Compulsory Licensing: How to Gain Access to Patented Technology

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ABSTRACT

Voluntary patent licenses are often difficult for institutions to obtain, particularly those in developing countries. This chapter discusses why, how, and by whom compulsory patent licenses may be obtained and used. The main focus is on patented research tools rather than patented end products.

1. INTRODUCTION

Some scientific discoveries and inventions, particularly in biotechnology, have no obvious practical application; to use the metaphor of a river, we might say that they are patented at a point upstream from practical application. Broad patent claims often hamper the development of downstream applications.[1] For instance, in the United States, DNA sequences (genes) are legally considered to be chemical compounds and can therefore be patented. The gene's functions, even those that are not yet known, can therefore be exploited only by authorization of the patent owner.

One example of the problems that can occur when downstream researchers need to use upstream discoveries is the case of antigen MSP-1, an important candidate for the development of an antimalaria vaccine. The Program for Appropriate Technology in Health (PATH), which is working to develop such a vaccine, found that the antigen was protected by more than 20 partially overlapping patents. Extensive negotiations and a considerable amount of time and money were required to obtain permission to use it. A representative of the program notes:

> Why does the IP landscape for MSP-1 not sort itself out through traditional channels such as technology transfer and the courts? Developers who want assurance of the rights to use MSP-1 would have to obtain licenses from no less than eight organizations.Though theoretically possible, a licensing transaction of this type would take years, require significant staff time, and cost hundreds of thousands of dollars in attorney fees. While companies routinely make such efforts on behalf of commercial products, the economics of malaria vaccines make developers more reluctant to invest in such cumbersome technology acquisition.[2]

Several studies in the United States[3] and elsewhere[4] have examined the potential impact of research tool patents. Although the U.S. National Academies of Sciences found that private companies and research institutions in developed countries are generally able to deal with the complexities of patent law, it warned that "*the patent landscape, which already is becoming complicated in areas such as gene expression and protein-protein interactions, could become considerably more complex and burdensome over time*."[5] A Swiss survey on the obstacles to research stemming from patent protection found that a majority of companies and

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institutions favored the creation of either an exception for the clinical use of the patented subject matter or the granting of compulsory licenses.[6]

Small companies and research institutions will likely be more adversely affected by upstream patents than will large companies or institutions. Entities in developing countries that lack the legal, financial, technological and negotiating capacity to engage in complex negotiations, may be significantly constrained. For instance, a survey of 103 Indian pharmaceutical companies revealed that the most common reason firms decided to abandon R&D projects was because of restricted access to patented upstream technologies.[7]

Some initiatives are being considered that would allow low-income countries access to technology under special conditions. The Science and Intellectual Property in the Public Interest project (SIPPI) of the American Association for the Advancement of Science (AAAS)[8] has promoted the idea that technology managers in developed countries should include legally enforceable provisions in licensing agreements to preserve the possibility of sharing protected technologies with third parties for humanitarian reasons in developing countries.[9]

Patented upstream technology can create barriers to agricultural research,[10] unless the use of the protected subject matter is permitted under a research exception or otherwise consented by the patent owner. Golden Rice, which has been genetically modified to contain pro-Vitamin A or beta-carotene, is a tool for combating vitamin A deficiency in developing countries. Syngenta Seeds AG negotiated access to all major technologies necessary for Golden Rice production[11] and then granted the inventors of Golden Rice the right to sublicense breeding institutions in developing countries, free of charge, provided that the rice would be used only for subsistence farming and not for commercial purposes. Subsistence farming has been defined as any farm not generating income more than US$10,000 from the sale of rice. Syngenta is not interested in commercializing Golden Rice in developed countries, where vitamin A deficiency is almost unheard of.[12]

Other examples of removal of patent barriers through "humanitarian IP management" include Cornell University's transfer of papaya-ringspot-virus-resistant papaya to Thailand; several projects brokered by the International Service for the Acquisition of Agri-biotech Applications (ISAAA); and the agreement between Yale University and Bristol-Myers Squibb regarding the patent on stavudine (d4T), a widely used HIV/AIDS antiretroviral drug. Humanitarian IP management could be expanded to involve research and experimentation as well as the transfer of patented technologies.

2. PATENTS AND DOWNSTREAM RESEARCH

A *compulsory license* is an authorization given by a "national authority" to a natural or legal person for the exploitation of the subject matter protected by a patent; the consent of the patent title holder is not necessary. Compulsory licenses may be required to import or produce a given product, or to use a patented technology for research. They are especially important when there are no close substitutes for a product or process and a research exception is not available or is too narrow.[13]

Compulsory licenses are granted in order to attain various public-policy objectives, such as: to address emergencies and public-health needs, to counteract anticompetitive business practices, or to permit the exploitation of a patent in cases of lack of working thereof.

The right to use compulsory licenses was recognized in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994.[14] The Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration), adopted by the 4th WTO Ministerial Conference in November 2001,[15] confirmed, inter alia, that each WTO member was free to determine the grounds under which it would grant compulsory licenses.[16]

In the United States, compulsory licenses have been widely used for government use and in settlements for antitrust cases.[17] Countries such as Zambia and Zimbabwe have recently issued compulsory licenses to facilitate access to cheap medicines; others, such as Malaysia and Indonesia, have

issued government-use provisions for the same purpose. A public non-commercial use provision is somewhat different from a compulsory license for commercial production. Public non-commercial use provisions, which exist in many countries, authorize a government department to exploit, by itself or through a contractor, a patented invention, without the consent of the patent right holder, as long as such exploitation is to provide a public service and for noncommercial purposes. Other countries, such as Brazil and South Africa, have threatened to grant compulsory licenses in order to obtain cheaper medicines.[18] A compulsory license is likely to be less advantageous to the patent owner than a voluntary license. It is therefore to the advantage of patent owners to price their products fairly and grant voluntary patent licenses with reasonable terms and conditions.

Compulsory licenses may be needed when patents restrict the freedom to operate (FTO) [19] in a given field of R&D. Such licenses are subject to several conditions, notably that the licensee must remunerate the patent holder. These conditions are examined in section 3 below.

3. COMPULSORY LICENSES FOR RESEARCH

3.1 *Who can apply?*

National laws normally allow companies, nongovernmental organizations, and research institutions to apply for compulsory licenses. In some countries, licensees must first demonstrate that they have the technical or economic capacity to utilize the license properly.

3.2 *When can a compulsory license be applied for?*

Some types of compulsory licenses, such as those granted to remedy abuses, for example, lack of working, cannot be granted until four years after the date of filing of the patent application or three years from the date of the grant of the patent, whichever date comes second.[20] These terms do not apply when the compulsory licenses are granted on other grounds, such as when public health is at stake, in emergency situations, or where necessary to remedy anti-competitive practices.

3.3 *Prior negotiation of a voluntary license*

Except in the case of emergency, anti-competitive practices, and government use, the potential compulsory licensee must first request a voluntary license on reasonable commercial terms from the patent owner.[21] Such "reasonable commercial terms" must be consistent with standard commercial practice and must ultimately be in accordance with the requirements set by national law and by the competent authority. If such a voluntary license is denied, the potential licensee may apply for a compulsory license—though it may be necessary to prove that the patent owner has refused to grant a voluntary license within a reasonable time period.

Many patents for research tools are held by universities—where the initial invention has often been made—that sometimes decline to provide voluntary licenses to certain applicants or are unable to do so. The reasons for this may be multifold. One reason may be that the university has already granted an exclusive license; another reason may be that the university is in licensing negotiations with another party. Determining reasonable commercial terms when the patent owner is a university is also difficult. However, there are many universities with extensive experience in these matters, and their standard practices may serve as models. This is certainly one reason why universities should be encouraged to retain humanitarian-use rights.[22]

3.4 *How should the application be made?*

National laws govern both the substantive requirements and the relevant procedures for obtaining a compulsory license.

3.4.1 *The appropriate authority*

In most countries, compulsory licenses are granted by the government's executive branch. In others, such authority lies with the judiciary branch. The services of legal professionals are not generally required, but may be advisable.

3.4.2 *Grounds for the application*

The appropriate authority should be provided with a reasoned justification for the application. The application should, to the greatest extent

possible, specify the legal provisions and grounds on which it is sought. Requests must abide by the restrictions set by national law.[23]

The application should specify the scope and duration of the requested compulsory license. An application may request access to all of the subject matter covered by a patent, or it may request access to only certain elements of a patent, or certain uses of a patented invention.

To avoid the trouble of having to file future license extensions, it is advisable to request the license for the full remaining term of the patent.

3.4.3 *Identification of the applicant*

The applicant, if not a natural person, will normally have to submit copies of the relevant statutes or bylaws. In addition, any person representing the applicant will have to demonstrate his or her capacity to do so. Depending on national law, the applicant may also have to provide evidence of sufficient economic or technical capacity to utilize the compulsory license (information about personnel, funding, activities, partnerships, publications, and so on).

3.4.4 *Identification of patents*

The identification of the patents involved can be determined by indicating the product or technologies at stake. The compulsory license application may refer to all patents relating to the products or technologies the applicant seeks to exploit. In other words, one application can request the rights to many patents. In the United States, there have been cases in which compulsory licenses were even granted for both current and future patents.[24]

3.4.5 *Conditions of the compulsory license*

Remuneration. Governments have considerable discretion to define the level and kind of remuneration that the patent owner should receive. The general rule is that remuneration should be adequate, taking into account both the particular circumstances of each case and the economic value of the compulsory license.[25] Following are some of the methods that have been used to calculate remuneration:[26]

- The 1998 Japan Patent Office (JPO) Guidelines (for government-owned drug patents) specify royalties that amount to 2%–4% of the generic product price; this amount can be increased or decreased by as much as 2%, for a range of 0%–6%.
- The 2001 United Nations Development Programme (UNDP) Human Development Report proposed a base royalty rate of 4% of the generic drug price. This can be increased or decreased by 2%, for a range of 2%–6%, depending upon various factors (how innovative the medicine is, or the role of governments in paying for research and development).
- In accordance with the WTO Decision of 30 August 2003, the 2005 Canadian government established royalty guidelines for compulsory licensing of patents to countries that lack the capacity to manufacture medicines. The royalty rate (between 0.02% and 4% of the price of a generic drug) is determined by a country's rank in the UN Human Development Index. For most developing countries, the royalty rate is less than 3%. For most countries in Africa, the rate is less than 1%.
- The tiered-royalty method is unusual in that the royalty rate is based upon the price of a brand-name drug, not the generic equivalent, in the high-income country in which the patent is owned. The base royalty (4% of the brand-name price) is adjusted to account for relative income per capita or, for countries with a particularly high burden of disease, relative income per diseased person.

These guidelines are used to determine royalty rates for products, not research tools. For research tools, royalty payments may be lower since no products are yet on the market.

With regard to agricultural technology, a relevant precedent may be the determination of 1,1% of the net sales of products within the Multilateral System in the context of the standard material transfer agreement adopted, in June 2006, by the Governing Body of the FAO

International Treaty on Plant Genetic Resources for Food and Agriculture.[27]

Finally, the act granting a compulsory license should specify time of payment, basis for the calculation of fees or royalties, currency of payment, the bank account where the payment will be deposited, and other relevant details.

Other conditions. In all cases, a compulsory license will be nonexclusive:[28] that is, the patent owner or other voluntary or compulsory licensors may simultaneously exploit the patented invention or research tool. According to some national laws, the license may be revoked if not utilized within a certain term. Moreover, a compulsory licensor can request that a license be terminated, if and when the circumstances that first necessitated the license cease to exist and are unlikely to recur.[29]

3.4.6 *Appeal*

A compulsory license may be delayed if the patent owner appeals the validity of the license or the level of remuneration that it grants.[30] For this reason, in some countries, a license can be put into effect even while appeal procedures are pending.

4. CONCLUSIONS

The problems generated by patent infringement on downstream use of inventions, especially in developing countries, can be minimized through a number of approaches. Countries should adopt and enforce strict criteria of patentability and broad exceptions for research. If patents on research tools limit FTO, the first step should be to negotiate voluntary licenses on reasonable terms and conditions, particularly as this may allow for the licensing of knowledge not disclosed in the patent. If it cannot be achieved, or proves too cumbersome or costly to do so, the next step should be to apply for compulsory licenses. Applicants need to be certain that they have the capacity to exploit the licenses and the financial ability to remunerate the patent holder or patent holders. Nonprofit research institutions may often find this particularly difficult because even with a compulsory license, commercial partners will need to be in place to produce and distribute products that were developed under compulsory licenses. This is one reason for further investments in capacity building and the establishment of strong institutional networks. ■

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1 Steil B, DG Victor and R Nelson. 2002. *Technological Innovation and Economic Performance* (A Council on Foreign Relations Book). Princeton University Press: Princeton and Oxford, p. 21.

2 Intellectual Property Rights and Vaccines in Developing Countries. Meeting report. Geneva, World Health Organization, 2004 (WHO/IVB/04.21). www.who.int/vaccines-documents/DocsPDF05/Dip-789-screen.pdf. Quoted in Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH). 2006. *Public Health, Innovation and Intellectual Property Rights*, World Health Organization. p. 77.

3 In a seminal contribution on this issue, Heller and Eisenberg stated: "*... the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an* anticommons *in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development. Otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health.*" (Heller M and RS Eisenberg. 1998. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 280: 698–701). See also Tran C. 2006. WARF Stem Cell Patents Challenged: Research Could Get Faster and Cheaper If the Patents Are Narrowed, Some Scientists Say. *The Scientist*. 10 October 2006.

4 See, for example, Cho MK, S Illangaskekare, MA Weaver, DGB Leonard and JF Merz. Effects of Patents and Licences on the Provision of Clinical Genetic Testing Services. *Journal of Molecular Diagnostics* 2003: 3–8.

5 National Research Council. 2006. *Reaping the Benefits of Genomic and Proteomic Research Intellectual Property Rights, Innovation and Public Health*. The National Academies Press: Washington, DC. www.nap.edu/books/0309100674/html/.

6 Thumm N. 2005. Patents for Genetic Inventions: A Tool to Promote Technological Advance or a Limitation for Upstream Inventions? *The International Journal of Technological Innovation and Entrepreneurship* 25: 1410–17.

7 See Sampath G. 2005. Breaking the Fence: Can Patent

Rights Deter Biomedical Innovation in "Technology Followers"? Maastricht, UNU/INTECH, Discussion Paper Series No. 2005-10. www.intech.unu.edu/publications/discussion-papers/2005-10.pdf (CIPIH, p.77).

8 See sippi.aaas.org/.

9 See also, in this *Handbook*, chapter 2.2 by A Brewster, AL Chapman and SA Hansen.

10 The effects of patents, although territorial in nature, may extend beyond the territory of cultivation and reach derivatives of patented plants or genes. Monsanto, for instance, does not have a patent on Roundup Ready® soybean in Argentina, which is exporting processed soybean flour to European countries. In Argentina, the original Monsanto materials have been used in breeding since 1996, and around 160 local varieties containing the gene have been developed and registered by third parties. Although Monsanto, did not oppose the commercialization of those varieties, it has filed requests to the customs authorities of several European countries (where Monsanto does have patent protection for Roundup Ready® soybeans) demanding that the importation of soya flour produced in Argentina be prevented, and has initiated litigation against European importers. See also Correa C. 2006. La disputa sobre soja transgénica. *Monsanto vs. Argentina*, *Le Monde Diplomatique/El Dipló*, Buenos Aires, April 2006.

11 See for example, Kryder D, SP Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No 20. ISAAA: Ithaca, NY. www.isaaa.org/kc/bin/isaaa_briefs/index.htm.

12 www.goldenrice.org/Content2-How/how9_IP.html.

13 In some jurisdictions, research or experimentation exceptions may allow follow-on research *on* an invention, but not *with* it. This distinction is commonly accepted under European law. See, for example, Cornish W. 1998. Experimental Use of Patented Inventions in European Community States. *International Review of Industrial Property and Copyright Law,* 2. no.7; Correa C. 2005. *International Dimension of the Research Exception*, SIPPI Project, AAAS, Washington, D.C. sippi.aaas.org/intlexemptionpaper.shtml. In the United States, research without the authorization of the patent owner is narrowly admitted for scientific purposes only. The Federal Circuit Court of Appeals held in *Madey v. Duke* that regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or nonprofit status of the user is not determinative (64 U.S.P.Q. 2d 1737 (Fed. Cir. 2002).

14 See Article 31 of the TRIPS Agreement available at www.wto.org.

15 WT/MIN(01)/DEC/W/2, 14 November 2001. www.wto.org (full text in Annex I).

16 Paragraph 5 (b): "*Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*"

17 See, for example, Correa C. 1999. *Intellectual property rights and the use of compulsory licences: options for developing countries*. Trade-Related Agenda, Development and Equity, Working Papers. Geneva, South Centre; Reichman J and Hasenzahl C. 2002. Non voluntary licensing of patented inventions: history, TRIPs, and Canadian and United States Practice. Bridges (UNCTAD/ICTSD) Vol. 6, No. 7.

18 See *supra* note 2, CIPIH, p. 135.

19 FTO may be achieved through inventing around, nonassert covenants, opposition to the grant of a patent or invalidation thereof. For a comprehensive discussion on the various options for obtaining FTO, see in this *Handbook*, chapter 14.1 by A Krattiger.

20 See Article 5A of the Paris Convention for the Protection of Industrial Property.

21 See Article 31(b) of the TRIPS Agreement.

22 See, also in this *Handbook,* chapter 2.1 by AB Bennett.

23 If the permitted grounds are too narrow, a request for compulsory license may fail. For instance, the free trade agreement between the United States and Jordan (2000) limited the grounds on which compulsory licenses can be granted as follows: "*Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirement, provided that importation shall constitute working.*" (Article 4.20).

24 Correa C. 1999. Intellectual property rights and the use of compulsory licenses: options for developing countries. Trade-Related Agenda, Development, and Equity, Working Papers, South Centre, Geneva. Available at www.southcentre.org.

25 Article 31(h) of the TRIPS Agreement. The obligation to pay a remuneration is waived in the case of a compulsory license granted under the system established by the WTO Decision of 30 August 2003 (incorporated as Article 31bis of the TRIPS Agreement, but still subject to ratification) to import pharmaceutical products in cases where the importing country has established that it lacks sufficient manufacturing capacity in pharmaceuticals. Payment in these cases will only take place under the compulsory license granted in the exporting country.

26 Love J. 2005. Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies. World Health Organization: Geneva. (WHO/TCM/2005.1), p 83–85.

27 Correa C. 2006. Considerations on the Standard Material Transfer Agreement under the FAO Treaty on Plant Genetic Resources for Food and Agriculture. *The Journal of World Intellectual Property* 9(2): 137–65. See also the text of the adopted standard agreement at ftp://ftp.fao.org/ag/cgrfa/gb1/SMTAe.pdf.

28 Article 31(d) of the TRIPS Agreement.

29 Article 31(g) of the TRIPS Agreement.

30 The TRIPS Agreement specifically provides that "*the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member*" (Article 31(i)).