Form PCT/IB/382

Legal Implications in Countries with Compulsory Licensing Rules

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The World Intellectual Property Organization (WIPO) added a new feature in January 2012 in an effort to promote licensing. Patent Cooperation Treaty (PCT) applicants may submit form PCT/IB/382, which informs others that the patent application is available for licensing. The form also allows PCT applicants to specify certain licensing terms, such as whether the invention is available for exclusive or nonexclusive licensing, and the countries in which the application is available for licensing. The licensing indications are found in the bibliographic data section on the PATENTSCOPE website, but are not published with the international application itself. Applicants can submit the licensing form any time after the filing of a PCT application up until 30 months after the priority date. To date, form PCT/IB/382 has been filed for 188 PCT applications; these PCT applications are included on the PATENTSCOPE website list of patent applications that are available for licensing.

In 2010, the WIPO working group endorsed the development and use of form PCT/IB/382 to help foster dissemination of technical information and facilitate access to technology contained in PCT and national applications and patents. This new feature is part of a plan the WIPO working group endorsed that also included providing information concerning oppositions to patents, revocation and lapse of patents, and the issuance of compulsory licenses. The information about licensing availability from form PCT/IB/382 has been integrated into WIPO's PATENTSCOPE search system to permit information about patents and applications to be determined more readily; however, the other provisions are not currently available through the PATENTSCOPE search feature.

While groups such as the American Intellectual Property Law Association support the addition of the PCT licensing feature to the PATENTSCOPE website,[1] no one has fully examined the implications of filing form PCT/IB/382 for PCT applications. In particular, it is unclear what consequences may result from submitting form PCT/IB/382 in countries with compulsory licensing rules.

Compulsory Licensing

Compulsory licensing is a provision under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 31 of the TRIPS agreement allows governments to grant compulsory licenses, as long as certain procedures are followed and certain terms are fulfilled. The Doha Declaration on TRIPS and Public Health, adopted by the World Trade Organization in 2001, clarifies that all member states have the right to grant compulsory licenses to protect public health and improve access to medicines.[2] Compulsory licenses permit governments to grant someone other than the patent owner the right to produce the patented product or process without the owner's consent if a certain amount of compensation is paid to the patent owner. These agreements are intended to provide safeguards against the lack of use of patents or misuse of patent holders' monopoly rights that are detrimental to public health. Except in situations of national emergency or other cases of extreme urgency, the prospective licensee must negotiate with the patent holder and ask for a voluntary license on reasonable commercial terms before seeking a compulsory license.[3]

Compulsory licensing provisions are common in many patent systems, even though they are rarely implemented. The provisions are often used as a strategic tool to improve the negotiating position of a government toward a patent holder to improve access to a particular invention. The risk of enforcing compulsory licenses is that the routine use of compulsory licenses may reduce innovation and investment by diminishing the value of a patent.[4]

Different governments employ compulsory licenses to different extents. In March 2012, the Indian Patent Office controversially issued a compulsory license to an Indian company, Natco Pharma, allowing Natco Pharma to produce Bayer's cancer drug Nexavar.[5] The Indian Patent Office based its decision largely on the grounds that the patented version of the drug is too expensive for most Indian patients, and that Bayer was producing inadequate amounts of the drug for the Indian market. In March 2013, the Intellectual Property Appellate Board (IPAB) upheld the Indian Patent Office's decision to grant a compulsory license for Nexavar.[6] Bayer had challenged the Indian Patent Office's grant of a compulsory license on several grounds, including that Natco Pharma had not made reasonable efforts to obtain a voluntary license.[7] Bayer argued that Natco Pharma's offer letter did not include terms and conditions and was more of a threat than a request for a voluntary license. In rejecting Bayer's argument, the IPAB stated that rather than clearly rejecting Natco Pharma's request for a voluntary license, Bayer should have stated there was room for negotiation even though the amount stated by Natco Pharma was not considered to be a bargaining point by Bayer. The IPAB found that because of Bayer's outright rejection of Natco Pharma's offer, Natco Pharma had no obligation to negotiate further and that the legal requirements for the granting of a compulsory license had been met.[8] Bayer announced it will appeal the decision.[9]

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The United States Patent and Trademark Office criticized the compulsory license as not complying with international standards of patent law.[10] However, this situation demonstrates that some governments are willing to grant compulsory licenses based not on a national emergency or other extreme circumstances, but based instead on the belief that a drug should be cheaper and broadly available to its citizens.[11] It also highlights the importance of negotiation strategies, particularly in India.

In May 2012, China's State Intellectual Property Office issued new regulations stating that the government can order compulsory licenses for generic drugs when there is a "national emergency or any extraordinary circumstances, or for public interest purposes."[12] This provision gives the Chinese government broad leeway to allow the manufacture of generic versions of drugs that are subject to patent protection. To date, no compulsory licenses have been granted in China.

The governments of other countries, such as Thailand, have issued compulsory licenses for generic versions of HIV drugs, while certain governments, like Japan's, have regulations allowing for compulsory licenses, but have never invoked these regulations.[13]

Implications of Filing Form PCT/IB/382

The recent implementation of a compulsory license in India and the possibility of compulsory licenses being used in key countries such as China and Japan raise concerns for global pharmaceutical companies. Companies should carefully consider the effects of filing documents such as form PCT/IB/382 indicating that their patent assets are available for licensing, particularly in these countries.

The consequences of filing form PCT/IB/382 in countries with compulsory licensing provisions are unclear, but are worth considering. In countries that allow for compulsory licenses, filing form PCT/IB/382 could be seen as a commitment or preliminary agreement on the part of the patent applicant to license its technology in that country. If the patent applicant fails to take steps to negotiate a license in good faith, a government that grants compulsory licenses may view this as grounds for granting a compulsory license based on lack of use of a patent or misuse of a patent applicant's monopoly rights. However, publishing a form stating that an application is available for licensing seems unlikely to create a preliminary agreement sufficient to create an obligation to negotiate in good faith in the absence of additional communication between the two parties. For example, form PCT/IB/382 lacks many of the terms that are required for a final agreement, including the parties involved, the compensation for the license, and the duration of the license. However, as some jurisdictions, particularly those based on the civil law system, are willing to extend standards of good faith to negotiations,[14] it is possible that indicating a willingness to license an application may create an obligation on the part of the patent applicant and that a breach of this obligation may be viewed as grounds for granting a compulsory license.

The counterargument could be made that filing form PCT/IB/382 makes it less likely that a government will issue a compulsory license. The apparent willingness of a patent applicant to license its technology may suggest that a market failure due to lack of use or misuse of monopoly rights is unlikely. A government may be less likely to take an active part in licensing negotiations or compel the patent applicant to license its product based on the perceived willingness of the applicant to negotiate a license to its invention. The IPAB's decision to uphold the Indian Patent Office's grant of a compulsory license for Nexavar was based in part on Bayer's rejection of Natco Pharma's request for a voluntary license.[15] If Bayer had filed form PCT/IB/382 indicating its willingness to negotiate a voluntary license in India, it is possible that the IPAB may have ruled differently on this ground of Bayer's argument.

It remains to be seen what effects, if any, filing form PCT/IB/382 will have in countries with governments that grant compulsory licenses. These potential implications will likely be clarified as more patent applicants file form PCT/IB/382. It will be interesting to see if patent applicants exclude India from the list of countries available for licensing in efforts to avoid compulsory licensing in India. However, until more information is available regarding the effects of form PCT/IB/382 in various countries, pharmaceutical companies should carefully evaluate the potential effects on a country-by-country basis before filing form PCT/IB/382, particularly as the effects relate to the application of compulsory licenses by different governments. ■

Endnotes

1. *See* Letter from David W. Hill, AIPLA President, to Francis Gurry, Dir. Gen., WIPO, Comments on "Development of a Request for Indication for Licensing Purposes in PCT Applications" (WIPO Circular C. PCT 1305) (June 15, 2011), *available at* www.aipla.org/advocacy/intl/Documents/AIPLA%20Comments%20to%20WIPO%20on%20PCT%20Apps%20Indication%20for%20Licensing%20-%206.14.11.pdf.

2. *See* Nat'l Bd. of Trade, The WTO Decision on Compulsory Licensing 7 (2008), *available at* www.kommers.se/Documents/dokumentarkiv/publikationer/2008/rapporter/report-the-wto-decision-on-compulsory-licensing.pdf.

3. *Id.* at 19.

4. *Id.* at 7.

5. Stewart Bishop, *USPTO Official Slams Use of Compulsory Patent Licenses*, Law360 (June 27, 2012), www.law360.com/articles/353114/uspto-official-slams-use-of-compulsory-patent-licenses.

6. Patralekha Chatterjee, *India's First Compulsory License*

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Upheld, but Legal Fights Likely to Continue, INTELL. PROP. WATCH (Mar. 4, 2013), www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue.

7. Someshwar Banerjee & Aruna Verma, *Compulsory Licenses Are Pro-Public, Not Anti-Inventor*, INTELL. ASSET MGMT. (Apr. 3, 2013), www.iam-magazine.com/reports/Detail.aspx?g=05dbb612-d26d-4dc8-b4dc-8ff0f0e04127.

8. *Id.*

9. Chatterjee, *supra* note 6.

10. Bishop, *supra* note 5.

11. Ryan Davis, *China's Compulsory License Rule Has Drug Cos. on Edge*, LAW360 (June 12, 2012), www.law360.com/articles/349358/china-s-compulsory-license-rule-has-drug-cos-on-edge.

12. *Id.*

13. *Id.*

14. Aarti Arunachalam, An Analysis of the Duty to Negotiate in Good Faith: Precontractual Liability and Preliminary Agreement 63 (Aug. 1, 2002) (unpublished LLM thesis, University of Georgia School of Law), *available at* http://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1003&context=stu_llm.

15. Banerjee & Verma, *supra* note 7.