Judgments of Intellectual Property High Court, Third Division
Date of the Judgment: 2005.11.16
Case Number: 2005(Gyo-Ke)No.10184

Title(Case):
A case where, holding that there seems to have been no need to obtain approval specified by Cabinet Order for the exploitation of the patented invention, the court upheld the JPO decision to refuse an application for registration of extension to the term of the patent right

Reference: Article 67-3(1)(i) of the Patent Act

Summary of the Judgment:

X, et al. hold a patent right for a patented invention entitled "housing for ocular perfusion and irrigation liquid bag" (hereinafter referred to as the "Patent"). The patented invention relates to a housing for an ocular perfusion and irrigation liquid bag equipped with a multi-chamber bag that houses glutathione solution used for intraocular and extraocular perfusion and irrigation upon ophthalmic surgery, as well as equipped with a pH indicator whereby pH changes due to CO2 generation can be visually observed from changes in color tone of the solution.

X, et al. filed an application for registration of extension of the term of the Patent (hereinafter referred to as the "Application") based on the drug approval obtained under Article 14(1) of the Pharmaceutical Affairs Act for "oxiglutathione solution-containing kit," which contains oxiglutathione as an active ingredient and is used for "ocular perfusion and irrigation upon ophthalmic surgery" (this approval shall hereinafter be referred to as the "Approval").

Prior to the granting of the Approval, a third party had already obtained approval under the Pharmaceutical Affairs Act for a drug that contains oxiglutathione as an active ingredient and is used for ocular perfusion and irrigation in ophthalmic surgery (this approval shall hereinafter be referred to as the "Preceding Approval").

The JPO made an appeal decision to refuse the Application pursuant to Article 67-3(1)(i) of the Patent Act (hereinafter referred to as the "Act") on the grounds of the existence of the Preceding Approval.

Against the JPO decision, X, et al. argued that the JPO decision, based on the misconstruction of Article 67-3(1)(i) of the Act, erroneously determined that there seemed to have been no need to obtain the Approval for the exploitation of the patented invention.

The court dismissed the claim of X, et al., holding as follows.

With respect to the system for extension of the term of a patent right, Article 67(2) of the Act provides that, "The term of a patent right may be extended, upon application for registration of extension, by a period not exceeding five years, if there was a period of time during which it was impossible to exploit the patented invention due to the need to obtain approval or other disposition pursuant to laws intended to ensure safety in the exploitation of the patented invention, which is specified by Cabinet Order as requiring a considerable period of time for the disposition to be made appropriately in light of the purpose and procedure thereof." Article 67-3(1) of the Act sets forth grounds for refusal of an application for registration of extension, including "where there seems to have been no need to obtain a disposition specified by Cabinet Order as prescribed in Article 67(2) for the exploitation of the patented invention" (item 1).

The patent system is originally designed to grant a person who has made an invention an exclusive right to the invention for a particular period of time on the condition that the person disclose the technology relating to the invention. If it is necessary to obtain a disposition pursuant to laws intended to ensure safety in the exploitation of the patented invention, and a consideration period of time is required for the disposition to be made appropriately in light of the purpose and procedure thereof, the term of the patent right is in effect reduced by such a period of time. It can be construed that the patent term extension system has been established in order to give relief to a patent holder who faces such a disadvantage.

Article 3 of the Patent Act Enforcement Order designates registration under the Agricultural Chemicals Regulation Act and approval under the Pharmaceutical Affairs Act as dispositions specified by Cabinet Order as prescribed in Article 67(2) of the Act. More specifically, Article 3, item 2 of the said enforcement order designates drug approval prescribed in Article 14(1) of the Pharmaceutical Affairs Act as one such disposition. Article 14(1) of the Pharmaceutical Affairs Act (at the time of the filing of the Application; hereinafter the same for this article) provides that, "The Minister of Health, Labor and Welfare shall, upon application by a person who intends to manufacture drugs (excluding drugs designated under the standards set by the Minister of Health, Labor and Welfare)..., grant approval for manufacturing on an individual drug basis," and Article 14(2) provides that, "Approval set forth in the preceding paragraph shall be granted through examination of the name, ingredients, quantity, composition, administration, dosage, method of use, efficacy, effect, performance, side effects, etc. of the drug for which the application has been filed…, and shall not be granted if the drug falls under any of the following." Thus, Article 14 of the Pharmaceutical Affairs Act requires manufacturing approval to be obtained for each individual drug based on not only that individual drug's ingredients, efficacy, and

effect but also its name, administration, dosage, and method of use.

With respect to the effects of the patent right for which the term has been extended, Article 68-2 of the Act provides that, "The effects of the patent right for which the term has been extended (including cases where the term is deemed to have been extended pursuant to Article 67-2(5)) shall not extend acts other than the exploitation of the patented invention in respect of the product that is the subject matter of the disposition specified by Cabinet Order as prescribed in Article 67(2) because of which the extension has been registered (or the product to be used for the particular purpose that is specified by the disposition)."

This provision is designed as a general rule to cater to the possibility that the scope of areas where the patent term extension system is available will be expanded by Cabinet Order so as to include other legislation in addition to the Pharmaceutical Affairs Act. Under the Pharmaceutical Affairs Act, as mentioned above, drug approval shall be granted for each individual drug based on not only that individual drug's ingredients, efficacy, and effect but also its name, administration, dosage, and method of use. On the other hand, under the patent term extension system, it is appropriate to construe that the effects of the patent right for which the term has been extended shall extend to the exploitation of the patented invention not only in respect of the drug approved under the Pharmaceutical Affairs Act but also in respect of the "product" (e.g. drug) specified by the active ingredient as well as the "use" specified by the efficacy and effect of the drug.

Thus, unlike the Pharmaceutical Affairs Act, the patent term extension system addresses a "disposition" from the perspective of both the "product" (active ingredient) and the "use" (efficacy and effect). Therefore, the requirement that it was impossible to exploit the patented invention because of the need to obtain a disposition specified by Cabinet Order as prescribed in Article 67(2) of the Act, and the requirement prescribed in Article 67-3(1)(i) of the Act that there seems to have been the need to obtain a disposition specified by Cabinet Order as prescribed in Article 67(2) for the exploitation of the patented invention, should be construed, with respect to drugs for which approval is required under Article 14(1) of the Pharmaceutical Affairs Act, to question whether or not it was necessary to obtain a disposition for the exploitation of the patented invention from the perspective of the "product" (active ingredient) and the "use" (efficacy and effect). Without such construction, it would be impossible to uniformly construe the patent term extension system as a whole.

The court has examined the case based on the above-mentioned interpretations. According to the facts mentioned above, for a drug that contains "oxiglutathione" as an active ingredient and has the efficacy and effect (use) of "ocular perfusion and irrigation upon ophthalmic surgery," the Preceding Approval had already been granted under the Pharmaceutical Affairs Act prior to the grant of the Approval. In light of the

purport of the patent term extension system as determined above, it should be construed that the Preceding Approval had lifted the restrictions on the product and the use under the Pharmaceutical Affairs Act. Therefore, from the perspective of the product (active ingredient) and the use (efficacy and effect), there seems to have been no need to obtain the Approval for the exploitation of the patented invention. Consequently, the Application should be refused pursuant to Article 67-3(1)(i) of the Act, and the JPO decision that goes along with this reasoning did not make an erroneous determination.