Finally, PODS's registration of "pods" as a trademark also was shielded under *Noerr-Pennington*, as applying for and registering trademarks with the U.S. Patent & Trademark Office, an administrative agency, qualifies as petitioning activity.

Concluding that the *Noerr-Pennington* doctrine immunized PODS from antitrust liability for its alleged conduct, the court dismissed ABF's Section 2 counterclaims as well as related state law claims.

International Trade

Free Trade Agreements

US-Korea Free Trade Agreement and Patent Rights


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Introduction

The United States-Korea Free Trade Agreement (KORUS FTA) upon ratification will be the first free trade agreement between the United States and a major North Asian country as well as the most commercially significant free trade agreement since the 1994 North American Free Trade Agreement (NAFTA) between the United States, Canada, and Mexico. For Korea, it will be the second largest FTA, following the European Union-Korea Free Trade Agreement (EU-Korea FTA), which became effective July 1, 2011.

The KORUS FTA was first signed on June 30, 2007 and the renegotiated version was executed on December 4, 2010. The KORUS FTA is currently pending ratification by the U.S. Congress and the National Assembly of Korea. The U.S. International Trade Commission estimates that the reduction of Korean tariffs and tariff-rate quotas on goods alone would add $10 billion to $12 billion to the annual U.S. Gross Domestic Product and about $10 billion to annual merchandise exports to Korea.[1]

In addition to such trade gains, the KORUS FTA will significantly impact the Korean patent laws, in contrast to the EU-Korea FTA which has few provisions relating to patent rights. These revisions to the Korean patent laws will apply to the United States, as well as all members of the World Trade Organization (WTO) pursuant to the most-favored nation treatment article of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[2].

This article details changes the KORUS FTA will have on the Korean patent laws, including patent term extension, grace period to novelty, and a generic drug approval system for patented pharmaceuticals, as well as other Korean patent rights under consideration for revision during the KORUS FTA negotiations.

Issues on Patent Rights

– Addition of Korean Patent Term Adjustments for Examination Delay

Unlike the United States, where examination delays caused by the U.S. Patent and Trademark Office (USPTO) can be compensated by a patent term adjustment (i.e., one or more added days of patent term proportional to the time of USPTO delay), no such term compensation system currently exists in Korea.

The KORUS FTA establishes patent term adjustment in Korea where an *unreasonable delay* during patent prosecution is caused by the Korean Intellectual Property Office. "*Unreasonable delay*" is defined in the KORUS FTA as a delay in the patent issuance from the later of (i) more than 4 years from the filing date or (ii) 3 years from the examination request. Delays attributable to the applicant need not be included in the calculation. Patent allowances gained through appeal are included in the delay period determination. Under the KORUS FTA, the Korean patent term adjustment may be awarded only at the request of a patent owner and will apply to all patent applications filed on or after January 1, 2008. Notably, the definition of unreasonable delay in the KORUS FTA is a step back from the Middle Eastern FTAs such as the Oman FTA, Bahrain FTA and Morocco FTA, where unreasonable delay is defined as 2 years from the examination request.

A patent term adjustment simulation study analyzed Korean patents issued from January 2006 through February 2007.[3] Among the total of 155,514 patents registered during that period, about 75% of cases were owned by domestic entities and the balance by non-Korean based groups. Interestingly, 5.25% of the cases owned by foreign groups were eligible for patent term adjustment, whereas just 0.70% of the cases owned by domestic entities were eligible for patent term adjustment. Further, the expected patent term adjustment for foreign patents averaged about 8 to 10 months compared to an average of 7 to 9 months for patents owned by the domestic entities. Based on this study, it is thus anticipated that foreign applicants will receive more benefits from Korean patent term adjustment provisions. Pharmaceutical patents are also expected to receive some of the more substantial patent term adjustments among various technologies.

– Korean Prior Disclosure Grace Period Extended to 12 Months

Pursuant to general patent law provisions worldwide, once an invention is publicly disclosed, a patent application filed after the public disclosure can be rejected for lack of novelty and/

or inventive step in view of the prior disclosure. A number of countries, however, also provide for certain time-limited exceptions to this prior disclosure bar, particularly for a public disclosure made by the applicant inventor. In the United States, Australia, and Canada, an application can be granted if filed within 12 months of an inventor's own first public disclosure and, in Japan and Korea, an application can be granted if filed within 6 months of an inventor's first public disclosure. The KORUS FTA extends the Korean grace period provisions to 12 months for public disclosures made, authorized, or derived from the patent applicant and will apply to all patent applications filed on or after January 1, 2008.

– Korean Generic Drug Approval Aligned with U.S. Hatch-Waxman Act

For patented pharmaceuticals and agricultural chemical products, the KORUS FTA includes provisions regarding patent term restoration, drug approval-drug patenting linkage, and data exclusivity. The patent term restoration provision is similar to the current Korean Patent Act; the linkage and data exclusivity provision will be new additions.

In the United States, under the Drug Price Competition and Patent Term Restoration Act, also known as the "Hatch-Waxman Act," a generic drug company's abbreviated new drug application (ANDA) may be suspended for 30-months upon objection by the owner of relevant patent rights. The KORUS FTA introduces similar provisions to the Korean patent laws.

Under the existing Korean system, in contrast to the United States, an owner of patent rights relevant to a proposed generic drug introduction is not involved during the generic drug marketing approval process. Indeed, the patentee may not be aware of the generic drug until the Korea Food & Drug Administration grants marketing approval, and the generic company begins sales of the approved drug.

However, under the KORUS FTA, the Korean patent laws would be revised to be substantially aligned with the U.S. system and provide that, when a generic manufacturer submits an ANDA (i.e., relies on safety or efficacy information of a product that was previously approved), (i) the patentee is notified of the identity of the generic manufacturer; and (ii) the generic manufacturer is prevented from marketing a product without the consent of the patentee.

Under the KORUS FTA, once a generic company submits an ANDA, and the patentee is notified of that drug approval request, the patentee may file a suit against the generic company alleging patent infringement. The KORUS FTA does not specifically provide that the ANDA would be suspended upon the filing of the infringement litigation, but instead stipulates that the Korean government must "implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent . . . of the patent owner." It is expected that Korean lawmakers will enact supporting legislation analogous to the U.S. law that suspends the generic approval process as a consequence of the infringement litigation. Under the KORUS FTA, if the generic drug approval applicant receives a non-infringement decision, the ANDA then may be approved without further involvement by the patentee.[4]

During the KORUS FTA negotiations, U.S. authorities requested the establishment of a Korean suspension period of 30 months consistent with the U.S. Hatch-Waxman provisions. That request, however, was rejected on the Korean side, and the KORUS FTA does not specify a suspension period and instead as mentioned merely stipulates that the Korean government must "implement measures in its marketing approval process . . . ."[5] A 12-month suspension period during a patent infringement suit is currently being considered by Korean authorities.[6] The Korean government is also considering providing an incentive to the first generic entity to challenge a related patent.[7]

The KORUS FTA also establishes data exclusivity similar to the United States. Thus, under the KORUS FTA, a generic company is prohibited from submitting an ANDA for at least 5 years from the original company's marketing approval of a new pharmaceutical product and at least 3 years for new clinical information. The KORUS FTA defines a "new pharmaceutical product" as "one that does not contain a chemical entity that has been previously approved . . . for use in a pharmaceutical product," to clarify that it is not related to the "novelty" requirement for patentability under the Korean patent laws. The KORUS FTA also provides 10 years of data exclusivity for an agricultural chemical product under similar provisions.

It is expected that the KORUS FTA will effectively delay launch of generic drugs in Korea relative to current approval protocols. According to a 2006 Korean government estimate, revision of the Korean generic drug approval process under KORUS FTA could delay launch of a generic drug by an average of about 9 months resulting in a loss of sales of Korean generic products of about U.S. $37 to $79 billion annually. The KORUS FTA, as first signed in 2007, provided that the revision of the Korean generic drug approval process would be effective 18 months after the enactment date of the KORUS FTA. To minimize the impact on Korean pharmaceutical companies, during renegotiation of the KORUS FTA in December 2010, it was agreed that the Korean generic drug approval process would be effective 3 years following the enactment date of the KORUS FTA, in exchange for certain protections for the U.S. automobile industry.

– Patent Term Extension for Pharmaceutical Products

The KORUS FTA provides a patent term extension up to 5 years to compensate for patent term lost due to delay in regulatory marketing approval of a new pharmaceutical product. This provision was added for clarification since it is found in existing U.S. and Korean patent laws.

During negotiations, the United States requested that the period for marketing approval in the territory of the other party be considered in the calculation of the extension period, which could result in an additional 1 to 2 years of extended patent term. Such an expanded term calculation was not included in the final text of the KORUS FTA.[8]

– Abolition of Korean Patent Cancellation Provision based on Non-Working

Under the current Korean Patent Act, non-working of a patented invention for a certain period of time may be a basis for cancellation of the patent. More particularly, a compulsory license may be possible for a patent that was not worked for three years and, if the patent was not worked for two years from the date of the award of a compulsory license, the Korean Intellectual Property Office may cancel the patent right.

The United States requested abolition of this patent cancellation provision. Korea has agreed to removal of the provision in view that the existing law may unduly limit the patentee's rights and that to date no patent has been canceled based on the non-working provision.

– Compulsory Licensing Provisions of Korean Patent Act Maintained

Many patent law systems provide for a compulsory license in certain circumstances. TRIPS Article 31 also sets out a compulsory license in the case of a national emergency or other circumstance of extreme urgency and in cases of public non-commercial use.

Pursuant to the adoption of Article 31, in 2005 the Korean Patent Act was amended to stipulate that a compulsory license may be granted if: (i) it has not been worked for more than 3 consecutive years; (ii) it has not satisfied domestic demand; (iii) working the patented invention non-commercially is necessary for the interest of the public; (iv) working the patented invention is necessary to remedy a practice determined to be unfair; and (v) working the patented invention is necessary for the export of medicine to a country which has insufficient or no manufacturing capability.[9]

Three compulsory licenses have been requested in Korea in recent years: for Novartis' GLEEVEC® in 2003, Roche's FUZEON® in 2008, and Roche's TAMIFLU®in 2009. All three compulsory license requests were denied by Korean authorities.

During negotiations of the KORUS FTA, the United States attempted to limit Korea's authority to grant a compulsory license by introducing provisions similar to those in the U.S.-Australia FTA and the U.S.-Singapore FTA. Under those agreements, a compulsory license may be possible in the following restricted circumstances: (i) to remedy a practice determined after judicial or administrative process to be anticompetitive under the competition laws; (ii) in the case of public non-commercial use; and (iii) in the case of a national emergency or other circumstances of extreme urgency. Further, in the cases of (ii) and (iii), the patent owner cannot be required to transfer undisclosed information or technical know-how related to a patented invention.[10] Korean authorities, however, rejected the addition of such more restrictive provisions to the Korean laws.

– Treatment Method Claims to Remain Ineligible under Korea Patent Laws

Under the current Korean patent laws, claims reciting methods for the therapeutic treatment of humans are ineligible subject matter for patent protection on grounds of lack of industrial availability.[11] During the negotiation of the KORUS FTA, the United States requested that such method of treatment claims be acknowledged as patentable subject matter under Korean law consistent with U.S. practice. Korean authorities, however, rejected the U.S. requests, arguing that humanitarian concerns properly excluded such claims from patentable rights. The final text of the KORUS FTA thus continues to permit Korea to exclude patent claims directed to methods of treatment of humans as eligible patentable subject matter.

Conclusion

The KORUS FTA provides for significant changes in the Korean patent laws. The new provisions will apply not only to the United States but also to all of the members of the WTO, pursuant to the most favored nation treatment article of TRIPS.

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[1] http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta

[2] Article 4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

[3] Keun-Yeop Oh, et al, The ratio of patent for which patent term may be adjusted under the US-Korea FTA, and the expected adjustment, Patent 21, Vol. 73, pp. 10-15, 2007.

[4] Introduction to Drug Approval-Drug Patenting Linkage, Korea Food & Drug Administration, 2007.

[5] Article 18.9.5(b) of the US-Korea FTA.

[6] Detailed Explanation on the US-Korea FTA, Ministry of Foreign Affairs and Trade (Korea), p. 42, January 2010.

[7] p. 43, *ibid.*

[8] p. 45, *ibid.*

[9] Article 107 of the Korean Patent Act.

[10] Article 16.7.6 of US-Singapore Free Trade Agreement.

[11] Instead of such method of treatment claims, pharmaceutical composition claims that specify a therapy are utilized under Korean practice.