AIPPI Case Reporter

Latest Developments in Japanese IP Cases

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1. Patent/Infringement/Experimental Use Exemption for Generics

Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuhin K.K.
Tokyo District Court, Civil 29th Div., Decided July 18, 1997/Case No. 1996 (wa) 7430
Patent Law, Section 69, Para. 1 and Section 100, Para. 2;
The Drugs, Cosmetics and Medical Instruments Law, Section 14, Para. 3.

Tests for a drug-manufacturing license do not constitute patent infringement so far as the use of a patent was limited to obtaining data required under the Drug, Cosmetics and Medical Instruments Law. Such tests can be regarded as a use of a patent right exempted under Section 69, Para. 1 of the Patent Law.

FACTS

Otsuka Pharmaceutical (Patentee) has two patents: one relating to a novel carbostyril derivative called "procaterol hydrochloride" and the other relating to a bronchodilator comprising the new carbostyril derivative. Both of them were filed on April 28, 1976 and expired on April 28, 1996. Patentee manufactures the bronchodilator under its patents and sells it under the name of "Meptin."

Towa Yakuhin (Towa), with an intent to manufacture and sell its own bronchodilator as a generic drug, obtained an approval for the manufacture of a generic drug (generic drug license) under the Drug, Cosmetics and Medical Instruments Law (Drug Approval Law). Under the Drug Approval Law, Towa, as a generic drug manufacturer, needed certain biological data which can be obtained by using patented procaterol hydrochloride. With the generic drug license, Towa started, shortly after the expiration of the relevant patents, selling to a third party its product "Epkarol." The Epkarol contained procaterol hydrochloride as an effective ingredient.

Patentee sued Towa before the Tokyo District Court, claiming that Towa should be enjoined from manufacturing, importing and using the Epkarol until

October 28, 1998 and a destruction of the Epkarol which had so far been manufactured. The date of October 28, 1998 was calculated based on the assumption that the generic drug license would have been available in 30 months after the expiration of the patents if necessary tests using patented invention were done only after the expiration of the patents. The patentee also sought the cancellation of the generic drug license in view of alleged past patent infringement.

ISSUES

1) Whether various tests conducted to obtain data for the generic drug license constitute patent infringement;

2) Whether such remedies as injunction and destruction are available after the expiration of the patents; and

3) Whether damages are available, and if so, what amount.

HOLDING

Before going into the discussion of the specific issues, the court gave comments on the availability of cancellation of the generic drug license in view of patent infringement. Under the Drug Approval Law, Section 14, Para. 3 and related regulations, generic drug manufacturers are released from fundamental researches and animal tests which are usually costly. Unlike patented manufacturers, generic drug manufacturers are not required to conduct investigations and surveillance after the launch of their products. Under Section 74*bis* of the Drug Approval Law, the drug license could not be canceled even if the generic drug in question constituted infringement of a patent.

(On Post-Expiration Use)

There were no arguments that procaterol hydrochloride was used by Towa for tests required under the Drug Approval Law. Such procaterol hydrochloride fell within the scope of the patents in question. Therefore, there were no questions about the fact that the patents were used by Towa before their expiration.

However, the Patent Law provides for in Section 69 that the effect of a patent right cannot extend to the use of patented invention for the purpose of tests or researches. Therefore, this provision should be construed considering a balance between the patent law and other relevant systems.

> "If the effect of a patent right extends to the use of patented invention for tests and researches which aim at enhancing technologies to further stages, it would tilt the balance of protection in favor of the patentee excessively, resulting in the adverse effect to the development of technology and industry. The use of such patented invention falls within the working of patented invention as defined in Section 69, Para. 1 of the Patent Law.

a certain period of time. These procedures are followed in order to secure the quality, efficacy and safety of the generic drug to be the same as those of the patented product. They are not intended as a system to protect the dominant position of the patentee or the patented manufacturer. The Patent Law anticipates the need of adjustment of interests between the Drug Approval Law and the Patent Law. The defendant used the patented invention for the purpose of tests which fell within the category of Section 69 of the Patent Law."

Based on the finding that the patents were not infringed by Towa, the court did not consider the other remaining issues.

COMMENTS

Judicial interpretations of the Patent Law, Section 69, Para. 1 with respect to tests for obtaining the manufacturing license under the Drug Approval Law are far from the conformity in Japan. Last year, in the series of cases brought by *Synthelabo* against generic drug manufacturers, the Nagoya District Court decided that tests for the purpose of obtaining data for the drug license infringed the patents involved and awarded an injunction order. (*Synthelabo v. Hotta Yakuhin Gosei Co.; Synthelabo v. Maruko Seiyaku Co.; and Synthelabo v. Taiyo Yakuhin Kogyo KK*, March 6, 1996; See the Case Reporter, AIPPI, Nov. 1996, pp 307–310) In appeal cases brought by *Synthelabo*, the Kanazawa Branch of the Nagoya High Court clearly found that tests for the generic drug license were conducted for a "commercial" purpose and therefore constituted patent infringement. (*Synthelabo v. Toyo Farmacie Co., and Synthelabo v. Dyte Co., Ltd. & KK Yoshindo*, March 18, 1996) In other cases, the Nagoya District Court followed these precedents and found patent infringement by tests for the generic drug license. (*Kyorin Pharmaceutical Co., Ltd. v. Hotta Yakuhin Gosei KK*, Aug. 28, 1996)

This year, lower courts have started ruling against patentees. For example, in the case of *Kanebo Corp. v. Fuji Seiyaku Kogyo KK et al.*, the Tokyo District Court supported in its July 14, 1997 decision arguments raised by Defendant. In this case, the court rejected the Plaintiff's claim for injunction under expired patents. Another example is the decision of the Kyoto District Court in the case of *Ono Yakuhin Kogyo Co., Ltd. v. Kyoto Yakuhin Kogyo KK* in which the court held that a claim for injunction under an expired patent had no grounds. The Tokyo District Court's decision in the case of *Ono Yakuhin Kogyo Co., Ltd. v. Kaigai Seiyaku KK* followed the same rationale.

The present case went into further step and articulated the rationale for excluding from patent ingringement tests performed to obtain data which were required under the Drug Approval Law. Under the circumstance that decisions of lower courts went far apart and that a conformity of judicial interpretation is needed, the issue of whether tests for the generic drug license would infringe the patent right may need to be tried before the higher courts. Given

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the recent reform of the Civil Procedure Law limiting appeals to the Supreme Court, this issue would be worth being tried before the highest court.

For the interest of comparative law, the German Federal Supreme Court pronounced its decision of April 17, 1997 that under certain circumstances, clinical tests for the drug license did not infringe the patent under the German Patent Law. In the United States, clinical tests for an FDA application (but not the application itself) are statutorily exempted (35 USC 271(e)).

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