PATENT COURT OF KOREA

THIRD DIVISION

DECISION

Case No.	2018Heo4041 Confirmation of Scope of Rights (Patent)
Plaintiff	A United States of America Representative B Counsel for Plaintiff Attorney Kyungtae KANG , Yuseok WON Patent Attorney Young KIM, Jiwoong PARK
Defendant	C CEO D and E Counsel for Defendant Yoon & Yang LLC Attorney in Charge Dongju KWON and Hyundong YEO Attorney Yeosoon JUNG, Sungmin PARK and Changsoo PARK Patent Attorney Jehwan JANG, Hyungil LEE and Chulkyun AN
Date of Closing Argument	October 23, 2019
Decision Date	December 20, 2019

ORDER

1. The IPTAB Decision 2016Dang2918, April 11, 2018 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. Plaintiff's Patented Invention at Issue Subject to Registration of Extension of Patent Term (Plaintiff's Exhibits 1, 2, 23-1, 23-2, and 24)(hereinafter the "Subject Invention")

1) Title of invention: Aryl Fused Azapolycyclic Compounds

2) International filing date/ date of claimed priority/ translation filing date/ date of registration/ patent number

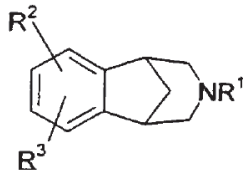
: November 13, 1998/ December 31, 1997/ June 30, 2000/ November 21, 2003/ No. 408138

3) Claims

a) Claims at the time of registration of patent

【Claim 1】 A compound of Formula I below or a pharmaceutically acceptable salt thereof:

Formula I

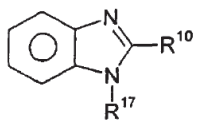


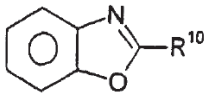
wherein R^1 is hydrogen, $(C_1\text{-}C_6)$alkyl, unconjugated $(C_3\text{-}C_6)$alkenyl, $XC(=O)R^{13}$, benzyl or $-CH_2CH_2\text{-}O\text{-}(C_1\text{-}C_4)$alkyl; R^2 and R^3 are selected, independently, from hydrogen, $(C_2\text{-}C_6)$alkenyl, $(C_2\text{-}C_6)$alkynyl, hydroxy, nitro, amino, halo, cyano, $-SO_q(C_1\text{-}C_6)$alkyl, $(C_1\text{-}C_6)$alkylamino-, $[(C_1\text{-}C_6)\text{alkyl}]_2$amino-, $-CO_2R^4$, $-CONR^5R^6$, $-SO_2NR^7R^8$, $-C(=O)R^{13}$, $-XC(=O)R^{13}$, aryl-$(C_0\text{-}C_3)$alkyl-, aryl-$(C_0\text{-}C_3)$alkyl-O-,

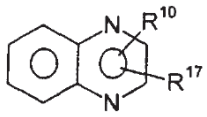
heteroaryl-(C_0-C_3)alkyl-, heteroaryl-(C_0-C_3)alkyl-O-, X^2(C_0-C_6)alkyl- and X^2(C_1-C_6)alkoxy-(C_0-C_6)alkyl-, wherein q is zero, one or two; wherein said aryl is selected from phenyl and naphthyl; wherein said heteroaryl is selected from five to seven membered aromatic rings containing one to four heteroatoms selected from oxygen, nitrogen and sulfur; wherein X^2 is absent or X^2 is (C_1-C_6)alkylamino- or [(C_1-C_6)alkyl]$_2$ amino-; the (C_0-C_6)alkyl- or (C_1-C_6)alkoxy-(C_0-C_6)alkyl- moiety of said X^2(C_0-C_6)alkyl- or X^2(C_1-C_6)alkoxy-(C_0-C_6)alkyl- contains at least one carbon atom, and wherein one to three of the carbon atoms of said X^2(C_0-C_6)alkyl- or (C_1-C_6)alkoxy-(C_0-C_6)alkyl- moiety may optionally be replaced by an oxygen, nitrogen or sulfur atom, with the proviso that any two such heteroatoms must be separated by at least two carbon atoms, and wherein any of the alkyl moieties of said (C_0-C_6)alkyl- or (C_1-C_6)alkoxy-(C_0-C_6)alkyl- may be optionally substituted with two to seven fluorine atoms; and wherein one of the carbon atoms of each of the alkyl moieties of said aryl-(C_0-C_3)alkyl- and said heteroaryl-(C_0-C_3)alkyl- may optionally be replaced by an oxygen, nitrogen or sulfur atom; and wherein each of the said aryl and heteroaryl groups may optionally be substituted with one or more substituents, preferably zero to two substituents, independently selected from (C_1-C_6)alkyl optionally substituted with one to seven fluorine atoms, (C_1-C_6)alkoxy optionally substituted with two to seven fluorine atoms, halo, (C_2-C_6)alkenyl, (C_2-C_6)alkynyl, hydroxy, nitro, cyano, amino, (C_1-C_6)alkylamino-, [(C_1-C_6)alkyl]$_2$amino-, -CO_2R^4, -$CONR^5R^6$, -$SO_2NR^7R^8$, -C(=O)R^{13} and -XC(=O)R^{13}; or R^2 and R^3, together with the carbons to which they are attached, form a four to seven membered monocyclic, or a ten to fourteen membered bicyclic, carbocyclic ring that can be saturated or unsaturated, wherein one to three of the nonfused carbon atoms of said monocyclic rings, and one to five of the carbon atoms of said bicyclic rings that are not part of

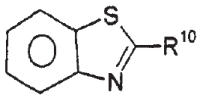
the benzo ring shown in Formula I, may optionally and independently be replaced by a nitrogen, oxygen or sulfur, and wherein said monocyclic and bicyclic rings may optionally be substituted with one or more substituents, preferably zero to two substituents for the monocyclic rings and zero to three substituents for the bicyclic rings, that are selected, independently, from $(C_1\text{-}C_6)$alkyl optionally substituted with one to seven fluorine atoms, $(C_1\text{-}C_6)$alkoxy optionally substituted with one to seven fluorine atoms, nitro, cyano, halo, $(C_2\text{-}C_6)$alkenyl, $(C_2\text{-}C_6)$alkynyl, hydroxy, amino, $(C_1\text{-}C_6)$alkylamino, $[(C_1\text{-}C_6)\text{alkyl}]_2$amino, $-CO_2R^4$, $-CONR^5R^6$, $-SO_2NR^7R^8$, $-C(=O)R^{13}$ and $-XC(=O)R^{13}$; each of R^4, R^5, R^6, R^7, R^8 and R^{13} is selected, independently, from hydrogen and $(C_1\text{-}C_6)$alkyl, or R^5 and R^6, or R^7 and R^8 together with the nitrogen atom to which they are attached, form a pyrrolidine, piperidine, morpholine, azetidine, piperazine, -N-$(C_1\text{-}C_6)$alkylpiperazine or thiomorpholine ring, or a thiomorpholine ring wherein the sulfur atom of the ring is replaced with a sulfoxide or sulfone; and each X is, independently, $(C_1\text{-}C_6)$alkylene; with the proviso that: (a) at least one of R^1, R^2 and R^3 must be other than hydrogen; and (b) when R^2 and R^3 are both hydrogen, R^1 cannot be hydrogen, $(C_1\text{-}C_6)$alkyl or unconjugated $(C_3\text{-}C_6)$alkenyl.

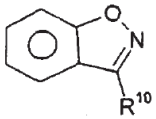
【Claim 2】 A compound according to Claim 1, wherein R^2 and R^3, together with the benzo ring of Formula I, form a bycyclic ring system selected from Formulae XXVI, XXVII, XXVIII, XXIX and XXX below:

Formula XXVI 

Formula XXVII 

Formula XXVIII 

Formula XXIX 

Formula XXX 

wherein R^{10} and R^{17} are selected, independently, from $(C_0\text{-}C_6)$alkyl-, $(C_1\text{-}C_6)$alkoxy-$(C_0\text{-}C_6)$alkyl-, nitro, cyano, halo, amino, $(C_1\text{-}C_6)$alkylamino-, $[(C_1\text{-}C_6)\text{alkyl}]_2$amino-, $-CO_2R_4$, $-CONR_5R_6$, $-SO_2NR_7R_8$, $-C(=O)R_{13}$, $-XC(=O)R_{13}$, phenyl and monocyclic heteroaryl, wherein the total number of carbon atoms in said $(C_0\text{-}C_6)$alkyl- and $(C_1\text{-}C_6)$alkoxy-$(C_0\text{-}C_6)$alkyl- does not exceed six, and wherein any of the alkyl moieties may optionally be substituted with one to seven fluorine atoms; heteroaryl is selected from five to seven membered aromatic rings containing one to four heteroatoms selected from oxygen, nitrogen and sulfur; and each of R^4, R^5, R^6, R^7, R^8 and R^{13} is as defined in Claim 1.

【Claims 3–6, 11 and 14】 Description omitted

【Claims 7–10, 12 and 13】 Deleted

b) Claims that have been corrected and made final pursuant to correction decision 2019Jeong51, October 7, 2019[1)]

【Claim 1】 5,8,14-Triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]hexadeca-2(11),3,5,7,9-pentaene[2)] or a pharmaceutically acceptable salt thereof.

【Claims 2–14】 Deleted

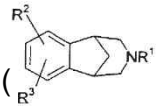
4) Main Content

1 Technological field and technological background The Subject Invention relates to aryl fused azapolycyclic compounds, as

1) Hereinafter, the 'Subject Invention' or 'Claim ○' refers to the Subject Invention or Claim after the correction, and reference shall be made to the 'patented invention prior to correction' or 'Claim ○ prior to correction' only where it is necessary to distinguish and indicate the Subject Invention prior to the correction or its individual claims. Meanwhile, Claim 1 is the sole claim of the Subject Invention, since its other claims were all deleted as a result of the correction made in the case of 2019Jeong51. Therefore, hereinafter the 'Subject Invention' shall mean Claim 1 of the Subject Invention.

2) The above compound's common name is 'Varenicline'.

3) "IC_{50}" is an abbreviation for "Inhibitory concentration 50%" and refers to the dose or concentration of a

defined more specifically by Formula I (). Compounds of Formula I bind to neuronal nicotinic acetylcholine specific receptor sites and are useful in modulating cholinergic function. Such compounds are useful in the treatment of inflammatory bowel disease including but not limited to ulcerative colitis, pyoderma gangrenosum and Crohn's disease; irritable bowel syndrome, spastic dystonia, chronic pain, acute pain, celiac sprue, pouchitis, vasoconstriction, anxiety, panic disorder, depression, bipolar disorder, autism, sleep disorders, tiredness due to jet lag, amyotrophic lateral sclerosis (ALS), cognitive dysfunction, hypertension, bulimia, anorexia, obesity, cardiac arrythmia, gastric acid hypersecretion, ulcers, pheochromocytoma, progressive supranuclear palsy; chemical dependencies and addictions selected from dependencies on or addictions to nicotine (and/or tobacco products), alcohol, benzodiazepines, barbiturates, opioids or cocaine; headache, stroke, traumatic brain injury (TBI), obsessive-compulsive disorder, psychosis, Huntington's Chorea, tardive dyskinesia, hyperkinesia, dyslexia, schizophrenia, multi-infarct dementia, age-related cognitive decline, epilepsy, including petit mal absence epilepsy, senile dementia of the Alzheimer's type (AD), Parkinson's disease (PD), attention deficit hyperactivity disorder (ADHD) and Tourette's Syndrome.

The Subject Invention also relates to the pharmaceutically acceptable acid addition salts of the compounds of Formula I. Examples of pharmaceutically acceptable acid addition salts of the compounds of Formula I are the salts of hydrochloric acid, *p*-toluenesulfonic acid, fumaric acid, citric acid, succinic acid, salicylic acid, oxalic acid, hydrobromic acid, phosphoric acid, methanesulfonic acid, tartaric acid, malate, di-*p*-toluoyl tartaric acid, and mandelic acid.

2 Detailed description of the invention

<Biological Assay>

The effectiveness of the active compounds in suppressing nicotine binding to specific receptor sites is determined by the following procedure which is a modification of the methods of Lippiello, P. M. and Fernandes, K. G. in [The Binding of L-[^{3}H]Nicotine To A Single Class of High-Affinity Sites in Rat Brain Membranes, Molecular Pharm., 29, 448–54(1986)] and of Anderson, D. J. and Arnenc, S. P. in [Nicotinic Receptor Binding of 3H- Cystisine, ^{3}H-Nicotine and

^{3}H-Methylcarmbamylcholine In Rat Brain, European J. Pharm., 253, 261–67(1994)]. The compounds of the Subject Invention that were tested in the above assay exhibited IC_{50} values[3)] of less than 10 μM.

<Embodiment 26>

5,8,14-Triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]hexadeca-2(11),3,5,7,9-pentaene hydrochloride

A)

1-(4,5-Diamino-10-aza-tricyclo[6.3.1.$0^{2.7}$]dodeca-2(7),3,5-trien-10-yl)-2,2,2-trifluoro ethanone

1-(4,5-Dinitro-10-aza-tricyclo[6.3.1.$0^{2.7}$]dodeca-2(7),3,5-trien-10-yl)-2,2,2-triflouroet hanone (3.0 g, 8.70 mmol) was hydrogenated in MeOH (30 mL) under H_2 (45 psi) over $Pd(OH)_2$ (300 mg of 20 wt%/C, 10 wt%). After 2.5 hours, the reaction was filtered through a Celite pad and rinsed with MeOH (30 mL). The solution was concentrated to a light brown oil which crystallized (2.42 g, 96%). (TLC 10% MeOH/CH_2Cl_2 R_f 0.56). APCI MS *m/e* 286.2[$(M+1)^+$]. Melting point 129–131℃

B) 1-(5,8,14-Triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]hexadeca-2(11),3,5,7,9-pentaene)-2,2,2-trifluoro-ethanone

1-(4,5-Diamino-10-aza-tricyclo[6.3.1.$0^{2.7}$]dodeca-2(7),3,5-trien-10-yl)-2,2,2-trifluoro ethanone (500mg, 1.75mmol) was stirred in THF (2mL). This mixture was treated with H_2O (2mL) and glyoxal sodium bisulfite addition compound hydrate (931mg, 3.50mmol) and then stirred at 55℃ for 2.5 hours. The reaction was cooled to room temperature and extracted with EtOAc (3×40mL). The combined organic layer was washed with H_2O (2×30mL), dried (Na_2SO_4), filtered, concentrated and chromatographed on silica gel to provide an off-white powder (329mg, 60%). (TLC 25% EtOAc/hexane R_f 0.40). Melting point 164–166℃.

C) 5,8,14-Triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]hexadeca-2(11),3,5,7,9-pentaene hydrochloride

1-(5,8,14-Triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]hexadeca-2(11),3,5,7,9-pentaene)-2,2,2-trifluoro-ethanone (320mg, 1.04mmol) was slurried in MeOH (2.0mL) and treated with Na_2CO_3 (221mg, 2.08mmol) in H_2O (2.0mL). The mixture was warmed to 70°C for 2 hours, then concentrated, treated with H_2O (20mL) and extracted with CH_2Cl_2 (3×10mL). The organic layer was dried through a cotton plug and concentrated to give a light yellow oil (183mg, 83%) which solidified upon

standing (melting point 138–140°C). This substance was dissolved in MeOH (10mL), treated with 3 M HCl/EtOAc (3mL), concentrated and azeotroped with MeOH (2×20mL) to give solids which were recrystallized from MeOH/Et_2O to afford product as a white solid (208mg, 97%). (TLC 5% MeOH/CH_2Cl_2(NH_3) R_f 0.26).

^{1}H NMR (400 MHz, CD_3OD) δ 8.94 (s, 2H), 8.12 (s, 2H), 3.70 (m, 2H), 3.54 (d, J=12.5 Hz, 2H), 3.35 (d, J=12.5 Hz, 2H), 2.49 (m, 1H), 2.08 (d, J=11.0 Hz, 1H). GCMS *m/e* 211 (M^+). 융점 225-230 °C.

융점	melting point

B. Registration of Extension of Term of Patent at Issue (Plaintiff's Exhibits 1 and 4)

1) Filing date of application for registration of extension/ filing number/ registration date of extension

: June 29, 2007/ 10-2007-65211/ October 24, 2007

2) Content of registration of extension

a) Claims subject to extension: Claim 1[4)]

b) Expiration date of term prior to registration of extension: November 13, 2018

c) Period of extension: one year, eight months and six days (due date for final expiration of patent term: July 19, 2020)

d) Content of approval, etc.

① Approval holder: A Pharmaceutical Korea Ltd.[5)]

② Date on which approval, etc. was obtained: March 30, 2007

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substance where the substance inhibits a reaction that creates 50% of the maximum inhibition (see Dictionary of Biological Psychology 2003).

4) At the time of registration of extension of term of patent at issue, the claims subject to the extension were Claims 1 and 2 prior to correction. However, as seen in paragraph D below, subsequently under the case of 2019Jeong51, a correction decision which limited Claim 1 prior to correction and deleted Claim 2 prior to correction, etc. was made final and conclusive. Accordingly, the Subject Invention's patent is considered to have been registered with the content after the correction, with the result that the claim subject to the registration of extension of term of patent at issue is Claim 1.

5) A Pharmaceutical Korea Ltd. is a non-exclusive licensee of the Subject Invention (Plaintiff's Exhibit 1).

③ Content of approval: drug import approval No. 69 based on provisions of Article 34(1) of Pharmaceutical Affairs Act

④ Compound name of active ingredient: 7,8,9,10-tetrahydro-6,10-methano-6*H*-pyrazino[2,3-h][3]benzazepine, (2*R*,3*R*)-2,3-dihydroxybutanedionate.$C_4H_6O_6$

⑤ Common name (item name): Varenicline Tartrate

⑥ Product (goods) name: Champix tablet

⑦ Efficacy and effectiveness (use): supplementary therapy for smoking cessation treatment

C. Invention for Review ([Appendix 2] of Plaintiff's Exhibit 3)

The invention for review relates to a drug, for which the Defendant obtained a drug manufacturing and marketing approval from the Minister of Food and Drug Safety on August 8, 2018, and is a pharmaceutical composition containing varenicline oxalate. Its explanatory document is attached in the [Appendix].

D. IPTAB Decision and Correction Decision

1) On September 23, 2016, the Defendant filed a petition in the IPTAB against the Plaintiff, as the patentee of the Subject Invention, with respect to the invention for review seeking a defensive confirmation trial on the scope of rights, arguing to the effect that "Since the 'product relevant to approval, etc.', on the basis of which the extension of term of patent at issue was registered, is 'varenicline tartrate', the effect of the patented invention prior to correction, for which an extension of term has been registered, only extends to 'acts of practicing varenicline tartrate', as the basis of registration of extension. Therefore, the invention for review, which relates to 'varenicline oxalate', does not fall within the scope of protection of Claim 1 and Claim 2 prior to correction, for which an extension of term has been registered."

2) The IPTAB heard the Defendant's above petition for trial under Case No. 2016Dang2918, and on April 11, 2018, rendered the trial decision at issue (Plaintiff's Exhibit 3) granting the Defendant's above petition for trial on the grounds that "Since the approval, on the basis of which the extension of term of patent at issue was registered, has 'varenicline tartrate' as its main ingredient and 'supplementary therapy for smoking cessation treatment' as its medical usage, the effect of patent rights in Claim 1 and Claim 2 prior to correction, for which an extension of term has been registered, must be viewed as extending only to 'using varenicline tartrate, the main ingredient, for the medical purpose of supplementary therapy for smoking cessation treatment'. Therefore, the invention for review, which has 'varenicline oxalate' as its main ingredient, does not fall within the scope of protection of Claim 1 and Claim 2 prior to correction, for which an extension of term has been registered."

3) Then, on May 10, 2018, the Plaintiff filed the action at issue in this court seeking the revocation of the IPTAB decision. At the same time, on May 27, 2019, the Plaintiff filed a petition for trial seeking a correction that would limit Claim 1 of the patented invention prior to correction to varenicline or a pharmaceutically acceptable salt thereof, and delete the other claims; the IPTAB heard the petition under Case No. 2019Jeong51, and on October 7, 2019, rendered the correction decision at issue granting the above petition for correction trial, and the above decision became final and conclusive around that time (Plaintiff's Exhibits 23-1 and 23-2).

2. Summary of Parties' Arguments

A. Plaintiff

For the following reasons, the invention for review must be deemed to fall within the scope of protection of the Subject Invention, for which an extension of term has been registered; in reaching a conclusion which is inconsistent with

this, the IPTAB erred in its decision:

1) The Subject Invention is a substance invention, the technical characteristic of which is the provision of new compounds, and the usefulness of such compounds would be sufficiently described by a broad outline of what they could be used for; the Subject Invention, in stating in its specification that it binds to nicotinic acetylcholine receptors and is useful in the treatment of dependency on nicotine, etc., contains a sufficient description of its usefulness and is therefore complete as an invention. In addition, since the Subject Invention describes in its specification the usefulness and preparation embodiments of varenicline, a new compound, it also satisfies the requirement of enablement. Therefore, the Subject Invention's scope of protection is recognized.

2) Furthermore, the invention for review is practically identical, in its active ingredient, therapeutic effect, and use, to ‘Champix Tablet’ (hereinafter, the ‘drug relevant to approval at issue’), which is a drug for which the Plaintiff has obtained an approval under the Pharmaceutical Affairs Act in order to practice the Subject Invention; the modification of a form of a salt in the invention for review to an oxalate is merely a selection which can easily be made by a person having ordinary skill in the art to which the invention pertains (hereinafter, a ‘person having ordinary skill in the art’).

3) As a result, the invention for review falls within the scope of protection of the Subject Invention, for which an extension of term has been registered.

B. Defendant

For the following reasons, the invention for review must be deemed not to fall within the scope of protection of the Subject Invention, for which an extension of term has been registered; the IPTAB decision, which is consistent with this, must be upheld:

1) In the specification of the Subject Invention, the usefulness of the

compounds specified in Claim 1, namely ‘varenicline or a pharmaceutically acceptable salt thereof’, is not described with a sufficient level of clarity such that the establishment of the invention could be affirmed or that the invention could easily be practiced by a person having ordinary skill in the art. Therefore, it is not possible to specify the technical scope of the Subject Invention, which either amounts to an incomplete invention or does not meet the requirement of enablement. Accordingly, the Subject Invention's scope of protection is not recognized.

2) In addition, whereas a tartrate falls within Class I as a commonly used pharmaceutical salt and is a salt which is recognized as GRAS (Generally Recognized As Safe; hereinafter, ‘GRAS’), an oxalate, on the other hand, is not only classified as Class II, but also not recognized as GRAS; from the position of a person having ordinary skill in the art, there is no reason why he/she would necessarily choose an oxalate, which may give rise to a problem in terms of safety. Therefore, it would not be easy for a person having ordinary skill in the art to substitute a salt of tartaric acid[6] with an oxalate in selecting the latter.

3) Furthermore, when judging how easy it would be to select a salt and whether the therapeutic effect is practically identical, each drug's pharmaceutical characteristics should be considered; compared to varenicline tartrate, varenicline oxalate shows a marked difference in its effect in that it has a superior absorption rate in the stomach, has superior stability, and better lends itself to storage. Accordingly, the oxalate salt that has been used in the invention for review should be viewed as not amounting to a form of a salt that can easily be selected by a person having ordinary skill in the art.

4) As a result, the invention for review does not fall within the scope of

6) ‘Salt of tartaric acid’ refers to the same substance as ‘tartrate’. Hereinafter, in the absence of special circumstances such as a quotation from the original text of the material being cited, reference thereto shall be made using the term ‘tartrate.’

protection of the Subject Invention, for which an extension of term has been registered.

3. Whether Scope of Protection of Subject Invention Can Be Recognized

A. Relevant Law

When the technical scope of the invention itself cannot be specified because some elements of an invention at the time of filing of a patent application are abstract or unclear, even on the basis of descriptions setting out the patent claims, detailed description of the invention, or other descriptions contained in drawings, in each case, of the patented invention, the patentee may not assert the scope of protection of such a patented invention (see Supreme Court Decision 2000Hu235, June 14, 2002); as for a patented invention which is impossible to practice, since it is an invention which has been registered in violation of Article 42(3) of the Patent Act, its scope of protection shall not be recognized (see Supreme Court Decision 99Hu1973, December 27, 2001).

B. Whether Invention is Incomplete

For the following reasons, the Subject Invention can be practiced repeatedly by a person having ordinary skill in the art and is composed with a sufficient level of specificity and objectivity such that the likelihood of achieving the technical effect sought to be achieved by the invention can be predicted; accordingly, it shall be deemed to be complete as an invention:

1) If an invention can be practiced repeatedly by a person having ordinary skill in the art and is composed with a sufficient level of specificity and objectivity such that the likelihood of achieving the technical effect sought to be achieved by the invention can be predicted, then the invention shall be deemed to be complete. Whether an invention is complete shall be judged by reference to the patent claims, by considering as a whole matters such as the objective, composition, and effect of the invention set out in the description of the

invention, in accordance with the state of the art at the time of filing; the recognition is not necessarily based solely on the specific embodiments in the description of the invention (see Supreme Court Decision 2017Hu523, January 17, 2019).

Meanwhile, in the case of an invention of a compound, since the technical effect which the invention seeks to achieve can be said to be the provision of a substance that is useful in the industry, it would be complete as an invention if the compound is capable of being prepared by a person having ordinary skill in the art, in accordance with the state of the art at the time of filing, through the description of the invention, and if it is composed with a sufficient level of specificity and objectivity such that its industrial utility can be predicted.

2) According to the following descriptions in the specification (Plaintiff's Exhibit 24) of the Subject Invention, the objective sought to be achieved by the Subject Invention is to provide aryl fused azapolycyclic compounds, specifically varenicline or a pharmaceutically acceptable salt thereof, which is defined by Formula I and can be used to treat dependencies on and addiction to nicotine (and/or tobacco products), etc.

> [0001] The present invention relates to aryl fused azapolycyclic compounds, as defined more specifically by Formula I below. Compounds of Formula I bind to neuronal nicotinic acetylcholine specific receptor sites and are useful in modulating cholinergic function. Such compounds are useful in the treatment of ...(omitted)... chemical dependencies and addictions selected from dependencies on or addictions to nicotine (and/or tobacco products), alcohol, benzodiazepines, barbiturates, opioids or cocaine ...(omitted)...
>
> [0005] The present invention relates to aryl fused azapolycyclic compounds of Formula I below and the pharmaceutically acceptable salts thereof.
>
> [0066] The present invention also relates to a pharmaceutical composition

for use in aiding the reduction of nicotine addiction or the cessation or lessening of tobacco use in a mammal, including a human, which comprises a compound of Formula I, or a pharmaceutically acceptable salt thereof, in an amount that is effective in aiding the reduction of nicotine addiction or the cessation or lessening of tobacco use, and a pharmaceutically acceptable carrier.

3) Furthermore, in the specification of the Subject Invention, the method for preparing varenicline and its hydrochloride is disclosed in Embodiment 26, and, by way of data which can confirm the formation of the above compound, data from nuclear magnetic resonance spectroscopy (^{1}H-NMR), data from gas chromatography mass spectrometry (GCMS), and melting points have been included (see Plaintiff's Exhibit 24, paragraphs [0341]–[0349]).

4) In addition, in the specification of the Subject Invention, it is stated that the compounds in Claim 1 aid the reduction of nicotine addiction or the cessation or lessening of tobacco; it also contains specific statements to the effect that, as a result of conducting a biological assay, which separated the membrane suspension prepared from rats' brain tissue and, using cytisine, etc. on such a suspension, measured the effect of nicotine-suppressing active compounds that bind to neuronal nicotinic acetylcholine-specific receptor sites, the compounds of the Subject Invention which were tested in the above assay were shown to exhibit IC_{50} values of less than 10 μM (see Plaintiff's Exhibit 24, paragraphs [0066] and [0154]–[0166]).

5) Therefore, from the position of a person having ordinary skill in the art, it is possible to prepare varenicline or a pharmaceutically acceptable salt thereof and confirm its formation, and the invention is composed with such level of specificity and objectivity that its industrial utility—that, as varenicline binds to neuronal nicotinic acetylcholine-specific receptor sites and modulates cholinergic function, it can be used in the treatment of dependencies on and addiction to

nicotine (and/or tobacco products), etc.—is sufficiently predictable; accordingly, the Subject Invention can be said to be complete.

C. Whether There Is Violation of Enablement Requirement

For the following reasons, the description of the invention is drafted with such level of clarity and detail that a person having ordinary skill in the art can easily practice the invention; therefore, the Subject Invention shall be deemed to satisfy the requirement of enablement:

1) Article 42(3) of the Patent Act requires the description of an invention to be drafted clearly and in detail such that a person having ordinary skill in the art would be able to easily practice the invention. This aims to clarify the technical content and scope sought to be protected by the patent, by disclosing the content of the invention with respect to which a patent application has been filed, so that third parties may easily understand it through the specification alone; accordingly, the level of description in the specification required by the above provision refers to a level which would enable a person having ordinary skill in the art to precisely understand the relevant invention on the basis of the description in the specification and at the same time repeat it, without carrying out undue experimentation or applying special knowledge in light of the state of the art at the time of filing.

Meanwhile, in the case of an ‘invention of a product’, since ‘practicing’ of the invention refers to actions such as production and use of the product, in the invention of a product, if a person having ordinary skill in the art can produce and use the product itself on the basis of the detailed description of the invention without carrying out undue experimentation or applying special knowledge in light of the state of the art at the time of filing of the patent application, and a person having ordinary skill in the art can sufficiently predict the effectiveness of the invention in light of the state of the art at the time of

filing of the patent application, even if it is not proved through specific experiments, etc., then the invention would satisfy the written description requirement prescribed above (see Supreme Court Decision 2014Hu2061, May 26, 2016).

2) As seen earlier in paragraph B, the specification of the Subject Invention discloses the specific method for preparing varenicline and its hydrochloride and, by way of methods which can confirm the formation of these substances, states three measured values from nuclear magnetic resonance spectroscopy (^{1}H-NMR), gas chromatography mass spectrometry (GCMS), and melting points, respectively. In addition, in the cases of pharmaceutically acceptable salts of varenicline other than varenicline hydrochloride, for which a specific method of preparation is not described, since these are salts that can be prepared through an acid–base reaction, which is widely known in the relevant technological field, by reacting varenicline free base with various acids, a person having ordinary skill in the art can, in the absence of special circumstances, easily prepare such salts based on the descriptions in the specification of the Subject Invention and the contemporaneous state of the art.

3) Furthermore, from the specification of the Subject Invention, a person having ordinary skill in the art can sufficiently predict its industrial utility that, as varenicline binds to neuronal nicotinic acetylcholine-specific receptor sites and modulates cholinergic function, it can be used in the treatment of dependencies on and addiction to nicotine (and/or tobacco products), etc.

4) Therefore, a person having ordinary skill in the art shall be deemed to be able to understand and repeat the invention precisely on the basis of the descriptions in the specification of the Subject Invention without carrying out undue experimentation or applying special knowledge.

D. Summary of Analysis

Taking together the matters considered above, the Subject Invention is complete as an invention, and, since the description of the invention is sufficiently clear and detailed such that a person having ordinary skill in the art can easily practice the invention, it satisfies the requirement of enablement. Therefore, the Subject Invention's scope of protection is recognized.

4. Whether Invention for Review Falls Within Scope of Protection of Subject Invention for Which Extension of Term Has Been Registered

A. Relevant Law

Article 89 of the old Patent Act (prior to its amendment on December 2, 2011 by Act No. 11117; hereinafter the same shall apply), by providing that ‘if a patented invention is an invention specified by Presidential Decree and requires an approval or registration, etc. pursuant to provisions of another statute (hereinafter, "approval, etc.") to be practiced but, due to tests on activity and safety, etc. needed for such an approval, etc. a long period of time is expended, then, notwithstanding the provision of Article 88(1), the term of the relevant patent may be extended by up to five years to compensate for the period during which the invention could not be practiced’, operates a regime whereby the term of a patent is extended by the period during which an invention could not be practiced due to efforts to obtain an approval, etc. under the Pharmaceutical Affairs Act, etc. (see e.g. Supreme Court Decision 2017Hu882, November 29, 2017). As a type of ‘invention specified by Presidential decree’ referred to above for which ‘a long period of time is expended’, subparagraph 1 of Article 7 of the Enforcement Decree of the old Patent Act mentions an invention of a drug which, in order for the patented invention to be practiced, requires an approval pursuant to the provisions of Article 26(1) or Article 34(1) of the old Pharmaceutical Affairs Act (prior to its amendment on April 11, 2007 by Act No. 8365).

Meanwhile, on the effect of a patent, the term of which has been extended, Article 95 of the old Patent Act provides that such an effect ‘does not extend to acts other than that of practicing the patented invention on the product relevant to approval, etc. (insofar as the purpose of the product is specified in the approval, etc., the product used for such a purpose), by reason of which the extension has been registered’. In prescribing the scope of effect of a patent, the term of which has been extended, in this way, the Patent Act does not use the patent claim as the reference but simply stipulates ‘practicing the patented invention on the product relevant to approval, etc., by reason of which the extension has been registered’; it does not limit the scope to practicing the ‘item’ relevant to approval, etc.

In view of such provisions of the statute and the purpose of the regime, the scope of a drug patent, the term of which has been extended, shall be judged by focusing on whether a drug is identical to the drug for which item approval has been obtained pursuant to the Pharmaceutical Affairs Act in order that the patented invention could be practiced, in terms of the specified active ingredient which is expected to show a therapeutic effect on a specified disease, the therapeutic effect, and the use. Even where there is a difference between the drug, for which the patentee has obtained item approval pursuant to the Pharmaceutical Affairs Act, and the invention for review in terms of pharmaceutically acceptable salts, etc., if that difference is no more than something that can easily be selected by a person having ordinary skill in the art, and the therapeutic effect or use arising from the pharmacological action of the active ingredient absorbed by the body is substantially the same, then the effect of the patent, the term of which has been extended, shall be deemed to extend to the invention for review (see Supreme Court Decision 2017Da245798, January 17, 2019).

B. Analysis

As has been seen earlier, in order to practice the Subject Invention, A Pharmaceutical Korea Ltd., a non-exclusive licensee of the Subject Invention, obtained an import approval pursuant to the Pharmaceutical Affairs Act for the drug relevant to approval at issue, which contains varenicline tartrate, and the invention for review relates to varenicline oxalate; the active ingredient of the drug relevant to approval at issue and that of the invention for review are the same in that they are both 'varenicline', and the difference lies in the form of salt that is pharmaceutically acceptable.

Therefore, in order to determine whether the invention for review falls within the scope of protection of the Subject Invention, for which an extension of term has been registered, a review must be carried out pursuant to the above principles of law as to whether the drug relevant to approval at issue and the invention for review are practically identical in terms of the therapeutic effect or use arising from the active ingredient, and whether the substitution of varenicline tartrate in the drug relevant to approval at issue with varenicline oxalate as in the invention for review is something that can easily be selected by a person having ordinary skill in the art; these points are considered below.

1) Whether therapeutic effect or use is practically identical

For the following reasons, the drug relevant to approval at issue and the invention for review shall be deemed to be practically identical in their therapeutic effect or use:

a) The active ingredient of the drug relevant to approval at issue and that of the invention for review are both varenicline; according to the descriptions in the specification of the Subject Invention, varenicline binds to neuronal nicotinic acetylcholine-specific receptor sites, is useful in modulating cholinergic function, and is useful in the treatment of conditions such as dependencies on and

addiction to nicotine (and/or tobacco products) (see Plaintiff's Exhibit 24, paragraph [0001]).

b) Meanwhile, based on the above pharmacological action of varenicline, the drug relevant to approval at issue obtained a drug import approval with supplementary therapy for smoking cessation treatment as its efficacy and effectiveness, and since the invention for review is also a pharmaceutical composition which has supplementary therapy for smoking cessation treatment as its use, the drug relevant to approval at issue and the invention for review must be seen as having uses that are practically identical.

c) Furthermore, in order to practice the invention for review, on August 8, 2018, the Defendant obtained a drug manufacturing and marketing approval from the Minister of Food and Drug Safety for a drug (hereinafter, the 'Defendant's product') with product names 'Nicotine Tablet 0.5 mg (Varenicline Oxalate Hydrate) and 'Nicotine Tablet 1 mg (Varenicline Oxalate Hydrate)', with 'supplementary therapy for smoking cessation treatment' as its efficacy and effectiveness.

The main content of the "Regulation on Pharmaceuticals Approval, Notification, and Review (Ministry of Food and Drug Safety Notification No. 2017-77, partly amended on September 29, 2017)", which applied at the time of application for approval of the Defendant's product, is as below; the Defendant's product was assessed to constitute a drug prescribed in Article 28(5) of the above Regulation on Review as a new salt (tartrate → oxalate hydrate) of the drug relevant to approval at issue, which had previously been approved, on the basis of data on absorption, distribution, metabolism, and excretion which, after administering a beagle with the Defendant's product, confirmed that the concentration of varenicline in the blood is equal to such a concentration following administration of the drug relevant to approval at issue (Plaintiff's

Exhibit 14). In other words, the invention for review: ① is a prescription drug which has been approved domestically for the first time as a drug containing a new salt of an active ingredient that is identical to that of the drug relevant to approval at issue, which has already been approved; ② has a basic chemical framework that is identical to the drug relevant to approval at issue; ③ is presumed to be almost equal to the drug relevant to approval at issue in terms of efficacy/effectiveness, usage/dose, side effects, pharmacological action, etc.; ④ as an orally administered drug, it is clear that it is definitely broken down in the digestive organ into an ingredient which is identical to that of the drug relevant to approval at issue to be absorbed; and ⑤ the type of salt in question constitutes a salt that is often used as a drug.

Article 2 (Definitions)

1–7. (omitted)

8. "Drug requiring safety–efficacy review data submission (hereinafter, "drug requiring data submission")" refers to a drug which is not a new drug but requires a safety–efficacy review on the basis of these provisions, and which falls under II in the Type of Drug and Scope of Data Submission in Enclosed Table 1.

9. "Incrementally modified drug" is a "drug requiring data submission" under subparagraph 8, which falls within any one of the following items and is deemed by the Minister of Food and Drug Safety to have been improved, in terms of safety, efficacy, and usefulness (medication compliance and convenience, etc.) compared to drugs that have already been approved (reported), or to involve an inventive step in terms of pharmaceutical technology.

A–C (omitted)

D. A prescription drug which has been approved domestically for the first time as a drug which contains a new salt or isomer of an active ingredient that is identical to that of a new drug which has already been approved

Article 28 (Scope of Submission, etc. of Data Required for Review of Safety–Efficacy of Incrementally Modified Drugs, etc.)

①–④ (omitted)

⑤ A drug which, notwithstanding Article 27(1), falls under subparagraph 9(d) of Article 2, wherein the basic chemical structure is identical (e.g. isomer, salt type, and ester compound which is broken down within the body to be converted into to an active daughter nucleus that is identical to that of a previously approved (or reported) item) to that of a drug that has been approved domestically; the efficacy, effectiveness, usage-dose, side effects, pharmacological action, etc. are presumed to be almost equal to those of an approved drug; as an orally administered drug, it is clear that it is definitely broken down in the digestive organ into an ingredient which is identical to that of a domestically approved drug to be absorbed; and such a salt, etc. is often used as a drug, may substitute the data set out in subparagraphs 4 to 6[7] of Article 7 with data on clinical trial results.

Accordingly, the Defendant was able to substitute data on toxicity and data on pharmacological action with data on clinical trial results; specifically, the data which the Defendant submitted for the above review after carrying out experiments itself are the data considered above on absorption and excretion by a beagle, data proving bioequivalence[8] of the Defendant's product's 1 mg formulation and Champix 1 mg, the drug relevant to approval at issue, by way of data on clinical trial results, and data on a comparative dissolution test which was intended to replace a bioequivalence test on the Defendant's product's 0.5 mg formulation (Plaintiff's Exhibit 14).

d) Meanwhile, formulating a drug with the active ingredient in its salt form, having been combined with an acid, rather than in its free-base form, is aimed at increasing the solubility, absorption rate, and stability of the drug; where the acid that forms the salt has been changed, the above characteristics

7) Subparagraph 4, data on toxicity; subparagraph 5, data on pharmacological action; and subparagraph 6, data on clinical trial results.

8) "Bioequivalence" means that after two drugs with the same ingredient (i.e. a test drug and a comparison drug) have been administered to the body, the extent of absorption and the pharmacokinetic characteristics are identical; the Ministry of Food and Drug Safety assesses this on the basis of the two drugs' C_{max} and AUC.

cannot remain completely the same. While the impact such characteristics have on the therapeutic effect ought to be judged individually depending on the issues at hand, since the actual therapeutic effect exhibited after the administration of a drug in the form of a salt that has been combined with an acid is due to the pharmacological action resulting from the absorption within the body of the active ingredient after its separation from the acid, even if the type of salt which has bonded with the drug has changed, where the concentration of the active ingredient in the blood is assessed to be equal, then, in the absence of special circumstances, it cannot be said that there is a meaningful difference in terms of therapeutic effect resulting from the active ingredient.

On the one hand, the drug relevant to approval at issue is a compound wherein varenicline and tartaric acid have formed a weak bond through ionic bonding, and when it enters the stomach following oral administration, it disassociates[9] with the result that it is separated into varenicline and tartaric acid. Tartaric acid which has been separated in this way is excreted from the body via the internal metabolism, and it is only varenicline, the active ingredient, which is absorbed in the small intestine to bind to α4β2 nerve cells' nicotinic acetylcholine receptors, exhibiting the pharmacological action of preventing nicotine from binding to those receptors. The invention for review, on the other hand, is also orally administered, disassociated in the stomach and separated into varenicline and oxalic acid, with only varenicline being absorbed in the small intestine to bind to α4β2 nerve cells' nicotinic acetylcholine receptors, resulting in the pharmacological action of preventing nicotine from binding to those receptors.

Of course, since the drug relevant to approval at issue and the invention for review use different types of salt, they can display some differences in their

9) "Disassociation" is the process by which a solid ionic compound such as sodium chloride (NaCl) separates within a solution into ions.

physicochemical or pharmaceutical characteristics, such as solubility, absorption rate, and stability. However, when the following points are considered, the invention for review and the drug relevant to approval at issue are not meaningfully different in terms of the therapeutic effect that results from the pharmacological action of varenicline, the active ingredient, and must be deemed to be practically identical: the circumstance that, as seen earlier, when the Defendant applied for approval of the Defendant's product to practice the invention for review, by way of clinical trial data it conducted a clinical trial with the objective of carrying out a comparative evaluation of the pharmacokinetic characteristics and safety/drug tolerance of the drug relevant to approval at issue, which has been approved previously, and the Defendant's product, and, by demonstrating that concentration in the blood of varenicline, the active ingredient in both drugs, is at an equal level, merely proved their bioequivalence and, save for this, obtained the approval without conducting any clinical trial that could confirm the therapeutic effect and side effects of the Defendant's product itself; and, accordingly, the usage, dose, and precautions for use, being the specific content of approval for the Defendant's product, were all drafted on the basis of data on clinical trials and data on preclinical studies regarding toxicity and pharmacological action conducted by the Plaintiff (Plaintiff's Exhibits 13 and 14).

e) In this regard, the Defendant argues to the effect that since the difference in the pharmaceutical characteristics, which stems from the difference in the type of salt used by the invention for review and the drug relevant to approval at issue, respectively, has an impact on the therapeutic effect, such difference must be taken into account when judging whether the therapeutic effect is practically identical, with the result that the invention for review and the drug relevant to approval at issue are not identical in their therapeutic

effects.

However, as has been seen earlier, despite the difference in the type of salt, the drug relevant to approval at issue and the invention for review, both as orally administered drugs, have identical administration channels and absorption processes, and, with the concentration in the blood of varenicline, as the active ingredient, being at an equal level, there is no meaningful difference in terms of therapeutic effect; accordingly, the drug relevant to approval at issue and the invention for review must be deemed to be practically identical. Therefore, the Defendant's argument above cannot be accepted.

2) Whether selection of salt is easy

For the following reasons, it is proper that varenicline oxalate in the invention for review be viewed as a form of a salt that can easily be selected by a person having ordinary skill in the art:

a) First, according to the statements in the specification of the Subject Invention (Plaintiff's Exhibit 24), as examples of a pharmaceutically acceptable acid addition salt of varenicline, salts of oxalic acid are expressly stated in addition to those of tartaric acid.

> [0075] The present invention also relates to the pharmaceutically acceptable acid addition salts of the compounds of Formula I. Examples of pharmaceutically acceptable acid addition salts of the compounds of Formula I are the salts of hydrochloric acid, *p*-toluenesulfonic acid, fumaric acid, citric acid, succinic acid, salicylic acid, oxalic acid, hydrobromic acid, phosphoric acid, methanesulfonic acid, tartaric acid, malate, di-*p*-toluoyl tartaric acid, and mandelic acid.

b) Further, as seen earlier, in the review process for approval, the Defendant's product was merely assessed as constituting a drug under Article 28(5) of the above Regulation on Review on the grounds that the type of salt it contains is something that is often used as a drug, and so on; it has not been

designated as an incrementally modified drug by being recognized as having been improved in terms of safety, efficacy, and usefulness compared to the drug relevant to approval at issue, or as involving an inventive step in its pharmaceutical technology. Meanwhile, the examiner of the Ministry of Food and Drug Safety considered that data relating to toxicity was not necessary for the review process regarding the approval application material submitted by the Defendant, because examples of using oxalate in drugs had been confirmed, and the amount used fell within the amount that had previously been approved (see p. 28, Plaintiff's Exhibit 14).

c) In addition, according to the statements in "Handbook of Pharmaceutical Salts," a book published in 2002 on pharmaceutically used salts, salt-forming agents can be divided into three classes; among these, oxalic acid, which has been used in the invention for review, is not a naturally occurring substance, but since it has been classified to date as a Class II salt-forming agent which exhibits low toxicity and superior tolerance even when used in large quantities (Plaintiff’s Exhibit 16), it can easily be selected by a person having ordinary skill in the art. GRAS, on the other hand, is a status granted by the US Food and Drug Administration (FDA) in relation to the safety of food additives (Plaintiff’s Exhibit 19), and whether a substance is recognized as GRAS does not have a decisive impact on the decision as to whether it would be easy to select a certain acid as a drug’s salt-forming agent.

d) The above circumstances back the argument that varenicline oxalate constitutes a form of a salt that can be generally selected, and it is not possible to find any other circumstance that would hinder a person having ordinary skill in the art from selecting varenicline oxalate. Therefore, it would be right to view a person having ordinary skill in the art as being able to select oxalic acid as varenicline's salt-forming agent without particular difficulty to form varenicline

oxalate.

e) Discussion of Defendant's arguments

① In response, the Defendant argues to the effect that differences in the pharmaceutical characteristics have an impact on the therapeutic effect, and this must be taken into account when judging how easy it would be to select a salt or whether the therapeutic effect is practically identical; that the invention for review has a different therapeutic effect than the drug relevant to approval at issue due to the pharmaceutical characteristics of oxalate, which can be distinguished from tartrate; and that it would not be easy for a person having ordinary skill in the art to select oxalate.

However, as has been seen earlier, in order to practice the invention for review, approval was obtained for the Defendant’s product following an exemption from submission of a considerable amount of data relating to safety and efficacy, on the premise that through a bioequivalence test, varenicline tartrate and varenicline oxalate were shown not to have a meaningful difference in terms of therapeutic effect, and when such circumstance is taken into account, it cannot be said that a meaningful difference in therapeutic effect was brought about through the above change in the salt, and the Defendant’s argument, which is based on this premise, cannot be accepted and need not be considered further.

② Further, the Defendant argues to the effect that since the Plaintiff has obtained a separate patent registration for varenicline tartrate, and, based on the statements in the specification thereto, there is negative information on the other salts set out in the specification ofthe Subject Invention, including oxalate, it would not be easy for a person having ordinary skill in the art to select oxalate as has been done in the invention for review.

On February 3, 2006, the Plaintiff obtained a patent registration for varenicline tartrate under Patent No. 551184 (Defendant’s Exhibit 20), and the

specification thereof includes the following (Defendant's Exhibit 2):

> The L-tartrate salt of the present invention exhibits properties, including those of high solid-state stability and compatibility with certain drug product formulation excipients, that render it superior to previously disclosed salts of 5,8,14-triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]-hexadeca-2(11),3,5,7,9-pentaene. Further, the D-tartrate and D.L-tartrate salts exhibit properties that make them appropriate for drug product formulation use. (see rows 4–6, p. 3)
>
> Although in general the salts of 5,8,14-triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]-hexadeca-2(11),3,5,7,9-pentaene are all crystalline, the majority of such salts are so significantly hygroscopic as to render them poor candidates for pharmaceutical formulation use. The L-tartrate salt of 5,8,14-triazatetracyclo[10.3.1.$0^{2.11}$.$0^{4.9}$]-hexadeca-2(11),3,5,7,9-pentaene is very slightly hygroscopic, has high aqueous solubility and is highly melting. These characteristics, combined with its relative inertness towards common excipients, make it highly suitable for pharmaceutical formulation use. (see rows 2–6 from the bottom, p. 4[10])

However, since the above content of the specification should be viewed as doing no more than mentioning in general terms varenicline tartrate's strengths from the perspective of a study of formulations rather than specifically comparing tartrate salts with certain forms of salts, it cannot be said to induce a person having ordinary skill in the art, having come across it, to abandon the selection of an oxalate salt itself, or to make such a selection difficult. Therefore, the Defendant's arguments in this regard cannot be accepted.

C. Summary of Analysis

Taking together the points considered above, although the Defendant's invention for review differs from the drug relevant to approval at issue in its salt, it has an identical active ingredient, varenicline, and is practically identical

10) The relevant content is set out on p. 8 based on the original specification of Patent No. 551184, but as a result of the Defendant extracting a part of the above specification and submitting it as Defendant's Exhibit 2, it is set out on p. 4 based on the documentary evidence submitted by the Defendant.

in terms of therapeutic effect and use that results from the active ingredient, and a person having ordinary skill in the art can easily select the changed salt; therefore, the invention falls within the scope of protection of the Subject Invention, for which an extension of term has been registered.

5. Conclusion

Since the invention for review falls within the scope of protection of the Subject Invention, for which an extension of term has been registered, in reaching a conclusion which is inconsistent with the above analysis, the IPTAB erred in its decision. The Plaintiff's claim to revoke the IPTAB decision is therefore well grounded and shall be granted.

Presiding Judge Kyuhong LEE

Judge Sungyop WOO

Judge Jinhee LEE

[Appendix]

Explanatory Document on Invention for Review

1. Title of Invention for Review

Pharmaceutical Composition Containing Varenicline Oxalate

2. Detailed Explanation of Invention for Review

The invention for review, as a pharmaceutical composition which contains varenicline oxalate, does not contain varenicline tartrate.

The pharmaceutical composition according to the invention for review is useful in a supplementary therapy for smoking cessation treatment.

The pharmaceutical composition according to the invention for review may contain one or more excipients selected from pharmaceutically acceptable diluents, binders, disintegrants, glidants, lubricants, etc. and may be formulated in the form of a tablet or capsule. End.