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Recent examples of the use of compulsory licenses on patents[1]

KEI Research Note 2

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I. INTRODUCTION

The term "compulsory License" is used to describe a number of mechanisms for non-voluntary authorizations to use patents. The most important global norm for the use of compulsory licenses is Article 31 of the WTO TRIPS Agreement, which addresses uses "of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government." Other TRIPS provisions that are important are Articles 1, 6, 7, 8, 31 bis, 40 and 44, as well as the provisions of the 2001 Doha Declaration on TRIPS and Public Health.

Contrary to many popular news reports and statements by misinformed government officials and industry lobbyists, the WTO rules are quite liberal in terms of the grounds for granting compulsory licenses. There are no limitations on the scope of disease. Indeed, there is no requirement that compulsory licenses be limited to cases involving health care problems at all.

This paper reports on a number of recent examples of the use of compulsory licenses, in both developed and developing economies. The examples cover a wide variety of technologies, legal mechanisms, and grounds for non-voluntary authorizations to use patents.

II. NORTH AMERICA

A. UNITED STATES

1. Mandatory compulsory license for patents whose term was extended by GATT implementation

In 1995, as mandated by the Uruguay Round Agreements Act, patent terms in the United States were changed from 17 years from the date the patent was granted to 20 years from the date the patent application was filed. This extended patent terms for many products, including pharmaceuticals. In 1996, Congress enacted a statutory mandatory compulsory license for products brought to market prior to patent expiration, provided that a generic manufacturer had previously made "substantial investment" toward bringing a product to market in anticipation of the pre-1995 patent expiration.[2] The mandatory compulsory license applied to over 100 brand name pharmaceutical products. However, the benefits of these compulsory licenses were undermined because drug registration issues were not addressed in the GATT implementation legislation.

2. Cases involving government use under 28 USC 1498

In 2001, DHHS Secretary Tommy Thompson used the threat to use 28 USC 1498 to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack.[3]

In 2005, the US Department of Justice cited its right to use patents in 28 USC 1498 when it opposed injunctive relief for infringement of the 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.[4]

In a November 2005 Congressional Hearing, DHHS Secretary Michael Levitt testified before the House of Representatives that he had effectively required the patent owners for Tamiflu (Roche/Giliead) to invest in US manufacturing facilities for the product, so that the United States government would have access to Tamiflu if confronted with an avian flu pandemic.[5]

In 2007, the US Supreme Court was petitioned to hear an appeal of Zoltek Corp. v. U.S.[6] Zoltek has a US patent on a process for making material used in F-22 fighter jets, but the U.S. imports the product from an unlicensed foreign manufacturer without paying royalties to Zoltek. The United States argues that it may, in effect, has a royalty-free compulsory license

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[2] 104TH CONGRESS, Report, SENATE, 2d Session, 104-394, PHARMACEUTICAL INDUSTRY SPECIAL EQUITY ACT OF 1996, REPORT together with MINORITY VIEWS [To accompany S. 1277]. For more information: http://thomas.loc.gov/cgi-bin/cpquery/?&item=&&sid=cp104pqlQi&&refer=&r_n=sr394.104&&dbname=cp104&&sid=cp104pqlQi&&sel=TOC_0&

[3] For more information: http://www.cptech.org/ip/health/cl/cipro/

[4] The United States' Statement Of Interest, November 2005., NTP, INC., Plaintiffs, V. RESEARCH IN MOTION, LTD., Defendant., Civil Action No. 3:01CV767.

[5] See video excerpts from November 8, 2005 Hearings of the Subcommittee on Health of the House Committee on Energy and Commerce, http://www.cptech.org/ip/health/tamiflu/hearingexcerpts11082005.html

[6] Petition available at: http://www.scotusblog.com/movabletype/archives/Zoltek.pdf

for government use of the product because the patented process is carried out in a foreign country, meaning that the patent holder is not entitled to "reasonable and entire compensation" under 28 USC 1498.

3. Cases involving Bayh-Dole Act

In 1997, a March-In rights petition by Cell-pro was denied, and ultimately their infringing device was pulled from the market despite its clinical advantages and lack of a licensed alternative.

In 2001, DHHS used its authority to exercise March-In rights for patents on stem cell lines resulting from publicly funded research and held by the Wisconsin Alumni Foundation (WARF) as leverage to secure an open license on those patents.[7]

In 2004, DHHS and NIH refused to grant March-In rights in a case brought by Essential Inventions involving patents on the AIDS drug ritonavir/Norvir[8]. Abbott Laboratories had increased their U.S. price of the drug by 400% in one day to promote sales of their new combination therapy and undermine sales of competitors' drugs. A similar request by Essential Inventions for march-in rights to patents involving the glaucoma drug latanoprost (Xalatan) was also denied.[9]

In 2006, the Centers for Disease Control threatened to use March-In rights to issue compulsory licenses on patents on reverse genetics, which are needed to manufacture vaccines for avian flu.

In 2007, Essential Inventions requested Robert Portman, Director of the Office of Management and Budget, to take steps to develop and accept alternative competitive sources of supply for federal procurement of two HIV-AIDS medicines: stavudine/d4T and ritonavir[10]. Due to public funding for the development of both drugs, the US government has a royalty free, nonexclusive, worldwide statutory license to the patents for each product.[11] On March 1, 2007, Essential Inventions met with OMB officials, and extended the proposal to include the AIDS drug emtricitabine (Emtriva).

4. Cases involving merger reviews

In 2002, the US Federal Trade Commission (FTC) ordered[12] 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

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[7] September 5, 2001, "National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement," http://www.nih.gov/news/pr/sep2001/od-05.htm. Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service: http://stemcells.nih.gov/staticresources/research/registry/MTAs/Wicell_MOU.pdf

[8] For more information: http://www.essentialinventions.org/drug/ritonavir.html

[9] For more information: http://www.essentialinventions.org/drug/latanoprost.html

[10] For more information: http://www.essentialinventions.org/eii2omb-5jan07.pdf

[11] See U.S. Code tit. 35. §§ 202(c)(4) and 209(d)(I).

[12] For more information: http://www.ftc.gov/opa/2002/07/amgen.htm

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 US 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.[13] Boston Scientific, which eventually won the bidding to acquire Guidant, was required to license DES patents to a potential entrant, Abbott.

5. Cases involving non-merger remedies to anticompetitive practices

In 2002, the US Department of Justice required Microsoft to license on reasonable and non-discriminatory terms intellectual property rights in a number of different protocols needed to create products that were interoperable with Microsoft Windows.[14]

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 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[15].

6. Cases involving the new US Supreme Court standard for granting injunctions on patents[16]

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[17].

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

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

[14] United States Of America, Plaintiff V. Microsoft Corporation, Defendant. Civil Action No. 98-1232 (CKK), FINAL JUDGMENT, (November 12, 2002), available at: http://www.usdoj.gov/atr/cases/f200400/200457.htm. For a detailed account of work to implement the order, see: INTERIM JOINT STATUS REPORT ON MICROSOFT'S COMPLIANCE WITH THE FINAL JUDGMENTS, available at: http://www.usdoj.gov/atr/cases/f201300/201386.htm.

[15] For more information: http://www.ftc.gov/os/adjpro/d9302/070205opinion.pdf and http://www.ftc.gov/os/adjpro/d9302/070205finalorder.pdf

[16] eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839-1841 (U.S. 2006), available at: http://www.supremecourtus.gov/opinions/05pdf/05-130.pdf

[17] Finisar Corp. v. DirecTV Group, Inc, available at: http://www.fr.com/news/Finisar-Judgement.pdf

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[18].

B. CANADA

In a September 2001 Speech on the Myriad Gene Patent, the Ontario Health Minister called for compulsory licensing of patents on genes relevant to tests for breast cancer. In January 2002, the Ontario Advisory Committee on New Predictive Genetic Technologies published "the Ontario Report to Premiers: Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare." This report noted that the Doha Declaration calls upon nations to take measures "to protect public health and, in particular, to promote access to medicines for all," and concluded:

> *In order to prevent the statement from providing a hollow right, the concept of promoting access to medicines for all must include providing access to the diagnostic procedures necessary to determine when and which medicines to provide. The federal government should, therefore, amend the Patent Act to specifically allow thepotential for compulsory licensing of patents relating to the provision of genetic diagnostic and screening tests should this power be necessary.*

On October 18, 2001, Health Canada overrode the Bayer patents on ciprofloxacin, and authorized generic manufacture for purposes of building a stockpile as protection against an attack of certain strains of anthrax. In announcing the action, Paige Raymond Kovach, a spokeswoman for Health Canada, said: "These are extraordinary and unusual times . . . Canadians expect and demand that their government will take all steps necessary to protect their health and safety."

On May 14, 2004, Canada passed BILL C-9: An Act to amend the Patent Act and the Food and Drugs Act. The law came into force on May 14, 2005 creating Canada's Access to Medicines Regime (CAMR). The purpose of the legislation is to allow Canadian manufacturers to export medicines to countries lacking manufacturing capacity. Proposed royalties paid to the patent holder vary according to the importing country's Human Development Index. The benefits of the Act are limited to products listed on "Schedule 1," the list of patented pharmaceutical products that are eligible to be exported under the compulsory license. Civil society groups supported the passage of the legislation, yet they also pointed out a number of flaws in the bill.

There have been three requests for compulsory licenses under the CAMR. The first was a December 14, 2004 request from Essential Inventions, for the manufacture and export of Imatinib Mesylate to Chile. The Canadian government was not responsive. The second was a request from Apotex and MSF for the manufacture and export of a fixed dose combination for the treatment of AIDS. The third was a February 13, 2006 request from Biolyse Pharma Corporation, for patents on oseltamivir phosphate and sold by Roche under the brand name Tamiflu.

[18] Voda v. Cordis Corp., No. CIV-03-1512, 2006 WL 2570614 (W.D. Okla. Sept. 5, 2006)

On August 31, 2005, Schedule 1 of the Patent Act was amended to add lamivudine (150 mg) + nevaripine (200 mg) + zidovudine (300 mg) tablets – the fixed dose combination in the Apotext/MSF application.

On July 1, 2006, the Canadian government published a proposed amendment to Schedule 1 of the Patent Act to add oseltamivir phosphate (75 mg capsules and 12 mg/mL powder for oral suspension), which is used in the treatment and prophylaxis of Type A and Type B influenza[19]. In September 2006, the product was included in Schedule 1.

Apotex claims as defense to an infringement claim, that it's sales of generic copies of AstraZeneca's Zestril and Merck's Prinivil tables are permitted under terms of a compulsory license. A trial started in January 2006.[20]

On May 7, 2004, Torpham successfully appealed a rejection of a compulsory license application involving Merck patents for the manufacture and sale of Lisinopril.[21] Torphan had sought a license to the use the patents for purposes of manufacturing and exporting to the United States. The court help that the request for the compulsory license had sufficient merit to be proceed to the next stage. The court held that serving export markets abroad constitutes Canadian demand for the patented product.

On September 16, 1998, Brantford asked a Canadian federal court for an order compelling Merck to licence patents needed to manufacture SESIC. On April 30, 1999, Brantford filed another application for a compulsory license. The case involved a number of procedural disputes and appeals, such as a February 2, 2005 court decision rejecting Merck's efforts dismiss the compulsory licensing application on certain procedural grounds.[22] A hearing on the compulsory license was held in April 2005 before the Patent Appeal Board. On September 1, 2005, the Patent Appeal Board upheld an earlier rejection of the compulsory license. Brantford appealed to the court. On November 7, 2006, a court in British Columbia upheld the rejection of the compulsory license, holding the Commissioner of patents had not erred in determining that patent abuse had not been established, since it was reasonable for the Commissioner to find on the evidence that there was no genuine market demand for the product, and that it was reasonable to find that not enough time had been afforded Merck to respond to Brantford's request for a licence, and Merck's silence could not be construed as a refusal to license.[23]

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[19] Official publication: http://canadagazette.gc.ca/partI/2006/20060701/html/regle11-e.html
[20] AstraZeneca Annual Report and Form 20-F Information 2005
[21] Torpham v. Commissioner of Patents and Canada (AG), May 7, 2004 FCTD (MacKay J.) Abuse of Exclusive Rights/Section 65 of the Patent Act/Compulsory Licence /Request to Supply Bulk Lisinopril for Production of Tablets in Canada for Export to the U.S.
[22] Merck v. Brantford Chemicals and Commissioner of Patents and Canada (Attorney General), February 2, 2005 FCA (Rothstein, Evans, Malone JJ.A.) Compulsory Licence/Patent Act/Res Judicata/Functus Officio/Final Decisions.
[23] http://decisions.fct-cf.gc.ca/en/2006/2006fc1341/2006fc1341.html. Citation: 2006 FC 1341, Vancouver, British Columbia, November 7, 2006, BRANTFORD CHEMICALS INC. (sub. nom. APOTEX PHARMACHEM INC.)Appellant, and THE COMMISSIONER OF PATENTS, ATTORNEY GENERAL OF CANADA and MERCK & CO., INC. Respondents. REASONS FOR JUDGMENT AND JUDGMENT.

III. EUROPE

A. ECJ Decision in IMS Health

On April 29, 2004, the European Court of Justice issued a preliminary ruling on compulsory licensing of intellectual property rights under European competition law, in the IMS Health vs NBC case. The ECJ held that under certain circumstances an obligation to license an intellectual property right exists. The four conditions were:

1. The intellectual property right should constitute, upstream, an indispensable factor in the downstream supply of a (secondary) product.
2. The potential licensee should intend to produce new goods or services not offered by the owner of the right, and for which there is a potential consumer demand.
3. The refusal should not be justified by objective reasons.
4. The refusal should be of such a nature that it reserves for the owner of the right the market for the provision of the product, by eliminating all competition on that market.

B. The 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.

This regulation set out the following requirements and conditions for implmening the WHO's 30 August 2003 decision on the export of medicines to countries that lack sufficient manufacturing capacity.

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."

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.

C. UNITED KINGDOM

Following the passage of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection Of Biotechnological Inventions, the United Kingdom amended its patent law to provide for mandatory compulsory cross-licenses of certain biotechnology inventions used for agriculture. The license is available to plant breeders who demonstrate a technical advance. The December 6, 2006 UK Gowers Review noted the British Society of Plant Breeders complained the provision is "ineffective in the UK at least", because to prove an advance the product must actually be created, thereby infringing the patent, in calling for an expanded research exception, to permit broader use of the compulsory license.

D. GERMANY

In 2000, Roche asked the German government to grant a compulsory license on a patent protecting the Blood Screening HIV Probe owned by Chiron. On May 22, 2001, a licensing agreement was reached between Roche and Chiron. In return for its license, Roche agreed to end its attempts to obtain a compulsory license.[24]

E. FRANCE

1. RU 486

France considered the use of compulsory licenses in the case of the abortion pill RU 486, which was developed by the French pharmaceutical manufacturer ROUSSEL UCLAF. In response to threats of boycotts by pro-life organizations, the company withdrew the product from the market. In the subsequent efforts by the French government to reverse the decision, a court ruled the government could obtain access to the medicine by using the ex-officio license system. Earlier, however, the product was already back on the market, so the ex officio license was not needed

2. BRAC1 and BRAC2 patents on breast cancer tests.

France was among several European countries who were outraged by the high prices of breast cancer diagnostic tests, because of the Myriad gene patents. In 2004, France amended its

[24] ARTICLE 5 - OTHER ACTIONS
5.1 Patent Validity; Enforceability. Immediately upon the Effective Date, or as soon as possible thereafter, ROCHE shall discontinue any opposition, challenge,
compulsory license application or the like with respect to the CHIRON Licensed Patents.
5.2 Compulsory Licensing. ROCHE covenants and agrees on behalf of itself and its Affiliates to not support any third party in seeking compulsory licensing of the
CHIRON Licensed Patents in any jurisdiction. As used in this Section, "support" shall have the same meanings as in Section 7.2(b).

patent law to allow the broader use of ex officio licenses, and in particular, to authorize the government to issue ex officio licenses to patents on certain dialogistic technologies. The new act provide that:

> Where the interests of public health demand, and in the absence of a voluntary agreement with the patent holder, the minister responsible for industrial property, may, by order of the minister responsible for public health, request ex officio licenses in accordance with Article L. 613-17 for any patent granted for:
>
> a) a medicine, a medical device, a medical device for in vitro diagnosis, a related therapeutic product;
>
> b) processes for obtaining them, [or] for products necessary in obtaining such medicines or for processes for manufacturing such products
>
> c) a diagnostic method ex vivo.

F. BELGIUM

Belgium modified its patent law in 2005, creating a new compulsory cross-license for biotechnology inventions, and also a new compulsory license for public health purposes.[25]

G. ITALY

1. Sorin/Chrion dispute

On 14 June 1994, Sorin Biomedica S.p.A. filed a lawsuit with the Court of Milan, Italy against Chiron Corporation and Ortho Diagnostic Systems S.p.A. for a declaration of nullity and noninfringement of the Italian counterpart to Chiron's European Patent 0 318 216 (the " '216 patent"). Sorin additionally filed a request with the Italian Ministry of Industry, Commerce and Artisanship ("ICA") for compulsory license to the '216 patent. Chiron filed a counterclaim and sought a finding that the patent is valid and infringed by Sorin. The ICA suspended Sorin's request for compulsory license pending the outcome of the litigation.

2. Merck antiboiotic (Imipenem Cilastatina) patents

On 23 February 2005, the Autorità garante della concorrenza e del mercato (the AGCM) opened an investigation into abuses of a dominant position by refusals to license rights to active pharmaceutical products by two large pharmaceutical companies -- GlaxoSmithKline and Merck & Co Inc (Cases A363 and A364).

On 21 June 2005, the AGCM ordered a compulsory license for Merck patents on antibiotics that use the active ingredients Imipenem Cilastatina.

[25] VAN OVERWALLE, G. & VAN ZIMMEREN, E., 'Reshaping Belgian Patent Law: The Revision of the Research Exemption and the Introduction of a Compulsory License for Public Health', IIP Forum (Japanese journal) 2006;64:42-4.

3. Glaxo patents on migraine drug

On 8 February 2006, the AGCM closed the investigation into the Glaxo Group's refusal to grant a licence to Fabbrica Italiana Sintetici SpA (FIS), a chemical company, for the manufacture in Italy of an active ingredient, Sumatriptan Succinate, used in the production of migraine medicines. According to the AGCM press release, "To remedy the earlier refusal to license, Glaxo granted the licences originally requested by FIS, but also set conditions such as to allow the time to be made up which had been lost because of the original refusal. Those conditions include the granting of a number of additional procedural licences, whereby Glaxo has allowed FIS to save the time otherwise required to research and test an efficient manufacturing process for Sumatriptan Succinate. FIS will thus be enabled to offer the active ingredient to manufacturers of generics as early as if Glaxo had never refused the original request for a licence."[26] The AGCM sought to prevent delays in bringing generic pharmaceuticals to market, thus paving the way for substantial price reductions. FIS initially used the compulsory license entirely for the export market, supplying generic firms that were selling products in markets outside of Italy (such as Spain), where the patents had expired. It did so outside of the framework of the WTO 30 August 2003 decision on exports on medicines manufactured under a compulsory license, which Spain and other EU members had "opted out" as an importer. This was possible in part because the TRIPS waives all restrictions on exports in cases where the licenses were issued to remedy to anticompetitive practices.

4. Merck patents on prostate and male-pattern baldness drug

On 21 March 2007, the AGCM required Merck to "grant free licences to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Complementary Protection Certificate."[27] Finasteride is the active ingredient of a drug marketed initially under the brand name Proscar and Propecia. It is used to treat hypertrophy of the prostate, cancer of the prostrate, and male-pattern baldness. The Merck royalty free compulsory licenses were remedies to Merck's earlier refusal to license the patents to Italian manufactures of active pharmaceutical ingredients. Again, the licenses anticipate exports to "other European countries."

IV. ASIA

[26] AGCM. 21 February 2006. PRESS RELEASE: Pharmaceuticals: Antitrust says Glaxo has made amends and abuse of dominant position discontinued Granting of licence opens way for manufacture of generic migraine drugs. PROCEEDING reference n. A363, case GLAXO-PRINCIPI ATTIVI.
[27] 26 March 2007. PRESS RELEASE, A364 - MERCK - ACTIVE INGREDIENTS (CONCLUSION OF INVESTIGATION): ANTITRUST AUTHORITY RULES MERCK MUST GRANT FREE LICENCES FOR THE ACTIVE INGREDIENT FINASTERIDE. The Authority accepts and renders obligatory a commitment presented by the companies Merck & Co. Inc. and Merck Sharp & Dohme (Italia) in order to conclude the investigation launched in February 2005 into possible abuse of a dominant position. Expected price reductions for the drug to benefit consumers and the National Health System. http://www.agcm.it/agcm_eng/COSTAMPA/E_PRESS.NSF/92e82eb9012a8bc6c125652a00287fbd/28653b373e56772ac12572ab003a4d68

A. CHINA

In 2005, China used the threat to a compulsory license to obtain voluntary licenses to manufacture generic Tamiflu.

B. INDIA

In February 2005, India amended its patent law, to provide for patent protection for pharmaceutical inventions. The legislation created a mandatory compulsory license for products that were already manufactured and marketed in India. The new provision was added under Section 11 A of the Indian Patent Act read as follows::

> "(7) On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application:
> Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted:
> Provided further that the rights of a patentee in respect of applications made under sub-section (2) of section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent:
> Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises[28]." [Emphasis added]

C. INDONESIA

On October 5, 2004, Indonesia issued a government use compulsory license to manufacture generic versions of two HIV-AIDS drugs, lamivudine and nevirapine, until the end of the patent term in 2011 and 2012 respectively. The license includes a royalty rate of 0.5% of the net selling value[29]. Production of the ARVs has started by PT Kimia Farma.

D. MALAYSIA

On September 29, 2004, the Malaysian Minister of Domestic Trade and Consumer Affairs issued a two-year government use compulsory license to import from India didanosine (ddI), zidovudine (AZT) and lamivudine+zidovidine (Combivir)[30]. The Ministry of Health proposed a royalty rate of 4% of the value of the generic product.

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[28] The Indian Patents (Amendments) Act 2005, available at: http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf

[29] Translated text of the actual license is available at: http://lists.essential.org/pipermail/ip-health/2004-December/007233.html

[30] Translated text of the actual license is available at: http://www.cptech.org/ip/health/c/malaysia/arv-license.html. For more information: Chee Yoke Ling, Malaysia's Experience in Increasing Access to

E. KOREA

On January 30, 2002, the People's Health Coalition for Equitable Society, the Association of Physicians for Humanism, and the Korean Pharmacists for Democratic Society jointly filed for a compulsory license for Glivec, a drug to treat chronic myelogenous leukemia (CML), and gastrointestinal stromal tumor (GIST). The request was rejected[31].

In October 2005, the Korea Food and Drug Administration (KFDA) announced it was considering a compulsory license for the manufacture of generic versions of Tamiflu.[32]

F. TAIWAN

On July 26, 2004, the Taiwan Intellectual Property Office (TIPO) issued a compulsory license to Gigastorage for 5 patents related to CD-R of Phillips. The term of the license is through the expiration of the patent terms.

In November 2005, Taiwan issued a compulsory license for patents needed to manufacture and sell generic versions of Tamiflu.[33] According to this report by Deutsche Presse-Agentur dpa:

> The Intellectual Property Office (IPO) granted compulsory licensing to Taiwan pharmaceutical companies after talks with Roche and Gilead Science - the U.S. developer of Tamiflu - broke down. 'Roche and Gilead insisted they can supply enough Tamiflu if bird flu erupts in Taiwan. Our argument was: When there is a bird flu pandemic, millions of people will be hospitalized or dead, and some countries might confiscate Tamiflu or ban its export. We cannot gamble our people's lives on their unreliable promise,' Lai Chin-hsiang, secretary-general of the Department of Health (DOH), told Deutsche Presse-Agentur dpa. Under the compulsory license, valid until December 31, 2007, Taiwan drug firms can make Tamiflu for domestic use and should use it only when there is a shortage of supply from Roche.[34]

G. THAILAND

On November 29, 2006, the Thailand Ministry of Health announced a government use compulsory license to import (from India) and locally produce efavirenz until 2011. [35] The proposed royalty was 0.5 percent of the price of the generic product, a figure that is subject to additional negotiations with the patent owner.

Antiretroviral Drugs: Exercising the "Government Use" Option (Third World Network, IPR Series No 9, 2006), available at: http://www.twnside.org.sg/title2/IPR/IPRS09.pdf

[31] For more information: http://www.cptech.org/ip/health/cl/recent-examples.html#Korea

[32] Kim Cheong-won, "Health Regulator Seeks to Produce Bird Flu Drug," *the Korea Times*.

[33] Kathrin Hille, "Taiwan employs compulsory licensing for Tamiflu," *FT,* November 25 2005.

[34] Taiwan issues compulsory license for making Tamiflu, Nov 25, 2005.

[35] Translated text of the actual license is available at: http://www.cptech.org/ip/health/c/thailand/thaicl4efavirenz.html

On January 25, 2007 the Thailand government announced two additional government use compulsory licenses on patents for the AIDS drug Kaletra (LPV+RTV)[36] and the heart disease drug Plavix (clopidogrel bisulfate),[37] also with a proposed royalty of 0.5 percent.

V. LATIN AMERICA

A. ARGENTINA

On October 18, 2005, Health Minister Gines Gonzalez Garcia announced the government would issue compulsory licenses on the patents for Tamiflu. However, it was later determined that patents on Tamiflu had not been not granted in Argentina.

B. DOMINICAN REPUBLIC

There have been requests for compulsory licenses on the patents for Plavix, a heart disease drug. On May 14, 2002, the French embassy in Dominican Republic wrote to Sr. Hugo Guiliani Cury, Secretary of State of the Dominican Republic, expressing opposition to the compulsory license[38].

C. CHILE

In December 2004, Essential Inventions requested a compulsory license to supply Glivec to Chile[39].

D. ECUADOR

In 2003, Acromax, a local manufacturer, petitioned the patent office to grant a compulsory license for the fix-dose combination of Lamivudine (3TC) and AZT (sold under the trade-name Combivir by Glaxo). The request was rejected and Glaxo granted Ecuador preferential prices on all their HIV-AIDS medicines. ACROMAX appealed and the request was rejected again.[40]

E. BRAZIL

[36] Translated text of the actual license is available at: http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra_en.pdf
[37] Translated text of the actual license is available at: http://www.cptech.org/ip/health/c/thailand/thai-cl-clopidogrel_en.pdf
[38] The letter (in Spanish) is available at: http://www.cptech.org/ip/health/c/dr/
[39] For more information: http://www.essentialinventions.org/drug/imatinibmesylate/index.html
[40] Lucia Gallardo, El negocio del VIH/SIDA Patentes farmaceuticas ¿para que y para quien? (2006, Universidad Andina Simon Bolivar).

On January 8, 2001, 12 days before President Clinton left office, USTR filed a complaint over the Brazil compulsory licensing law in the WTO Dispute Settlement Body. USTR officials called this the "Merck" case. At issue was Article 68 of Brazil's patent law, which allows compulsory licenses to be issued in situations where the patent holder does not locally manufacture the patented product (known as a "local working" provision). The US received a large amount of negative publicity, and on June 25, 2001, the Bush administration withdrew the complaint. However, under the agreement between the two countries, Brazil agreed to provide the US with advance notice if a license is issued under Article 68 of the Brazil patent act, and disputes would be discussed through a bilateral "Consultative Mechanism." The agreement was not made public.

In early 2001, Brazil announced it was considering compulsory licenses for patents on nelfinavir and efavirenz.

In March 2001, the Brazil government reached a settlement with Merck, for price discounts on efavirenz, in return for not issuing a compulsory license.

On August 22, 2001, Brazilian Health Minister Jose Serra announced the Brazilian government would issue a compulsory license for the manufacture of the antiretroviral drug nelfinavir (sold under the brand name Viracept by Roche) to the Brazilian pharmaceutical producer Far Manguinhos. On August 28, the two parties resumed talks, and on August 31, they reached an agreement; Roche will sell the drug in Brazil at an additional 40% discount, and Brazil will not issue the compulsory license.

On September 5, 2003, the Brazilian government issued a decree that would allow it to produce or import generic anti-AIDS drugs without the consent of companies holding the patent on those medications. The health minister made it clear that the decree was meant to apply to antiretroviral drugs - specifically lopinavir, efavirenz and nelfinavir. The ministry said in a statement it had negotiated with the name-brand companies in August seeking a reduction of more than 40%, but was offered a maximum discount of 6.7%. Brazil and Merck reached an agreement in November.

In 2005, Health Minister Humberto Costa signed a decree declaring the patent of Kaletra in the public interest and appropriate for compulsory licensing. A subsequent settlement with Abbott reduced the price of by 46 percent.

In 2005, the government of Brazil declared that they were considering issuing compulsory licenses to permit the manufacture of Viread. "As a result of discussions with the Brazilian government Gilead reached agreement with the Brazilian Health Ministry in May 2006 to reduce the price of Viread in Brazil by approximately 50%."[41]

Brazil also used the threat of compulsory licenses on the patents for Gleevic to obtain a price discount of more than 65 percent.

VI. AFRICA

[41] SEC Form 10-Q -- Quarterly report [Sections 13 or 15(d)], Period of Report: 2006-09-30.

Compulsory licensing in Africa is now fairly common, but often not widely publicized. A typical compulsory license may be based upon model authorizations prepared by organizations who are engaged in providing treatment for AIDS, in order to satisfy donor requirements that purchases of generic medicines are consistent with trade rules.

A. CAMEROON

On January 2005, the nonprofit corporation Essential Inventions requested the Minister of Public Health to grant ex officio licenses for the patents relevant for importation, manufacture or sale of generic versions of the following medicines used in the treatment of HIV/AIDS: Nevirapine/Viramune®, Lamivudine/3TC®, and Fixed dose combinations of Lamivudine and Zidovudine/Combivir®. The request is still pending[42].

B. GHANA

In October 2005, the Minister of Health issued a government use compulsory licenses for importation into Ghana of Indian generic HIV-AIDS medicines[43].

C. GUINEE

On April 18, 2005, the Ministry of Health issued compulsory licenses for importation on patents on drugs to treat HIV-AIDS.

D. ERITREA

On June 5 2005, the Minister of Health issued compulsory licenses for importation into Eritrea of generic HIV-AIDS medicines[44].

E. MOZAMBIQUE

On April 5, 2004, Mozambique's Deputy Minister of Industry and Commerce issued Compulsory License no. 01/MIC/04 for patent rights to lamivudine, stavudine and nevirapine. The license was granted to Pharco Moçambique Lda, a local producer that plans on manufacturing the antiretrovirals as a fixed-dose combination. Royalties are not to exceed 2% of sales[45].

F. SOUTH AFRICA

On March 7, 2001, Indian pharmaceutical manufacturer CIPLA formally requested the South African Department of Trade and Industry issue compulsory licenses to patents on the

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[42] For more information, http://www.essentialinventions.org/docs/cameroon/
[43] Text of the actual license is available at: http://www.cptech.org/ip/health/cl/Ghana.png
[44] Text of the actual license is available at: http://www.cptech.org/ip/health/cl/Eritrea.png
[45] Translated text of the actual license is available at: http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf

following HIV drugs: nevirapine, lamivudine, zidovudine, stavudine, didanosine, efavirenz, indinavir and abacavir.

On September 19, 2002, Hazel Tau, working with the Treatment Action Campaign (TAC), filed a complaint with South Africa's Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (GI). Twelve parties would join the complaint, which charged GSK and BI with excessive pricing in respect of ritonavir, lamivudine, ritonavir+lamivudine and nevirapine.

On October 16, 2003, after an extended investigation, the South Africa Competition Commission issued a statement, saying:

> pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) have contravened the Competition Act of 1998. The firms have been found to have abused their dominant positions in their respective anti-retroviral (ARV) markets.
>
> In particular the Commission has found the firms have engaged in the following restrictive practices:
>
> 1. Denied a competitor access to an essential facility
> 2. Excessive pricing
> 3. Engaged in an exclusionary act

On December 10, the competition commission announced it had reached a settlement with GSK. The settlement required GSK to

1) extend a voluntary licence granted to Aspen Pharmacare in October 2001 in respect of the public sector to include the private sector;
2) grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare;
3) permit the licensees to export the ARVs to sub-Saharan African countries;
4) permit the importation of the drugs for distribution in South Africa if the licensee does not have manufacturing capability in South Africa;
5) permit licensees to combine the relevant ARV with other antiretroviral medicines; and
6) 6) charge royalties of no more than 5% of the net sales of the relevant ARVs.

Shortly thereafter, a similar settlement was reached with BI.

G. SWAZILAND

On April 20, 2004, the Ministry of Health and Social Welfare in Swaziland noted the existence of an emergency relating to AIDS, and authorized procurement of medicines for HIV/AIDS "in the best cost/effective way possible on the international market irrespective of the existence of any patent or other Intellectual Property protection applicable in Swaziland until such time as it will no longer be considered essential to address the current Public Health crisis related to HIV/AIDS."

H. ZAMBIA

On September 21, 2004 the Zambian Minister of Domestic Trade and Consumer Affairs issued a compulsory license for lamivudine, stavudine and nevirapine. The license was granted to Pharco Ltd., a local producer, which will produce a triple fixed-dose combination. A maximum royalty rate of 2.5% applies[46].

I. ZIMBABWE

In May 2002, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs declared a Period of Emergency in order to override antiretroviral drug patents for a period of 6 months[47]. The declaration included a government use compulsory license to make, use or import generic HIV/AIDS medicines. In 2003, the period of emergency was extended by five years (until 31 December 2008). With assistance from India, Zimbabwe has begun local production of antiretrovirals though the generic company Varichem Pharmaceuticals (Private) Limited.

VII. MIDDLE EAST

A. ISRAEL

"In January 1992, BTG-Israel filed an application in the Israeli Patent Office for a compulsory license to manufacture BTG's Bio-Hep-B under Biogen's Israeli patent which license, upon approval, would enable BTG to produce the vaccine in Israel and likely to export the vaccine to countries in which neither Biogen nor others have been granted a blocking patent. In September 1995 the Registrar ruled in an interlocutory decision that BTG-Israel is entitled to a compulsory license to the Biogen patent. Biogen's appeal of the interlocutory decision was rejected."[48]

"Biogen appealed the Registrar's decision to the District Court of Tel Aviv, Israel, and moved for a stay of the license, which was granted ex parte pending hearings with both parties. Following hearings which took place in December 1996, the motion was denied in January 1997; however, the ex parte stay was left in force pending Biogen's appeal to the Supreme Court and maintained by the Supreme Court pending the decision by the District Court on the merits of Biogen's appeal. The District Court heard the appeal in early March 1997, and in June 1997 the District Court denied Biogen's appeal and subsequent motion for a stay pending Biogen's appeal of the District Court decision to the Supreme Court on the merits. In March 1998 the Supreme Court granted Biogen the right to appeal the District Court's decision. A date has not yet been set for the hearing. In the absence of any action by the Supreme Court, the compulsory license is now effective and allows BTG-Israel to produce the vaccine in Israel upon receipt of regulatory approval and to export the vaccine to countries in which neither Biogen nor others have been granted a blocking patent."[49]

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[46] Text of the actual license is available at: http://www.cptech.org/ip/health/c/zambia/zcl.html
[47] Text of the actual license is available at: http://www.cptech.org/ip/health/c/zimbabwe/zim05242002.html
[48] BIO-TECHNOLOGY GENERAL CORP., 10-K Report, April 1, 1996.
[49] SAVIENT PHARMACEUTICALS INC, Form:10-K Filing Date: 3/26/1998.

The Biogen Israeli patent expired in December 1999, before the Supreme Court ruled on the compulsory license.