Patent Right	Date	March 25, 2021	Court	Intellectual Property High Court, Second Division
	Case number	2020 (Gyo-Ke) 10097		

- An intervener that intervened in a trial for invalidation under Article 148, paragraph (1) of the Patent Act has a standing to be sued as a "petitioner" under Article 179, paragraph (1) of the Patent Act.
- Whether it was necessary to receive a disposition under Article 14 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices for working a patented invention related to pharmaceuticals should be determined in light of the reasons for which the Patent Act institutes the system for extending a patent term, and in this process, the content of the disposition should be determined substantially from such perspective and should not be determined formally only on the basis of what is described as the "active components" in a certificate of marketing approval.
- A case in which the court determined that: in light of such factors as the significance in adopting the form of a salt for a pharmaceutical compound, the awareness of this among persons skilled in the art, the content of the tests conducted for applying for a marketing approval, and the information described in the package insert and interview form, it is inappropriate to determine formally that the active component of the pharmaceutical product subject to the disposition is "nalfurafine hydrochloride," which was described in the certificate of marketing approval issued for a prior disposition; rather, it is appropriate to find that the subject pharmaceutical product substantially have, as its active components, both "nalfurafine," which is a free base that attracted attention in the examination for approval of the subject pharmaceutical product as a component having efficacy and effects, and "nalfurafine hydrochloride," which is its active ingredient mixed in the subject pharmaceutical product.
- If it is not found that it was necessary to receive a disposition specified by Cabinet Order as referred to in Article 67, paragraph (2) of the Patent Act prior to the amendment by Act No. 108 of 2016, with regard to a part of the "use" of the subject product for which the patent term extension was registered, it is possible to invalidate only the relevant part of the registration of extension in a trial for invalidation.

Case type: Rescission of Trial Decision to Invalidate Registration of Patent Term Extension

Result: Partially Granted

References: Article 67, paragraph (4) of the Patent Act; Article 67, paragraph (2),

Article 125-3, paragraph (1), item (i), and Article 125-2, paragraph (1), item (i) of the Patent Act prior to the amendment by Act No. 108 of 2016; Article 14 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices; Article 148, paragraph (1) and Article 179 of the Patent Act
Related rights, etc.: Patent No. 3531170, Application for Registration of Patent Term Extension No. 2017-700309
Decision of JPO: Invalidation No. 2020-800003

Summary of the Judgment

1. This case is a lawsuit seeking rescission of a trial decision made by the JPO in which the JPO invalidated the registration of patent term extension regarding a patent right for an invention titled "Antipruritic agent" (hereinafter this invention is referred to as the "Invention" and this registration of the patent term extension is referred to as the "Registration of Extension"). The issues of this case are: [i] whether an intervener that intervened in the trial under Article 148, paragraph (1) of the Patent Act (hereinafter such intervener is referred to as an "intervener under paragraph (1)," and intervening under that paragraph is referred to as "intervening under paragraph (1)") has standing to be sued in a lawsuit seeking rescission of a trial decision; [ii] in order to work the Invention, whether it was necessary to receive the disposition under Article 14 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Pharmaceuticals and Medical Devices Act") for working a patented invention related to pharmaceuticals (the disposition in question is hereinafter referred to as the "Disposition"); and [iii] if there are grounds for invalidation regarding a part of a registration of extension, whether the registration of extension can be invalidated only with regard to the relevant part thereof.
2. In this judgment, the court partially rescinded the JPO decision, determining that: an intervener under paragraph (1) has standing to be sued; it was necessary to obtain the Disposition in order to work the Invention; and a registration for extension can be invalidated only partially. The court's determination is as outlined below.
(1) Whether an intervener under paragraph (1) has standing to be sued

Article 148, paragraph (1) of the Patent Act provides that "A person that may file a request for a trial pursuant to Article 132, paragraph (1) may intervene in the trial as a petitioner up until such time as the proceedings reach a conclusion," thus clearly stipulating that an intervener under paragraph (1) may intervene in a trial for patent invalidation or trial for invalidation of registration of patent term extension as a

"petitioner." Consequently, an intervener under paragraph (1) is construed to have a standing to be sued as a "petitioner" under Article 179, paragraph (1) of the Patent Act.

In addition, only a person that may file a request for a trial for invalidation may intervene in the trial under paragraph (1), and it is understood that an intervener under paragraph (1) is naturally entitled to act in respect of all trial or appeal proceedings even in the absence of provisions such as Article 148, paragraph (4) of the Patent Act. What is more, it is provided that an intervener under paragraph (1) may continue to pursue the trial proceedings even after the original party withdraws the request for that trial (paragraph (2) of that Article). These facts represent that an intervener under paragraph (1) truly has a status of "petitioner," and this results in an interpretation that an intervener under paragraph (1) has a standing to be sued in a lawsuit seeking rescission of a trial decision.

(2) Whether it was necessary to obtain the Disposition in order to work the Invention

A. The purpose of the system for registration of patent term extension is to allow the patentee to reclaim a period of time during which the patentee has been unable to work the patented invention because of the necessity to receive a Cabinet Order disposition. Therefore, whether it was necessary to receive the Disposition in order to work the Invention should be determined in light of the reasons for which the Patent Act institutes such system for extending a patent term, and in this process, the content of the Disposition should be determined substantially from such perspective and should not be determined formally only on the basis of what is described as the "active components" in a certificate of approval under Article 14 of the Pharmaceuticals and Medical Devices Act. This view can be understood as conforming to the purport of the judgment of the Third Petty Bench of the Supreme Court, 2014 (Gyo-Hi) 356, rendered on November 17, 2015, Minshu Vol. 69, No. 7, at 1912.

B. Taking into account such factors as the significance in adopting the form of a salt for a pharmaceutical compound, the awareness of this among persons skilled in the art, the content of the tests conducted for applying for a marketing approval, and the information described in the package insert and interview form, it is inappropriate to determine formally that the active component of the pharmaceutical product subject to the Disposition (hereinafter referred to as the "Pharmaceutical Product") is "nalfurafine hydrochloride," which was described in the certificate of marketing approval issued for Prior Disposition. Rather, it is appropriate to find that the Pharmaceutical Product substantially have, as its active components, both "nalfurafine," which is a free base that attracted attention in the examination for approval of the Pharmaceutical Product as a component having efficacy and effects, and "nalfurafine hydrochloride," which is

its active ingredient mixed in the Pharmaceutical Product.

Consequently, there is an error in the JPO decision in which the JPO considered "nalfurafine hydrochloride" as the sole active component of the Pharmaceutical Product and denied "nalfurafine" as its active component, and finally determined that it cannot be said that it was necessary to receive the Disposition in order to work the Invention.

(3) If there are grounds for invalidation regarding a part of the registration of extension, whether the registration of extension can be invalidated only with regard to relevant part thereof

Since the Registration of Extension was made in a manner such that it covered the "improvement of pruritus for chronic liver disease patients," for which Prior Disposition had already made it possible to work the Invention, it cannot be said that it was necessary to receive the Disposition with regard to the part of the Registration of Extension in which the "improvement of pruritus for chronic liver disease patients" is designated as the "use" of the subject product. Thus, there are grounds for invalidation regarding a part of the Registration of Extension. If there are grounds for invalidation regarding a part of a registration of extension, there is no reason for invalidating the registration of extension in whole by regarding it as being indivisible. Rather, if a disposition specified by Cabinet Order as referred to Article 67, paragraph (2) of the Patent Act prior to the amendment by Act No. 108 of 2016 is not found to have been necessary, with regard to a part of the "use" of the subject product for which the extension was registered, it is construed that the registration of extension may be and should be invalidated only with regard to the relevant part in a trial for invalidation.

It is understood that the JPO invalidated the Registration of Extension only partially based on the fact that Prior Disposition had already made it possible to work the Invention for the part of the "use" of the subject product, i.e., the "improvement of pruritus for chronic liver disease patients," and in this respect, the JPO decision can be affirmed.