Appeal decision

Appeal No. 2017-12572

USA
Appellant InfaCare Pharmaceutical Corporation

Patent Attorney KAJI, Toshikazu

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The case of appeal against the examiner's decision of refusal for Japanese Patent Application No. 2014-544965 "STANNSOPORPHIN" [International Publication: June 6, 2013 as WO2013/082559, National Publication: January 5, 2015 as National Publication of International Patent Application No. 2015-500243] has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The application is an application with an international filing date of November 30, 2012 (claiming priority under Paris Convention with a priority date of December 1, 2011 in the United States (US)), for which a notice of reason for refusal was issued on August 8, 2016, a written opinion and a written amendment were submitted on February 9, 2017, and a decision of refusal was issued on April 14. In response, a notice of appeal was filed on August 24.

No. 2 The Invention

The inventions according to Claims 1 to 10 of the present application (hereinafter referred to as "the present invention 1" to "the present invention 10", respectively, or collectively referred to as "The Invention") are specified in the following by the matters recited in Claims 1 to 10 of the scope of the claims that has been amended by the written amendment on February 9, 2017:

"[Claim 1]

Stannsoporfin for the use in a method of treating hyperbilirubinemia or the symptoms thereof in an infant,

comprising administering a therapeutic amount of Stannsoporfin to the infant with hyperbilirubinemia where no exclusion factor is present and at least one of a baseline total bilirubin level is elevated above a predetermined threshold and at least one risk factor is present;

said exclusion factor is selected from a clinical suggestion of neonatal thyroid disease, current uncontrolled thyroid disease in the mother excluding maternal Hashimoto's thyroiditis, treatment or need for treatment in the infant with medications

that may prolong the QT interval excluding eythromycin ointment for eye prophylaxis, a family history of Long QT syndrome, a family history of sudden infant death syndrome, known porphyrias, risk factors for porphyrias, a family history of porphyrias, a maternal history of systemic lupus erythematosus, maternal use of phenobarbital 30 days before, or after delivery, if breastfeeding, maternal current drug or alcohol abuse, maternal history of drug or alcohol abuse, an Apgar score less than or equal to 6 at age 5 minutes, congenital anomalies or infections, acidosis, sepsis, hepatitis; an excess risk of requiring surgery or exposure to operating room lights in the foreseeable future, cardiorespiratory distress defined as a respiratory rate >60 breaths per minute, a diagnosis of transient tachypnea of the newborn, abnormal auditory or ophthalmologic findings, clinically significant abnormalities on a screening laboratory evaluation, elevated direct or conjugated bilirubin (>1.0 mg/dL if TSB is <5.0 mg/dL or >20% of TSB if TSB is >5.0 mg/dL), persistent hypoglycemia (blood glucose <40 mg/dL) despite standard of-care treatment, liver diseases defined as ALT and/or AST greater than 2 times the upper limit of normal [ULN], abnormal renal function defined as creatinine and/or blood urea nitrogen greater than 2 times the ULN, any blood smear finding of -structural red cell abnormalities, such as spherocytosis, not caused by isoimmune hemolysis, temperature instability defined as temperature consistently (3 consecutive times) greater than 36°C and/or greater than 37.5°C axillary, use of photosensitizing drugs or agents; dehydration, defined by hypernatremia, serum sodium greater than ULN, use of intravenous immunoglobulin (IVIG) or albumins, post-delivery treatment with medications that are known or suspected to displace bilirubin from albumin (e.g., ceftriaxone or sulfa-based antibiotics), serious morbid conditions including but not limited to pulmonary disease, cardiovascular disease, exposure to any investigational medications or devices after delivery, participation in a clinical trial, and combinations thereof,

said at least one risk factor is hemolytic disease,

wherein the predetermined threshold is the level about 1 to about 3 mg/dL below the threshold for administration of phototherapy according to 2004 AAP nomogram corresponding to the infant's age,

wherein said therapeutic amount of Stannsoporfin is from about 0.75 mg/kg to about 5 mg/kg on the basis of the infant's weight.

[Claim 2]

Stannsoporfin according to Claim 1, wherein the infant is Coombs positive.

[Claim 3]

Stannsoporfin according to Claim 1, further comprising determination of post treatment total bilirubin levels following administration of the Stannsoporfin is performed from about 6 and to about 72 hours after administering the Stannsoporfin to the infant.

[Claim 4]

Stannsoporfin according to Claim 1, wherein the predetermined threshold is selected from about 1 to 3 mg/dL below a threshold for administration of phototherapy to an infant up to about 12 hours of age per the 2004 AAP guidelines, about 1 mg/dL below a threshold for administration of phototherapy to an infant up to about 12 hours

of age per the 2004 AAP guidelines, about 2 mg/dL below a threshold for administration of phototherapy to an infant up to about 12 hours of age per the 2004 AAP guidelines, at the threshold for administration of phototherapy to an infant up to about 12 hours of age per the 2004 AAP guidelines, about 1 to 3 mg/dL below a threshold for administration of phototherapy to an infant from about 12 to 48 hours of age per the 2004 AAP guidelines; about 2 mg/dL below a threshold for administration of phototherapy to an infant from about 12 to 48 hours of age per the 2004 AAP guidelines, about 3 mg/dL below a threshold for administration of phototherapy to an infant from about 12 to 48 hours of age per the 2004 AAP guidelines.

[Claim 5]
Stannsoporfin according to Claim 1, wherein administering a therapeutic amount of Stannsoporfin is performed at a time selected from within about 6 hours of birth, within about 12 hours of birth, within about 24 hours of birth, and within about 48 hours of birth.

[Claim 6]
Stannsoporfin according to Claim 1, wherein the infant is of a gestational age from about 35 to about 43 weeks.

[Claim 7]
Stannsoporfin according to Claim 1, wherein a therapeutic amount of Stannsoporfin is selected from 0.75 mg/kg, 1.5 mg/kg, 3.0 mg/kg, and 4.5 mg/kg on an infant's weight basis.

[Claim 8]
Stannsoporfin according to Claim 1, wherein Stannsoporfin is administered by intramuscular injection.

[Claim 9]
Stannsoporfin according to Claim 1, further comprising administering phototherapy where total bilirubin levels following administration of Stannsoporfin are above the baseline total bilirubin levels.

[Claim 10]
Stannsoporfin according to Claim 1, further comprising determining post treatment total bilirubin levels following administration of Stannsoporfin, wherein post treatment total bilirubin levels are at least 5% below the baseline total bilirubin levels 24 hours after administering a therapeutic amount of Stannsoporfin to the infant, wherein post treatment total bilirubin levels are at least 10% below the baseline total bilirubin levels 48 hours after administering a therapeutic amount of Stannsoporfin to the infant, or wherein post treatment total bilirubin levels are at least 20% below the baseline total bilirubin levels 72 hours after administering a therapeutic amount of Stannsoporfin to the infant."

No. 3 Outline of reasons for refusal stated in the examiner's decision

Reasons 1 for refusal stated in the examiner's decision is that the present invention is an invention of Stannsoporfin itself, and the compounds described in Cited Documents 1 and 2 do not differ from those of Stannsoporfin of Claims 1 to 10 as a compound itself, and thus the present invention corresponds to the provision of Article 29(1)(iii) of the Patent Act, and is not patentable.

Further, Reason 2 shows that the present invention is not patentable under the provision of Article 29(2) of the Patent Act.

No. 4 Judgment by the body

(1) Inventions described in the Cited Documents

Pediatrics, 1999, 103(1), p.1-5 (hereinafter referred to as "Cited Document 1".), a publication distributed before the priority date of the present application cited in the reasons for refusal stated in the examiner's decision and National Publication of International Patent Application No. 2010-505854 (hereinafter referred to as "Cited Document 2") disclose the following matters:

Note that the original text of Cited Document 1 is written in foreign language, and thus is shown by a translation from the body. Note that underlines are provided by the body.

- Cited Document 1

(1a)

"Objective. To assess the efficacy of Sn-mesoporphyrin (SnMP), a potent inhibitor of bilirubin production, in: a)...(omitted)...

... (Omitted)...

Conclusion. A single dose of SnMP proved effective in controlling hyperbilirubinemia in full-term breastfed newborns with high bilirubin levels between 48 and 96 hours...(Omitted)..." (ABSTRACT)

- Cited Document 2

(2a)

"[Claim 1]

A method of treating hyperbilirubinemia in an infant of at least about 38 weeks gestational age, comprising:

administering a low dose of stannsoporfin to an infant in need thereof." (The scope of claims)

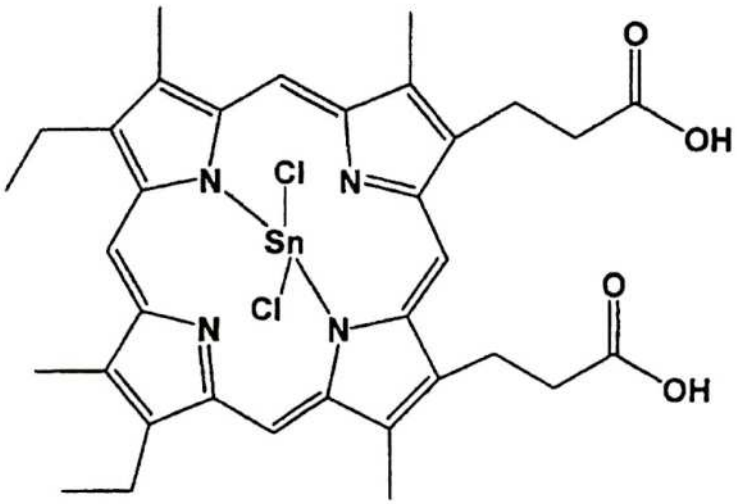
(2b)

"[0030]

Stannsoporfin (tin (IV) mesoporphyrin IX dichloride; Chemical Abstracts Registry Number 106344-20-1) is also known by the trade name Stanate(R), (which is a registered trademark of InfaCare Pharmaceutical Corp., Plymouth Meeting, Pa). Stannsoporfin has the following structure:

[0031]

[Chemical Formula 1]



having molecular formula C34H36Cl2N4O4Sn and molecular weight 754.29."
(paragraphs [0030] to [0031])

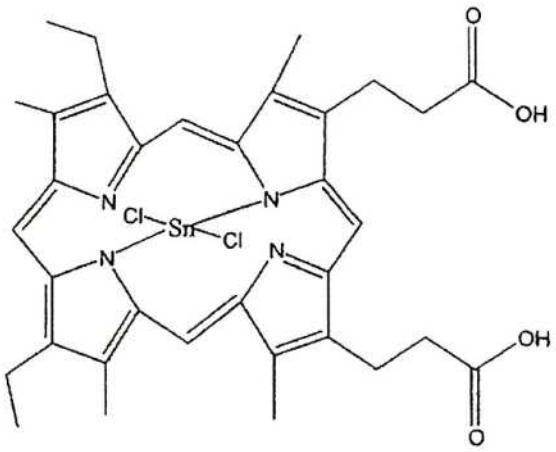
It can be seen from the above (1a) that Cited Document 1 describes an invention of "A compound of Sn-mesoporphyrin" (hereinafter referred to as "Cited 1 Invention").

Further, it can be seen from the above (2a) and (2b) that Cited Document 2 describes an invention of " A compound of Stannsoporfin (tin (IV) mesoporphyrin IX dichloride." (hereinafter referred to as "Cited 2 Invention").

(2) Comparison / Judgment

The specification of the present application discloses in paragraph [0084] that "In some embodiments, the metalloporphyrin is tin mesoporphyrin (also referred to as stannsoporfin)" and in paragraphs [0158] to [0159] that "In some embodiments, the metalloporphyrin is tin IV mesoporphyrin IX dichloride (also called stannsoporfin or SnMP)." The following chemical formula is shown as a structure of tin IV mesoporphyrin IX dichloride:

[Chemical Formula 1]



It can be seen from these descriptions that "Stannsoporfin" of the present invention 1 is tin mesoporphyrin. Thus "Sn-mesoporphyrin" of Cited 1 Invention and "Stannsoporfin (tin (IV) mesoporphyrin IX dichloride)" of Cited 2 Invention both correspond to "Stannsoporfin" of the present invention 1.

The present invention 1 is specified by a number of matters specifying the use of "Stannsoporfin", such as "for the use in a method of treating hyperbilirubinemia or the symptoms thereof in an infant" and "comprising administering a therapeutic amount of Stannsoporfin to the infant with hyperbilirubinemia where no exclusion factor is present and at least one of a baseline total bilirubin level is elevated above a predetermined threshold and at least one risk factor is present", in which every last word is expressed by an expression of "Stannsoporfin". Thus in summary, it is recognized as an invention of a compound of "Stannsoporfin". Stannsoporfin itself is not changed as a compound no matter how the use is specified, and thus the present invention 1 is an invention of a compound Stannsoporfin itself, regardless of the matters specifying the use.

Consequently, the present invention 1 is no different as a compound from Cited 1 Invention or Cited 2 Invention, respectively.

Further, the present inventions 2 to 10 depend from the present invention 1, and these inventions respectively include the matters specifying their uses, whereas the last word is expressed by "Stannsoporfin.". Therefore, similar to the present invention 1, the present inventions 2 to 10 are also the inventions of a compound Stannsoporfin itself.

Consequently, the present inventions 2 to 10 are also no different as a compound from the Cited 1 Invention or Cited 2 Invention, respectively.

As aforementioned, the present inventions 1 to 10 are the inventions described in Cited Document 1 or Cited Document 2.

(3) Appellant's allegation

The Appellant mainly repeats in the written opinion and a notice of appeal the counterargument to the effect that none of the cited document describes the use specified by the present invention, the present invention is different in its use from the

invention described in Cited Documents, and finally involves an inventive step. The Appellant fails to express any particular opinion on Reason 1, particularly the fact that the present invention is an invention of Stannsoporfin itself regardless of the matters specifying the use.

As discussed above, however, it must be said that the present inventions 1 to 10 are inventions of the compound Stannsoporfin itself, regardless of how the use is specified, and it does not mean specifying compounds itself as different ones. Thus there is no difference between Cited 1 Invention or Cited 2 Invention and the present invention. Therefore, the Appellant's allegation cannot be accepted.

Therefore, even if taking into account the Appellant's allegation, the present inventions 1 to 10 are still the inventions described in Cited Document 1 or Cited Document 2.

No. 5 Conclusion

For the above reasons, the present inventions 1 to 10 are described in Cited Document 1 or Cited Document 2. Thus the inventions correspond to the inventions specified in Article 29(1)(iii) of the Patent Act and are thus not patentable.

Therefore, the appeal decision shall be made as described in the Conclusion.

August 1, 2018

Chief administrative judge: TAKIGUCHI, Naoyoshi
Administrative judge: ASANO, Mina
Administrative judge: MAEDA, Kayoko