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South Korea

Rejection of Compulsory License for AIDS Drug Patents Becomes Final

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Korea HIV/AIDS Network of Solidarity ("KANOS") and IPlleft v. Trimeris Inc. and Duke University, Case Nos. 2009 Jaetong 1 ho and 2009 Jaetong 2 ho, Korean Intellectual Property Office

Korean civic groups filed a petition seeking a compulsory license against Korean patents covering the AIDS drug Fuzeon. After an intensive six-month review, the Korean Intellectual Property Office ("KIPO") rejected the petition on June 19, 2009. The KIPO decision has now become final and conclusive, since no appeal was filed.

KIPO reviewed the totality of circumstances and weighed the public interests in light of the "especially necessary for the public interest" requirement under the Korean Patent Act. Importantly, in reaching its decision, KIPO found that granting a compulsory license solely based on drug supply issues caused by drug pricing negotiations will likely damage the fundamental nature of patent rights to protect the patented invention.

Background

Similar to many other countries, a compulsory license may be allowed in Korea under certain circumstances (Article 107, Paragraph 1, of the Korean Patent Act). Among others, where the working of a patented invention is especially necessary for the public interest, a person who intends to work the patented invention may file a petition seeking a compulsory license, if a consultation with the patentee or exclusive licensee is not possible or if no agreement can be reached.

Fuzeon is an HIV/AIDS drug used by patients who have developed resistance to first-line therapies. It is generally used as part of a cocktail therapy (triple combination therapy) for treating HIV/AIDS patients. In Korea, Roche Korea obtained market approval for Fuzeon in May 2004. However, due to stalled negotiations with the Ministry for Health, Welfare and Family Affairs ("MOH") over drug pricing, Fuzeon was unable to be launched into the Korean market.

On December 23, 2008, two civic groups filed a petition seeking a compulsory license against the Korean patents covering Fuzeon. The civic groups alleged that a compulsory license was especially necessary for the public interest because Fuzeon was an essential drug to HIV/AIDS patients, no substitutable drug was available, and the drug was not supplied for four years due to stalled drug price negotiations, resulting in severe restrictions to the patients' right to access the medicine.

KIPO's Decision

As part of its review process, KIPO received responses from the patentee and exclusive licensee. Further, KIPO sought opinions from the Industrial Property Dispute Resolution Committee and the MOH, as provided in Article 109 of the Korean Patent Act. KIPO also held an oral hearing.

While KIPO found that Fuzeon is necessary for certain AIDS patients and closely related to the lives of those patients and therefore necessary for the public interest, it reviewed the totality of circumstances and concluded that a compulsory license was not "especially necessary for the public interests" in the present case.

In reaching the above conclusion, KIPO first recognized that granting a compulsory license would likely damage the fundamental nature of patent rights to protect the patented invention - particularly if the only reason for the lack of access was due to drug pricing negotiation issues.

Further, KIPO noted that even if a compulsory license were granted, it would be very doubtful whether the petitioners could satisfy patients' right to access the drug, since the petitioners failed to present specific plans and working methods such as how they themselves will manufacture, make a third party manufacture on their behalf, or import the patented drug.

KIPO also noted that, according to the drug industry, other HIV/AIDS drugs have been continuously developed and commercialized in and outside Korea. In addition, since the drug at issue was being supplied to local patients through a compassionate program, Roche Korea began to supply the drug to local patients through its compassionate program from February, 2009. There were only two patients who requested the drug under the program.

KIPO found that the issue of patients' access to the drug had been resolved, resulting in a lower level of urgency.

Comment

The present case was the first case in which a compulsory license was sought under the standard of "especially necessary" for the public interest.

Article 107 (1)(i) of the Korean Patent Act was amended in 2005 to add "especially" such that compulsory licenses must be "especially necessary" for the public interest. Prior to the present case, in 2003, a compulsory license was sought for a patent covering a cancer drug, Glivec. (The Association of Pharmacists for Healthy Society, et al. v. Novartis AG, KIPO, March 4, 2003)

The civic group argued that the price was too high, and thus, a compulsory license was necessary for the public interest. Even under the previous standard of "necessary" for the public interest, KIPO took a similar stance in finding that lack of access caused by high drug prices was insufficient to warrant a compulsory license. In rejecting the petition, KIPO concluded that a high price without a contagious disease or urgent national/social crisis did not outweigh the basic objective of the patent system.

Further, it noted that the government-sponsored insurance program reduced the actual financial burden on patients to only 10% of the actual costs, and there was normal supply and availability of the drug at issue through importation.

In sum, petitioners must not only establish that a compulsory license is "necessary" but must now overcome the higher standard of being "especially necessary" for the public interest. When balancing interests, KIPO has taken a "totality of the circumstances" approach - weighing the benefits of the patent system and the fundamental right to patents against the needs and benefits resulting from a compulsory license.

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