KNOWLEDGE ECOLOGY INTERNATIONAL

Legal framework for Compulsory Licenses on Drugs

March 16, 2007

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1. Trade Related Aspects of Intellectual Property (TRIPS) Article 31.b - Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[fn] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a

valid patent is or will be used by or for the government, the right holder shall be informed promptly;

[fn]"Other use" refers to use other than that allowed under Article 30.

2. Doha World Trade Organization Ministerial Declaration On The Trips Agreement And Public Health

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

   In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

   a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
   b. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
   c. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

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d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

3. World Trade Organization Fact Sheet- TRIPS And Health: Frequently Asked Questions

Compulsory licensing of pharmaceuticals and TRIPS

A certain amount of confusion exists about the TRIPS Agreement's provisions and compulsory licensing for medicines. These are some answers to questions that are frequently asked.

What is compulsory licensing?

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

Does there have to be an emergency?

Not necessarily. This is a common misunderstanding. The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences.

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The TRIPS Agreement does list a number of conditions for issuing compulsory licences, in Article 31. In particular:

-normally the person or company applying for a licence has to have tried to negotiate a voluntary licence with the patent holder on reasonable commercial terms. Only if that fails can a compulsory licence be issued, and

-even when a compulsory licence has been issued, the patent owner has to receive payment; the TRIPS Agreement says "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization", but it does not define "adequate remuneration" or "economic value".

There's more. Compulsory licensing must meet certain additional requirements: it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and it should be subject to legal review in the country.

You said "normally" …

Yes, this is where the confusion about emergencies arises. For "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try first for a voluntary licence. It's the only instance when the TRIPS Agreement specifically links emergencies to compulsory licensing: the purpose is to say that the first step of negotiating a voluntary licence can be bypassed in order to save time. But the patent owner still has to be paid.

http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

4. United States Executive Order 12889 -Implementation of the North American Free Trade Agreement

December 27, 1993

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the North American Free Trade Agreement Implementation Act (Public Law 103–182, 107 Stat. 2057)(the NAFTA Implementation Act) and section 302 of title 3, United States Code, and in order to implement the North American Free Trade Agreement(NAFTA), it is hereby ordered:

Section 6. Government Use of Patented Technology.

(a) Each agency shall, within 30 days from the date this order is issued, modify or adopt procedures to ensure compliance with Article 1709(10) of the NAFTA regarding notice when patented technology is used by or for the Federal Government without a license from the owner, except that the requirement of Article 1709(10)(b)regarding reasonable efforts to obtain advance authorization from the patent owner:

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(1) is hereby waived for an invention used or manufactured by or for the Federal Government, except that the patent owner must be notified whenever the agency or its contractor, without making a patent search, knows or has demonstrable reasonable grounds to know that an invention described in and covered by a valid United States patent is or will be used or manufactured without a license; and

(2) is waived whenever a national emergency or other circumstances of extreme urgency exists, except that the patent owner must be notified as soon as it is reasonably practicable to do so.

(b) Agencies shall treat the term ''remuneration'' as used in Articles 1709(10)(h) and (j) and 1715 of the NAFTA as equivalent to ''reasonable and entire compensation'' as used in section 1498 of title 28, United States Code.

(c) In addition to the general provisions of section 7 of this order regarding enforceable rights, nothing in this order is intended to suggest that the giving of notice to a patent owner under Article 1709(10) of the NAFTA constitutes an admission that the Federal Government has infringed a valid privately-owned patent.

5. 28 U.S.C. § 1498(a) Patent and copyright cases

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States. Nothwithstanding [1] the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust.

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

The court shall not award compensation under this section if the claim is based on the use or manufacture by or for the United States of any article owned, leased, used by, or in the possession of the United States prior to July 1, 1918.

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A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the invention by the Government. This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which Government time, materials or facilities were used.

6. Recent U.S. Examples of the Use of Compulsory Licenses on Patents

[These are only a few of the U.S. examples included in a longer document, available at: http://www.keionline.org/index.php?option=com_content&task=view&id=30]

Government use under 28 USC 1498

In 2001, DHHS Secretary Tommy Thompson threatened to use 28 USC 1498 in order to authorize imports of generic ciprofloxacin for stockpiles against a possible anthrax attack.

In 2005, the U.S. Department of Justice cited its right to use patents in 28 USC 1498 when it opposed injunctive relief for infringement of patents relating to the Blackberry email services supplied to both the government and private firms that used the Blackberry device to communicate with the government.

Merger reviews

In 2002, the U.S. Federal Trade Commission (FTC) ordered a compulsory cross-license of the Immunex tumor necrosis factor ("TNF") patent, to Serono, including the "freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States." Note the permission to export, which is anticipated by Article 31.k of the TRIPS. In this case, the compulsory cross-license allows a Swiss firm to compete with the U.S. patent owner.

In 2005, the FTC ordered a compulsory license of Guidant's intellectual property surrounding the RX delivery system for Drug-Eluting Stents (DES) as a condition of Guidant's acquisition by either Johnson & Johnson or Boston Scientific.i Boston Scientific, which eventually won the bidding to acquire Guidant, was required to license DES patents to a potential entrant, Abbott.

Non-merger remedies to anticompetitive practices

In February 2007, in a case involving a failure to disclose patents on the standard, an FTC antitrust remedial order compelled memory chipmaker Rambus to license its patented technology on certain specified terms and limited the maximum royalty rates that Rambus can collect for use

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of its patents to 0.25 percent for SDRAM products; 0.5 percent for DDR SDRAM products, as well as SDRAM memory controllers or other non-memory chip components; and 1 percent for DDR SDRAM memory controllers, or other non-memory chip components. After three years, the royalty rate will be zero percent.

New U.S. Supreme Court standard for granting injunctions on patents

In June 2006, a court granted Microsoft a compulsory license to use two patents owned by z4 Technologies that relate to Digital Rights Management systems used by Microsoft for its Windows and MS Office software programs.

In July 2006, a court granted DirectTV a compulsory license to use the Finisar patent on integrated receiver decoders (satellite set top boxes), for a royalty of $1.60 per device.

In August 2006, a court granted Toyota a compulsory license on three Paice patents for hybrid transmissions, for a royalty of $25 per automobile.

In September 2006, a court granted Johnson and Johnson a compulsory license to use three of Dr. Jan Voda's patents on guiding-catheters, medical devices for performing angioplasty.

7. Regulation (Ec) No 816/2006 Of The European Parliament And Of The Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

1. There are no limits on the scope of diseases. It extends to all medicinal products as defined in Article 1(2) of Directive 2001/83/EC on medicinal products for human use (1), active ingredients and diagnostic kits ex vivo.

2. The compulsory licenses are mandatory: "Member States shall grant a compulsory licence to any person making an application in accordance with Article 6 and subject to the conditions set out in Articles 6 to 10."

3. Prior negotiation with right owners is waived "in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial." In these cases, "the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country." In other cases, remuneration may consider "humanitarian or noncommercial circumstances relating to the issue of the licence."

4. The "safety and efficacy of medicinal products" may be evaluated through evaluation of "the scientific opinion procedure as provided for under Article 58 of Regulation (EC) No 726/2004, or . . . any similar procedures under national law, such as scientific opinions or export certificates intended exclusively for markets outside the Community."

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5. In Article 18.2, when compulsory licenses to data are issued under this regulation, EU "protection periods" for test data "shall not apply." This waiver of data exclusivity for a case involving a compulsory license is quite important. Note that the remuneration for the patent is the sole remuneration in such cases.

8. World Bank Report: The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand - August 2006

[Excerpt from Executive Summary]

Thailand is in the vanguard of developing countries that are seeking to provide antiretroviral therapy (ART) as the standard of care to large numbers of people with symptomatic HIV disease. . . . .Because Thailand stands to gain a great deal from bilateral agreements to reduce trade barriers with trading partners such as the United States, the Royal Thai government may be tempted to relinquish its rights to grant compulsory licenses for AIDS drugs in exchange for proffered trade advantages. The report finds that the cost of such concessions would be large. For example, by exercising compulsory licensing to reduce the cost of second-line therapy by 90 percent, the government would reduce its future budgetary obligations by US$3.2 billion discounted (B 127 billion discounted) through 2025 and would cut by more than half the cost per life-year saved of the NAPHA program, from US$2,145 to US$940 (or B 85,800 to B 37,600) per life-year saved. The size of royalty payments that the WTO mandates to accompany compulsory licensing is indeterminate and is subject to negotiation. Thailand could enhance its bargaining power vis-à-vis the multinational pharmaceutical industry by coordinating its negotiations with other middle- and low-income countries.

9. Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand

By the Ministry of Public Health and The National Health Security Office of Thailand, February 2007 [Excerpt. Full document available at http://www.cptech.org/ip/health/c/thailand/thai-cl-white-paper.pdf]

Issue No. 4: What are the mechanisms and criteria used to determine which drugs to issue Government Use of Patent?

The Subcommittee to implement the Government Use of patent on drugs and medical supplies established by the National Health Security Board on 17 April 2006 is a mechanism to consider which drugs to issue Government Use of patent (Document No. 22). This subcommittee is chaired by the Secretary General of the National Health Security Office, and involves all concerned departments in the Ministry of Public Health and Ministry of Commerce as well as

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consumer groups, communities of people living with diseases and medical specialists. The criteria to determine which drugs to issue a Government Use of patent includes drugs and medical supplies that are:

- listed in the National Essential Drug List, or
- necessary to solve important public health problems, or
- necessary in emergency or extreme urgency, or
- necessary for the prevention and control of outbreaks/epidemic/pandemics, or
- necessary for life saving

The price of these drugs and medical supplies must be too high to be affordable by the government to supply to the beneficiaries of the national health insurance schemes to achieve the universal access policy.

Issue No. 5: The Government Use of Patents will save the government some funds but what are the benefits to the people?

The main objective of announcing and implementing the Government Use of patent is to increase the access to essential medicines among the Thai people. The Government does not save any budget and in some cases has to spend more. For those ARVs which have limited coverage, like Efavirenz and Lopinavir+Ritonavir, many more people will have access to the drugs with the same budget level. In the case of Clopidogrel, the patients under the National Public Health Insurance Plan had no or very little access before, and the government had to pay an additional amount to allow access to the lower priced generic version of Clopidogrel. It should be reiterated that drugs derived from the implementation of the three Government Use of patent will be distributed only to those patients under any of the three public health insurance plans paid by the government. The drugs can not be sold to the private sector or to those who are willing to pay out of pocket for their drugs.

[i] For more information: http://www.ftc.gov/opa/2006/04/bostonscigui.htm

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