Camostat Mesilate Case
Experimental Use Exemption
Supreme Court
Case H10 (Uke) No. 153 (April 16, 1999)

Production for testing and experiments to obtain data for the purpose of gaining regulatory approval to market a generic version of a patented drug after the expiration of the patent on that drug falls under the experimental use exemption of Patent Law Art. 69, and thus would not constitute infringement of the subject patent.

FACTS

1. Company X (innovator pharmaceutical company) has a patent covering a compound (active ingredient) and a pharmaceutical product comprising the compound. Company X produced and sold the patented pharmaceutical product under the patent.
2. Company Y (generic product maker) produced, before the expiration of the subject patent, the patented compound and the patented pharmaceutical product to produce data for obtaining marketing approval for a generic version of Company X's product ("generic product").
3. Company X filed a lawsuit claiming infringement of its patent, and sought an injunction to stop the sale of the generic product and damages.

ISSUE

The Patent Law Art. 69(1) stipulates that the effects of the patent right shall not extend to the working of the patented invention for the purposes of experiment or research ("experimental use exemption").

The defendant argued that the experimental use exemption under art. 69(1) can be applied to the act of producing and using the patented compound for experiments necessary to obtain data for regulatory approval to market the generic product.

The issue was whether or not the experimental use exemption can be applied to experiments to obtain data for gaining regulatory approval to market a generic product.

COURT DECISION

The Supreme Court ruled as follows.

"In the case where someone has a patent right to a chemical compound or a pharmaceutical product comprising the compound, an act of a third party to produce, during the patent term, the chemical compound or the pharmaceutical product falling within the technical scope of the patented invention, and to use them to conduct experiments to obtain information to be attached to a request for marketing approval (under the Pharmaceutical Affairs Law, Article 14) for the purposes of producing and selling a pharmaceutical product comprising the active ingredient that is the same as that of the patented pharmaceutical product ("generic product") after the expiration of the patent, falls under the category of "working of the patented invention for the purpose of experiment and research" under the Patent Law, Article 69(1), and thus would not constitute infringement of the subject patent."

The court noted that, if such preparatory testing were not allowed, it would not be possible to produce generic versions of the patented drug until well after the expiration of the patent, thus granting the patentee an unintended extension of the term of the patent.

In addition, the Court stated in the decision that an act of a third party that exceeded the scope of testing necessary for regulatory approval, that is, production of the patented active ingredient or the patented pharmaceutical product for the purposes of selling the generic version of the patented pharmaceutical product after the expiration of the subject patent would constitute infringement of the subject patent.