, etc. of Subject Approval, the period during which the Subject Extended Invention would not have been practiced should be calculated based on the period from June 23, 2010 (patent registration date) to August 10, 2010 (clinical trial termination date) and the period from January 31, 2013 (date of filing an application for the Subject Approval) to December 31, 2013 (the date when the Subject Approval decision was notified to the applicant).

5. ***Patent Court Decision, 2016Heo8636, decided June 30, 2017 (Solifenacin Case)*** ····· ***163***

The validity of patent with its patent term extended affects not only the medicine designated by the clause for manufacturing and import permit but also the medicine regulated to receive permit for manufacturing and import as they are practically treated as equivalents as well as the medicine which

does not require separate permit for manufacturing and import that are practically equivalent to medicine that receive permits for manufacturing and import.

The challenged inventions of the plaintiffs in this case had “solifenacin” in common as active ingredient with the subject invention in this case and their respective salts were altered from “succinic acid” to “fumaric acid” or “tartaric aid” and according to ‘Regulation Regarding Safety and Validity Examination for Medicine, etc.’, any medicine of new composition with new category of effect or active ingredient with altered salts were designated as medicine subject to manufacturing and import permit thus making these challenged inventions neither eligible to be treated as practically equivalent items thus making it able to receive manufacturing and import permit nor to be treated as medicine that are already practically equivalent to a medicine that was permitted for manufacturing and import which makes separate permit unnecessary and therefore, these challenged inventions fall under the category of medicine that must receive manufacturing and import permit separate from the subject invention in this case. Therefore, the validity of patent for the subject invention in this case with extended patent term does not affect these challenged inventions.

6. Patent Court Decision, 2017Heo776, decided July 14, 2017 (Extended Head Pile Case) ····· ***206***

The recognition of intentional exclusion of some element from the scope of claim during the patent application process must be determined by taking not only just the specification of the invention into consideration but also the opinion suggested by the patent examiner from application until patenting as well as the intent of patent applicant and grounds for amendment in amendment and opinion documents. Therefore, rather than comparing the composition before and after reduction because the scope of claim was reduced during the patent application process and concluding that all composition existing between the two scenarios were intentionally excluded from the scope of claim and combining various circumstances revealed

throughout the application process, such exclusion can only be recognized when the intent of exclusion from the scope of claim for some element is clearly exhibited by the applicant. And such legal principle applies the same for when there is an opinion testimony through submission of opinion document and such without any reduction in scope of claim (Refer to Supreme Court Decision, 2014Hu638, decided April 26, 2017).

But the patent application for 'composition of head elements 1 and 2 being extended equally left and right' among element 2 of the subject invention in this case was disclosed for the scope of claim but later deleted intentionally by the applicant which should be recognized as intentional exclusion from the scope of claim. Therefore, it cannot be said that the 'extension line featuring length of protrusion on exterior and exterior of main body at 25mm' of the invention in question with such intentional exclusion of element is equivalent to element 2.

7. Patent Court Decision, 2016Heo7947, decided June 16, 2017 (Window Frame Case) ····· 228

It can be said that the invention was executed due to the state of recognition of technical composition of invention by unspecified number of people including the transferee with the item being transferred with the technical composition of the invention being easily understood by disassembly or analysis of this item by a person with ordinary skills within the field of technology that corresponds with this invention even when the technical composition of the invention cannot be simply understood from the exterior appearance as the same item as the invention was transferred for the purpose of sale or subcontracting unless there are special circumstances such as obligation of confidentiality for the transferee.

Meanwhile, the former Patent Act Article 29(1)(i) states that the practice of invention which was publicly known or executed has to be argued and proved by the party arguing for invalidation of patent but the existence of obligation for confidentiality must be argued and proven by the patent owner.

8. ***Patent Court Decision, 2017Heo1304, decided August 25, 2017 (Detonation Device Case)*** ····· ***240***

Decision on whether the determination of solution principles for the corresponding invention in a situation where the characteristic element that grants inventiveness for the corresponding claim was disclosed very specifically compared to other elements should be based on the corresponding element. It may be regarded that the principle of solution based on specific means to solve problem of claims 1 and 3 in this case lies in 'easily and sturdily connecting the shock tube and spark detonator through the connecting part'. However, the connecting part of the challenged invention as well features a structure for easily and sturdily connecting shock tube with spark detonator and this is shared in common with the connecting part of claims 1 and 3 in this case. As shown above, the circuit which was practically equivalent to the circuits of claims 1 and 3 in this case was disclosed in Prior Art 1 and the defendant has included the elements of the connecting part disclosed in claim 5 incorporated in claim 1 to overcome the grounds for rejection of acknowledgement of inventiveness and it can be seen that the composition of this connecting part was very strict as disclosed above. However, if the specific means to solve problem of claims 1 and 3 in this case determines the solution principle as just 'connecting structure to easily and sturdily connect spark detonator with shock tube' regardless of the specifically limited connecting part as shown above, the scope of equivalence despite the amendment of strictly limiting the scope of claim as shown above would result in being a wider scope despite the amendment and reduction of claim which would be unreasonable.

9. ***Patent Court Decision, 2017Heo2277, decided September 28, 2017 (Fish Scales Biomaterial Case)*** ····· ***274***

It is difficult to conceive the subject invention in this case from the preceding invention as the subject invention in this case and the preceding invention differ in terms of target product, applied technology, composition, and effect even though it was initially viewed to be easily conceived from the

‘manufacturing process for collagen sheet for wound dressing by treating fish scales with hydrochloric acid’ of the preceding invention as ‘decelluarization’ of fish scales were commonly present in both inventions in the decision of rejection from the patent examiner and the decision of IPTAB.

10. Patent Court Decision, 2016Heo6524, decided October 19, 2017 (Blood Coagulation Mutation Case) ····· ***291***

The technology to activate factor X into factor Xa outside of the body is a well-known and commonly used art.

However, unless a person with ordinary skills has gone through confirmation through specific experiment at the time of the priority date for the claimed invention in this case, it is difficult to predict whether the usual change of factor X would take place after activation of ‘preceding invention mutation’ and furthermore, it is even more difficult to predict what kind of activity would be exhibited by the activated form of the blood coagulation factor. The invention in Claim 1 has also confirmed that it has effect of long plasma half-life through experiments in multiple phases. Also, it is difficult to say that there was disclosure or hint of technical ideology of having long plasma half-life as blood coagulation factors when ‘preceding invention mutation’ is activated or to say that there was motivation to opt for such technical ideology.

Therefore, it is difficult to assess that there was possibility of simply attempting to invent or reasonable expectation for success beyond simple hope for success in this case and the premise that a person with ordinary skills applied well-known and commonly used art on preceding invention to generate each mutation in this case and confirmed their effects easily is only possible after already knowing the technical intent and effect of Invention Claim 1 in this case thus making it impermissible.

11. Patent Court Decision, 2016Heo9196, decided August 18, 2017 (Gliatimin Case) ····· ***320***

Even if actual drugs consumers are general consumers, considering medical doctors, pharmacists, etc. are involved in actual sales and trade relations, when the registered trademark of this case and the previously registered trademarks are used together for identical and similar products, the similarity thereof should be determined not only by general consumers who are the final consumers of drugs, but also by medical doctors, pharmacists, etc., and thus the recognition of medical doctors, pharmacists, etc. should be considered together with that of ordinary consumers or traders.

For the following reasons, the "GLIA" part that is a part of the registered trademark of this case and the previously registered trademarks cannot be seen to have no or weak distinctiveness.

① In general, the English word "GLIA", or its Korean transliteration "글리아", means "neuroglia" or "glial cells" having important interactions between neurons as non-neuronal cells other than the vasculature in the central and peripheral nervous system. ② However, it seems that not only general consumers, but also even experts such as medical doctors, pharmacists, etc., do not easily recognize that the "GLIA" part signifies "neuroglia" or "glial cells". ③ Furthermore, even if "GLIA" signifies neuroglia, the relationship between glial cells themselves and brain dysfunction, such as memory decay syndrome and degenerative cerebral syndrome, does not seem to be widely known, and there are no materials to admit the relationship. Thus, it is difficult to construe that the "GLIA" part of the registered trademark of this case and the previously registered trademarks directly indicates the efficacy and use of a therapeutic agent for brain diseases among the designated goods.

Furthermore, both marks are composed of 9 letters of the alphabet, and when read in Korean, both marks have the same number of five syllables identically. Also, the three syllables that are pronounced relatively strongly in light of the emphasis position of the Korean language and have the most prominent influence on the auditory sense are the same as "글리아". Furthermore, the initial sound of the fourth syllable of both marks are aspirated sounds pronounced by strongly bursting air out in a "ㅌ(t)" sound, and the middle

sound “ㅣ(i)” and the final sound “ㄴ(n)” of the fifth syllable are the same. Accordingly, in spite of the difference in the middle sound of the fourth syllable and the initial sound of the fifth syllable, as both marks will be heard to be similar as a whole, the name is determined to be similar.

12. Patent Court Decision, 2016Na1691 decided June 29, 2017 (Outback Case) ····· ***334***

Each of the business marks of this case is a domestically well-known business mark of the plaintiff and has acquired reputation and has strong distinctiveness. Furthermore, each of the infringing marks of this case is identical and similar to each business mark of this case, and the defendants who are copiers are assumed to have intentional bad faith. However, considering that the evidence presented alone does not prove that there is a relationship between both services in terms of business competition and contention by the duplication of a customer base, that the plaintiff's business size is incomparably larger than the defendants' business size, and that the plaintiff has maintained reputation and credence as a “family-centered and nature-friendly family restaurant” with a strong reputation among consumers, it is very unlikely that ordinary consumers or traders would be confused such that automated accommodation having a negative image is believed to be run by the plaintiff directly or by an individual or a legal entity having an intimate relationship with the capital or organization of the plaintiff.

However, it is determined that the defendants have damaged the good image and value of the mark by using the plaintiff's well-known business mark of this case for services having a negative image, and also have damaged a source indication function of the well-known business mark of this case.

Thus, the plaintiff is entitled to a claim for injunction under Article 4 of the “Unfair Competition Prevention and Trade Secret Protection Act”(hereinafter, referred to as the “Unfair Competition Prevention Act”) and a claim for damages under Article 5 of the same act, against the defendants.

PATENT COURT OF KOREA
FIFTH DIVISION
DECISION

Case No.: 2016Heo4733 Invalidation of Registration (Patent)

Plaintiff: Hanmi Pharm. Co. Ltd.

Defendant: Bayer HealthCare LLC

Date of Closing Argument: March 22, 2017

Decision Date: May 12, 2017

ORDER

1. The IPTAB Decision on Case No. 2015Dang865 rendered on April 25, 2016 is revoked.

2. The cost arising from this litigation shall be borne by the Defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Background

A. The Decision Below

1) The Plaintiff filed a petition against the Defendant seeking invalidation of the patented invention at issue described in Item B below (hereinafter the "Subject Invention") under IPTAB Case No. 2015 Dang 865 on March 13, 2015, arguing that the Subject Invention does not meet the description requirements under Article 42(4)(i) of the old Korean Patent Act (before revision by Act No. 8197 on January 3, 2007; hereinafter referred to as "the old Patent Act"), Claims 1, 2, 5, 8, and 10-15 lack novelty, and all the claims lack inventiveness.

2) In this regard, the IPTAB rendered a decision dismissing the Plaintiff's petition on April 25, 2016, stating that "the Subject Invention meets the description requirements under Article 42(4)(i) of the old Patent Act, Claims 1, 2, 5, 8, and 10-15 are novel based on Prior Art 1,[1] and all the claims are inventive based on Prior Art 1, 2[2] and 3[3]."

B. Subject Invention (Plaintiff's Exhibit 2)

○ Title of Invention: Pharmaceutical Composition Comprising an

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1) This Prior Art was not submitted in the current action. It discloses an invention entitled "Diaryl Ureas for Diseases Mediated by PDGFR" in International Publication No. WO 2005/284 published on January 6, 2005.

2) This was submitted as Prior Art 2 in the current action.

3) This was submitted as Prior Art 1 in the current action.

Omega-Carboxyaryl Substituted Diphenyl Urea for the Treatment of Cancer

○ International Filing Date/Priority Date/Registration Date/Registration No.: February 22, 2006/March 7, 2005/November 27, 2013/No. 1335932

○ Claims

Claim 1. A pharmaceutical composition for treating hyper-proliferative disorders including cancer which is a tablet comprising the *p*-toluenesulfonic acid salt[4] of 4-{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-phenoxy}-pyridine-2-carboxylic acid methyl amide[5] as active agent in a portion of at least 55% by weight of the composition (hereinafter, referred to as "Claim 1 of the Subject Invention; the remaining claims are also referred to in the same manner)

Claim 2. The pharmaceutical composition of claim 1 comprising the active agent in a portion of at least 75% by weight of the composition.

Claim 3. The pharmaceutical composition of claim 1 comprising a filler in a portion of from 3 to 20 %, a disintegrant in a portion of from 5 to 12 %, a binder in a portion of from 0.5 to 8 %, a lubricant in a portion of from 0.2 to 0.8 % and a surfactant in a portion of from 0.1 to 2 % by weight of the composition.

Claim 4. The pharmaceutical composition of claim 1 comprising

4) This is referred to as sorafenib tosylate.

5) This is referred to as its generic name, "sorafenib."

microcrystalline cellulose as a filler in a portion of from 3 to 20 %, croscarmellose sodium as a disintegrant in a portion of from 5 to 12 %, hypromellose as a binder in a portion of from 0.5 to 8 %, magnesium stearate as a lubricant in a portion of from 0.2 to 0.8% and sodium lauryl sulfate as a surfactant in a portion of from 0.1 to 2 % by weight of the composition.

Claim 5. The pharmaceutical composition of any of claims 1 to 4 is an immediate release tablet.

Claim 6. The pharmaceutical composition of any of claims 1 to 4 wherein the active agent is micronized.

Claim 7. The pharmaceutical composition of claim 6 wherein the micronized form has a mean particle size of from 0.5 to 10 μm.

Claim 8. The pharmaceutical composition of any of claims 1 to 4 comprising water in an amount of less than or equal to 6 % by weight of the composition.

Claim 9. The pharmaceutical composition of any of claims 1 to 4 showing a hardness of more than 80 N.

Claim 10. The pharmaceutical composition of any of claims 1 to 4 which is an oval tablet with a longest diameter of less than or equal to 25 mm.

Claim 11. The pharmaceutical composition of any of claims 1 to 4 which is a round tablet with a diameter of less than or equal to 13 mm.

Claim 12. The pharmaceutical composition of any of claims 1 to 4 wherein the amount of the active agent is from 54 mg to 1096 mg.

Claim 13. The pharmaceutical composition of any of claims 1 to 4 for oral administration.

Claim 14. The pharmaceutical composition according to any of claims 1 to 4 in combination with one or more cytotoxic agents, signal transduction inhibitors, with other anti-cancer agents or therapies, or with admixtures and combinations thereof.

Claim 15. A process for manufacturing a pharmaceutical composition according to any of claims 1 to 4 wherein the active agent is blended with at least one pharmaceutically acceptable excipient.

Claim 16. The process of claim 15 wherein:

a) the active agent and at least one pharmaceutically acceptable excipient are wet granulated,

b) the granulate is blended with the lubricant, with or without one or more additional pharmaceutically acceptable excipient,

c) and the post blend granulate is subdivided into single units.

claim 17. The process of claim 16 wherein the product of step c) is coated with one or more further pharmaceutically acceptable excipients.

Claim 18. The process of claim 15 wherein the active agent and at least one pharmaceutically acceptable excipient

are blended without granulation and directly compressed to tablets.

Claim 19. The process of claim 15 wherein the active agent alone or the active agent and at least one pharmaceutically acceptable excipient are treated by a dry granulation method and then compressed to tablets.

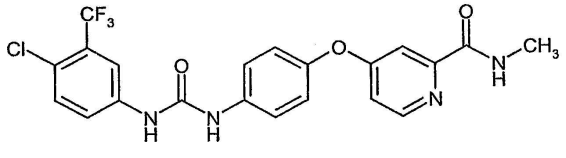
Claims 20-22 Deleted

○ Main Content

1 Background Art and Technical Problems

▸ This invention relates to novel pharmaceutical compositions, their use for treating hyper-proliferative disorders such as cancer, either as a sole agent or in combination with other anti-cancer therapies, and their process for preparing (paragraph [0001]).

▸ It has been discovered that the diphenyl urea of formula (I) below,



(I)

and its pharmaceutically acceptable salts are potent inhibitors of raf, VEGFR-2, p38, and PDGFR kinases (paragraph [0002]).

▸ Despite the progress with regard to kinase inhibitors in the relevant field, there remains a need for improved medicines for the treatment of cancer. In particular, there remains a need for improved oral pharmaceutical compositions which can be taken in easily and therefore would increase the patient's compliance (paragraph [0005]).

2 Objective of the Subject Invention

▸ The objective of the present invention is to provide a pharmaceutical composition comprising the compound of formula (I) which should be applied no more than three times a day in order to achieve an effective blood concentration level of the compound of formula (I). In the case of a tablet or capsule as oral pharmaceutical composition it should not be too large to provide good swallowing and no more than two should have to be taken in at the same time. (paragraph [0006])

3 Composition or Principles to Solve the Technical Problems

▸ The present invention pertains to a pharmaceutical composition comprising the compound of the formula (I) in a high concentration and at least one pharmaceutically acceptable excipient (paragraph [0007])

▸ Significantly, the pharmaceutical composition according to the invention has a good bioavailability of the compound of the formula (I), and an effective plasma level is achieved. Furthermore, the pharmaceutical composition according to the invention provides a good stability of the compound of the formula (I). (paragraph [0008])

▸ Although the tablets based on the invention comprise a high concentration of compound of the formula (I), they surprisingly show a good releas ability, good bioavailability, high stability and sufficient hardness. The fact that the pharmaceutical composition based on the invention comprises the compound of the formula (I) in a high concentration, indicates that its size is good for swallowing. Therefore, the pharmaceutical composition can be taken easily and supports high compliance of patients' (paragraph [0009]).

▸ Preferred pharmaceutical composition is the composition comprising the p-toluenesulfonic acid salt of 4-{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-phenoxy}-pyridine-2-carboxylic acid methyl amide in a portion of at least 55%, preferably at least 62%, more preferably at least 69%, most preferably at least 75% by weight of the composition. (paragraph [0017])

C. Prior Arts

1) Prior Art 1 (Plaintiff's Exhibit 4)

Prior Art 1 is a paper entitled "Phase I Clinical and Pharmacokinetic Study of the Novel Raf Kinase and Vascular Endothelial Growth Factor Receptor Inhibitor BAY 43-9006[6] in Patients with Advanced Refractory Solid Tumors" in *Journal of Clinical Oncology*, Vol. 23, No. 5, pp. 965-972 published on February 10, 2005, and its main disclosure is as follows:

- BAY 43-9006 is a novel dual-action Raf kinase and vascular endothelial growth factor receptor inhibitor that inhibits tumor cell proliferation and angiogenesis. This study established the safety and pharmacokinetics of BAY 43-9006 in 69 patients with advanced refractory solid tumors. (page 965, Purpose).

- The maximum-tolerated dose (MTD) was 400 mg bid continuous. Dose-limiting toxicities (DLTs) were grade 3 diarrhea and fatigue at 800 mg bid, and grade 3 skin toxicity at 600 mg bid. (page 965, Results).

- Oral BAY 43-9006 was well tolerated and appeared to provide some clinical benefits. Based on the results of this study, BAY 43-9006 at 400 mg bid continuous is recommended for ongoing and future studies (page 965, Conclusion).

- This phase I clinical trial was initiated to determine the dose-limiting toxicities (DLTs), maximum-tolerated dose (MTD), and pharmacokinetics of oral daily BAY 43-9006. Preliminary antitumor activity and inhibition of PMA stimulated ERK-phosphorylation in peripheral blood lymphocytes (PBLs) of treated patients were also assessed (page 966, 11^{th} to 6^{th} lines from the bottom of the left column)

6) "BAY 43-9006" in Prior Art 1 refers to "sorafenib."

○ Since 400 mg bid continuous dosing was initially not considered the MTD, dose escalation occurred until 600 mg and 800 mg, respectively. Because of DLTs, the dose level 400 mg bid continuous dosing was eventually recommended for further phase II testing. Since all dose levels lower than 100 mg bid continuous dosing were associated with low bioavailability, we pooled these early dose levels and summarized the data for safety and preliminary efficacy as noncontinuous dosing schedules. BAY 43-9006 tosylate was supplied as 50-mg tablets. (page 966, 13th to 3rd lines from the bottom of the right column)

2) Prior Art 2 (Plaintiff's Exhibit 5)

Prior Art 2 is an invention directed to "RAF-MEK-ERK pathway inhibitors to treat cancer" disclosed in U.S. Patent Application Publication No. 2003/125359 published on July 3, 2003, and its main disclosure is as follows:

○ Materials and methods for treating certain cancers are described, preferably cancers that result from the up-regulation of the RAF-MEK-ERK pathway, and more preferably chronic myelogenous leukemia, and which cancer is preferably resistant to the inhibition of the Bcr-Abl tyrosine kinase, imatinib. (ABSTRACT)

○ [T]reating patients with non-toxic doses of, preferably, 200-400 mg and higher of the Raf kinase inhibitor BAY 43-9006 will result in remissions, or minimally stabilization of the growth of the cancer. (paragraph [0017], lines 6-10)

○ The pharmaceutical compositions comprise from approximately 1% to approximately 95% of the appropriate inhibitor, dosage forms that are in single dose form preferably comprising from approximately 20% to approximately 90% active ingredient, and dosage forms that are not in

single dose form preferably comprising from approximately 5% to approximately 20% active ingredient. Unit dose forms are, for example, dragees, tablets, ampoules, vials, suppositories or capsules. Other dosage forms are, for example, ointments, creams, pastes, foams, drops, sprays, dispersions, etc. The pharmaceutical compositions of the present invention are prepared in a manner known per se, for example by means of conventional mixing, granulating, confectioning, dissolving or lyophilising processes. (paragraph [0030])

○ Pharmaceutical compositions will preferably be used in oral form, and can be obtained, for example, by combining a RAF-MEK-ERK pathway inhibitor, with or without a Bcr-Abl tyrosine kinase inhibitor, with one or more solid carriers, granulating a resulting mixture, where appropriate, and processing the mixture or granules, if desired, where appropriate with the addition of additional excipients, to form tablets or dragee cores. Suitable carriers are especially fillers, such as sugars, for example lactose, saccharose, mannitol or sorbitol, cellulose preparations and/or calcium phosphates, for example tri-calcium phosphate or calcium hydrogen phosphate, and also binders, such as starches, for example corn, wheat, flee or potato starch, methylcellulose, hydroxypropylmethyl-cellulose, sodium carboxymethylcellulose and/or polyvinylpyrrolidone, and/or, if desired, disintegrators, such as the above-mentioned starches and also carboxymethyl starch, cross-linked polyvinylpyrrolidone, or alginic acid or a salt thereof, such as sodium alginate. Additional excipients are especially flow conditioners and lubricants, for example silicic acid, talc, stearic acid or salts thereof, such as magnesium or calcium stearate, and/or polyethylene glycol, or derivatives thereof. (paragraph [0033])

2. Whether or Not the IPTAB Erred

A. Questions Presented

1) Summary of the Plaintiff's Arguments[7)]

Claim 1 of the Subject Invention could have been easily derived by combining well-known and commonly used technology with Prior Art 1. The specification of the Subject Invention does not have any description indicative of a significant effect within the numerical limitation. Further, the effects described in the specification are those that are generally considered in the pharmaceutical technical field. Accordingly, Claim 1 lacks inventiveness.

In addition, as for Claims 2-19 of the Subject Invention, the claimed features lack inventiveness for the same ground as Claim 1, or the additions or limitations therein are generally known in the pharmaceutical technical field. and do not have any description indicative of significant effect. Accordingly, Claims 2-19 lack inventiveness.

2) Summary of the Defendant's Arguments

The Subject Invention is not a numerical limitation invention. Even if the Subject Invention is categorized as a numerical limitation invention, it aims to yield a highly loaded tablet containing a high load of sorafenib tosylate to increase dosing compliance while exhibiting superior releas ability, high stability, and sufficient hardness, and thus it has qualitatively different technical problem and effect from those of Prior Arts 1 and 2. Moreover, the Subject Invention could not have been easily derived from Prior Arts. Accordingly, the inventiveness of the Subject Invention is not denied by the Prior Arts.

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7) In the first hearing dated December 14, 2016, the Plaintiff withdrew its argument that the Subject Invention lacks novelty based on the Prior Arts.

3) Questions Presented

The issue is whether the Subject Invention lacks inventiveness based on the combination of the Prior Arts with well-known and commonly used technology.

B. Whether Claim 1 of the Subject Invention Lacks Inventiveness

1) Comparison of Claim 1 with Prior Art 1

Claim 1	Prior Art 1
A pharmaceutical composition for treating hyper-proliferative disorders including cancer which is a tablet comprising the *p*-toluenesulfonic acid salt of 4-{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-phenoxy}-pyridine-2-carboxylic acid methyl amide as active agent in a portion of at least 55% by weight of the composition.	◆ BAY 43-9006 is a novel dual-action Raf kinase and vascular endothelial growth factor receptor inhibitor that inhibits tumor cell proliferation and angiogenesis. This study established the safety and pharmacokinetics of BAY 43-9006 in 69 patients with advanced refractory solid tumors. (Prior Art 1, p. 965, “Purpose”) ◆ BAY 43-9006 tosylate was supplied as 50-mg tablets. (Prior Art 1, p.966)

2) Analysis of the Commonalities and Differences

Claim 1 and Prior Art 1 are identical in that they are both tablets comprising a sorafenib tosylate salt as an active agent, that are pharmaceutical compositions for treating hyper-proliferative disorders including cancer.

Claim 1 is different from Prior Art 1 in that the former limits that the composition comprises sorafenib tosylate in an amount of at least 55% by weight of the composition, whereas Prior Art 1 does not specify the amount of sorafenib tosylate included in the 50mg tablet

and thus it is difficult to know the ratio of sorafenib tosylate contained in the composition.

3) Analysis on Differences

A) It is reasonable to conclude that the numerical limitation in Claim 1 could have been easily derived from the Prior Arts by a person of ordinary skill in the art, in view of the following findings based on the statements in Plaintiff's Exhibits 4, 6, 7, and 9-1 to 9-9 and the purport of the overall argument together:

① In view of Prior Art 1 disclosing that "[b]ased on the results of this study, BAY 43-9006 at 400 mg bid continuous is recommended for ongoing and future studies" (page 965, Conclusion) and "[s]ince 400 mg bid continuous dosing was initially not considered the MTD, dose escalation occurred until 600 mg and 800 mg, respectively. Because of DLTs, the dose level 400 mg bid continuous dosing was eventually recommended for further phase II testing" (page 966, 13^{th} to 9^{th} lines from the bottom of the right column), it can be understood that a total daily dose of sorafenib tosylate recommended for the phase II clinical testing as of the priority date of the Subject Invention reaches 800mg, which is a considerably high load. Further, in view of Prior Art 2 disclosing that "treating patients with non-toxic doses of, preferably, 200-400 mg and higher of sorafenib result in remissions, or minimally stabilization of the growth of the cancer" (paragraph [0017]), a person of ordinary skill in the art would have recognized that in order to obtain an anticancer effect from sorafenib tosylate having a molecular weight

greater than that of sorafenib, the dose of sorafenib tosylate should be greater than the dose of sorafenib of at least 200~400mg (in view of the said disclosure in Prior Art 2 along with the molecular weight of sorafenib tosylate, the dose of sorafenib tosylate should be about 273-549mg[8] or greater).

In other words, a person of ordinary skill in the art would have understood from the disclosures of the Prior Arts that the single dose of sorafenib tosylate to obtain an anticancer effect is considerably high.

② As of the priority date of the Subject Invention, it was well known that a weight of a tablet in view of aged patients' compliance ranges from 120 to 700mg (Plaintiff's Exhibit 7: page 325, 5th line from the bottom of the left column through 2nd line of the right column). Thus, a person of ordinary skill in the art would have understood that in order to make a single tablet containing the single dose of sorafenib tosylate, i.e., 400mg, it should be a highly-loaded tablet comprising sorafenib tosylate in an amount of at least about 57% by weight of the composition.[9]

Meanwhile, Prior Art 1 administrates sorafenib tosylate as a 50mg tablet, which however is to easily control the dose escalation so as to confirm dose-limiting toxicities (DLTs) or maximum-tolerated dose (MTD). Therefore, administrating sorafenib tosylate as a 50mg

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8) 200 to 400mg of sorafenib can be converted to 273mg (200×637.027/464.825) ~549mg (400×637.027/464.825) of sorafenib tosylate.

9) 57%≒(400mg/700mg)g00s

tablet in Prior Art 1 cannot be considered an obstacle to recognize the need of developing a highly-loaded tablet comprising a high amount of sorafenib tosylate.

③ When designing a preparation for oral administration containing a high ratio of the drug, the standard prescription method of a tablet well known as of the priority date of the Subject Invention in the field of drug preparation, is to evaluate the formability and disintegrability of the drug itself in turn, and to adopt a simple and basic formulation if the evaluated properties are good, or adjust prescription properly if they are poor (Plaintiff's Exhibit 6, Figs. 4-3).

Thus, a person of ordinary skill in the art who is willing to prepare a sorafenib tosylate tablet for oral administration would obviously have first evaluated and confirmed the compressibility, disintegra bility, etc., of sorafenib tosylate itself and then tablet it following the standard prescription method based on the result. This is also supported by Prior Art 1 which discloses administrating sorafenib tosylate as a tablet in phase I clinical testing, thereby showing that sorafenib tosylate can be formulated as a tablet for oral administration.

④ Even before the priority date of the Subject Invention, there were many examples of high-loaded tablets containing at least 55% of an active ingredient (Plaintiff's Exhibits 9-1 to 9-9).

⑤ There is no evidence to recognize as of the priority date of the Subject Invention that a person of ordinary skill

in the art would have faced some technical obstacle to try a highly-loaded tablet of sorafenib tosylate in spite of the above standard prescription method, e.g., sorafenib tosylate was known to be inappropriate for being formulated to a highly-loaded tablet, etc.

⑥ Claim 1 does not have any special technical means to formulate sorafenib tosylate as a highly-loaded tablet, except for limiting the ratio of sorafenib tosylate to at least 55% by weight of the composition.

B) In this regard, the Defendant argues that Prior Arts fail to suggest or provide a clue about development of a highly-loaded tablet of sorafenib tosylate because Prior Art 1 merely presents the dose-limiting toxicities (DLTs) and the maximum-tolerated dose (MTD) for oral administration of sorafenib tosylate; and Prior Art 2 merely presents a novel therapeutic use of sorafenib, and a suitable therapeutic dose is determined through phase II clinical testing; thus neither discloses an amount of sorafenib tosylate in a tablet.

As argued by the Defendant, a suitable therapeutic dose is determined through phase II clinical testing. However, in view of the circumstances mentioned in Item 2-B-3)-A)-① and ②, above, we can reasonably conclude that a person of ordinary skill in the art as of the priority date of the Subject Invention would have obtained sufficient motivation from the Prior Arts to develop a highly-loaded tablet of sorafenib tosylate. Thus, the Defendant's argument cannot be accepted.

C) Based on the Defendant’s Exhibits 15, and 16, among others, the Defendant argues that a tablet generally includes

an active ingredient lower than 50 wt% and an excipient in a larger amount so that an appropriate level of hardness and sufficient disintegra bility is achieved; it is technical common knowledge in the art that a highly-loaded tablet may fail to exhibit desirable compressibility, elution, and stability, etc. due to a lower amount of excipient. Further, development of a highly-loaded tablet is not always attempted for all drugs, and even if attempted, a success would not have been predictable. The Defendant thus argues that the inventiveness of the Subject Invention is not denied because the Subject Invention nevertheless successfully prepared a highly-loaded tablet of sorafenib tosylate.

However, ⓐ as discussed above, a person of ordinary skill in the art could have easily recognized the need of developing sorafenib tosylate as a highly-loaded tablet in view of the Prior Arts and there were many examples of highly-loaded tablets for different active ingredients before the priority date of the Subject Invention (Plaintiff's Exhibits 9-1 to 9-9), and thus a person of ordinary skill in the art would have obviously tried to developing a highly-loaded tablet first. Further, ⓑ when preparing a highly-loaded tablet, it is a common process to first evaluate a drug's own formability and, if it is found to be good, adopt a standard formulation with minimum excipients. Further, it cannot be said that excessive experiments or undue costs and times are required to confirm the physical properties of an active ingredient (Plaintiff's Exhibit 6, Figs. 4-3). Moreover, ⓒ without excessive experiments or undue costs and time, a person of ordinary skill in the art with an intention of tableting sorafenib tosylate would have confirmed whether sorafenib tosylate has physical properties

suitable to be prepared as a highly-loaded tablet. In addition, ⓓ Defendant's Exhibit 15 is a research paper merely disclosing that metformin hydrochloride with poor compressibility or fluidity can be prepared as a high-loaded tablet using melt granulation technology. Defendant's Exhibit 16 is a research paper merely disclosing that when formulating an active ingredient AMG458 into a highly-loaded tablet, the possibility of preparing a highly-loaded tablet can be rapidly evaluated through specific methods such as "shear cell" and "compaction simulator." Therefore, no technical common knowledge as argued by the Defendant is described therein and there is no other evidence to recognize as such. Rather, based on the fact that it is a common process to adopt the standard formulation with minimum excipients if a drug's properties, such as compressibility, are good, it is desirable to use an excipient in an amount as small as possible. Furthermore, ⓔ aside from limiting the wt% of sorafenib tosylate, Claim 1 does not have any technical means limitative or adopted to formulate sorafenib tosylate into a highly-loaded tablet. Thus, the Defendant's argument that inventiveness of Claim 1 of the Subject Invention may not be denied based on the fact that it is unpredictable whether or not sorafenib tosylate has physical properties suitable to be formulated into a highly-loaded tablet before conducting actual experiments cannot stand. Accordingly, the Defendant's argument is without merit.

4) Whether a Significant Effect Is Exhibited

A) The specification of the Subject Invention discloses Tablets A to D and the experimental results for the properties of Tablets B and C. According to the results, 97% and 99%

of the compound of formula (I) contained in Tablets B and C is released within 60 mins and the tablets have a stability of more than 18 months and a hardness of more than 100 N (Plaintiff's Exhibit 2: paragraphs [0129]-[0135]).

However, as discussed above, it is the well-known standard method of tablets prescription that a person skilled in the art would first test formability (physical properties including whether a suitable hardness can be achieved) and disintegra bility (physical properties affecting elution) of the drug itself and, if such properties are good, a simple and basic prescription is adopted. The experiments disclosed in the specification of the Subject Invention are no more than preparing a highly-loaded tablet of sorafenib tosylate according to the standard prescription method and then confirming whether the prepared tablet possesses suitable properties as a tablet (disintegra bility, formability, etc.). There is no reason to conclude that undue efforts are required for confirming such properties.

B) Further, the result that the active ingredient was nearly completely released in 60 minutes seems to be due to the use of the micronized active agent when preparing Tablets B and C and to the use of croscarmellose sodium as a disintegrant to prepare the tablet for immediate releaase. Nothing suggests that the complete release is due to the claimed feature of Claim 1.

C) Defendant's Exhibit 1 discloses that "when tablets having sorafenib tosylate in a lad of 50, 75, 90, and 100% are prepared by a dry powder compression method, all of the tablets, excluding the tablet comprising 25% of mannitol prepared by a compression force of 1100 lbs, have a tensile strength of at least 3N/㎟ and a fracture strength of

at least 100N (Table 1), and when preparing tablets prepared by wet granulation using 5% of PPV or HPMC as a binder, all the tablets containing sorafenib tosylate in a load of 75 and 90% have a tensile strength of at least 3N/mm^2 and a fracture strength of at least 100N (Table 2).” We can understand from this disclosure that, as the amount of avicel (which is an excipient having good compression and hardness characteristics) increases, the tensile strength of the tablet prepared by a dry powder compression method increases, and the tablet prepared of 100% of sorafenib tosylate alone has a tensile strength of at least 3N/mm^2 and a fracture strength of at least 100N.

However, as discussed above, it is the well-known common process that a person skilled in the art would first test compressibility of the drug itself and, if such property is good, the standard formulation is adopted. Given this, the effect shown in Defendant’s Exhibit 1 is nothing more than a mere confirmation of the physical properties of sorafenib tosylate itself by a person of ordinary skill in the art according to a well-known method.

D) Defendant’s Exhibit 2 shows that when the tablets containing 55% of either sorafenib or sorafenib tosylate are prepared and tested in the same composition and method, the sorafenib tosylate tablet is superior to the sorafenib tablet in terms of elution, hardness, and disintegration.

However, Prior Art 1 already discloses a sorafenib tosylate tablet. Therefore, the mere fact that the sorafenib tosylate tablet has superior properties to the sorafenib tablet does not compel a conclusion that Claim 1 has a significant effect.

E) The Defendant argued that Claim 1 has a qualitatively different effect based on the Prior Arts in that the former provides a highly-loaded tablet having increased dosing compliance while exhibiting superior releas ability, high stability, and sufficient hardness.

However, Claim 1 merely limits the wt% of sorafenib tosylate in the tablet but not the total weight of the tablet itself. Therefore, it is difficult to conclude that patients' compliance was increased by the composition in Claim 1. Even if the claimed composition improved patients' compliance, the compliance is one of the elements naturally considered in a process of drug formulation. In addition, while the effect of increasing patients' compliance argued by the Defendant stems from formulating sorafenib tosylate into a highly-loaded tablet, a person of ordinary skill in the art would have easily recognized the need to develop a highly-loaded tablet of sorafenib tosylate from the Prior Arts, as discussed above. Further, the degree of increase in patients' compliance is within the extent that would have been anticipated by a person of ordinary skill in the art. Given the above, the working effects of the Subject Invention cannot be viewed as significant or qualitatively different. Accordingly, this argument by the Defendant does not stand as well.

5) Summary of Analysis

As discussed above, the features of Claim 1 would have easily been invented from Prior Arts 1 and 2 by a person of ordinary skill in the art and are not recognized as having significant working effects. Thus, Claim 1 lacks inventiveness based on Prior Arts 1 and 2.

C. Whether Claim 2 Lacks Inventiveness

Claim 2, which depends from Claim 1, merely further limits the amount ratio of sorafenib tosylate as "comprising the active agent in a portion of at least 75% by weight of the composition." Thus, Claim 2 lacks inventiveness on the same ground as Claim 1.

D. Whether Claims 3 and 4 Lack Inventiveness

Claim 3, which depends from Claim 1, defines that the pharmaceutical composition comprises a filler in a portion of from 3 to 20 %, a disintegrant in a portion of from 5 to 12 %, a binder in a portion of from 0.5 to 8 %, a lubricant in a portion of from 0.2 to 0.8 % and a surfactant in a portion of from 0.1 to 2 % by weight of the composition. Further, in addition to the claimed feature in Claim 3, Claim 4 limits the filler to microcrystalline cellulose, the disintegrant to croscarmellose sodium, the binder to hypromellose, the lubricant to magnesium stearate, and the surfactant to sodium lauryl sulfate.

However, "Pharmaceutical Dosage Forms: Tablet," Vol. 1 (Plaintiff's Exhibit 10), a basic reference book in the field of pharmaceutics published in 1989, discloses a tablet containing about 8% of microcrystalline cellulose as a filler (page 154); a tablet containing 5-10 wt% of sodium carboxymethylcellulose such as croscarmellose sodium as a disintegrant (page 174); methyl cellulose, which is in the same series as hypromellose, is used as a binder (page 162); 0.5 to 2 wt% of magnesium stearate is used as a lubricant (page 171); and 0.2 to 2 wt% of magnesium lauryl sulfate, which is the nearly same compound as sodium lauryl sulfate defined in Claim 4 except for the difference in the metal salt, is used as an excipient (page 178).

In light of the above, a tablet comprising many excipients such as filler, disintegrant, binder, lubricant, and surfactant in the claimed

amount range in Claim 3 corresponds to well-known and commonly used technology in the art to which the Subject Invention belongs. Further, the specification of the Subject Invention does not have any description capable of suggesting a special technical significance regarding using croscarmellose sodium as a disintegrant or hypromellose as a binder. Therefore, a person of ordinary skill in the art would have had no difficulty in selecting an appropriate component from disintegrants or binders in the same series.

Thus, Claims 3 and 4 merely add well-known and commonly used technology to Claim 1 and thus lack inventiveness for the same ground as Claim 1.

E. Whether Claim 5 Lacks Inventiveness

Claim 5, which depends from Claims 1-4, defines that the tablet is "immediate-release type tablet."

However, an immediate-release type tablet is one of commonly used tablet types in the field of formulation (Plaintiff's Exhibit 14: page 231, right column, lines 7-11). Therefore, a person of ordinary skill in the art would have had no technical difficulty in adopting such a tablet in the case where a rapid release is required as needed.

Accordingly, Claim 5 merely adds well-known and commonly used technology to Claims 1-4 and thus lacks inventiveness for the same ground as Claim 1.

F. Whether Claims 6 and 7 Lack Inventiveness

Claims 6 and 7, which depend from Claims 1-4 and Claim 6, respectively,

recite that the active agent is "micronized" and "the micronized form has a mean particle size of from 0.5 to 10 μm."

However, it is a well-known and commonly used technology in a process of preparing a solid dosage form for oral administration such as tablet, capsule, etc., to first make the particle size of an active agent smaller through a process such as milling, then conduct wet or dry granulation, to dry it, and lastly compress it into a tablet or fill it in a capsule to complete a final dosage form (Plaintiff's Exhibit 11, pages 2-28). Therefore the claimed feature that the active agent is micronized in Claim 6 is well-known and commonly used technology. Further, the specification of the Subject Invention does not have any description suggesting technical significance of limiting the mean particle size of the micronized active agent to 0.5 to 10㎛. Given the above, the claimed numerical range in Claim 7 is merely what would have been selected by a person of ordinary skill in the art as he or she sees fit.

Accordingly, Claims 6 and 7 lack inventiveness on the same ground as Claim 1.

G. Whether Claim 8 Lacks Inventiveness

Claim 8, which depends from Claims 1-4, defines that "the pharmaceutical composition comprises water in an amount of less than or equal to 6 % by weight of the composition."

However, it is technical common knowledge that a pharmaceutical composition in a solid state, like a tablet, should comprise water as small amount as possible. Further, the specification of the Subject Invention does not show any technical significance regarding limiting the amount of water to less than or equal to 6% by weight of the composition. Accordingly, Claim 8 lacks inventiveness for the same

ground as Claim 1.

H. Whether Claim 9 Lacks Inventiveness

Claim 9, which depends from Claims 1-4, defines that the tablet shows a hardness of more than 80 N.

However, Table 1 of Defendant's Exhibit 1 submitted by the Defendant shows that even a tablet comprising solely of sorafenib tosylate shows a hardness of more than 80N. Given this, the claimed feature merely describes the physical properties of sorafenib tosylate itself. Moreover, based on the disclosure of Defendant's Exhibit 2, 100N is a standard hardness of a tablet. Thus, the claimed numerical limitation on hardness falls within the scope of hardness that common tablets are required to possess.

Thus, Claim 9 lacks inventiveness on the same ground as Claim 1.

I. Whether Claims 10 and 11 Lack Inventiveness

Claim 10, which depends from Claims 1-4, defines that the tablet is "an oval tablet with a longest diameter of less than or equal to 25 mm." Further, Claim 11, which depends from Claims 1-4, defines that the tablet is "a round tablet with a diameter of less than or equal to 13 mm."

However, Plaintiff's Exhibit 7 discloses that a round tablet with a size of 0.48~1.27㎝[10] is commonly used (fifth to fourth lines from the bottom of the left column of page 325), which overlaps with the size

10) This is a value obtained by converting 3/16~1/2inch based on cm.

defined in Claim 11. Further, an oval tablet is a widely used form, and a person of ordinary skill in the art would have appropriately selected the size of the longest diameter of the oval tablet as a range suitable to easily swallow considering the size of the commonly used round tablets. Thus, the specification of the Subject Invention does not have any basis supporting a particular technical significance regarding limiting the size of the round or oval tablet.

Thus, Claims 10 and 11 lack inventiveness for the same reason as Claim 1.

J. Whether Claim 12 Lacks Inventiveness

Claim 12, which depends from Claims 1-4, defines that "the amount of the active agent is from 54 mg to 1096 mg."

However, as described above, Prior Art 1 discloses the one-time dose of sorafenib tosylate is 400mg. Given this, limiting the amount of the active agent contained in the tablet to the claimed numerical range would have been easily derived from Prior Arts 1 and 2 by a person of ordinary skill in the art. Thus, Claim 12 lacks inventiveness.

K. Whether Claim 13 Lacks Inventiveness

Claim 13, which depends from Claims 1-4, defines that the tablet is for "oral administration."

However, the sorafenib tosylate 50mg tablet disclosed in Prior Art 1 is for oral administration, which is identical to the claimed feature in Claim 13. Thus, Claim 13 lacks inventiveness based on the Prior Arts.

L. Whether Claim 14 Lacks Inventiveness

Claim 14, which depends from Claims 1-4, defines that the pharmaceutical composition is used in combination with one or more cytotoxic agents, signal transduction inhibitors, or with other anti-cancer agents or therapies, as well as with admixtures and combinations thereof.

However, Prior Art 2 also discloses a pharmaceutical composition for treating cancer in combination with other anti-cancer agents (Plaintiff's Exhibit 5: paragraphs [0007], [0008], [0027], and [0033]).

Thus, Claim 14 lacks inventiveness based on the Prior Arts.

M. Whether Claims 15-19 Lack Inventiveness

1) Whether Claim 15 lacks inventiveness

Claim 15 is directed to a process for manufacturing a pharmaceutical composition according to any of Claims 1 to 4 wherein the active agent is blended with at least one pharmaceutically acceptable excipient.

However, Prior Art 2 discloses that its pharmaceutical composition is obtained by blending an active ingredient and at least one solid carrier (paragraph [0033] of Plaintiff's Exhibit 5), which is identical to the claimed feature "the active agent is blended with at least one pharmaceutically acceptable excipient" in Claim 15. Further, in the field of pharmaceutical technology, preparing a pharmaceutical composition such as tablet, etc. by blending an active agent with at least one pharmaceutically acceptable excipient is a well-known and commonly used technology by itself. Given this, a person of ordinary skill in the art would have easily conceived the claimed invention in Claim 15 by combining Prior Art 2 or well-known and commonly used technology

with Prior Art 1. Thus, Claim 15 lacks inventiveness based on the Prior Arts.

2) Whether Claims 16 and 17 lack inventiveness

Claim 16, which depends from Claim 15, limits the invention to "wet granulation of the active agent and at least one excipient, blending the granulate with a lubricant, and then subdividing them into single units." Further, Claim 17, which depends from Claim 16, adds the step of coating the product of Claim 16.

However, when preparing a tablet, a method which performs wet granulation, blends the granulate with a lubricant, and performs tableting is well-known and commonly used (Plaintiff's Exhibit 10: page 136, the "Unit Operation" section; and page 137, Table 2), as well as adding the coating step after wet granulation (Plaintiff's Exhibit 10: page 247).

As discussed above, Claims 16 and 17 merely add well-known and commonly used technology to the invention in Claim 15. Thus, said claims lack inventiveness for the same reason as Claim 15.

3) Whether Claims 18 and 19 lack inventiveness

Claim 18, which depends from Claim 15, defines that the active agent and at least one pharmaceutically acceptable excipient are blended without granulation and directly compressed to tablets. Further, Claim 19, which depends from Claim 15, defines that the active agent alone or the active agent and at least one excipient are treated by a dry granulation method and then compressed to tablets.

However, when preparing a tablet, a method which directly performs tableting without granulation or a method which performs tableting by a dry granulation method are all well-known and commonly used

(Plaintiff's Exhibit 7: page 318, left column, "Direct Compression" section; and page 318, right column, "Compression Granulation" section; Plaintiff's Exhibit 10: page 136, "Unit Operation" section; and page 137, Table 2).

Thus, Claims 18 and 19 merely add well-known and commonly used technology to the invention in Claim 15. Accordingly, said claims lack inventiveness on the same ground as Claim 15.

N. Summary of Discussion

As discussed above, all of Claims 1-19 lack inventiveness based on the Prior Arts. Thus, the Subject Invention should be invalidated. The IPTAB erred deciding to the contrary.

3. Conclusion

Based on the foregoing, the Plaintiff's petition to revoke the IPTAB decision is well grounded and therefore shall be granted. Judgment rendered as in the Order.

Presiding Judge Youngjoon OH
Judge Dongju KWON
Judge Donggyu KIM

PATENT COURT OF KOREA
FIRST DIVISION
DECISION

Case No.: 2016Heo7695 Rejection (Patent)

Plaintiff: 3M Innovative Property Company

Defendant: Commissioner of the Korean Intellectual Property Office

Date of Closing Argument: June 28, 2017

Decision Date: August 17, 2017

ORDER

1. The IPTAB decision rendered in Case No. 2016Won2362 (announced August 16, 2016) shall be vacated.

2. The litigation costs shall be borne by the Defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Facts

A. Claimed Invention (Defendant's Exhibit 5, final specification as amended on November 26, 2014)

(1) Title of the Invention: Higher Transmission Light Control Film

(2) Translation Filing Date / International Filing Date / Priority Date / Korean Patent Application No.: May 14, 2010 / October 13, 2008 / October 16, 2007 / No. 10-2010-7010587

(3) Claims (hereinafter Claim 1 of the Claimed Invention will be referred to as "Claim 1")

[Claim 1] A light control film, comprising:
a light input surface and a light output surface opposite the light input surface; alternating transmissive and absorptive regions disposed between the light input surface and the light output surface;
a first interface between a transmissive region and an adjacent absorptive region (hereinafter "**Element 1**");
an interface angle θ1 an interface angle θ1 defined by the first interface and a direction perpendicular to the light output surface (hereinafter "**Element 2**");
with each transmissive region having an index of refraction N1, and each absorptive region having an index of refraction N2, where N1-N2 is not less than 0.005 (hereinafter "**Element 3**"); and
where θ1 is not greater than 3 degrees (hereinafter "**Element 4**").

[Claims 2-5] (*omitted*)

4) Main Content and Drawings

(a) Technical Field

The Claimed Invention generally relates to light control films (LCF)[1] and displays incorporating the same (*see* paragraph [0001]).

(b) Problem to Be Solved

The Claimed Invention is directed to an LCF having an enhanced brightness and uniformity of transmitted light while maintaining a well-defined viewing cutoff angle. A portion of the light entering the LCF undergoes Total Internal Reflection (TIR) within the LCF, increasing the amount of light transmitted through the film. In one aspect, the LCF is placed between the light source and an image plane of a backlit display, to improve the display brightness and uniformity without reducing resolution. (*See* paragraph [0015].)

(c) Solution to the Problem

Included wall angle θ_T is two times the interface angleθ_I ··· for symmetric absorptive regions (*see* paragraph [0025]).

In one aspect, the Claimed Invention can be directed to LCFs where the included wall angle can be not greater than 6°. ···

1) A film attached to a display to make it clear when viewed from the front of the display but invisible when viewed from the side. It is generally called a security film and is the same as a Light Collimating Film.

As such, in one aspect, the interface angle can be 3°, or not greater than 3° or less, for example 2.5°, 2°, 1°, or 0.1°, or less. Smaller wall angles can form grooves having a relatively high aspect ratio (H/W) at a smaller pitch "P," and can provide a sharper image cutoff at a lower viewing angle. (*See* paragraph [0027])

[Fig. 3] A perspective view of an LCF

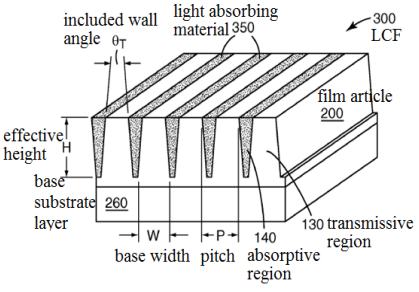
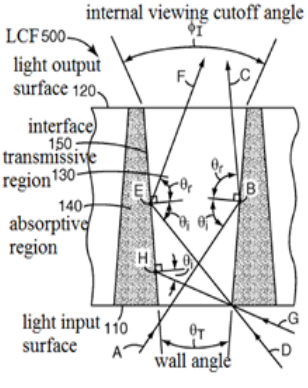


FIG. 5 shows an LCF 500 according to one aspect of the Claimed Invention. The light transmission of the LCF is greater than the light transmission through prior art LCFs, since some of the light impinging on absorptive regions 140 is reflected by TIR. LCF includes transmissive regions 130 comprising a material having index of refraction Nl, and absorptive regions140 comprising a material having an index of refraction N2 which is not greater than Nl. The critical angle, θc (not shown) for the interface is θc= arcsin(N2/Nl). Light rays impinging on interface 150 at angles greater than θc undergo TIR at interface 150. Light rays impinging on interface 150 at angles less than θc are absorbed by absorptive regions 140 (*See* paragraph [0029]).

The included wall angle θ_T, transmissive index N1, and absorptive index N2, are adjustable parameters for control of the transmission of light through light output surface 120. Selection of these parameters can cause some of the light which would otherwise be absorbed by absorptive region 140, to instead be reflected from interface 150 and directed through the output surface within the intended internal viewing cutoff angle Φ_I. (*See* paragraph [0030].)

[Fig. 5] A schematic sectional view of the LCF



B. Prior Arts

(1) Prior Art 1 (Plaintiff's Exhibit 7)

(A) Prior Art 1 relates to "a light-collimating film" published in International Publication No. WO 2007/084297 (published on July 26, 2007)

(B) Main Content and Drawings

(a) Technical Field

Prior Art 1 relates to a Light Collimating Film (title of the invention).

(b) Solution to the Problem

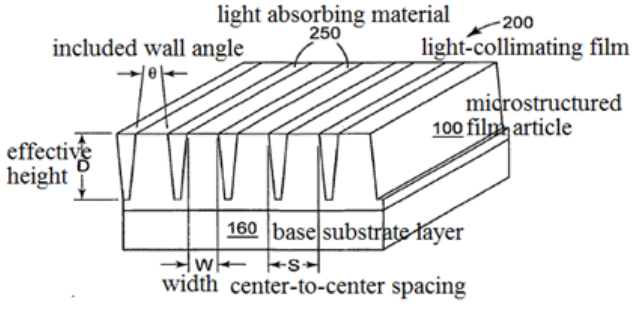
The transparent microstructures between grooves have an included wall angle θ as depicted in FIG. 2; a maximum transparent microstructure width, W; an effective height, D; center-to-center spacing, S; and a maximum viewing range, Φ_T. Wall angle θ is equal to 2 times the angle formed between the transparent film interface with the light absorbing element nearly along the "D" dimension direction and a plane normal to the microstructured surface (*see* page 4, lines 17-22).

In preferred embodiments, the included wall angle of the microstructures averages less than 6° and more preferably averages less than 5° (e.g., less than 4°, 3°, 2°, 1°, or 0 °). Smaller (i.e., steeper) wall angles are amenable to producing grooves having a relatively high aspect ratio (D/W) at a smaller center-to-center spacing S5, thereby providing a sharper image viewability cutoff at lower viewing angles (*see* page 5, lines 4-8).

To reduce reflections at the light transmissive film/light absorbing material interface, it may be desirable to match or nearly match the index of refraction of the transmissive film material with the index of refraction of the light absorbing material over all or a portion of the visible spectrum. Accordingly, the difference in the index of refraction of the cured transparent film in comparison to the (e.g., cured) light absorbing

elements typically ranges from 0 to 0.002. Reducing such reflections tends to reduce the formation of ghost images[2] (*see* page 6, lines 9-15).

[Fig. 2] A perspective view of a light-collimating film



(2) Prior Art 2 (Plaintiff's Exhibit 8)

(A) Prior Art 2 relates to Japanese Laid-Open Patent Publication No. 2006-171701, published on June 29, 2006, "a view angle controlling sheet and liquid crystal display apparatus using the same."

(B) Main Content and Drawings

(a) Technical Field

Prior Art 2 relates to a view angle controlling sheet having the function of preferably controlling the light beam from a light source of a liquid crystal display apparatus (*see* paragraph [0001]).

2) A ghost image: A secondary image that appears on the image surface of an optical system, and the main reason for the ghost image is multiple reflections of light incident on the optical system.

(b) Problem to Be Solved

An objective of Prior Art 2 is to provide an inexpensive view angle controlling sheet to be disposed between the light source and the display panel of a liquid crystal display apparatus, effective for limiting the light beam output angle for the peeping prevention, the reflection prevention, or the like while providing a high light beam transmittance to the observer side so as to provide the excellent light utilization efficiency (*see* paragraph [0004]).

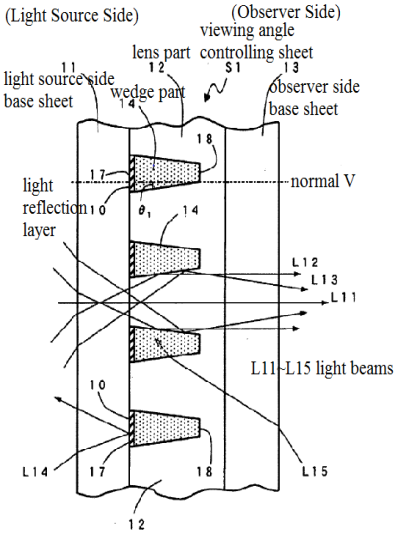
(c) Solution to the Problem

Claim 1 of Prior Art 2 relates to a view angle controlling sheet to be disposed between the light source and the liquid crystal panel of a crystal display apparatus, ··· wherein with the premise that the angle formed by the slant face portion of the wedge part and the normal of the light output plane is θ, θ is in a range of $3^{\circ} \leq \theta \leq 15^{\circ}$ (*see* paragraph [0006]).

According to Prior Art 2, in the case the angle θ formed by the slant face portion of the wedge part and the normal of the light output plane is less than 3° the diffused light beam from the light source cannot reach sufficiently to the observer front side so that the luminance improving effect cannot be obtained. On the other hand, in the case θ is more than 15°, due to too small the area of the lens part for having the diffused light beam from the light source transmitted, the luminance is lowered. In order to maintain the front side luminance using the view angle controlling sheet of Prior Art 2, the preferable range of θ is 3° or more and 15° or less (*see* paragraph [0009]).

Claim 4 of Prior Art 2 is characterized in that with the premise that the refractive index of the main material comprising the wedge part is N2 and the refractive index of the material comprising the lens part is N1, the relationship of N2<N1 is satisfied. According to Prior Art 2, since the refractive index difference of the light transmissible resin as the material comprising the lens part and the main material comprising the wedge part is provided larger by N2<N1, the total reflection in the slant face portion of the wedge part can be carried out efficiently so that the luminance deterioration in the front side can be restrained (*see* paragraph [0012]).

[Fig. 1] A first embodiment of a view angle controlling sheet



C. Prosecution History

(1) First Final Rejection

(A) The KIPO examiner issued a Notice of Preliminary Rejection on September 26, 2014 on the grounds that the pre-amendment Claim 1,[3] cannot be registered under

3) A light control film, comprising:
a light input surface and a light output surface opposite the light input surface;
alternating transmissive and absorptive regions disposed between the light input surface and the light output surface, each transmissive region having an index of refraction N1, and each absorptive region having an index of refraction N2, where N1-N2 is not less than 0.005;
a first interface between a transmissive region and an adjacent absorptive region; and
an interface angle θ1 defined by the first interface and a direction

Article 29(2) of the Korean Patent Act for lacking of inventiveness over Japanese Laid-Open Patent Publication No. 2006-343711 (December21, 2006; hereinafter the "Cited Reference") (*see* Defendant's Exhibit 2).

(B) In response, the Plaintiff submitted an argument on November 26, 2014, along with an amendment by which Claim 1 has been amended in part, as indicated above in Section 1.A.(3). In the argument, the Plaintiff stated that the Cited Reference is designed to have an interface angle of 3 degrees to 15 degrees, while the Claimed Invention is designed to have an interface angle of 3 degrees or less, and that due to this difference in construction, the Claimed Invention has inventiveness over the Cited Reference (*see* Plaintiff's Exhibit 3). However, the KIPO examiner issued a Notice of Final Rejection (hereinafter, the "First Final Rejection") on March 19, 2015 on the grounds that changing the range of the interface angle, while including all the features of the Cited Reference, is merely a design modification that those skilled in the art would have easily made by choice (*see* Defendant's Exhibit 3).

(C) In response, the Plaintiff filed an administrative appeal against the First Final Rejection with the Intellectual Property Trial and Appeal Board ("IPTAB") (Case No. 2015Won3473). On September 30, 2015, the IPTAB rendered a decision to revoke the First Final Rejection on the following grounds (*see* Defendant's Exhibit 4):

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perpendicular to the light output surface, where θ1 is not greater than 3 degrees.

"The Cited Reference discloses that an angle (θ) formed by the slant surface portion of the wedge-shaped portion and the normal of the outgoing light beam plane is in the range of 3 degrees to 15 degrees. Thus, despite having an overlapping value(s) in the boundary of the numerical range for the interface angle with that of the Claimed Invention (for instance, an interface angle of 3 degrees), the Cited Reference clearly discloses as follows:

··· the luminance improvement effect cannot be obtained because the diffused light beam cannot reach an observer-side front face when θ is lower than 3 degrees. In order to maintain the front face luminance with the view angle controlling sheet, θ preferably ranges from 3 degrees to 15 degrees.

In view of the foregoing, the Cited Reference teaches to set the interface angle of 3 degrees or larger and thus, explicitly excludes the technical feature of having an interface angle not greater than 3 degrees in Claim 1. Accordingly, Claim 1 would not have been easily derived by those skilled in the art from the corresponding elements of the Cited Reference."

(2) Second Final Rejection

(A) At the re-opened examination, the KIPO examiner issued a Notice of Preliminary Rejection on October 28, 2015 stating that Claim 1 would have been easily derived by those skilled in the art by simply combining Prior Art 1 with the element of Prior Art 2 corresponding to Element 4 of Claim 1 (*see* Plaintiff's Exhibit 4).

(B) In response to the Notice of Preliminary Rejection above, the Plaintiff filed an argument on January 28, 2016 stating that since (i) neither Prior Art 1 nor Prior Art 2 discloses or suggests anything related to the interface angle θ1 not greater than 3 degrees or the refractive index difference N1-N2 not less than 0.005 as in Claim 1, and (ii) with the special numerical limitations above, Claim 1 can provide a remarkable effect in enhancing the luminance of a display, those skilled in the art would not have easily conceived Claim 1 from Prior Art 1 and Prior Art 2. Regardless, the KIPO examiner issued again a Notice of Final Rejection (hereinafter, the "Second Final Rejection") on March 22, 2016 stating that the grounds of rejection above were not satisfactorily resolved (*see* Plaintiff's Exhibit 5).

(3) The IPTAB Decision

Accordingly, the Plaintiff filed an administrative appeal against the Second Final Rejection (Case No. 2016Won2362). The IPTAB rendered a decision on August 16, 2016 dismissing the appeal on the grounds that (i) Prior Art 1 discloses substantially the same elements as Elements 1, 2, and 4 of Claim 1, and Prior Art 2 discloses substantially the same element as Element 3 of Claim 1 by stating that in the case of N2<N1, the luminance deterioration on the front side can be restrained, and that the refractive index difference is 0.08 (N1-N2=0.08); (ii) there would not have been any technical difficulty in combining Prior Art 1 and Prior Art 2, and both Prior Art 1 and Prior Art 2 do not teach away from their combination; thus, those skilled in the art would have easily combined Prior Art 1 and Prior Art 2; and (iii) accordingly, Claim 1 lacks inventiveness in view of the combination of Prior Art 1 and Prior Art 2 (*see* Plaintiff's Exhibit 6).

[Factual Basis] Undisputed facts, Plaintiff's Exhibits 1 to 8, Defendant's Exhibits 1 to 5, and the purport of the overall argument.

2. Summary of the Parties' Arguments

A. Plaintiff's Argument for Revocation of the IPTAB Decision

1) The Defendant's argument that the Claimed Invention lacks inventiveness over Prior Art 1 alone, or Prior Art 2 as the primary reference, constitutes a new ground of rejection to which the Plaintiff has not given any opportunity to respond during the examination or the administrative trial. If this new ground of rejection was notified, the Plaintiff would have been able to successfully resolve it by making any necessary amendments, including deleting the element of the interface angle of 3 degrees, which overlaps in part with Prior Art 2. In this regard, the Defendant should not be allowed to argue a new ground of rejection during the present revocation action of the IPTAB decision.

2) Prior Art 1 discloses that when a refractive index difference between a transmissive material and a light absorbing material is greater than 0.002, it would increase reflections at the light transmissive film/light absorbing material interface and form many ghost images, and explicitly excludes the element of the refractive index difference being equal to or greater than 0.005 as in Claim 1. Prior Art 2 also discloses the numerical range of the interface angle that is opposite to the numerical range of Element 4 in Claim 1 over the boundary of 3 degrees and excludes an interface angle of less than 3 degrees for luminance on the front side, while Claim 1 sets the interface angle to 3 degrees or less and improves display

uniformity and brightness over the entire viewing angle. Claim 1 aims to provide a light control film with improved display uniformity and brightness by means of organically combining the elements related to the refractive index difference and the interface angle. Such combinations, however, are not indicated in either of Prior Art 1 and Prior Art 2 at all. Further, both Prior Art 1 and Prior Art 2 do not provide any suggestion or motivation for their combination, which even leads into the loss of the technical significance of reducing the formation of ghost images as originally provided from Prior Art 1. Thus, Claim 1 would not have been easily derived by those skilled in the art in view of the combination of Prior Art 1 and Prior Art 2. In this regard, Claim 1 is not found to lack inventiveness over each or the combination of Prior Art 1 and Prior Art 2.

B. Defendant's Argument

1) Prior Art 1 presents substantially the same elements as Elements 1, 2, and 4 of Claim 1. Further, Element 3 of Claim 1 limits the refractive index N1 of a transmissive region and the refraction index N2 of an absorptive region in Element 1 of Claim 1 to having a difference in the range of 0.005 or greater (i.e., $N1-N2 \geq 0.005$). However, the effect resulting from the claimed numerical limitation above is neither distinguishable nor remarkable. In addition, Prior Art 2, which is the same as Prior Art 1 in terms of technical field and objective, discloses that the lens portion (transmissive region) and the wedge-shaped portion (absorptive region) have refractive indices of 1.56 and 1.48, respectively, so that the difference therebetween is 0.08 (i.e., N1-N2=0.08), and this feature is substantially the same as Element 3 of Claim 1.

Accordingly, Claim 1 would have been easily conceived by those skilled in the art in view of Prior Art 1 alone or the combination of the feature of N1-N2=0.08 in Prior Art 2 with Prior Art 1 and thus lacks inventiveness.

2) Prior Art 2 discloses substantially the same elements as Elements 1, 2, and 3 of Claim 1. Further, Element 4 of Claim 1 limits the interface angle ($\theta 1$) in Element 2 of Claim 1 to 3 degrees or less (i.e., $\theta 1 \leq 3°$). However, the effect resulting from the claimed numerical limitation above is neither distinguishable nor remarkable. In addition, Prior Art 2 discloses that the angle formed by the slant face portion of the wedge part and the normal of the outgoing light beam plane (i.e., the interface angle θ) is set to be $3° \leq \theta \leq 15°$. This numerical range, however, overlaps with that of Element 4 of Claim 1 over the boundary of 3°, and Prior Art 1, which is the same as Prior Art 2 in terms of technical field and objective, also discloses an included wall angle of less than 6° (i.e., the interface angle of less than 3°). Accordingly, Claim 1 would have been easily conceived by those skilled in the art in view of Prior Art 2 alone or the combination of the feature of the included wall angle of 6° or less (i.e., the interface angle of less than 3°) in Prior Art 1 with Prior Art 2 and thus lacks inventiveness.

3) Although the Claimed Invention was finally rejected due to lack of inventiveness only on the ground of the combination of Prior Art 1 and Prior Art 2 during the examination and the administrative trial, the Defendant's argument that Claim 1 lacks inventiveness in view of each or the combination of Prior Art 1 and Prior Art 2 is consistent in essence with the grounds for the final rejection above and thus does not constitute a new ground of rejection.

3. Whether Claim 1 Lacks Inventiveness When Prior Art 1 Is Relied upon as the Primary Reference

A. Whether the Defendant's Argument Constitutes a New Ground of Rejection

1) Standard of Analysis

To finally reject a patent application at the examination, the KIPO examiner should preliminarily reject the application first to give the applicant a full opportunity to respond to the rejection, and in order for the IPTAB to decide that the KIPO examiner's decision of final rejection is proper on new grounds other than those of the final rejection during the administrative trial regarding the final rejection, the applicant must be given the opportunity to respond before the IPTAB cites the new grounds as the basis of its decision (*see* Articles 62, 63, and 170 of the Korean Patent Act). Given that the provisions under the Korean Patent Act ensuring procedural rights as the above are compulsory, the IPTAB errs in denying the appeal from the KIPO's final rejection stating that it was justified on new grounds, to which the Plaintiff was never given an opportunity to respond. In the same vein, in the revocation action against IPTAB decision on an appeal from final rejection, the Commissioner of KIPO is not allowed to raise such a new ground absent any prior opportunity for the applicant to respond thereto at the examination or administrative trial. However, even if a ground of rejection is newly raised by the KIPO's Commissioner at the revocation proceeding, the new ground may serve as a basis for determining whether the IPTAB decision is proper, as long as the ground is consistent in essence with a previously notified ground(s) raised at the examination or administrative trial and is thus merely a supplementation of the previously notified ground(s) (*see* Supreme Court Decision 2013Hu1054, rendered on September 26, 2013).

2) Analysis

(A) According to the IPTAB decision, Claim 1 would have been easily conceived by those skilled in the art by combining the element of N1-N2=0.08 in Prior Art 2 with Prior Art 1 and is thus found to lack inventiveness. On the other hand, the Defendant argued in this litigation as the ground of justifying the conclusion of the IPTAB decision that Claim 1 would have been easily conceived by those skilled in the art in view of Prior Art 1 and is thus found to lack inventiveness.

(B) In view of the procedures below and the grounds of rejection found by taking into account the description in each of Plaintiff's Exhibits 2 to 6 and Defendant's Exhibits 1 to 5 together with the purport of the overall arguments, the Defendant's argument that Claim 1 lacks inventiveness in view of Prior Art 1 does not necessarily take away from the Plaintiff's opportunity to present any response and amendment regarding this inventiveness issue. Accordingly, the Plaintiff's assertion that the Defendant's argument above constitutes a new ground of rejection is dismissed.

1) In the Notice of Preliminary Rejection dated October 28, 2015, the KIPO examiner indicated that Claim 1 lacks inventiveness on the grounds that despite the absence of any disclosure in Prior Art 1 corresponding to Element 3 of Claim 1, a refractive index of a material is only a matter of choice that those skilled in the art would have easily made as needed, and thus, there would not have been any difficulty in constructing Element 3 of Claim 1.

2) The grounds of rejection set forth in the IPTAB decision and the Defendant's argument in this litigation equally state that Claim 1 lacks inventiveness when Prior Art 1 is relied upon as the primary reference, and that the difference between the Claimed Invention and Prior Art 1 relates to Element 3 of Claim 1 providing the difference between refractive indices of the transmissive region and the absorptive region (N1-N2) as not less than 0.005.

3) The issue of whether an invention claimed in a patent application has inventiveness is determined by taking into consideration all circumstances, including the technical level and technical common sense at the time of filing, basic problems desired to be solved in the technical field, technical problems and effects of the claimed invention and a prior art invention(s), and the issue of whether there is any suggestion or motivation for combining prior arts. In particular, whether there is any prior art that provides a suggestion or a motivation for or teaches away from a combination of prior art inventions is merely one of many factors to consider in determining inventiveness.

4) In determining inventiveness in view of Prior Art 1 and the combination of Prior Art 1 and Prior Art 2, the important factors to consider include: the circumstances such as what technical problem and effect of Element 3 of Claim 1 are, whether the technical problem or effect is disclosed in Prior Art 1 or is generally recognized in the relevant art, what technical means are provided to solve the technical problem, and whether there would have been any difficulty in

adopting the technical means described in Claim 1 among those provided to solve the problem. The IPTAB too reviewed whether Claim 1 lacks inventiveness on the following grounds: (i) setting the size of difference in the refractive index is merely a matter of choice that those skilled in the art would have easily made as appropriate depending on the material used for a film(s); and (ii) the Claimed Invention is also silent on the critical significance or effect resulting from the refractive index difference of 0.005.

5) Therefore, the Plaintiff was given the full opportunity to respond by submitting an argument regarding whether those skilled in the art would have easily overcome the difference between Claim 1 and Prior Art 1, or by amending Element 3. The Plaintiff asserted that, in its argument submitted on January 28, 2016, no prior arts disclosed or implied the refractive index difference between the transmissive and the absorptive regions not less than 0.005, and that the Claimed Invention provided a remarkable effect of improving the display luminance by setting limitations on the interface angle and the refractive index difference between materials used in the transmissive region and the absorptive region.

B. Element-by-element Comparison between Claim 1 and Prior Art 1

Claim 1	Prior Art 1 (Plaintiff's Exhibit 7)
[Element 1] A light control film, comprising: a light input surface and a light output	○ a light-collimating film (200), a top surface of a microstructured film article (100), a surface where the

Claim 1	Prior Art 1 (Plaintiff's Exhibit 7)
surface opposite the light input surface; a first interface between a transmissive region and an adjacent absorptive region; and	microstructured film article (100) contacts a base substrate layer (160), transparent microstructures between grooves (or a transmissive film material), a light absorbing material, an interface of a transparent film with a light absorbing element (*see* Fig. 2 and p. 4, lines 10-24)
[Element 2] an interface angle θ1 defined by the first interface and a direction perpendicular to the light output surface;	○ "The included wall angle (θ) is equal to 2 times the angle formed between the transparent film interface with ··· a plane normal to the microstructured surface" (*see* p. 4, lines 17-24).
[Element 3] with each transmissive region having an index of refraction N1, and each absorptive region having an index of refraction N2, where N1-N2 is not less than 0.005;	○ "To reduce reflections at the light transmissive film/light absorbing material interface, it may be desirable to match or nearly match the index of refraction of the transmissive film material with the index of refraction of the light absorbing material over all or a portion of the visible spectrum. Accordingly the difference in the index of refraction of the cured transparent film in com- parison to the (e.g. cured) light absorbing elements typically ranges from 0 to 0.002. Reducing such reflections tends to reduce the formation of ghost images" (*see* p. 6, lines 9-15).
[Element 4] where θ1 is not greater than 3 degrees.	○ "··· the included wall angle of the microstructures averages less than

Claim 1	Prior Art 1 (Plaintiff's Exhibit 7)
	6° ··· thereby providing a sharper image viewability cutoff at lower viewing angles" (*see* p. 5, lines 4-8)

C. Summary of Comparison

1) Claim 1 and Prior Art 1 are the same as each other in terms of: (i) Element 1, *i.e.*, a light control film[4] (a light collimating film) comprising a light input surface (a top surface of a microstructured film article), a light output surface (a surface where the microstructured film article contacts a base substrate layer), a transmissive region (transparent microstructures between grooves or transmissive film material), an absorptive region (a light absorbing material) and a first interface (an interface of a transparent film having light absorbing elements); and (ii) Elements 2 and 4, *i.e.*, an interface angle θ1, defined as the angle between the first interface and a direction perpendicular to the light output surface, is not greater than 3 degrees (an included wall angle of less than 6 degrees, which is two times the angle defined between the transparent film interface with the light absorbing element and a plane normal to the microstructured surface).

2) With respect to Element 3, however, Claim 1 is different from Prior Art 1 in that Claim 1 specifies the difference in the index of refraction between a transmissive region and an absorptive region (*i.e.*, N1-N2) as not less than 0.005, while

4) The description in parenthesis refers to the element in prior art corresponding to Claim 1. The same applies in Section 4.C. below.

Prior Art 1 discloses that the difference in refractive index between a light transmissive film material and a light absorbing material is in the range of between 0 and 0.002.

D. Whether Those Skilled in the Art Would Easily Overcome the Difference

In view of the following, as found based on the disclosure of each of the Plaintiff's Exhibits 7 to 8, and Defendant's Exhibit 5 together with the purport of the overall argument, the foregoing difference would not have been easily overcome by those skilled in the art.

1) The Claimed Invention relates to a light control film that increases the axial brightness of light (in front of a display user) and enhances uniformity of the brightness within viewing angle, while providing a sharp viewing cutoff angle. According to Element 3 of Claim 1, the difference in the index of refraction between an absorptive region and a transmissive region (N1-N2) is in the range of N1-N2$\geq$0.005 in order to cause total internal reflection (TIR) at an interface between the absorptive region and the transmissive region of the light control film, thereby increasing the amount of light (luminance) passing through the film and eventually increasing the luminance of the display (*see* Defendant's Exhibit 5, paragraphs [0015], [0019] and [0029]).

2) The specification of Prior Art 1 includes a portion reading as follows:

To reduce reflections at the light transmissive film/light absorbing material interface, it may be desirable to match or nearly match the refractive index of the transmissive film

material with that of the light absorbing material over all or a portion of the visible spectrum. Accordingly the difference in the index of refraction of the cured transparent film in comparison to the (e.g. cured) light absorbing elements typically ranges from 0 to 0.002. Reducing such reflections tends to reduce the formation of ghost images (*see* Plaintiff's Exhibit 7, p. 6, lines 9-15).

According to the description above, Prior Art 1 limits the difference in refractive index between the light transmissive film material and the light absorbing material to next to none, in the range of between 0 and 0.002, to reduce reflections at an interface between the light transmissive film material and the light absorbing material, thereby reducing the formation of ghost images. Prior Art 1 neither discloses nor implies anything relating to increasing the luminance of the light passing through a light control film using total reflections caused by a difference in refractive index.

3) Thus, Claim 1 and Prior Art 1 are different from each other in terms of the technical problem to be solved through refractive index difference, and in terms of the effect resulting from the refractive index difference.

4) Based on the fact that Prior Art 1 discloses the technical feature of adjusting the refractive index of the light transmissive film material and the light absorbing material, and Prior Art 2 discloses limiting the difference in refractive index between a lens portion (light transmissive region) and a wedge part (light absorbing region) to 0.08, the Defendant argues that those skilled in the art would have easily overcome the foregoing difference by combining Prior Arts 1 and 2. As discussed above, however, Prior Art 1 matches or

nearly matches the refractive index difference of the transmissive film material with that of the light absorbing material, thereby preventing reflections at an interface, while Prior Art 2 discloses that the difference in refractive index between the material comprising the lens part and the material comprising the wedge part (N1-N2) as N1>N2, thereby causing reflections at an interface (a slant face of the wedge part) (*see* Plaintiff's Exhibit 8, paragraph [0012]). Thus, upon combining the element in Prior Art 2 providing a larger refractive index difference, it will be difficult to achieve the objective of Prior Art 1 through the difference in refractive index, *i.e.*, obtaining the effect of reducing the formation of ghost images by reducing the occurrence of reflections at the interface. Further, Prior Art 1 fails to include any other portion that suggests or motivates introduction of the refractive index difference of Prior Art 2. Thus, those skilled in the art would not have easily overcome the difference of Claim 1 by combining Prior Arts 1 and 2.

5) The Defendant argues that the method of using the total reflection of light to increase the luminance of the light control film and the method of removing the total reflection of light to remove ghost images are replaceable with each other and thus those skilled in the art would have easily chosen one method as needed without undue technical effort. The Defendant's produced evidence alone, however, is not enough to conclude that the foregoing had been technical common sense prevailing at the time of filing or had been obvious among those skilled in the art.

E. Summary of the Analysis

In view of the foregoing, those skilled in the art would not have easily derived Claim 1 in view of Prior Art 1 or in view of the combination of Prior Art 1 and Prior Art 2. Thus, Claim 1 does not lack inventiveness over the Prior Arts.

4. Whether Claim 1 Lacks Inventiveness When Prior Art 2 Is Relied upon as the Primary Reference

A. Whether the Defendant's Argument Constitute a New Ground of Rejection

1) Standard of Analysis

The ground of rejection newly raised by the Commissioner of the KIPO in the revocation action against IPTAB decision on an appeal from final rejection may serve as a basis for determining whether the IPTAB's decision is proper only when the new ground is consistent in essence with the previously notified ground, for which an opportunity to respond was given at the examination or administrative trial, and thus is no more than a supplementation to the previously notified ground. In case a new ground of rejection raised in litigation concerns inventiveness of the claimed invention, the new ground is consistent in essence with the previous ground of rejection if:

> The same prior art are cited to show that each element of the claimed invention was already made public;
>
> Both grounds of rejection are consistent in major part with each other with respect to the factual premises necessarily reviewed in determining the inventiveness of the claimed invention over the

prior art references (such as the level of skills, technical commonsense and the fundamental problem to be resolved in the art at the time of filing), the key elements focused in the determination, the issues subject to determination (such as the technical problem to be solved, technical means to solve the problem, and motivation/suggestion of combination or difficulty in combination); and

the same direction of argument or amendment is expected from the Applicant in overcoming the rejection and thus the Applicant is regarded as having been given an actual opportunity to respond to the new ground of rejection.

Even if a ground newly raised in litigation cites the same prior arts used to find lack of inventiveness at the examination and administrative trial and is merely different in whether prior arts are combined or how they are combined, it constitutes an impermissible new ground of rejection inconsistent in essence with the ground previously raised at the examination and administrative trial if: the factual premises, the key elements in the determination, or the issues subject to determination is changed, and thus the applicant has never been given an opportunity to submit argument or make amendment to that ground.

2) Analysis

(A) The IPTAB decision states that Claim 1 lacks inventiveness because it would have been easily conceived by those skilled in the art by combining the element of N1-N2=0.08 in Prior Art 2 with Prior Art 1. On the other hand, the Defendant argues in this litigation as the ground of justifying the conclusion of the IPTAB decision that Claim 1 would have been easily conceived

by those skilled in the art in view of Prior Art 2 or the combination of the included wall angle in a range of less than 6° in Prior Art 1 (*i.e.*, an interface angle of less than 3°) with Prior Art 2, and is thus found to lack inventiveness.

(B) In view of the following facts and reasons found as a result of taking into account the disclosure of each of Plaintiff's Exhibits 2 to 6 and Defendant's Exhibits 1 to 5, together with the purport of the overall arguments, the ground of rejection the Defendant cites in the litigation is not consistent in essence with the ground of rejection for which an opportunity to respond was given at the examination and administrative trial, and thus constitutes a new ground of rejection.

1) The difference between the Claimed Invention and the Prior Arts discussed in the Notice of Second Final Rejection and the IPTAB's decision is different from that raised in the Defendant's argument in this litigation. In other words, the Notice of Second Final Rejection and the IPTAB's decision state that Claim 1 is different from the invention previously made public (Prior Art 1) in terms of refractive index difference in Element 3, but here the difference between Claim 1 and the invention previously made public (Prior Art 2) lies in the interface angle of Element 4 according to the Defendant's argument.

2) As a result of the difference above, the ground of rejection in the Notice of Second Final Rejection and the IPTAB decision is also different from the Defendant's argument in terms of the factual premises

necessarily considered in determining inventiveness and the reasoning to the conclusion. In others words, when comparing the Claimed Invention with Prior Art 1 to determine inventiveness as in the Notice of Second Final Rejection and the IPTAB decision, inventiveness is determined based on what technical problem and effect is achieved by Element 3 from the aspect of the refractive index difference, whether the technical problem or effect is disclosed in Prior Art 1 or had been commonly recognized in the art, what types of technical means for solving the problem exist, whether Prior Art 1 suggests or motivates a combination of the corresponding elements of Prior Art 2 to Prior Art 1, among others. On the other hand, when comparing the Claimed Invention with Prior Art 2 to determine inventiveness, as in the Defendant's argument, the same questions as above will be discussed based on Element 4, *i.e.*, the interface angle range.

3) Although it is not specified which of Prior Art 1 and Prior Art 2 is the primary reference at the examination or administrative trial proceedings, the Claimed Invention was found to lack inventiveness over the combination of Prior Art 1 and Prior Art 2 on the grounds that Prior Art 1 discloses elements corresponding to Elements 1, 2 and 4, and Prior Art 2 discloses an element corresponding to Element 3. Given this, it is hard to expect the Plaintiff to consider whether the Claimed Invention lacks inventiveness over a completely different combination between the element in Prior Art 1 that corresponds to Element 4, and the elements in Prior Art 2 that correspond to Elements 1,

2 and 3 when making amendments to the Claimed Invention or submitting arguments on the point.

4) The Plaintiff is likely to cite different elements to argue that the Claimed Invention does not lack inventiveness when responding to the ground of rejection cited in the IPTAB decision and to the Defendant's argument in this action, and is likely to attempt to amend the specification in different ways. Indeed, the Plaintiff argues that, had the Defendant notified the alleged ground of rejection raised in the litigation before, it would have amended the interface angle range by excluding the angle of 3°, the boundary of the range, in order to overcome the ground of rejection.

5) The ground of rejection raised by the Defendant in this litigation is similar in reasoning to the ground of the First Final Rejection, which vacated by IPTAB on the following grounds:

"Although the Cited Reference discloses the angle (θ) formed by the slant face portion of the wedge part and the normal of the light output plane is in a range of between 3° and 15°, which overlaps with the boundary of the interface angle range in the Claimed Invention (i.e., when the interface angle is equal to 3°), the Cited Reference still discloses that in the case the angle (θ) formed by the slant face portion of the wedge part and the normal of the light output plane is less than 3°, the diffused light beam from the light source cannot reach sufficiently to the observer front side so that the luminance improving effect cannot be obtained and also discloses that in order to maintain the front side

luminance using the view angle controlling sheet of the present invention, the preferable range of the angle (θ) is 3°-15° or less. Thus, the Cited Reference explicitly excludes the feature of Claim 1 setting the interface angle to a range of less than 3° by teaching to set the interface angle to a range of 3° or higher. As such, those skilled in the art could not have easily conceived Claim 1 in view of the corresponding element of the Cited Reference."

In light of the above, the Plaintiff would have hardly anticipated that the same ground of rejection as before would be raised relying on Prior Art 2 which discloses similar technical matters to the Cited Reference.

(C) Therefore, the Defendant's argument that the IPTAB decision was proper when it found Claim 1 lacks inventiveness based on Prior Art 2 or the combination of Prior Arts 1 and 2 interferes with the Plaintiff's procedural rights and is hereby rejected.

3) However, we will still review whether Claim 1 lacks inventiveness based on Prior Art 2 as the primary reference below.

B. Element-by-element Comparison between Claim 1 and Prior Art 2

Claim 1	Prior Art 2 (Plaintiff's Exhibit 8)
[**Element 1**] A light control film, comprising: a light input surface and a light output surface opposite the light input surface;	a view angle controlling sheet S1 comprising a lens part 12, a surface where the lens part 12 and a light beam side base sheet 11 contact, a

Claim 1	Prior Art 2 (Plaintiff's Exhibit 8)
a first interface between a transmissive region and an adjacent absorptive region; and	surface where the lens part 12 and an observer side base sheet 13 contact, a wedge parts 14, and a slant surface where the wedge parts 14 and the lens part 12 contact (*see* Fig. 1 and paragraphs [0024] and [0026])
[**Element 2**] an interface angle θ1 defined by the first interface and a direction perpendicular to the light output surface;	the angle θ formed by the slant face of the wedge part and the normal of the light output plane (*see* paragraphs [0006] and [0009]) a refractive index N1 of the material for the lens part and a refractive index N2 of the main material for the wedge part (*see* paragraph [0012])
[**Element 3**] with each transmissive region having an index of refraction N1, and each absorptive region having an index of refraction N2, where N1-N2 is not less than 0.005;	providing a refractive index difference as N2<N1 between the light transmissive resin as a material for the lens part (having a refractive index N1) and the main material for the wedge part (having a refractive index N2) (*see* paragraph [0012])
[**Element 4**] where θ1 is not greater than 3 degree.	assuming that the slant face of the wedge part 14 forms an angle θ with the normal of the light output plane, the angle θ is in the range of $3° \leq \theta \leq 15°$ (*see* paragraphs [0006] and [0009])

C. Summary of Comparison

1) Claim 1 and Prior Art 2 are the same as each other in terms of: (i) Element 1, *i.e.*, a light control film (a viewing angle control sheet) comprising a light input surface (a surface where the lens part and a light beam side base sheet contact),

a light output surface (a surface where the lens part and an observer side base sheet contact), a transmissive region (the lens part), an absorptive region (a wedge part) and a first interface (a slant face where the wedge part and the lens part contact); (ii) Element 2, *i.e.*, an interface angle θ1 defined by the first interface and a direction perpendicular to the light output surface (an angle θ formed between the slant face where the wedge part and the lens part contact and the normal); and (iii) Element 3, *i.e.*, the difference in the index of refraction between the transmissive region and the absorptive region (*i.e.*, N1-N2) being not less than 0.005 (the refractive index difference between the light transmissive resin, as the material comprising the lens part, and the material comprising the wedge part is to be N2<N1, *e.g.*, a lens part refractive index of 1.56 and a wedge part refractive index of 1.48).

2) With respect to Element 4, Claim 1 specifies the interface angle θ1 as being less than 3 degrees, while Prior Art 2 discloses that the angle between the slant face where the wedge part and the lens part contact and the normal is in the range of $3° \leq \theta \leq 15°$.

D. Whether Those Skilled in the Art Would Easily Overcome the Difference

In view of the following as found based on the disclosure of each of Plaintiff's Exhibits 7 to 8 and Defendant's Exhibit 5 together with the purport of the overall arguments, the foregoing difference would not have been easily overcome by those skilled in the art.

1) The Claimed Invention relates to a light control film that increases the axial brightness of light and enhances brightness uniformity within the viewing angle, while providing a sharp viewing cutoff angle. With respect to Element 4, setting the interface angle θ1 to within the range of $\theta 1 \leq 3°$ is to form grooves with a relatively high aspect (H/W), thereby providing a sharper image cutoff at lower viewing angles (*see* Defendant's Exhibit 5, paragraphs [0015] and [0027]).

2) An objective of Prior Art 2 is to provide an inexpensive viewing angle control sheet that is effective in preventing peeping or reflection among others, while providing a high light beam transmittance to the observer side so as to provide efficient light utilization (*see* Plaintiff's Exhibit 8, paragraph [0004]). Further, the specification of Prior Art 2 states as follows:

…, in the case the angle θ formed by the slant face portion of the wedge part and the normal of the light output plane is less than 3°, the diffused light beam from the light source cannot reach sufficiently to the observer front side so that the luminance improving effect cannot be obtained. On the other hand, in the case θ is more than 15°, the area of the lens part that the diffused light beam from the light source is transmitted becomes too small and the luminance is lowered. In order to maintain the front side luminance using the viewing angle control sheet of the present invention, the preferable range of θ is 3° or more and 15° or less (*See* Plaintiff's Exhibit 8, paragraph [0009]).

According to the foregoing description, Prior Art 2 intends to obtain an effect of improved front side luminance by limiting the angle (θ) formed by the slant face portion of the wedge

part and the normal to the range of $3° \leq \theta \leq 15°$ to allow the diffused light to fully reach in the front direction. On the other hand, while Prior Art 2 has an objective of preventing peeping or reflection, it is different from Claim 1 in terms of the numerical range of the interface angle and thus is not found to have an effect in providing a sharper image cutoff at lower view angles like in Claim 1. Therefore, Claim 1 and Prior Art 2 are different in terms of the technical problem to be solved in view of the interface angle and of the effect resulting from the interface angle.

3) Although the angle (θ) formed by the wedge part and the normal in Prior Art 2 overlaps with the interface angle ($\theta 1$) in Claim 1 when the interface angle is in the range of 3 degrees, this numerical value is no more than a boundary between the numerical range of the two inventions. Further, the numerical limitations suggested by the two inventions and the resulting effects therefrom are different from each other. Thus, the feature of Prior Art 2 residing in limiting the angle formed by the slant face portion of the wedge part to the range of $3° \leq \theta \leq 15°$ is not substantially the same as Element 4 of Claim 1. Further, those skilled in the art would not have easily reached Element 4 of Claim 1 in view of Prior Art 2.

4) The Defendant argues that the method of removing the total reflection of light by adjusting the interface angle such that it is greater than 0° had been a well known technology that those skilled in the art would have easily refer to and overcome the foregoing difference. The disclosure of Defendant's Exhibits 8 to 9 alone, however, is not sufficient to show that removing the total reflection of light by adjusting the interface angle to be higher than 0° had been well known in the art at the time of filing.

5) The Defendant argues that the foregoing difference would have been easily overcome by those skilled in the art by combining Prior Art 1 and Prior Art 2 since Prior Art 2 considers the numerical range of $0° < \theta < 3°$ in view of its disclosure of a physical strength and manufacturing advantages according to the angle (θ) larger than 0° and Prior Art 1 discloses the included wall angle less than 6° (*i.e.*, the interface angle less than 3°). Prior Art 2 states that "since the wedge part is substantially isosceles trapezoidal or trapezoidal unsymmetrical in the right and left direction, the vertex of the upper bottom surface of the wedge part can be an obtuse angle so that the die for producing the wedge part, or the like can be produced easily, and furthermore, the strength of the wedge part can be improved so as to produce a high quality view angle controlling sheet (including a film) can be produced stably" (*see* Plaintiff's Exhibit 8, paragraph [0008]). This description, however, is no more than showing that the wedge part's strength may be improved depending on its shape. In view of this, those skilled in the art would not have easily reached the interface angle in Element 3. Further, the technical problem in Prior Art 2 is to maintain a front side luminance by adopting a predetermined angle (θ) range, and it recognizes the difficulty of improving the front side luminance when the included wall angle is less than 6° as in Prior Art 1 (*i.e.*, when the interface angle is less than 3°) (*see* Plaintiff's Exhibit 8, paragraph [0009]). Further, Prior Art 2 does not provide any other portion suggesting or motivating the introduction of the element in Prior Art 1 relating to the included wall angle. Accordingly, those skilled in the art would not have easily overcome the foregoing difference by combining Prior Art 1 and Prior Art 2.

E. Summary of the Analysis

Therefore, the alleged lack of inventiveness when Prior Art 2 is relied upon as the primary reference constitutes a new ground of rejection, for which the Plaintiff was not given an opportunity to respond, and may not be raised in the litigation. Even if it is concluded to the contrary, Claim 1 still would not have been easily conceived by those skilled in the art in view of Prior Art 2 or the combination of Prior Art 1 and Prior Art 2, and thus does not lack inventiveness.

5. Conclusion

In light of the above, the IPTAB decision contrary to the foregoing is erroneous and the Plaintiff's request to revoke the IPTAB decision is well-grounded and thus granted. Decision entered as ordered.

Presiding Judge Hwansoo KIM
Judge Jootag YOON
Judge Hyunjin CHANG

PATENT COURT OF KOREA
THIRD DIVISION
DECISION

Case No.: 2015Heo7889 Invalidation of Registration (Patent)

Plaintiff: ICOS CORPORATION

Defendants: 1. Jaeil Pharmaceuticals, Co., Ltd.
2. Kuhnil Pharmaceutical Co., Ltd.
3. FNG Research
4. Daewoong Pharmaceutical, Co., Ltd.
5. CTC BIO, Inc.
6. Yuhan Corporation
7. Chong Kun Dang Pharm. Co., Ltd.

Intervenor for the Defendants: Hanmi Pharm. Co., Ltd.
Intervenor for the Defendant 7: Samjin Pharm. Co., Ltd.

Date of Closing Argument: December 19, 2016
Decision Date: February 3, 2017

ORDER

1. All of the Plaintiff's petitions against the Defendants are dismissed.

2. The litigation cost including that from the intervention shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB decisions 2014Dang791, 2014Dang829 (consolidated), 2014Dang886 (consolidated), 2014Dang1135 (consolidated), 2014Dang1350 (consolidated) and 2014Dang2195 (consolidated) dated September 25, 2015 shall be revoked.

OPINION

1. Background

A. Patented Invention at Issue (Plaintiff's Exhibit 2) (hereinafter the "Subject Invention")

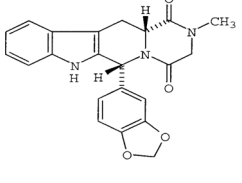
1) Title of Invention: Unit Dosage Form

2) Priority Date/ International Filing Date/ Registration Date/ Registration Number: April 30, 1990 / April 26, 2000 / April 28, 2006 / No. 577057

3) Patentee: Plaintiff

4) Claims

[Claim 1] A pharmaceutical unit dosage form for the treatment of sexual dysfunction, comprising 1 to 20 mg of a compound having the structural formula I below, with the said unit dosage form suitable for oral administration up to a maximum total dose of 20 mg per day.



[Claim 2] The pharmaceutical dosage form of claim 1 comprising 2 to 20 mg of the compound in unit dosage form.

[Claim 3] The pharmaceutical dosage form of claim 1 comprising 5 to 20 mg of the compound in unit dosage form.

[Claim 4] The pharmaceutical dosage form of claim 2 comprising 2.5 mg of the compound in unit dosage form.

[Claim 5] The pharmaceutical dosage form of claim 3 comprising 5 mg of the compound in unit dosage form.

[Claim 6] The pharmaceutical dosage form of claim 3 comprising 10 mg of the compound in unit dosage form.

[Claim 7] The pharmaceutical dosage form of claim 1 comprising 2 mg of the compound in unit dosage form.

[Claim 8] The pharmaceutical dosage form of claim 1 comprising 1 to 5 mg of the compound in unit dosage form.

[Claim 9] The pharmaceutical dosage form of claim 1 comprising 20 mg of the compound in unit dosage form.

[Claim 10] The pharmaceutical dosage form of any one of the claims 1 to 9, wherein the unit dose is in a form selected from the group consisting of a liquid, a tablet, a capsule, and a gelcap.

[Claim 11] The pharmaceutical dosage form of any one of the claims 1 to 9, wherein the unit dose is in the form of a tablet.

[Claim 12] The pharmaceutical dosage form of any one of the claims 1 to 9, wherein the sexual dysfunction is male erectile dysfunction.

[Claim 13] The pharmaceutical dosage form of any one of the claims 1 to 9, wherein the sexual dysfunction is female arousal disorder.

[Claims 14-19] *(Deleted)*

5) Summary of Invention

According to the descriptions below disclosed in the specification of the Subject Invention, of which the technical problem to be solved is to provide a pharmaceutical unit dosage form of the compound of formula I, which is a potent phosphodiesterase type 5 (PDE5) inhibitor, suitable for providing unit dose that can exhibit the therapeutic effect for sexual dysfunction without the adverse effects related to PDE5 inhibition, suitable for oral administration. In order to achieve this, the Subject Invention suggests up to 20 mg for a maximum total dose per day of the compound of formula I, and 1-20 mg for the amount of the compound of formula I in the unit dosage form.

A) Field of the Invention

The present invention is related to a highly selective phosphodiesterase (PDE) enzyme inhibitor and to its use in a pharmaceutical unit dosage form. In particular, the present invention relates to a potent inhibitor of cyclic guanosine 3', 5'-monophosphate specific phosphodiesterase type 5 (PDE5) that when incorporated into a pharmaceutical product is useful for the treatment of sexual dysfunction. The unit dosage form described herein is characterized by selective PDE5 inhibition, and accordingly, provides a benefit in therapeutic areas where inhibition of PDE5 is desired, with minimization or elimination of adverse side effects resulting from inhibition of other phosphodiesterase enzymes (paragraph [0003]).

B) Solution to the Problem

Applicants have discovered that one such tetracyclic derivative, (6R, 12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-piperazino[2', 1': 6,1]pyrido[3,4-b]indole-1,4-dione, alternatively named (6R-trans)-6-(1,3-benzodioxol-5-yl)-2,3,6,7,12,12a-hexahydro-2-methylpyrazino[1', 2': 1,6]pyrido[3,4-b]indole-1,4-dione, and referred to herein as Compound (I), can be administered in a unit dose that provides an effective treatment without the side effects associated with the presently marketed PDE5 inhibitor, sildenafil. Prior to the present invention such side effects were considered inherent to the inhibition of PDE5 (paragraph. [0009]).

Significantly, the applicants' clinical studies also reveal that an effective product having a reduced tendency to cause flushing in susceptible individuals can be provided. Most unexpectedly, the product can also be administered with clinically insignificant side effects associated with the combined effects of a PDE5 inhibitor and an organic nitrate. Thus, the contraindication once believed necessary for a product containing a PDE5 inhibitor is unnecessary when Compound (I) is administered as a unit dose of about 1 to about 20 mg, as disclosed herein. Thus, the present invention provides an effective therapy for sexual dysfunction in individuals who previously were untreatable or suffered from unacceptable side effects, including individuals having cardiovascular disease, such as in individuals requiring nitrate therapy, having suffered a myocardial infarction three or more months before the onset of sexual dysfunction therapy, and suffering from class 1 congestive heart failure, or individuals suffering from vision abnormalities (paragraph [0010]).

B. Prior Arts

1) Prior Art 1 (Plaintiff's Exhibit 5)

Prior Art 1 is an invention directed to "'use of cGMP- phosphodiesterase inhibitors to treat impotence,'" published as International Patent Publication No. WO 97/03675 on February 6, 1997, and its main disclosure is as follows:

- This invention relates to the use of tetracyclic derivatives which are potent and selective inhibitors of cyclic guanosine 3', 5'-monophosphate specific phosphodiesterase (cGMP specific PDE) in the treatment of impotence (page 1, lines 3-5).
- The specific compounds of the invention are: (6R, 12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione (Compound A); and (3S, 6R, 12aR)-2,3,6,7,12,12a-hexahydro-2,3-dimethyl-6-(3,4-methylenedioxyphe

nyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione (Compound B); and physiologically acceptable salts and solvates (e.g. hydrates) thereof (page 3, lines 23-29).

- Unexpectedly, it has now been found that compounds of formula (I), and in particular Compounds A and B, are useful in the treatment of erectile dysfunction. Furthermore, the compounds may be administered orally, thereby obviating the disadvantages associated with i.c. administration. Thus, the present invention concerns the use of compounds of formula (I), and in particular Compounds A and B, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in a male animal, including man (page 3, line 30 to page 4, line 6).
- For administration to man in the curative or prophylactic treatment of the disorders identified above, oral dosages of a compound of formula (I), and in particular Compounds A and B will generally be in the range of from 0.5-800mg daily for an average adult patient (70kg). Thus, for a typical adult patient, individual tablets or capsules contain from 0.2-400mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day. Dosages for buccal or sublingual administration will typically be within the range of from 0.1-400 mg per single dose as required. In practice, the physician will determine the actual dosing regimen which will be most suitable for an individual patient, and it will vary with the age, weight and response of the particular patient. The above dosages are exemplary of the average case but there can be individual instances in which higher or lower dosage ranges may be merited, and such are within the scope of this invention (page 5, lines 1-14).
- Direct compression of tablets for oral administration (page 12, line 15)

1.	mg/tablet
Active ingredient	50.0
Crospovidone USNF	8.0
Magnesium Stearate Ph Eur	1.0
Anhydrous Lactose	141.0

2) Prior Art 2 (Plaintiff's Exhibit 6)

Prior Art 2 is an invention directed to "'method of producing a solid dispersion of a poorly water soluble drug,'" published as International Patent Publication No. WO 96/38131 on December 5, 1996, describing as follows:

○ The present invention relates to solid dispersions in the form of co-precipitates of poorly water soluble drugs and their compositions with a pharmaceutically acceptable carrier or excipient therefor. Specifically, the invention relates to co-precipitates of (a) a potent and selective inhibitor of cyclic guanosine 3',5'-monophosphate specific phosphodiesterase (cGMP specific PDE) and (b) a potent and selective gastrin and CCK B antagonist, processes for the preparation of such solid dispersions, pharmaceutical compositions containing the same and their use thereof in therapy (page 1, lines 5-13).

○ There is provided by the present invention a process of preparing a solid dispersion comprising (6R, 12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione (hereinafter referred to as Compound A) or salts or solvates (e.g., hydrates) thereof, and a pharmaceutically acceptable carrier or excipient therefor, which process comprises co-precipitating Compound A and the pharmaceutically acceptable carrier or excipient (page 4, lines 15-21).

○ It has been shown that Compound A is a potent and selective inhibitor of PDE5. Thus, Compound A is of interest for use in therapy, specifically for the treatment of a variety of conditions where inhibition of PDE5 is thought to be beneficial. As a consequence of the selective PDE5 inhibition exhibited, cGMP levels are elevated, which ···. Elevated cGMP levels may also mediate relaxation of the corpus cavernosum tissue and consequent penile erection in the treatment of male sexual dysfunction. The solid dispersions of Compound A therefore have utility in the treatment of a number of disorders, including ··· (omitted) ··· symptoms associated with male sexual dysfunction (page 7, line 27 to page 8, line 9).

○ For administration to man in the curative or prophylactic treatment of

the disorders identified above, oral dosages of Compound A will generally be in the range of from 0.5-800mg daily for an average adult patient (70kg). Thus, for a typical adult patient, individual tablets or capsules contain from 0.2-400mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day. Dosages for intravenous, buccal or sublingual administration will typically be within the range of from 0.1-400 mg per single dose as required. In practice, the physician will determine the actual dosing regimen which will be most suitable for an individual patient and it will vary with the age, weight and response of the particular patient. The above dosages are exemplary of the average case but there can be individual instances in which higher or lower dosage ranges may be merited and such are within the scope of this invention (page 8, line 30 to page 9, line 7).

○ Co-precipitation of Compound A: Hydroxypropyl methylcellulose phthalate using acetone/water (page 14, lines 30-35)

	%
Compound A	25 - 90
Hydroxypropyl methylcellulose phthalate (HPMCP)*	10 - 75

* Grades HP55 and HP50.

Compound A (1g) and HPMCP (1g) were dissolved in a 9:1 mixture of acetone/water (27 ml). 0.25M Hydrochloric acid (83ml) was added. The resultant co-precipitate was filtered, washed with water (5x3ml), dried in vacuo and milled (page 15, lines 1-3).

○ Tablets for oral administration
Co-precipitate of Compound A: HPMCP and Compound B: HPMCP were formulated as follows:
Compound A: HPMCP co-precipitate was blended with the excipients. The resultant mix was compressed into tablets (page 15, line 31 to page 17).

1.	mg/tablet
Compound A: HPMCP co-precipitate	100.0
Microcrystalline cellulose	289.2
Colloidal silicon dioxide	0.8
Crospovidone	8.0
Magnesium stearate	2.0

C. Procedural History of the IPTAB Decisions

1) The Defendant Jaeil Pharmaceutical as IPTAB decision 2014Dang791 on March 31, 2014, the Defendants Kuhnil Pharmaceutical and FNG Research as IPTAB decision 2014Dang829 on April 4, 2014, the Defendant Daewoong Pharmaceutical as IPTAB decision 2014Dang886 on April 11, 2014, the Defendant CTC BIO as IPTAB decision 2014Dang1135 on May 14, 2014, the Defendant Yuhan Corporation as IPTAB decision 2014Dang1350 on June 11, 2014, the Defendant Chong Kun Dang as IPTAB decision 2014Dang2195 on September 2, 2014, each filed a patent invalidation action of the Subject Invention against the Plaintiff alleging that "the Subject Invention lacks inventiveness since it would have been easily invented by a person having ordinary skill in the art (referred to herein as 'a person skilled in the art') from Prior Art 1 or Prior Arts 1 & 2, or the specification of the Subject Invention fails to meet the description requirements."

2) The IPTAB has consolidated and reviewed all of the Defendants' actions above, and subsequently granted them on September 25, 2015 on the grounds that "the Subject Invention lacks inventiveness based on Prior Arts 1 and 2."

[Factual Basis] Statements in Plaintiff's Exhibits 1, 2, 3, 5, and 6, and the purport of the overall argument

2. The Parties' Arguments

A. Summary of the Plaintiff's Arguments

1) Since the technical feature of the Subject Invention resides in

providing the dose and administration method of the compound of formula I (hereinafter, 'tadalafil') maintaining full efficacy for the treatment of erectile dysfunction while minimizing adverse effects, a person skilled in the art cannot easily derive the dose and administration method limited in the Subject Invention from the Prior Arts according to the reasons below.

A) The Prior Arts disclose the dose of tadalafil administered into the human body only in an extremely broad range of 0.5-800mg, but do not include any descriptions regarding clinical trial or other grounds supporting such dose. Further, the Prior Arts do not mention anything about the adverse effects of tadalafil. Therefore, a person skilled in the art would not recognize 0.5-800mg as an effective dose for human, but recognize it only as a range possible to show therapeutic effect for erectile dysfunction when tadalafil is administered to human.

B) Since unit dosage form of 50mg or 25mg tadalafil described in the embodiments of the Prior Arts is only an example of the amount that can be used when formulating tadalafil, the amount cannot be deemed as an effective administration dose of tadalafil maintaining the therapeutic effect and minimizing the adverse effects in the treatment of erectile dysfunction.

C) The effective administration dose of tadalafil for human cannot be predicted from the fact alone that IC_{50} of sildenafil, which is a PDE5 inhibitor, is 3-3.9nM and that of tadalafil is 2nM, without consideration on the numerous factors that impact dose such as pharmacokinetic and pharmacodynamic data, etc.

D) The dose of the Subject Invention is much lower than expected from the results of phase 1 clinical trial. Three (3) pharmaceutical companies participated in clinical trials. After three (3) phase 1 clinical trials, another phase 1 clinical trial was once again performed to supplement the trials as to the elder volunteers almost simultaneously with phase 2 clinical trials. Even after that, two (2) more phase 2 clinical trials were conducted. As such, the dose and administration method of the Subject Invention was derived from the efforts that cannot be viewed as common.

2) The effect of the dose and administration method limited by the Subject Invention is an effect that a person skilled in the art cannot expect from the Prior Arts for the following reasons.

A) Since a person skilled in the art would know that the efficacy reduces as the administration dose decreases, he/she would not have thought to merely lower the dose to solve adverse effects. In this regard, the Subject Invention achieved the effect that maintains full efficacy for treatment of erectile dysfunction while substantially eliminating the adverse effects, i.e., flushing, vision abnormalities, and blood pressure drop when co-administered with nitrates, etc., which were deemed as unavoidable by inhibition of PDE5, even with a lower dose than that was predicted by a person skilled in the art. In particular, no practical adverse effects were shown at the dose of 5 mg or less, compared with the placebo group. A person skilled in the art cannot expect these effects from the Prior Arts.

B) The Prior Arts are silent about the effects that can be

compared with those of the Subject Invention. except that tadalafil has therapeutic activity for erectile dysfunction. Thus, a person skilled in the art would refer to sildenafil, which was the only approved drug for erectile dysfunction at the time of the priority date. However, the dose and administration method limited in the Subject Invention show extremely superior effect to sildenafil in terms of adverse effects such as flushing, blood pressure drop when co-administered with nitrate, vision abnormalities, etc., as well as in terms of the therapeutic efficacy. Specifically, tadalafil has high selectivity of PDE5 over PDE6, and thus, the adverse effects related to vision abnormalities are significantly lower than sildenafil. Such an effect is significant and could not have been expected by a person skilled in the art at the time of the priority date.

3) Thus, the inventiveness of the Subject Invention is not denied based on the Prior Arts. In this regard, the IPTAB erred in its decisions, which shall be revoked.

B. Summary of Arguments of the Defendants and the Intervenors

1) The inventiveness of the Subject Invention is denied for the following reasons.

A) Prior Arts 1 and 2 disclose that a daily dose of tadalafil, which is a medicine for treating sexual dysfunction, is 0.5-800mg, that it can be administered once or several times per day, and that 25mg or 50mg tadalafil tablet as a formulation that can be administered once daily. Further,

at the time of the priority date, it was well known that vision abnormalities, flushing, etc., could be observed as an adverse effect due to the PDE5 inhibition mechanism of PDE5 inhibitors such as tadalafil. From the above, a person skilled in the art can easily derive a total daily dose of up to 20 mg as the optimized dose showing efficacy while reducing adverse effects.

B) The pattern for therapeutic effect for erectile dysfunction of the Subject Invention merely corresponds to the typical dose- response profile of drugs, and the Subject Invention does not show any effect that cannot be predicted by a person skilled in the art. Further, the Subject Invention's effect reducing the adverse effects cannot be acknowledged as an effect of limiting the dose of tadalafil, and the effect is just at a level which can be predicted by a person skilled in the art.

2) Since the specification of the Subject Invention does not describe the experimental results demonstrating efficacy and the adverse effects when administrating a maximum total dose of 1mg or 20mg per day, the claims of the Subject Invention are not supported by the description, and the specification of the Subject Invention is not described in a way that a person skilled art can easily practice the present invention.

3. Whether the Subject Invention Lacks Inventiveness

A. Legal Standards

1) A medicine refers to a product used for the diagnosis, alleviation, treatment, management, or prophylaxis of a human

disease (Article 96(2) of Patent Act), and a medical use invention refers to that which provides a novel use of a medicament based on the finding of an unknown property, i.e. a specific pharmacological effect of a medicinal substance. A medicinal use invention – for a medicament additionally specified with its medicinal use – is patentable subject matter as a product invention apart from the medicinal substance itself. That is, in a medicinal use invention claimed as a product invention, the medicinal substance and its medicinal use make up the invention. The medicinal use here is not a medical activity but expression of the properties exhibited by a medicine. It serves as an element of the invention which imparts new significance to the medicament product. Further, in order for a medicament to exhibit full efficacy with minimal adverse effects, it should be used on the disease for which it has pharmacological efficacy, and the administration method - including the dosing cycle, administration site, administration route, etc. - and the dose to be administered to a patient should be properly designed. Such an administration method and dose can be an element that imparts new significance to a medicine, in that they make the medicine to exhibit its full efficacy based on the finding of an unknown property, i.e., a specific pharmacological effect of a medicinal substance. Further, by changing the administration method and dose, even the same medicament can exhibit unexpected effects in the treatment or prevention of a disease, such as increased pharmacological effects, reduced adverse effects, improved patient convenience, etc (*see* Supreme Court Decision 2014Hu768 rendered *en banc* on May 21, 2015).

2) In the field of medical invention, finding an optimal dose and administration method including dosing cycle, administration site, administration route to maintain the efficacy, improve

patient convenience, and preventing toxicity or adverse effects, is a technical problem that should be necessarily solved, and the processes and method of finding the dose and administration are well known to a person skilled in the art in the field. Thus, it is in principle within the scope of creative ability of a person skilled in the art to optimize the dose and administration method to maintain the desired efficacy and prevent the toxicity or adverse effects in order to solve the problem relating to increasing the efficacy and reducing the adverse effects of a known drug. However, unless otherwise stated, the inventiveness should not be denied if the beneficial effects of the specific dose and administration method are significantly unpredictable from the technical level of a person skilled in the art, or if a person skilled in the art cannot predict from the prior art references the specific dose and administration method that maintains full efficacy while preventing toxicity or adverse effects.

B. Inventiveness of Claim 1 of the Subject Invention

1) The technical field and objective of Claim 1 of the Subject Invention and Prior Art 1

A) As discussed above, Claim 1 of the Subject Invention is directed to a potent inhibitor of cyclic guanosine 3',5'-monophosphate specific phosphodiesterase type 5 (PDE5) useful for the treatment of sexual dysfunction, and Prior Art 1 is also directed to a potent and selective inhibitor of cyclic guanosine 3',5'-monophosphate specific phosphodiesterase (cGMP specific PDE) useful for the treatment of erectile dysfunction. Thus, the technical field of Claim 1 of the Subject Invention and Prior Art 1 is identical.

B) The objective of Claim 1 of the Subject Invention is to provide a unit dose and administration method which can maintain therapeutic effect for sexual dysfunction without the adverse effects associated with PDE5 inhibition of tadalafil.

However, according to the descriptions of Plaintiff's Exhibit 5, Prior Art 1 discloses that the efficacy of orally administered drug for erectile dysfunction according to the conventional art is low and that the conventional treatment of erectile dysfunction can cause the patient the adverse effects of inflammation and ischemia, etc. Further, along with the facts that tadalafil, a selective PDE5 inhibitor, is effective for treating erectile dysfunction, that oral administration may be convenient for human and may prevent the disadvantages of other administration routes, Prior Art 1 suggests the fact that the oral daily dose will be in the range of 0.5-800mg for an average adult patient. Based on the facts above, it can be recognized that the objective of Prior Art 1 is also to provide the therapeutic use of tadalafil for erectile dysfunction, the dose of tadalafil to be administered to human, and the preparation method of pharmaceutical composition, the treatment method, etc. Especially, Prior Art 1 describes that "[t]he above dosages are exemplary of the average case but there can be individual instances in which higher or lower dosage ranges may be merited, and such are within the scope of this invention." Therefore, the Prior Art 1 is deemed to provide not only the therapeutic use of tadalafil, but also the dose as one of its objectives.

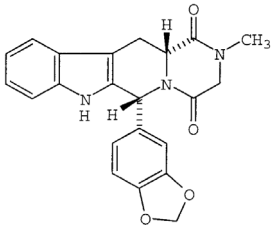
Thus, Claim 1 of the Subject Invention and Prior Art 1 do not have substantial difference in terms of the objective.

C) Therefore, since Claim 1 of the Subject Invention and

Prior Art 1 belong to the same technical field and share the same objective, the Plaintiff's argument that Claim 1 of the Subject Invention has distinguished objective from Prior Art 1 is rejected.

2) Comparison of Claim 1 of the Subject Invention and Prior Art 1

A) Element-by-element comparison

Claim 1 of the Subject Invention	Prior Art 1
A pharmaceutical unit dosage form for the treatment of sexual dysfunction, with the said unit dosage form suitable for oral administration up to a maximum total dose of 20 mg per day. 	○ For administration to man in the curative or prophylactic treatment of the disorders identified above, oral dosages of a compound of formula (I), and in particular Compounds A and B will generally be in the range of from 0.5-800mg daily for an average adult patient (70kg). Thus, for a typical adult patient, individual tablets or capsules contain from 0.2-400mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day. Dosages for buccal or sublingual administration will typically be within the range of from 0.1-400 mg per single dose as required. In practice, the physician will determine the actual dosing regimen which will be most suitable for an individual patient, and it will vary with the age, weight and response of the particular patient. The above dosages are exemplary

Claim 1 of the Subject Invention	Prior Art 1
	of the average case but there can be individual instances in which higher or lower dosage ranges may be merited, and such are within the scope of this invention (page 5, lines 1-14). ○ The present invention concerns the use of compounds of formula (I), and in particular Compounds A and B, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition con- taining either entity, for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in a male animal, including man (from page 3, line 30 to page 4, line 6).

B) Analysis of Commonalities and Differences

First of all, Claim 1 of the Subject Invention and Prior Art 1 are the same in that both are an orally administered medicament for treating sexual dysfunction, and comprise tadalafil.

However, whereas Claim 1 of the Subject Invention limits the maximum total daily dose to 20mg or less, Prior Art 1 suggests the daily dose as 0.5-800mg (hereinafter, "'Difference 1'"). Further, they differ in that Claim 1 of the Subject Invention limits the amount of tadalafil in the unit dosage form to 1-20mg, but Prior Art 1 limits that to 0.2-400mg (hereinafter, "'Difference 2'").

C) Analysis on Difference 1

(1) Difficulty in Composition

We review whether a person skilled in the art could have not predicted from Prior Art 1 that the full efficacy of tadalafil is maintained while the toxicity or adverse effects is minimized in the range of "up to a maximum total dose of 20mg per day" limited in Claim 1 of the Subject Invention.

(a) Common process of clinical trials

The following facts are found when putting together the purport of the overall argument with the descriptions in Plaintiff's Exhibits 23 and 24, Defendant 4's Exhibit 1, Defendant 5's Exhibits 1-1, 1-2, and 2, Defendant 6's Exhibits 2 and 10, and witness testimony of Sang-Gun Kim and Ji-Young Park.

① Pre-clinical trial is required to collect information regarding safety and efficacy of a drug substance before it is tried on humans. In drug safety tests, a drug substance is administered to laboratory animals, to measure the NOAEL (no observed adverse effect level), at which no toxicity or adverse effects is observed. For drug efficacy, *in vitro* tests and disease model animal tests (*in vivo* tests), etc. are performed. In *in vitro* tests, the response of the drug substance in test tubes is examined by using cell lines among others, and effective concentration (EC_{50}) is measured. In disease model animal tests, the response of the drug substance is observed at each administered dose in disease model animals, and the information on pharmacokinetics is obtained by measuring plasma concentration of the drug, elimination half-life, metabolism rate, excretion rate, etc.

② Phase 1 clinical trial is required to confirm safety and to obtain information on pharmacokinetics by administrating the drug substance to healthy volunteers. In drug safety tests, the adverse events are

observed by escalating the administered dose from the maximum recommended starting dose (MRSD).[1] When determining the MRSD, the NOAEL, i.e. the level no adverse effect is observed in animal testing, is first determined in the pre-clinical trials; it is then converted into the human equivalent dose (HED)[2] reflecting the body surface area; the MRSD is determined by dividing the HED by the safety factor (typically 10). The dose may be lowered based on the pharmacologically active dose (PAD, the dose to which HED value is reflected) tested in the preclinical trials. In addition, at this stage, the information of each administered dose regarding pharmacokinetics such as the plasma concentration of the drug, elimination half-life, metabolism rate, excretion rate is obtained, and the administered dose and administration method for phase 2 clinical trials are designed considering the pharmacokinetics information from the above and the preclinical phase 1 clinical trials.

③ Phase 2 clinical trial is required to confirm the clinical effect in the patients suffering from the specific disease, and to collect information for design of dose and administration period among others. At this stage, two or three designed doses are selected and administered to the small number of patients to evaluate efficacy.

④ Phase 3 clinical trial evaluates the efficacy by performing the trial on many patients with the doses selected from phase 2 clinical

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1) Generally, the MRSD of phase 1 clinical trial is determined according to the method presented in "'Guidance on Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers'" provided by CDER (Center for Drug Evaluation and Research) of the U.S. FDA (Food and Drug Administration).

2) Human equivalent dose (HED) is calculated by multiplying the animal dose by the conversion factor, which reflects the body surface area. Here, the conversion factor is a ratio of human/animal κ_m factors, and κ_m factor is the value of body weight (kg) divided by surface area (m^2).

trial as proper for application to the patients to confirm whether the tested drug is better than the existing therapeutic agents and whether it is eligible for marketing approval.

⑤ In the clinical trials performed in order, the results of previous trials may affect the plan of the subsequent trials; the product development strategy may be modified based on the results obtained from the later clinical trials; and additional clinical trials at initial stages may be required depending on the information obtained during the development procedure. For instance, additional trials for drug interactions based on later data on blood concentration or additional studies to design new doses or non-clinical trial based on the occurrence of adverse events at a later stage may be required. In addition, the clinical trials on a new indication or pharmacokinetics, or therapeutic exploratory studies may be conducted at the phase 1 or 2 clinical trials.

(b) Review of the conventional arts

The following facts are found, putting the purport of the overall argument together with the above evidence and the respective descriptions of Plaintiff's Exhibits 8, 14, and 25, Defendant 3's Exhibits 7-1, 7-2, and 7-3, and Defendant 5's Exhibits 3, and 8.

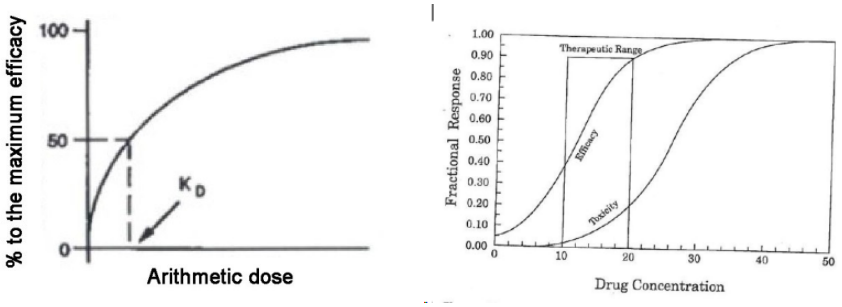
① Before the priority date of the Subject Invention, the pharmacological mechanism was known that cGMP in corpus cavernosum is changed into 5'-GMP by PDE5 and is inactivated; PDE5 cannot change cGMP to 5'-GMP when a PDE5 inhibitor, which is similar to cGMP and binds to a PDE5 receptor better than cGMP does, is administered; and as a result, the cGMP levels in corpus cavernosum are increased and the vasodilating effect is sustained. Further, Prior Arts 1 and 2 provide a therapeutic use of tadalafil for erectile dysfunction using the above pharmacological mechanism of PDE5 inhibitor.

② Prior Art 1 and Prior Art 2 describe “For administration to man, the oral dosage of the compound of formula I, in particular Compounds A and B will generally be in the range of from 0.5-800mg daily for an average adult patient (70kg),” and thus disclose the daily dose of tadalafil as 0.5-800mg.

③ Prior Art 1 describes “for a typical adult patient, individual tablets or capsules contain 0.2-400mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day,” and discloses the manufacturing method of orally administered tablet comprising 50mg of active compound of tadalafil in Example 3.A.

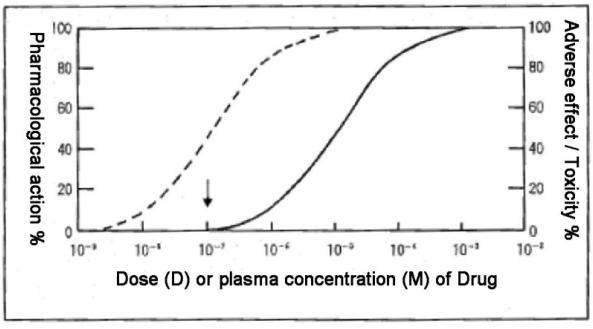
④ Prior Art 2 also describes “for a typical adult patient, individual tablets or capsules contain 0.2-400mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day,” and discloses the manufacturing method of co-precipitate of Compound A : HPMCP which comprises 25-90% of Compound A and 10-75% of HPMCP, and the manufacturing method of orally administered tablet comprising 100mg of the co-precipitate of Compound A : HPMCP in Example 1.

⑤ Generally, when the drug dose is increased, as depicted in the graph below, the efficacy increases at the early stage, however, after reaching a certain degree, even if the dose is increased, the drug efficacy does not increase anymore and is maintained at a certain level due to the saturation of body receptors participating in the efficacy exertion.



⑥ As in the graph above, as the drug dose is decreased, the adverse effects of the drug substance are generally reduced. However, there are exceptions where an adverse event occurs even if the drug dose is decreased.

⑦ When performing the studies as to the dose of medicinal products, a person skilled in the art always bears in mind the evaluation of the pharmacological action and the adverse effects/toxicity, and designs dosage regimen to exhibit the full pharmacological action while minimizing adverse effects. In the figure below, the dotted line indicates the pharmacological action, and a solid line indicates the adverse effects/toxicity. In order to exhibit full pharmacological action while minimizing adverse effects, the dose at the point where the dose and the drug concentration in blood plasma reach optimal value, at which the arrow points is selected.



⑧ Generally, when determining the dose of a medicine, the relation between the dose and response, and ED (Effective Dose) 50% (hereinafter 'ED50') are calculated from dose-response curve, and the dose is increased to calculate the relation between the dose and adverse effects (toxicity), and LD (Lethal Dose) 50% (hereinafter 'LD50') according to dose-adverse effect (toxicity) curve. As ED50 is lower and LD50 is higher, the drug is evaluated as safer, and commonly, if LD50/ED50 [it is called as a safety factor or a therapeutic index (TI)] is at least 10, the drug is evaluated as a safe drug. When the dose of the drug with a large safety factor or therapeutic index is reduced because of adverse effects, the efficacy is not remarkably decreased, whereas the adverse effects are. On the contrary, when the dose of the drug with a small safety factor or therapeutic index is reduced because of the adverse effects, the efficacy is reduced along with the adverse effects.

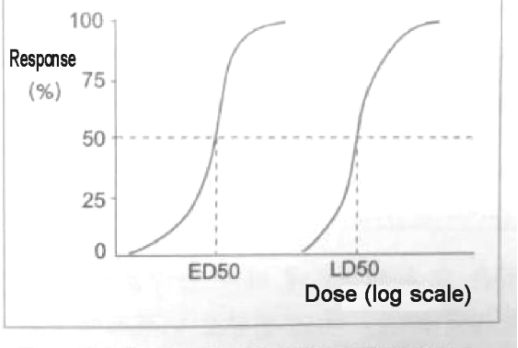


Figure 2-6. Dose-response curves of ED_{50} and LD_{50}

⑨ Before the priority date of the Subject Invention, the adverse effects of sildenafil, a PDE inhibitor, were reported. According to the report, sildenafil was known to show adverse effects including 16% occurrence of headache, 10% occurrence of flushing, 7% occurrence of indigestion, clinically significant decrease in blood pressure in individuals taking organic nitrate, etc., and its use is limited in the case of patients suffering from vision abnormalities. However, such

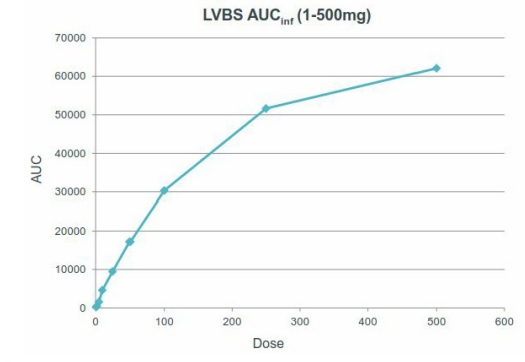
adverse effect profile was known as reflection of the inherent pharmacological characteristics of PDE5 inhibitor, and the frequency of adverse effects was reported increase as the dose of sildenafil is increased.

(c) The finding process of the dose of Claim 1 of the Subject Invention

The following facts are acknowledged when considering the purport of the overall argument together with the evidence mentioned above and the respective descriptions in Plaintiff's Exhibit 12, Defendant 3's Exhibit 6, Defendant 7's Exhibits 5-1, 5-2, 6, and 7, and Defendant 5's Exhibit 13.

① Around 1994, Glaxo Wellcome synthesized IC351 (the compound thereafter named as tadalafil[3]) and conducted three phase 1 clinical trials from August 7, 1995 to April 19, 1996, for the first time, after determining the dose with 500mg as an upper limit and 1mg as a lower limit using the method estimating human doses from the pharmacokinetic and pharmacodynamic data obtained from the animal tests performed to develop dose and administration method of IC351 in humans. At the first phase 1 clinical trial (LVBS), Glaxo Wellcome explored safety, tolerance, and pharmacokinetics, etc. in the dose range of 1-500mg (specifically, 500mg, 250mg, 100mg, 50mg, 25mg, 1mg), and confirmed that AUC (area under blood concentration-time curve; hereinafter, 'AUC') increases proportionally to the dose up to 100mg as shown in the graph below. Glaxo Wellcome conducted the second phase 1 clinical trial (LVBT) with 100mg dose, and the third phase 1 clinical trial (LVBU) with 50mg dose.

3) It seems that the fact that IC351 is a substance with the chemical structure of formula I in Claim 1 of the Subject Invention was known only after the priority date of the Subject Invention.



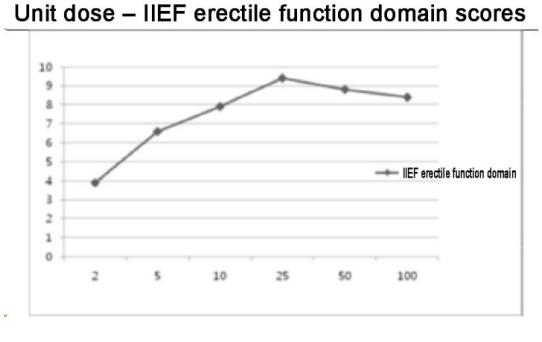
② During phase 2 clinical trial (LVBI) with 100mg dose starting from November 6, 1997 to determine human dose of IC351, the Plaintiff designed again phase 1 clinical trial (LVBH) and conducted it with 100mg, 50mg, 10mg doses from November 17, 1997 to April 28, 1998. As a result of the above phase 1 clinical trial, it was confirmed that AUC increases proportionally to the dose of IC351 up to 50mg dose, while in the range of 50-100mg, AUC was not exactly proportional to dose, and that the accumulation rate is higher in the low dose than in the high dose.

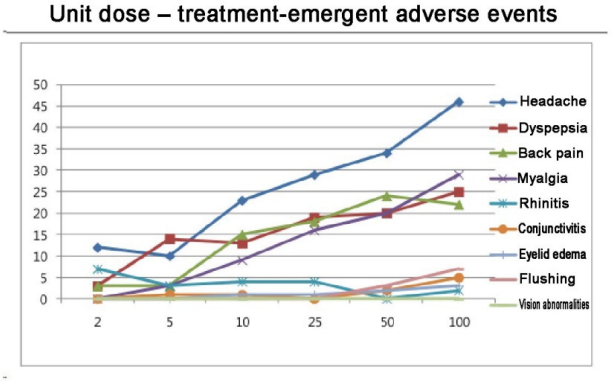
③ Later, the joint company Lilly-ICOS conducted phase 2 clinical trial (LVBG) with the doses of 100mg, 50mg, 25mg, 10mg from May 8, 1998 to October 7, 1998; and conducted additional phase 2 clinical trial (LVBF) with the doses of 2mg, 5mg, 10mg, 25mg from September 4, 1998 to December 7, 1998. As a result of the phase 2 clinical trial above, the pharmacokinetic response depending on the dose of IC351 was confirmed to have no significant difference between 10mg and 100mg, and the dose response was almost saturated particularly around 10mg, and the therapeutic effect reached plateau between 10mg and 25mg.

④ Meanwhile, the Plaintiff filed Investigational New Drug application for IC351 before the U.S. FDA on November 6, 1997,

which was received on November 10, 1997. However, on December 9, 1997, the U.S. FDA ordered clinical hold due to safety concerns shown in the preclinical trial results of IC351. That is, arteritis occurred in beagle dogs administered with high dose, and the dose was equivalent to, or less than the dose administered to human in the initial clinical trials. On December 16, 1997, the U.S. FDA requested submission of data including 6-month period toxicity study in rats and dogs, 6-month period toxicity study in monkeys, which would be helpful for determining whether the incidence of arteritis was specific to dogs, and pharmacokinetic data of multiple doses on the target groups, etc. Subsequently, the Plaintiff submitted the data relating to the phase 1 clinical trial (LVBH) on May 15, 1998, the draft protocol of phase 2 clinical trial (LVBF) on June 26, 1998, and the final protocol of phase 2 clinical trial (LVBF) on July 3, 1998, respectively. On July 20, 1998, the U.S. FDA requested submission of pharmacological safety study data on the influence of IC351 to gastrointestinal motility and gastric secretion, on July 27, 1998, they requested the revision of the protocol of the phase 2 clinical trial (LVBF) and received the revised protocol, and then on July 29, 1998, lifted the clinical hold.

⑤ The profile of therapeutic effect and adverse effects of tadalafil described in the specification of the Subject Invention can be depicted as in the graph below.





(d) Detailed Analysis

From the circumstances below which can be recognized from the acknowledged facts above, the dose and the administration method specified in Claim 1 of the Subject Invention are within the scope in which a person skilled in the art can predict that tadalafil would maintain the full efficacy while minimizing the adverse effects, based on the dose and administration method disclosed in Prior Art 1 and the technical facts known at the time of the priority date of the Subject Invention. Thus, there is no particular difficulty to derive the dose and administration method specified in Claim 1 of the Subject Invention in the process of the clinical trials which would have been necessarily conducted by a person skilled in the art.

① When preparing an actual formulation, a person skilled in the art would consider the administered dose as a priority, determine the drug amount contained in a unit dosage form, and recognize that the amount of the active ingredient contained in the unit dosage form should be designed as a dose for a single administration, except for high-dose formulations. Thus, from the fact that the amount of tadalafil in the tablet disclosed in Prior Art 1 is 50mg, a person skilled in the art would recognize 50mg as a single daily dose, and would easily find out that tadalafil's therapeutic effect on erectile dysfunction

will show when the single daily dose is 50mg.

② From that Prior Art 1 suggests 0.5mg as a lower limit of a daily dose, a person skilled in the art can predict that as the dose escalates from 0.5mg, the efficacy will increase at the early stage, but after it reaches a certain level, it will not increase anymore and reach plateau even if the dose is increased.

③ From the expectations ① and ② above, a person skilled in the art would try to observe dose-response of tadalafil, starting from 0.5mg dose and escalating it to 50mg, and confirm whether the plateau (the point where the drug efficacy does not increase any more even if the dose is increased) exists within the dose range.

④ Since it was known that PDE5 inhibition mechanism causes the adverse effects of headache, flushing, dyspepsia, vision abnormalities, rhinitis, etc., a person skilled in the art can easily recognize that the administration of tadalafil, a PDE5 inhibitor, would result in such adverse effects, although Prior Art 1 has no explicit descriptions regarding the adverse effects of tadalafil. Further, a person skilled in the art can predict that if the adverse effects occur by administering tadalafil, such adverse effects can be reduced by lowering the dose since the adverse effects resulting from PDE5 inhibition mechanism was known to show in dose-dependent manner.

⑤ In the medicinal field aiming to treat life-threatening disease, there are many cases which have to bear the adverse effects to a certain level that come from the treatment for life supporting. On the contrary, in the field of the medicinal invention to improve the life quality such as the treatment of sexual dysfunction, in the most cases, minimizing the adverse effects would take preference over maximizing efficacy. Further, in spite of the commercial success of sildenafil, sildenafil was evaluated to have limitations due to the considerably

harmful adverse effects. When the adverse effects due to the PDE5 inhibition mechanism occur in the use of tadalafil, a person skilled in the art would try to find out a dose which minimizes the adverse effects by reducing the dose of tadalafil.

⑥ In the drug development process, it is common for a person skilled in the art to modify the drug development strategy based on clinical trial results, to conduct again the clinical trials of the previous phase, or to conduct additional clinical trials of the previous phase. Further, when processing the clinical trials, even if the adverse effects occur at a certain dose, it is common to overlook the adverse effects and conduct the subsequent phase and then return to the previous phase with low doses considering the correlation of drug efficacy and toxicity, etc. to secure the safety of the drug.

⑦ No material suggests that a person skilled in the art would consider that tadalafil cannot exert efficacy or shows serious adverse effects within the dose range of the maximum daily dose limited in Claim 1 of the Subject Invention.

(2) Significance of the Effects

We now review whether the efficacy and adverse effect of tadalafil in the range of "up to a maximum total dose of 20 mg per day" specified in Claim 1 of the Subject Invention are significant effects that a person skilled in the art could not have expected.

(a) The therapeutic effect and adverse effects described in the specification of the Subject Invention

① Example 5 describes that "this study was to evaluate the hemodynamic effects of concomitant administration of tadalafil and short-acting nitrates on healthy male volunteers. In this study, the subjects received either tadalafil at a dose of 10 mg or a placebo,

daily for seven days. On the sixth or seventh day, the subjects received sublingual nitroglycerin (0.4 mg) while supine on a tilt table. The nitroglycerin was administered 3 hours after tadalafil dosing, ··· there were no discontinuations among the twenty-two healthy male subjects (ages 19 to 60 years old). In a preliminary analysis of this study, tadalafil ··· showed no serious adverse events. ··· The most common adverse events were headache, dyspepsia, and back pain. Tadalafil demonstrated minimal, if any, effect on mean systolic blood pressure, and mean maximal nitroglycerin-induced decrease in systolic blood pressure."

② Example 6 describes that "tadalafil was administered to patients in need thereof at a range of doses, in both daily dosing and for on demand therapy. Doses from 5 to 20 mg of tadalafil were efficacious and demonstrated less than 1% flushing and no reports of vision abnormalities. It was found that a 10 mg dose of tadalafil was fully efficacious and demonstrated minimal side effects. ··· Tadalafil significantly improved ··· the ability to attain and maintain an erection in both "on demand" and daily dosing regimens."

③ Example 7 describes as follows.

- ○ Tadalafil was administered in 2 mg, 5 mg, 10 mg, and 25 mg doses, "on demand" and once every not more than 24 hours. Treatment with all nitrates, azole antifungals ··· was not allowed at any time during the study.
- ○ At endpoint, patients who rated their penetration ability (IIEF Question 3) as "almost always or always" were as follows: 17.5% in the placebo group, 38.1% in the 2 mg group, 48.8% in the 5 mg group, 51.2% in the 10 mg group, and 83.7% in the 25 mg group. Comparisons revealed statistically significant differences in change in penetration ability between placebo and all dose levels of tadalafil.

○ At endpoint, patients who rated their ability to maintain an erection (IIEF Question 4) during intercourse as "almost always or always" are as follows: 10.0% in the placebo group, 19.5% in the 2 mg group, 32.6% in the 5 mg group, 39.0% in the 10 mg group, and 69.0% in the 25 mg group. Comparison revealed statistically significant differences in change in penetration ability between placebo and the three higher dose levels of tadalafil.

○ This study also included a safety evaluation. ··· The most commonly reported treatment-emergent adverse events were headache, dyspepsia, and back pain. The incidence of treatment-emergent adverse events appeared related to dose.

○ Overall, this study demonstrated that all four doses of tadalafil, namely 2 mg, 5 mg, 10 mg, and 25 mg, taken "on demand" produced significant improvement, relative to placebo, in the sexual performance of men with erectile dysfunction.

○ Administration of tadalafil showed to effectively treat male erectile dysfunction, as illustrated in the following table.

IIEF ERECTILE FUNCTION DOMAIN (Change from Baseline)			
Unit Dose of Compound (I)	**n**	**Mean ± SD**	**p**
placebo	131	0.8 ± 5.3	
2 mg	75	3.9 ± 6.1	<.001
5 mg	79	6.6 ± 7.1	<.001
10 mg	135	7.9 ± 6.7	<.001
25 mg	132	9.4 ± 7.0	<.001
50 mg	52	9.8 ± 5.5	<.001
100 mg	49	8.4 ± 6.1	<.001

n is number of subjects, SD is standard deviation.

○ It was observed that the percent of treatment-emergent adverse events increased with an increasing unit dose of tadalafil, as illustrated in the following table:

Treatment-Emergent Adverse Events (%)							
	Unit Dose of Compound (I) (mg)						
Event	Placebo	2	5	10	25	50	100
Headache	10	12	10	23	29	34	46
Dyspepsia	6	3	14	13	19	20	25
Back Pain	5	3	3	15	18	24	22
Myalgia	3	0	3	9	16	20	29
Rhinitis	3	7	3	4	4	0	2
Conjunctivitis	1	0	1	1	0	2	5
Eyelid Edema	0	0	0	1	1	2	3
Flushing	0	0	0	<1	0	3	7
Vision Abnormalities	0	0	0	0	0	0	0

○ The above table shows an increase in adverse events at 25 mg through 100 mg unit doses. Accordingly, even though efficacy in the treatment of ED was observed at 25 mg to 100 mg doses, the adverse events observed from 25 mg to 100 mg doses must be considered.

④ The specification of the Subject Invention describes that “a unit dose of about 1 to about 20 mg, preferably about 2 to about 20 mg, more preferably about 5 to about 20 mg, and most preferably about 5 to about 15 mg, of tadalafil, administered up to a maximum of 20 mg per 24-hour period, both effectively treats ED and minimizes or eliminates the occurrence of adverse side effects. Importantly, no vision abnormalities were reported and flushing was essentially eliminated. Surprisingly, in addition to treating ED, with at about 1 to about 20 mg unit dose tadalafil, with a minimum of adverse side effects, individuals undergoing nitrate therapy also can be treated for ED by the method and composition of the present invention.”

(b) Detailed Analysis

From the following circumstances deduced from the above and the

facts found in Item (1) above, the effects exerted in the range of "up to a maximum total dose of 20 mg per day" specified in Claim 1 of the Subject Invention cannot be deemed as significant effects in terms of increased efficacy, decreased adverse effects, or improved patient convenience, etc. which cannot be predicted by a person skilled in the art.

① As discussed above, it is general that as the dose increases, the efficacy increases at the early stage. However, after reaching a certain level, the efficacy will not increase anymore and remain the same, and the erectile dysfunction treatment profile of tadalafil in Example 7 above is generally consistent with a typical dose-response profile.

② The fact that the adverse effects such as headache, flushing, dyspepsia, vision abnormalities, rhinitis, etc. occur from the inhibition mechanism of PDE5 was already known, and it was also already known that the adverse effects due to PDE5 inhibition mechanism above are produced in dose-dependent manner. Therefore, the descriptions that "it was observed that the percent of treatment-emergent adverse events increased with an increasing unit dose of tadalafil" described in Example 7 and the descriptions described in the table, i.e., the fact that the adverse effects of headache, dyspepsia, back pain, myalgia, conjunctivitis, eyelid edema, flushing, etc. tend to show increased occurrence rate as the administered dose increases, is consistent with the technical common knowledge and known technology above.

③ The specification describes that "a unit dose of about 1 to about 20 mg, preferably about 2 to about 20 mg, more preferably about 5 to about 20 mg, and most preferably about 5 to about 15 mg, of tadalafil, administered up to a maximum of 20 mg per 24-hour period, both effectively treats ED and minimizes or eliminates the occurrence of adverse side effects," and Example 6 merely describes "was efficacious," "was fully efficacious," "significantly improved ··· the

ability" as to the therapeutic effect for erectile dysfunction. The above descriptions are not sufficient to be recognized as the quantitative and objective data for the therapeutic effect for erectile dysfunction of "up to a maximum total dose of 20 mg per day." Further, Example 7 discloses test results of administrating 2 mg, 5 mg, 10 mg, and 25 mg doses, "on demand and once every not more than 24 hours," but the phrase "on demand and once every not more than 24 hours" does not exclude the meaning that tadalafil can be administered several times in 24 hours. Thus, the efficacy of "up to a maximum total dose of 20 mg per day" is not confirmed from the data on any doses in Example 7. Especially, the table in Example 7 only describes the efficacy of the unit dose, but not the efficacy of the daily maximum total dose.

④ Example 5 describes that in concomitant administration of 10mg tadalafil and nitroglycerin on healthy male volunteers, tadalafil demonstrated minimal effect on mean maximal nitroglycerin-induced decrease in systolic blood pressure, however, Example 7 describes that when tadalafil was administered in 2 mg, 5 mg, 10 mg, and 25 mg doses, treatment with all nitrates were ceased. Moreover, there is no objective basis to consider that the test results of Example 5 obtained from healthy volunteers would also support the effect in patients having cardiovascular diseases suffering from hypertension, angina, etc. Further, the specification does not describe which effect would show when 20mg tadalafil and nitroglycerin are concomitantly administered.

⑤ Before the priority date of the Subject Invention, it was known that sildenafil's selectivity of PDE5 over PDE6 is 10; that a lower selectivity would lead to adverse side effect of vision abnormalities; and that sildenafil was evaluated as not lived up to the expectations in spite of its commercial success since it has serious adverse effects. Therefore, a person skilled in the art would have tried to minimize the occurrence of the adverse effect induced by the PDE5 inhibition mechanism of tadalafil. In this regard, as it was disclosed in Prior Art

1 that tadalafil is a potent and selective PDE5 inhibitor, a person skilled in the art can sufficiently predict that tadalafil would show less adverse effect of vision abnormalities compared to sildenafil due to its property as potent and highly selective PDE5 inhibitor. Furthermore, Example 7 discloses the fact that tadalafil shows 0% occurrence of vision abnormalities for all doses irrespective of administered dose, and this is consistent with the above prediction of a person skilled in the art.

⑥ It was known before the priority date of the Subject Invention that sildenafil showed 10% occurrence of flushing due to the PDE5 inhibition mechanism, and it was reported that the frequency of adverse effect increases as sildenafil dose increases. Meanwhile, since Prior Art 1 discloses that tadalafil is a potent and selective PDE5 inhibitor, a person skilled in the art would have sufficiently predicted that tadalafil would show lower occurrence of adverse effect of facial flushing compared to sildenafil due to its property of tadalafil. Further, Example 7 shows 0-1% of flushing at the dose less than 50mg, 3% at the dose of 50mg, and 7% at the dose of 100mg. This is consistent with the above prediction of a person skilled in the art, and it is a known technology that the occurrence rate of adverse effect generally increases as the dose increases.

(3) Discussion on the Plaintiff's Arguments

(a) The Plaintiff argues that since the Prior Arts describe the dose of tadalafil only in a broad numerical range, do not mention about the adverse effects of tadalafil, and do not disclose clinical trials or other grounds supporting the dose, a person skilled in the art would recognize such descriptions merely as a possibility of showing therapeutic effect on erectile dysfunction when tadalafil is administered, not as an effective dose for human. The Plaintiff further argues that 50mg and 25mg unit form of tadalafil described in the working examples of the Prior Arts are a mere exemplification of an

amount that can be used when tadalafil is manufactured as a formulation, but is not described to the effect that the dose of tadalafil can be used for the treatment of erectile dysfunction showing therapeutic effect while minimizing the adverse effects. In addition, the Plaintiff alleges that the effective administration dose for human cannot be predicted only from IC_{50} values of tadalafil and sildenafil described in the Prior Arts. Furthermore, with regard to minimizing the adverse effect, the Plaintiff alleges that a person skilled in the art would not merely have attempted to decrease the dose to solve the problem of adverse effects since the efficacy would also decrease as the dose decreases.

In this regard, as discussed above, Prior Art 1 is directed to the use of tadalafil for the treatment of erectile dysfunction or male sexual dysfunction, and suggests general dose for oral administration by disclosing tadalafil amount in unit dosage form as 50mg. Such description cannot be deemed as merely mentioning a random dose because a person skilled in the art would have recognized the amount contained in the above unit dosage form as a dose suitable to exert the therapeutic effect when used for the above therapeutic use. Further, since it was already known that PDE5 inhibitor like tadalafil shows adverse effects of headache, flushing, dyspepsia, vision abnormalities, rhinitis, etc. due to PDE5 inhibition mechanism and that such adverse effects are dose dependent, even if Prior Art 1 does not explicitly describe the adverse effects of tadalafil, a person skilled in the art would have easily recognized that the above adverse effects will occur when tadalafil is administered.

In addition, to determine the dose of a drug product, a person skilled in the art would thoroughly review every preclinical data including IC_{50} and consider the conventional knowledge, etc. regarding the drugs with identical efficacy or the drugs with similar structure. Based on the above, a person skilled in the art would have estimated a dose that is expected to be sufficiently safe for humans and set it as a starting dose, subsequently administered the dose, escalating it

step-by-step until the dose exceeds the estimated single dose of the clinical trial. Further, a person skilled in the art would have researched the pharmacological actions, pharmacokinetics, and adverse effects related to the dose increase, and determined the multiple doses and administration period according to the test results, and find the dose and administration method to maintain the maximum efficacy with minimum adverse effects. The above process falls within the technical common knowledge and the dose and administration method of tadalafil limited in Claim 1 are not deemed as different from those determined by the well-known process above.

It is true that the purport of the overall argument the descriptions of Plaintiff's Exhibit 47, and witness testimony of Sang-gun Kim and Ji-young Park suggest that a person skilled in the art could not have predicted that tadalafil's effective dose for human would be only half of that of sildenafil merely from the fact that IC_{50} of sildenafil and tadalafil, PDE5 inhibitors, is 3-3.9nM and 2nM, respectively. However, the fact above alone cannot be said to hinder a person skilled in the art from finding the effective dose for human through clinical trials by thoroughly reviewing every data from the preclinical trials and considering the conventional knowledge about the drugs with identical efficacy and the drugs with similar structure, etc. Therefore, we cannot conclude that it would have been difficult for a person skilled in the art to find the dose and administration method of tadalafil limited in Claim 1 of the Subject Invention, simply based on the reasons that the Prior Arts describe the dose of tadalafil merely in a broad numerical range, do not mention the adverse effects of tadalafil, and disclose only IC_{50} values of sildenafil and tadalafil without clinical trial results supporting the effective dose for human or any other grounds.

Thus, the Plaintiff's argument above is without merit.

(b) The Plaintiff asserts that the development of the dose limited in Claim 1 of the Subject Invention is based on efforts beyond the common level since the claimed dose is much lower than expected

from the results of phase 1 clinical trials; three (3) pharmaceutical companies participated in the development; another phase 1 clinical trial was conducted again almost at the same time with phase 2 clinical trial even after conducting three (3) phase 1 clinical trials in order to supplement the results in elder volunteers; and then two (2) more phase 2 clinical trials were conducted.

In this regard, the standards of inventiveness of patented invention is not based on the degree of difficulty of the procedure that the inventor went through to achieve the invention, but based on whether a person skilled in the art can easily derive such invention from the Prior Arts and others. As discussed above, in the field of medicinal invention, it is within the scope of creative ability of a person skilled in the art to optimize the dose and administration method of a known substance to maintain the efficacy while minimizing the toxicity or adverse effects. Further, considering that the clinical trial process may be influenced by the individual situations such as the investment scale of a company performing clinical trials, the size of a trial, the technical level of the clinicians, etc., and may be to some extent related to the developer's determination on the marketability, etc., it cannot be concluded that such procedure of clinical trials necessarily came from the technical difficulties.

Thus, the Plaintiff's argument is without merit.

(c) Further, the Plaintiff asserts that considering that most of the patients have chosen 50mg, 150mg as sildenafil dose, even though 25mg, 50mg, 100mg of sildenafil doses were approved, a person skilled in the art would have considered high-dose such as 50mg or 100mg when determining the dose of tadalafil referring to sildenafil.

In this regard, as discussed above, to determine a dose of a drug, a person skilled in the art would have thoroughly reviewed every preclinical data including IC_{50} and considered the conventional knowledges on the drugs with identical effect or the drugs with similar structure. Based on the above, a person skilled in the art would have

estimated a dose that is expected sufficiently safe for humans and set it as a starting dose, subsequently administered by escalating the dose to determine the optimal dose and administration method of a drug. Therefore, we cannot conclude that a person skilled in the art would have determined the dose of tadalafil referring to the approved doses or the doses with patient preference of sildenafil.

Moreover, a person skilled in the art would not have selected high doses in priority when determining the dose of tadalafil, considering that the dose with patient preference and the optimal dose which enhances the efficacy while minimizing the adverse effects belong to different area, and that unlike the case which has to bear the adverse effects to a certain level that come with the treatment for life supporting, in the field of the medicinal invention to improve the life quality such as treatment for sexual dysfunction, to find the dose minimizing adverse effects would be considered as more important in the clinical trials.

Here too, the Plaintiff's argument fails.

(d) The Plaintiff argues that a person skilled in the art could not have expected the effects of the dose and administration method limited in Claim 1 of Subject Invention at the time of priority date since the claimed dose and administration method achieved the effect that maintains full efficacy for treatment of erectile dysfunction while substantially eliminating the adverse effects, i.e., flushing, vision abnormalities, and blood pressure drop when co-administered with nitrates, etc., which were deemed as unavoidable by inhibition of PDE5, and particularly substantially no adverse effects were shown at the dose of 5 mg or less, compared with the placebo group.

However, as discussed in Item '(2)(b)' above, we cannot conclude that the adverse effect of blood pressure drop when co-administered with nitrates would not occur in the patients suffering from cardiovascular diseases at all the doses specified in Claim 1 of the Subject Invention. Similarly, we cannot be certain that the absence of

adverse effects such as flushing and vision abnormalities could not have been predicted by a person skilled in the art at the time of the priority date.

Thus, Plaintiff's argument above is rejected.

(e) The Plaintiff argues that since the Prior Arts include no descriptions on the effects comparable with Claim 1 of the Subject Invention, except that tadalafil has therapeutic effect for erectile dysfunction, a person skilled in the art would have referred to sildenafil, which was the only approved drug for erectile dysfunction at the time of the priority date; however, the dose and administration method limited in Claim 1 of the Subject Invention are exceptionally more excellent compared to sildenafil in terms of the adverse effects of flushing, decrease in blood pressure when nitrate is co-administered, vision abnormalities, and also in terms of therapeutic effects. In particular, the Plaintiff alleges that while tadalafil shows significantly reduced adverse effect of vision abnormalities compared to sildenafil due to its very high PDE5/PDE6 selectivity, high PDE5/PDE6 selectivity of tadalafil was unknown at the time of the priority date, and thus such an effect is unexpectedly significant.

In this regard, Prior Art 1 does not explicitly disclose the adverse effects of tadalafil, however, discloses that tadalafil is a PDE5 inhibitor. Therefore, a person skilled in the art would have obviously recognized that tadalafil would have had the adverse effects due to PDE inhibition such as flushing, drop in blood pressure in the patients taking nitrates. Further, as discussed above, it is difficult to recognize that the dose range limited in Claim 1 of the Subject Invention shows unexpectedly significant effect of reducing the adverse effects,

In addition, as long as the use of tadalafil for the treatment of sexual dysfunction is disclosed in Prior Art 1, the effect in the range of the total daily dose of tadalafil specified in Claim 1 of the Subject Invention should be compared with that inferred from the dose of tadalafil disclosed in Prior Art 1, but not with sildenafil. However,

since tadalafil's high selectivity for PDE5 is merely an intrinsic property and no new use was found over the Prior Art 1 based on such high selectivity, the discovery that tadalafil produces reduced adverse effects of vision abnormalities, flushing, etc. because of its intrinsic property is deemed as merely identifying the pharmaceutical effect already disclosed in Prior Art 1 during the drug development process.

Thus, the Plaintiff's argument above is also without merit.

(f) The Plaintiff argues that from the fact that the denial rate of drug approval is as high as 18.8% in which the denial was due to the failure to select optimal dose and administration method of new drug candidate, it is recognized that the development of dose and administration method is a difficult factor in the success of new drug development; and since the development of dose and administration method requires cost and efforts for the long-term clinical trials, it should be encouraged to protect it as a patent and thus its inventiveness should be acknowledged.

First of all, according to the descriptions of Plaintiff's Exhibit 46, it is acknowledged that 151 applications failed to obtain product approval in the first review cycle among 302 new drug applications, and 15 applications among them were rejected because of failure to select optimal dose (Plaintiff's Exhibit 46, Figure in page 380, Table 2 in page 381); and the approval success rate largely differs by diseases (Plaintiff's Exhibit 46, page 380, Table 1). From the above facts, it is recognized that about 5% of new drug applications was rejected due to the optimal dose problem, however, it is difficult from the above numbers to conclude that the selection of optimal dose for a new drug is significantly difficult, or that the failure rate of selecting the optimal dose above represent the overall failure rate for treatment of sexual dysfunction.

Further, granting patents for all the medicinal inventions only for the reason that the clinical trials required long time and great expense, it

would not comply with the fundamental purpose of the Patent Act which grants an exclusive right for a certain period in return for contributing to industrial development by publishing novel and inventive invention. Moreover, under the current law system, to compensate for the cost, time, and effort of the new drug developer on the clinical trials, a generic applicant for a product approval cannot refer to the clinical trials data of the original developer during the re-examination period of the original new drug. Therefore, the data obtained from the clinical trials is substantially protected. As to the period required for the clinical trials for new drug product approval, it can be compensated by the patent term extension. Considering the above, the fact alone that the cost and efforts are required for the long-term clinical trials in developing the dose and administration method does not necessarily mean that the dose and administration should be protected as a patent.

Thus, the Plaintiff's above argument is also rejected.

(g) The Plaintiff argues that since the competence of Korea in clinical trials for developing administration method and dose is at a world-class level, protecting inventions related to the dose and administration method would contribute to the domestic industrial development in the long term, and thus the inventiveness thereof should be broadly acknowledged.

However, during the drug development process, the dose and administration method can be derived through clinical trials, and such clinical trials are generally conducted before the expiration of substance patent and medicinal use patent. Therefore, it is not practical for a person who is not a patentee of the substance to conduct clinical trials and develop the dose and administration method. In addition, it is difficult to recognize the correlation between the domestic industrial development and granting the dose and administration method as a patent when they are commonly identified during the drug development process.

Thus, the Plaintiff's argument here is also without merit.

D) Discussion on Difference 2

Claim 1 of the Subject Invention limits the amount of tadalafil contained in unit dosage form to 1-20mg. If the daily dose is determined, the amount in the unit dosage form can be appropriately selected according to the daily dose by a person skilled in the art as needed. Thus, limiting the amount of the unit dosage form as in Claim 1 of the Subject Invention has no particular technical significance.

Therefore, since a person skilled in the art can easily overcome Difference 2, no difficulty in composition or significant effect is present.

3) Summary

Based on the foregoing, a person skilled in the art can easily overcome the differences between Claim 1 of the Subject Invention and Prior Art 1 based on Prior Arts 1 and 2, and thus no difficulty in composition is shown. Further, no significant effect is shown since the effect is no more than that can be expected by a person skilled in the art. Thus, the inventiveness of Claim 1 of the Subject Invention is denied.

C. Inventiveness of Claims 2 to 13 of the Subject Invention

1) Claims 2 to 9 of the Subject Invention are dependent claims which directly or indirectly refer to Claim 1 of the Subject Invention, and limit the amount of tadalafil contained in the unit dosage form to 2-20mg, 5-20mg, 2.5mg, 5mg, 10mg, 2mg, 1-5mg, and 20mg respectively.
However, as discussed above, if the daily dose is determined, the amount in the unit dosage form can be properly selected according to the daily dose by a person skilled in the art as

needed. Thus, specifying the amount of the unit dosage form as in Claims 2 to 9 of the Subject Invention has no special technical significance.

2) Claims 10 and 11 of the Subject Invention refer to any one of Claims 1 to 9 of the Subject Invention, and limit the form to liquid, tablet, capsule, or gelcap. However, Prior Art 1 discloses the form of tablet and capsule comprising tadalafil (Plaintiff's Exhibit 5, pages 14-18), and a person skilled in the art can select a proper form of unit dosage form as needed. Therefore, the element additionally limited by Claims 10 and 11 of the Subject Invention has no specific technical significance.

3) Claims 12 and 13 of the Subject Invention refer to any one of Claims 1 to 9 and additionally limit the medicinal use to male erectile dysfunction or female arousal disorder.
However, since Prior Art 1 discloses that tadalafil is useful for the treatment of male erectile dysfunction or female sexual dysfunction including orgasmic dysfunction related to clitoral disturbance (Plaintiff's Exhibit 5, page 4, lines 25-28), the feature additionally limited in Claims 12 and 13 of the Subject Invention is identical to that of Prior Art 1.

4) Therefore, the inventiveness of Claims 2 to 13 of the Subject Invention is not recognized based on Prior Arts 1 and 2.

D. Summary of Analysis: Whether the IPTAB erred in its decisions

Considering all the foregoing, the Subject Invention is invalid for lack of inventiveness. Thus, the IPTAB did not err in its decisions contrary to the Plaintiff's belief.

4. Conclusion

Therefore, the Plaintiff's action is without merit, and is dismissed as stated in the Order.

Presiding Judge Hyeongjun PARK
Judge Hyejin LEE
Judge Hyeonseop JIN

PATENT COURT OF KOREA
ELEVENTH DIVISION
DECISION

Case Nos.: 2016Heo4498 Invalidation of Patent Term Extension (Patent)
2016Heo4504 (consolidated) Invalidation of Patent Term Extension (Patent)
2016Heo4511 (consolidated) Invalidation of Patent Term Extension (Patent)
2016Heo5620 (consolidated) Invalidation of Patent Term Extension (Patent)

Plaintiffs: 1. HanWha Pharma Co., Ltd.
2. Intro Pharm Tech Co., Ltd.
3. Huons Co. Ltd, as a party taking over Huons global, Co. Ltd.'s lawsuit.
4. Ildong Pharmaceuticals Co. Ltd. (company registration number: *******-*******) as a party taking over the lawsuit by Ildong Holdings Co. Ltd. (previously Ildong Pharmaceuticals, Co. Ltd, company registration number: 110111-0012776)

Defendant: Astellas Seiyaku Kabushiki kaisha

Date of Closing Argument: February 13, 2017

Decision Date: March 16, 2017

ORDER

1. The Plaintiffs' petitions are dismissed.

2. The litigation cost shall be borne by the Plaintiffs.

PLAINTIFF'S DEMAND

[2016Heo4498] The IPTAB decision regarding Case No. 2015Dang2502 between Plaintiff 1 and the Defendant dated May 23, 2016 shall be revoked.

[2016Heo4504] The IPTAB decision regarding Case No. 2015Dang2508 between Plaintiff 2 and the Defendant dated May 23, 2016 shall be revoked.

[2016Heo4511] The IPTAB decision regarding Case No. 2015Dang2521 between Plaintiff 3 before the takeover of proceedings by its successor and the Defendant dated May 23, 2016 shall be revoked.

[2016Heo5620] The IPTAB decision regarding Case No. 2015Dang2660 between Plaintiff 4 before the takeover of proceedings by its successor and the Defendant dated May 23, 2016 shall be revoked.

OPINION

1. Background

A. The Patented Invention Subject to Patent Term Extension (hereinafter the "Subject Patent")

1) **Title of Invention:** Remedy for overactive bladder comprising acetic acid anilide derivative as the active ingredient

2) **International Filing Date/ Priority Date / Application Number/ Registration Date/ Patent Number:** November 4, 2003/ November 7, 2002/ KR 10-2005-7008158/ June 23, 2010/ Patent No. 967070

B. The Subject Patent Term Extension ("PTE")

1) Procedural History

A) The Subject PTE Application / Application No.: March 28, 2014/ KR 10-2014-37236

B) The PTE Applicant: Defendant

C) Extendable term as filed: 382 days[1] [domestic clinical trial period after the registration date of the patent (48 days in total, which is from June 23, 2010 [the registration date of the patent] to August 10, 2010 [the clinical trial termination date]) + period spent for product import approval (334 days in total, which is from January 31, 2013 [the filing date for product import approval application] to December 31, 2013 [the product import approval date])].

D) Decision for registering extension: January 20, 2015

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1) Article 6 (description manner of an application for registering extension) (1)(vi) of the stipulation regarding the old extension system operation of a patent term (August 21, 2015, before the amendment of No. 2015-19 of the KIPO Notification), which is the regulation of office work within KIPO) stipulates that "the period of filing an extension describes, such as "OOO days," the period calculated by the stipulation of Article 4."

2) Content of the PTE

A) Claims whose term was extended: Claims 1-10 (hereinafter, “the Subject Extended Invention”)

B) Expiration date before extension: November 4, 2023

C) Extended term: 382 days

D) Content of approval or registration: Article 29 of the product import approval of pharmaceutical

C. History and content of product import approval of pharmaceutical (hereinafter, “the Subject Approval”)

1) History of the Subject Approval

Astellas Korea Co., Ltd. (hereinafter, “Astellas Korea”) filed an application for a product import approval of pharmaceutical regarding Betmiga sustained-release tablet 50 mg (drug substance: Mirabegron), i.e., the pharmaceutical for which the Subject Approval was filed. The history of corresponding clinical trial and product import approval is as follows. The Subject Approval was carried out including product approval and GMP evaluation for Betmiga sustained-release tablet 50mg, (i.e., drug product), and, and DMF examination for Mirabegron, (i.e., drug substance) at the same time.

	Date	Event			
		Patent Grant/ clinical trial	Product Approval (Safety and Efficacy examination[2] / Standards and Test Methods examination[3])	GMP evaluation[4]	DMF examination[5]
1	December 21, 2009	Start of the clinical trial			
2	June 23, 2010	Registration of the Patent Right			
3	August 10, 2010	Clinical trial termination			
4	January 31, 2013		Filing an application for product import approval	Filing an application for GMP evaluation	Filing of DMF files

2) Safety and Efficacy examination refers to the examination on the safety and efficacy such as a clinical trial result, toxicity, pharmacological action, etc. of a pharmaceutical subject to approval (hereinafter referred to as "S/E examination").

3) Pharmaceutical's standards and test methods examination refers to the examination on whether to set a standard for the manufacture of a pharmaceutical item and the quality management [e.g., character, purity, content, quantitative method, special test (digestive capacity, microorganism test), etc.] and a specific test method for confirming the above. (hereinafter referred to as "S/T examination").

4) Pharmaceutical manufacture and quality management standard (Good Manufacturing Practice) refers to the standard that should be complied with in the overall manufacturing process from the purchase of substance to the manufacture, package, shipment, including the structure/facility of factories for preparing superior pharmaceuticals with guaranteed quality. Good Manufacturing Practice evaluates whether such standards are satisfied (hereinafter referred to as "GMP evaluation").

5) Drug substance information (Drug Master File) refers to the information regarding drug substance, i.e., facility specification of the corresponding substance factory, impurities, remaining organic solvent, process management, packaging materials, safety test materials, etc. regarding drug substance. Drug Master File evaluates the above items (hereinafter referred to as "DMF examination").

	Date	Event			
		Patent Grant/ clinical trial	Product Approval (Safety and Efficacy examination / Standards and Test Methods examination)	GMP evaluation	DMF examination
5	March 20, 2013		Request for the supplemental documentation of Safety/Efficacy and Standards/Test Methods		Request for DMF supplemental documentation
6	May 29, 2013		Submission of the supplemental documentation of Safety/Efficacy and Standards/Test Methods		Submission of DMF supplemental documentation
7	July 3, 2013				Reply to the consultation for material (Standards/Test Methods) examination[6]
8	July 4, 2013		Consultation reply		
9	July 25, 2013			Request for GMP supplemental documentation	

6) "DMF examination" is conducted by dividing into ① material examination regarding the quality of drug substance conducted in a pharmaceutical standard division, and ② material examination regarding the manufacture facility of drug substance and factual survey conducted in a pharmaceutical quality division. "Material (S/T) examination consultation reply" refers to the consultation reply for ①.

	Date	Event			
		Patent Grant/ clinical trial	Product Approval (Safety and Efficacy examination / Standards and Test Methods examination)	GMP evaluation	DMF examination
10	December 4, 2013				Consultation reply for substance (GMP)[7]
11	December 12, 2013			Submission of GMP supplemental documentation	
12	December 20, 2013			Consultation reply	
13	December 31, 2013		Pharmaceutical product import approval		
14	December 31, 2013		Issuance of product import approval certificate		

2) Content of the Subject Approval

A) Date of decision of product import approval: December 31, 2013

B) Date when the product import approval certificate arrived to the applicant (issuance date of the product import approval certificate): December 31, 2013

7) "Substance (GMP) consultation reply" refers to a consultation reply for ② of footnote 6).

C) Content of the approval: product import approval of pharmaceutical under the stipulation of Article 42(1) of the Pharmaceutical Affairs Act.

D) Product for which the approval was filed: Betmiga sustained-release tablet 50 mg (Mirabegron)

E) Use of the product for which the approval was filed: treatment of urinary urgency, urinary frequency, and/or urgent urinary incontinence symptoms that may be occurred in overactive bladder patients

D. Decision of the IPTAB

1) On April 10, 2015, Plaintiff 1 filed for IPTAB 2015Dang2502, Plaintiff 2 filed for IPTAB 2015Dang 2508, Plaintiff 3[8] before the takeover of proceedings filed for IPTAB 2015Dang 2521, Plaintiff 4[9] before the takeover of proceedings filed for

8) The name of the company at the time of filing the petition was "Huons Co., Ltd (corporate registration number: 110111-0400202)" but the company name was changed into "Huons global Co., Ltd" on May 3, 2016 and through a company division under a commercial law, "Huon Co., Ltd (corporate registration number: 131111-0446029)" was newly established. Meanwhile, the above newly established company takes all the rights/duties regarding the business parts of the pharmaceutical, including the subject suit.

9) The company name at the time of filing the petition was "Ildong Pharmaceuticals Co., Ltd (corporate registration number: 110111-0012776)" but the company name was changed into "Ildong Holdings Co., Ltd" on August 1, 2016 and through a company division under a commercial law, "Ildong bioscience Co., Ltd," "Ildong Hyaltech Co., Ltd," and "Ildong Pharmaceuticals Co., Ltd. (corporate registration number: ******-*******)" were newly established. Meanwhile, "Ildong Pharmaceutical Co., Ltd (corporate registration number: ******-*******)," which is a newly established company, takes all the

IPTAB 2015Dang 2660 and argued, each against the Defendant, that "① the Subject PTE should be invalidated under Article 134(1)(iii) of the Patent Act because the extended term exceeds the period during which the Subject Extended Invention would not have been practiced; and ② the Subject PTE should be invalidated under Article 134(1)(ii) of the Patent Act because the extension has been registered with respect to an application of which approval, etc. under the Pharmaceutical Affairs Act was not obtained by the patentee, or an exclusive licensee or a registered non-exclusive licensee; "and filed an invalidation trial for the Subject PTE (hereinafter, "each petition of the subject case").

2) IPTAB deliberated on each petition of the subject case by consolidating those petitions and made a decision to dismiss each petition of the subject case based on the following reasons (hereinafter, "the IPTAB Decisions").

① The period spent for a clinical trial after the registration date of the patent right is 48 days, which is from June 23, 2010 (i.e., the registration date of the patent) to August 10, 2010 (i.e., the termination date of the clinical trial), and the period spent for product import approval regarding Betmiga sustained-release tablet 50 mg, i.e., the pharmaceutical for which the Subject Approval was filed, is 334 days, which is from January 31, 2013 (i.e., the filing date of product import approval) to December 31, 2013 (i.e., the date of product import approval).

For calculating the Extendable term of the Subject PTE, the period attributable to the patentee should be excluded from the above 334 days. In the case where Safety/Efficacy examination request, Standards/Test Methods examination request, application for GMP evaluation, and DMF

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rights/duties regarding the business parts of the pharmaceutical, including the subject suit.

request, etc. which are required for obtaining a product approval of pharmaceuticals, are submitted/filed before Ministry of Food and Drug Safety (MFDS),[10] each division in charge within MFDS independently carry out the examination and individually request for documentation supplementation when there is a material in need of supplementation. Therefore, even when a certain division request for supplementation and the examination is stopped during the supplementation, if other divisions carries out the examination, the approval is not considered to be delayed during that period due to the reason attributable to the patentee.

The period during which the examination is stopped in MFDS includes Ⓐ from March 20, 2013 (i.e., the date of supplemental request in relation to Safety/Efficacy and Standards/Test Methods examination and DMF) to May 29, 2013 (i.e., the submission date of the supplemental documentation) (hereinafter, "period 1") and Ⓑ from July 25, 2013 (the date of supplemental request in relation to GMP) to December 12, 2013 (i.e., the submission date of the supplemental documentation) (hereinafter, "period 2"). However, GMP evaluation was carried out during the period 1, and Safety/Efficacy and Standards/Test Methods examination and DMF review were carried out during the period 2. Therefore, among the periods spent for product import approval regarding Betmiga sustained-release tablet 50 mg, i.e., the pharmaceutical for which the Subject Approval was filed, there is no overlapped period for supplementation request. Accordingly, the period during which the Subject Extended Invention would not have been practiced is 382 days, which is the sum of 48 days (period spent for the clinical trial after the registration date of the patent) and 334 days (period spent for product import approval regarding Betmiga sustained-release tablet 50 mg, i.e., the pharmaceutical for which the Subject Approval was filed).

Since the Extendable term of the Subject PTE does not exceed the period during which the Subject Extended Invention would not have been practiced, the Subject PTE does not have an invalidation ground stipulated under Article 134(1)(iii) of the Patent Act.

② If a person who received a product approval of pharmaceutical is closely related with the patentee, even if that person was not "a registered non-exclusive licensee" at the time of receiving the approval thereof, if

the grant/registration of the non-exclusive license was completed during the process of registering the extension of the patent term, this case does not correspond to an invalidation ground stipulated under Article 134(1)(ii) of the Patent Act.
Astellas Korea, who received the Subject Approval for practicing the Subject Patent, was not registered as a non-exclusive licensee of the Subject Extended Invention at the time of receiving the product import approval regarding Betmiga sustained-release tablet 50 mg, i.e., the pharmaceutical for which the Subject Approval was filed. However, the non-exclusive license on the Subject Patent was registered on January 24, 2014, i.e., before the filing date of the Subject PTE Application. Therefore, the Subject PTE does not have any invalidation grounds stipulated under Article 134(1)(ii) of the Patent Act.

[Factual Basis] Undisputed facts, statements in Plaintiff's Exhibits 1 to 4, Defendant's Exhibits 2-1 to 2-8, 5, 13, 14, 20, and 24, and the purport of the overall argument

2. Arguments of the Parties

A. Summary of the Plaintiffs' arguments

1) Arguments regarding Article 134(1)(iii) of the Patent Act

If an applicant for product approval submits materials suitable for stipulation or materials that do not have a tremendous problem in

10) As shown below, the organization at the time of reporting the clinical trial termination related with the Subject Approval was "Korea Food & Drug Administration." However, after that, according to the reorganization, Korea Food & Drug Administration was abolished on March 23, 2013 and Ministry of Food and Drug Safety was established. In the followings, as long as there is no separate description, regardless of before/after the reorganization, it will be referred to as "Ministry of Food and Drug safety."

pharmaceutical, a supplemental request is not required. Therefore, in the case where MFDS request a documentation supplementation during the review period of the approval material thereof, this should be considered to be attributable to the approval applicant. Therefore, the period from the date of supplementation request to the date of the submission of supplemental documentation is the period that does not correspond to a material review period and corresponds to the period elapsed due to the reason attributable to the approval applicant. However, the calculation method for extendable term adopted in the IPTAB Decisions is unlawful in light of the followings: Ⓐ a patentee may not prepare materials for some items as a strategic mean to cause a situation letting one division carry out the examination and then letting other divisions carry out the examination later by submitting remaining materials. In this case, the period spent for submitting the remaining materials is excluded from the period elapsed due to the reason attributable to the patentee, and this causes an unfair result,

Ⓑ the method to calculate the extendable term that there is no "delay" in the approval procedure under the consideration of whether other divisions of MFDS carry out the examination contradicts with the law, which states that the "spent" period, instead of "delayed" period due to the reason attributable to the patentee should be excluded from the period during which the subject invention would not have been practiced. In addition, this method does not have any legal basis, and Ⓒ this calculation method causes an unfair result of further extending the patent term compared to the case of obtaining a product import approval with a best mode without a patentee receiving a supplementation request from MFDS.

Therefore, it would be proper to calculate the Extendable term of the patent term of the subject case based on one of Calculation Methods 1 to 4 below[11]. However, the Subject PTE was made by

11) Calculation Methods 1 to 3 are argued by the Plaintiffs 1 to 3 and

exceeding the period during which the extension invention would not have been practiced due to the incorrect calculation method of the Extendable term thereof, unlike the above Calculation Methods 1 to 4. Consequently, the Subject PTE corresponds to “the case where the period extended by the extension registration exceeds the period during which the subject invention thereof would not have been practiced” stipulated under Article 134(1)(iii) of the Patent Act. Thus, the registration thereof should be invalidated.

A) Calculation Method 1

Extendable term= clinical trial period after the registration date of the patent (① of table below) + period during which the subject invention would would not have been practiced for the Safety/Efficacy examination (② of table below) − elapsed period due to the reason attributable to the patentee for Safety/Efficacy examination (③ of table below) = **132 days**

Calculation Method 4 was argued by Plaintiff 4. However, said calculation methods are all judged by the Plaintiffs' argument. The specific argument of each calculation method follows the finally summarized content: the gist of Calculation Methods 1 and 2 is summarized by the argument materials dated December 19, 2016 submitted by the representatives of Plaintiffs 1 to 3 (on the second argument date, it was submitted as a brief); the gist of Calculation Method 3 is summarized by the argument materials dated February 13, 2017 submitted by the representatives of Plaintiffs 1 to 3 (on the fourth argument date, it was submitted as a brief), and the gist of Calculation Method 4 is summarized by the description of the brief dated February 10, 2017 submitted by the representative of Plaintiff 4.

<table>
<tr><td rowspan="2"></td><td rowspan="2">Date</td><td colspan="4">Event</td><td>Extendable term</td><td>Period attributable to patentee</td></tr>
<tr><td>Patent Grant/ clinical trial</td><td>Product Approval (Safety and Efficacy examination/ Standards and Test Methods examination)</td><td>GMP evaluation</td><td>DMF examination</td><td></td><td></td></tr>
<tr><td>1</td><td>December 21, 2009</td><td>Start of the clinical trial</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>2</td><td>June 23, 2010</td><td>Registration of the Patent Right</td><td></td><td></td><td></td><td rowspan="2">①
48 days</td><td></td></tr>
<tr><td>3</td><td>August 10, 2010</td><td>Clinical trial termination</td><td></td><td></td><td></td><td></td></tr>
<tr><td>4</td><td>January 31, 2013</td><td></td><td>Filing an application for product import approval</td><td>Filing an application for GMP evaluation</td><td>Filing of DMF files</td><td rowspan="5">②
154 days</td><td></td></tr>
<tr><td>5</td><td>March 20, 2013</td><td></td><td>Request for the supplemental documentation of Safety/Efficacy and Standards/Test Methods</td><td></td><td>Request for DMF supplemental documentation</td><td rowspan="3">③
70 days</td></tr>
<tr><td>6</td><td>May 29, 2013</td><td></td><td>Submission of the supplemental documentation of Safety/Efficacy and Standards/Test Methods</td><td></td><td>Submission of DMF supplemental</td></tr>
<tr><td>7</td><td>July 3, 2013</td><td></td><td></td><td></td><td>Reply to the consultation for material (Standards/Test Methods) examination</td><td></td></tr>
<tr><td>8</td><td>July 4, 2013</td><td></td><td>Consultation reply</td><td></td><td></td><td></td></tr>
</table>

	Date	Event				Extendable term	Period attributable to patentee
		Patent Grant/ clinical trial	Product Approval (Safety and Efficacy examination/ Standards and Test Methods examination)	GMP evaluation	DMF examination		
9	July 25, 2013			Request for GMP supplemental documentation			
10	December 4, 2013				Substance (GMP) consultation reply		
11	December 12, 2013			Submission of GMP supplemental documentation			
12	December 20, 2013			Consultation reply			
13	December 31, 2013		Pharmaceutical product import approval				
14	December 31, 2013		Issuance of product import approval certificate				
Approved Extendable term		**132 days = [48 days + 154 days -70 days]**					

B) Calculation Method 2

Extendable term = clinical trial period after the registration date of the patent (① of table below) + [the entire materials review period of MFDS (② of table below) − period “elapsed” due to the patentee's attributable cause (③+④ of table below)] =**172 days**[12)]

12) The purport of this is as follows: the examination period of all the items

<table>
<tr><td rowspan="2"></td><td rowspan="2">Date</td><td colspan="4">Event</td><td>Extendable term</td><td>Period attributable to patentee</td></tr>
<tr><td>Patent Grant/ clinical trial</td><td>Product Approval (Safety and Efficacy examination/ Standards and Test Methods examination)</td><td>GMP evaluation</td><td>DMF examination</td><td></td><td></td></tr>
<tr><td>1</td><td>December 21, 2009</td><td>Start of the clinical trial</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>2</td><td>June 23, 2010</td><td>Registration of the Patent Right</td><td></td><td></td><td></td><td rowspan="2">① 48 days</td><td></td></tr>
<tr><td>3</td><td>August 10, 2010</td><td>Clinical trial termination</td><td></td><td></td><td></td><td></td></tr>
<tr><td>4</td><td>January 31, 2013</td><td></td><td>Filing of an application for product import approval</td><td>Filing an application for GMP evaluation</td><td>Filing of DMF files</td><td rowspan="3">② 334 days</td><td></td></tr>
<tr><td>5</td><td>March 20, 2013</td><td></td><td>Request for the supplemental documentation of Safety/Efficacy and Standards/Test Methods</td><td></td><td>Request for DMF supplemental documentation</td><td rowspan="2">③ 70 days</td></tr>
<tr><td>6</td><td>May 29, 2013</td><td></td><td>Submission of the supplemental documentation of Safety/Efficacy and Standards/Test Methods</td><td></td><td>Submission of DMF supplemental documentation</td></tr>
</table>

should be included in the period during which a subject invention would not have been practiced, while regardless of whether the examination of the other divisions was conducted during the supplementation period of the examination process of one division, all the supplementation periods should be considered as the period “elapsed” due to the attributable cause of a patentee and should be excluded.

	Date	Event				Extendable term	Period attributable to patentee
		Patent Grant/ clinical trial	Product Approval (Safety and Efficacy examination/ Standards and Test Methods examination)	GMP evaluation	DMF examination		
7	July 3, 2013				Reply to the consultation for material (Standards/Test Methods) examination		
8	July 4, 2013		Consultation reply				
9	July 25, 2013			Request for GMP supplemental documentation			
10	December 4, 2013				Substance (GMP) consultation reply		④ 140 days
11	December 12, 2013			Submission of GMP supplemental documentation			
12	December 20, 2013			Consultation reply			
13	December 31, 2013		Pharmaceutical product import approval				
14	December 31, 2013		Issuance of product import approval certificate				
Approved Extendable term		**172 days = [48 days + 334 days -70 days -140 days]**					

C) Calculation Method 3

Extendable term = clinical trial period after the registration date of the patent + [longest examination period among the actual examination period per examination items − supplementation period during the longest examination procedure thereof] + examination period of pharmaceutical examination adjustment division = 48 days + **237 days**[13], which is the longest period among ②, ③, ④ of the table below + 11 days = **296 days**

② = Safety/Efficacy, Standards/Test Methods examination period− supplementation period = 84 days

③ = GMP evaluation period − supplementation period = 183 days

④ = DMF examination period − supplementation period = 237 days

	Date	Event							
		Patent Grant/ clinical trial	Period calculation ①	Product approval (S/E examination / S/T examination)	Period calculation ②	GMP evaluation	Period calculation ③	DMF evaluation	Period calculation ④
1	December 21, 2009	Start of the clinical trial							
2	June 23, 2010	Registration of the Patent Right	48 days						
3	August 10, 2010	Clinical trial termination							

13) The purport of this is as follows: when the longest period is given during the actual examination period, it would be sufficient to all complete each examination and receive a product approval.

	Date	Event									
		Patent Grant/ clinical trial	Period calculation ①	Product approval (S/E examination / S/T examination)	Period calculation ②		GMP evaluation	Period calculation ③		DMF evaluation	Period calculation ④	
4	January 31, 2013			Filing an application for product import approval	154 days	70 days	Filing an application for GMP evaluation	323 days	140 days	Filing of DMF files	307 days	70 days
5	March 20, 2013			Request of SE and ST supplemental documentation						Request of DMF supplemental documentation		
6	May 29, 2013			Submission of SE and ST supplemental documentation						Submission of DMF supplemental documentation		
7	July 3, 2013									Documents (S/T) evaluative consultation reply		
8	July 4, 2013			Consultation reply								
9	July 25, 2013						Request of GMP supplemental documentation					
10	December 4, 2013									Substance (GMP) consultation reply		
11	December 12, 2013						Submission of GMP supplemental documentation					
12	December 20, 2013				11 days		Consultation reply					
13	December 31, 2013			Pharmaceutical product import approval								

	Date	Event							
		Patent Grant/ clinical trial	Period calculation ①	Product approval (S/E examination / S/T examination)	Period calculation ②	GMP evaluation	Period calculation ③	DMF evaluation	Period calculation ④
14	December 31, 2013			Issuance of product import approval certificate					
Approved Extendable term		Clinical trial period 48 days + 237 days, which is the longest period among ②, ③, ④ [307 days - 70 days] + examination days of the approval examination adjustment division: 11 days = 296 days							

D) Calculation Method 4

Extendable term = clinical trial period after the registration date of the patent (① of table described in Calculation Method 2) + [entire document review period of MFDS (② of table described in Calculation Method 2) - supplementation period during DMF registration evaluation (③ of the table described in Calculation Method 2)] = 48 days + 334 days - 70 days = **312 days**

2) Argument regarding Article 134(1)(ii) of the Patent Act

The legislative purport of Article 134(1)(ii) of the Patent Act is to publicly announce the existence of a non-exclusive license and protect a third party's interest. Therefore, at the time of filing the Subject Approval or at the time of approving the subject case, the registration of non-exclusive license should be completed. However, Astellas Korea, who is the non-exclusive licensee of the Subject Patent, has not finished the registration of non-exclusive license at the time of filing the Subject Approval and then finally registered the non-exclusive

license in January 24, 2014, i.e., after the Subject Approval. Accordingly, the period of non-exclusive license is merely retroactive to June 23, 2010, i.e., the registration date of the patent. Therefore, the Subject PTE was made with respect to an application of which approval under the Pharmaceutical Affairs Act was not obtained by the patentee, or an exclusive licensee or a registered non-exclusive licensee . Therefore, the Subject PTE has an invalidation ground under Article 134(1)(ii) of the Patent Act. Thus, The IPTAB Decisions which made a contrary judgment from the above is unlawful.

B. Summary of the Defendant's argument

1) Argument regarding Article 134(1)(iii) of the Patent Act

A) Regarding Calculation Method 1 of the Plaintiffs' argument, in order to obtain a pharmaceutical product import approval, ① clinical trial, ② Safety/Efficacy examination, ③ Standards/ Test Methods examination, ④ GMP evaluation, and ⑤ DMF examination procedures should all be passed. Therefore, the Plaintiffs' argument which only considers a clinical trial period and S/E examination period as “the period during which the Subject Extended Invention would not have been practiced” is improper.

B) Regarding Calculation Methods 2 and 4 of the Plaintiffs' argument, Ⓐ primarily, in the case where a certain division of the MFDS spends a supplementation period according to the supplementation request, while other divisions separately carry out the examination on the Subject Approval Request and the like, the supplementation period thereof is not considered as the delayed period due to the reason attributable to the patentee. Therefore, the casual

relationship with the approval delay is not recognized. Therefore, without having to review whether the supplementation request thereof corresponds to reasons attributable to the patentee, the supplementation period thereof cannot be excluded from “the period during which the Subject Extended Invention would not have been practiced.” Ⓑ preliminarily, even if the judgment on the casual relationship with the approval delay becomes different, based only on the situation where there is a supplementation request, it cannot be estimated that it is attributal to the patentee. MFDS's supplementation request can be made when each examination division needs further materials for review even though an approval applicant submits all the necessary materials, or the corresponding examination division fails to recognize the material even though the materials were actually submitted, or even though the materials are normally submitted without incompletion/omission, there could be a request for suggestion of further sufficient basis or explanation on the submitted material for practicing the best public health administration for the purpose of securing public's safety. However, the above-mentioned cases are not the cases caused by the approval applicant's fault. Therefore, it is unfair to presume that the delay is always attributable to the approval applicant based only on the situation where there is a supplementation request from the MFDS.

C) Regarding Calculation Method 3 of the Plaintiffs' argument, due to of the MFDS' the internal structure and procedure where examination are independently carried out, each examination division does not concurrently request the supplementation request but individually request the

supplementation requests, and if this makes the approval period get longer, such a situation cannot be considered as a reason attributable to the patentee. Therefore, the Plaintiffs' argument having the contrary premise from the above is not proper.

D) Like the Plaintiffs' argument, even supposing that the materials supplementation period is recognized as the period elapsed due to the reason attributable to the patentee, and supposing the period when MFDS' other examination divisions carry out the examination is further excluded, during the period from August 10, 2010 (clinical trial termination date of the Subject pharmaceutical) to January 31, 2013 (product approval filing date), various preparation works were carried out for filing approval such as carrying out a bridging test, preparing a bridging test material, requesting separate examination for Safety/Efficacy and Standards/Test Methods, etc. For these preparations, at least 1 year had been spent. Therefore, these periods should naturally had been included in “the period during which the invention would not have been practiced for obtaining approval and the like” under Article 89 of the Patent Act. However, since the above period is much longer than the period argued by the Plaintiffs to be excluded from the Subject PTE, consequently, the Subject PTE is not considered to exceed the fairly extendable period. Thus, the Subject Extended Period is not considered to have an invalidation ground under Article 134(1)(iii) of the Patent Act.

2) Argument regarding Article 134(1)(ii) of the Patent Act

Article 134(1)(ii) of the Patent Act is not a stipulation for restricting

the registration period of a non-exclusive license but a stipulation for deciding the subject who files the extension. Further, a registration of a non-exclusive license is merely required for a non-exclusive licensee to have a valid claim or defense against a patent assignee or an exclusive-licensee. Therefore, even though Astellas Korea, who is the non-exclusive licensee of the Subject Patent and filed the Subject Approval, is registered as a non-exclusive licensee after the Subject Approval, as long as the non-exclusive license was registered before the Subject Application for PTE, it does not correspond to the invalidation ground under Article 134(1)(ii) of the Patent Act.

3. Discussion

A. Discussion regarding the argument on Article 134(1)(iii) of the Patent Act

1) Relevant Law

A) Article 89 (1) of the Patent Act stipulates “notwithstanding Article 88 (1), where approval or registration under other Acts or subordinate statutes were required in order to work a subject invention, and it has taken an extended period of time to complete the activity test, the safety tests, etc., necessary to obtain such approval or registration (hereinafter referred to as “approval”) and which is prescribed by Presidential Decree, the term of the patent right may be extended by a period, up to five years, during which the subject invention would not have been practiced.” and Article 89(2) of the Patent Act stipulates that “for the purposes of paragraph (1), the period required due to reasons attributable to the person who has obtained approval shall not be included in “period during

which the invention would not have been practiced" in paragraph (1)."

Meanwhile, Article 91 of the Patent Act enumerates the grounds for rejecting a patent term extension application, and Article 91(3) of the Patent Act stipulates the case "where the length of extension requested exceeds the period during which the relevant subject invention could not be practiced under Article 89."

As above, the patent term extension system under the Patent Act is a system for granting patent term extension up to 5 years during which a subject invention would not have been practiced, if the approval needs to be obtained under other Acts in order to conduct the subject invention during the patent term and it takes a long period of time to complete tests and examinations necessary for obtaining the approval.

In the case of pharmaceutical and agrochemical inventions, approval and registration should be obtained from the regulatory authority under the Pharmaceutical Affairs Act or the Agrochemicals Control Act which aims at securing safety and efficacy (hereinafter, referred to as "approval under the Pharmaceutical Affairs Act") and it takes a long period of time to complete tests and examinations necessary for obtaining the approval. In this case, even if the patent is effective, the patentee cannot practice the subject invention during such a period and cannot enjoy benefit from exclusive owning of the patent right and thus has a disadvantage that research and development costs cannot be recovered. This leads to a lack of fairness in the patent right in the field of pharmaceuticals and agrochemicals

compared to the patent right in other industrial fields. Therefore, in order to resolve the unfairness issue, to protect and encourage pharmaceutical inventions, and to promote technical development in the relevant field, Article 89 (1) of the Patent Act provides a system for granting patent term extension by a period, of up to five years, during which the subject invention would not have been practiced due to obtaining approval under the Pharmaceutical Affairs Act.

Meanwhile, a third party who can freely practice the subject invention after the expiration of the originally established patent term has a disadvantage that due to the patent term extension, he/she cannot practice the subject invention until the expiration of the extended patent term. Therefore, in order to control the relationship of interest between the patentee and a third party and to enable the patentee to take procedures for obtaining approval in good faith and promptly, Article 89(2) of the Patent Act stipulates that a period which has elapsed for reasons attributable to the patentee should be excluded from the period during which the subject invention would not have been practiced.

B) Meanwhile, according to Article 34(1) of the old Pharmaceutical Affairs Act (before amendment of Act No. 10788 of June 7, 2011)[14], a person who intends to conduct a clinical

14) According to the statements in Defendant's Exhibit No. 2-4, it can be known that the date of approving the clinical trial protocol of the subject pharmaceutical is October 13, 2009, the date of starting the clinical trial is December 21, 2009, and the date of terminating the clinical trial is August 10, 2010. Therefore, the approval of clinical trial protocol of this case is applied by Article 34 of the old Pharmaceuticals Act (before amendment of

trial with pharmaceutical, etc. shall prepare a clinical trial protocol and receive an approval of the commissioner of the MFDS.

Further, Articles 31 and 32 of the old Pharmaceutical Affairs Enforcement Rule (before the amendment of Article 52 of the decree of Ministry of Health and Welfare of May 6, 2011, hereinafter the same) stipulate the description content of a clinical trial protocol and implementation standards of a clinical trial. In addition, Article 9(6) of the old Regulation on Safety of pharmaceutical, etc. (before the amendment of Article 1081 of ordinance of the Prime Ministry, May 9, 2014[15]), hereinafter the same) stipulates the materials regarding the clinical trial grade as one of the materials regarding safety/efficacy that should be submitted by an applicant for product approval. Moreover, without approval under the Pharmaceutical Affairs Act, an act of manufacturing/ selling pharmaceuticals is generally and abstractly prohibited. The act of manufacturing/selling is not allowed until respective and specific remedies under

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Act No. 10788, June 7, 2011) and Articles 31 and 32 of the Enforcement Rule of the old Pharmaceutical Affairs Act (before amendment of Act No. 52 of the ordinance of Ministry of Health and Welfare, May 6, 2011), which were applied at the time of the approval date thereof, i.e., October 13, 2009.

15) Article 24 of the Enforcement Rule of the old Pharmaceutical Affairs Act, which relates to an product import approval of pharmaceutical, was all revised into Article 188 of the ordinance of Ministry of Health and Welfare on March 23, 2013 so the above provision was deleted. At the same time, "Regulation on Safety of Medicinal Product, etc.," which is an ordinance of the prime ministry, was legislated and implemented, and Article 4 thereof was newly established with the same purport. Other than this, there are regulations on the materials to be submitted in the process of product import approval of pharmaceutical, etc.

the relevant administrative laws are obtained.

Thus, as long as there is no approval under the Pharmaceutical Affairs Act, the prohibition of the act of manufacturing/selling is continued. However, patent term extension allowable under the Patent Act is not for all the periods like the period during which the patentee or its licensee who can lawfully practice the subject invention on behalf of the patentee licensee (hereinafter, those will be referred to as "the patentee, etc.") did not make an effort for obtaining approval under the Pharmaceutical Affairs Act. It is limited to the period during which the patentee, etc. had intention and capability to practice the subject invention but could not practice the subject invention, i.e., the period required for obtaining approval under the Pharmaceutical Affairs Act, etc.

Accordingly, the beginning of "the period during which the subject invention would not have been practiced" under Article 89 of the Patent Act is a later date among the date when the patentee, etc. initiated the validity and safety tests etc. necessary for obtaining approval under the Pharmaceutical Affairs Act and the date when the patent right was registered, and the termination thereof is the date where approval under the Pharmaceutical Affairs Act is notified to the applicant, and thus, becomes effective.

Further, Article 89(2) of the Patent Act excludes the period which has elapsed for reasons attributable to the patentee, etc. from the period during which the subject invention would not have been practiced. In this case, "the period which has elapsed for reasons attributable to the patentee" means the period during which approval under

the Pharmaceutical Affairs Act, etc. was delayed for reasons attributable to the patentee, i.e., the period during which a considerable causal relationship is recognized between the reason attributable to the patentee and the delay of the approval under the Pharmaceutical Affairs Act.

2) Discussion on the unlawfulness of the IPTAB Decisions argued by the Plaintiffs

A) In light of the process, etc. of Subject Approval, the period during which the Subject Extended Invention would not have been practiced should be calculated based on the period from June 23, 2010 (patent registration date) to August 10, 2010 (clinical trial termination date) and the period from January 31, 2013 (date of filing an application for the Subject Approval) to December 31, 2013 (the date when the Subject Approval decision was notified to the applicant). Based on the above, the Plaintiffs' argument regarding “a period elapsed for reasons attributable to the patentee, etc.” that should be excluded from the above each period will be judged as follows:

B) Firstly, “Calculation Method 1” argued by the Plaintiffs will be reviewed. Calculation Method 1 argued by the Plaintiffs has a premise that “the period during which the patent would not have been practiced” under Article 89 of the Patent Act refers to the clinical trial period spent for a long time for Safety/Efficacy evaluation for medicines, like the literal description of Article 89 of the Patent Act, and the period spent for the administrative review of the submitted clinical trial materials, and has a purport that only ① the period spent for the clinical trial after the

registration date of the patent and ② the period excluding the period elapsed due to reasons attributable to the patentee, etc. should be considered as the period during which the Subject Extended Invention would not have been practiced.

Regarding this, the product import approval of pharmaceutical can be obtained in case of passing all of ① a clinical trial, ② Safety/Efficacy examination, ③ Standards/Test Methods examination, ④ GMP evaluation, and ⑤ DMF examination procedures, according to Articles 31(2), 34(1), 42(1) of the old Pharmaceutical Affairs Act (before amendment of Article 13114 of the Act, January 28, 2015)[16] and Articles 4(1) and (9) of the old Regulation on Safety of pharmaceutical, etc. Therefore, in the Subject Approval process, period spent in S/E examination, S/T examination, GMP evaluation, and DMF examination, etc. all should be considered as the basis for calculating the period during which the subject invention would not have been practiced. Meanwhile, Article 89(1) of the Patent Act stipulates that "··· the term of a patent on an invention may be extended ··· to compensate for the period during which the invention would not have been practiced, if the invention is specified by Presidential Decree ··· but it takes a long time to undergo necessary tests for efficacy, safety, etc. for such approval, etc." In the above, "tests for validity, safety, etc." is merely one example regarding

16) The date of submitting an application of an product import approval of the subject pharmaceutical is January 31, 2013, and the date of deciding the product import approval is December 31, 2013. Therefore, the product import approval of pharmaceutical is applied by Article 42 of the old Pharmaceutical Affairs Act (before amendment of Article 13114 of the legislation, January 28, 2015) at the time of the date of deciding the approval thereof.

the calculation of the period during which the invention would not have been practiced. Therefore, it cannot be interpreted that “the period during which the patent would not have been practiced” is only limited to a clinical trial period and S/E examination period.

Therefore, the Plaintiffs' argument has contrary premise from the above. That is, the Plaintiffs argued for the unlawfulness of the IPTAB Decisions which calculate the period during which the Subject Extended Invention would not have been practiced, including S/T examination period, GMP evaluation period, DMF examination period as well as a clinical trial period and S/E examination period. However, such Plaintiffs' argument is not persuasive.

C) Next, “Calculation Method 2” argued by the Plaintiffs will be reviewed.

Calculation Method 2 argued by the Plaintiffs has a premise that the period excluded from the period during which a subject invention would not have been practiced corresponds to the “spent” period regardless of whether the period is “delayed” due to reasons attributable to the patentee. The gist of this method is that if a supplementation period is conducted according to the supplementation request of a certain examination division, regardless of whether other divisions carry out an examination during the supplementation period thereof, the entire supplementation period should be excluded from the period during which the Subject Patent would not have been practiced.

Regarding this, the period which can be excluded from

the period during which the Subject Extended Invention would not have been practiced should be the period which is recognized to have a considerable causal relationship between the reasons attributable to the patentee and the delay of approval, etc., as mentioned above. However, the drug examination department of MFDS is divided into a plurality of divisions in charge of divided works. Each examination on submitted materials is independently conducted by each responsible MFDS examination division.

Therefore, unless there is a special occasion, it is general practice that even if the examination conducted by a certain division is stopped due to the division's request for documentation supplementation, other examinations are continuously being conducted by other divisions.
As such, even if a period for documentation supplementation was spent due to a certain division's request for documentation supplementation, if other examination procedures were being conducted by other divisions, a period which overlaps with the period during which other examination procedures were being conducted by other divisions during the period of documentation supplementation cannot be recognized as a period of delay due to the reasons attributable to the patentee. Thus, the overlapped period cannot be excluded from the period during which the Subject Patent would not have been practiced.

Thus, unlike the Plaintiffs' argument, the IPTAB Decisions, which calculated the period during which the Subject Patent would not have been practiced based on the judgment that during the period spent for documentation supplementation requested by a certain examination division, a period which overlaps with the period during

which examination procedures were being conducted by other examination divisions is not recognized as the period of delay due to the reasons attributable to the patentee, is lawful.

D) Next, “Calculation Method 3” argued by the Plaintiffs will be reviewed.

Calculation Method 3 argued by the Plaintiffs has a premise that it is improper that the calculation of the period spent due to the reasons attributable to patentee may vary depending on whether the supplementation period overlaps or not. The gist of this method is that the period during which a subject invention would not have been practiced should be calculated by selecting the longest one from the actual examination periods taken by respective examination divisions without considering whether the supplementation period overlaps or not, and then excluding the period for amendment spent according to the amendment request of the examination division from the longest examination period.

Regarding this, when judging “the period elapsed due to reasons attributable to the patentee” stipulated under Article 89(2) of the Patent Act, it should be judged how long the approval procedure was delayed due to the patentee's neglecting of the due diligence generally required in social norms under given conditions in reality such as examination/approval procedure and structure, etc. of MFDS, etc. However, Calculation Method 3 is a method which calculates the period during which the approval procedure was delayed due to the reason attributable to the patentee by ignoring the structural/

procedural problems existing in reality during the MFDS' internal examination process and merely replacing the actual examination/approval process with an imaginary ideal examination/approval process, and thus is not proper. That is, as mentioned above, there is always a possibility where each examination division within MFDS independently carries out an examination regarding the materials for filing an approval, whereby a request for documentation supplementation is issued individually as well.

Therefore, there may be a case where supplementation request of each examination division of MDFS are made at different times (not made at the same time) and accordingly, the patentee, etc. submits supplemental materials, etc. in different times and as a result, the period spent for approval is delayed, and as for such a case, it would be highly probable to consider that such a delayed period is attributed to the structural issue or internal situation of MFDS' internal examination process beyond the patentee’s liability. Thus, the reason is not attributed to the patentee.

Meanwhile, the Plaintiffs argue with a purport that in the case where an applicant of product approval strategically submits an application before the materials necessary for the examination are not completely prepared, it is not reasonable to recognize a supplementation period as an extendable period based on the reason that the examination on other examination items is carried out despite of the request for supplementation.

However, at the time of filing an application for the Subject Approval, under the laws relevant to the old Pharmaceutical

Affairs Act, it was possible to file a request for examination of safety and efficacy and a request for examination of standards and test methods concurrently with an application for the product import approval, or to request a preliminary examination solely before filing an application for the product import approval of pharmaceuticals and then submit the notification of the examination results when filing an application for the product import approval of the pharmaceutical (*see* Articles 24(1)(i) and (ii) etc. of the Enforcement Rule of the old Pharmaceutical Affairs Act). Especially, the latter method was designed for allowing more prompt processing of the product approval step through a preliminary examination[17].

Given the circumstances above, the applicant for approval is not considered to have a due diligence of requesting a product import approval and S/E and S/T examinations collectively only when all materials are completed so that all the examination procedures can be simultaneously conducted. In addition, there is no evidence in the present case to see that the applicant intentionally separately filed the requests for S/E and S/T sole preliminary examinations with an intention of delaying the approval procedure. Therefore, based only on the reasons argued above, the corresponding procedure is not considered to be delayed

17) As shown in item B. 2) below, in this case, Astellas Korea, as a non-exclusive licensee of the Subject Patent, firstly filed for a S/T sole preliminary examination and S/E sole preliminary examination regarding the Subject approval targeted pharmaceutical, and then on January 31, 2013, it filed for an product import approval of pharmaceuticals. Accordingly, the examination processes thereof were carried out together (after that, each sole preliminary examinations above were withdrawn).

due to the reasons attributable to the patentee, etc.
Thus, unlike the Plaintiffs' arguments, the IPTAB Decisions which calculated the period during which the Subject Extended Invention would not have been practiced by considering how long the approval procedure was delayed due to reasons attributable to patentee under given conditions in reality such as MFDS's actual examination and approval procedure and structure, etc., is lawful.

E) Next, "Calculation Method 4" argued by the Plaintiffs will be reviewed.
Calculation Method 4 argued by the Plaintiffs has the following purport: in the case where the substance of a drug product is the target of registering DMF, DMF registration should be necessarily made prior to the manufacture/sales of the corresponding medicine or completion of an product import approval, and regardless of whether the S/E examination and S/T examination or GMP evaluation are completed, a drug product approval cannot be completed without DMF registration; consequently, the supplementation period during the review period of DMF registration corresponds to "the period elapsed due to the reason attributable to the patentee, etc." regardless of the MFDS' supplementation during review period of materials for filing a product approval of drug product; consequently, in the DMF examination regarding the registration of drug substance at the time of the Subject Approval, 70 days, which is the period from March 20, 2013 (the day of the request for documentation supplementation in relation to S/T examination) to May 29, 2013 (the submission date of supplemental documentation thereof) should be considered as the period elapsed due to the reason attributable to the patentee and should be excluded

from the period during which the Subject Extended Invention would not have been practiced.

Regarding this, as mentioned above, in the Subject Approval, the product approval regarding Betmiga sustained-release tablet 50mg, i.e., the drug product, was carried out concurrently with the DMF examination regarding mirabegron, i.e., drug substance; in order to receive an product import approval of pharmaceutical, not only the DMF examination procedure for drug substance but also S/E examination, S/T examination, and GMP evaluation for the drug product all should be passed; the DMF examination is carried out by dividing into material (S/T) examination regarding the quality of drug substance carried out in a pharmaceutical standard division, and material examination and a factual survey regarding the manufacture facility of drug substance carried out in a pharmaceutical quality division, and among those, if one examination division made a supplementation request and the examination of the corresponding examination division is stopped until the supplemental documentation is submitted, it is general that the other DMF registration examination division or other examinations division of product import approval continue the examination; and in this case, during the period from March 20, 2013 to May 29, 2013, argued by the Plaintiffs, the examination of GMP evaluation examination division was continued.
In view of the above facts, even if a supplementation period for submitting supplemental materials is spent during the DMF examination, in the case where the other division separately conducts the examination regarding the registration of the Subject Approval, the supplementation period thereof is not considered as the period delayed due

to the reason attributable to the patentee, etc. Consequently, the casual relationship between the reason attributable to the patentee and the delay of approval, etc. is not considered to be recognized. Thus, the Plaintiffs' above argument is also not persuasive.

F) Regarding this, the Plaintiffs argued as follows: at the time of the Subject Approval, during the DMF examination, S/T examination result was replied on July 3, 2013 and the S/E examination result and S/T examination result related with product approval were replied on July 4, 2013 so the examinations on these items were all completed. After that, on July 25, 2013, the request for documentation supplementation from GMP examination division was requested overlapping with the GMP material supplementation request during the DMF examination. The examination was stopped from the above-mentioned days to December 12, 2013 when the corresponding supplemental documentation was submitted. Therefore, the said period during which the examination stopped corresponds to the period elapsed due to the reason attributable to the patentee, etc. Moreover, even though MFDS requested the submission of GMP supplemental documentation until October 7, 2013, the supplemental documentation was submitted on December 12, 2013. Therefore, it is clear that at least those periods should be the period elapsed due to the reason attributable to the patentee, etc.

Regarding this, according to the respective statements in Defendant’s Exhibit 2-7 and 2-8, the followings are recognized: on July 25, 2013, MFDS requested the submission of GMP supplemental documentation to Korea Astellas Pharamceuticals until October 7, 2013, and Astellas

Korea submitted the GMP supplemental documentation to MFDS on December 12, 2013.

However, Plaintiff 4's Exhibit No. 6 discloses that during the DMF examination, there was a request for submitting supplemental documentation for GMP on July 25, 2013, and the supplemental documentation thereof seemed to be submitted on December 12, 2013. However, in view of the respective statements in Defendant's Exhibit No. 13 the fact inquiry result of this court (replied on February 1, 2017) regarding the National Institute of Food and Drug Safety Evaluation of MFDS and all the arguments presented so far, the following facts are recognized: at the time of the Subject Approval, after the DMF report was submitted on January 31, 2013, the DMF registration examination division requested a documentation supplementation on March 20, 2013 regarding the registration of "mirabegron" drug substance of Betmiga sustained-release table 50 mg, and received the supplemental documentation on May 29, 2013. Other than this, the DMF registration examination division kept proceeding with the examination regarding DMF without a request for submitting supplemental documentation, replied a material (S/T) examination consultation regarding the quality of drug substance on July 3, 2013, and replied the substance (GMP) consultation regarding the drug substance manufacture facility, etc. on December 4, 2013 to each pharmaceutical examination adjustment division. Therefore, some statements in Plaintiff 4's Exhibit No. 6, which conflict with the above facts, are unreliable.

Further, there is no evidence to recognize that together with the material supplementation request of GMP evaluation examination division on July 25, 2013, the DMF registration

examination division also requested a documentation supplementation in relation to the drug substance manufacture facility (GMP).

Thus, the above argument, with a purport that the DMF registration examination division also requested the overlapping documentation supplementation request from July 25, 2013 (the date when the GMP evaluation examination division requested supplemental documentation at the time of the Subject Approval) to December 12, 2013 (the date of submitting the supplemental documentation thereof), is not persuasive.

Meanwhile, proviso of Article 55(3) of examination regulation for reporting a product approval of pharmaceutical (before the amendment of MFDS Notification No. 2013-238, November 25, 2013) stipulates that "in the case where an appealing person who receives a supplementation request asks for a period extension by describing the period necessary for the supplementation based on the reason that the supplementation cannot be made within the requested period of supplementation, the supplementation period should be decided considering the above."

Further, according to the fact inquiry result of this court (replied on November 29, 2016) regarding the National Institute of Food and Drug Safety Evaluation of MFDS, the pharmaceutical quality division, which is the GMP evaluation examination division at the time of the Subject Approval, approved the extension of the supplementation period according to the order of submitting the above GMP supplemental material until January 10, 2014 by the request of Astellas Korea. Further, Astellas Korea recognized

that the supplemental documentation was submitted on December 12, 2013, which is about 1 month earlier than the above. Therefore, based only on the situation where the supplemental documentation thereof was submitted on December 12, 2013, instead of October 7, 2013, i.e., the initial due date of submitting the supplemental material, it would be difficult to correspond to the reason attributable to the patentee, etc.

In view of all the situations as above, it would be highly probable to consider that even after July 4, 2013 when S/E examination result and S/T examination result related with the product import approval at the time of the Subject Approval was replied, the examinations of DMF registration examination division and the other examination divisions were continued.

Still, according to statements in Defendant's Exhibit 2-7 and 2-8, based on the reason of "confirming the incomplete matter," the GMP evaluation examination division requested the submission of supplemental materials to Astellas Korea on July 25, 2013. Among the supplementation period thereof, there is a room to consider that at least the examination of the GMP evaluation examination division was stopped during the period from December 4, 2013 (the date when the substance (GMP) consultation reply of DMF registration examination division is completed) to December 12, 2013 (the date when the supplemental documentation was submitted by the request of GMP evaluation examination division).

However, in view of the respective statements in Plaintiff 4's Exhibits 4, 7, 8, and 13, and Defendant's Exhibits 14,

fact inquiry result of this court(replied on November 29, 2016) regarding the National Institute of Food and Drug Safety Evaluation of MFDS and all the arguments presented so far, the following facts are recognized: when a product approval of pharmaceutical is requested, the preliminary examination thereof is carried out, and then the pharmaceutical examination adjustment division conducts a series of works of: sending a consultation request to each corresponding division such as each division of pharmaceutical examination division, pharmaceutical quality division, etc., and then based on the consultation reply of each examination division, finally reviewing the propriety of the quality approval, and examining whether to allow the product approval and DMF registration; generally, S/E and S/T examinations are handled in a pharmaceutical examination division, GMP evaluation examination is handled in a pharmaceutical quality division, and DMF registration examination is handled in a pharmaceutical examination division or a pharmaceutical quality division.

During the review process thereof, if there is an incomplete matter among the supplementation request matters of each division of pharmaceutical examination divisions and the general approval requirements, the pharmaceutical examination adjustment division request a supplementation, and a pharmaceutical quality division, etc. itself independently proceeds with the review after the supplementation request and the receipt of the supplemental documentation , and only reports the final result such as GMP evaluation propriety, etc. to the pharmaceutical examination adjustment division; the pharmaceutical examination adjustment division reviews the propriety of the product approval including the examination and the evaluation reply, etc. regarding the S/E examination

result and S/T examination result, GMP evaluation materials received through the above process, and examines the final product approval through a consultation with each division of pharmaceutical examination divisions and the pharmaceutical policy division and the related divisions, as necessary; the Subject Approval and the registration of drug substance were all made on December 31, 2013, while the consultation reply of S/E examination and S/T examination divisions was notified on July 4, 2013, the consultation reply of the material (S/T) examination of the DMF registration examination division was notified on July 3, 2013, the consultation reply of the substance (GMP) of the DMF registration examination division was notified on December 4, 2013, and the consultation reply of the GMP evaluation examination division was notified on December 20, 2013; meanwhile, it is recognized that MFDS suggests, as 5 to 25 days, the period for reviewing the product approval propriety of a pharmaceutical examination adjustment division, and as mentioned above even in the case where the supplementation requests of each examination division of MFDS are not simultaneously made and due to the different periods, some periods are further spent to arrive at the final product approval, it would be highly probable to consider that this is caused by the structural cause of the internal examination process of MFDS or the internal situation thereof.

Other than the above, the followings may be considered: the considerable period of time spent to complete the product import approval of the pharmaceutical of this case after the consultation reply of each examination division was arrived at the pharmaceutical examination adjustment division during the Subject Approval process, role and

function of the pharmaceutical examination adjustment division in the product approval of imported pharmaceutical and DMF registration process, etc. Upon collectively considering the above, it would be correct to consider that even during the period of from December 4, 2013 (the date when the substance (GMP) consultation reply of DMF registration examination division arrives at the pharmaceutical examination adjustment division) to December 12, 2013 (the date when the supplemental documentation was submitted according to the material supplementation request of GMP evaluation examination division), the product approval propriety review of the pharmaceutical examination adjustment division and the propriety review of DMF registration were conducted.

Therefore, the period from July 25, 2013 (the date of request for documentation supplementation from GMP evaluation examination division) to December 12, 2013 (the date of submission of the supplemental documentation) is also not considered as the period during which the approval is delayed due to the reason attributable to the patentee. Thus, the Plaintiffs' above argument is consequently groundless.

3) Whether the Subject PTE is lawful

A) As mentioned above, unlike the IPTAB Decisions, “the consultation reply dates” of each examination division of MFDS have all been confirmed at the time of this petition. However, the above “consultation reply date” refers to the date when the pharmaceutical examination adjustment division replies the review result thereof after each division of pharmaceutical examination divisions

review the examination result, and around that time, the examinations of each division of pharmaceutical examination division were considered to be completed. Therefore, based on the above, the lawfulness of the Subject PTE will be judged.

B) The clinical trial start date of this case (December 21, 2009) corresponds to "the date when a patentee, etc. starts the test such as efficacy/safety, etc. necessary for receiving an approval, etc. by the Pharmaceutical Affairs Act, etc." However, since the registration date of the patent (June 23, 2010) is later than the clinical test start date, the period during which the Subject Extended Invention would not have been practiced should be calculated based on 48 days, i.e., the period from June 23, 2010 to August 10, 2010 (clinical trial termination date) (the period spent for a clinical trial after the registration date of the patent which corresponds to the start date) and 334 days, i.e., the period from January 31, 2013 (the date of filing an application for the Subject Approval) to December 31, 2013 (the date when the decision of the Subject Approval arrived to the applicant). Based on the above, "the period elapsed due to the reason attributable to the patentee" that should be excluded from the above period will be reviewed.

Firstly, the periods during which the examinations of each division of MFDS are stopped includes Ⓐ the period from March 20, 2013 (the date of requesting the documentation supplementation for S/E and S/T supplemental documentation and also the date of requesting the documentation supplementation of DMF) to May 29, 2013 (the date of submitting the supplemental materials)

(hereinafter, “Period 1”) and Ⓑ the period from July 25, 2013 (the date of requesting GMP documentation supplementation) to December 12, 2013 (the date of submitting the supplemental documentation) (hereinafter, “Period 2”).

However, during “Period 1,” the examination of GMP evaluation examination division was continued. Therefore, the supplementation period thereof is not considered as the period delayed due to the reason attributable to the patentee, etc., and a considerable causal relationship between the reason attributable to the patentee, etc. and the delay of approval, etc. is not recognized.

Further, regarding the DMF registration examination, substance (GMP) consultation reply was made on December 4, 2013. Therefore, in “Period 2,” from July 25, 2013 to December 3, 2013, the examination of the DMF registration examination division was conducted. Therefore, the above period is not considered as the period delayed due to the reason attributable to the patentee. Therefore, a considerable causal relationship between the reason attributable to the patentee, etc. and the delay of approval, etc. is also not recognized. Meanwhile, in “Period 2,” there is a room to consider that the examination of GMP evaluation examination division was stopped during the period from December 4, 2013 to December 12, 2013. However, as mentioned above, during the above period, the pharmaceutical examination adjustment division is considered to review the product approval and propriety of DMF registration. Consequently, regarding the above period, a considerable causal relationship between the reason attributable to the patentee, etc. and the delay of approval, etc. is not recognized.

C) Therefore, there is no “period elapsed due to reasons attributable to the patentee” that should be excluded from the period during which the Subject Extended Invention would not have been practiced. Thus, it is lawful to calculate the period during which the Subject Extended Invention would not have been practiced into 382 days, which is the sum of 48 days (period spent for a clinical trial after the registration date of the patent) and 334 days (period spent in product import approval regarding Betmiga sustained-release table 50 mg, which is the pharmaceutical for which the Subject Approval was filedpharmaceutical).

4) Summary of Discussion

If so, the IPTAB Decisions holding that the Subject Extension Registration is not considered to have an invalidation ground under Article 134(1)(iii) of the Patent Act, is lawful, unlike the Plaintiffs' argument. Further, the extended term of the Subject PTE does not exceed the period during which the Subject Extended Invention would not have been practiced. Therefore, without having to further judge the Defendant's other arguments, the Subject PTE does not have any invalidation ground stipulated under Article 134(1)(iii) of the Patent Act.

B. Discussion on the argument regarding Article 134(1)(ii) of the Patent Act

1) Relevant Law

Article 134 (1) of the Patent Act stipulates that “in any of the following cases, any interested party or examiner may request a trial to invalidate the registration of an extension of the term of a patent

right under Article 92," while stating in its subparagraph (ii) the case "where an extension had been registered with respect to the application of which approval under Article 89 was not obtained by the patentee or an exclusive licensee thereof or a registered nonexclusive licensee." Meanwhile, Article 90(1) of the Patent Act provides a list of items that a PTE applicant should describe in its application form, which includes "the grounds for extension prescribed by Decree of the Ministry of Trade, Industry, and Energy (accompanied by materials substantiating the grounds)" as prescribed in its subparagraph (vi). Further, Article 90 (6) of the Patent Act stipulates that "a PTE applicant may make an amendment to the matters referred to in paragraph (1) 3 through 6, which are described in the application for registration of an extension (excluding the patent number of the patent right to be extended under subparagraph 3) until the Commissioner of Korean Intellectual Property Office (KIPO) transmits a certified copy of the decision for registration or rejection of the extension." Further, Article 53 of the Enforcement Rule of the Patent Act provides a list of documents corresponding to Article 90(1)(vi) of the Patent Act, among of which is "a document of proof that a person who obtained approval or registration under subparagraph (i) is the patentee, the exclusive licensee or the registered non-exclusive licensee of the patent right" as prescribed in its subparagraph (iii).

As addressed above, the Patent Act limits the term of extension to being the period during which the patentee had intention and capability to practice the subject invention but could not practice the subject invention. Accordingly, in the case where an application for approval under the Pharmaceutical Affairs Act is filed after the registration date of the patent, in order for the period thereafter to be included in "the period during which the subject invention would not have been practiced" under Article 89 of the Patent Act, the patentee, or the exclusive licensee or non-exclusive licensee, who can lawfully practice the subject invention on behalf of the patentee, should file an

application for approval. In this regard, unlike an exclusive license right, a non-exclusive license right arises when there is an explicit/implicit agreement between the patentee and the licensee and there are no formality requirements for the creation of such an agreement. Further, the registration of a non-exclusive license right is a mere condition that is required for making a counterclaim against a third party (see Article 102 and Article 118(3) of the Patent Act). Thus, herein, any interested party, who has already reached such an agreement at the time of filing an application for approval under the Pharmaceutical Affairs Act, would qualify for the non-exclusive licensee as prescribed above and it does not necessarily require the completion of the registration of the non-exclusive license right at that time. However, in the case where the non-exclusive licensee already obtained an approval after filing an application for approval under the Pharmaceutical Affairs Act, in order to obtain a patent term extension, the PTE applicant should file an application for PTE with KIPO with an application form that satisfies the requirements prescribed in Article 90(1)(vi) of the Patent Act. Thus, in compliance with Article 90(6) of the Patent Act, in such a case, the registration of the non-exclusive license right of a non-exclusive licensee and the submission of a document proving the same should be submitted until KIPO's examiner transmits a certified copy of the decision for registration or rejection of the extension.

Therefore, in consideration of Article 134(1)(ii) of the Patent Act where the PTE invalidation ground is prescribed as the case “where an extension had been registered with respect to the application of which approval under Article 89 was not obtained by the patentee or an exclusive licensee thereof or a registered nonexclusive licensee,” it should be considered that although the scope of an applicant for an approval that is required in obtaining PTE includes a non-exclusive licensee in addition to a patentee and an exclusive licensee, the registration of the non-exclusive license right is a mandatory entry in

a PTE application form and a document of proof, and thus, if PTE was granted without the registration of the non-exclusive license right, such a registration does not meet the legitimate PTE requirements. Thus, it would be proper to construe said PTE invalidation ground as being applicable to any illegitimate registration of PTE, and its intent does not reside in regulating that the non-exclusive licensee who filed an approval should have completed the registration of the non-exclusive license right at the time of the filing the same.

2) Discussion

In view of the respective statements in Plaintiff's Exhibit 2 and 3, Defendant's Exhibit 2-1, 2-4, 19, and 25 to 32 and all the arguments presented so far, the following facts are recognized: ① Astellas Korea conducted a clinical trial regarding the Subject Patent from December 21, 2009 to August 10, 2010 and the reported the termination of a clinical trial to Korea Food & Drug Administration[18] on August 24, 2010, ② the Defendant registered the Subject Patent and entered a non-exclusive license on the Subject Patent with Astellas Korea whereby the effective period of the agreement is "from June 23, 2010 to November 4, 2023," as the effective territory is "all regions in Korea," and the grant of the license is "production, use, transfer, rental, import, subscription to transfer, subscription to rental," ③ In connection with the pharmaceutical for which the Subject Approval was filed, Astellas Korea, as the non-exclusive licensee of the Subject Patent, filed for S/T sole preliminary examination for the pharmaceutical subject to approval on November 30, 2012 and filed an application for

18) According to Article 2 of the addendum to "MFDS and the organization of the affiliated organization thereof" enacted under Article 24458 of the Presidential Decree on March 23, 2013, "Korea Food & Drug Administration" was abolished on March 23, 2013, and "MFDS" was established. Therefore, the organization name at the time of reporting the clinical trial termination was Korea Food & Drug Administration."

S/E sole preliminary examination on December 3, 2012 before the MFDS, and once the European Medicines Agency approved the above medicine on December 20, 2012, Astellas Korea filed an application for an product import approval for the pharmaceutical for which the Subject Approval was filed (after that, each sole preliminary examination, which was conducted together, was withdrawn on May 29, 2012), ④ Astellas Korea completed the registration of the above non-exclusive license on January 24, 2014, and the Defendant filed an application for the Subject PTE on March 28, 2014 and submitted the evidential materials regarding the registration to the examiners of the KIPO, and ⑤ the examiners of the KIPO granted the Subject PTE on January 20, 2015 and at that time, a certified copy thereof was delivered to the Defendant. There is no evidence contrary to the above facts.

According to the findings above, Astellas Korea was in the position of a non-exclusive licensee who can lawfully practice the Subject Patent at the time of filing an application for the product approval concerning the pharmaceutical for which the Subject Approval was filed. Further, the registration of the non-exclusive license and the submission of the documents proving the same were duly made before the transmission of a certified copy of the registration of the Subject PTE by the examiner of the KIPO. Consequently, the Subject PTE has no invalidation ground stipulated under Article 134(1)(ii) of the Patent Act.

3) Summary of Discussion

Unlike the Plaintiffs' arguments, the IPTAB Decisions holding that the Subject PTE does not have an invalidation ground under Article 134(1)(ii) of the Patent Act, are lawful.

4. Conclusion

Therefore, the Plaintiffs' petitions to revoke the IPTAB Decisions are without merit and therefore dismissed. Accordingly, the decision is made as in this order.

Presiding Judge Daekyeong LEE
Judge Woosoo KIM
Judge Hyeongjun PARK

PATENT COURT OF KOREA
THIRD DIVISION
DECISION

Case Nos.: 2016Heo8636 Scope of Rights Confirmation (Patent)
2016Heo9189 (consolidated) Scope of Rights Confirmation (Patent)

Plaintiff: Astellas Pharma Inc.

Defendants: 1. Corepharmbio Co., Ltd.
2. Hanmi Pharm Co., Ltd.

Date of Closing Argument: June 2, 2017

Decision Date: June 30, 2017

ORDER

1. The Plaintiff's petitions against the Defendants are dismissed.

2. The litigation cost shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision rendered in Case No. 2015Dang3931 (announced September 13, 2016) and No. 2016Dang547 (announced October 12, 2016) shall be vacated.

OPINION

1. Facts

A. Subject Patent (Plaintiff's Exhibit 2)

1) Title of Invention: Novel Quinuclidine Derivatives and Medicinal Composition Thereof

2) International Filing Date / Priority Date / Registration Date / Patent Number: December 27, 1995 / December 28, 1994 / May 23, 2003 / No. 386487

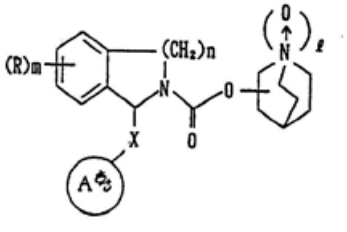
3) Patentee: Plaintiff

4) Claims (corrected according to IPTAB Decision No. 2007Jeong35 finalized on July 16, 2008; Claim 1 of the Subject patent is hereinafter referred to as "Claim 1" and the other claims are referred to in the same manner)

[Claim 1]

A quinuclidine derivative represented by the following formula (I):

Formula (I)



where the symbols in the formula have the following meanings:
Ring A:
an aryl group having 6 to 14 carbon atoms;
a cycloalkyl group having 3 to 8 carbon atoms;
a cycloalkenyl group having 3to 8 carbon atoms; or
a 5- or 6- membered heteroaryl group or a 5- to 7-membered saturated heterocyclic group having 1 to 4 hetero atoms selected from the group consisting of an oxygen atom, a nitrogen atom and a sulfur atom,
wherein Ring A may be substituted by a substituent selected from the group consisting of a halogen atom; a hydroxyl group; an alkoxy group having 1 to 6 carbon atoms, a carboxyl group; an alkoxycarbonyl group having 1 to 6 carbon atoms; an acyl group having 1 to 6 carbon atoms; a mercapto group; an alkylthio group having 1 to 6 carbon atoms; a sulfonyl group; an alkylsulfonyl group having 1 to 6 carbon atoms; a sulfinyl group; an alkylsulfinyl group having 1 to 6 carbon atoms; a sulfonamido group; an alkanesulfonamido group having 1 to 6 carbon atoms; a carbamoyl group; a thiocarbamoyl group; a mono- or di-alkylcarbamoyl group having 1 to 6 carbon atoms; a nitro group; a cyano group; an amino group; a mono- or di-alkylamino group having 1 to 6 carbon atoms; a methylenedioxy group; an ethylenedioxy group; or an alkyl group having 1 to 6 carbon atoms which may be substituted by a halogen atom, a hydroxyl group, an alkoxy group having 1 to 6 carbon atoms, an amino group or mono- or di- alkylamino group having 1 to 6 carbon atoms,
X: a single bond or a methylene group;
R: a halogen atom; a hydroxyl group; an alkoxy group having 1 to 6 carbon atoms; a carboxyl group; an alkoxycarbonyl group having 1 to 6 carbon atoms; an acyl group having 1 to 6 carbon atoms; a mercapto group; an alkylthio group having 1 to 6 carbon atoms; a sulfonyl group; an alkylsulfonyl group having 1 to 6 carbon atoms; a sulfinyl group; an alkylsulfinyl group having 1 to 6 carbon atoms; a sulfonamido group; an alkanesulfonamido group having 1 to 6 carbon atoms; a carbamoyl group; a thiocarbamoyl group; a mono- or di alkylcarbamoyl group having 1 to 6 carbon atoms; a nitro group; a cyano group; an amino group; a mono- or di- alkylamino group having 1 to 6 carbon atoms; a methylenedioxy group; an ethylenedioxy group; or an alkyl group having 1 to 6 carbon

atoms which may be substituted by a halogen atom, a hydroxyl group, an alkoxy group having 1 to 6 carbon atoms, an amino group or a mono- or di- alkylamino group having 1 to 6 carbon atoms;
ℓ: 0 or 1;
m: 0 or an integer of 1 to 3; and
n: an integer of 1 or 2,
a salt thereof, an N-oxide thereof, or a quaternary ammonium salt thereof.

[Claim 2]

The quinuclidine derivative, a salt thereof, an N-oxide thereof or a quaternary ammonium salt thereof according to claim 1, wherein R represents a halogen atom, an alkyl group having 1 to 6 carbon atoms; a hydroxyl group; an alkoxy group having 1 to 6 carbon atoms; a nitro group; a cyano group; an amino group; or a mono- or di- alkylamino group having 1 to 6 carbon atoms, and
the ring A represents an aryl group having 6 to 14 carbon atoms, a cycloalkyl group having 3 to 8 carbon atoms, a cycloalkenyl group having 3 to 8 carbon atoms, or a 5- or 6- membered monocyclic heteroaryl group or a 5- to 7-membered saturated heterocyclic group having 1 to 4 hetero atoms selected from the group consisting of an oxygen atom, a nitrogen atom and a sulfur atom,
in which the ring A may be substituted by a halogen atom, an alkyl group having 1 to 6 carbon atoms, a hydroxyl group, an alkoxy group having 1 to 6 carbon atoms, a nitro group, a cyano group, an amino group or a mono- or di-alkylamino group having 1 to 6 carbon atoms.

[Claim 3]

The quinuclidine derivative, a salt thereof, an N-oxide thereof, or a quaternary ammonium salt thereof according to claim 2, wherein m is 0, and the ring A represents an aryl group having 6 to 14 carbon atoms, a cycloalkyl group having 3 to 8 carbon atoms or a cycloalkenyl group having 3 to 8 carbon atoms which may be substituted by a halogen atom, an alkyl group having 1 to 6 carbon atoms, a hydroxyl group or an alkoxy group having 1 to 6 carbon atoms.

[Claim 4]

The quinuclidine derivative, a salt thereof, an N-oxide thereof, or a quaternary ammonium salt thereof according to claim 3, wherein the ring A represents a phenyl group which may be substituted by a halogen atom or an alkyl group having 1 to 6 carbon atoms, an cycloalkyl group having 3 to 8 carbon atoms, a pyridyl group, a furyl group, or a thienyl group

[Claim 5]

The quinuclidine derivative, a salt thereof, an N-oxide thereof, or a quaternary ammonium salt thereof according to any one of claims 2 to 4, wherein X represents a single bond.

[Claim 6]

The quinuclidine derivative, a salt thereof, an N-oxide thereof or a quaternary ammonium salt thereof according to any one of claims 2 to 4, wherein n is 2.

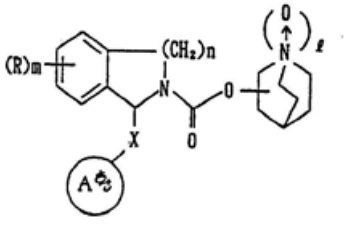
[Claim 7]

A quinuclidine derivative, a salt thereof, an N-oxide thereof or a quaternary ammonium salt thereof according to claim 1, which is selected from the group consisting of 3-quinuclidinyl
1-phenyl-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate,
3-quinuclidinyl 1-(4-pyridyl)-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate,
3-quinuclidinyl 1,2,3,4-tetrahydro-1-(2-thienyl)-2-isoquinolinecarboxylate,
3-quinuclidinyl 1,2,3,4-tetrahydro-1-(3-thienyl)-2-isoquinolinecarboxylate,
3-quinuclidinyl 1-(2-furyl)-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate,
3-quinuclidinyl 1-(4-chlorophenyl)-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate,
3-quinuclidinyl 1-(4-fluorophenyl)-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate,
3-quinuclidinyl 1,2,3,4-tetrahydro-1-(4-tolyl)-2-isoquinolinecarboxylate,
3-quinuclidinyl 1-cyclohexyl-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate,
3-quinuclidinyl 1-(3-furyl)-1,2,3,4-tetrahydro-2-isoquinoline carboxylate,
and optically active substances thereof.

[Claim 8]

A pharmaceutical composition comprising a quinuclidine derivative represented by the following formula (I), which is a muscarinic M3 receptor antagonist, a salt thereof, an N-oxide thereof or a quaternary ammonium salt thereof and a pharmaceutically acceptable carrier, useful for prevention and treatment of urinary diseases including urinary incontinence or pollakiuria in neurogenic pollakiuria, neurogenic bladder, nocturnal enuresis, unstable bladder, cystospasm or chronic cystitis or respiratory diseases including chronic obstructive pulmonary diseases, chronic bronchitis, asthma or rhinitis.

Formula (I)



where the symbols in the formula have the following meanings:
Ring A:
an aryl group having 6 to 14 carbon atoms;
a cycloalkyl group having 3 to 8 carbon atoms;
a cycloalkenyl group having 3to 8 carbon atoms; or
a 5- or 6- membered heteroaryl group or a 5- to 7-membered saturated heterocyclic group having 1 to 4 hetero atoms selected from the group consisting of an oxygen atom, a nitrogen atom and a sulfur atom,
wherein Ring A may be substituted by a substituent selected from the group consisting of a halogen atom; a hydroxyl group; an alkoxy group having 1 to 6 carbon atoms, a carboxyl group; an alkoxycarbonyl group having 1 to 6 carbon atoms; an acyl group having 1 to 6 carbon atoms; a mercapto group; an alkylthio group having 1 to 6 carbon atoms; a sulfonyl group; an alkylsulfonyl group having 1 to 6 carbon atoms; a sulfinyl group; an alkylsulfinyl group having 1 to 6 carbon atoms; a

sulfonamido group; an alkanesulfonamido group having 1 to 6 carbon atoms; a carbamoyl group; a thiocarbamoyl group; a mono- or di-aklylcarbamoyl group having 1 to 6 carbon atoms; a nitro group; a cyano group; an amino group; a mono- or di-alkylamino group having 1 to 6 carbon atoms; a methylenedioxy group; an ethylenedioxy group; or an alkyl group having 1 to 6 carbon atoms which may be substituted by a halogen atom, a hydroxyl group, an alkoxy group having 1 to 6 carbon atoms, an amino group or mono- or di- alkylamino group having 1 to 6 carbon atoms,

X: a single bond or a methylene group;

R: a halogen atom; a hydroxyl group; an alkoxy group having 1 to 6 carbon atoms; a carboxyl group; an alkoxycarbonyl group having 1 to 6 carbon atoms; an acyl group having 1 to 6 carbon atoms; a mercapto group; an alkylthio group having 1 to 6 carbon atoms; a sulfonyl group; an alkylsulfonyl group having 1 to 6 carbon atoms; a sulfinyl group; an alkylsulfinyl group having 1 to 6 carbon atoms; a sulfonamido group; an alkanesulfonamido group having 1 to 6 carbon atoms; a carbamoyl group; a thiocarbamoyl group; a mono- or di alkylcarbamoyl group having 1 to 6 carbon atoms; a nitro group; a cyano group; an amino group; a mono- or di- alkylamino group having 1 to 6 carbon atoms; a methylenedioxy group; an ethylenedioxy group; or an alkyl group having 1 to 6 carbon atoms which may be substituted by a halogen atom, a hydroxyl group, an alkoxy group having 1 to 6 carbon atoms, an amino group or a mono- or di- alkylamino group having 1 to 6 carbon atoms;

ℓ: 0 or 1;

m: 0 or an integer of 1 to 3; and

n: an integer of 1 or 2

B. Grant of Patent Term Extension

1) According to Article 34(1) of the old Pharmaceutical Affairs Act (before amendment of Act No. 8035 on October 4, 2006 effective from April 5, 2007; hereinafter same), the Plaintiff obtained a product import approval for a drug (Approval No. 16) from the Commissioner of the Korea Food & Drug

Administration ("KFDA") (later changed to the Minister of the Ministry of Food and Drug Safety ("MFDS") under the revised Government Organization Act): the name of the imported product of "VESIcare tablet 5mg (solifenacin succinate)"; the classification number of "medicines for urogenital organs and anus (02590)"; the drug substances and their amount of "solifenacin succinate 5.0 mg as a principle component, and an excipient, a coating agent, a binder, etc., in one tablet (154mg)"; the classification of medicine of "prescription medicine"; and the form and shape of "light yellow circular film-coated tablet."

2) According to Articles 89 and 90 of the old Korean Patent Act (before amendment of Act No. 8357 on April 11, 2007), the Plaintiff filed a Patent Term Extension ("PTE") application for the Subject patent on June 26, 2007 requesting that the Commissioner of the KIPO extend the patent term of the Subject patent by one year, six months, and sixteen days, which is the period during which the Subject patent could not be practiced for the reason that it took one year, six months, and sixteen days to obtain a product import approval for the drug described in Item 1) above in order to practice the Subject patent. Regarding "an approval, etc. under Article 89 of the Korean Patent Act," the PTE application describes as follows:

【Date of approval, etc. under Article 89 of the Korean Patent Act】	March 30, 2007.
【Contents of approval (Contents of registration)】	Product Import Approval No. 16
【Compound name of active ingredient】	(1S)-(3R)-1-azabicyclo[2.2.2]oct-3-yl 3,4-dihydro-1-phenyl-2(1H)-isoquinoline carboxylate

【Generic name (item name)】 solifenacin succinate

【Product name (Trade name)】 VESIcare tablet

【Efficacy and effect (use)】 Treatment of hypersensitive urinary bladder disorders)

3) Under Article 92(1) of the old Korean Patent Act, the KIPO examiner granted the PTE application on August 21, 2007, stating that the patent term of Claims 1-8 shall be extended by one year, six months, and sixteen days. Thus, the patent term expiration date of Claims 1-8 was extended from December 27, 2015 to July 13, 2017.

C. Challenging Inventions

1) Challenging Invention 1, for which the Defendant Corepharmbio Co., Ltd (hereinafter, "Defendant Corepharmbio") obtained a product approval on July 25, 2016 from the Minister of the MFDS to practice, is directed to "a pharmaceutical composition comprising solifenacin fumarate" and the details are as follows:

1. Name of Challenging Invention 1

Pharmaceutical composition

2. Description of Challenging Invention 1

Challenging inventions 1 is a pharmaceutical composition containing solifenacin fumarate consisting of ingredients described in Table 1 below,

[Table 1]

Purpose of compounding	Ingredient Name
Principle component	solifenacin fumarate
Excipient	lactose hydrate
Binder	hypromellose
Disintegrant	crospovidone
Lubricants	magnesium stearate
coating substrate	Easycoat (IG6407R1510)

and is a pharmaceutical composition having a medicinal use of preventing or treating urinary diseases such as urinary incontinence or pollakiuria in neurogenic pollakiuria, neurogenic bladder, nocturnal enuresis, unstable bladder, cystospasm or chronic cystitis

2) Challenging invention 2, for which the Defendant Hanmi Pharm Co., Ltd (hereinafter referred to as "Defendant Hanmi") obtained a product approval from the Minister of the MFDS on January 24, 2017 to practice, is directed to "a pharmaceutical composition containing solifenacin tartrate" and the details are as follows.

1. Name of Challenging invention 2

Pharmaceutical composition containing solifenacin tartrate

2. Description of Challenging invention 2

A pharmaceutical composition that contains solifenacin tartrate as a principle component (which means a material actually included in a pharmaceutical composition) and does not comprise solifenacin succinate. Further, said pharmaceutical composition is useful for prevention and treatment of hypersensitive urinary bladder disorders such as urinary incontinence or pollakiuria, etc.

D. The Decision Below

1) The Defendant Corepharmbio filed a negative scope confirmation action against the Plaintiff with the IPTAB on July 15, 2015 (Case No. 2015Dang3931), and the Defendant Hanmi filed the same on March 3, 2016 (Case No. 2016Dang547,) arguing that “all of the Challenging Inventions do not fall within the scope of the Subject patent on which the PTE has been granted as described in Item B-3) above.”

2) The IPTAB rendered decisions accepting the Defendant Corepharmbio's petition on September 13, 2016 and the Defendant Hanmi's petition on October 12, 2016, holding that “the Challenging Inventions do not fall within the scope of Claims 1-8 of the Subject patent on which the PTE has been granted since the patent right of said claims is limited to “solifenacin succinate”, which is the approved product on which the PTE has been granted, during the extended patent term (hereinafter, “the IPTAB Decision”)

[Factual Basis] Statements in the Plantiff’s Exhibits. 1, 2, 3, 4, 6, 7, 8, 14, 15, 16, and 17 and Defendant 1’s Exhibit 1, and the purport of the overall argument

2. Summary of Arguments

A. Summary of the Plaintiff’s Arguments

The IPTAB erred in its decisions for the following reasons and thus the IPTAB Decisions should all be vacated.

1) Primary Argument

The technical characteristic of the Subject patent lies in creating a medically useful novel compound. The reason why it took a long time to obtain the product import approval for the Plaintiff's drug is that safety/efficacy of solifenacin, which is a compound in the form of a free base, must be confirmed. The purport of the PTE system is to extend the patentee's market exclusivity for a certain period of time even after the expiration of the patent term of a medicinal substance patent, thereby promoting researches and developments in the pharmaceutical field. Thus, regarding the scope of the patent right of the patent during the extended term, “products whose approval was the basis for registering the extension” in Article 95 of the old Korean Patent Act should be construed based on the active ingredient of the medicinal substance patent. Thus, the patent right of the Subject patent whose term was extended is exerted to every form of salt containing solifenacin as an active ingredient.

Accordingly, the Challenging Inventions comprising solifenacin as an active ingredient fall within the scope of the Subject patent.

2) Supplemental Argument

Even if “products whose approval was the basis for registering the extension” in Article 95 of the old Korean Patent Act are not construed to mean only the active ingredient of the medicinal substance patent, if it is allowed for follow-on drug manufacturers to develop drugs having the same active ingredient but in a different salt form during the extended term of the Subject patent and easily obtain a manufacture/sales approval by relying on Plaintiff’s safety/efficacy data, this would be against the purport of the PTE system against the purpose of the Patent Act.

Given the above, the patent right of the Subject patent during the

extended term should be at least construed as covering the Challenging Inventions comprising “solifenacin fumarate” and “solifenacin tartrate,” which are substantially identical to “solifenacin succinate,” as principle components.

Thus, the Challenging Inventions fall within the scope of the Subject patent for which the PTE is granted.

B. Summary of the Defendants' Arguments

1) Defendant Corepharmbio

A) Article 89 of the old Korean Patent Act stipulates that in the case of an invention which requires a product import approval, etc. on a drug in order to practice the patented invention, the patent term may be extended in consideration of the fact that the patentee cannot practice the patented invention for a long time during which it takes time to perform safety/efficacy study necessary to obtain the approval, etc.

Further, as for the scope of the patent right of the patent whose term has been extended, Article 95 of the old Korean Patent Act stipulates “the effects of a patent right do not extend to any other acts except working the patented invention for products whose approval was the basis for registering the extension.” These regulations are intended to place a limit to the scope of the effect of the patent right during the extended term so that it can only reach the overlapped scope between the scope where a barrier for practicing the patent right is removed by obtaining a product import approval prescribed under the

Pharmaceutical Affairs Act during the patent term and the scope of the patented invention.

However, the target of the safety/efficacy study performed by the Plaintiff for obtaining the product import approval was a drug containing "solifenacin succinate" as a principle component.

Accordingly, the scope where a ban of practicing is removed within the term of the Subject patent is limited to drugs containing "solifenacin succinate" as a principle component and it does not stretch out to a drug containing "solifenacin fumarate" as a principle component. Thus, the effect of the patent right of the Subject patent during the extended term should be limited to practicing of drugs containing "solifenacin succinate" as a principle component, i.e., the target product on which the PTE has been granted.

Thus, Challenging invention 1, which is a drug containing "solifenacin fumarate" as a principle component, does not fall under the scope of the Subject patent during the extended term.

B) Even if the effect of the patent right of the Subject patent during the extended term is exerted up to the substantially same scope of "solifenacin succinate," solifenacin succinate and solifenacin fumarate cannot be considered to be substantially the same for the following reasons, and thus, Challenging invention 1 does not fall under the scope of the Subject patent during the extended term:

(1) Even if the active ingredient is the same, drugs that

only differ in the form of a salt may have different activity/safety. Thus, in order to obtain a manufacture/sales approval on a drug, activity/safety study data should be submitted. As the Defendant Corepharmbio obtained a manufacture/sales approval for a drug by submitting activity/safety study data through animal and clinical testing regarding a drug comprising solifenacin fumarate, a pharmaceutical comprising solifenacin succinate and a pharmaceutical comprising solifenacin fumarate are pharmaceuticals that differ in the form of a salt and thus are differently treated.

(2) If the same pharmaceutical as pharmaceutical (A) is additionally listed on the List of Benefit in Kind for Medicines, the price of pharmaceutical (A) will be reduced by 53.55%. However, even if pharmaceutical (B) that only differs in the form of a salt is additionally listed, the price of the pharmaceutical (A) will not be reduced. Thus, pharmaceuticals that only differ in the form of a salt are different even in terms of the price.

(3) Separately from the Subject patent, a patent application directed to a pharmaceutical comprising solifenacin fumarate was recognized as being novel and inventive and thus granted as a patent by the USPTO. Therefore, from the technical viewpoint, a pharmaceutical comprising solifenacin fumarate, i.e., Challenging invention 1, cannot be considered substantially identical to a pharmaceutical comprising solifenacin succinate.

2) Defendant Hanmi

A) Korea was obliged to adopt the PTE system due to the trade pressures from developed countries such as the U.S., rather than balancing profits between the patentee and the generic drug makers as done in the U.S. Article 95 of the Korean Patent Act stipulates that the extended patent right only takes effect to "products whose approval was the basis for registering the extension." Further, in a product approval or safety/efficacy examination regarding a pharmaceutical, a principle component is at issue. During the period during which the patentee could not have manufactured/sold the drug due to obtaining the approval, etc., the patentee still enjoyed exclusive right for the patented invention. Therefore, if the effect of the patent right during the extended term is equally treated to the patent right before an extension is granted, this would be improper since undue benefits will be given to the patentee.

Given the above, the effect of the extended patent right should be interpreted as only taking effect to pharmaceuticals having the same principle component as the pharmaceutical whose approval was the basis for registering the extension.

Thus, Challenging invention 2, which is a pharmaceutical comprising "solifenacin tartrate" as a principle component, does not fall under the scope of the Subject patent during the extended term when the effect of the patent right only takes effect to an act of practicing a pharmaceutical comprising "solifenacin succinate" as a principle component.

B) Even if the effect of the patent right during the extended term can cover the substantially same scope of "solifenacin succinate," in the case of pharmaceuticals having different salt, it is necessary to separately submit materials for safety/efficacy examination and the like contrary to simple generic drugs. If the form of salt is modified, physicochemical properties such as solubility or hygroscopicity are changed and the degree of absorption of drug is changed as well. Thus, an approved drug cannot be considered to be substantially identical to pharmaceuticals having different salt. Thus, Challenging invention 2 does not fall under the scope of the patent right of the Subject patent during the extended term.

C) The subject patent application was filed on December 27, 1995. Article 89(1) of the Korean Patent Act as of the filing date (before amendment by Act No. 5576 on September 23, 1998) stipulated that the PTE can be granted only for 2 years or more as a period during which the patented invention could not have been executed. However, the Subject patent does not correspond to the case where the patented invention could not have been executed for 2 years or more. Thus, the grant of the PTE on the Subject patent violates the provision in the Patent Act and thus is invalid. Thus, since the term of the Subject patent already expired on December 27, 2015, Challenging invention 2 does not fall under the scope of the Subject patent.

3. Whether the Challenging Inventions fall within the Scope of the subject patent

A. The scope of the effect of the patent right of the Subject patent

1) Relevant Law

The old Korean Patent Act (before amendment by Act No. 8357 on April 11, 2007)
Article 88 (Term of Patent Right)
(1) The term of a patent right shall commence upon registration of the patent right under Article 87 (1) and be in force for twenty years from the filing date of the patent application.

Article 89 (Extension of Term of Patent Right)
Notwithstanding the provisions of Article 88 (1), where approval or registration under provisions of other Acts or subordinate statutes were required in order to work a patented invention, and it has taken an extended period of time to complete the activity test, the safety tests, etc., necessary to obtain such approval or registration (hereinafter referred to as an "approval") and which is prescribed by the Presidential Decree, the term of the patent right may be extended by a period, up to five years, during which the patented invention could not have been executed.

Article 95 (Effects of Patent Right Term of Which has been Extended)
The effects of a patent right, the term of which has been extended, shall not extend to any other acts except the working of the patented invention with respect to such products for which an approval was the basis for registering the extension (or where the approval was obtained for any specific use of the product, with respect to the product adapted for such specific use).

The Enforcement Decree of the old Korean Patent Act (before amendment by Presidential Decree No. 20127on June 28, 2007)

Article 7 (Invention subject to Application for Registration of Patent Right Duration Extension)
For the purpose of Article 89 of the Act, the term "invention as prescribed by the Presidential Decree" means any of the following inventions:
1. Invention of medicines which is subject to the item license under Article 26 (1) or 34 (1) of the Pharmaceutical Affairs Act for the purpose of embodying the patented invention

The old Pharmaceutical Affairs Act (before amendment by Act No. 8035 on October 4, 2006 and enforcement on April 5, 2007)

Article 2 (Definitions)
(4) For the purpose of this Act, the term "medicines" means articles falling under any of the following subparagraphs:
1. Articles listed in the Korean Pharmacopoeia other than non-pharmaceutical drugs;
2. Articles used for the purpose of diagnosis, medical care, alleviation, treatment or prevention of diseases of human beings or animals, excluding appliances, machinery or equipment; and
3. Articles, other than appliances, machinery or equipment, used for the purpose of exerting pharmacological effect upon the structure or functions of human beings or animals.

Article 26 (License, etc. for Manufacturing Industry)
(1) Any person who intends to carry on the business of manufacturing medicines shall obtain a license from the Commissioner of the Korea Food and Drug Administration as prescribed by the Ordinance of the Ministry of Health and Welfare. Any person who intends to do the business of manufacturing non-pharmaceutical drugs shall file a report thereof with the Commissioner of the Korea Food and Drug Administration, obtain a license by item from him or file a report by item with him. In this case, where he intends to alter matters prescribed by the Ordinance of the Minister of Health and Welfare from among licensed matters or reported matters, he shall obtain permission for such alteration or file an alteration report as prescribed by the Ordinance of the Ministry of Health and Welfare.

(6) In the case as referred to in paragraph (1), if the items to be licensed are new medicines or medicines designated by the commissioner of the Korea Food and Agriculture Administration, test results and pertinent literature on their safety and effectiveness and other necessary data shall be submitted in accordance with the Ordinance of the Ministry of Health and Welfare
(8) In granting a license for the manufacturing industry and manufacturing items of medicine, etc. as referred to in paragraph (1), the matters necessary for the object, standard, condition, control, etc. of the license, shall be determined by the Ordinance of the Ministry of Health and Welfare.

Article 34 (Permission, etc. on Import of Medicines, etc.)
(1) Any importer (hereinafter referred to as "importer") shall obtain permission from, or file a report to the Commissioner of the Korea Food and Drug Administration, by items under the conditions as prescribed by the Ordinance of the Ministry of Health and Welfare. This provisions shall also apply in the case where he desires to modify the permitted or reported matters.
(5) In granting a license for import items of medicine, etc. as referred to in paragraph (1), the matters necessary for the object, standards, condition, control, etc. of the license, shall be determined by the Ordinance of the Ministry of Health and Welfare.

The Enforcement Regulation of the old Pharmaceutical Affairs Act (before amendment by No. 401 under the Ordinance of the Ministry of Health and Welfare on May 4, 2007)

Article 23 (Application for Approval on Manufacture/Import Item)
(1) Any person who desires to obtain a product approval on pharmaceuticals under Article 26(1) or Article 34(1) of the Act should submit an application (including an application in the form of an electronic document) according to Annexed Document Form No. 12 to the Commissioner of the KFDA by enclosing documents (including documents in the form of an electronic document) indicated in the following items:

1. Pharmaceuticals/Non-pharmaceuticals
A. Notification of safety/efficacy examination results under Article 27 from which two years have not yet lapsed or materials necessary for the safety/efficacy examination (the conditions are omitted)
B. Notification of standards and test methods examination results under Article 2722 from which two years have not yet lapsed or materials regarding standards and test methods (the conditions are omitted)

C. In the case of items corresponding to the following, bioequivalence test plan, test materials regarding bioequivalence test, comparative clinical study plan or comparative clinical study results (the conditions are omitted)

E. In the case of imported products, documents regarding manufacture and sales of the corresponding item corresponding to the following. In this case, details on the requirements of documents to be attached shall be notified by the Commissioner of the KFDA.

(1) a certificate of manufacture by which the government or public agency of the country of production proves that the item has been manufactured in accordance with the Acts of the country of production

(2) a certificate of sales by which the government or public agency of the country of approval or registration proves that the item has been sold in accordance with the Acts of the country

F. Among general pharmaceuticals, in the case of obtaining an approval on a pharmaceutical comprised of a single ingredient and having the same ingredient as the tablets, capsules, or suppositories for which the manufacture (import) product approval was already granted, materials notified by the Commissioner of the KFDA, such as comparative elution test materials, etc.

G. In the case of DNA recombinant pharmaceuticals/cell culture pharmaceuticals/biological formulations/cell therapy agents and gene therapy agents and pharmaceuticals recognized as being applicable by the Commissioner of the KFDA, a material proving that the practice

circumstance of each item satisfies the standards on manufacture of pharmaceutical and management of quality of Attachment 4 and the standard on manufacture and quality management of biological formulations, etc. of Attachment 4-4

H. In the case of an item using drug substance under Article 24(1)(vi) (hereinafter, "a target drug substance on which the report should be completed"), a Notification of report on drug substance under Article 24(3) and attached materials; however, in the case of drug substance on which the report was already completed under Article 24(3), such a material does not need to be submitted.

I. Materials regarding the name and location of the manufacturer manufacturing the principle component of the pharmaceutical, notified by the Commissioner of the KFDA

Article 24 (Report on Manufacture/Import Item)

① Items of pharmaceutical, etc. on which report should be completed under Article 26(1) or 34(1) of the Act are indicated in each of the following items. However, items of pharmaceuticals for which the manufacture/product import approval is limited under Article 21, items of pharmaceuticals which should undergo the safety/efficacy examination under Article 27(1), biological formulations, radioactive pharmaceuticals, DNA recombinant pharmaceuticals/cell culture pharmaceuticals/gene therapy agents, and cell therapy agents, etc., are excluded, and in the case where an item corresponds to items 1 to 4 is a drug substance on which a report should be completed, items 1 to 4 do not apply.

1. items disclosed in the Korean Pharmacopoeia or the Korean Herbal (Botanical) Pharmacopoeia other than the Korean Pharmacopoeia
2. items disclosed in official compendium and formulary recognized by the Commissioner of the KFDA. However, items that are not domestically approved are excluded.
3. items satisfying the standard manufacturing criteria on pharmaceuticals standardized and notified by the Commissioner of the KFDA
4. pharmaceuticals or non-pharmaceuticals whose standards and test

methods are notified by the Commissioner of the KFDA
6. pharmaceuticals notified by the Commissioner of the KFDA as a target item on which a report should be completed

Article 26 (Standards etc. on Approval)
Under Article 2(9), 26(8) or 34(5) of the Act, the Commissioner of the KFDA has an authority to determine details on standards, conditions, and management, etc. of approval or approval alteration for the business of manufacturing and the manufacture/import items of pharmaceuticals etc. that are not determined under Articles 21 to 25 and 83.

Article 45 (Product Import Approval: Register and Certification of Approval)
When a product import approval for a drug is granted or a report on a pharmaceutical is received by the Commissioner of the KFDA or the Regional Commissioner, the corresponding matters according to each of the following items shall be described in the Approval Register and the Report Receipt Register and in the case of granting an approval, the Certification of Approval according to Annexed Document Form No. 25 and in the case of receiving a report, the Certification of Completion of Report according to Annexed Document Form No. 15-4 or 15-5 shall be issued.

1. In the case of a product import approval
A. Approval number and approval date
B. Name of product

2) The scope of the patent right of the patented invention during the extended term

A) The PTE system under Article 89 of the old Korean Patent Act, Article 7(1) of the Enforcement Decree of the old Korean Patent Act, etc. is a system for granting patent term extension by a period, of up to five years, during which a patented invention could not have been executed,

if an approval needs to be obtained under other Acts in order to conduct the patented invention during the patent term and it takes a long time to obtain the approval due to necessary activity/safety tests.

In the case of pharmaceutical and agrochemical inventions, approval and registration should be obtained from the regulatory authority under the Pharmaceutical Affairs Act or the Agrochemicals Control Act which aims at securing safety and efficacy (hereinafter, referred to as "approval, etc. under the Pharmaceutical Affairs Act, etc.") and it takes a long period of time to complete tests and examinations necessary for obtaining the approval.

In this case, even if the patent is in force, the patentee cannot practice the patented invention during such a period and cannot enjoy benefit from exclusive owning of the patent right and thus has a disadvantage that research and development costs cannot be recovered. This leads to a lack of fairness in the patent right in the field of pharmaceuticals and agrochemicals compared to the patent right in other industrial fields. Therefore, in order to resolve the unfairness issue, to protect and encourage pharmaceutical inventions, and to promote technical development in the relevant field, Article 89 of the old Patent Act provides a system for granting patent term extension by a period, of up to five years, during which the patented invention could not have been executed due to obtaining approval under the Pharmaceutical Affairs Act, etc.

Meanwhile, without approval, etc. under the Pharmaceutical Affairs Act, etc., an act of manufacturing/selling pharmaceuticals is generally and abstractly prohibited. The act of manufacturing/selling is not allowed until respective

and specific remedies under the relevant administrative laws are obtained. Thus, as long as there is no approval under the Pharmaceutical Affairs Act, the prohibition of the act of manufacturing/selling is continued.

However, Article 95 of the old Patent Act stipulates that the effect of the patent right during the extended term only effectuates to an act of practicing the patented invention directed to the product[1] whose approval was the basis for registering the extension and based on which the PTE has been granted. As such, given that the old Korean Patent Act allowing the PTE system while providing a separate provision for limiting the scope of the patent right during the extended term, the effect of the patent right of the patented invention during the extended term should not be considered as affecting the entire scope of the patented invention in question, but in principle, should be considered as effectuating to an act of practicing the patented invention regarding the product whose approval was the basis for registering the extension, i.e., the scope of a product approval for manufacturing and selling/importing a pharmaceutical under the Pharmaceutical Affairs Act, etc., based on which the PTE has been granted. If the effect of the patent right during the extended term effectuates beyond the scope of the obtained an approval, etc. for manufacture and import under the Pharmaceutical Affairs Act, etc., this would not only go against the literal description of Article 95 of the old Korean Patent Act, which restricts the effect of the patent right during the

1) In the approval, etc., in the case where the specific use of the product is determined, this term refers to "a product that is used for that particular use," and the same applies hereinafter.

extended term to an act of practicing the product whose approval "was the basis for registering the extension" but also impart unjust profit to the patentee beyond the scope of compensation for disadvantage by recovering the period during which the patented invention could not have been executed. This would lead to loss of balance between the patentee and the third party.

Meanwhile, as reviewed above, it is clear that an "approval, etc." prescribed under Article 95 of the Korean Patent Act refers to "a product approval for manufacture/import" prescribed under the Pharmaceutical Affairs Act and the "product" refers to a pharmaceutical for which an approval for manufacture/import has been granted under the old Pharmaceutical Affairs Act, etc. In conclusion, how far the effect of the patent right during the extended term would effectuate depends on how far the scope of a pharmaceutical for which a product approval for manufacture/import has been granted under the old Pharmaceutical Affairs Act, etc.

B) Articles 26(1) and 26(8) and 34(1) and 34(8), etc. of the old Pharmaceutical Affairs Act prescribe that any person who desires to conduct manufacturing of pharmaceuticals as a business shall obtain an approval from the Commissioner of the KFDA and obtain a product approval for each pharmaceuticals, etc. as provided by the Ordinance of the Ministry of Health and Welfare, and any person who desires to import pharmaceuticals shall obtain an approval from the Commissioner of the KFDA or file a report on each pharmaceutical as provided by the Ordinance of the Ministry of Health and Welfare. Further, necessary matters on subjects/standards/conditions/and management regarding

an approval for business of manufacture of pharmaceuticals, a product approval for manufacture, and a product approval for import shall be determined by the Ordinance of the Ministry of Health and Welfare.

Article 23(1) of the Enforcement Regulation of the old Pharmaceutical Affairs Act, which is delegated by the Ordinance, stipulates that any person who desires to obtain a pharmaceutical manufacture/import approval should submit an application according to Annexed Document Form No. 12 to the Commissioner of the KFDA with enclosing materials necessary for the safety/efficacy examination, materials regarding standards and test methods, and bioequivalence test plan, test materials regarding bioequivalence test, etc. The application for obtaining a pharmaceutical manufacture/ import approval according to Annexed Document Form No. 12 should indicate the name of product (in the case of an import, the name of imported product), class of medicines, drug substances (raw materials) and their amount, receipt number for drug substance report, form and shape (shape and structure), manufacturing method, efficacy/effect, dosage/regimen, instructions for use, packaging unit, storage method, expiration (expiry) date, standards and test methods, manufacturer (in the case of an import), remarks, etc. (Article 34(1) of the Enforcement Regulation under the old Pharmaceutical Affairs Act prescribes that when a manufacture product approval or a product import approval for a drug is granted by the Commissioner of the KFDA, the approval number, approval date, and product name shall be described in the Approval Register and the Certification of Approval according to Annexed Document Form No. 25 shall be issued and the matters described in

the Certification of Pharmaceutical Manufacture/Import approval according to Annexed Document Form No. 25 are identical to those described in an application for obtaining a pharmaceutical manufacture/import approval).

Further, Article 6 of KFDA Notification No. 2007-18 "Regulations on Review of Application (Report) to obtain Pharmaceutical/ Non-pharmaceutical Manufacture/Import approval[2)]" stipulates that the matter which is described in the Certification of Pharmaceutical Manufacture/Import approval according to Articles 26, 34, or 45 of the Enforcement Regulation of the Pharmaceutical Affairs Act to be reviewed and managed with respect to a subject of an approval or approval alteration includes the name of product, classification number and division (professional or general), drug substances and their amount, outer form and shape, manufacturing method, efficacy/effect, regimen/ dose, instructions for use, packaging unit, storage method, and expiration (expiry) date, standards and test methods, manufacturer, location, approval conditions, etc.

Meanwhile, under Article 24(1) of the Enforcement Regulation of the old Pharmaceutical Affairs Act, items of pharmaceuticals for which the manufacture/import approval is limited, items of pharmaceuticals which should undergo the safety/efficacy examination, items of pharmaceuticals disclosed under Korean Pharmacopoeia, etc. except for biological formulations, radioactive pharmaceuticals, DNA

2) This Notice was applied at the time of the product import approval of this case and has been revised several times, thereby now providing the nearly same regulations as KFDA Notice "Regulations on Pharmaceutical Product Approval/Report/Examination."

recombinant pharmaceuticals/cell culture pharmaceuticals/ gene therapy agents, cell therapy agents, etc., and pharmaceuticals notified as items subject to report by the Commissioner of the KFDA are defined as items of pharmaceuticals for which the manufacture/ import item report should be completed. Further, under Article 26 of the Enforcement Regulation of the old Pharmaceutical Affairs Act, the Commissioner of the KFDA has an authority to determine details on standards, conditions, and management, etc. of approval or approval alteration for the business of manufacture and the manufacture/ import items of pharmaceuticals etc. that are not determined under Articles 21 to 25 of the Enforcement Regulation of the old Pharmaceutical Affairs Act.

KFDA Notification No. 2006-25 “Designation of Drug Product to be Reported,” which is delegated by said Enforcement Regulation, stipulates that pharmaceuticals other than new pharmaceuticals, new pharmaceutical for which the approval was not previously obtained, pharmaceuticals which should undergo the safety/efficacy examination, radioactive pharmaceuticals, designated pharmaceutical against misuse and abuse, biological formulations, DNA recombinant pharmaceuticals, cell culture pharmaceuticals, gene therapy agents, cell therapy agents, human placenta-derived pharmaceuticals, etc. correspond to a pharmaceutical on which a report should be made (Article 2).

Further, KFDA Notification No. 2007-18 “Regulations on Review of Application (Report) for Pharmaceutical/ Non-pharmaceutical Manufacture/Import approval” stipulates that if two or more formulations are the same in terms of

the standards of the principle component per unit dosage form, the content thereof, and the dosage form/ administration route, they may be treated as one item when filing an application for obtaining an product approval or making a product report (Article 3(1)(iii)); and if they have the same regimen/dosage, etc. (e.g., Amoxicillin cap. 250mg, 500mg, Hanbang cataplasma $5cm^2$, $25cm^2$) or they are identical in the content of the principle component but different in taste (fragrance), color, shape, etc., they may be treated as one item when fling a package approval (report) (Article 3(2)).

Further, KFDA Notification No. 2006-58 "Regulations on Safety/Efficacy Examination of Pharmaceuticals" prescribes that pharmaceuticals corresponding to Attached Form 2, etc. as an item which a pharmaceutical that is not a new pharmaceutical and which requires safety/efficacy examination correspond to pharmaceuticals which require submission of materials (Article 2(1)(ii)) and pharmaceuticals categorized under the new efficacy group (including isomers and salts, etc.), a new composition or amount decrease/increase of an active ingredient (comprising isomers and salts, etc.), pharmaceuticals with a new administration route, new dosage forms (with the same administration route), etc. correspond to pharmaceu- ticals which require submission of materials (Attached Form 2). Items for which the approval (report) was already completed, and items which have the same type, standard, and amount (in the case of a liquid phase formulation, concentration) of the active ingredient and the dosage form are excluded from the safety/efficacy examination (Article 3(1)(i)); however, in such a case, the examination regarding safety/efficacy should be performed when a new

additive that has been never domestically used is mixed, the approval conditions, etc. are modified based on the report on clinical test results, etc., or when the item corresponds to patch preparations, implants, other preparations where uniqueness is recognized in the dosage form (e.g., nitroglycerin preparations, etc.) or when the product approval was already obtained but there is a need to make an approval alternation to the efficacy/ efficacy-related matters (e.g., efficacy/effect and regimen/ dose, etc.) among the already approved matters (Article 3(2)).

C) According to the aforementioned relevant regulations under the old Pharmaceutical Affairs Act, pharmaceuticals for which the manufacture/import approval should be obtained are separate from pharmaceuticals for which the manufacture/ import report should be made. “New pharmaceuticals, new pharmaceuticals for which the approval was not previously obtained, pharmaceuticals which should undergo the safety/efficacy examination, radioactive pharmaceuticals, etc.” correspond to the pharmaceuticals for which the manufacture/import approval should be obtained. The examination for the manufacture/import approval, in principle, is conducted according to items (each item) and “the name of product, classification number, and division (professional or general), drug substances and their amount, outer form and shape, manufacturing method, efficacy/effect, regimen/dosage, instructions for use, packaging unit, storage method, and expiration (expiry) date, standards and test methods, manufacturer, place of location, approval conditions” correspond to the matters to be reviewed during the examination for the pharmaceutical

manufacture/import approval.

Meanwhile, according to said “Regulations on Review of Application (Report) for Pharmaceutical/Non-pharmaceutical Manufacturing/Import approval,” if two or more formulations are identical in terms of the specifications of the principle component per unit dosage form and the content and dosage form/administration route thereof, they may be treated as one item; and if they have the same regimen/dosage, etc. or if they are identical in the content of the principle component and only different in taste (fragrance), color, shape, etc., they may be treated as one item. Therefore, the matters of the pharmaceuticals for which the manufacture/import approval should be obtained are not completely consistent with the matters to be reviewed during the examination for the manufacture/ import approval. Further, in the case where a certain pharmaceutical has the same formulation as the item of pharmaceutical for which the product approval was already obtained, with respect to the active ingredient's type, specifications, and contents (in the case of a liquid phase formulation, concentration), it is not a pharmaceutical for which the manufacture/import approval should be obtained, but in the case where it corresponds to a pharmaceutical which should undergo the safety/efficacy examination, e.g., the case where a new additive that has been never domestically used is mixed, it may correspond to a pharmaceutical for which the manufacture/import approval should be obtained.

Given the aforementioned relevant regulations together, the pharmaceutical product for which the pharmaceutical

manufacture/import approval should be obtained is formally specified by the matters to be reviewed during the examination for the pharmaceutical manufacture/import approval, e.g., the pharmaceutical's product name, classification number and division (professional or general), drug substances and their amount, outer form and shape, manufacturing method, efficacy/effect, regimen/dosage, etc.

However, under the “Regulations on Review of Application (Report) for Pharmaceutical/Non-pharmaceutical Manufacturing/ Import Approval,” it may be treated as the substantially same item so that one manufacture/import approval can be granted. Further, the case where a certain pharmaceutical is substantially identical to the pharmaceutical for which a pharmaceutical manufacture/ import approval was already obtained and therefore there is no need to separately obtain a pharmaceutical manufacture/import approval, is not prescribed as a pharmaceutical for which the pharmaceutical manufacture/import approval should be obtained. In light of the above, it is reasonable to see that even if a pharmaceutical product is different from the pharmaceutical product for which the manufacture/import approval was obtained, it corresponds to “products whose approval was the basis for registering the extension” which is substantially the same as the approved drug product under the old Pharmaceutical Affairs Act, etc.

Thus, it is reasonable to see that the effect of the patent right during the extended term takes effect to not only the above pharmaceuticals specified by the manufacture/import approval but also pharmaceuticals which are prescribed as being treated as the substantially same product so that

only one manufacture/import approval can be granted or pharmaceuticals which cannot be separately approved since they are substantially the same as the already approved pharmaceuticals, etc. On the contrary, if "products whose approval was the basis for registering the extension" under Article 95 of the old Korean Patent Act is only construed as pharmaceuticals which are completely consistent with pharmaceuticals specified with respect to the manufacture/ import approval, the case where a third party can execute the patented invention without obtaining a manufacture/ import approval for a drug under the aforementioned relevant regulations may occur and this may cause a possibility of evading the law, e.g., an injunction from the patentee exercising his/her just right from the grant of the PTE. This is contrary to not only the purport of the PTE system which intends to compensate the period during which the patentee could not practice the patented invention in order to obtain a manufacture/import approval but also the principle of equity.

3) Subject Case

A) As described above, the Plaintiff obtained a product import approval for a drug (Approval No. 16) from the Commissioner of the KFDA (later changed to the Minister of the MFDS under the revised Government Organization Act): the name of the imported product of "VESIcare tablet 5mg (solifenacin succinate)"; the classification number of "medicines for urogenital organs and anus (02590)"; the drug substances and their amount of "solifenacin succinate 5.0 mg as a principle component, and an excipient, a coating agent, a binder, etc., in one tablet (154mg)"; the classification of medicine of "prescription

medicine"; and the form and shape of "light yellow circular film-coated tablet." Further, based on the approval, the PTE was granted for Claims 1-8 of the Subject patent.

Meanwhile, the Challenging Inventions correspond to a pharmaceutical which has the same active ingredient as the Subject patent, i.e., "solifenacin," except for changing the salt form from "succinate" to "fumarate" or "tartrate'." Upon reviewing the foregoing evidence, the statements in the Plaintiff's Exhibit Nos. 5 and 9, Defendant 1's Exhibit Nos. 2, 3, and 4, Defendant 2's Exhibit Nos. 1 and 2, and the purport of the overall argument together, the fact that each of the Defendants obtained a manufacture/import approval for drugs relating to the Challenging Inventions by submitting bioequivalence study data through clinical study along with the pharmaceutical safety/efficacy data of the pharmaceutical on which the Plaintiff had obtained a product import approval as above can be established.

B) However, Article 2(1)(ii) and Attachment 2, etc. of "Regulations on Safety/Efficacy Examination of Pharmaceuticals" merely indicate that drugs having a new efficacy group where the salt modified and drugs where the salt modified and therefore the active ingredient is newly formulated correspond to pharmaceuticals for which materials should be submitted for an examination of safety/efficacy and fall under a category where a manufacture/import approval can be obtained. There is no regulation to the effect that a pharmaceutical containing a new salt as an active ingredient is treated as the substantially same item with a pharmaceutical containing a different form of salt as an active ingredient so that only one manufacture/import approval can be granted or it corresponds to a

pharmaceutical which is substantially identical to an already approved pharmaceutical so that a separate approval is not required.

Thus, the Challenging Inventions containing "solifenacin fumarate" or "solifenacin tartrate" as a principle component correspond to pharmaceuticals for which the manufacture/sales product approval should be obtained separately from the pharmaceutical containing "solifenacin succinate" as a principle component, which is the product for which the Plaintiff obtained the product import approval in order to practice the Subject patent. Thus, the effect of the patent right of during the extended term based on the product import approval for the drug containing "solifenacin succinate" as a principle component does not stretch to the Challenging Inventions that are irrelevant to an act of practice of the patented invention directed to the target product.

C) In this regard, the Plaintiff argued as follows:

The Subject patent is based on a novel solifenacin free base substance invention, and "solifenacin fumarate" and "solifenacin tartrate," which are the principle component of the Challenging Inventions, respectively, have no pharmacological/pharmacokinetic difference from "solifenacin succinate."

Further, the specification of the Subject patent describes that fumarate and tartrate as well as succinate can be adopted for a solifenacin free base. In addition, the Defendants obtained pharmaceutical product approvals on the Challenging Inventions by merely submitting clinical

study results regarding bioequivalence while citing the safety/efficacy data of the product for which the Plaintiff had obtained the product import approval. With the fact alone, the pharmaceutical for which the Plaintiff obtained the approval and the Challenging Inventions correspond to the substantially same products.

Therefore, it is proper to see that the effect of the patent right during the extended term is exerted on the Challenging Inventions as well. This is also reasonable from the viewpoint of international harmonization of the PET system.

Having perused the foregoing evidence, the statements in the Plaintiff's Exhibit 9, and the purport of the overall argument based on Witness Jeong-Hee Yoo's testimony together, the Subject patent is directed to a novel quinuclidine derivative having a muscarinic M_3 receptor antagonistic effect. Claims 1-7 of the Subject patent are directed to “a quinuclidine derivative of formula (I), a salt thereof, an N-oxide thereof or a quaternary ammonium salt thereof.” Claim 8 is directed to “a pharmaceutical composition comprising a quinuclidine derivative of formula (I), a salt thereof, an N-oxide thereof or a quaternary ammonium salt thereof and a pharmaceutically acceptable carrier, useful for prevention and treatment of urinary diseases including urinary incontinence or pollakiuria in neurogenic pollakiuria, neurogenic bladder, nocturnal enuresis, unstable bladder, cystospasm or chronic cystitis or respiratory diseases including chronic obstructive pulmonary diseases, chronic bronchitis, asthma or rhinitis,” while the structure of the formula (1), wherein Ring A is a phenyl group; l and m represent 0; n represents 2; and

X represents a single bond, becomes “solifenacin.” Further, the Subject patent describes free base compounds having the same chemical structure as solifenacin (Example 7) and presents a novel quinuclidine derivative in a free base form.

Further, the Subject patent describes succinate, fumarate, tartrate, etc. as well as a quaternary ammonium salt of the quinuclidine group as a portion of many organic acids that can be selected to form a salt with solifenacin. Generally, a salt of a drug is combined with a compound in a free base form in order to increase solubility and absorption of the drug. Further, solifenacin succinate is a compound where solifenacin and succinic acid are weakly combined by an ionic bond, and if it is orally administered to the human body and enters into the stomach, the ionic bond is broken by gastric juice of strong acid and is divided into solifenacin and succinic acid. The succinic acid is discharged outside of the body through internal metabolism, and only solifenacin is absorbed to enterocytes and arrives at the bladder through blood and reacts with a human's muscarinic M_3 receptor, whereby a pharmacological effect is exhibited. Further, not only succinate but also fumarate and tartrate are classified as “Class 1,” which indicates commonly used pharmaceutical salts. The *in vivo* administration and absorption process of solifenacin succinate is the same as solifenacin fumarate and solifenacin tartrate.

When filing the applications for the manufacture/sales product approvals on the Challenging Inventions, the responsibility of submission of by citing many safety/ efficacy materials, including materials on toxicity,

pharmacological action, and clinical study results regarding "VESIcare tab." for the reasons that the Challenging Inventions are pharmaceuticals for which safety/efficacy examination materials should be submitted as prescribed under Article 2(viii) of "Regulations on Product approval/ Report/Examination on Pharmaceuticals," which was applied at the time of filing the application for the product approval and correspond to "pharmaceuticals which have the chemically same basic framework as those domestically approved (this means "VESIcare tab." for which the Plaintiff obtained the product import approval; hereinafter same), are assumed to be almost equivalent to pharmaceuticals whose efficacy, effect, regimen, dose, side effects, pharmacological action, etc. are already approved, and are obviously seen as being orally administered, being bound to decompose in a digestive organ, and absorbed as an ingredient identical to the domestically approved pharmaceuticals, and salts, etc. of which are frequently used" prescribed under Article 28(5).

Further, the materials relating to the bioequivalence study submitted by the Defendants when filing the applications for obtaining the approvals on the Challenging Inventions were obtained from the clinical phase I study targeted for healthy people, which administered each of the pharmaceuticals of the Challenging Inventions and confirmed that the concentration in blood of solifenacin, which is an active ingredient, is an equivalent level to the administration of "VESIcare tab."

However, on the other hand, given the foregoing evidence, the statements in Plaintiff's Exhibit Nos. 9 and 11, Defendant 1's Exhibit Nos. 4 and 8, and Defendant 2's

Exhibit 2, and the purport of the overall argument together, the following has been found. Bioavailability of a drug differs depending on a particle size of a main drug (principle component), crystal, solvent, salt formation, etc. and it may also differ depending on the type and amount of diluent, filler, binder, disintegrant, etc. Further, solubility and absorption of a salt which is combined with a compound in the form of a free base in order to increase solubility and absorption of drug differ according to the type of salt, and thus, are known as affecting the concentration of the drug in blood over time. Safety/ efficacy of drug may be affected as well. Various salt compounds (succinate, fumarate, tartrate, hydrochloride, etc.) of solifenacin presented by the Subject patent are known as having different physicochemical properties such as melting point, solubility, stability to humidity, toxicity, etc. The Plaintiff's experimental results show that solifenacin succinate has a melting point of 147-148℃ and solubility in water of 99㎎/㎖ or more, whereas solifenacin fumarate has a melting point of 182-183℃ and solubility in water of 12㎎/㎖ and solifenacin tartrate has a melting point of 193-194℃and solubility in water of 32 ㎎/㎖. Solifenacin fumarate was confirmed as having further superior stability to solifenacin succinate in a formulation prepared by a wet granulation process, and this feature was granted as a separate patent in the U.S. (U.S. Patent No. 8,765,785). Further, a dose of "VESIcare tab.," which contains solifenacin succinate as a principle component, is 5㎎ (the amount per unit dose is the same), while a dose of the pharmaceutical of Challenging invention 1, which contains solifenacin fumarate, is 4.98㎎ (the amount per unit dose is the same) and a dose of the pharmaceutical of Challenging invention 2, which contains

solifenacin tartrate as a principle component, is 5.33mg (the amount per unit dose is the same). This is caused due to the difference in terms of solubility and absorption of the salts. Further, the test materials submitted at the time of filing the applications for obtaining the manufacture/ sales approval for the Challenging Inventions, stating that "VESIcare tab." and the pharmaceuticals of the Challenging Inventions satisfy the standards for determining bioequivalence, were obtained by appropriately controlling the type or amount of excipient, a process for preparing a formulation, etc. in consideration of physicochemical properties of the compound wherein the form of salt is modified.

Given the findings above, even if the pharmaceuticals of the Challenging Inventions and "VESIcare tab." are confirmed as having the same bioequivalence study results and exhibiting the same medicinal use of treating hypersensitive urinary bladder disorders, it is difficult to consider that the pharmaceuticals of the Challenging Inventions and "VESIcare tab." are substantially the same pharmaceutical since the difference in terms of items such as ingredients, etc. is not deemed to be minor or formal when viewed as a whole. Further, in view of the relevant regulations under the old Pharmaceutical Affairs Act, etc., it is clear that if the Plaintiff had intended to practice "solifenacin fumarate" or "solifenacin tartrate," instead of "solifenacin succinate" for which the product import approval was already granted, within the paten term of the Subject patent, the Plaintiff should have obtained separate product import approval for each salt form. As for the scope of the product to which the effect of the patent right during the extended term reaches, the U.S. Patent

Act establishes separate regulations in Articles 156(b) and 156(f)(2), which prescribe to the effect that in the case of pharmaceuticals, said scope includes an active ingredient's salts or esters. However, there is no regulation to this effect under Korean laws. Further, the presence or absence of the recognition of the PTA system, the requirements and the allowable scope of said system, the scope to which the extended patent right reaches, etc. may be differently determined according to each country's specific circumstance and legislative policy. Given the above, the foregoing findings and the evidence submitted by the Plaintiff are insufficient to consider that the pharmaceuticals of the Challenging Inventions and "VESIcare tab." containing "solifenacin succinate" as a principle component, i.e., the pharmaceutical for which the import approval under the old Pharmaceutical Affairs Act, etc. has been granted and on which the Subject PTE has been granted, can be treated as the substantially same item in terms of "target products for which an approval has been granted." Further, there is no evidence to see to the contrary.

D) Thus, the Plaintiff's primary and preparatory arguments contrary to the above cannot be accepted.

B. Summary of Discussion: Whether or not the IPTAB erred in its decisions

Given the above circumstances together, the Challenging Inventions do not fall within the scope of Claim 1 of the Subject patent during the extended term. As long as the Challenging Inventions do not fall within the scope of Claim 1 of the Subject patent, they do not fall within the scope of Claims 2-8, which depend from said claim, either.

Thus, contrary to the Plaintiff's argument, the IPTAB did not err in its decisions with the same conclusion.

4. Conclusion

Thus, the Plaintiff's petitions to reverse the IPTAB decisions are without merit and therefore dismissed.

Presiding	Judge	Hyeongjun PARK
	Judge	Hyeonseop JIN
	Judge	Byeongguk KIM

PATENT COURT OF KOREA
FOURTH DIVISION
DECISION

Case No.: 2017Heo776 Scope of Rights Confirmation (Patent)

Plaintiff: EXT Inc.

Defendant: Smartech Engineering Ltd.

Date of Closing Argument: June 7, 2017

Decision Date: July 14, 2017

ORDER

1. The Plaintiff's petition is dismissed.

2. The cost arising from this litigation shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision 2016Dang2657 dated December 30, 2016 shall be revoked.

OPINION

1. Background

A. Plaintiff's Patented Invention at Issue (Plaintiff's Exhibits 2, 3; and Defendant's Exhibit 1) (hereinafter the "Subject Invention")

1) Title of Invention: An extended head pile with inside and outside reinforcement

2) Filing Date of Application/ Date of Registration/ Registration Number: 2005. 5. 30. / 2007. 9. 17. / No. 760888

3) Claims[1)]

[Claim 6] A pile for supporting the load of a structure, (referred to as "**Element 1**" hereinafter), comprising: a first head portion (3)[2)] that has inner and outer surface areas so that the sums of the bearing capacities of the inner and outer portions that extends to the left and right with respect to the central axis of a first supporting wall (1) are the same; and a second head portion (4)[3)] that has inner and outer surface areas so that the sums of the

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1) As Claims 1-5, 7, and 8 were deleted, Claim 6 became the only claim of the Subject Invention. Thus, "the Subject Invention" below refers to Claim 6 of the Subject Invention.

2) Numerals or alphabets in the parenthesis refer to the reference numbers in the main drawing of the Subject Invention. Every applicable part of the Subject Invention and the Challenging Invention are all presented in the same manner below.

3) Numerals or alphabets in the parenthesis refer to the reference numbers in the main drawing of the Subject Invention. Every applicable part of the Subject Invention and the Challenging Invention are all presented in the same manner below.

bearing capacities of the inner and outer portions that extends to the left and right with respect to the central axis of a second supporting wall (2) are the same (hereinafter "**Element 2**"); wherein a circular structure is formed so that the bearing stresses of the first and second supporting walls (1, 2) and the first and second head portions (3, 4) are bilaterally symmetrical; wherein a hammering surface (6) is provided at the top of the circular structure; and a central hole (7) is formed between the first and second head portions (3, 4) (hereinafter "**Element 3**"); wherein the pile is an extended head pile with inside and outside reinforcement parts consisting of sequential lamination for integral formation, while an inclined surface (10) is integrally formed throughout all sides of the upper portion of the first and second head portions (3, 4) (hereinafter "**Element 4**").

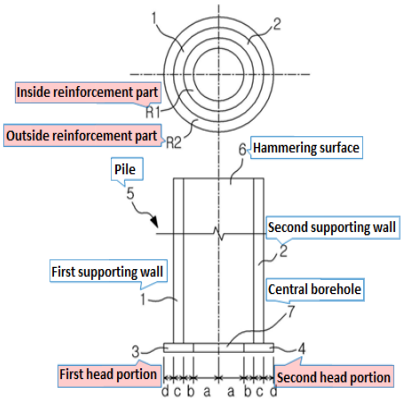
4) Main Content and Drawing

The Subject Invention is related to an extended head pile for supporting the load of a structure used in foundation works. The conventional method of inserting a pile into excavated hole, and merely situating and burying the pile in the ground had a problem that the proof stress of the pile is easily wasted because a surrounding friction is not present, and the general concrete placing method had a problem that the difficulty and cost of construction are high since it uses a continuous excavator in the longitudinal direction at the construction site.

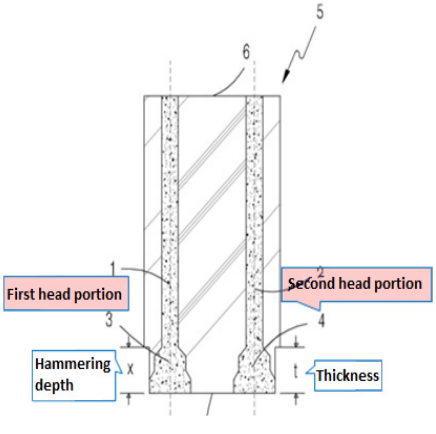
The objective of the Subject Invention is to provide an extended head pile with inside and outside reinforcement parts that can improve efficiency and economy by increasing constructional proof stress of the pile without affecting the weight and the volume of the pile; and ensure stability, construction workability, and economy by improving the bearing capacity of the pile that supports the load of a structure; and increase a constructional proof stress by hammering after a drilled piling while it can also be applied to the auger drilled piling method.

The Subject Invention forms the head larger than the outer diameter of the pile due to the inside and outside reinforcement parts which are extended left and right with respect to the central axis at the front end portion of the pile, in order to increase the bearing capacity of the front end of the pile. In particular, the Subject Invention enables easy design and manufacture of a pile since the extended head portion is extended in the same length with respect to the central axis in an ordinary pile whose pile diameter is from Φ300 to Φ500, and attaining exact pile proof stress without error since the sum of the bearing capacity has the same surface area with respect to the central axis in a large size pile whose diameter is equal or larger than Φ500.

[Fig. 1]



[Fig. 6]



B. Challenging Invention (Amended on September 13, 2016) (Appendix 2 of Plaintiff's Exhibit 1)

The Challenging Invention is related to “PHC pile comprising an extended front end shoe” which the Defendant practices, and its description and drawing are provided in the Appendix.

C. The Decision Below (Plaintiff's Exhibit 1)

1) The Defendant filed a defensive scope of rights confirmation action with the IPTAB against the Plaintiff, the patentee of the Subject Invention, arguing that the Challenging Invention does not fall within the Scope of the Patented Invention at Issue on August 30, 2016.

2) In this Regard, the IPTAB examined the case as Case No. 2016Dang2657 and rendered a decision in favor of the Defendant on December 30, 2016 on the ground that "Elements 2 and 4 of the Subject Invention and the corresponding elements of the Challenging Invention are neither identical nor equivalent. Thus, the Challenging Invention does not fall within the scope of the Subject Invention."

2. Whether or Not the IPTAB Erred

A. Summary of the Plaintiff's Arguments

Considering the following reasons, the Challenging Invention falls within the scope of the Subject Invention, but the IPTAB concluded otherwise. Thus, the IPTAB erred in its decision.

1) Element 2 of the Subject Invention includes the element of forming the protruded length towards outside and inside in equal length in the Challenging Invention. Further, the said element is not deliberately excluded during the prosecution of the application for the Subject Invention.

2) Element 4 (“sequential lamination for integral formation, while an inclined surface is integrally formed throughout all sides of the upper portion of the first and second head portions”) of the Subject Invention and the element of “comprising the upper and lower planes both with flat plate members” in Challenging Invention are equivalent.

B. Whether or Not Both Inventions Are Equivalent

1) Coarmpison of the Patented Invention and the Challenging Invention

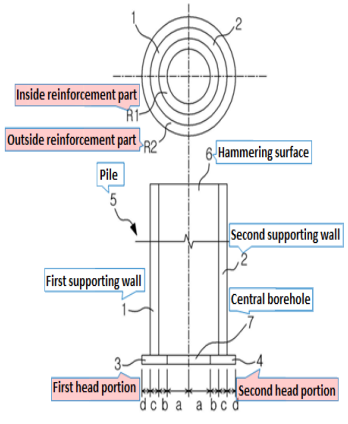
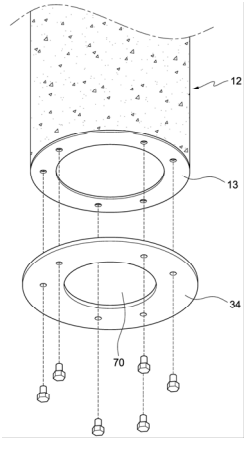
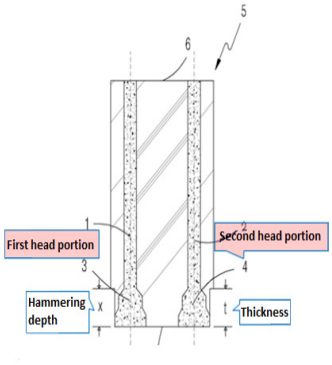
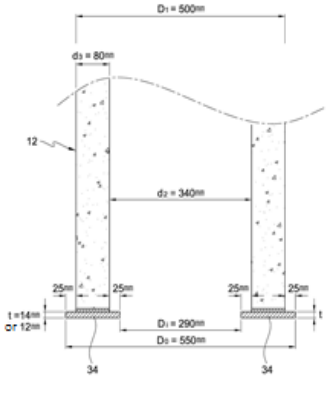
A) Element-by-element Comparison

Elements	Subject invention (Defendant's Exhibit 1)	Challenging Invention (Appendix)
1	A pile for supporting the load of a structure	A PHC pile for supporting load of a structure and delivering the same to the ground.
2	a first head portion (3)[4] that has inner and outer surface areas so that the sums of the bearing capacities of the inner and outer portions that extends to the left and right with respect to the central axis of a first supporting wall (1) are the same; and a	An extended front end shoe (34) is engaged to the front end portion of a body (12) so that the center of the circular shape of the body (12) and the center of the circular shape of the extended front end shoe (34) are aligned with each other, and the

4) Numerals or alphabets in the parenthesis refer to the reference numbers in the main drawing of the Subject Invention. Every applicable part of the Subject Invention and the Challenging Invention are all presented in the same manner below.

Elements	Subject invention (Defendant's Exhibit 1)	Challenging Invention (Appendix)
2	second head portion (4)[5] that has inner and outer surface areas so that the sums of the bearing capacities of the inner and outer portions that extends to the left and right with respect to the central axis of a second supporting wall (2) are the same;	length of the extended front end shoe (34) protruded in the horizontal direction from the inner surface of the body (12) and the length of the extended front end shoe (34) protruded in the horizontal direction from the outer surface of the body (12) are both 25mm.
3	wherein a circular structure is formed so that the bearing stresses of the first and second supporting walls (1, 2) and the first and second head portions (3, 4) are bilaterally symmetrical; wherein a hammering surface (6) is provided at the top of the circular structure; and a central hole (7) is formed between the first and second head portions (3, 4);	A PHC pile (100) is comprised with a cylindrical member that extends in the vertical direction and includes a body (12) which has a thickness (d3), wherein a through hole (70) is formed in the center of the extended front end shoe (34), wherein the hammering surface which exists at the uppermost end in the vertical direction is hammered during the penetrating installation process of the PHC pile comprising an extended front end shoe (34) at the front end portion.
4	wherein the pile is an extended head pile with inside and outside reinforcement parts consisting of sequential lamination for integral formation, while an inclined surface (10) is integrally formed throughout all sides of the upper portion of the first and second head portions (3, 4).	The extended front end shoe (34) comprised with steel, and the upper and lower planes which have thickness (t) are both flat circular plate members.

5) Numerals or alphabets in the parenthesis refer to the reference numbers

Elements	Subject invention (Defendant's Exhibit 1)	Challenging Invention (Appendix)
Main drawings	[Fig 1]  	[Fig 1] 
	[Fig 6]  	[Fig 4] 

in the main drawing of the Subject Invention. Every applicable part of the Subject Invention and the Challenging Invention are all presented in the same manner below.

B) Analysis on the Commonalities and Differences

① Elements 1 and 3

As shown in the above comparison table, Elements 1 and 3 of the Subject Invention and the corresponding features of the Challenging Invention are identical in terms of the following aspects: They are both related to a pile for supporting the load of a structure (PHC pile),[6] the first and second head portions (extended front end shoe) are bilaterally symmetrical circular structures (cylindrical members) so that the supporting stresses are equal, they both comprise a hammering surface on the upper portion of the circular structure (cylindrical member), a central hole is formed between the first and the second head portions (extended front end shoe).[7]

② Element 2

In the meantime, Element 2 and the corresponding feature of the Challenging Invention are identical, in that they have the first and second head portions (extended front end shoe) extending to the left and right with respect to the central axis of the first and second supporting walls (body). However, they are different in that the inner and outer portions of Element 2 have areas where the sums of the bearing capacity thereof are the same, while both the inner and outer protrusion of the body of the extended front end shoe are 25mm-long in the Challenging Invention (hereinafter "**Difference 1**").

③ Element 4

Moreover, Element 4 and the corresponding feature of the Challenging Invention are different in that while Element 4 is integrally formed by

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6) Numerals or alphabets in the parenthesis refer to the elements of the Challenging Invention that correspond to the elements of the Subject Invention. The same is applied below when comparing the two inventions.

7) These are undisputed facts between the parties.

sequential lamination while an inclined surface is integrally formed throughout all sides of the upper portion of the first and second head portions, the upper plane and the lower plane of the extended front end shoe of the Challenging Invention are both comprised with plate member and do not include an inclined surface at the top thereof (hereinafter "**Difference 2**").

2) Analysis on Difference 1 – Whether the element of the same length protrusion is deliberately excluded

A) Relevant Law

When determining whether a specific element is deliberately excluded from the claims, the opinion asserted by the KIPO examiner, not only the specification but also the intention of the Applicant, and the ground for amendment as appeared in the submitted response, amendment, among others during the prosecution from the filing to approval should be considered. Thus narrowing a claim does not necessarily mean that all the difference in the claim between pre- and post-amendment is deliberately excluded. Meanwhile, a specific element is deliberately excluded from the claims if it was the Applicant's intention to exclude the element from the scope of the invention in view of the circumstances during the prosecution. This principle is also applicable when there was a statement of opinion by filing a response without narrowing the claims (Supreme Court Decision 2014Hu638, rendered on April 26, 2017).

B) Analysis

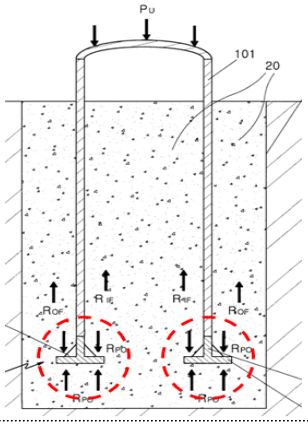
However, due to the following reasons, the element of 'extending the first and second head portions left and right in the same length' in Element 2 in the Subject Invention was originally included in the claims at the time of filing but was intentionally deleted by the Applicant and is therefore considered as deliberately excluded. Thus,

the deliberately excluded element, which is identical with 'the extended front end shoe whose inner and outer protruded length of the body are both 25mm' of the Challenging Invention is not equivalent to Element 2.

① First, regarding the method to determine how long to extend the first and second head portions to the left and right, the specification of the Subject Invention (Defendant's Exhibit 1) recites two methods, which is to extend to the left and right for the same length with respect to the central axis and to have inner and outer surface areas where the sums of the bearing capacities of the inner and outer portions with respect to the central axis are the same (see paragraphs <31>, <79>-<86>). Further, at the time of filing, Claims 1-4 recited the methods of extending to the left and right for the same length with respect to the central axis, and Claims 5-8 recited the methods of extending to have inner and outer surface areas so that the sum of the bearing capacities of the inner and outer portions to the left and right with respect to the central axis are the same (Defendant's Exhibit 10).

② KIPO examiner issued a notice of rejection to A, the CEO of the Plaintiff and Applicant of the Subject Invention on September 11, 2006 (the "Applicant"), purporting that the elements of 'extending to the left and right for the same length with respect to the central axis' and 'extending to the left and right so that the sums of the bearing capacity are the same' in Claims 1-8 (the entire claims of

[Fig 2a] of Defendant's Exhibit 8

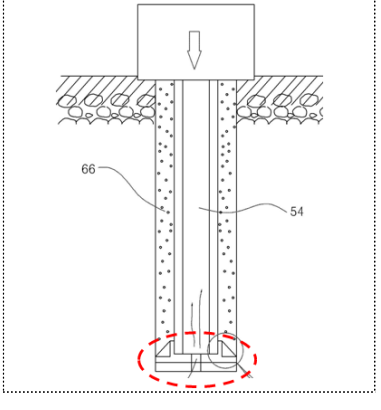


the Subject Invention) can both be easily conceived by a skilled person in the art from the element of ‘a hollow circular plate that has the same width protruding from the inner and outer diameters’ such as [Fig. 2a] in the specification of a prior art (Defendant's Exhibit 8) which was included in Korean Laid-Open Patent Publication No. 2004-48710 published on June 10, 2004 (Defendant's Exhibit 2).

③ In response thereto, the Applicant filed an amendment (Defendant's Exhibit 4), which incorporated the element of the ‘inclined surface formed at all sides of the upper portion of the first and second head portions’ in Claims 2, 4, 6, and 8, and deleted all the other claims, along with a response on November 9, 2006, stating that the essence of the Subject Invention is that the first and second head portion of the extended head pile is composed to have the same inner and outer length or the same sum of the bearing capacities, and integrated with the inclined surface so that eccentricity does not occur at the time of hammering after burying the pile and can provide a stable proof stress (Defendant's Exhibit 3).

④ Then the KIPO examiner re-issued the final notice of rejection to the Applicant on March 7, 2007, stating that the elements of ‘extending to the left and right for the same length with respect to the central axis’ and ‘extending to the left and right so that the sums of the bearing capacities are the same’ that were included in the remaining Claims 2, 4, 6, and 8 can also be

[Fig 6] of Defendant's Exhibit 9



easily conceived by a skilled person in the art from an ‘extended head pile’ such as [Fig. 6] of the specification from the prior art (Defendant's Exhibit 9), which is included in Korean Laid-Open Patent Publication No. 2004-52779 published on June 23, 2004 (Defendant's Exhibit 5).

⑤ Then, the Applicant added the element of ‘integrally formed sequential lamination, while an inclined surface is integrally formed throughout all sides of the upper portion of the first and second head portions’ to Claim 6 and deleted all the other claims, filing an amendment (Defendant's Exhibit 7) along with a response (Defendant's Exhibit 6) stating that the technical element of the Subject Invention is that since 'the first and second head portions of the extended head pile are composed to have the same sum of the bearing capacities while integrally formed with the inclined surface, and the first and second head portions are sequentially laminated,' eccentricity does not occur at the time of hammering the pile after burying and can provide stable proof stress, on 3 May, 2007. As a result, the patent was granted on August 24, 2007.

⑥ Considering the above prosecution of the application of the Subject Invention, it is reasonable to conclude that the Applicant deliberately deleted the element of ““extending to the left and right for the same length from the central axis,” which was included in Claims 1-4 at the time of filing, in order to avoid the element of the front end head portion of a pile disclosed in the prior art of Defendant's Exhibits 8 and 9, which were cited as references in the rejection for lack of inventiveness. Further, the patent was granted because the Applicant substituted the deleted elements with the element of “forming an inclined surface integrally at all sides of the upper portion of the first and

second head portions, while integrally sequentially laminating" in Claim 6, which is not disclosed in the above prior arts, and emphasized that the element is the essence of the Subject Invention in its response on May 3, 2007.

D) Discussion on the Plaintiff's Argument

① In this regard, the Plaintiff first argues that having 'the inner and outer surface areas so that the sums of the bearing capacities of the inner and outer portions are the same' of Element 2 in the Subject Invention means merely determining the inner and outer surface considering the deformation due to the subgrade reaction and the following change of the bearing capacity so that the sums of the bearing capacities of the inner and outer portions are the same, and includes the feature of 'forming the protruded length to the inner and outer sides equally' as shown in the Challenging Invention.

However, the bearing capacity of the pile head portion is calculated by multiplying the bearing stress by the surface area, and when designing a pile, as opposed to the Plaintiff's argument, it is well-known in the art that a pile design is premised on the equal bearing stress throughout the whole surface area. Thus, the bearing capacity of the pile head portion is determined by the surface area, and having equal inside and outside surface areas inevitably means that the protruded length of the inside reinforcement part, having relatively smaller radius pile head portion, is longer than that of the outside reinforcement part. Thus, Element 2 does not include the feature of 'forming the protruded lengths to the inner and outer sides to be equal' of the Challenging Invention, and the Plaintiff's argument is without merit.

② Further, the Plaintiff argues that whether a specific feature is deliberately excluded from the scope of a patented invention must be determined based on the prosecution history of each claim, and since the feature of 'forming the protruded lengths to the inner and outer sides to be equal' of the Challenging Invention is not deliberately excluded during the prosecution because it also has an equal sum of bearing powers of the inner and outer portions.

However, as discussed above, Element 2 does not literarily include the feature of 'forming the protruded lengths to the inner and outer sides to be equal' in the Challenging Invention, and there are no descriptions that the feature of 'having inner and outer surface areas so that the sums of the bearing capacities are the same' includes the feature that 'the inside and outside protruded lengths are equal' in the specification of the Subject Invention (Defendant's Exhibit 1). Rather, considering the fact that the Subject Invention consistently separates the method of 'making the surface areas equal' and 'making the lengths equal' separately from the method of determining the extended length to the left and right of the first and second head portion in description (paragraphs <31>, <79>-<86>), and that both methods were separately described in the Claims at the time of filing as well (Defendant's Exhibit 10), the feature of 'forming the protruded lengths to the inner and outer sides to be equal' of the Challenging Invention should be considered as deliberately excluded during the prosecution of the application. Thus the Plaintiff's above argument is also without merit.

3) Analysis on Difference 2 – Whether Element 4 is equivalent to the Challenging Invention

A) In the meantime, the upper and lower planes of the extended

front end shoe of the Challenging Invention are both comprised with flat plate members and there are no features formed at the top. Thus, we can reasonably conclude that the Challenging Invention lacks the feature that corresponds to the element of the integrated inclined surface which is sequentially laminated on the first and second head portions of Element 4.

B) Moreover, while the element of 'integrally forming the inclined surface at all sides of the upper portion of the first and second head portions, while integrally formed by sequential laminating' of Element 4 has an effect that can provide a stable proof stress since eccentricity does not occur when hammering the pile after burying, the extended front end shoe of the Challenging Invention lacks the element that has the same effect. Thus, the corresponding features of the two inventions should not be considered equivalent.

4) Summary of Discussion

Considering the above, since Elements 2 and 4 of the Subject Invention and each corresponding feature of the Challenging Invention are neither identical nor equivalent, the Challenging Invention does not fall within the scope of the Subject Invention.

3. Conclusion

Thus, the IPTAB decision which concluded that the Challenging Invention does not fall within the scope of the Subject Invention shall

be upheld, and the Plaintiff's petition to revoke the IPTAB decision is without merit and therefore dismissed.

Presiding Judge Chungsuk LEE
Judge Boohan KIM
Judge Jinhee LEE

Description and Drawings of the Challenging Invention

1. Description

A. Title of the Challenging Invention

PHC pile comprising an extended front end shoe

B. Brief Description of the Drawings

[Fig. 1] and [Fig. 2] are simplified exploded perspective views of the front end (lower end) of a PHC pile in the Challenging Invention that illustrates the extended front end shoe (34) assembled to the front end (lower end) of the body (12) in a PHC pile at different directions.

[Fig. 3] is a simplified assembly perspective view of the front end of the PHC pile in the Challenging Invention that illustrates the assembled status of the extended front end shoe (34) to the front end of a body (12) after the status of [Fig. 1]

[Fig. 4] is a simplified sectional view of the front end of a PHC pile along the A-A line of [Fig .3]

C. Elements of the Challenging Invention

The Challenging Invention is related to a PHC (Pretensioned spun high strength concrete pile) pile that supports the load of a structure, which is a 'PHC pile comprising an extended front end shoe' that comprises an extended front end shoe at the front end (lower end) of

a PHC pile to extend the surface area of a pile and improve the proof stress of a pile.

[Fig. 1] and [Fig. 2] are simplified exploded perspective views of the lower end portion of a PHC pile in the Challenging Invention that illustrates the extended front end shoe (34) assembled to the front end (lower end) of the body (12) of the hollow portion which is manufactured with prestressed concrete in a PHC pile at a different direction. [Fig. 3] is a simplified assembly perspective view of the front end of the PHC pile in the Challenging Invention that illustrates the assembled status of the extended front end shoe (34) to the front end (lower end) of the body (12) of the hollow portion after the status of [Fig. 1]. [Fig. 4] is a simplified sectional view of the front end of the PHC pile along the A-A line of [Fig .3]

PHC pile (100) comprises a body (12) which is manufactured with prestressed concrete that has the longitudinal tension induced by a tendon. The body (12) is formed with a cylindrical member, which is elongated in a vertical direction and comprises a hollow portion at the center that penetrates the length of the entire body (12) in a vertical direction to have a thickness (d3). For convenience, illustration of the upper end of the body (12) is omitted. A finishing plate (13) comprised with steel is provided integrally with the body (12) made of concrete on the front end portion body (12). The outer diameter of the finishing plate (13) is the equal with the outer diameter of the body (12).

An extended front end shoe (34) is provided at the front end of the main body (12) so as to be coupled to the finish plate (13). The extended front end shoe (34) is comprised with a circular flat plate member having a thickness (t) which is made of steel. Specifically, it is comprised with a ring-shape member that has a circular periphery

and a circular through hole periphery and upper and lower planes that are composed of flat plate[8] with a circular through hole in the center.

The extended front end shoe (34) is integrally engaged to the front end of the body (12) of the PHC pile, by penetrating the extended front end shoe (34) and fixing a bolt to the finishing plate (13) while the extended front end shoe (34) is in a close contact with the finishing plate (13).

As described above, when the extended front end shoe (34) is engaged to the front end of the body (12), the position where the body (12) engages to the extended front end shoe (34) in the Challenging Invention and each specification (size) of the extended front end shoe (34) and the body (12) is as below:

Outer diameter of the body (12) of the PHC pile D1: 500mm
Inner diameter of the body (12) of the PHC pile d2: 340mm
Thickness of the body (12) of the PHC pile d3: 80mm
Outer diameter of the extended front end shoe (34) D0: 550mm
Inner diameter of the extended front end shoe (34) Di: 290mm
Thickness of the extended front end shoe (34) t: 14mm or 12mm
Material of the extended front end shoe (34): SS400 or SS490 steel

The extended front end shoe (34) is engaged to the front end portion of the body (12) so that the center of the circular shape of the extended front end shoe (34) and the center of the circular shape of the body (12) are aligned with each other. Thus, the length of the extended front shoe (34) protruding in the horizontal direction from the inner surface of the body (12) is 25 mm and the length of the extended front end shoe (34) protruding in the horizontal direction

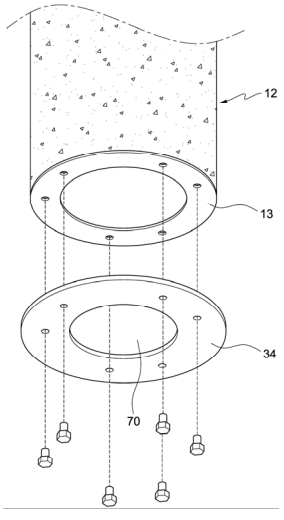
8) A typographical error in the original specification of Challenging Invention is corrected (“if composed” to “are composed”).

from the outer surface of the body (12) is 25 mm.

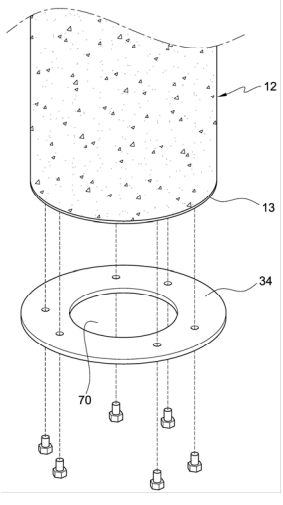
In the process of penetrating and installing the PHC pile having the extended front end shoe (34) into the ground, the hammering surface which exists at the uppermost end in the vertical direction is hammered, and the extended front end shoe (34) exhibits a bearing capacity while being in close contact with the ground when the PHC pile is installed in the ground.

2. Drawings

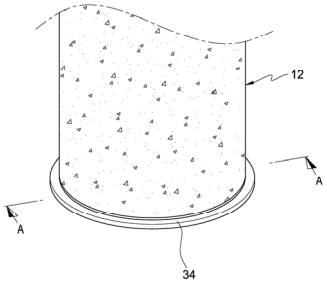
[Fig 1]



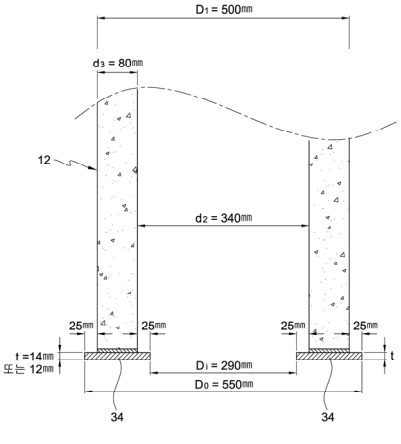
[Fig 2]



[Fig 3]



[Fig 4]



PATENT COURT OF KOREA
FIFTH DIVISION
DECISION

Case No.: 2016Heo7947 Invalidation of Registration (Patent)

Plaintiff: R.S. System Inc.

Defendant: GS WINDOOR Inc.

Date of Closing Argument: May 12, 2017

Decision Date: June 16, 2017

ORDER

1. The Plaintiff's petition is dismissed.

2. The cost arising from this litigation shall be borne by the Plaintiff.

PLAINTIFF'S DEMAND

The IPTAB Decision rendered in Case 2015Dang4399 (announced September 30, 2016) shall be revoked.

OPINION

1. Facts

A. Details of the IPTAB Decision at Issue

1) Defendant requested an invalidation trial on Claims 1, 2, and 6 of the Subject invention (hereinafter, Claims 1, 2, and 6 at issue) arguing that Claims 1, 2, and 6 at issue should be invalidated because it was publicly practiced in the Republic of Korea before the filing date of application of the Subject invention, since 'window frame for folding door' (hereinafter, "window frame") which has the same elements with Claims 1, 2, and 6 at issue was already installed at the Hanam Pork house in Cheon Cheon-Dong, Suwon city (refered as 'Suwon Hanam Pork house' below) before the filing date of the application of the Subject invention.

2) The IPTAB rendered a decision affirming defendant's above request (hereinafter, "Decision at Issue") since Claims 1, 2, and 6 at issue are publicly practiced in the Republic of Korea before the filing date of the application of the Subject invention and it should be invalidated, since the window frame, which was installed in 'Suwon Hanam Pork house' before the filing date of the application of the Subject invention, includes all the elements of Claims 1, 2, and 6 at issue, and the above window frame could be accessed by random people at the construction site, and it was installed in an open place where the assembly process could be seen.

B. Subject invention (Plaintiff's Exhibit 2)

1) Title of Invention: Window frame for folding door having a structure that prevents condensation

2) Filing Date of Application / Date of Registration / Registration Number: 2012. 7. 6./ 2012. 11. 2./ No. 1199523

3) Right holder: Plaintiff

4) Scope of the Claims

【Claim 1】

Window frame for folding door having a structure that prevents condensation, wherein said window frame (100) comprising a left side frame (110) on vertical direction, a right side frame (120) vertically arranged at a predetermined interval parallel with the left side frame (110), a upper frame (130) in a horizontal direction which both ends are seated on the upper ends of the left side frame (110) and the right side frame (120), a lower frame (140) in a horizontal direction where the lower ends of the left side frame (110) and the right side frame (120) are seated, an upper bracket (150) for coupling the left and right side frames (110, 120) to the upper frame (130), and a lower bracket (160) for coupling the left and right side frames (110, 120) to the lower frame (140), wherein the left and right side frames (110, 120) has a hollow rectangular bar shape, further comprising first central grooves (111, 121) formed along the longitudinal direction of the center of the outer surface, wherein the upper frame (130) has a rectangular bar shape, and a second center groove (131) is formed along the longitudinal direction of the center of the outer surface,

and further comprising a hollow portion (133) formed on both sides of the second center groove (131), which is partitioned by the second center groove (131) and a partition wall (132), wherein the lower frame (140) comprises a hollow outer frame (141) where the lower end of the left side frame (110) or right side frame (120) is seated on the upper portion, and an inner frame (142) whose end is located collinearly with the inner surface of the left side frame (110) or the right side frame (120) while inserted to the inside of the outer frame (141), wherein the upper bracket (150) comprises an upper embedded coupling portion (151) which is inserted to the second center groove (131) of the upper frame (130) and screwed to the upper frame (150), and an upper exposed coupling portion (152) which is inserted to the first center groove (111, 121) of the left or right side frame (110, 120) and screwed to the left or right side frame, and wherein the lower bracket (160) comprises a lower embedded coupling portion (161) which is inserted to the inside of the outer frame (141) and screwed to the left or right side frame (110, 120), and a lower exposed coupling portion (162) which is inserted to the first center groove (111, 121) on the left or right side frame (110, 120) and screwed to the left or right side frame (110, 120).

【Claim 2】

Window frame for folding door having a structure that prevents condensation of claim 1, characterized by a first slot (131a) formed on both side walls of the second center groove (131) of the upper frame (130), and a first protrusion (151a) formed on both sides of the upper embedded coupling portion (151) of the upper bracket (150) and slidably fitted into the first slot (131a).

【Claim 3 - 5】 (Omitted)

【Claim 6】

Window frame for folding door having a structure that prevents condensation of claim 1, further comprising a water blocking plate (134) extending downwards from the lower end of the outer surface of the upper frame (130).

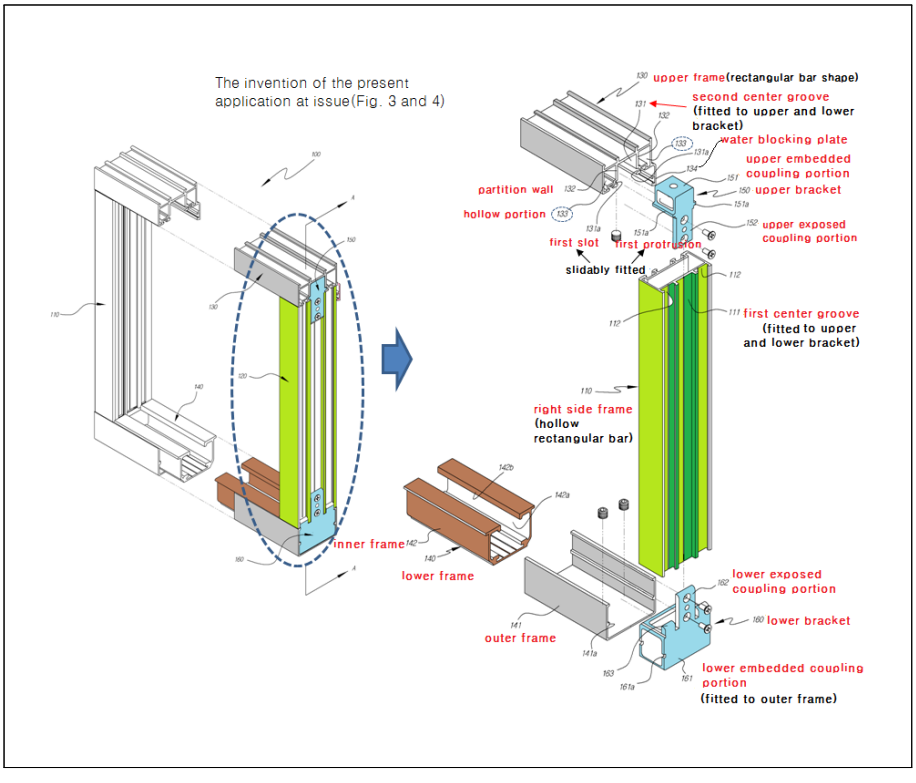
5) Main Content and Drawing

Conventional window frame of a folding door had the following problems:

① It has a structure that is very vulnerable at blocking water since the left and right side frames (11a, 11b) are hollow shapes whose upper and lower portion are open, and especially rain or moisture can be infiltrated into the upper opening and infiltrated water can be introduced indoors through the lower opening portion, ② even though the upper frame (12) has a long length, the supporting structure for the upper frame (12) is weak, so there is a high possibility of a curving deformation which the middle portion of the upper frame (12) is sagged downward, and ③ the bonding strength of the connecting portion of each frame is weak ([0009-0010]).

To overcome the above conventional problems, the Subject invention has a purpose as follows:

① To prevent condensation by covering the opened upper portion of left and right side frame by upper frame, so that at least it can prevent the infiltration of rain or water from the upper portion of the left and right side frame, ② to prevent sagging deformation of the upper frame as the left and right side frames support the upper frame, and ③ to provide a window frame, which has a bracket including frames which are formed in a frameless structure, while having solid coupling as the corner portion of each frame is coupled by the upper and lower brackets ([0024]).



[Factual Basis] Undisputed facts, Plaintiff's Exhibits 1-3, and the purport of the overall argument

2. Summary of the Plaintiff's Argument for Revocation of the IPTAB Decision

A. The owner of the 'Suwon Hanam Pork House,' and the staffs of the enterprise who was in charge of the interior construction of 'Suwon Hanam Pork House' are a party or a person who was controlled by the party. Thus, they have a contractual or customary confidentiality obligation regarding the window frame installed in the 'Suwon Hanam Pork House.'

B. The interior construction site of the ‘Suwon Hanam Pork House’ is not accessible by an outsider, and even if it was accessible, it is difficult to say that the window frame’s shape, structure, and the structure that prevents condensation inside the window frame which is the characteristic feature of the Subject invention were in a condition that can be easily understood.

C. Thus, Claims 1, 2, and 6 at issue have novelty since the window frame installed in the ‘Suwon Hanam Pork House’ was not publicly practiced in the Republic of Korea before the filing date of the application of the Subject invention.

D. The decision of the IPTAB at issue should be revoked since the IPTAB erred in its decision by concluding differently.

3. Whether Claims 1, 2 and 6 at issue have been publicly known or worked in the Republic of Korea prior to the filing date the application (Novelty).

A. Relevant Law

Article 29 (1) (1) of the Old Patent Act (before amended by Law 11654 of March 22, 2013, same below) states that any invention which has been publicly known or worked in the Republic of Korea or in a foreign country prior to the filing of the patent application lacks novelty and is not patentable. In the above recitation, ‘publicly known’ doesn’t necessarily means that it has been recognized by random people but means that at least the invention is in a state which random people can recognize it, and ‘publicly practiced’ means that the content of the invention has been worked, for example, worked as a way of transferring without any restriction such as confidentiality

arrangements, and the invention was in a state which random people can recognize it (Supreme Court Decision, 2011Hu4011, decided April 26, 2012).

In case that the same product as the invention was transferred due to a sale, contract, etc., unless there are special circumstances such as the assignee had confidentiality agreements, although the technical feature cannot be easily recognized through the appearance of the product, if a person of ordinary skill in the art could easily recognize the technical feature of the invention through disassembling or analyzing the product, it could be said that the invention was publicly practiced since the invention was in a state where random people, including assignee can recognize its technical feature by the transfer of the product.

Meanwhile, regarding Article 29 (1) subparag. 1 of the Old Patent Act, a person who claims invalidity of a patent should argue and prove that the invention is publicly known or worked, and the patentee who disaffirms that the invention is publicly known or worked should argue and prove the existence of confidentiality arrangements.

B. Analysis

Considering the following facts, which are acknowledged by Defendant's Exhibit No. 1, 2, 3, and a review of all the arguments, it should be considered reasonable that Claims 1, 2 and 6 at issue were publicly practiced before July 6, 2017, the filing date of the application of the Subject invention.

① ‘Suwon Hanam Pork House’ made a contract with ‘Design Movb’ (former name: GID Design Co., Ltd., hereinafter referred to as “Design Movb”) regarding the interior construction on

'Suwon Hanam Pork House,' and 'Design Movb' made a subcontract with Plaintiff regarding the construction of the window frame in the 'Suwon Hanam Pork House.' Plaintiff installed the above window frame in the 'Suwon Hanam Pork House' in early June of 2012, according to the above subcontract.

② The 'Suwon Hanam Pork House' or 'Design Movb' paid the installation fee to Plaintiff, who is the subcontractor, after the installation of the above window frame, and Plaintiff delivered the above window frame to the 'Suwon Hanam Pork House' before June 18, 2012, their opening date.

③ The owner of the 'Suwon Hanam Pork House' acquired an ownership of the above window frame as the window frame was delivered, and there are no special circumstances where the owner and staff of the 'Suwon Hanam Pork House' have any confidentiality agreements regarding this issue.

④ The window frame installed in the 'Suwon Hanam Pork House' is characterized by the inner structure of the left, right, upper, and lower frame; and the spatial arrangement and detailed coupling feature of the upper and lower bracket which is a coupling means of the above frames, and it is difficult to easily understand its inner structure through its appearance. However, a person of ordinary skill in the art can disassemble the window frame using simple tools, and easily understand the inner components and the coupling relationship among the inner components (according to the result of the on-site inspection held by the IPTAB on September 20, 2016, in fact, it took about 1 hour to disassemble the window frame and to identify the inner structure. The above upper frame, upper bracket, lower frame, lower bracket, etc. of the window frame each have a structure

that is coupled by screws, and it is easy to disassemble using a tool such as a screwdriver).

⑤ The window frame installed in 'Suwon Hanam Pork House' at issue is identical with Claims 1, 2 and 6 at issue (these are undisputed facts between the parties).

⑥ Thus, it is can be considered reasonable that the above window frame, which is identical with Claims 1, 2, and 6 at issue, was in a state that random people can recognize before June 18, 2012, the opening date of the 'Suwon Hanam Pork House,' at the latest, by being delivered to the 'Suwon Hanam Pork House' in a state without any confidentiality arrangements.

C. Discussion regarding the rest of Plaintiff's arguments

1) Plaintiff's arguments

The window frame of the 'Suwon Hanam Pork House' was installed only 3 weeks before the filing date of the application of the Subject invention, and although an exception of public disclosure of Article 30 (1) of the Patent Act was not claimed, Article 30 (3) of the Patent Act should be applied to the Subject invention considering the intention of the amendment to the Article 30 (3) of the Patent Act that is amended by Law 13096 at January 28, 2015. Namely, due to the intention of protection by the inventor, it should be considered that the invention does have novelty, even though the Plaintiff missed the procedure of claiming the exception of public disclosure on the filing date of the application of the Subject invention.

2) Discussion

The Article 2 (1) of Supplementary Provision of Patent Act, which

was amended by the Law 13096 at January 28, 2015, recites "The amended rule of the Article 30 (3) is applied on patent applications which are filed after the enforcement of this Law," and the Article 1 of Supplementary Provision recites "The enforcement of this Law starts from 6 months after its proclamation." However, since the application of the Subject invention was filed at July 6, 2012, the above amended Article 30 (3) of Patent Act is not applicable.

Meanwhile, in a case that the application is filed without any indication that the exception of inventor-initiated disclosure of Article 30 (1) subparag. 1 of Old Patent Act is applicable, on the application form, the effect of the exception to the inventor-initiated disclosure rule is not applicable, the above subparag. 1 cannot be applied by the amendment of the procedure, although the procedure regulated in the above Article 30 (2) was not executed (Supreme Court Decision, 2010Hu2353, decided June 9, 2011.). Considering the Defendant's exhibit 4 and the review of all the arguments, since the Plaintiff filed the application of the Subject invention without any indication that the exception of inventor-initiated disclosure is applicable at the time of filing, the effect of the exception of inventor-initiated disclosure is not applicable, even if the Plaintiff submitted a document containing an indication that the exception of inventor-initiated disclosure is applicable afterwards, and moreover, there is no evidence to prove that such document was submitted.

As a result, the Article 30 (3) of Patent Act amended by the Law 13096 at January 28, 2015 is not applicable to the Subject invention. Further, since the Plaintiff filed the application of the Subject invention without any indication that the exception of inventor-initiated disclosure is applicable at the time of filing, there is no chance that Article 30 (1) of Old Patent Act can be applied. Accordingly, the Plaintiff's above argument cannot be accepted.

D. Summary of Discussion

Thus, Claims 1, 2, and 6 at issue should be invalidated since they were publicly practiced before the filing date of application and conforms to the Article 29 (1) (1) of Old Patent Act.

4. Conclusion

The IPTAB decision is consistent with the above analysis and shall be upheld.

The Plaintiff's petition to revoke the IPTAB decision is without merit and therefore dismissed.

Presiding Judge Youngjoon OH
Judge Dongju KWON
Judge Donggyu KIM

PATENT COURT OF KOREA
THIRD DIVISION
DECISION

Case No.: 2017Heo1304 Scope of Rights Confirmation (Patent)

Plaintiff: A

Defendant: B

Date of Closing Argument: August 11, 2017

Decision Date: August 25, 2017

ORDER

1. The IPTAB Decision regarding Claims 1 and 3 of KR Patent No. 1230156 with respect to Case No. 2016Dang810 rendered on Jan. 20, 2017 shall be revoked.

2. The cost arising from this litigation shall be borne by the Defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Facts

A. The Decision below

1) The Defendant filed an action to confirm the scope of a patent against the Plaintiff on March 31, 2016, arguing that the Defendant's Challenged invention, as specified in the appendix, falls within the scope of Claims 1, 3, 6 and 7 of the Plaintiff's Invention at Issue, as described below in Section B.

2) KIPO examined this case in Case No. 2016Dang810 and rendered on January 20, 2017 the decision (hereinafter, referred to as “the Subject Decision”) as follows: the Challenged invention falls within Claims 1 and 3 of the Invention at Issue, and does not fall within Claims 6 and 7 of the Invention at Issue on the ground that Claims 6 and 7 of the Invention at Issue are the same as the prior arts that have been widely known, and thus, novelty is denied.

3) Disagreeing with the Subject Decision, the Plaintiff filed a petition for cancellation of the Subject Decision. The Defendant also filed a petition for cancellation of the Subject Decision in Case No. 2017Heo1168 with respect to the portion in which the Challenged invention does not fall within Claims 6 and 7 of the Invention at Issue. Therefore, the case is currently ongoing in the Patent Court.

B. The Invention at Issue (Plaintiff's Exhibit No. 3)

1) Title of Invention: A Triggering Apparatus of a Non-Electric Detonator Using a Spark Trigger and a Method Using the Same

2) Filing Date of Application/Date of Registration/Registration No.: Dec.16, 2010/Jan. 30, 2013/KR Patent No.1230156

3) Patent Holder: the Plaintiff

4) Claims of the Invention at Issue

[Claim1] A triggering apparatus of a non-electric detonator using a spark trigger, the spark trigger wherein a firing circuit comprising a spark terminal formed with a spark tip composed of two electrodes for generating a spark by a high voltage current is built in and is supplied with power from an electric blasting machine through a leading wire to generate a spark at the spark terminal, and the spark generated at the spark terminal is transmitted to the non-electric detonator installed at a tunnel face through a signal tube connected to the spark terminal (hereinafter, referred to as "**Elements 1-1**"), wherein the firing circuit comprises: two lead wires connected to the leading wire and electrically connected to the respective electrodes of the spark tip; and an electric resistance connecting the two lead wires to the spark tip in parallel (hereinafter, referred to as "**Elements 1-2**"), and wherein the spark trigger comprises: an electronic board having the firing circuit; a body part surrounding the electronic board; a housing in which the spark tip of the firing circuit is placed, into which the signal tube is inserted to be connected to the spark tip, and with which the vise is formed in a conical shape whose diameter decreases toward the end and is divided into vise racks at its far end; and a vise cap tightening the vise racks as being coupled to the conical vise to make the signal tube to be fastened to the vise (hereinafter, referred to as "**Elements 1-3**").

[Claim 2] omitted

[Claim 3] A triggering apparatus of a non-electric detonator using a spark trigger of Claim 1, wherein the firing circuit further comprises a capacitor for connecting the two lead wires in parallel with the spark tip at a position between the electric resistance and the spark tip.

[Claims 4-10] omitted

5) Main Content

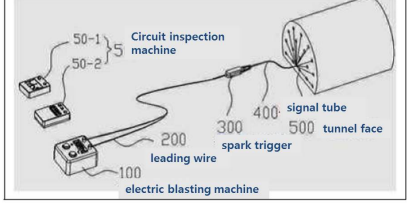
[0001] The present invention relates to blasting using a non-electric detonator in the field such as tunnels and underground excavation, and more particularly, relates to a triggering apparatus of a non-electric detonator using a spark trigger for safely and reliably igniting the non-electric detonator at low cost using an electric exploder and a spark trigger, and a triggering method using the same.

[0010] The present invention solves the problems of the two triggering methods shown above and provides a triggering apparatus of a non-electric detonator using a spark trigger for safely and reliably igniting the non-electric detonator from a distance at low cost and a triggering method using the same.

D. Detailed description of the invention

[0026] The present triggering apparatus comprises an installation step of connecting a spark trigger to a signal tube of a non-electric detonator that is ultimately connected to a tunnel face and then to a leading wire before shunting to a

Fig. 1



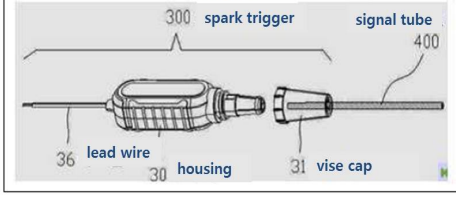
safety zone; an inspection step of inspecting whether there is an abnormality in a firing circuit formed with the spark trigger and the leading wire; and a blasting step of charging and blasting after connecting the leading wire to a blasting machine.

[0027] The above triggering apparatus is composed of a circuit inspection machine (50), an electric blasting machine (100), a leading wire (200) and a spark trigger (300). Particularly, the spark trigger is a key element of the present invention.

[0028] The spark device (300) is a device that ignites a signal tube by generating a strong spark in the signal tube (400) of a non-electric detonator after receiving a high voltage current generated by the electric blasting machine (100) through the leading wire (200) of several hundred meters. The structural elements thereof and the composition of parts are as follows.

[0029] Fig. 2 is a perspective view showing the external shape of a spark trigger of a triggering apparatus of a non-electric detonator using a spark trigger in accordance with an embodiment of the present invention.

Fig. 2



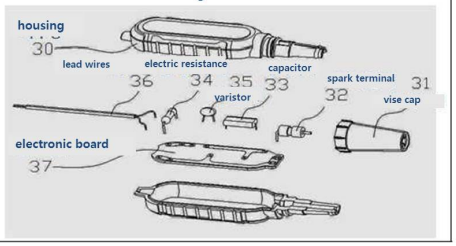
[0030] As shown in the figure, the spark trigger (300) is composed of a plastic housing (30) for protecting electronic parts, a vise cap (31) made of transparent plastic material for binding a signal tube, and lead wires (36) connected to the leading wire.

[0031] Fig. 3 is a exploded view showing each part of the spark trigger of a triggering apparatus of a non-electric detonator using the spark trigger in accordance with an embodiment of the present invention.

[0032] Inside the housing (30) of the spark trigger, which is made of

plastic injection, it is composed of electronic parts comprising a spark terminal (32), a capacitor (33), an electric resistance (34), a varistor (35), lead wires (36), and an electronic board (37) and the like, and a vise cap (31) made of transparent plastic material.

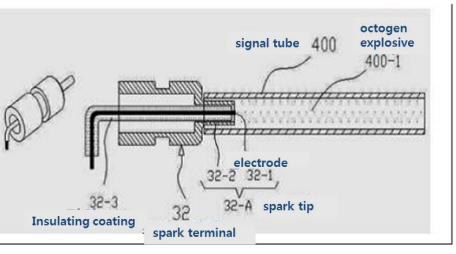
Fig. 3



[0045] The structural elements of the spark terminal which causes a spark in the signal tube of the non-eclectic detonator among the above parts will be described as follows.

[0046] Fig. 4 is a perspective view and a cross-sectional view showing a spark terminal of a spark trigger of a triggering apparatus of a non-electric detonator using a spark trigger in accordance with an embodiment of the present invention.

Fig. 4



[0047] As shown in the figure, the spark terminal (32) comprises a spark tip (32-A) composed of two electrodes (32-1, 32-2) with a tight gap, and the gap between the two electrodes is determined by the thickness of an insulating coating (32-3).

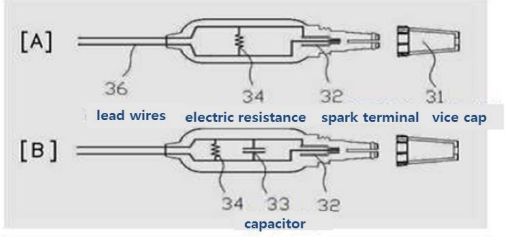
[0050] As shown in the figure, the spark tip (32-A) composed of the two electrodes is inserted into the signal tube (400), causing a strong spark to explode the octogen explosive (400-1) coated within the signal tube.

[0051] The spark terminal is made of brass or similar conductive metal. Teflon wire or enamel wire is used for the insulating coating that forms the spark tip.

[0052] In the above, the types and roles of the parts of the spark trigger are examined, and the circuit configuration of each electronic part will be described below.

[0053] Fig. 5 is a circuit diagram showing two embodiments of a firing circuit of a spark trigger of a triggering apparatus of a non-electric detonator using a spark trigger in accordance with an embodiment of the present invention.

Fig. 5



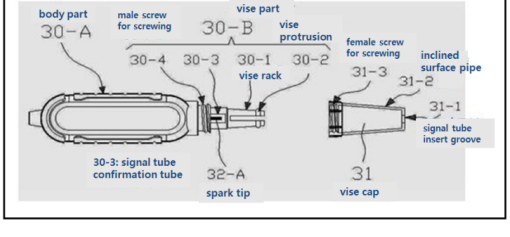
[0054] Fig. 5[A] is a circuit diagram of a spark trigger composed of a spark terminal (32), an electric resistance (34) and lead wires (36).

[0058] Fig. 5[B] is a circuit diagram of a spark trigger composed of a spark terminal (32), a capacitor (33), an electric resistance (34) and lead wires (36).

[0069] The circuit configuration of the spark trigger is described in the above. The elements and functions of the external configuration of the spark trigger will be explained as follows.

[0070] Fig. 8 is a view showing a configuration of a housing and a vise cap of a spark trigger of a triggering apparatus of a non-electric detonator using a spark trigger in accordance with an embodiment of the present invention.

Fig. 8



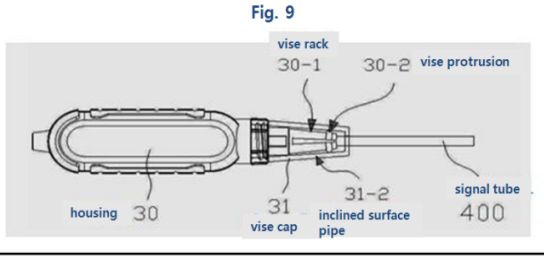
[0071] The housing (30) of the spark trigger is made of a plastic

material, which is light and easy to mold, and the housing (30) is composed of a body part (30-A) for protecting the electronic parts and a vise part (30-B) for joining the signal tube.

[0072] The vise part (30-B) consists of multi-partitioned vise racks (30-1) that serve to tighten the signal tube so that it does not come off, and vise protrusions (30-2) that add the strength of tightening by a inclined surface pipe (31-2) of the vise cap, a signal tube confirmation groove (30-3) to confirm whether the spark tip is inserted into the signal tube, and a male screw (30-4) for screwing the vise cap.

[0073] Fig. 9 is a view showing a combination of a housing and a vise cap of a triggering apparatus of a non-electric detonator using a spark trigger in accordance with an embodiment of the present invention.

Fig. 9



[0074] As shown in the figure, when the vise cap (31) is screwed to the housing (30), the vise racks (30-1) are pressed against the inclined surface tube (31-2) of the vise cap to tightly tighten the signal tube so that the signal tube is not released.

C. The Challenged invention

The Challenged invention consists of two inventions comprising: a spark trigger and a triggering method using the spark trigger. More details are followed in the appendix. The portions regarding Claims 1 and 3 of the Invention at Issue are directed to the spark trigger.[1)]

1) The invention relating to the triggering method is being decided in Patent

D. References

1) Reference 1 (Plaintiff's Exhibit No. 11)[2)]

Cited Reference 1 relates to an invention entitled “An Electric Power Amplifying Apparatus and a Triggering Method of a Non-Electric Detonator by Using the Same” and is disclosed in Korean patent publication No. 2010-3347 published on Jan. 8, 2010. The main content is as follows.

> The present invention has been made to replace the triggering method of a shock tube using a non-electric detonator, as described above, and it is an object of the present invention to provide an electric power amplifying apparatus for safely and reliably igniting a non-electric detonator at low cost using a shock tube[3)] of a non-electric detonator, and a triggering method of a non-electric detonator using the same. (Paragraph <2>)
>
> The mechanical structure of the present invention is characterized in that it is formed with an electric power amplifying apparatus to which a typical electric blasting machine, typical lead wires, and a spark terminal are attached. (Paragraph <7>)
>
> In particular, the electric power amplifying apparatus among the above-mentioned components is a core device which can correct a lost electric current due to an electric resistance accumulated by a leading wire of several hundred meters or several kilometers connected to an

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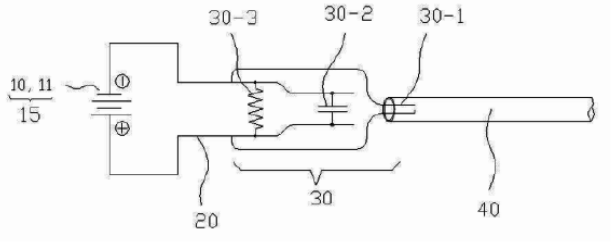
Court Decision No. 2017 Heo 1168 on the same date as the subject decision.

2) The inventor and the applicant of Cited Reference 1 are the same as the inventor and the patent holder of the Invention at Issue. This application is rejected for lack of an inventive step over Cited Reference 2.

3) This is identical to the signal tube of the Challenged invention. Explosives loaded in the tube by a high pressure spark are sequentially exploded to

electric blasting machine, thereby allowing sufficient spark discharge to occur in a spark terminal. The apparatus comprises a capacitor for temporarily storing a current, a spark terminal for generating a spark discharge, and an electric resistance for discharging a current stored in the capacitor for a predetermined time, and corrects the lost current according to the length and thickness of the lead wire to cause a strong spark to occur in a shock tube of a non-electric detonator, thereby amplifying the shock tube of a non-electric detonator. (Paragraph <8>)



2) Reference 2 (Plaintiff's Exhibit No. 14)

Cited Reference 2 is directed to an invention entitled “Firing Arrangements” disclosed in U.S. Patent No. 5,341,742 on June 25, 1992.

3) Reference 3 (Plaintiff's Exhibit No. 15)

Cited Reference 3 is directed to an invention entitled “Electric Noise Suppressor” disclosed in U.S. Patent No. 5,900,796 on May 4, 1999.

4) Reference 4 (Plaintiff's Exhibit No. 16)

Cited Reference 4 is directed to an invention entitled “Split Ferrite

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ignite the non-electric detonator installed in the explosive at the blast site.

Bead Case for Flat Cable" disclosed in U.S. Patent No. 5,095,296 on May 10, 1992.

[Factual Basis] Undisputed facts, significant facts in the Patent Court, statements in Plaintiff's Exhibits. 1-3 and 11-16, and the purport of the overall argument

2. Summary of the Interested Parties' Arguments

A. Plaintiff's Arguments

1) It is recognized that the spark trigger of the Challenged invention comprises all the elements of Claims 1 and 3 of the Invention at Issue except the coupling unit. However, the technical elements of Claims 1 and 3 of the Invention at Issue reside in the coupling unit composed of a vise formed in a conical shape at the end of the spark trigger and having a far end divided into vise racks and a vise cap tightening the vise racks as being coupled to the vise. Accordingly, since the Challenged invention comprises a coupling unit which is different from the above in structure, the Challenged invention differs from Claims 1 and 3 of the Invention at Issue in constitution.

2) Upon comparing the Challenged invention with Claims 1 and 3 of the Invention at Issue, they are different in the principle of solving problems as well as in the working effect of the coupling unit. Therefore, it cannot be recognized that the coupling unit of the Challenged invention is equivalent to the coupling unit of Claims 1 and 3 of the Invention at Issue.

3) In order to overcome the rejection ground for lack of an

inventive step in the filing process of the present invention, the Defendant deliberately excluded the remaining coupling unit except Elements 1-3 from the claim scope as will be shown below. Therefore, the Challenged invention does not fall within the scope of Claims 1 and 3 of the Invention at Issue.

4) The firing circuit of the spark trigger in the Challenged invention is the same as that disclosed in Cited Reference 1 or 2, and the coupling unit thereof is the same as that disclosed in Cited References 3 and 4. Therefore, the Challenged invention would have been easily conceived by a skilled person in the art from combining the coupling unit of Cited References 3 and 4 to Cited Reference 1 or 2. Accordingly, since the Challenged invention corresponds to a freely exploited technology, it does not fall within the scope of Claims 1 and 3 of the Invention at Issue.

5) Nonetheless, the IPTAB, which decided to the contrary, erred in its decision. Therefore, the Subject Decision shall be vacated.

B. Defendant's Arguments

1) The Challenged invention share the identical solution principles as Claims 1 and 3 of the Invention at Issue and the substituted elements exhibit the same effects as the elements of Claims 1 and 3 of the Invention at Issue. Since such substitution would have been easy for a skilled person in the art, the Challenging invention that substitutes only the coupling unit of the spark trigger of Claims 1 and 3 of the Invention at Issue belongs to the scope of equivalence of

Claims 1 and 3 of the Invention at Issue.

2) Accordingly, the IPTAB, which made the same conclusion as the above, did not err in its decision.

3. Discussion

A. Relevant Law

In order to recognize that the Challenged invention falls within the claim scope of the patented invention, each of the elements described in the claim scope of the patented invention and the organic combination between the elements must be included in the Challenged invention. Meanwhile, when the principle of solving problems is the same in both inventions even if some of the elements described in the claims of the Challenged invention are substituted or modified, when such a substitution can achieve the same object as the patented invention and exhibits substantially the same effect as the patented invention, and when such a substitution would have been obvious to a skilled person in the art, the Challenged invention corresponds to an invention that is the same as the one that has been already known prior to the filing of the patented invention or an invention that would have been easily conceived by a skilled person in the art from the prior art. Unless there are special circumstances such as deliberately excluding the substituted elements of the Challenged invention from the claim scope through the application procedure of the patented invention, the Challenged invention is deemed equivalent to the constitution described in the claim scope of the patented invention, thereby still falling within the claim scope of the patented invention. The fact that the two inventions share the identical solution principles means that the substituted elements in the challenged invention

corresponds to a non-essential part of the patented invention and thus, the challenged invention comprises the technical elements of the patented invention. In understanding the technical elements of the patented invention, it is not necessary to extract a part of the elements described in the claims of the patented invention, but to practically explore and judge what is the principle of solving problems on which the solution peculiar to the patented invention is based or what is the core of the technical idea, taking the detailed description of the invention of the specification as well as the widely known technology at the time of filing into consideration, when comparing the patented invention with the prior art (refer to Supreme Court Decision No. 2007Hu3806 rendered on June 25, 2009, Supreme Court Decision No. 2012Hu498 rendered on May 29, 2014 and Supreme Court Decision No. 2014Hu2788 rendered on May 14, 2015).

B. Whether the Challenged invention Falls within the Scope of Equivalence of Claims 1 and 3 of the Invention at Issue

1) Element-by-Element Comparison and Analysis

Feature	The Invention at Issue	The Challenged invention	Remark
1-1	A triggering apparatus of a non-electric detonator using a spark trigger, the spark trigger wherein a firing circuit comprising a spark terminal formed with a spark tip composed of two electrodes for generating a spark by a high voltage current is built in and is supplied with power from an electric blasting machine through a leading wire to generate a spark at the spark terminal, and the	A triggering apparatus of a non-electric detonator using a spark trigger, the spark trigger (30) wherein a firing circuit comprising a spark terminal (320) formed with a spark tip composed of two electrodes for generating a spark by a high voltage current is built in and is supplied with power from an electric blasting machine through a leading wire (20) to generate a spark at the	Identical

Feature	The Invention at Issue	The Challenged invention	Remark
	spark generated at the spark terminal is transmitted to the non-electric detonator installed at a tunnel face through a signal tube connected to the spark terminal,	spark terminal (320), and the spark generated at the spark terminal (320) is transmitted to the non-electric detonator installed at a tunnel face (50) through a signal tube (40) connected to the spark terminal (320),	
1-2	wherein the firing circuit comprises: two lead wires connected to the leading wire and electrically connected to the respective electrodes of the spark tip; and an electric resistance connecting the two lead wires to the spark tip in parallel,	wherein the firing circuit comprises: two lead wires (360) connected to the leading wire (20) and electrically connected to the respective electrodes of the spark tip; and an electric resistance (340) connecting the two lead wires to the spark tip in parallel,	Identical
1-3	and wherein the spark trigger comprises: an electronic board having the firing circuit; a body part surrounding the electronic board; a housing in which the spark tip of the firing circuit is placed, into which the signal tube is inserted to be connected to the spark tip, and with which the vise is formed in a conical shape whose diameter decreases toward the end and is divided into vise racks at its far end; and a vise cap tightening the vise racks as being coupled to the conical vise to make the signal tube to be fastened to the vise.	and wherein the spark trigger (30) comprises: an electronic board (37) comprising the firing circuit; a body part (300-A) surrounding the electronic board (37); a rectangular housing (300) in which the spark tip of the firing circuit is placed, which is formed with a cylindrical hollow space (309) whose diameter gradationally decreases toward the end to insert the signal tube (40) to be connected to the spark tip, and with which a vise (300-B) including fully partitioned vise racks (301) is formed; and a vise cap (310) tightening the vise racks (301) to couple the signal tube (40) to the vise (300-B),	Different

Feature	The Invention at Issue	The Challenged invention	Remark
3	The firing circuit further comprises a capacitor for connecting the two lead wires in parallel with the spark tip at a position between the electric resistance and the spark tip.	The firing circuit further comprises a capacitor (330) for connecting the two lead wires in parallel with the spark tip at a position between the electric resistance (340) and the spark tip, and a fuse (380).	Identical

As shown in the above table, the Challenged invention comprises Elements 1-1 and 1-2 of Claim 1 and Feature 3 of Claim 3 of the Invention at Issue. (At this point, there is no dispute between the interested parties. Refer to the First **protocol/record for pleading**.)

However, the two inventions are different since Claims 1 and 3 of the Invention at Issue comprise a coupling unit provided with a vise formed in a conical shape at the end of the housing and having a far end divided into vise racks and a vise cap tightening the vise racks as being coupled to the vise, while the Challenged invention comprises a coupling unit where vise racks (301) which is formed in a rectangular shape at the end of the housing of the spark trigger and of which the middle part is folded over to overlap the upper vise rack (301-b) with the lower vise rack (301-a), and the overlapped upper and lower vise racks are fastened by inserting the coupling protrusions (304) of the lower vise rack (301-a) into the coupling grooves (312) of the vise cap (310) (hereinafter, referred to as "**the Difference**").

2) Analysis on the Difference

In relation to the Difference, it will be examined whether the coupling unit of the Challenged invention is equivalent to Elements 1-3 of Claims 1 and 3 of the Invention at Issue.

A) Whether or not the two inventions share the identical solution principles

Taking the following into consideration, the solution principles on which the solution peculiar to Claims 1 and 3 of the Invention at Issue is based is not the same as that of the Challenged invention.

① Considering the descriptions in the specification of the Invention at Issue, the technical elements of Claims 1 and 3 of the Invention at Issue and the technical objective to be achieved thereby are i) to quickly discharge the charge filled in the capacitor even when the ignition fails by placing a circuit with an electric resistance that can act as a safety device in the housing of the spark trigger capable of igniting the non-electric detonator and ii) to easily and firmly connect a shock tube to the spark trigger through a conical vise formed integrally with the above housing and having vise racks which form a cut-out groove in the longitudinal direction and a vise cap formed with the same conical shape as the vise to be overlapped thereover to firmly tighten the vise racks.

As discussed above, there is no dispute between the interested parties in that the constitution of the circuit of the spark trigger of Claims 1 and 3 of the Invention at Issue (Elements 1-1, 1-2 and 3) does not practically differ from the descriptions described in Cited Reference 1. It can be seen that to quickly discharge the charge filled in the capacitor even when the ignition fails by placing a circuit with an electric resistance that can act as a safety device in the housing of the spark trigger capable of igniting the non-electric detonator corresponds to a well-known technology.

② The examiner of the KIPO who examined the patent application of the subject case issued on Aug. 20, 2012 the Notice of Preliminary Rejection (Plaintiff's Exhibit No. 6) on the ground that Claim 1 of the

Invention at Issue lacks an inventive step over Cited Reference 1. At that time, Claim 1 is described as follows (Plaintiff's Exhibit No. 5).

> 『A triggering system of a non-electric detonator using a spark trigger, the spark trigger wherein a firing circuit comprising a spark terminal formed with a spark tip composed of two electrodes for generating a spark by a high voltage current is built in and is supplied with power from an electric blasting machine through a leading wire to generate a spark at the spark terminal, and the spark generated at the spark terminal is transmitted to the non-electric detonator installed at a tunnel face through a signal tube connected to the spark terminal, wherein the firing circuit comprises: two lead wires connected to the leading wire and electrically connected to the respective electrodes of the spark tip; and an electric resistance connecting the two lead wires to the spark tip in parallel』

In response thereto, the Defendant amended the above claim on Oct. 22, 2012 as follows. The main contents of the amendment are to change “a triggering system” to “a triggering apparatus” and to add Elements 1-3 described in Claim 5 before amended to Claim 1, as shown in the underlined portion below (Plaintiff's Exhibit No. 7).

> 『A triggering apparatus of a non-electric detonator using a spark trigger, the spark trigger wherein a firing circuit comprising a spark terminal formed with a spark tip composed of two electrodes for generating a spark by a high voltage current is built in and is supplied with power from an electric blasting machine through a leading wire to generate a spark at the spark terminal, and the spark generated at the spark terminal is transmitted to the non-electric detonator installed at a tunnel face through a signal tube connected to the spark terminal, wherein the firing circuit comprises: two lead wires connected to the leading wire and electrically connected to the respective electrodes of the spark tip; and an electric resistance connecting the two lead wires to the

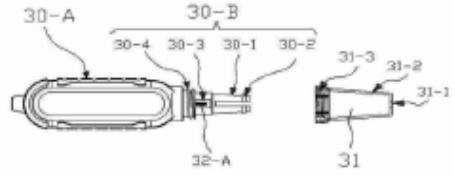
spark tip in parallel, and wherein the spark trigger comprises: an electronic board having the firing circuit; a body part surrounding the electronic board; a housing in which the spark tip of the firing circuit is placed, into which the signal tube is inserted to be connected to the spark tip, and with which the vise is formed in a conical shape whose diameter decreases toward the end and is divided into vise racks at its far end; and a vise cap tightening the vise racks as being coupled to the conical vise to make the signal tube to be fastened to the vise.』

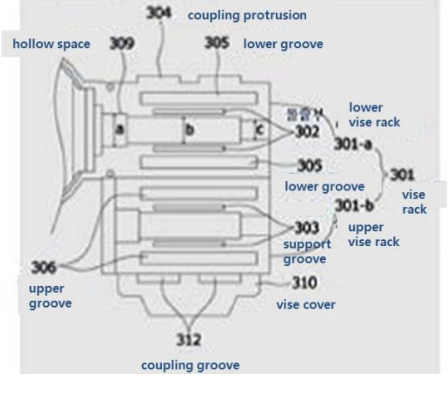
Further, the Defendant submitted the response brief along with the Amendment and stated that "Claim 1 is amended to comprise the elements of Claim 5, which are recognized as having an inventive step" (Plaintiff's Exhibit No. 8). In consideration of the overall prosecution history, Elements 1-3 causes Claims 1 and 3 of the Invention at Issue to have an inventive step over the cited reference and the Defendant also recognizes this fact. Accordingly, it is reasonable to understand that the principle of solving problems on which the solution peculiar to Claims 1 and 3 of the Invention at Issue is based resides in "easily and firmly connecting a shock tube to the spark trigger through the coupling unit."

③ The coupling unit of the Challenged invention has a common feature with the coupling unit of Claims 1 and 3 of the Invention at Issue in easily and firmly connecting the spark trigger to the shock tube. However, as examined above, the circuit, which is essentially identical to the circuit of Claims 1 and 3 of the Invention at Issue, is disclosed in Cited Reference 1. In order to overcome the rejection ground for lack of an inventive step, the Defendant included the elements of the coupling unit described in original Claim 5 in Claim 1 and very narrowly limited the constitution of the coupling unit as described above. However, if the solution specific to Claims 1 and 3

of the Invention at Issue understands the principle of solving problems regardless of the constitution of the coupling unit, which is specifically limited as above, or only as 'the coupling unit for easily and firmly connecting the spark trigger to the shock tube,' which has a higher concept than the constitution of the coupling unit, such an amendment that narrowly limits the claim scope still recognizes broad scope of equivalence despite the amendment or the reduction in the claim scope, and thus, is unreasonable. In light of these circumstances, the principle of solving problems on which the solution peculiar to Claims 1 and 3 of the Invention at Issue should be understood as 'easily and firmly connecting the shock tube to the spark trigger through a conical vise formed integrally with the housing of the spark trigger and having vise racks which form a cut-out groove in the longitudinal direction and a vise cap formed with the same conical shape as the vise to be overlapped thereover to firmly tighten the width of the vise racks, and keeping it firm after they are tightened,' as understood from Elements 1-3.

④ The coupling is achieved in Claims 1 and 3 of the Invention at Issue by coupling the hollow conical vise (30-B) provided with the vise racks (30-1), which form a cut-out groove on its far end, to the vise cap (31) that tightens the vise racks (30-1) as being coupled to the vise. Unlike this, the coupling with the shock tube is achieved in the Challenged invention by which the vise rack (301) divided into two sections such as the lower vise rack (301-a) and the upper vise rack





(301-b) are formed integrally with the housing of the spark trigger, the upper vise rack (301-b) is folded to be overlapped over the lower vise rack (301-a), and the vise cap (310) formed with the lower vise rack is folded thereover, thereby inserting and fixing the coupling protrusions (304) into the coupling grooves (312). Accordingly, since the Challenged invention fails to comprise not only the elements corresponding to the conical vise and the vise cap of Claims 1 and 3 of the Invention at Issue but also the elements corresponding to the vise racks (30-1) that get narrowed in the coupling process and presses the shock tube (since the widths a, b, and c of the hollow space in which the shock tube is placed are already fixed, it is not the structure that applies pressure as they get narrowed in the coupling process), the principle of solving problems of the Challenged invention is not the same as that of Claims 1 and 3 of the Invention at Issue.

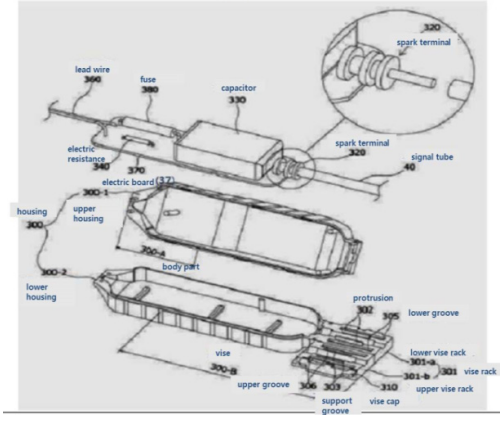
B) Whether or not the two inventions exhibit the practically same effect

On the other hand, even if Claims 1 and 3 of the Invention at Issue and the Challenged invention share the identical solution principles, it should not be recognized in light of the following circumstances that the coupling unit of the Challenged invention exhibit the same effect as Elements 1-3 of the Invention at Issue.

① The coupling unit adopted by the two inventions have a common feature in that they have a structure of easily coupling the signal tube to the spark trigger and firmly tightening them not to be loose.

② However, as described above, Elements 1-3 is a structure in which the conical vise (30-B) whose cross-sectional area gradually decreases toward its far end is integrally formed with the housing (30-A) at the end and the vise cap (31) is coupled to the vise (30-B), wherein the vise (30-B) has a hollow space and is divided into the

vise racks (30-1) at the far end and thus, as the vise cap (31) is inserted and coupled to the vise (30-B), the vise racks (30-1) are gradually tightened and presses the signal tube housed inside.



③ Meanwhile, as described above, the coupling unit of the Invention at Issue is a structure in which the vise rack (301) is integrally formed with the lower housing of the spark trigger and is divided into the lower vise rack (301-a) and the upper vise rack (301-b), and in a state in which the signal tube is positioned in the hollow space (309) of the lower vise rack, the upper vise rack (301-b) is folded to be overlapped over the lower vise rack (301-a) and then, the vise cap (310) is folded to insert and fix the coupling protrusions (304) to the coupling grooves (312).

④ Upon comparing the two inventions in working effect, the coupling unit of Elements 1-3 is formed with two members including the vise integrally formed with the housing and the vise cap separated from the vise, while the coupling unit of the Challenged invention is integrally formed with the housing. Thus, the two inventions are different from one another in the ease of manufacture (the coupling unit of the Challenged invention can be manufactured at the same time during the injection process of the housing, while the vise cap of Elements 1-3 should be separately manufactured from the housing). Also, since the vise cap and the vise of Elements 1-3 are two separate members, there is possibility of loss or the like. However, since the coupling unit of the Challenged invention is an integral structure with

the housing, there is no fear of loss or the like. Therefore, the coupling unit of the Challenged invention is different from Elements 1-3 of Claims 1 and 3 of the Invention at Issue in terms of portability.

⑤ Further, the coupling process of the coupling unit of Elements 1-3 is completed by which the end of the signal tube is placed in the hollow space of the vise (30-B) after being inserted to the vise cap (31) followed by coupling the vise cap (31) onto the vise (30-B) according to a predetermined method (it may be a method of rotating the vise cap, however, it is not described in the specification of the Invention at Issue). On the other hand, the coupling process is completed in the Challenged invention by which after placing the signal tube in the hollow space (309) of the lower vise rack (301-a), the upper vise rack (301-b) is folded to be overlapped over the lower vise rack (301-a) and then, the vise cap (310) is folded to insert the coupling protrusions (304) into the coupling grooves (312).

Accordingly, the coupling unit of the Challenged invention does not need to first insert the signal tube to the coupling unit such as the vise cap during the coupling process, unlike Elements 1-3. Further, in the Challenged invention, the firmness of the coupling with the signal tube depends on how tight the coupling is between the coupling grooves (312) and the coupling protrusions (304). In addition, since the diameter of the hollow space does not change during the coupling process, it can be seen that the smallest diameter of the hollow space, c should be formed smaller than the diameter of the signal tube (if the diameter c is formed larger than the diameter of the signal tube, the signal tube will be in a loose state).

On the other hand, due to the presence of the cut-out groove formed by the vise racks (30-1) in Elements 1-3, the width between the vise racks (30-1) decreases as the vise (30-B) is coupled to the vise cap

(31), thereby tightly pressing the signal tube. Thus, it can be understood that even if the smallest diameter of the hollow space within the vise is slightly larger than the diameter of the signal tube, there is no obstacle to the coupling.

3) Summary of Analysis

Accordingly, the Challenged invention is not the same as Claims 1 and 3 of the Invention at Issue and does not fall within the scope of equivalence thereof. Therefore, the Defendant's argument based on the premise contrary to the above cannot be accepted.

C. Whether or Not the Coupling Unit of the Challenged invention Is Deliberately Excluded from the Claim Scope

1) The Plaintiff argues that the Challenged invention does not fall within the scope of Claims 1 and 3 of the Invention at Issue since the Defendant includes Elements 1-3 to Claim 1 and deliberately excludes the remaining coupling unit except Elements 1-3 from the claim scope in order to overcome the rejection ground for lack of an inventive step during the filing process of the Invention at Issue.

2) As discussed above, Claims 1 and 3 of the Invention at Issue was described as ‘a triggering system of a non-electric detonator adopting a structure in which an electric resistance is placed in the circuit of a triggering apparatus.’ Presenting Cited Reference 1 that has practically the same circuit as the above, the Examiner issued a Notice of Preliminary Rejection for lack of an inventive step. In response thereto, the Defendant made an amendment by narrowing the claim scope to include the elements described in Claim 5 (Elements 1-3 of Claims 1

and 3 of the Invention at Issue), which was not pointed out for lack of an inventive step, to Claim 1 in order to overcome the rejection ground. Further, Elements 1-3 is not just described as 'the fastening unit' but very specifically and narrowly described as '… a housing in which the spark tip of the firing circuit is placed, into which the signal tube is inserted to be connected to the spark tip, and with which the vise is formed in a conical shape whose diameter decreases toward the end and is divided into vise racks at its far end; and a vise cap tightening the vise racks as being coupled to the conical vise to make the signal tube to be fastened to the vise,' and this description helped to overcome the lack of an inventive step rejection. Taking all of the above into account, it can be recognized that the Defendant deliberately excludes the remaining coupling unit having a different structure from Elements 1-3 (to which the coupling unit of the Challenged invention corresponds) from the claim scope by reducing the claim scope.

Accordingly, even if the coupling unit of the Challenged invention is deemed equivalent to Elements 1-3 of Claims 1 and 3 of the Invention at Issue, it should be recognized that the Challenged invention does not fall within the scope of Claims 1 and 3 of the Invention at Issue.

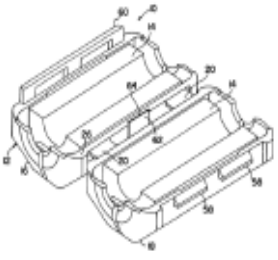
D. Whether or Not the Challenged invention Corresponds to a Freely exploited Technology

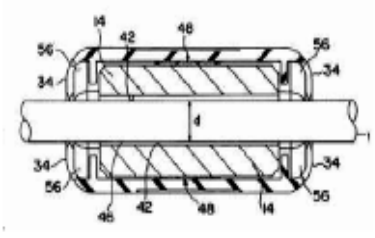
1) Since the circuit of the spark trigger of the Challenged invention is identical to that of Cited Reference 1 or 2 and the coupling unit thereof is identical to that of Cited

References 3 and 4, the Plaintiff argues that the Challenged invention would have been easily conceived by a skilled person in the art by combining the coupling unit of Cited References 3 and 4 to Cited Reference 1 or 2 and therefore, the Challenged invention corresponds to a freely exploited technology.

2) Upon examining, the circuit of the spark trigger of the Challenged invention is practically identical to that of Claims 1 and 3 of the Invention at Issue. (The Plaintiff voluntarily admits this fact. Refer to the First protocol/record for pleading.) Cited Reference 1 discloses the substantially identical circuit to that of Claims 1 and 3 of the Invention at issue, as discussed above. Therefore, the circuit of the spark trigger of the Challenged invention is essentially identical to that of Cited Reference 1.

3) Further, in relation to the coupling unit, Cited Reference 3 (Plaintiff's Exhibit No. 15) relates to an electric noise suppressor and discloses a clamp filter having a structure as shown below. According to Cited Reference 3, an upper cover and a lower cover (16, 18) respectively have a semispherical cross-section to be overlapped over one another and have a groove in the middle therebetween in the longitudinal direction to place a cable (1) therein. The lower cover (18) is provided with coupling protrusions (58), and the upper cover (16) is provided with a coupling member (60) having coupling grooves. After positioning the cable in the middle groove, the upper and lower covers (16, 18) are overlapped over one another to insert and fasten the coupling protrusions to the coupling grooves.





4) Cited Reference 3 is a device for suppressing an electric noise in a signal transmission cable, and thus, belongs to a different technical field from the spark trigger for igniting the non-electric detonator to which the Challenged invention belongs. The technical objective of suppressing an electric noise in Cited Reference 3 is not achieved by the coupling structure of a case shown above, but by using the case made of ferrite, which grips the cable in its circumferential direction to surround the cable. The above described coupling structure is no more than being adopted to tightly grip (to clamp) the cable by the case.

Meanwhile, the Challenged invention has a common feature with Cited Reference 3 in that the coupling unit of the Challenged invention also grips the shock tube to tightly couple the spark trigger to the housing. Therefore, with reference to the coupling structure of Cited Reference 3, a skilled person in the technical field to which the spark trigger belongs would have easily conceived the Challenged invention by combining the housing of the spark trigger of Cited Reference 1 to the coupling structure in which a gripping unit divided with two members to be overlapped over one another is hingedly connected and when the two members are coupled, the shock tube formed inside is tightly pressed in

order to firmly couple the shock tube to the spark trigger.

Accordingly, the Challenged invention corresponds to a freely exploited technology and therefore, the Challenged invention does not fall within the scope of Claims 1 and 3 of the Invention at Issue.

E. Summary of Discussion

Taking all the circumstances into consideration, the Challenged invention does not have the same constitution of the coupling unit as Claims 1 and 3 of the Invention at Issue. The coupling unit of the Challenged invention is not equivalent to that of Claims 1 and 3 of the Invention at Issue. Even if the coupling unit of the Challenged invention is equivalent to that of Claims 1 and 3 of the Invention at Issue, this corresponds to the elements deliberately excluded from the Defendant at the filing stage by the amendment or the Challenged invention corresponds to the freely exploited technology. Therefore, the Challenged invention does not fall within the scope of Claims 1 and 3 of the Invention at Issue. Accordingly, the IPTAB, which judged contrary to the above, erred in its decision.

4. Conclusion

If so, the Plaintiff's petition to revoke the IPTAB decision is well grounded and therefore shall be granted.

Presiding Judge Hyeongjun PARK
Judge Hyeonseop JIN
Judge Byeongguk KIM

[Appendix] The Challenged invention

A. Title of Invention: A triggering apparatus of a non-electric detonator using a spark trigger and a triggering method using the same

B. Brief Description of the Drawings

Fig. 1 is an external perspective view showing the Challenged invention.

Fig. 2 is a exploded view showing the Challenged invention.

Fig. 3 is a top plan view showing a lower vise rack of the Challenged invention.

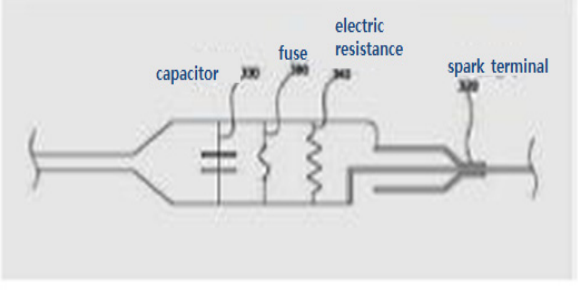
Fig. 4 is a diagram showing a firing circuit of the Challenged invention.

Fig. 5 is a general diagram showing a triggering apparatus in accordance with the Challenged invention.

C. Detailed Description of the Invention

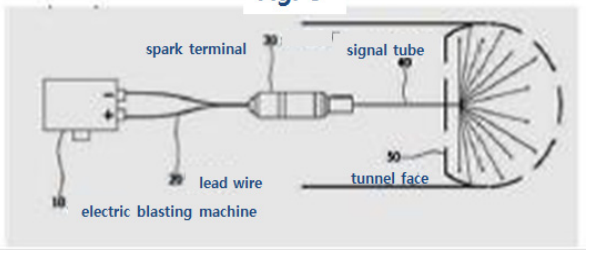
The present invention relates to a triggering apparatus of a non-electric detonator using a spark trigger, the spark trigger (30) wherein a firing circuit comprising a spark terminal (320) formed with a spark tip

Fig. 4



composed of two electrodes for generating a spark by a high voltage current is built in and is supplied with power from an electric blasting machine through a leading wire (20) to generate a spark at the spark terminal (320), and the spark generated at the spark terminal (320) is transmitted to the non-electric detonator installed at a tunnel face (50) through a signal tube (40) connected to the spark terminal (320), wherein the firing circuit comprises: two lead wires (360) connected to the leading wire (20) and electrically connected to the respective electrodes of the spark tip; and an electric resistance (340) connecting the two lead wires to the spark tip in parallel, and wherein the spark trigger (30) comprises: an electronic board (37) comprising the firing circuit; a body part (300-A) surrounding the electronic board (37); a rectangular housing (300) in which the spark tip of the firing circuit is placed, which is formed with a cylindrical hollow space (309) whose diameter gradationally decreases toward the end to insert the signal tube (40) to

Fig. 5



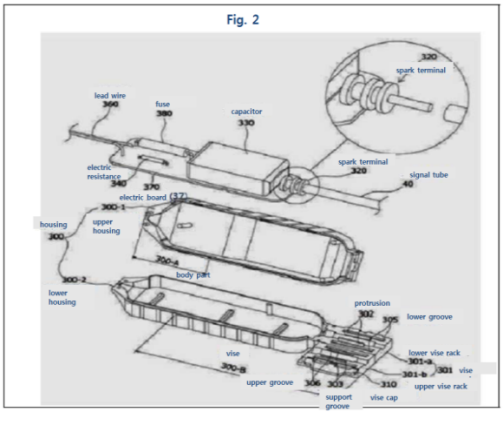
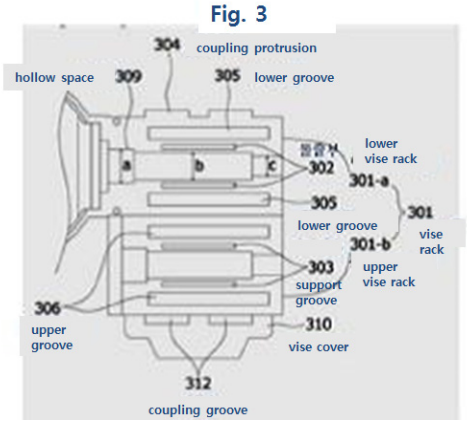


Fig. 3



be connected to the spark tip, and with which a vise (300-B) including fully partitioned vise racks (301) is formed; and a vise cap (310) tightening the vise racks (301) to couple the signal tube (40) to the vise (300), wherein the vise rack (301) is provided with protrusions (302) on the outside of the cylindrical hollow space whose diameter gradationally decreases in order to firmly couple the signal tube (40) and the spark tip, and comprises a lower vise rack (301-a) having lower grooves (305) on the outside of the protrusions (302), and an upper vise rack (301-b) having support grooves (303) into which the protrusions (302) are inserted and upper grooves (306) formed in the same shape at the position corresponding to the lower grooves (305). In this case, the diameter of the cylindrical hollow space (309) into which the spark tip and the signal tube (40) are inserted in the vice rack (301) is divided into a, b, and c based on a position close to the body part (300-A), and the diameter thereof is a> b ≥ c .

The vice cap (310) is provided with coupling grooves (312) and coupling protrusions (304) are provided on the outside of the lower grooves (305). When the upper vise rack (301-b) is overlapped on the lower vise rack (301-a), the coupling grooves (312) of the vise cap (310) are placed on a slightly upper portion of the coupling protrusions (304), and when the user presses the vise cap (310), the coupling protrusions (304) are inserted into the coupling grooves (312), thereby coupling the lower vise rack (301-a) and the upper vise rack (301-b).

At this time, the protrusions (302) of the lower vise rack (301-a) are inserted into the support grooves (303) of the upper vise rack (301-b), and the coupling protrusions (304) are inserted into the coupling grooves (312) of the vise cap (310) by applying a pressure. In this manner, the gap between the lower and upper grooves (305, 306) as well as the diameter of the cylindrical hollow space (309) becomes narrower. Therefore, the vise cap (310) is coupled to the lower vise

rack (301-a), thereby tightening the vise rack (301).

The firing circuit further comprises a capacitor (330) for connecting the two lead wires in parallel with the spark tip at a position between the electric resistance (340) and the spark tip, and a fuse (380).

Meanwhile, the housing (300) is divided into a lower housing (300-2) and an upper housing (300-1).

The present invention relates to a triggering method using a triggering apparatus of a non-electric detonator using a spark trigger, the spark trigger (30) wherein a firing circuit comprising a spark terminal (320) formed with a spark tip composed of two electrodes for generating a spark by a high voltage current is built in and is supplied with power from an electric blasting machine through a leading wire (20) to generate a spark at the spark terminal (320), and the spark generated at the spark terminal (320) is transmitted to the non-electric detonator installed at a tunnel face (50) through a signal tube (40) connected to the spark terminal (320), wherein the method comprises: an installation step of connecting the spark trigger (30) in which an electric resistance (34) and a capacitor (330) are connected with a fuse (380) in parallel to the signal tube (40) of a non-electric detonator that is ultimately connected to a tunnel face and then to a leading wire before shunting to the safety zone (**a1**); an inspection step of inspecting whether there is a disconnection, a short circuit, or normality of the firing circuit using a circuit tester or a resistor meter, which is connected to the leading wire (20) as an external circuit inspection device and then taking action if a disconnection or a short circuit is found (**a2**); and a blasting step of after confirming that the firing circuit is normal, connecting the leading wire (20) to the electric blasting machine (10), applying a high voltage current of the electric blasting machine from the leading wire to the spark trigger (30) through the lead wires (360), while breaking the fuse (380) first (**a3**),

wherein in the inspection step (**a2**), the external circuit inspection device inspects whether or not the leading wire (20) is disconnected by supplying a measuring current less than a specified value by the fuse (380) to the firing circuit of the spark trigger (30) so that when the current does not flow, it is judged as a disconnection, and when the continuity and resistance are detected due to the resistance value obtained by the sum of the resistance of the leading wire (20) and the electric resistance of the firing circuit, it is judged as normality, and when the continuity and resistance are detected due to the resistance value lower than the one obtained by the sum of the resistance of the leading wire (20) and the electric resistance (340) of the firing circuit, it is judged as a short circuit.

D. Drawings

Fig. 1

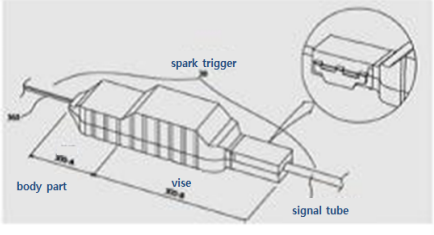


Fig. 2

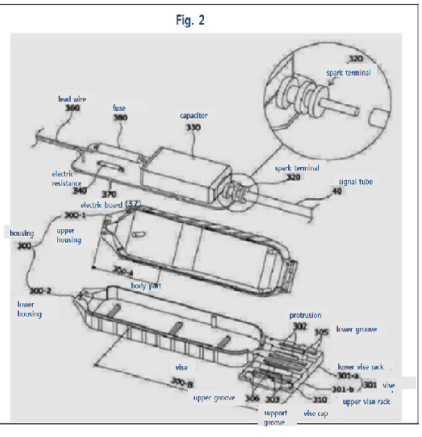


Fig. 3

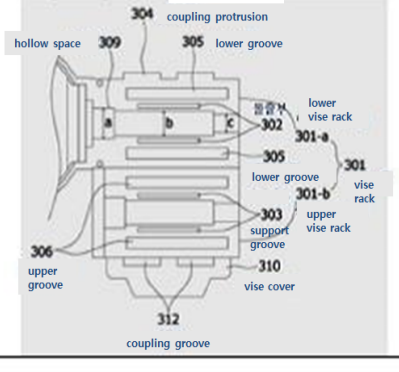


Fig. 4

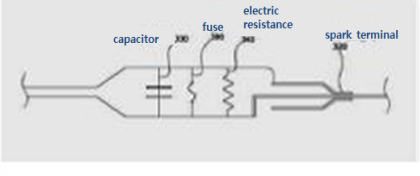
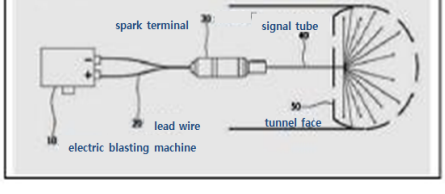


Fig. 5



PATENT COURT OF KOREA
SECOND DIVISION
DECISION

Case No.: 2017Heo2277 Rejection (Patent)

Plaintiff: BODY ORGAN BIOMEDICAL CORPORATION

Defendant: Commissioner of the Korean Intellectual Property Office (the "KIPO")

Date of Closing Argument: August 29, 2017

Decision Date: September 28, 2017

ORDER

1. The IPTAB Decision 2015Won4737 rendered on January 31, 2017 shall be revoked.

2. The cost arising from this litigation shall be borne by the Defendant

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Facts

A. Claimed Invention at Issue (Plaintiff's Exhibit 2, Defendant's Exhibit 1)

1) Title of Invention: A METHOD FOR PREPARING A BIOMATERIAL

2) International Filing Date/ Translation Filing Date/ Application Number
February 15, 2008/ August 6, 2010/ 2010-7017516

3) Claim Construction (as finally amended on August 17, 2015)

[Claim 1]
A method for preparing a tissue repair material from scales, comprising the step of: acellularizing[1] a fish scale to remove some of the albumin[2] and glycosaminoglycan[3]; grinding the fish scale into a plurality of ground particles (hereinafter referred to

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1) A host recognizes a homogeneous and heterogeneous cell antigen as a foreign substance, and as a result, tissue inflammation or immune rejection may occur. Acellularizing is a process of removing cells from fish scales to prevent such events.

2) Albumin is a simple protein, which is widely distributed in cells or body fluid. It constitutes a basic material of cells together with globulin, and binds to several substances in blood or maintains the osmotic pressure of blood vessels.

3) Glycosaminoglycan is a polysaccharide, which is present as a form of proteoglycan (a generic name of molecules in which the side chains of glycosaminoglycan is covalently bonded to protein) bonded to protein. It usually exists in the epidermis or connective tissue and is involved in the support or flexibility of tissues. It is known that removing glycosaminoglycan from connective tissue causes the slowdown of movement and bioactivity of cells.

as “Element 1”), wherein the ground particles contain a mixture of sponge like matrix and powder (hereinafter referred to as “Element 2”).

[Claims 2 to 28] *Omitted*

4) Main Content and Drawing

[1] Technical field and prior art

The present invention relates to a biomaterial and preparation method thereof, and particularly to a biomaterial prepared from fish scales for use in tissue repair and implantation.
The biomaterial is a synthetic and biocompatible material that is used to construct artificial organs, rehabilitation devices, or prostheses and replace natural body tissues. For over decades, collagen fiber, hydroxyapatite (HAP) and tri-calcium phosphate (TCP) are some biomaterials with great biocompatibility and safety to be used in human tissue implants. However, these biomaterials have disadvantages such as low mechanical strength, risk of chemical residue in cross linking, terrestrial animal transmitted diseases (paragraphs [0001] to [0003] of the specification).

[2] Technical problem to be solved and solution

It is an aspect of the invention to provide a biomaterial having a high mechanical strength, low possibility of contracting terrestrial contagious diseases and is applicable to tissue repair or implants.
It is an aspect of the invention to provide a biomaterial prepared from fish scales by a process which includes acellularizing the fish scales; and grinding the fish scales into ground particles, wherein each of the ground particles contain a mixture of sponge like matrix and powder.
The fish scale could have an average diameter of less than 20 cm. For example, the fish scales can have a diameter of about 10-20 cm. The fish scales could be grinded into smaller sizes for special use. For example, the average size of the ground particles can be less than about 10 ㎛ in

diameter (paragraphs [0005], [0008], [0011] to [0013] of the specification).

[3] Effects of the invention

The biomaterial derived by the methods illustrated above retains the original bonding and the 3D structure of the fish scales, and therefore, it has a high mechanic strength, low possibility of contracting terrestrial contagious diseases and is applicable in repairing tissue or tissue implants (paragraph [0018] of the specification).

B. Reference (Defendant's Exhibit 2)

An article entitled “Preparation and partial characterization of a collagen sheet from fish (Lates calcarifer) scales” published in “International Journal of Biological Macromolecules, Vol 42” on January 1, 2008. The main content and drawing thereof are as follows.

[1] Summary

Fish scales, which are hitherto discarded as waste, were collected and cleaned thoroughly. The scales were hydrolyzed under controlled acidic conditions, neutralized and made in to a sheet, i.e., fish scale collagen[4] sheet (FCS). The FCS was characterized through infrared spectroscopy (IR), thermo-gravimetric analysis (TGA), scanning electron microscopy (SEM), and its mechanical properties were also analyzed. The IR study has shown that the sheet contains both organic and inorganic phases revealing that the scales are partially demineralized. The tensile strength of FCS is enough so that it could be used as a wound dressing material. The SEM studies have shown that FCS is porous and exhibited a fibrous nature (*Abstract* on page 6).

4) Collagen belongs to the extracellular matrix (ECM) together with proteins such as glycosaminoglycan. It is a protein which is present in connective tissues as a fibrous form.

[2] Materials and Methods

Dry fish scales were treated with different concentrations of HCl solutions (1:1, v/w, water/fish scales; i.e., 100 ml water/100 g fish scales; Table 1) for 24 h at room temperature (34±2 ○C). Later, the acid solution was decanted and the scales were washed with water. Then water was added to the scales (2:1,v/w) and the pH of the scales was adjusted to 7 using a 0.1N NaOH solution (to check the pH, a sample scale was cut vertically, pH paper was inserted and the pH was noted). Further, scales were washed with water and pulverized with a float of 1:1 (v/w, water/scales) using a domestic mixer for 15 min at 12,000 rpm (the scales treated with 2.81N HCl solution could be pulverized and made into paste), and the resulting paste was cast into a sheet in a polythene tray and dried at room temperature (34±2 ○C). The dried sheets are stored in polythene covers for further studies (*2.2. Methods* on page 7 and Fig. 1).

[3] Results and Discussion

SEM images of the collagen sheet (Figs. 4 and 5) showed its fibrous and porous nature. As the mineral present in the scale was partially dissolved by acid, the porous nature of the sheet was clearly seen. The fibrillar structure of collagen present in the sheet and its organization were clearly viewed (left column, 3rd paragraph on page 8).

The main objective of the preparation of FCS is to use it as a wound dressing material (left column, 2nd paragraph on page 9). The porous nature of sheet will help to absorb the wound fluid when it is applied on the wound thereby keeping the wound dry. This property helps in enhancing the rate of healing of the wound (right column, 1st paragraph on page 9).

C. The Decision Below

1) On July 29, 2014, the KIPO examiner issued a Notice of Preliminary Rejection on the grounds that Claims 1 to 11 before amendment do not meet the description requirements under Article 42(4)(i) of the Patent Act and Claims 1 to 22 do not meet the description requirements under Article 42(4)(ii) of the Patent Act, and thus, the application cannot be allowed.

   In response, the Plaintiff submitted a response and an amendment on September 29, 2014. However, on February 27, 2015, the KIPO examiner issued a second Notice of Preliminary Rejection on the grounds that all of the claims would have been easily conceived by a skilled person in the art, and thus, the application cannot be allowed under Article 29(2) of the Patent Act.

   In response, the Plaintiff submitted a response and an amendment on May 26, 2015. However, on July 17, 2015, the KIPO examiner issued a Final Rejection on the grounds that the previous rejection grounds have not yet been resolved.

2) The Plaintiff filed an appeal against the Final Rejection before the IPTAB on August 17, 2015 with the submission of an amendment for re-examination (Case No. 2015Won4737). However, on October 12, 2015, the KIPO examiner issued the re- examination decision upholding the Final Rejection.

   The IPTAB examined the case and dismissed the Plaintiff's appeal on the grounds that "Claim 1 does not have any special objective over the prior art, is not considered to have any constitutional difficulty, and cannot be regarded as having unexpectedly superior effects, and thus, is not recognized to have inventiveness over the prior art. If even a single claim is

to be subject to rejection, the application shall be rejected as a whole" on January 31, 2017.

[Factual Basis] Undisputed facts, Statements in Plaintiff's Exhibits 1 to 5, Defendant's Exhibits 1 and 2, and the purport of the overall argument

2. Summary of the Parties' Arguments

A. The Plaintiff's Arguments

Claim 1 is not easily conceivable from the prior art in view of differences in the technical field, objective, constitution, and effects from the prior art as detailed below, and thus, inventiveness of Claim 1 is not denied. However, the IPTAB decision is inconsistent with this and thus is erroneous.

1) Claim 1 is directed to a method for preparing a tissue repair material from scales, comprising the step of "acellularizing a fish scale for removing some of the albumin and glycosaminoglycan." Even after the acellularizing step, the original bonding and the 3D structure of the extracellular matrix are retained, mechanical strength is high, and immune rejection response of a host is not present. Thus, the claimed invention has superior effects with respect to tissue cultivation.

2) In contrast, the prior art relates to a method for preparing a wound dressing sheet having a function of absorbing wound fluid into the pores by utilizing the porous structure of the collagen sheet formed from decalcification. In this regard, the HCl treatment step in the prior art is simply for decalcification[5], and the step of acellularizing is not suggested

or implied. Moreover, after the HCl treatment step, the collagen of fish scales is dissolved, glycosaminoglycan is removed, and even the original bonding and the 3D structure are destroyed, whereby the structural strength of the resulting product becomes very weak.

B. The Defendant's Arguments

Claim 1 would have been easily conceived from the prior art for the following reasons and the inventiveness thereof is denied accordingly. Thus, the IPTAB decision is consistent with this and shall be upheld.

1) Even if the step of acellularizing is not disclosed in the prior art in the process of preparing a collagen sheet for wound dressing, it is essential to remove cells present in fish scales in order to avoid the adverse effects of the immune rejection response which may occur in a collagen sheet, a medical product applied to the human body.
Further, HCl is an acellularizing agent which is frequently used in this technical field. Thus, the HCl treatment step in the prior art involves acellularization. In addition, since glycosaminoglycan is widely known in this technical field to be a protein for use in cell repair, utilizing the extract of collagen and glycosaminoglycan from fish scales as biomaterials is obvious to a skilled person in the art at the time of the filing date of the application.

2) The collagen sheet prepared from the HCl treatment in the prior art is not very different from Claim 1 with respect to the

5) Decalcification refers to removing calcium from a hard tissue such as bone or a tissue with calcium deposit.

structure and strength. Moreover, there is no big difference in terms of biocompatibility and immune response after acellularization occurs. Thus, the effects expected from Claim 1 is predictable from the prior art.

3. Inventiveness of Claim 1

A. Element-by-element Comparison

Element	Claim 1	Prior Art
precedence	a method for preparing a tissue repair material from scales	a method for preparing a collagen sheet for wound dressing from fish scales
1	the step of acellularizing a fish scale for removing some of the albumin and glycosaminoglycan	fish scales are treated with 25% HCl solution for 24 h at room temperature (34±2 ○C) (*see* lines 1-4 of *2.2. Methods* on page 2, Table 1).
2	grinding the fish scale into a plurality of ground particles, wherein the ground particles contain a mixture of sponge like matrix and powder	scales treated with a HCl solution are pulverized using a mixer and made into paste, and the resulting paste is cast into a sheet (*see* lines 8-14 of *2.2. Methods* on page 2, Fig. 1).

B. Commonalities and Differences

1) The technical field of Claim 1 and the prior art is broadly similar in that both are directed to a method for preparing biocompatible biomaterials from fish scales. Claim 1 and the prior art are also the same in that the fish scale is grinded after being subject to a certain process, as shown in Element 2 and the corresponding element of the prior art.

2) However, the resultant product of Claim 1 is “a tissue repair material,” whereas the prior art relates to a method for preparing collagen sheet for wound dressing. As such, the specific technical field is different from each other.
In addition, Claim 1 recites “the step of acellularizing a fish scale for removing some of the albumin and glycosaminoglycan, “ whereas the prior art only discloses a process of preparing a collagen sheet through HCl treatment without reciting “acellularization.”
It will be discussed below whether Claim 1 is easily conceivable by a skilled person in the art from the prior art despite such differences.

C. Analysis of the Differences

It is difficult to recognize that Claim 1 is easily conceivable by a skilled person in the art from the prior art for the following reasons.

1) Claim 1 is a method for preparing a tissue repair material, which is used to repair tissue damages, as shown in the descriptions of the specification below:

The biomaterial of the invention contains tissue repair factors and may be manufactured into a tissue repair material for repairing a variety of tissue damages and tissue defect sites. In other examples, the biomaterial may be made as a dressing for transplantation, implantation on surgical grafts or implants to be implanted at, into, onto or near bone defect sites, cartilage repair sites or other tissue defect sites. Summarizing the above, the invention relates to a biomaterial in powder and/or matrix and/or flaky form prepared from the fish scales 9 for use in a variety of tissue repairs and implantations (paragraphs [0028], [0029]).

In contrast, the prior art relates to a method for preparing a wound dressing sheet applicable to wound sites such that the wound does not become worse and is rapidly cured. Thus, the resultant product and the application field of the prior art are different from those of Claim 1, and the technical constitution and the effects of the prior art are different from those of Claim 1 accordingly.

2) First, a tissue repair material, the resultant product of Claim 1, is used for tissue damage inside as well as outside the body and is required to have the capability to repair tissues and facilitate implantation. For this purpose, Claim 1 recites the step of acellularization.
   In contrast, the prior art aims to increase wound repair rate by forming pores in a collagen sheet and absorbing wound fluid to make the wound sites dry. For that purpose, the prior art only discloses a process of preparing a collagen sheet by subjecting fish scales to partial decalcification with a 25% HCl solution to make the scales into a paste, but does not suggest or imply acellularization at all.

3) Meanwhile, acellularization is essential for solving the problems of the immune rejection response which may occur when

biomaterials obtained from other animals are applied to the human body, and it is possible that acellularization of fish scales is accompanied during the process of the HCl treatment of the prior art. However, a skilled person in the art knowing the prior art would not have been motivated to conceive of a method for preparing a tissue repair material as recited in Claim 1 or readily would have arrived at Claim 1 from the constitution of the prior art, because the prior art is directed to a wound dressing sheet and does not describe acellularization at all.

Further, the prior art only focuses on the concentration of the HCl solution under which the fish scales could be made into a paste, as can be seen from Table 1 of the prior art. Accordingly, the prior art just analyzes whether the fish scales can be made into a paste while not being dissolved at 20%, 25% and 30% HCl solutions. Even Defendant's Exhibit 12, which was submitted to prove that the HCl solution is used as an acellularizing agent, utilized a low concentration (0.1M, 0.365%)[6] of HCl solution for acellularization. In view of this, it appears difficult to recognize that a skilled person in the art would be motivated to conceive of acellularization from the prior art utilizing a high concentration (25%) of HCl solution.

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6) Since 0.1M of HCl solution was added together with pepsin for acellularization, the HCl solution appears to assist the action of pepsin (*see* “Pepsin based protocols” on page 3, right column of Defendant's Exhibit 12). Accordingly, when only the HCl solution is added for acellularization, there is a possibility that the concentration of the HCl solution gets higher. Nevertheless, 0.1M (i.e., 0.365%) is remarkably lower than the 25% HCl solution. Thus, it does not appear that a high concentration of HCl solution as in the prior art is used for acellularization.

[Table 1] Effect of HCl solution on fish scales

Concentration	Observation
20% HCl solution (2.24N)	No effect on scale
25% HCl solution (2.81N)	Scales could be made into a paste and cast into aa sheet
30% HCl solution (3.37N)	Scales were dissolved

In addition, as can be seen from Defendant's Exhibit 11, there is a problem that glycosaminoglycan is dissociated from the collagen tissue with an acid treatment for acellularization. In this regard, unlike Claim 1, the prior art does not have any understanding that not all glycosaminoglycan is removed.

4) Even when comparing the effects of Claim 1 and the prior art, as shown in the following descriptions of the specification, in the case where only some of albumin and glycosaminoglycan are removed in the course of acellularization as recited in Claim 1, the original bonding and the 3D structure of ECM are retained, whereby the structure for cells to move into a tissue repair material and proliferate can be provided.

> The biomaterial derived by the methods illustrated above retains the original bonding and the 3D structure of the fish scales, and therefore, it has a high mechanic strength, low possibility of contracting terrestrial contagious diseases and is applicable to repair tissue or tissue implants (paragraph [0018] of the specification).
>
> During the step of acellularizing the fish scales, only most of the albumin and few glycosaminoglycans are removed, and collagen, elastin and most of the glycosaminoglycans remains in the extracellular matrix of the original structure. Therefore, the acellularized biomaterial can supply

the structure for cells to move in and has good biocompatibility (paragraph [0042] of the specification).

In contrast, the prior art just discloses the formation of pores in a collagen sheet through partial decalcification with the HCl solution as the effects, but fails to recognize or consider the usefulness of the entire structure of fish scales.

In addition, when a high concentration of HCl solution which renders the fish scales into a paste is used, as shown in Table 1 of the prior art, it is unavoidable that the original bonding and the 3D structure of fish scales is completely destroyed or at least partially destroyed whereby the structural strength is decreased.

D. Opinion on Other Arguments by the Defendant

1) With respect to the acellularization of biomaterials, the Defendant submitted Defendant's Exhibit 11[7] and argued that HCl had been used as an acellularizing agent before the filing date of the application and most glycosaminoglycans are retained with the use of per acetic acid, a kind of acid, and accordingly, Claim 1 would have been easily conceived by combining the above well-known facts with the prior art.[8]

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7) Defendant's Exhibit 11 is an article entitled “Decellularization of tissues and organs” published in www.sciencedirect.com on March 7, 2006.

8) Meanwhile, the Defendant presented similar arguments with the submission of Defendant's Exhibit 12. However, Defendant's Exhibit 12 is an article entitled “Systematic Comparison of Protocols for the Preparation of Human Articular Cartilage for Use as Scaffold Material in Cartilage Tissue Engineering” published in “TISSUE ENGINEERING: Part C, Volume 22, Number 12” on December 14, 2016. The article was

2) However, in an action to revoke the IPTAB decision dismissing an appeal against a final rejection, the commissioner of KIPO is not supposed to raise a new rejection ground to which an opportunity to file a response was not given during an examination or trial proceedings.

3) For the present case, considering statements in Plaintiff's Exhibit 4 and 5 along with the purport of the overall argument, the KIPO examiner issued a Notice of Preliminary Rejection on February 27, 2015, on the grounds that "it is disclosed in the prior art that fish scales are dissolved with HCl for 24 hours and grinded with a mixer. In addition, since the grounded product was derived from fish scales as in the application at issue, it is evident that it comprises a mixture of matrix and powder. Thus, Claim 1 would have been easily conceived by a skilled person in the art from the prior art." In response, the Plaintiff filed a response arguing that "the step of treating HCl in the prior art is for decalcification and the acellularization of the application differs from the decalcification in terms of objective and content." On July 17, 2015, the KIPO examiner issued a Final Rejection on the grounds that "while the acellularization of the application is not directly disclosed in the prior art, it is evident that fish scales are subject to acellularization as well as decalcification through the step of treating fish scales with HCl. In addition, the effects of the application of retaining collagen, elastin, etc. in extracellular matrix through acellularization to provide superior biocompatibility is not different from providing the

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published after the filing date of the application, and further, it cannot be recognized that an opportunity to file a response was given for the same reasons as Defendant's Exhibit 11. Thus, the article cannot be a basis for determination of the reasonableness of the IPTAB decision.

biocompatible collagen sheet through HCl treatment in the prior art." There is no evidence confirming that another Notice of Preliminary Rejection was issued at the IPTAB proceedings.

Under the circumstances, the rejection grounds to which an opportunity to file a response was given by the KIPO examiner stated that "fish scales may be subject to acellularization as well as decalcification through the step of treating fish scales with a high concentration of HCl solution in the prior art." However, Defendant's Exhibit 11 relates to "acellularization" *per se* by a HCl solution, which cannot be regarded as being the same as the HCl treatment in the prior art for the reasons discussed above. Thus, it cannot be considered that the main content of Defendant's Exhibit 11 is consistent with the rejection grounds to which an opportunity to file a response was given by the KIPO examiner or simply supplements the already-raised rejection grounds.

4) Therefore, the above arguments of the Defendant cannot be taken as a basis for determining the reasonableness of the IPTAB decision and thus are not accepted.

E. Summary of Analysis

In sum, inventiveness should not be determined in hindsight based on whether a skilled person in the art would easily derive the invention with the presumption that a skilled person in the art knows the technology described in the specification. It is not recognized that a skilled person in the art could have easily conceived of Claim 1 from the prior art, which substantially differs from the present invention with respect to the technical field, objective, constitution, and

effects. Thus, inventiveness of Claim 1 is not denied by the prior art.

4. Conclusion

The IPTAB erred in its decision. The Plaintiff's petition to revoke the IPTAB decision is well grounded and therefore shall be granted.

Presiding Judge Woosoo KIM
Judge Sanghoon NA
Judge Hosan LEE

PATENT COURT OF KOREA
FIRST DIVISION
DECISION

Case No.: 2016Heo6524 Rejection (Patent)

Plaintiff: The Children's Hospital of Philadelphia
United States of America

Defendant: Commissioner of the Korea Intellectual Property Office (the "KIPO")

Date of Closing Argument: August 31, 2017

Decision Date: October 19, 2017

ORDER

1. The IPTAB Decision 2014Won4744 dated June 30, 2016 shall be revoked.

2. The cost arising from this litigation shall be borne by the Defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Background

A. Claimed Invention at Issue (Plaintiff's Exhibit 2)

1) Title of Invention: COMPOSITIONS AND METHODS FOR MODULATING HEMOSTASIS

2) International Filing Date/ Date of Claimed Priority/ Document Submission Date under Article 203 of the Patent Act/ Application Number: November 15, 2006/ November 15, 2005/ June 13, 2008/ No. 10-2008-70143867

3) Claims (as amended on July 29, 2014; each claim of the claimed invention at issue shall be hereinafter referred to as the "Invention of Claim 1," etc., and the entire invention at issue shall be referred to as the "Subject Invention.")

【Claim 1】 A Factor[1] Xa[2] variant[3] which modulates hemostasis,

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1) Factor: It refers to any intrinsic substance showing physiological effect in physiology and cell biology which is the functional name of enzyme (protein). A **blood coagulation factor** refers to a blood protein group involved in a blood coagulation reaction.

2) An unactivated factor among blood coagulation factors is Romanized as [Ⅹ(10), Ⅺ(11), etc.], and the Roman alphabet suffixed with 'a' (Ⅹa, Ⅺa, etc.) refers to an activated form of each blood coagulation factor respectively. On the other hand, any blood coagulation factor prefixed with 'F' (FX, FXa, etc.) is used to express the same factor as the original blood coagulation factor. Unless the original text is quoted, hereinafter the factor will not be prefixed with 'F' for the purpose of convenience.

3) A variant means a part of amino acid residues forming a blood coagulation factor which has a substitution mutation. The Subject Invention is a

wherein Ile at position 16 in the chymotrypsin numbering system[4] is substituted by Leu, Phe, Asp or Gly.[5]

【Claim 16】 An isolated nucleic acid molecule comprising a nucleic acid sequence that encodes a human Factor X (FX) polypeptide, wherein Ile at position 16 in the chymotrypsin numbering system of said FX polypeptide is substituted by Leu, Phe, Asp or Gly, and said nucleic acid also encodes an intracellular proteolytic cleavage site, and said intracellular proteolytic cleavage site is between positions 15 and 16 in the chymotrypsin numbering system, or replaces an activation peptide.

【Claim 5】, 【Claim 7】, 【Claim 9】 ~ 【Claim 13】, 【Claim 15】, 【Claim 20】 ~ 【Claim 30】 (see Appendix)
【Claim 2】 ~ 【Claim 4】, 【Claim 6】, 【Claim 8】, 【Claim 14】, 【Claim 17】 ~ 【Claim 19】 Deleted.

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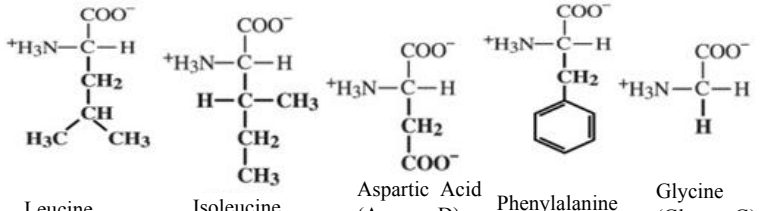
variant of Factor Xa, and the Prior Art is a variant of Factor Ⅹ.

4) Chymotrypsin numbering system: It is common to number amino acid residues in other serine proteases (Xa, etc. of the Subject Invention) based on the method of numbering the sequence of amino acid residues in chymotrypsin which is the representative serine protease (proteolytic enzyme with serine as an active center). Unless otherwise specified, hereinafter the number of an amino acid residue will mean **the number in the chymotrypsin numbering system**.

5) They refer to the names of amino acids having the following structure:



Leucine (Leu or L) | Isoleucine (Ile or I) | Aspartic Acid (Asp or D) | Phenylalanine (Phe or F) | Glycine (Gly or G)

4) Main Content

1. Field of the Invention and Background Art

<0004> The present invention relates to the fields of medicine and hematology. More specifically, the invention provides novel coagulation Factor X/Xa agents and methods of using the same to modulate the coagulation cascade in patients in need thereof.

<0007> The coagulation enzymes circulate in blood as inactive precursors, zymogens,[6] that require proteolytic cleavage for activation. Initiation of coagulation at the site of vascular damage leads to a series of reactions in which a zymogen[7] is converted to a protease through specific proteolytic cleavage and forms the enzyme for the successive reaction. This culminates in blood cell activation and the conversion of soluble fibrinogen to insoluble fibrin and hence the formation of the clot. Thus, proteolytic activation of the coagulation zymogens is a key regulatory feature of the coagulation cascade.

<0008> The conversion of the zymogen to serine protease requires cleavage following Arg^{15} (typically the bond between Arg^{15} and Ile^{16}) which typically removes an activation peptide and exposes a new N-terminus in the catalytic domain beginning with Ile^{16}. One example is the conversion of Factor X to Factor Xa (see Figures 1 and 2). In trypsin and Factor Xa, the new N-terminal sequence begins with Ile^{16}-Val^{17}-Gly^{18}-Gly^{19}. The N-terminal sequence then folds back into the catalytic domain and inserts into the N-terminal binding cleft in a sequence-specific manner which is referred to as “molecular sexuality”

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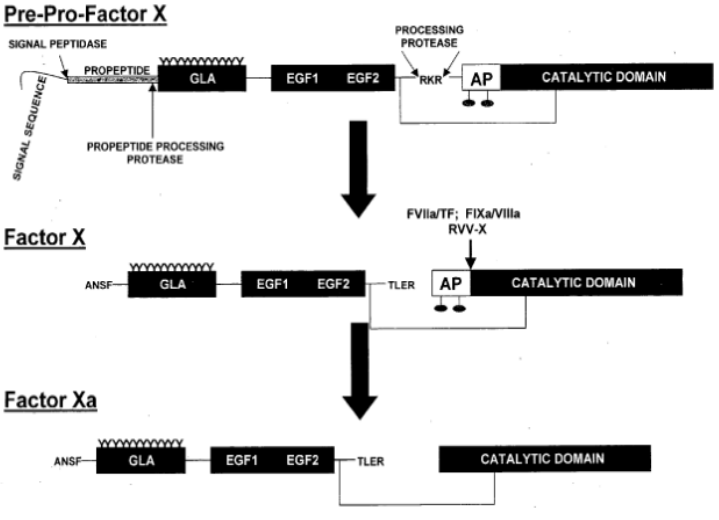
6) Zymogen: It is also called proenzyme. It means a precursor protein which has no catalytic activity and is biosynthesized and activated when reaching a proper site or time. The name of active enzyme is often prefixed with pro- or pre- or suffixed with -gen (prothrombin, trypsinogen, etc.; see Figure 1 of the Subject Invention). In the case of blood coagulation enzyme, precursors perform a kind of modulation and control functions in the respect that they are activated only if necessary.

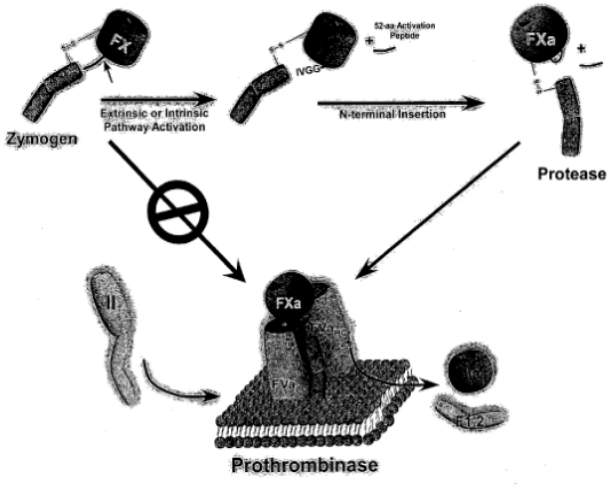
7) Protease: An enzyme that hydrolyzes the bond between protein and peptide and exists in organizations or cells of animals and plants, and micro-organisms.

(See Figure 2). N-terminal insertion leads to the formation of a salt bridge between the α-NH2 group of Ile^{16} and Asp^{194} in the interior of the catalytic domain.

[Figure 1] Processing of Factor X



[Figure 2] Zymogens to Protease Conversion



2. Problem to Be Solved

<0010> Depending on the state of the patient it may be desirable to develop altered coagulation cascade proteins which possess enhanced or reduced coagulation function.
<0012> In accordance with the present invention, compositions and methods are provided for influencing regulatory sites in the FX zymogen -> protease transition pathway thereby driving production of a more "zymogen-like" FXa species. The compositions and methods of the invention are effective to modulate hemostasis in patients in need thereof.

3. Solution to the Problem

<0013> In one embodiment, a variant Factor X/Factor Xa zymogen/ protease which modulates hemostasis is provided. Preferably, the variant zymogen protease is encoded by SEQ ID NO: 2, wherein nucleotides 1684-1695[8] of SEQ ID NO: 2 can be any amino acid with the proviso that nucleotides 1684-1686[9] do not encode Val or Ala.
More preferably, the variant zymogen/protease contains at least one modification in SEQ ID NO: I selected from the group consisting of a) Ile at position 16 is Leu, Phe, Asp or Gly; b) Val at position 17 is Leu, Ala, or Gly; and c) Asp at position 194 is Asn or Glu.
<0051><0052> In one embodiment, the nucleic acids encoding the Factor X zymogen variants may be further modified via insertion of an intracellular proteolytic cleavage site. In another embodiment, the entire 52 amino acid activation peptide can be removed and the intracellular protease cleavage site can be introduced in its place which will result in variant FXa.

4. Effects of Invention

<0064> Variant zymogen/protease nucleic acids encoding polypeptides having altered protease activities may be used according to this invention, for example, as therapeutic and/or prophylactic agents (protein or nucleic acid) which modulate the blood coagulation cascade. The present inventors have discovered that Factor X/Xa zymogen/protease molecules can increase coagulation and provide effective hemostasis.

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8) It refers to position Ile16 in chymotrypsin numbering.

9) It refers to position Ile16-Val17-Gly18-Gly19 in chymotrypsin numbering.

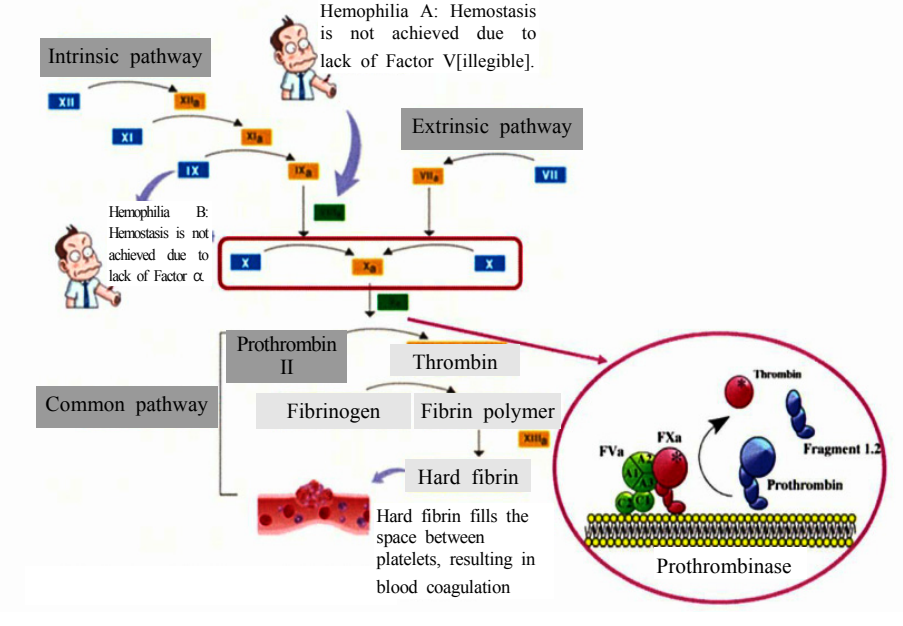
5) Background Art

A) Blood Coagulation Mechanism

The blood coagulation mechanism has been traditionally explained by the waterfall theory consisting of the intrinsic pathway, the extrinsic pathway, and the common pathway.

In the intrinsic pathway, starting with the activation of Factor XII and the action of the activated Factor XIIa, Factors XI, IX and X are activated in sequence as shown in the figure below. In the extrinsic pathway, the binding of Tissue Factor released from damaged tissue to Factor VII activates Factor VII, and then activates Factors IX and X.

Factor Xa forms the prothrombinase complex together with Factor Va and phospholipid in the presence of Ca^{2+}, and the prothrombinase complex activates prothrombin (Factor II) into thrombin (Factor IIa). The thrombin so formed acts on fibrinogen to convert it to fibrin, and Factor XIII acts thereon to form insoluble fibrin, which leads to blood coagulation.



[Source: Defendant's Exhibit 20 and Replacement of Figure 2 of the Subject Invention]

After all, the intrinsic pathway and the extrinsic pathway act to activate Factor X, and the activated form of Factor X is the Factor Xa.

B) Process of Activation of Factor X

Factor X is synthesized in the form of a precursor with a signal sequence and propeptide (pre-pro-Factor X) (see Figure 1 of the Specification of the Subject Invention). The above precursor becomes Factor X through the 'post-translational modification' process, and the 'post-translational modification' process includes carboxylation of Gla (gamma-carboxyglutamic) domain (see the Prior Art below), and cleavage of the signal sequence and propeptide (see Figure 1 of the Specification of the Subject Invention).

When cleavage between residues 15 and 16 (Arg15-Ile16) by the intrinsic tenase enzyme complex and the extrinsic tenase enzyme complex occurs, removing the activation peptide (AP), Factor X is activated into Factor Xa with the new N-terminal sequence beginning with Ile16-Val17-Gly18-Gly19 (see Figures 1 and 2 of the Specification of the Subject Invention).

In the Subject Invention, such unactivated Factor X corresponds to zymogen, and activated Factor Xa corresponds to protease.

B. Prior Art (Defendant's Exhibit 4)

The paper titled "Vitamin K epoxide reductase significantly improves carboxylation in a cell" released in Blood, Vol. 106, No. 12, pp. 3811-3815, on August 4, 2005. Major content thereof are as follows:

1. Abstract

Previously we reported that we could increase the fraction of carboxylated factor X by reducing the affinity of the propeptide for its binding site on human gamma glutamyl carboxylase (GGCX). We attributed this to an increased turnover rate. However, even with the reduced affinity propeptide, when sufficient overproduction of factor X is achieved, there is still a significant fraction of uncarboxylated recombinant factor X.

We report here that the factor X of such a cell line was only 52% carboxylated but that the fraction of carboxylated factor X could be increased to 92% by coexpressing the recently identified gene for **vitamin K epoxide reductase (VKOR)**. (p. 3811).

2. Introduction

Posttranslational modification of glutamic acid (Glu) to gamma carboxyl glutamic acid (Gla) is required for the activity of a few proteins, most of which are related to coagulation. These modified proteins are often called vitamin K−dependent proteins because they require reduced vitamin K for their Gla modification. The enzyme that catalyzes the modification of glutamate (Glu) to Gla is the gamma-glutamyl carboxylase (GGCX) (the left column on p. 3811).

In this study, using this HEK 293 cell line overproducing FX, we demonstrate that the percentage of carboxylated material can be dramatically increased, from approximately 50% to approximately 95%, by coexpression of the **VKOR** (the right column on p. 3811).

3. Method

< Construction of expression vectors > All constructs were made in a cell line, HEK293-FX (A6), expressing human FX with 1 mutation, Ile16Leu, and the prothrombin propeptide. We selected the FX-expressing cells with the neomycin analog G418. This particular cell line expresses FX at such high levels (7-9 μg/106 cells/24 hours) that only about 50% of the protein is carboxylated even though the FX propeptide was replaced by that of prothrombin. (the left column on p. 3812).

3. Discussion

The results presented here indicate that coexpressing **VKOR** and FX dramatically improved the extent of carboxylation in cell culture. The simplest explanation for the dramatic increase in carboxylation observed in our experiments is that VKOR is responsible for both the conversion of vitamin K epoxide to vitamin K and vitamin K to vitamin K hydroquinone (the left column on p. 3814).

In addition to the mechanistic implications of this research, there are also practical implications. At present substantial needs exist for (1) recombinant human FIX to treat hemophilia B patients; (2) FVIIa for treating patients with autoantibodies (inhibitors) to either FIX or FVIII and for bleeding that results from general trauma; and (3) activated protein C, for the treatment of sepsis. To date, these vitamin K–dependent proteins are produced in cell cultures with CHO, BHK, and human embryo kidney cells (HEK 293). A common problem for all these cell lines is that, if significant overproduction is achieved, a significant fraction of the recombinant protein produced is undercarboxylated and therefore inactivated. Including **VKOR** or 'both **VKOR** and GGCX' in the cell lines expressing these important enzymes should greatly increase the yield of active enzyme (the right column on p. 3814).

C. The Decision Below

1) On April 28, 2014, the KIPO examiner decided to reject the Subject Invention on the grounds that "Claims 1 to 30 as amended on December 19, 2013 fail to satisfy the requirements under Article 45[10] of the Patent Act."

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10) Article 45 (Scope of Single Patent Application)
(1) A patent application shall be filed for each invention: Provided, that a patent application may be filed for a group of inventions linked so as to form a single general inventive concept.
(2) The requirements for filing a patent application for a group of inventions under the proviso to paragraph (1) shall be prescribed by Presidential Decree.

2) On July 29, 2014, the Plaintiff filed a petition to revoke the above rejection with the IPTAB (Case No. 2014Won4744), submitting an amendment to the specification, etc. to amend Claims as stated in Paragraph A.3) above. Upon the submission of the amendment, the reexamination procedure before the administrative trial was initiated.

3) On July 24, 2015, the KIPO examiner decided to uphold the above rejection on the grounds that "the Invention in Claims 1, 5, 7, 9, 11 to 13, 15, 16, and 20 to 30 is easily conceived by a person with ordinary knowledge in the technical field of the invention (a "skilled person in the art") from the Prior Art and thus lacks an inventive step, and therefore is not patentable under Article 29(2) of the Patent Act."

4) On June 30, 2016, the IPTAB rendered its decision dismissing the Plaintiff's petition on the following grounds: "Since the Invention in Claim 1 is not deemed to involve any difficulty in construction compared to the Prior Art and effects thereof can be predicted, it can be easily conceived by a skilled person in the art from the Prior Art, and thus is not patentable. In a claimed invention with several claims, if there is a reason for rejecting one of the claims, the claimed invention should be rejected in whole."

[Factual Basis] Undisputed facts, statements in Plaintiff's Exhibits 1 to 5, Defendant's Exhibits 1 to 5 and 20, testimony of Witness Cheol-Woo Yu, and the purport of the overall argument

2. The Parties' Arguments

A. The Plaintiff's Arguments

The IPTAB decision shall be revoked since it is unlawful for the following reasons:

1) Given the fact that it is difficult for a skilled person in the art to learn from the Prior Art how the Ile16Leu variant existing in Factor X[11] (such a variant of the Prior Art will be hereinafter referred to as the "**Prior Art Variant**") affects not only carboxylation of Factor X, but also activation into Factor Xa, even if the method of activating Factor X into Factor Xa was widely known, it is difficult to expect a skilled person in the art to produce the Factor Xa variant of the Invention in Claim 1 by activating the Prior Art Variant. In addition, it is difficult to expect from the Prior Art the effect of the Invention in Claim 1, i.e., restoring coagulation speed only in the plasma environment, with a long plasma half-life exceeding two hours.[12] Accordingly, it does not appear that a skilled person in the art can easily conceive the Invention in Claim 1 from the Prior Art.

2) The expression[13] of the nucleic acid molecule of the Invention

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11) As discussed in Paragraph 1 above, it is described as "FX" in the original text.

12) In physiology, plasma means blood plasma remaining after centrifugally removing a blood corpuscle from blood. Thus, the plasma environment appears to mean the environment in which it is injected into a patent as a therapeutic agent.

13) Expression: The process by which various proteins making up an organism are formed by genetic information forming DNA, i.e., a gene.

in Claim 16 in a cell is followed by cleavage of the cleavage site by a protease existing in the cell. Once such cleavage occurs, a Factor Xa variant having the same variation as the Invention in Claim 1 is formed. As discussed in Paragraph 1) above, the Invention in Claim 1 cannot be easily conceived by a skilled person in the art from the Prior Art. Furthermore, a skilled person in the art cannot easily derive the insertion of the above cleavage site from the Prior Art. Therefore, it does not appear that a skilled person in the art can easily conceive the Invention in Claim 16 from the Prior Art.

3) As the Invention in Claims 5, 7, 9, 11 to 13, 15, and 20 to 30 are the invention in dependent claims of Claims 1 and 16, their inventive step is not denied by the Prior Art.

B. The Defendant's Arguments

For the following reasons, a skilled person in the art can easily conceive the Invention in Claims 1 and 16 from Prior Art 1, and thus, the IPTAB decision shall be upheld.

1) Invention in Claim 1

A) In the light of the fact that only after Factor X is converted into Factor Xa in the blood coagulation process, it functions as a factor that modulates hemostasis; the fact that it is common technical knowledge that in order to reduce the influence of many factors in the blood coagulation mechanism, it is advisable to inject activated Factor Xa rather than Factor X; and the fact that for the purpose of treating hemophilia (Factors VIII and IX deficiency), activated Factor Xa should be injected as a

matter of course, a skilled person in the art is motivated to produce the Prior Art Variant as the variant of the Invention in Claim 1.

B) The method of activating the Prior Art Variant into the Factor Xa variant and obtaining it is well-known and commonly used art (Defendant's Exhibits 6 to 8).

C) The effects of the Invention in Claim 1 are nothing but the effects inherent in the Prior Art Variant or predictable from the Prior Art.

2) Invention in Claim 16

A) As the insertion of the intracellular proteolytic site (amino acid sequence) to express Factor Xa directly in a cell is well-known and commonly used art, it is nothing but a change in design.

B) The effects of the Invention in Claim 16 are the effects predictable from the Prior Art.

3. Whether or not the IPTAB Erred

A. Whether the Inventiveness of the Invention in Claim 1 Is Denied

1) Comparison between the Invention in Claim 1 and the Prior Art

The comparison between the Invention in Claim 1 and the Prior Art is as set out in the table below.

Invention in Claim 1	Prior Art (Defendant's Exhibit 4)
A Factor **Xa** variant which modulates hemostasis, wherein Ile at position 16 in the chymotrypsin numbering system is substituted by Leu, Phe, Asp or Gly.	- Human **FX** variant which modulates hemostasis - Expressing human FX with 1 mutation, Ile16Leu, and the prothrombin propeptide

2) Commonalities and Differences Between the Subject Invention and the Prior Art

As shown in the comparison table in Paragraph 1) above, the two inventions are identical in the respect that they are related to the human blood coagulation Factor variant which modulates hemostasis, and that amino acid residues at position 16 are substituted from Ilu (Isoleucine) to Leu (Leucine) in terms of the location and specific content of variation.

However, the above substitution of amino acids is made in Factor X in the Prior Art, whereas in the Invention in Claim 1, the substitution is made in Factor Xa, the activated form of Factor X.

3) Technical Problem to Be Solved by the Invention in Claim 1 and Solution to the Technical Problem and Effects thereof

A) Technical Problem to Be Solved by the Invention in Claim 1

The technical problem to be solved by the Invention in Claim 1 is to provide effective compositions and methods for modulating hemostasis, i.e., driving production of more "zymogen-like" FXa species by influencing the hemostatic modulation sites in the transition pathway from Factor X to Factor Xa (Plaintiff's Exhibit 2, Paragraph <0012>).

B) Solution to the Technical Problem of the Invention in Claim 1

The Invention in Claim 1 solves the above technical problem by providing the Factor Xa variant, wherein Ile at position 16 in Factor Xa is substituted by Leu, Phe, Asp or Gly (the variant so substituted will be hereinafter referred to as "**Each Variant**") (Plaintiff's Exhibit 2, Paragraphs <0012>, <0013>, etc.).

C) Effects of the Invention in Claim 1

While FXa^{I16L}[14] among each of the variants at issue has an impaired ability to bind to the specific probe[15](active site probe) of Factor Xa, the assembly of such variant into prothrombinase certainly improves the affinity for the specific probe (active site probe), thereby restoring normal coagulation speed in the plasma environment, having a far longer plasma half-life 'exceeding two hours' than the half-life of wild-type Factor Xa which is 'less than two minutes' (Plaintiff's Exhibit 2, Paragraphs <0121-0130>, Tables 2 to 5, Figures 6 to 8, etc.).

4) Whether the Subject Invention Can Be Easily Conceived

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14) It is the variant, wherein Ile at position 16 is substituted by Leu. It is also referred to as "FXaI16L."

15) Probe: It collectively refers to substances used to specifically detect a specific substance, site, state, etc. The specification of the Subject Invention states as follows: "The term "probe" as used herein refers to an oligonucleotide, polynucleotide or nucleic acid, either RNA or DNA, whether occurring naturally as in a purified restriction enzyme digest or produced synthetically, which is capable of annealing with or specifically hybridizing to a nucleic acid with sequencvs complementary to the probe. A probe may be either single-stranded or double-stranded. The exact length of the probe will depend upon many factors, including temperature, source of probe and method of use." (see Plaintiff's Exhibit 2, Paragraph <0041>).

A) Disclosure, Suggestion, Motivation, etc. in the Prior Art

(1) The Prior Art solves the problem that there is a significant fraction of uncarboxylated recombinant Factor X in a cell line expressing Factor X at a high level and increases the yield of active enzyme,[16] by coexpressing VKOR (vitamin K epoxide reductase) and GGCX (γ-glutamyl carboxylase) in the HEK (human embryo kidney) 293-FX(A6) cell line, with 1 mutation of, Ile16Leu[17] and prothrombin propeptide.[18] Meanwhile, with respect to the purpose and effect of use of the Prior Art Variant, the Prior Art only says, "expresses FX at such high levels," as set out below, and no statement showing that its purpose or intent is to increase activation of Factor Xa is found. Also in the light of common technical knowledge, it is difficult to infer the above purpose or intent. Given the fact that the Prior Art did not verify activation after producing the Factor Xa variant by activating the Prior Art Variant as set forth in the specification of the Subject Invention, it becomes clearer that there was no such purpose or intent.

- Therefore these cells provide the best system to evaluate whether GGCX, VKOR, or VKOR plus GGCX can enhance carboxylation in vivo (Defendant's Exhibit 4, the right column on p. 3811).
- All constructs were made in a cell line, HEK293-FX (A6), expressing human FX with 1 mutation, Ile16Leu, and the prothrombin propeptide.

16) Witness Cheol-Woo Yu also testified to the effect that the Prior Art is intended to increase the productivity of γ-carboxylated Factor Ⅹ.

17) It means Ile at position 16 substituted by Leu.

18) The Prior Art states, "Previously we reported that we could increase the fraction of carboxylated FX by reducing the affinity of the propeptide for its binding site on human gamma glutamyl carboxylase (GGCX)." (Abstract at the top of page 3811). Such intent is also stated in Defendant's Exhibit 6 which is Reference 14 of the Prior Art (see Defendant's Exhibit 6, Abstract at the top of page 14322).

> We selected the FX-expressing cells with the neomycin analog G418. This particular cell line expresses FX at such high levels (7-9 μg/106 cells/24 hours) that only about 50% of the protein is carboxylated even though the FX propeptide was replaced by that of prothrombin. (Defendant's Exhibit 4, the left column on p. 3812).

(2) Moreover, any statement or suggestion showing that the use of the Prior Art Variant will contribute to an increase in carboxylation is not found in the Prior Art, and in the light of common technical knowledge, it is difficult to infer such function or action. In addition, an increase in carboxylation is merely one of the 'post-translational modification' processes which precede 'the stage in which Factor X is activated into Factor Xa' and 'the stage in which Factor Xa shows activity as a blood coagulation Factor.' Further, there is no specific statement or suggestion as to how the above increase in carboxylation can affect an increase in activity in 'the stage in which Factor Xa shows activity as a blood coagulation Factor,' and it is difficult to infer the same in the light of common technical knowledge.

(3) In addition, the Prior Art does not provide a special motive to produce the Factor Xa variant by activating the Prior Art Variant.

(4) After all, it does not appear that the technical idea that Each Variant which is the Factor Xa variant has a long plasma half-life as a blood coagulation Factor is disclosed or suggested in the Prior Art, or that any motive to adopt the above technical idea is presented therein.

B) Applicability of Activation Technology[19)]

(1) Unless verification through a specific experiment is made, a skilled person in the art cannot easily predict what activity the Prior Art Variant will show in the plasma environment if the Prior Art Variant is activated into the form of variant as in the Subject Invention.

(2) In addition, it is difficult to predict whether the activation process of the Prior Art Variant will involve an ordinary change as set forth in the specification below (Plaintiff's Exhibit 2). Further, it is more difficult to predict what activity the activated form will show as a blood coagulation factor. Witness Cheol-Woo Yu also purportedly testified as follows: "In order for Factor X to be formed as protein with complete activity, the Ile site at position 16 need to bind to the amino acid at position 194, but it is common knowledge in the art that the bond rarely happens due to the variation at position 16 and thus activation will rarely occur."

<0008> The conversion of the zymogen to serine protease requires cleavage following Arg15 (typically the bond between Arg15 and Ile16) which typically removes an activation peptide and exposes a new N-terminus in the catalytic domain beginning with Ile16. One example is the conversion of Factor X to Factor Xa (see Figures 1 and 2). In trypsin and Factor Xa, the new N-terminal sequence begins with Ile16-Val17-Gly18-Gly19. For other clotting enzymes, the new N-terminal sequence is a variation on the same theme.

The N-terminal sequence then folds back into the catalytic domain and inserts into the N-terminal binding cleft in a sequence-specific manner which is referred to as "molecular sexuality" (See Figure 2). Accordingly, variants with alternate N-terminal sequences are not likely to undergo molecular sexuality in a comparable way.

N-terminal insertion leads to the formation of a salt bridge between the α

19) See the Defendant's Arguments in paragraph 2.B. above.

-NH2 group of Ile16 and Asp194 in the interior of the catalytic domain. Salt bridge formation is associated with numerous changes in catalytic domain structure including: rearrangements of the so-called activation domains, shown in Figure 3; formation of the oxyanion hole required for catalysis and the formation of a substxate binding site.
These changes lead to the maturation of the active serine protease

(3) Also in the Invention in Claim 1, through several stages of experiment, the following effects are verified: "While FXa^{I16L} among each of the variants at issue has an impaired ability to bind to the specific probe (active site probe) of Factor Xa, the assembly of such variant into prothrombinase certainly improves the affinity for the specific probe (active site probe), thereby restoring normal coagulation speed in the plasma environment, and having a longer plasma half-life 'exceeding two hours' than the half-life of wild-type Factor Xa which is 'less than two minutes.'"

(4) The technology of activating Factor X into Factor Xa by using RVV-X[20] or tissue Factor-FVIIa is well-known and commonly used art in the technical field at issue as of the Priority Date of the Subject Invention, and also in the Subject Invention, each Variant was produced by applying the above well-known and commonly used art after forming the Factor X variant. However, as discussed above, as of the Priority Date of the Subject Invention, unless verification through a specific experiment is made, it is difficult for a skilled person in the art to predict whether the activation of the Prior Art Variant will involve an ordinary change of Factor X, and it is more difficult for a skilled person in the art to predict what activity the activated form will show as a blood coagulation factor. In addition, it does not appear that

20) It is the abbreviation for Russell's Viper Venom.

the technical idea that if the Prior Art Variant is activated, it has a long plasma half-life as a blood coagulation factor is disclosed or suggested in the Prior Art, or that any motive to adopt the above technical idea is presented therein. Accordingly, in the present case, it does not appear that there were reasonable expectations of success beyond the simple possibility of implementing the invention or the simple hope for success. Thus, the argument that a skilled person in the art can produce Each Variant by applying the above well-known and commonly used art to the Prior Art and easily verify the effects thereof because the technology of activating Factor X into Factor Xa is well-known and commonly used art[21] cannot be accepted since it is a determination made ex post facto, assuming that technical significance and effects of the Invention in Claim 1 are already known.

C) Predictability of Effects

The effects of the Invention in Claim 1 cannot be predicted from the Prior Art. The same applies even if statements in Plaintiff's Exhibit 5 and Defendant's Exhibit 21 are taken into account. Witness Cheol-Woo Yu also purportedly testified that "it was difficult to consider using Each Variant as an activated factor for therapy."

D) Summary of Analysis

In the end, it does not appear that a skilled person in the art can easily conceive the Invention in Claim 1 from the Prior Art, unless a determination is made ex post facto, assuming that the content disclosed in the specification of the Subject Invention is already known.

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21) See the Defendant's Arguments in paragraph 2.B. above.

5) Summary of Discussion: Whether the Inventive Step Is Denied

Accordingly, the inventive step of the Invention in Claim 1 is not denied by the Prior Art.

B. Whether the Inventiveness of the Invention in Claims 5, 7 and 9 Is Denied

As the Invention in Claims 5, 7 and 9 is the invention in dependent claims that limit or additionally specify the Invention in Claim 1, so far as the inventive step of the Invention in Claim 1 is not denied by the Prior Art as discussed in Paragraph A above, the inventive step of the Invention in Claims 5, 7 and 9 is also not denied.

C. Whether the Inventiveness of the Invention in Claim 10 Is Denied

As the Invention in Claim 10 comprises the composition of "the Factor Xa variant, wherein Ile at position 235 of sequence number 1 (at position 16 in the chymotrypsin numbering system) is replaced by Leu," and the above composition is also included in the Invention in Claim 1, so far as the inventive step of the Invention in Claim 1 is not denied by the Prior Art as discussed in paragraph A above, the inventive step of the Invention in Claim 10 is also not denied.

D. Whether the Inventiveness of the Invention in Claims 11 to 13 and 15 Is Denied

As the Subject Invention in Claims 11 to 13 and 15 is the invention in dependent claims that limit or additionally specify the Subject Invention in Claims 1, 5, 7, 9, and 10, or includes technical features of the Subject Invention in such Claims, so far as the inventive step of

the Subject Invention in Claims 1, 5, 7, 9, and 10 is not denied by the Prior Art as discussed in paragraphs A to C above, the inventive step of the Invention in Claims 11 to 13 and 15 is also not denied.

E. Whether the Inventiveness of the Invention in Claim 16 Is Denied

1) Composition of the Invention in Claim 16

The Invention in Claim 16 consists of an isolated nucleic acid molecule comprising a nucleic acid sequence that encodes a human Factor X (FX) polypeptide, wherein Ile at position 16 of said FX polypeptide is substituted by Leu, Phe, Asp or Gly ("Element 1"), and said nucleic acid also encodes an intracellular proteolytic cleavage site, and said intracellular proteolytic cleavage site is between positions 15 and 16, or replaces an activation peptide ("Element 2").

2) Technical Significance and Effects of the Invention in Claim 16

Given the statements in the specification below (Plaintiff's Exhibit 2), as the nucleic acid molecule of the Invention in Claim 16 includes "the sequence that encodes an intracellular proteolytic cleavage site", cleavage occurs by intracellular proteolytic enzyme (protease) in the process of being expressed into protein in a cell, ultimately resulting in the formation of the variant (Each Variant) of the Invention in Claim 1.

> <0051> In one embodiment, the nucleic acids encoding the Factor X zymogen variants may be further modified via insertion of an intracellular proteolytic cleavage site. In order to express "activated" zymogen-like FXa variants in mammalian cells, an intracellular proteolytic cleavage site can be inserted between positions Arg15 and 16 in the variant FX zymogen. Such cleavage sites include: Arg-Lys-Arg or Arg-Lys-Arg-Arg-

> Lys-Arg. These cleavage sites are efficiently recognized by proteases (PACE/furin-like enzymes) within the cell and are removed. This results in a processed variant FX(a) in which the heavy chain on the molecule now begins at position 16. Introduction of this cleavage site at said position will allow for the intracellular conversion of FX to FXa.
>
> <0052> In another embodiment, the entire 52 amino acid activation peptide can be removed and the intracellular protease cleavage site can be introduced in its place which will result in variant FXa.
>
> <0053> Ultimately these types of modifications allow for secretion of the "active" processed form of variant FX from a ceIl that expresses the modified variant FX. Secretion of the cleaved factor obviates a need for proteolytic cleavage during blood clotting or following the isolation of the protein.

3) Whether the Inventiveness Is Denied

First of all, it does not appear that the technical problem relating to Element 2 is disclosed or inherent in the Prior Art, and thus, we cannot conclude that a skilled person in the art can easily infer Element 2 from the Prior Art (the Defendant's argument that since the insertion of the intracellular proteolytic amino acid to express Factor Xa in a cell is well-known and commonly used art, it is nothing but a change in design cannot be accepted in this revocation action against the IPTAB decision, since the argument is as if presenting a new prior art containing the technical feature not included in the Prior Art rather than simply clarifying the technical significance of the Prior Art, supplementing the Prior Art, or supplementarily using it in the process of easy derivation).

Next, as discussed in Paragraph A above, a skilled person in the art cannot easily conceive the Invention in Claim 1 from the Prior Art.

Accordingly, the inventive step of the Invention in Claim 16 which

contains “the sequence that encodes an intracellular proteolytic cleavage site,” while having the technical features of the Invention in Claim 1, is not denied by the Prior Art.

F. Whether the Inventiveness of the Invention in Claims 20 to 30 Is Denied

As the Invention in Claims 20 to 30 is the invention in dependent claims that limit or additionally specify the Invention in Claim 16 or includes the technical features of the Invention in such Claim, so far as the Inventiveness of the Invention in Claim 16 is not denied by the Prior Art as discussed in Paragraph E above, the Inventiveness of the Invention in Claims 20 to 30 is also not denied.

G. The IPTAB Erred in Its Decision

Accordingly, the IPTAB decision is not consistent with the above analysis, and thus the IPTAB erred in its decision.

4. Conclusion

Therefore, the Plaintiff’s petition to revoke the IPTAB decision is well grounded and thus shall be granted as declared in the Order.

Presiding Judge Hwansoo KIM
Judge Jootag YOON
Judge Hyunjin CHANG

Claims of the Subject Invention

Claim 1. A Factor Xa variant which modulates hemostasis, wherein Ile at position 16 in the chymotrypsin numbering system is substituted by Leu, Phe, Asp or Gly.

Claim 2~4. (Deleted)

Claim 5. The Factor Xa variant in claim 1, wherein the sequence at positions 16-18 is selected from the group consisting of Leu-Val-Gly, Gly-Val-Gly, and Phe-Val-Gly.

Claim 6. (Deleted)

Claim 7. The Factor Xa variant in claim 1, wherein Ile at position 16 is substituted by Leu.

Claim 8. (Deleted)

Claim 9. The Factor Xa variant in claim 1, wherein said Factor Xa contains amino acids 41-179 and amino acids 235-488 of sequence number 1, and Ile at position 235 of sequence number 1 (at position 16 in the chymotrypsin numbering system) is Leu.

Claim 10. The Factor Xa variant consisting of amino acids 41-179 and amino acids 235-488 of sequence number 1, wherein Ile at position 235 of sequence number 1 (at position 16 in the chymotrypsin numbering system) is replaced by Leu.

Claim 11. The Factor Xa variant in claims 1, 5, 7, 9 or 10, wherein said Factor Xa variant exhibits lower substrate binding affinity for the active site than wild-type Factor Xa, which is improved when said Factor Xa variant is bound by Factor Va in the prothrombinase complex.

Claim 12. The Factor Xa variant in claims 1, 5, 7, 9 or 10, wherein said Factor Xa variant has a longer plasma half-life than wild-type Factor Xa.

Claim 13. A pharmaceutical composition for treatment of a hemostasis related disorder for which coagulation is required, comprising the Factor Xa variant of claims 1, 5, 7, 9 or 10 in a biologically compatible carrier, wherein said disorder is selected from the group consisting of hemophilia A and B, hemophilia A and B associated with inhibitory antibodies, coagulation factor deficiency, vitamin K epoxide reductase Cl deficiency, gamma- carboxylase deficiency, bleeding associated with trauma, injury, thrombosis, thrombocytopenia, stroke, coagulopathy, disseminated intravascular coagulation (DIC); over-anticoagulation treatment disorders, Bernard Soulier syndrome, Glanzman thromblastemia, and storage pool deficiency.

Claim 14. (Deleted)

Claim 15. A nucleic acid molecule encoding the Factor Xa variant of claims 1, 5, 7, 9 or 10, and comprising the nucleic acid sequence which encodes the intracellular proteolytic cleavage site, wherein said intracellular proteolytic cleavage site is between positions 15 and 16 in the chymotrypsin numbering system, or replaces an activation peptide.

Claim 16. An isolated nucleic acid molecule comprising a nucleic acid sequence that encodes a human Factor X(FX) polypeptide, wherein Ile at position 16 in the chymotrypsin numbering system of said FX polypeptide is substituted by Leu, Phe, Asp or Gly, and said nucleic acid also encodes an intracellular proteolytic cleavage site, and said

intracellular proteolytic cleavage site is between positions 15 and 16 in the chymotrypsin numbering system, or replaces an activation peptide.

Claim 17~19. (Deleted)

Claim 20. The nucleic acid molecule in claim 16, wherein Ile at position 16 is substituted by Leu.

Claim 21. The nucleic acid molecule in claim 16, wherein said FX polypeptide comprises a propeptide sequence.

Claim 22. The nucleic acid molecule in claim 16, wherein said activation peptide is replaced by the intracellular protease cleavage site.

Claim 23. The nucleic acid molecule in claim 16, wherein said intracellular proteolytic cleavage site is a PACE/furin cleavage site.

Claim 24. Any expression vector comprising the nucleic acid molecule in claim 16 or any of claims 20 to 23, operably linked to regulatory sequences.

Claim 25. The expression vector in claim 24, selected from the group consisting of an adenoviral vector, an adenovirus-associated vector, a retroviral vector, a plasmid, and a lentiviral vector.

Claim 26. A host cell comprising the nucleic acid molecule in claim 16 or any of claims 20 to 23, operably linked to regulatory sequences.

Claim 27. The host cell in claim 26, wherein said host cell is a CHO cell.

Claim 28. A method for producing FXa including culturing the host cell in claim 26, and purifying activated Factor X (FXa)

generated therefrom.

Claim 29. FXa produced by using the method in claim 28.

Claim 30. Activated Factor X(FXa) obtained by proteolytic cleavage of Factor X polypeptide encoded by the nucleic acid sequence of the nucleic acid molecule in claim 16 or any of claims 20 to 23.

Claims 31~33. (Deleted)

PATENT COURT OF KOREA
FOURTH DIVISION
DECISION

Case No.: 2016Heo9196 Invalidation of Registration (Trademark)

Plaintiff: ITALFARMACO S.P.A.
Italy

Defendant: DAEWOONG BIO CO., LTD.

Date of Closing Argument: July 14, 2017

Decision Date: August 18, 2017

ORDER

1. The IPTAB decision 2015Dang5584 dated November 10, 2016 shall be revoked.

2. The cost arising from this litigation shall be borne by the Defendant.

PLAINTIFF'S DEMAND

As ordered.

OPINION

1. Background

A. Defendant's Registered Mark at Issue (Plaintiff's Exhibit 2) (hereinafter "Subject Mark")

1) Filing Date of Application/ Date of Registration/ Registration Number: August 27, 2014/ August 28, 2015/ No. 1126451

2) Mark at Issue: **GLIATAMIN**

3) Designated Goods: Drugs, pharmaceutical agents affecting sensory organs, pharmaceutical agents affecting peripheral nervous system, vaccines, anti-inflammatory preparations, pharmaceutical agents affecting digestive organs, cardiovascular pharmaceutical preparations, capsules for medicines, ointments for pharmaceutical purposes, lozenges for pharmaceutical purposes, adjuvants for medical purposes, drugs for medical purposes, chemical preparations for medical purposes, diagnostic reagents for medicinal use, medicines for human purposes, preparations for treatment of senile hypomnesia, preparations for treatment of traumatic degenerative cerebellar syndrome, preparations for treatment of primary degenerative cerebellar syndrome, preparations for treatment of vascular degenerative cerebellar syndrome, and antidepressants in Class five (5) under classification of goods.

B. Plaintiff's Prior-registered Marks

1) Prior-registered Mark 1 (Plaintiff's Exhibit 3)

A) Filing Date of Application/ Date of Registration/ Registration

Date of Extension/ Registration Number
: June 9, 1993/ August 29, 1994/ June 23, 2014/ No. 297150

B) Mark at Issue: GLIATILIN 글리아티린

C) Designated Goods: Drugs, preparations for treatment of primary degenerative cerebellar syndrome, preparations for treatment of vascular degenerative cerebellar syndrome, preparations for treatment of traumatic degenerative cerebellar syndrome, preparations for treatment of senile hypomnesia, preparations for treatment of degenerative hyperlipemia, drugs for animals, medical plasters, adhesive plasters, mouth washes, disinfectants for hygiene purposes, fumigation preparations for medical purposes, disinfectants for chemical toilets, vermin destroying preparations, herbicides, and fungicides in Class five (5) under classification of goods.

2) Prior-registered Mark 2 (Plaintiff's Exhibit 4)

A) Filing Date of Application/ Date of Registration/ Registration Date of Extension/ Registration Number
: November 7, 1985/ October 13, 1986/ July 1, 2016/ No. 132064

B) Mark at Issue: GLIATILIN

C) Designated Goods: Drugs, preparations for treatment of degenerative hyperlipemia, preparations for treatment of senile hypomnesia, preparations for treatment of traumatic degenerative cerebellar syndrome, preparations for treatment

of vascular degenerative cerebellar syndrome, preparations for treatment of primary degenerative cerebellar syndrome in Class five (5) under classification of goods.

C. The Decision Below (Plaintiff's Exhibit 1)

1) The Plaintiff filed a petition seeking invalidation of the Subject Mark "**GLIATAMIN**" before the Intellectual Property Trial and Appeal Board (hereinafter "**IPTAB**") on December 11, 2015 against the Defendant, the owner of the Subject Mark, and asserted that: "The Subject Mark is similar to the Plaintiff's Prior-Registered Mark 1 "GLIATILIN 글리아티린" and Prior-registered Mark 2 "**GLIATILIN**" in terms of the mark and designated goods and, therefore, Article 7(1)7 of the old Trademark Act (referring to the Trademark Act before amended by Act No. 14033 on February 29, 2016; hereinafter "the old Trademark Act") is applicable. In addition, as a subsidiary of Daewoong Pharmaceuticals Co., Ltd. (hereinafter "Daewoong Pharmaceuticals"), the Defendant was in the position of being able to know the agreement and business relationship between the Plaintiff and Daewoong Pharmaceuticals, yet, despite having the knowledge that the Plaintiff used or was in preparation of using the Prior-registered Marks, the Defendant filed for and registered the Subject Mark which is the same or similar to the Prior-registered Marks for the same or similar goods, thereby making the Subject Mark to fall under Article 7(1)18 of the old Trademark Act. Accordingly, there exist grounds for invalidation of the Subject Mark under Article 7(1)7 or

Article 7(1)18 of the old Trademark Act, and the registration of the Subject Mark should be invalidated."

2) The IPTAB reviewed the above petition under Case No. 2015Dang5584 and, on November 10, 2016, issued a decision to revoke the Plaintiff's petition on the following grounds: "The appearance, sound, and meaning of the Subject Mark "GLIATAMIN" are different from those of the Prior-registered Mark 1 "글리아티린" and Prior-registered Mark 2 "GLIATILIN," and therefore, the Subject Mark is not similar to the Prior-registered Marks as a whole and may avoid the confusion of the source, thus, there is no ground for invalidation under Articles 7(1)7 and 7(1)18 of the old Trademark Act."

2. Summary of the Parties' Arguments and Issues

A. The Plaintiff's Argument

The IPTAB's decision is unlawful because, for the following reasons, the registration of the Subject Mark should have been invalidated in every respect, but the IPTAB's decision found otherwise.[1)]

1) Meanwhile, in this litigation, the Plaintiff initially argued that the Subject Mark is likely to cause confusion with the Prior-registered Marks which were widely known for a certain person's trademarks by domestic consumers and thus may deceive such consumers, and therefore, the Subject Mark falls under Article 7(1)11 of the old Trademark Act, but this argument was withdrawn on the second hearing of July 14, 2017.

1) The mark and designated goods of the Defendant's Subject Mark are the same or similar to those of the Plaintiff's Prior-registered Marks and thus it falls under Article 7(1)7 of the old Trademark Act.

2) Despite having the knowledge—through business transactions, etc.—that the Prior-registered Marks was in use by the Plaintiff as of the filing date of the Subject Mark, the Defendant nevertheless proceeded with the registration for the same or similar mark to the Prior-registered Marks, designating the same or similar goods, therefore, the Subject Mark falls under Article 7(1)18 of the old Trademark Act.

3) The Subject Mark is likely to cause confusion with other person's product or business which, in relation to the Prior-registered Marks, is conspicuously known by consumers as belonging to such other person, and thus falls under Article 7(1)10 of the old Trademark Act.

B. The Defendant's Argument

For the following reasons, the Subject Mark may not be deemed to fall under Articles 7(1)7, 7(1)18, and 7(1)10 of the old Trademark Act, and thus the IPTAB decision is consistent with this analysis and shall be upheld.[2)]

2) On the first hearing of March 3, 2017, the Defendant stated that, with regard to Article 7(1)7 and 7(1)18 of the old Trademark Act, it would not contest the fact that the Defendant knew, on or around the filing date of application for the Subject Mark, through business transactions, etc., that the Plaintiff used the Prior-registered Marks and the point that the designated goods of the Subject Mark are same or similar to those of the Prior-registered Marks.

1) The appearance, meaning, and sound of the Subject Mark are different from those of the Prior-registered Marks and thus cannot be deemed similar as a whole thereto, and therefore, the Subject Mark does not fall under Article 7(1)7 or Article 7(1)18 of the old Trademark Act.

2) The Prior-registered Marks cannot be deemed as the trademarks conspicuously recognized by consumers on or around the filing date of the Subject Mark, and the Subject Mark is not likely to cause confusion of source with the Prior-registered Marks, and therefore, the Subject Mark does not fall under Article 7(1)10 of the old Trademark Act, either.

C. Questions Presented

Therefore, the questions presented are: ① in respect to whether the Subject Mark falls under Article 7(1)7 or Article 7(1)18 of the old Trademark Act, whether the mark of the Subject Mark is similar to that of the Prior-registered Marks, and ② in respect to whether the Subject Mark falls under Article 7(1)10 of the old Trademark Act, whether the Subject Mark is a trademark that, in relation to the Prior-registered Marks, is likely to cause confusion with other person's product or business which is conspicuously recognized by consumers as belonging to such a person.

3. Whether the Mark of the Subject Mark is Similar to Those of the Prior-registered Marks

A. Relevant Law

In principle, to determine whether a composite trademark consisting of two or more letters or figures is similar to other trademarks, the composite trademark should be observed by using the appearance, sound, and meaning in whole as the standard. However, if a trademark has a part which may independently function as a source indicator of the goods (in other words, essential part) by giving consumers an impression about the trademark or by making consumers remember or be reminded of the trademark, in order to derive the proper conclusion of the overall observation, it is required to compare the essential part to determine the similarity of the marks.

Additionally, in trademark, the essential part alone, regardless of other features, becomes the subject of comparison in determining the similarity of marks for the general consumers due to its independent distinctiveness that is conspicuously recognized by the general consumers, therefore, the feature that has no or little distinctiveness cannot serve an essential part.

B. Subject That Determines the Similarity of Competing Marks

For the following reasons, when determining the similarity of the Subject Mark and the Prior-registered Marks, it is proper to include general consumers as well as experts such as doctors and pharmacists, within the scope of consumers and traders who are the Subject to determine the similarity thereof.

1) The designated goods of the Subject Mark and the Prior-

registered Marks are both “drugs.” Drugs are divided into an “over-the-counter drug,” the misuse or abuse of which is less concerned, the safety and efficacy of which may be expected even when used without a prescription of a doctor, and which is designated by the Minister of Food and Drug Safety as such, and a “prescription drug” which is not an over-the-counter drug (Articles 2(9) and (10) of the Pharmaceutical Affairs Act). However, the Subject Mark includes both prescription drugs related to treatment of brain diseases, such as “preparations for treatment of senile hypomnesia, preparations for treatment of traumatic degenerative cerebellar syndrome, etc.” and over-the-counter drugs, such as “drugs, anti-inflammatory preparations, pharmaceutical agents affecting digestive organs, etc.” in its designated goods.

2) Since advertisement of prescription drugs is prohibited (Article 68(6) of the Pharmaceutical Affairs Act and Article 84 of Enforcement Decree of the Pharmaceutical Affairs Act), it is not easy for general consumers—other than experts such as doctors and pharmacists—to know of information on prescription drugs. In the case of over-the-counter drugs, general consumers directly purchase drugs that they need at pharmacies, but it is the common practice that they purchase the drugs which pharmacists select based on customers’ explanation of symptoms. In addition, pharmacists are obligated to provide medication counseling to assist consumers in choosing the drugs of their needs (Article 1(12) and Article 24(4) of the Pharmaceutical Affairs Act), and therefore, in most cases, pharmacists intervene in consumers’ drug purchases.

3) Therefore, even though actual purchasers are general consumers, considering the practice that the doctors, pharmacists, etc. intervene in consumers’ purchases, in the event that the

Subject Mark and the Prior-registered Marks are used for the same or similar goods, the determination of the similarity between the competing marks should take the recognition of the general consumer as well as doctors and pharmacists, into consideration.

C. Distinctiveness of "GLIA" Part in Both Marks

In addition, for the following reasons, "GLIA," the common part of the Subject Mark and the Prior-registered Marks cannot be deemed as having no or little distinctiveness.

1) In general, the English word "GLIA" or its Korean transliteration "글리아" means "neuroglia" or "glia cell" which materially interacts between nerve cells as a nonneuronal cell for central and peripheral nervous systems other than vasculature system (Defendant's Exhibits 1-1~ 7 and 2-1~4).

2) However, according to the following survey results, it does not appear that not only general consumers but also even the experts such as doctors and pharmacists easily perceive the "GLIA" part to denote "neuroglia" or "glia cell."

A) At the request of the Plaintiff, Korea Research Center Co. Ltd. (hereinafter "**Korea Research**") conducted a "Trademark Recognition Survey" on 100 doctors, 100 pharmacists, and 100 laypeople residing in Seoul, Seoul metropolitan area, Busan, Daegu, Daejeon, and Gwangju from May 26, 2017 to June 2, 2017 (Plaintiff's Exhibits 33-1 and 2).

As a result, in response to the question "When you see or hear a drug name (trademark) called "글라아타민" or

"GLIATAMIN," is there any part (term) in the drug name that you know the meaning of?" 57% of the doctors, 63% of the pharmacists, and 20% of the laypeople answered "yes." However, in response to the follow-up question "If so, what is the part (term) that you know the meaning of (you can choose multiple responses)?" only 3 doctors, 3 pharmacists, and 1 layperson answered "글리아(GLIA)" (based on plural responses).

B) Meanwhile, at the request of the Defendant, Symfunny Brand Co., Ltd. (hereinafter "**Symfunny Brand**") conducted a "Glia Trademark Survey" (Defendant's Exhibit 75) on 100 doctors and 100 pharmacists across the country from April 24, 2017 to May 2, 2017. According to the survey results, in response to the question "Have you heard of the term "Glia"?" 54% of the doctors and 46% of the pharmacists answered "Yes, I have."

However, even in the above survey conducted at the request of the Defendant, in response to the question "Please write down the meaning of "Glia" whatever comes to your mind," only 48.3% of the doctors and 25.4% of the pharmacists answered that it was related to cranial nerve. Among them, only 19.6% of the doctors and 1.3% of the pharmacists exactly answered "glia cell," and 11.5% of the doctors and 22.9% of the pharmacists answered that it was related to glycosuria which was completely irrelevant to neuroglia or glia cell.

3) Furthermore, just because "GLIA" denotes neuroglia, it is difficult to conclude that the relationship between glia cell itself and brain diseases (such as weakness of memory and degenerative cerebellar syndrome) is widely known, and there is no data in support thereof. Therefore, it is difficult to

view that the "GLIA" part in the Subject Mark and in the Prior-registered Marks makes people instinctively perceive the efficacy, use, etc. of any medicine related to brain diseases among their designated goods.

D. Comparison of the Two Marks in Detail

Furthermore, for the following reasons, the Subject Mark "GLIATAMIN" as a whole should be deemed similar to the Prior-registered Mark 1 "글리아티린" and the Prior-registered Mark 2 "GLIATILIN", due to similarity in terms of pronunciation.

1) As seen above, "GLIA" part in the Subject Mark and in the Prior-registered Marks is not likely to make people perceive the efficacy, use, etc. of their designated goods, and for that reason it is difficult to view that the "GLIA" part has no or little distinctiveness, and both of the Registered Mark and the Prior-registered Marks have five alphabet letters without space after the "GLIA" part, making them appear as a single term, which leads to the conclusion that it is proper to observe the similarity of the two marks in its entirety.

2) However, both of the marks consist of nine alphabet letters, and when read in Korean, the two marks consist of the same number of syllables (i.e., five syllables). Furthermore, their first three syllables ("글리아") which are relatively strongly pronounced in light of the location of the accent in Korean

language and thus clearly affect our hearing, are also identical. Moreover, the initial consonant of the fourth syllable of the both marks is same "ㅌ," an aspirate pronounced with the forceful release of heavy breath; in addition, the medial vowel and the final consonant of the fifth syllable of the both marks are identical as "ㅣ" and "ㄴ." Therefore, despite the difference in medial vowels of the fourth syllables and in initial consonants of the fifth syllables, the two marks shall sound similar as a whole and therefore the two marks should be deemed similar in terms of pronunciation and sound.

3) On a side note, as a reference, according to the results of the survey above conducted by Korea Research at the request of the Plaintiff (Plaintiff's Exhibits 33-1 and 2), in response to the question "When you see or hear "글리아타민 (or GLIATAMIN)" and "글리아티린 (or GLIATLIN)" separately at different time or location, would you think they are similar?", 73% of the doctors, 81% of the pharmacists, and 66% of the laypeople answered "similar", while only 16% of the doctors, 10% of the pharmacists, and 15% of the laypeople answered "not similar."

E. Summary of Analysis

In conclusion, the mark of the Subject Mark "GLIATAMIN" is similar to the Prior-registered Mark 1 "GLIATILIN 글리아티린" and the Prior-registered Mark 2 "GLIATILIN," and its designated goods are the same or similar to those of the Prior-registered Marks.

In view of the fact that the Defendant admits that it knew, on or around the filing date of the Subject Mark, that the Plaintiff used the Prior-registered Marks through business transactions, the Subject Mark should be deemed to fall under Articles 7(1)7 and 7(1)18 of the old Trademark Act.

4. Conclusion

Accordingly, the registration of the Subject Mark should be invalidated under Articles 7(1)7, 7(1)18, and 71(1)1 of the old Trademark Act, and the IPTAB decision inconsistent with the above conclusion is unlawful without having to further examine the rest of the issues, and the Plaintiff's petition to revoke the IPTAB decision shall be granted.

Presiding	Judge	Chungsuk LEE
	Judge	Boohan KIM
	Judge	Jinhee LEE

PATENT COURT OF KOREA
TWENTY-FIRST DIVISION
DECISION

Case No.: 2016Na1691
Petition for Injunction against Trademark Infringement

Plaintiff and Appellant/Appellee:
Outback Steakhouse of Florida, LLC
United States

Defendants and Appellees/Appellants:
1. A
2. B
3. C

District Court's Decision: Jeonju District Court Decision, 2015GaHap 3760, decided August 24, 2016

Date of Closing Argument: March 14, 2017

Decision Date: June 29, 2017

ORDER

1. The District Court's Decision is hereby amended as follows:

A. The Defendants:

1) shall not use any mark listed in Appendix 2 for their business;

2) shall not produce, use, sell, distribute, import, export, or display or offer to sell any signs, banners, garage doors, direction boards, bedding supplies, shampoo/conditioner/lotion containers, pouch bags for toiletries, electric kettles, or promotional/advertising materials indicating any mark listed in Appendix 2;

3) shall destruct any signs, bedding supplies, slippers, gowns, shampoo/conditioner/lotion containers, props for cosmetic products, towels, pouch bags for toiletries, electric kettles, any other motel room amenities, and promotional/advertising materials listed in Appendix 3 with indication of any mark listed in Appendix 2 being used, stored, or displayed at the Defendants' offices, factories, warehouses, vehicles, and motels.

B. Defendants A and B:

1) shall delete and remove each mark listed in Appendix 2 from the exterior walls, garage doors, bathroom doors within the rooms, and internet website of the three-story motel buildings located in D of Deokjin-gu, Jeonju City;

2) shall jointly pay KRW 50 million, of which amount the following shall be compensated as well:

A) with respect to KRW 30 million, the amount calculated at an annual rate of 5% for a period from July 10, 2015 to August 24, 2016, and at an annual rate of 15% for a period starting from the next day to the date of full repayment;

B) with respect to KRW 20 million, the amount calculated at an annual rate of 5% for a period from July 10, 2015 to June 29, 2017, and at an annual rate of 15% for a period starting from the next day to the date of full repayment.

C. Defendant C:

1) shall delete and remove each mark listed in Appendix 2 from the exterior walls, garage doors, bathroom doors within the rooms of such motels of the three-story motel building located in E and four lots of land in Iksan City;

2) shall pay KRW 40 million, of which amount the following shall be compensated as well:

A) with respect to KRW 30 million, the amount calculated at an annual rate of 5% for a period from July 10, 2015, to August 24, 2016, and at an annual rate of 15% for a period starting from the next day to the date of full repayment;

B) with respect to KRW 10 million, the amount calculated at an annual rate of 5% for a period from July 10, 2015, to June 29, 2017, and at an annual rate of 15% for a period starting from the next day to the date of full repayment.

D. The remaining part of Plaintiff's petition against the Defendants is dismissed.

2. One-fifth of the total litigation cost shall be borne by the Plaintiff, and the remainder by the Defendants.

3. Paragraph 1 above may be provisionally executed.

PLAINTIFF'S DEMAND AND APPELANT'S DEMAND

Ⅰ. Plaintiff's Demand

In addition to Paragraph 1. A in Order above:

1. The Defendants shall not use any mark listed in Appendix 1 for their business.

2. The Defendants:

A. shall delete and remove each mark listed in Appendix 2 from the exterior walls, garage doors, bathroom doors within the rooms, and internet website of the motels operated by the Defendants;

B. shall deliver, to the bailiff delegated by the Plaintiff, the finished products and half-finished products, wrapping paper, packing containers, and promotional/advertising materials listed in Appendix 3, onto which any mark or sign listed in Appendix 2 is attached or indicated, which are stored in the Defendants' offices, factories, warehouses, sales offices, and stores;

C. In cases above, the bailiff shall give a public notice of the purport of such storage in an appropriate manner.

3. Defendants A and B shall jointly pay the Plaintiff KRW 150 million as well as an amount calculated at an annual rate of 20% for a period from July 10, 2015 to September 30, 2015, and at an annual rate of 15% for a period starting from the next day to the date of full repayment.

4. Defendant C shall pay the Plaintiff KRW 150 million as well as an amount calculated at an annual rate of 20% for a period from July 10, 2015, to September 30, 2015, and at an annual rate of 15% for a period starting from the next day to the date of full repayment.

5. Defendant A shall undergo procedures to transfer registration of the domain name "outbackmt.net" registered on February 10, 2015, with "OUTBACKMT" as the registrant's name, to Gabia Inc., a domain registration agency accredited by the Internet Corporation for Assigned Names and Numbers (ICANN).

Ⅱ. Appellant's Demand

1. The Plaintiff

The portion of the District Court's decision found in favor of the Defendants regarding additional payment as described below shall be vacated:

Defendants A and B shall jointly pay the Plaintiff KRW 120 million and an amount calculated an annual rate of 20% for a period from July 10, 2015 to September 30, 2015, and at an annual rate of 15% for a period starting from the next day to the date of full repayment; and Defendant C shall pay KRW 120 million and an amount calculated at an annual rate of 20% for a period from July 10, 2015 to

September 30, 2015, and at an annual rate of 15% for a period starting from the next day to the date of full repayment.

2. The Defendants

The portion of the District Court's decision found in favor of the Plaintiff shall be vacated, and the Plaintiff's claim against the Defendants corresponding to the portion so vacated shall be dismissed.

OPINION

1. The Scope of Trial by This Court

A. The Plaintiff's Demands against the Defendants

In the trial at the District Court, the Plaintiff demanded against the Defendants: (1) prohibition of use of any mark listed in Appendix 1; (2) prohibition of use of any mark listed in Appendix 2; (3) prohibition of production, etc. of signs, etc. indicating any mark listed in Appendix 2; (4) deletion, etc. of any mark listed in Appendix 2; (5) delegation of authority to the bailiff and public notice regarding finished products, etc. listed in Appendix 3, onto which any mark listed in Appendix 2 is attached or indicated; (6) destruction of direction boards, etc. listed in Appendix 3, onto which any mark listed in Appendix 2 is indicated; and (7) damages; and demanded against Defendant A, (8) registration of domain transfer (hereinafter to be indicated as in "Claim (1)").

B. Rulings in the District Court's Decision

The District Court dismissed the Plaintiff's claims against the Defendants for prohibition of use of any mark listed in Appendix 1 for their business (Claim (1)); granted in its entirety each of the Plaintiff's claims against the Defendants for prohibition of use of any mark listed in Appendix 2 for their business (Claim (2)), prohibition of production, etc. of signs, etc., onto which any mark listed in Appendix 2 is attached or indicated (Claim (3)), deletion, etc. of any mark listed in Appendix 2 (Claim (4)), and destruction of direction boards, etc. listed in Appendix 3, onto which any mark listed in Appendix 2 is indicated (Claim (6)); and partially granted the Plaintiff's claim against the Defendants for damages (Claim (7)). In addition, the District Court denied each of the Plaintiff's claims against the Defendants for delegation of authority to the bailiff and public notice regarding finished products, etc. listed in Appendix 3, onto which any mark listed in Appendix 2 is attached or indicated (Claim (5)) and the Plaintiff's demand against Defendant A for registration of domain transfer (Claim (8)).

C. Appeal by the Plaintiff and the Defendants and the Scope of Trial by This Court

Regarding the above, the Plaintiff appealed against the portion partially denied out of the claims for damages and demanded additional payment in relation thereto; and the Defendants appealed against the entire portion found in favor of the Plaintiff.

Thus, the dismissed portion and the portion found in favor of the Defendants become final; and the scope of trial by this Court shall be limited to the Plaintiff's claims against the Defendants for prohibition of use of any mark listed in Appendix 2 for their business (Claim

(2)), prohibition of production, etc. of signs, etc., onto which any mark listed in Appendix 2 is attached or indicated (Claim (3)), deletion, etc. of any mark listed in Appendix 2 (Claim (4)), destruction of direction boards, etc. listed in Appendix 3, onto which any mark listed in Appendix 2 is indicated (Claim (6)), and damages (Claim (7)).

2. Background

A. The Plaintiff's Status and Registration of the Service Marks

1) The Plaintiff is a corporation established in 1988 in the United States and is currently operating family restaurants in over 20 countries around the world including the Republic of Korea, with the trade name of "Outback" or "Outback Steakhouse."

2) For the marks used for its family restaurant business in Korea, the Plaintiff filed an application for each service mark and completed registration of those service marks, as described in the table below (hereinafter referred to as Business Mark 1, 2, and 3, in the following order, and collectively "Business Marks").

	Business Mark 1	Business Mark 2	Business Mark 3
Mark	OUTBACK 아 웃 백	OUTBACK	OUTBACK STEAKHOUSE
Registration No. (Date of Registration)	No. 0050644 (Date of Registration: Dec. 11, 1998 / Registration Date of Extension: May 8, 2008)	No. 0154502 (Sep. 18, 2007)	No. 0154501 (Sep. 18, 2007)

	Business Mark 1	Business Mark 2	Business Mark 3
Designated Services	Class 43: cafeteria services, restaurants, self-service restaurant services, canteen services, resting area, Western style restaurants, bakeries, food cooking agencies, restaurant chain services	Class 43: Restaurants	Class 43: Restaurants

B. The Defendants' Use of the Marks

1) Defendants A and B, working in partnership, have operated on the land F and three-story building in Geumgu-myeon, Gimje City since 2011 and on the land D and three-story building in Deokjin-gu, Jeonju City since 2014, and Defendant C has operated on the land E and four other lots of land and three-story building in Iksan City since 2011, unmanned accommodations with rooms for hire, each of which under the trade name "Outback" or "Outback Unmanned Motel." The Defendants have used each mark listed in Appendix 2—"아웃백," "OUTBACK," and " 

" ("**Infringing Marks**") —on the external facilities of the above accommodations such as store signs and sign boards, and internal facilities and amenities such as direction boards, price table, bedding supplies, and amenities.

2) Defendants A and B have opened and operated an Internet website in relation to the business of the unmanned accommodation in Jeonju, and this website indicates " 

" among the Infringing Marks.

3) Defendants A and B have sold the land F and the three-story accommodation located in Geumgu-myeon, Gimje City, to G in around March 2016 and completed registration of ownership transfer.

[Factual Basis] Undisputed facts; statements and images in Plaintiff's Exhibits 1 through 3, 15 through 17, 26, 27, 41, and 43 and in Defendant's Exhibits 11 and 13 (including each branch number); the reply from provision of tax information to North Jeonju Tax Office and Iksan Tax Office at District Court level; and the purport of the overall argument.

3. Summary of the Plaintiff's Arguments

A. Infringement of Service Mark Rights

The Defendants infringed the Plaintiff's service mark rights by using the Infringing Marks similar to the Business Marks, which are the Plaintiff's registered service marks, for the services identical or similar to the designated services.

B. Confusion in Business Entities

Using the Infringing Marks similar to the Business Marks widely

known within Korea as the Plaintiff's business marks, the Defendants caused confusion between the Defendants' business and the Plaintiff's business facilities or activities, such act of the Defendants constituting an act of unfair competition stipulated in subparagraph 1(b) of Article 2 of the Unfair Competition Prevention and Trade Secret Protection Act ("UCPA").

C. Damage to Distinctiveness and Reputation

The Defendants damaged the distinctiveness and reputation of the Business Marks by using the Infringing Marks similar to the Business Marks widely known within Korea as the Plaintiff's business marks, for decadent love hotels, such act of the Defendants constituting an act of unfair competition stipulated in subparagraph 1(c) of Article 2 of the UCPA.

4. Regarding Infringement of Service Mark Rights

A. Similarity of the Services

This Court first examined whether the designated services for the Business Marks—cafeteria services, resting areas, restaurants, etc.—are identical or similar to the unmanned accommodation, which is the service using the Infringing Marks.

Similarity of designated services must be determined based on the perception of general consumer in light of the trade practice such as the nature and content of services provided, means of provision, service providers, and scope of consumers (Supreme Court Decision, 2003Hu1192, decided May 12, 2005; Supreme Court Decision, 2006Hu3298, decided June 14, 2007).

In that the designated services for the Business Marks provide some

of the necessities of life to customers, the two types of services may be deemed, to a certain extent, to share similar nature and content of services and consumers.

However, (1) the two types of services have different means of providing services (face-to-face service and unmanned service) and specific nature and content; (2) the two are distinguished in that one has persons who desire to eat food as its consumers, while the other has persons who look for lodging; and (3) based only on the evidence submitted by the Plaintiff, such as Plaintiff's Exhibits 24-1 through 5, 25, and 44, it is difficult to conclude that provision of both services by the identical businesses is general practice of transaction or that general consumers usually believe so.

Thus, the designated services for the Business Marks and the services using the Infringing Marks cannot be deemed identical to each other.

B. Discussion

Therefore, it cannot be concluded that the Defendants infringed the Plaintiff's registered service mark rights and there is no need to further examine the rest of the requirements for infringement of service mark rights.

5. Regarding Confusion of Business Entities

A. Relevant Law

Subparagraph 1(b) of Article 2 of the UCPA stipulates that "an act of causing confusion with another person's commercial facilities or activities by using marks identical or similar to another person's name,

trade name, or emblem, or any other mark indicating another person's business, which is widely known in the Republic of Korea" is one of the acts of unfair competition. Here, "mark indicating another person's business, which is widely known in the Republic of Korea" refers to the marks by which purchasers or consumers widely perceive a specific business distinguishable from another business across Korea or within a certain area in Korea. With respect to whether any mark indicates another business widely known in Korea, a prima facie case is established based on the circumstances of transaction, the period, methods, modality and frequency of use, and scope of transaction, as well as whether the mark is widely known objectively in consideration of socially accepted perception. Similarity of business marks must be decided through overall comparison, objective comparison, and comparison by recollection of two business marks used for the same type of business in terms of their appearance, sound, and meaning to examine whether general consumers or purchasers in a specific circumstance of transaction are likely to misconceive or confuse the source of business. Acts of causing confusion with another person's commercial facilities or activities include not only an act of confusing that the business marks themselves are identical, but also an act of using a mark identical or similar to another person's business mark widely known in Korea and thereby misleading general consumers or purchasers into wrongfully believing that the business of the relevant business mark is closely related to the user of the identical or similar mark in terms of capital, organization, etc. Whether such acts constitute consumer confusion with another person's business marks must be determined in comprehensive consideration of the business mark's being well-known, level of distinctiveness, degree of similarity of marks, actual practice of business, existence of business competition due to overlapping customers, and malice (purpose of use) of imitators (Supreme Court Decision, 2011Da9822 decided December 22, 2011).

B. Whether the Business Marks are Business Marks Widely Recognized by consumers in Korea

1) Established Facts

Each of the following facts is either undisputed between the parties, or can be admitted in comprehensive consideration of the purport of each statement and image in Plaintiff's Exhibits 1, 4, 6 through 14, 19, 28, and 30 through 32 (including each branch number).

A) The Plaintiff is a corporation established in 1988 in the United States and is currently operating approximately 1,200 family restaurants in over 20 countries around the world including the Republic of Korea, with the trade name of "Outback" or "Outback Steakhouse." The Plaintiff opened the first Outback Steakhouse restaurant in Korea in 1997 and currently operates about 80 such restaurants across the nation.

B) While operating the family restaurants as described above, the Plaintiff has mainly used Business Mark 3 (OUTBACK STEAKHOUSE) or " OUTBACK STEAKHOUSE® ," which is the same mark in a different color (hereinafter "Business Mark 4" and collectively "**Business Marks**" including Business Mark 4) for the restaurants' signs, menus, price tables, packaging, wet tissue, and receipts. In the marketplace, the terms such as "아웃백 스테이크하우스," "아웃백" and "Outback" have been used to refer to the Plaintiff or the restaurants operated by the Plaintiff.

C) The Plaintiff ran television commercials and newspaper advertisement in which celebrities such as Dong-Gun Jang,

So-Young Ko, In-Sung Jo, and Si-Kyung Sung, and also placed advertisement using social network services including Facebook, and the advertising expenditure amounts to approximately KRW 19 billion from 2013 to the first half of 2015.

D) Operating about 80 restaurants within Korea, the Plaintiff's revenues between 2010 and 2014 were as follows:

(Unit: USD)

	2010	2011	2012	2013	2014
Total Income	235,309,803	289,120,996	292,732,096	289,629,719	238,828,123
Expenses	201,750,017	251,284,537	252,285,533	258,206,463	231,371,125
Pre-tax Profit	33,559,787	37,836,459	40,446,563	31,423,255	7,456,998

E) The Plaintiff's "Outback Steakhouse" was selected as the best family restaurant for ten consecutive years from 2005 to 2014 in the National Brand Competitive Index (NBCI) surveyed by the Korea Productivity Center. In 2014, Outback Steakhouse won higher consumer satisfaction than any other family restaurants in the online survey conducted by the Korea Consumer Agency. In 2015, it was also ranked the first in the consumer preferences of family restaurants surveyed by *The Korean Economic Daily*.

2) Specific Conclusion

Considering within the period of the Plaintiff's domestic operation; period, methods, and modality of use of the Business Marks; advertisements; revenues; and level of awareness within the market as

discussed in above Paragraph (1), when taking into account the fact that consumers of family restaurants are not limited to any specific age group or gender and that the Plaintiff's restaurants are evenly distributed across the nation, the Business Marks are widely known in Korea as the Service Marks of the Plaintiff's (although the Defendants argued that "아웃백" or "Outback" is a significant geographical designation and therefore has no distinctiveness, the statements in Defendant's Exhibits 1 through 5 are not sufficient to support that "아웃백" or "Outback" constitutes a conspicuous geographical designation, this is more so based on the fact that the above-described mark has reached to the level of well-knownness as discussed above; the Defendant's argument above is therefore not accepted).

C. Specific Conclusion on Confusion in Business Entities

1) Being Well-Known, Level of Distinctiveness, Degree of Similarity of Marks, and Malice of Imitators

As discussed in Paragraph B above, the Business Marks are well-known and have strong distinctiveness.

In addition, since the Infringing Marks are identical to the Business Marks in terms of sound and meaning, or the essential part "OUTBACK" is identical in terms of sound and meaning, has the same designation and concept, they are identical or similar to the Business Marks. Given that the similarity between the two marks, malice of the Defendants as imitators can be deduced.

2) Actual Sales and Existence of Business Competition

However, considering only with the Plaintiff's evidence such as Plaintiff's Exhibits 24-1 through 5, 25, and 44, it is difficult to conclude that the Plaintiff's family restaurant business and the Defendant's

unmanned accommodation business being serviced by the identical business entities is general practice of transaction or that general consumers usually think that way, evidence submitted by the Plaintiff is not sufficient to support that any business operating family restaurants often tends to diversify its business to unmanned accommodation service. In this respect, it cannot be accepted that the two services are in a relationship of business competition due to overlapping customers, etc.

In addition, in comparison to the Plaintiff's business scale, the Defendants' business scale is very small [the former being much more than 1,000 times larger than the latter as of 2013 (Plaintiff's Exhibit 10: reply from provision of tax information to North Jeonju Tax Office and Iksan Tax Office at District Court level)].

As discussed above, the possibility of business competition due to overlapping customers remains extremely low; the Plaintiff's business scale is incomparably larger than that of the Defendants'; with over 80 restaurants across the nation, the Plaintiff has maintained reputation and credibility and retained favorable evaluation from consumers as "family-centered and nature-friendly family restaurant" through advertisement featuring celebrities and activities of social contribution (Plaintiff's Exhibits 36 through 40). Based on the foregoing, it is highly unlikely for general consumers or purchasers to misperceive that the Plaintiff directly operates unmanned accommodations, which have negative image, or such facilities are operated by any individual or corporation closely related to the Plaintiff in terms of capital, organization, etc. (as discussed in Paragraph 6. B below, the Defendants' act of using the Business Marks constitutes damage to the favorable image and value held by the Plaintiff's Business Marks; since the rationale that the business identical to the Plaintiff or any individual or corporation closely related to the Plaintiff in terms of capital, organization, etc. engages in an act of damaging the favorable image and value held by the Business Marks goes against the rule of

thumb, it is extremely unlikely that general consumers or purchasers would be led to mistaking one for the other).

3) Summary

Based on the foregoing, notwithstanding the business marks' being well-known, strong distinctiveness, the marks' identicalness and similarity, and imitators' malice, they cannot be deemed to cause general consumers or purchasers to misconceive that a close relationship in terms of capital, organization, etc. exists between the Plaintiff, which is the business using the Business Marks, and the Defendants, which are the users of the Infringing Marks.

6. Regarding Damage to Distinctiveness and Reputation

A. Relevant Law

Subparagraph 1(c) of Article 2 of the UCPA stipulates that "in addition to the act of causing confusion provided for in item (a) or (b), an act of doing damage to distinctiveness or reputation attached to another person's mark by using the mark identical or similar to another person's name, trade name, trademark, or container or package of goods, or any other mark indicating another person's goods or business, which is widely known in the Republic of Korea, or by selling, distributing, importing, or exporting goods bearing such marks, without good cause prescribed by Presidential Decree, such as the purpose of noncommercial use" is one of the acts of unfair competition. In consideration of the purport and process of legislation of such provisions, the expression "widely known in the Republic of Korea" should be interpreted as the level of famousness of being widely known to most of the general public in addition to relevant purchasers, going beyond the level of famousness of merely being

known to purchasers or consumers across Korea or within a certain area in Korea, and whether being widely known within Korea can be determined based on the period, methods, modality and frequency of use; scope of business; actual practice of such business; and whether it is widely known objectively in terms of socially accepted ideas. Damage to distinctiveness refers to damage to a specific mark's function as a source identifier as a product mark or business mark (Supreme Court Decision, 2002Da13782, decided May 14, 2004), and damage to reputation refers to an act of using a specific mark that has reached the level of famousness for any service with negative image and thereby damaging the favorable image and value of such mark, it is not necessarily required that such business mark be used for any service of the same or similar type or in competition to damage the distinctiveness or reputation of a mark that has reached the level of famousness.

B. Discussion

1) Whether the Business Marks are Famous

As discussed in Paragraph 5. B above, the Business Marks constitute the famous business marks of the Plaintiff.

2) Identicalness and Similarity of Business Marks

Since the Infringing Marks are identical to the Business Marks in terms of sound and meaning, or the essential part which is the "OUTBACK" part is identical in terms of sound and meaning, , they are identical or similar to the Business Marks.

3) Damage to Distinctiveness and Reputation of the Business Marks

Based on the admitted facts discussed in Paragraph 5. B above, each

statement in Plaintiff's Exhibits 20-1 through 5 and 36 through 40, and the purport of the overall argument, the following circumstances are acknowledged: (1) The Plaintiff has obtained nationwide distinctiveness through advertisement, etc. by creating the Business Marks and consistently using them at its restaurants across the nation; (2) The Plaintiff has maintained the reputation and credibility of family-centered and nature-friendly family restaurants based on restaurant interior, website, advertisement featuring celebrities, and activities of social contribution (Plaintiff's Exhibits 36 through 40); but (3) the Defendants used the Business Marks in the course of operating unmanned accommodations attached with negative image of being used as love hotels—in particular, the Defendants used a mark highly similar to Business Mark 4 (

), which is the Plaintiff's representative brand, by modifying the mountain-shaped figure on the top of Business Mark 4 into an explicit shape of a naked women lying on her side (

). Based on the foregoing facts, it is concluded that the Defendants used the famous Business Marks of the Plaintiff for a service with negative image and thereby damaged the favorable image and value of the mark and also damaged the function as a source identifier of the famous Business Marks.

4) Summary

Given the foregoing examination, the Defendants' act of using the Business Marks amounts to damage to distinctiveness and reputation stipulated in Subparagraph 1(c) of Article 2 of the UCPA.

In this regard, the Plaintiff is entitled to a right to request prohibition under Article 4 of the UCPA (Paragraph C below) and a right to compensate damages under Article 5 of the UCPA (Paragraph D below).

C. Duty to Prohibit and Destroy

1) Portions Granted

As discussed above, the Defendants' act of using the Infringing Marks in the course of operating unmanned accommodations constitutes an act of unfair competition involving damage to distinctiveness and reputation. In this respect, in accordance with Article 4 of the UCPA, (1) the Defendants shall not use the Infringing Marks for their business; (2) the Defendants shall not produce, use, sell, distribute, import, export, or display or offer to sell any signs, banners, garage doors, direction boards, bedding supplies, shampoo/conditioner/lotion containers, pouch bags for toiletries, electric kettles, or promotional/ advertising materials indicating the Infringing Marks; (3) Defendants A and B shall delete or remove the Infringing Marks from the exterior walls, garage doors, bathroom doors within the rooms, and internet website of the three-story motel buildings operated by the Defendants above located in D of Deokjin-gu, Jeonju City,; and Defendant C shall delete or remove the Infringing Marks from the exterior walls, garage doors, and bathroom doors within the rooms of the three-story motel buildings operated by Defendant C located in E and four lots of land in Iksan City,; and (4) the Defendants shall have a liability to destruct the infringing objects indicating the Infringing Marks being used, stored, or displayed at the Defendants' offices, factories, warehouses, vehicles, and motels (although the Plaintiff also filed a claim against "other places similar thereto," this will be deemed a result of mistake or typo of the Plaintiff's demand because the claims above did not specify any particular place).

2) Portions Denied

Whether to accept a request for prohibition under Article 4 of the UCPA shall be decided as at the date of closing argument in the

proceedings at the trial court (Supreme Court Decision, 2006Da22722, decided November 13, 2008; Supreme Court Decision, 2011Da97065, decided June 27, 2013).

However, given that Defendants A and B sold to a third party the "three-story accommodation in the land F located in Geumgu-myeon, Gimje City" they had operated before the closing argument, evidence submitted by the Plaintiff is not sufficient to conclude that Defendants A and B were operating the accommodation above located in Gimje City as at the date of closing argument. In this respect, out of the demand against Defendants A and B, the Plaintiff's demand for deletion, etc. of the Infringing Marks related to the accommodation above cannot be accepted because the Plaintiff demanded destruction and removal of the objects do not involve an act of unfair competition by the Defendants above as at the date of closing argument.

D. Duty to Compensate for Damages

1) Plaintiff's Argument

Pursuant to Article 14-2(2) and (5) of the UCPA, the Defendants are liable to reimburse any damage incurred by the Plaintiff due to damage to distinctiveness and reputation (= loss equivalent to the Defendants' business interest + loss resulting from damaged reputation and credibility).

Defendants A and B shall be liable to jointly pay KRW 150 million and damages for delay therefor to the Plaintiff, as demanded by the Plaintiff, with respect to KRW 174,439,285 as a loss equivalent to the business interest (Article 14-2(2) of the UCPA) and KRW 2.3 billion as a loss resulting from damaged reputation and credibility (Article 14-2(5) of the UCPA).

Defendant C shall be liable to pay KRW 150 million and damages for delay therefor to the Plaintiff, as demanded by the Plaintiff, with

respect to KRW 159,540,762 as a loss equivalent to the business interest (Article 14-2(2) of the UCPA) and KRW 2.3 billion as a loss resulting from damaged reputation and credibility (Article 14-2(5) of the UCPA).

2) Claim for Compensation of Damages Equivalent to Business Interest

A) Purport of the Plaintiff's Argument

The Plaintiff's argument that the Defendants incurred the Plaintiff a loss equivalent to the "business interest of the Defendants" due to the Defendants' act of damaging distinctiveness and reputation appears to purport that the Plaintiff incurred a loss due to a lost profit equivalent to the amount of profits above.

B) Relevant Law

Article 14-2(5) of the UCPA, which serves as a supplementation to Article 14-2(2), are intended to relieve burden of proof of the infringed party in terms of business loss equivalent to a lost profit in a claim for damages due to unfair competition, not to presume business loss equivalent to a lost profit. In this context, in order for a person who claims damages to be governed by the subject provision, he needs to actually make argument for and prove any business loss incurred equivalent to a lost profit. However, given the purport of the abovementioned provisions, it shall be deemed that an occurrence of any loss described above can be sufficiently argued and proved through the existence of likelihood or probability of loss, and thus, as long as a person claiming for damages proves that he engages in the same business assumed by the infringer, occurrence of business loss equivalent to a lost profit resulting from an act of unfair competition can be presumed de facto, except in extenuating circumstances (Supreme Court Decision, 2006Da22722, decided November 13, 2008; Supreme Court Decision, 2007Da22514, 22521 decided October 29,

2009; Supreme Court Decision, 2013Da45037, decided October 29, 2015).

C) Specific Conclusion

Since evidence submitted by the Plaintiff is not sufficient to conclude that the Defendants engage in the same type of business assumed by the Plaintiff, the legal provisions above, which presumes business loss equivalent to a lost profit when engagement in the same type of business is proved, is not applicable.

In addition, as discussed in Paragraph 5. C. (2) above, the Plaintiff's family restaurant service and the Defendants' unmanned accommodation service cannot be deemed to be in a competitive relationship due to overlapping customers. Given such facts, evidence submitted by the Plaintiff such as Plaintiff's Exhibits 34 and 35 is not sufficient to conclude that the Defendant's act of damaging distinctiveness and reputation has any likelihood or probability of causing a lost profit to the Plaintiff, and there is no evidence to otherwise prove the likelihood or probability of any business loss equivalent to a lost profit.

D) Summary

Thus, the claim for damages equivalent to business interest of the Defendants is without merit, without the need for further analysis.

3) Claim for Compensation of Damages from Intangible Loss

A) Relevant Law

Article 751(1) of the Civil Act stipulates the liability for compensation of damage to non-property caused by an illegal act, and damage to non-property which is not limited to mental anguish but includes intangible loss that cannot be calculated in quantity but can be assessed monetarily based on socially accepted ideas. In this respect, a

person who damaged a corporation's honor or credibility is liable to pay such corporation damages of non-property loss (Supreme Court Decision, 2003Da33868, decided August 16, 2004; Supreme Court Decision, 2005Da37710, decided November 10, 2005). In addition, any intangible loss caused by damaged distinctiveness and reputation as stipulated in the UCPA is a kind of damages under Article 751(1) of the Civil Act, and shall be considered to be included in "the damage to business interest in an act of unfair competition" under Article 5 of the UCPA.

Further, since the intangible loss caused by damaged distinctiveness and reputation under the UCPA cannot be proved with a specific amount of damages due to the nature of such loss, the Court may acknowledge a due amount of damages based on the purport of the overall argument and the results of examination of evidence pursuant to Article 14-2(5) of the UCPA.

B) Occurrence and Scope of Liability for Compensation of Damages

By the rule of thumb, it is clear that the Defendants' act of damaging distinctiveness and reputation would further damage the Plaintiff's reputation or credibility, causing intangible loss to the Plaintiff, the Defendants is liable to compensate intangible loss to the Plaintiff.

With respect to the amount of damages to be compensated by the Defendants, the purport of the overall argument and various circumstances found in the results of examination of evidence taken into account, including the degree of reputation and credibility of the Plaintiff and value of the Plaintiff's brand; scale of the Plaintiff's business; degree of the damage to distinctiveness and reputation; type and nature of damage expected; degree of actual damage; degree of malice; duration of a damaging act by the Defendants and the Defendants' scale of business; and the regional scope of the Defendants' business, the amount of damages to be jointly paid by Defendants A and B shall be set as KRW 50 million and that to be

compensated by Defendant C as KRW 40 million.

4) Final Amount of Damages Granted

A) Defendants A and B

Defendants A and B shall jointly pay the Plaintiff KRW 50 million. In addition, they shall pay the following: (1) with respect to KRW 30 million of the KRW 50 million, which was granted by the District Court, the delay damages at an annual rate of 5% as stipulated in the Civil Code for the period from July 10, 2015, which is after the date of relevant unlawful act as claimed by the Plaintiff, to August 24, 2016, the date of the District Court' decision, in which it was deemed reasonable for the Defendants above to contest existence and scope of their liability; and at an annual rate of 15% as stipulated in the Act on Special Cases Concerning Expedition, etc. of Legal Proceedings from the following day to the date of full repayment; and (2) with respect to KRW 20 million of the KRW 50 million, which is additionally granted by this Court, the delay damages at an annual rate of 5% as stipulated in the Civil Code for the period from July 10, 2015, which is after the date of relevant unlawful act as claimed by the Plaintiff, to June 29, 2017, the date of this Court's decision, in which it is deemed reasonable for the Defendants above to contest existence and scope of their liability; and at an annual rate of 15% as stipulated in the Act on Special Cases Concerning Expedition, etc. of Legal Proceedings from the following day to the date of full repayment.

B) Defendant C

Defendant C shall pay the Plaintiff KRW 40 million. In addition, Defendant C shall pay the following: (1) with respect to KRW 30 million of the KRW 40 million, which was granted by the District Court, the delay damages at an annual rate of 5% as stipulated in the Civil Code for the period from July 10, 2015, which is after the date of relevant unlawful act as claimed by the Plaintiff, to August 24,

2016, the date of the District Court's decision, in which it was deemed reasonable for the Defendant above to contest existence and scope of their liability; and at an annual rate of 15% as stipulated in the Act on Special Cases Concerning Expedition, etc. of Legal Proceedings from the following day to the date of full repayment; and (2) with respect to KRW 10 million of the KRW 40 million, which is additionally granted by this Court, the delay damages at an annual rate of 5% as stipulated in the Civil Code for the period from July 10, 2015, which is after the date of relevant unlawful act as claimed by the Plaintiff, to June 29, 2017, the date of this Court's decision, in which it is deemed reasonable for the Defendant above to contest existence and scope of their liability; and at an annual rate of 15% as stipulated in the Act on Special Cases Concerning Expedition, etc. of Legal Proceedings from the following day to the date of full repayment.

7. Conclusion

Based on the foregoing, each of the Plaintiff's claim for the Defendants is well grounded and therefore is granted to the extent of the scope of acknowledgement above, and each of the remaining demand is without merit and therefore denied. Appeal of the Plaintiff and Defendants A and B shall be partially accepted, and the District Court's decision shall hereby be amended as above and decided as declared in Order.

Presiding Judge Hwansoo KIM
Judge Jootag YOON
Judge Hyunjin CHANG

[Appendix 1]

Plaintiff's Registered Service Marks

1. 

2. OUTBACK
아 웃 백

[Appendix 2]

Marks Used by the Defendants

1. 

2. 아웃백

3. OUTBACK

[Appendix 3]

Infringing Objects (To Be Destroyed)

- Business marks in the signs, banners, garage doors, and websites of the motels operated by the Defendants.

  Direction boards, room number plates, bedding supplies, slippers, gowns, shampoo/conditioner/lotion containers, props for cosmetic products, towels, pouch bags for toiletries, electric kettles, and any other motel room amenities within the motels operated by the Defendants.

  Bathroom doors within the rooms of the motels operated by the Defendants.