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Latest Developments in Japanese IP Cases

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1. PATENT: Infringement/Injunction/Damages

Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.
April 16, 1999/Case No. 1998(ju)153
Supreme Court, Second Petty Bench
Patent Law Section 69(1)

The Supreme Court of Japan rendered an awaited decision on the issue of experimental use exemption and tests done by generic drug makers during a patent term. The Court found that tests carried out during a patent term in an attempt to obtain governmental approvals for manufacture and sales of patented drugs after the expiration of a patent do not constitute patent infringement under Section 69(1) of the Patent Law. This Supreme Court decision puts the question to rest in favor of generic drug manufacturers from a judicial point of view.

BACKGROUND

This matter started when a French pharmaceutical company, Synthélabo, sued several Japanese generic drug manufacturers at the Toyama and Nagoya District Courts in 1995. Synthélabo accused that the Japanese drug manufacturers had infringed on its two patents which had their terms extended because of the TRIPS related patent law amendment introducing a uniform 20 years patent term. The generic manufacturers carried out tests during the patent term in an attempt to obtain governmental approvals for manufacture and sales after the expiration of the patents. The defense was that since the use of the patented inventions was for "experiment or research," it did not constitute patent infringement under Section 69(1) of the Patent Law, which exempts the working of a patented invention for the purpose of experiment or research from the scope of patent protection. Also, because the defendants were preparing for the manufacture and sales after the expiration of the patents when the

patent law amendment was announced to extend the patent term, they had, according to the defendants, a kind of intermediate user rights based on transitory provisions that accompanied the law amendment.

The Nagoya District Court granted preliminary injunction orders in three separate rulings.[1] Synthélabo v. Taiyo Yakuhin Kogyo K.K., case No. 1995(yo)771 on March 6, 1996. The court found that the experimental exemption of Section 69(1) was not applicable because the tests carried out by the generic manufacturers were not for the purpose of advancing technology and only for the purpose of selling the defendants' products. Because the both patents expired on March 26, 1996, the preliminary injunctions lasted only 20 days.

The Toyama District Court denied preliminary injunction orders, but in appeal, the Kanazawa branch of the Nagoya High Court granted such orders on March 16, 1996 for essentially the same reasons as those given by the Nagoya District Court.

Probably, the judges in these courts had in mind an earlier Tokyo District Court decision for the Ethofumesate case which was part of the global litigations between Monsanto and Stauffer,[2] in which it was found that: "the experiments on agricultural chemicals carried out in the present case for obtaining government registration required for the sales of such chemicals were not intended to advance technology and were only for the sale of the accused herbicide, and therefore do not fall under the 'experiment or research' provided under Section 69 of the Patent Law."

These decisions were followed by a rush of law suits against generic drug manufacturers. It then became clear from a decision rendered on July 18, 1997 that the Tokyo District Court believed that tests carried out by generic drug manufacturers were for "experiment or research" under Section 69(1) and therefore the experimental use exemption was applicable.[3] This was in clear contrast to the finding of the Nagoya District and High Courts.

The Osaka District Court found infringement, but was reluctant to give any relief to patentees because the amounts of patented drugs made and used by generic drug manufacturers were very small and the damages amounted to only several hundreds of US dollars worth.[4] In more recent decisions, the same Osaka District Court found no infringement under Section 69.[5] The German Supreme Court decision in the so-called Clinical Trial II case[6] may have influenced these two courts.

After many decisions along the lines discussed above from various district courts, on March 31, 1998, the Tokyo High Court,[7] which is most experienced in patent matters, rendered an eagerly awaited decision on this issue. The court rejected an appeal made by Otsuka Pharmaceuticals against the above-mentioned Tokyo District Court decision in which experiments carried out by a generic drug manufacturer for obtaining a governmental approval for sale after the expiration of a patent were found not to constitute patent infringement under the experimental use exemption.

More recently in January and February 1999, the Osaka and Nagoya High

Courts rendered several further decisions on this issue.[8] The two courts found that the experimental use exemption was applicable for such testing, which is basically in agreement with the Tokyo High Court. This is in contrast to two other decisions another division of the Nagoya High Court handed down in December 1998 and January 1999[9] in which no remedies were given to the plaintiff because damages were minimal, but patent infringement was found for such tests.

PROCEEDINGS AT THE LOWER COURTS

The present appeal before the Supreme Court originates from a Kyoto District Court decision of May 15, 1997 (Case No. 1996(wa)1898) and a subsequent Osaka High Court decision of May 13, 1998 (Case No. 1997(ne)1476). In the original lawsuit at the Kyoto District Court, Ono Pharmaceuticals asked for an injunction order based on an expired patent. Ono's patent (No. 1122708) had expired on January 21, 1996. Ono argued that because the defendant carried out experiment during the patent term in order to obtain a government approval for manufacture and sale of a drug which falls under the scope of the patented invention, it infringed on Ono's patent and therefore should not be able to sell the approved drugs even after the expiration of the patent term. Since it normally takes at least two and a half years for generic drug manufacturers to obtain governmental approval and start the sale of their products from the start of the experiment, if the defendant did not infringe on Ono's patent, according to Ono, it could not sell the accused product for at least two and a half years after the expiration of the patent. The defendant did not dispute the fact that it carried out the experiment during the patent term. The issues raised were: whether the accused product falls under the scope of the patented claims; whether the experiment constituted patent infringement; whether it is possible to issue an injunction against the sale of the accused product based on an expired patent; and whether it is possible to issue an injunction against the sale of the accused product based on past illegal acts.

In its decision of May 15, 1997, the Kyoto District Court did not find any basis in the statutes for granting an injunction based on an expired patent. The Court stated that:

> "If rights to obtain an injunction order can be enforced even after the patent expires, it would amount to the same results as the patent term is extended. This goes against the reasons for providing the fixed term for patents and allowing limited extensions."

This court did not consider whether the experiments carried out by the defendant are exempted from patent infringement under Section 69(1) of the Patent Law.

Ono appealed this decision before the Osaka High Court, and added a claim for damages of 8,711,391 yen (about 73,000 US dollars) for infringement during the patent term and the two and a half years period after the expiration of

the patent.

The Osaka High Court directly answered the question of experimental use exemption. The Court stated in its decision that:

> "Therefore, even though the provision for 'the working of the patented invention for the purpose of experiment and research' discussed above contains no literal qualifications, it is clear that the manufacture and stocking of patented products in preparation for sale after the expiration of the patent term is not allowed under the guise of 'experiment and research.'
>
> However, the outcome of 'experiment and research' is not necessarily directly related to tangible fruits and may not contribute directly to the development of science and technology. Rather, it can often be the case that information which can be used merely as the foundation of future scientific and technological developments may be obtained as a result of multifaceted examination and analysis of the patented invention, and such information may only indirectly contribute to the progress of science and technology. Thus, it would not be appropriate to interpret 'experiment and research' only as cases in which direct and specific fruits are gathered."

In response to the argument of Ono that it would be unfair for original drug developers if the generic drug manufacturers could perform experiments during the patent term in view of the greater obstacles before original drug manufacturers, such as long research periods, high investments and erosion of patent terms due to lengthy governmental approval processes, the court stated that:

> "However, the issue of erosion of the patent term has been addressed in the patent law amendment of 1987, which allowed the limited extension of the patent term specifically for pharmaceuticals, etc. (Section 67(2) of the Patent Law; even if such extension is insufficient, it is a matter of legislation and policy), and it cannot be denied that an early entry of generic drugs into the market is beneficial to the general public. It would not be appropriate to place an emphasis only on the profits of original drug manufacturers."

In this decision, the Osaka High Court did not consider the rest of issues raised by the parties and rejected the appeal.

HELD

As shown in the English tranlation attached to this report, the decision of the Supreme Court is short. The Court emphasized the importance of the balance between monopolizing rights enjoyed by the patentee during a limited period of time and benefits of the public resulting from the disclosure of inventions. It reasoned that if experiments done by generic drug manufacturers during the patent term constitute patent infringement despite the provisions of Section 69(1) of the Patent Law, an arbitrary extension of the patent term would effectively result, and such extension is not allowable under the Patent Law, which clearly limits the patent term.

COMMENTS

This decision was rendered unusually quickly. It took less than one year for the Supreme Court to issue a decision with its own opinion. This is clearly one of welcome signs for changes in the Japanese judicial system in general. This type of appeals used to take two years or more to decide, if the Supreme Court chose to address some substantive issues. Inconsistent positions taken by courts on basically the same issue probably forced the Supreme Court to act fast. In fact, this speed is what the Court has recently been preaching. With the new Code of Civil Procedure, which contains a number of specific measures to allow courts to finish cases within shorter periods of time, having come into effect in January 1998, the Supreme Court has been publicly emphasizing the importance of speed whenever possible.

On the other hand, many of the issues raised during the lower court proceedings in this particular case and in other similar court cases were left untouched in this decision. For example, the relationship between the patent term extension for pharmaceutical patents and the experimental use exemption is an important issue, and it would have been better to have the Supreme Court's opinions on it. Such omission of issues from this decision may be understood as a signal from the Supreme Court that such issues are not considered important. However, this is not clear. The lack of details is evident when compared with extensive expositions made by the German Supreme Court in comparable cases in Germany.[10]

Note

1. Synthélabo v. Hotta Yakuhin Gosei Co., case No. 1995(yo)769
   Synthélabo v. Maruko Seiyaku Co., Ltd., case No. 1995(yo)770
2. Tokyo District Court, Monsanto v. Stauffer, 1985(wa)7463, March 25, 1987, and the Ethofumesate case, Federal Supreme Court of Germany, February 21, 1989 (22 IIC 542 (1991)).
3. Case Nos. 1996(wa)7011, 1996(wa)7430, and 1996(wa)22313.
4. Kyorin Pharm. v. Zensei Yakuhin, February 7, 1997, Case No. 1996(yo)2213.
5. April 16, 1998, Case No. 1996(wa)6677 and five other cases, Ono Pharm. v. Kyowa Yakuhin K.K., et al.
6. Rendered on April 17, 1997.
7. Case No. 1997(ne)3498.
8. For example, February 16, 1999, Case No. 1998(ne)1052, the 4th civil division of the Nagoya High Court.
9. For example, January 19, 1999, Case No. 1998(ne)1058, the 1st civil division of the Nagoya High Court.
10. Clinical Trials I and II, Federal Supreme Court of Germany, July 11, 1995 and April 17, 1997.

(Dr. Shoichi OKUYAMA, Okuyama & Co., Patent Attorney)

English translation of the Supreme Court decision of April 16, 1999 on the issue of experimental useexemption and generic drugs

Handed down on April 16, 1999
The Second Petty Bench of the Supreme Court
Case No. 1998(ju)153

Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.

Against the decision the Osaka High Court rendered on May 13, 1998 in a case involving a request for an injunction on pharmaceutical products (Case No. 1997(ne)1476) between the above-mentioned parties, an appeal has been filed by the Appellant. Therefore, this court decides as follows:

DECISION

The present appeal is rejected.
The cost of this appeal is to be borne by the Appellant.

OPINION

Concerning the reasons for requesting the acceptance of the appeal set forth by the attorneys for the Appellant, Keizo TAKASAKA, Yoichiro NATSUZUMI, Hanroku TORIYAMA, Yasuaki IWAMOTO, Hirofumi ATA, and Yoichi TANABE:

1. In the present lawsuit, the Appellant, who owns a patent on chemical substances and drugs which contain them as effective components, has demanded an injunction against the sale of the Appellee's drugs and a damages award, arguing that the manufacture and use of drugs which are identical to the patented drugs in terms of their effective components, dosages, usage, quantities, indications, efficacy, etc. during the patent term for the purpose of obtaining data that accompany an application for the approval of manufacture under Section 14 of the Pharmaceutical Affairs Law constitute infringement on the patent. The Appellee, on the other hand, has argued that it did not infringe on the patent owned by the Appellant because, for example, the above-mentioned acts would qualify for "the working of the patented invention for experiment and research" under Section 69(1) of the Patent Law.

2. When a party has a patent on chemical substances or drugs which contain such chemical substances as effective components, even if a third party carries out the necessary experiments for obtaining data to be filed accompanying an application for approval to manufacture provided under Section 14 of the Pharmaceutical Affairs Law by making and using chemical substances or drugs belonging to the technical scope of the patented invention during the patent

term for the purpose of manufacturing and selling drugs which have the same effective components, etc. as the patented drugs (referred to as "generic drugs" hereinafter) after the patent term has ended, such acts should be deemed the "working of the patented invention for experiment and research" provided in Section 69(1) of the Patent Law and should not therefore be considered to constitute patent infringement. The reason for this is as follows:

1) The patent system is to encourage inventive activities by providing those who disclose inventions with rights to monopolize the use of the inventions during a certain period of time, and give third parties opportunities to use the disclosed inventions, so that it can contribute to the development of industry. In consideration of this, one aspect of the foundation of the patent system is that once the patent term expires, anyone should be able to freely use the inventions, so that the society in general would benefit.

2) The Pharmaceutical Affairs Law stipulates that prior approval by the Minister of Health and Welfare is to be obtained for the manufacture of drugs for ensuring safety, etc., and that upon carrying out various experiments, data, etc. on the experimental results must accompany an application when requesting such an approval. It is the same with generic drugs for which a certain period of time must be spent conducting experiments before requesting an approval on their manufacture. For such experiments, it is necessary to manufacture and use chemical substances or drugs that fall under the technical scope of the patented invention owned by the patentee. If under the Patent Law, such experiments are not to be interpreted as "experiment" stipulated in Section 69(1) of the Patent Law and so such manufacture, etc. are not possible during the patent term, the third party cannot, as a result, freely exploit the invention for a substantial period of time even after the term of the patent expires. This result is against the foundation of the patent system mentioned above.

3) On the other hand, it is considered to be an act of patent infringement, and impermissible, for a third party to manufacture generic drugs during the patent term to be assigned after the expiration of the patent or to make or use chemical substances of the patented invention to be used as components of such drugs beyond the extent that is necessary for experiments to be carried out in order to file for the approval of manufacture under Section 14 of the Pharmaceutical Affairs Law. As far as such consideration is applicable, the patentee enjoys the benefits of monopoly over the patented invention during the patent term. If it is possible to exclude others from carrying out manufacture, etc. for the experiments required in applying for the approval of manufacture of generic drugs during the said term, it would be the same as extending the patent term for a substantial period of time. Such extension of the patent term exceeds what is expected under the Patent Law as benefits to be given to the patentee."

3. In view of the above, under the facts lawfully established during the original proceedings, the acts of the Appellee discussed above should be considered to fall under "the working of the patented invention for experiment and research" provided in Section 69(1) of the Patent Law and do not constitute infringement on the patent owned by the Appellant. The judgement of the original court is justifiable in its conclusion. The gist of the arguments made by the attorneys for the Appellant is based on their own views to attack the original decision, and cannot be accepted.

Thus, we decide as set forth in the section of Decision as unanimously agreed upon by all the judges.

Presiding Judge: Shinichi KAWAI
Judges: Hiroshi FUKUDA
Koji KITAGAWA
Tsuguo KAMEYAMA

(Translation: Dr. Shoichi Okuyama)