Judgments of Intellectual Property High Court, Fourth Division
Date of the Judgment: 2005.10.11
Case Number: 2005(Gyo-Ke)No.10345

Title(Case):
A case wherein, presenting the construction of each provision on the patent term extension system, the court upheld the JPO decision to refuse the application for registration of extension of the term of the patent right

Reference: Article 67(2), Article 67-2(1) and (2), Article 67-3(1)(i) and Article 68-2 of the Patent Act (prior to the revision by Act No. 41 of 1999), Article 1-3(ii) of the Order for Enforcement of the Patent Act (prior to revision by Act No. 430 of 1999), Article 38-15 of the Ordinance for Enforcement of the Patent Act, and Article 14(1) of the Pharmaceutical Affairs Act

Summary of the Judgment:

This case is a dispute over the acceptability of the application for registration of extension of the term of the patent right with respect to Patent No. 1901277 with the title of the invention "Microcapsulation of water-soluble polypeptide." The JPO decision affirmed the decision of refusal, and the court also upheld the JPO decision.

1. The court reviewed each provision on the patent term extension system under the Patent Act (prior to the revision by Act No. 41 of 1999) and held as follows.

"The requirement that 'there is the need to obtain a disposition specified by Cabinet Order for the exploitation of the patented invention' is regarded as a prerequisite for registering an extension. … This requirement is based on the anticipation of general cases relating to the 'subject matter of the disposition specified by Cabinet Order as prescribed in Article 67(2).' Article 68-2 of the Act provides, in parentheses, for a specific case, that is, the case 'where, in the disposition concerned, any specific use of such a product to be used is specified,' with respect to the 'subject matter of the disposition specified by Cabinet Order as prescribed in Article 67(2).' Therefore, it is possible to say that with respect to drugs, the Patent Act addresses a 'disposition' from the perspective of both the 'product' (active ingredient) and the 'use' (efficacy and effect), separately from the provision under the Pharmaceutical Affairs Act. In that case, the requirement that 'there is the need to obtain a disposition specified by Cabinet Order' in Article 67(2) and Article 67-3(1)(i) of the Act, in other words, the requirement that 'there is the need to obtain a disposition specified by Cabinet Order for the exploitation of the patented invention' in the previous holding, should be

construed as the requirement that 'there is the need to obtain a disposition from the perspective of the product (active ingredient) and the use (efficacy and effect)' with respect to drugs for which approval is required under Article 14(1) of the Pharmaceutical Affairs Act."

2. The facts found by the court are as follows.

"The patented invention … relates to a pharmaceutical composition adjusted into the form of a microcapsule containing buserelin acetate as an active ingredient. … The (second) disposition was made on December 25, 1998. The subject matter of the disposition was a preparation formulated from buserelin acetate, which is an active ingredient, with the product name 'Suprecur MP1.8 (sustained-release formulation of buserelin acetate).' The 'active ingredient' subject to the disposition was buserelin acetate, and the 'product' subject to the disposition was buserelin acetate. In addition, the 'uses' were the reduction of endometriosis and uterine myoma and the alleviation of symptoms caused by uterine myoma, which are menorrhagia, lower abdominal pain, lower back pain and anemia. On the other hand, a drug formulated from buserelin acetate, Suprecure, was approved as a drug for endometriosis in the form of nasal drops on June 28, 1988, and uterine myoma was approved as an additional indication on March 27, 1992."

3. On the premise of the above, the court determined as follows.

"Based on the facts, it is certainly possible to say that the applicant has not been able to exploit the patented invention claimed in the application, that is, a pharmaceutical composition adjusted into the form of a microcapsule containing buserelin acetate as an active ingredient. However, it is impossible to conclude that there was the ' need to obtain the (second) disposition from the perspective of the product (active ingredient) and the use (efficacy and effect)' for the exploitation of the patented invention because the drug was approved on June 28, 1988 under the Pharmaceutical Affairs Act based on the use (efficacy and effect) for treatment of endometriosis and uterine myoma (the latter was additionally approved on March 27, 1992) while regarding buserelin acetate as the product (active ingredient). The (second) disposition under the Pharmaceutical Affairs Act was necessary not from the perspective of the product (active ingredient) and the use (efficacy and effect) but due to differences in the dosage form.

Therefore, the JPO decision to refuse the application on the grounds that the application falls under Article 67-3(1)(i) of the Act is upheld."