

PRACTICAL EXAMPLES AND EXPERIENCES ON PATENT RELATED IMPEDIMENTS TO TRANSFER OF TECHNOLOGY

**Prepared by the Third World Network
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This submission responds to a request by the WIPO Secretariat for practical examples and experiences on patent - related incentives and impediments to the transfer of technology pursuant to the decision of the 20th session of the WIPO Standing Committee on the Law of Patents (SCP).

This submission focuses on cases and experiences where patents are a barrier to technology transfer with the right holder adding a price premium and increasing the price of accessing/using the technology; imposing unreasonable conditions for use of the protected technologies or simply refusing to license out of for fear of competition from the licensee. The cases also reveal that technology transfer is also hindered by the restrictive terms required in licensing agreements by the patent holder.

Part 1 of this submission contains some general literature on the relationship between patents and technology, addressing also patent related impediments to technology transfer. Parts 2-5 of this submission contain selected cases and experiences involving patent related impediments to transfer of technology in the area of environmentally sound technologies, agriculture and biotechnology, pharmaceutical/medical technologies, and other technologies. It is not the intent of this paper to exhaustively cover all cases where patents have been an impediment to technology transfer.

1. GENERAL LITERATURE

- 1.1 **Kim, L. (2002), “*Technology Transfer and Intellectual Property Rights: Lessons from Korea’s Experience*”, UNCTAD/ICTSD Working Paper (Geneva: UNCTAD/ICTSD).**
Available at: <http://www.iprsonline.org/unctadictsd/docs/Kim2002.pdf>

Summary: This paper shows that this paper shows that:

- (a) IPR protection would hinder rather than facilitate technology transfer to and indigenous learning activities in the early stage of industrialization when learning takes place through reverse engineering and duplicative imitation of mature foreign products;
- (b) only after countries have accumulated sufficient indigenous capabilities with extensive science and technology infrastructure to undertake creative imitation in the later stage that IPR protection becomes an important element in technology transfer and industrial activities. The paper underscores the point that Japan, Korea, and Taiwan, not to mention the United States of America and Western European countries during their industrial revolutions, could not have achieved their current levels of technological sophistication if strong IPR regimes had been forced on them during the early stage of their industrialization.

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The contribution of reverse engineering cannot be quantified, but in-depth studies reveal that such practices were dominant and widespread in electronics (Kim, 1980), chemicals (Westphal, Kim, and Dahlman, 1985), machinery (Kim and Kim, 1985), computers (Kim, Lee, and Lee, 1987), and pharmaceuticals (Kim, Kim and Lee, 1989). In other words, Korea’s experience indicates that the majority of important or crucial information needed to solve technical problems in the mature

technology stage can be obtained, free of charge, through non-market-mediated informal mechanisms, if developing countries have local capability to undertake reverse engineering tasks, because they are readily available in various forms. Even if such technology was patented, Korea did not enforce IPRs and luckily foreign patent holders were lenient in controlling such duplicative imitation then, as it was no longer useful in sustaining their own international competitiveness. However, IPRs, if enforced more rigorously in the future, would undoubtedly pre-empt such reverse engineering efforts and consequent technological learning by developing countries at this stage.

- 1.2 Kumar, N. (2001), “Determinants of Location of Overseas R&D Activity of Multinational Enterprises: The Case of US and Japanese Corporations”, *Research Policy*, 30, pp. 159-174.**
Available at: <http://www.sciencedirect.com/science/article/pii/S004873339900102X> (not freely available)

Summary: This paper analyzes the determinants of location of overseas R&D activity of US and Japanese multinational enterprises (MNEs) in a three-dimensional setting. Large domestic market, the abundance of low cost R&D manpower, and the scale of national technological effort favour the location of overseas R&D in a country. Tests covering sectoral composition support the proposition that a significant proportion of MNEs' R&D activity follows that of leaders in their own fields. Lack of adequate patent protection or restrictive trade regime does not affect the attractiveness of a country otherwise well-suited for R&D activity. Internationalization of R&D activity of Japanese MNEs is confined to relatively low technology-intensive industries compared to US MNEs.

- 1.3 Kumar, N. (2002), “Intellectual Property Rights, Technology and Economic Development: Experience of Asian Countries”, *RIS Discussion Paper no. 25/2002* (New Delhi: Research and Information System for the Non-Aligned and Other Developing Countries (RIS))**
Available at:
http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Development/IPR_TechnologyandEconomicDevelopment-Nagesh_Kumar.pdf

Summary: There has been a lot of controversy on the role of intellectual property protection (IPP) regime especially the patent system in fostering innovation, technology and industrial development of a country. IPP is expected to encourage innovation by rewarding the inventor. Strong IPP regime may also inhibit diffusion of knowledge and even technology development in the countries that are technology followers. Countries have fine-tuned their IPP regimes as per their developmental requirements. Against this backdrop, the on-going attempt to harmonize and strengthen the IPP regimes worldwide, as a part of the TRIPs Agreement, is widely seen to be adversely affecting the technological activity in developing countries by choking the knowledge spillovers besides implications for the access and affordability to lifesaving drugs by the poor. This paper critically reviews the literature on the role of IPP regime with a particular reference to the Asian countries to draw policy options for consideration by the Commission.

- 1.4 Michael W Nicholson, Federal Trade Commission, 2002 *Intellectual Property Rights and International Technology Diffusion*, Paper prepared for Responding to “Responding to Globalization” conference at Boulder, CO.**
Available at: <http://www.colorado.edu/ibs/pec/gadconf/papers/nicholson.pdf>

Summary: The TRIPs agreement does not appear likely to alleviate any wealth differences arising from the existing North-South technology divide. Open-economy endogenous growth models suggest a dynamic shift towards further concentration of industrial R&D in the Northern countries. While

production of goods developed as an outcome of this R&D may shift to Southern countries through the actions of multinationals, empirical evidence indicates this technology transfer will not likely lead to such benefits as productivity growth in the host country. Essentially, this means that stronger IPRs lead to technology transfer that benefits the North but not the South.

1.5 Amy Jocelyn Glass, *Intellectual Property Policy and International Technology Diffusion*, Department of Economics, Texas A&M University, College Station
Available at: <http://econweb.tamu.edu/aglass/ippitd.pdf>

Summary: Can a host country benefit from strengthening intellectual property (IP) protection in order to attract foreign direct investment (FDI)? Indeed, by limiting the degree that host firms may legally make use of technology spillovers, IP protection can succeed in attracting FDI. However, the FDI occurs in industries that generate the smallest benefits for the host country: industries with smaller technology gaps, smaller spillovers through FDI relative to exports, smaller absorption, fewer host rivals, and larger cost reductions for multinationals. Additionally, IP protection creates inefficiencies by raising the costs of host firms. Host countries should pursue other means of attracting FDI.

2. ENVIRONMENTALLY SOUND TECHNOLOGY (EST)

2.1 Resource: The Energy and Resources Institute (TERI) (2009). *Emerging Asia contribution on issues of technology for Copenhagen*. New Delhi: The Energy and Resources Institute (Project Report No. 2008RS09). Available at: http://www.teriin.org/div/Paper_AEI.pdf

Summary: The Indian institute TERI led a study on technology transfer and climate change issues in which research institutes from five Asian countries (China, India, Indonesia, Malaysia and Thailand) participated. The study concluded that where important patents are in the hands of a few dominant players; this creates a monopolistic situation where dissemination of knowledge is restricted on account of limited access and higher prices of climate friendly technologies. It cites the case of the Chinese Yantai Integrated Coal Gasification Combined Cycle (IGCC) demonstration power plants, in which Chinese companies failed to get technology from foreign companies “due to high cost and reluctances to transfer the key technologies on the part of patent holders”. After prolonged negotiations, the project was stopped.

The Study also points out that the IPRs create a barrier not only in terms of direct costs (that is, royalties or license fees) but also increased spending by the recipient company, either due to refusal of technology transfer or unreasonable conditions put in the technology transfer agreements. For instance a Malaysian company Solartif managed to get access to foreign technology only on condition of buying machines from the technology holder. The costs of acquiring technology through imports as a result of conditions in technology transfer agreements “do not get reflected as a part of IPR costs, since these are not royalties or licence fees, but are nevertheless associated with them”.

Results of the Study were presented at a Conference in New Delhi on 21 October 2001. SciDevNet reported on the Conference and this news report is available at <http://www.scidev.net/global/climate-change/news/link-between-patent-law-and-tech-transfer-not-proven-.html>

Extracts from Study (Pg: 33):

“In the Chinese Yantai IGCC demonstration power plant, Chinese companies failed to get technology

from foreign companies due to high cost and reluctance to transfer the key technologies on the part of patent holders and after a long round of negotiations, the project finally had to be stopped.

IPR costs become a bigger issue in technologies such as clean coal etc., because these require access to a number of technologies along the process. Thus even if one considers of one technological process, in order to be able to adapt it at a domestic level, getting access to multiple technologies and linked patents raises the overall cost.”

Extracts from Study (Pg: 34):

In another case, the Malaysian company, Solartif after initial difficulties managed to gain access to a foreign technology but on a condition of buying machines from the same company. There have also been instances, for instance, in LED, where countries have gone for import of technologies, as it is a cheaper and easier option than manufacturing domestically due to IPR issues involved therein.

2.2 Resource: Zhuang, Wei (2011), “ Intellectual property rights and transfer of clean energy technologies”, Int. J, Public Law and Policy, Vol.1, No. 4, 2011

Summary: The article highlights some of the IP related problems that were faced by wind companies in China. The study makes the following findings:

- There has been a major boom in China in companies that manufacture wind power equipment. However, to produce a piece of complete wind power equipment, China has to buy foreign design and technologies related to core components, such as gearboxes, which generally contribute to the largest part of the price.
- The requirements for China to access patented wind-energy technologies are also very strict. Zhuang (2011) cites a survey by Zhou et al. (2010)¹ that on average Chinese companies have to pay high licensing fees for the technology and 5 per cent royalties per piece of equipment when the final product is sold domestically; however, higher royalty fees usually apply when the final product incorporating foreign patent(s) is exported. Most importantly, Chinese innovation is discouraged because R&D activities relating to the patent are commonly only possible after the agreement of the licensor.
- Technologies transferred are not the most advanced. Because the ‘unlikeliness’ of leading manufactures in the industry to license to potential competitors, studies show that developing countries manufacturers in China and India often have to obtain technology from second or third tier wind power companies who had less to lose in terms of international competition, and more to gain with regard to license fees.²
- China has not acquired the corresponding technological capacities. Much wind power equipment is produced by Chinese enterprises, however, the real owners of the technologies are foreign companies and China has not acquired corresponding technological capabilities.³ Most

¹Zhou, Yuanchuan, Zou, Ji and Wang, Ke (2010). How to conquer the IPR barriers in the low carbon technologies?.

How to conquer the IPR barriers in the low carbon technologies?.

How to conquer the IPR barriers in the low carbon technologies?.

³UNDP China (2010). China Human Development Report 2009/10: China and a Sustainable Future: Towards a Low Carbon Economy and Society, p.41., reproduced in Zhuang (2011)

applicants for renewable energy-related patents have been foreign enterprise subsidiaries in China; China's top three applicants for wind power patents are all developed country enterprises. During the past twenty years, the gap in wind turbine technology between China and developed countries has not been narrowed.

- 2.3 Resource:** Hutchison, Cameron J., **Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries? (October 18, 2012).** University of Ottawa Law & Technology Journal, Vol. 3, pp. 517-537, 2006. Available at: <http://www.uoltj.ca/articles/vol3.2/2006.3.2.uoltj.Hutchison.517-537.pdf>

Summary: The Study contains two main findings on the TRIPS regime as it relates to climate change technology transfer.

First, strong patent protection rights increase the cost of technological acquisition while having no positive bearing on increased foreign direct investment in, or technology trade to, many developing countries. The overall effect of TRIPS, then, is that it likely hinders technology transfer and dissemination in developing countries. Secondly, and more specifically, TRIPS forecloses an effective remedy of international compulsory licensing in cases where developed country patent holders refuse to license technologies to developing country firms due to fear of competition. While this kind of refusal to license may be cured by a remedy of compulsory licensing within domestic markets, TRIPS placed severe limits on compulsory licensing to supply export markets. An important avenue of technology transfer has therefore been closed off under TRIPS

Extracts from Study (Pg: 531):

“While the matter has not been adequately studied in the context of EST transfer, there is evidence of patent abuse in the environmental protection context. In the ozone regime, fear of competition led to refusal by certain patent holders to license technologies to firms in some developing countries: according to Korean firms and R&D institutions, there were cases where the private firms and even public institutions of industrialised countries refused to license such ESTs like HfC-134a, fuel cell and IGCC (Integrated gasification Combined Cycle).”

“The refusal to export non-ozone depleting substances to Korea forced local firms to invest twelve-million dollars over a six-year period to develop their own technology.”

- 2.4 Resource:** Jayashree Watal, “*The issue of technology transfer in the context of the Montreal Protocol: case study of India*”, in Veena Jha and Ulrich Hoffmann (Eds.), **Achieving Objectives of Multilateral Environmental Agreements: a Package of Trade Measures and Positive Measures. Elucidated by Results of Developing Country Case Studies, UNCTAD/ITCD/ TED/6, Geneva**
Available here: http://unctad.org/en/Docs/itcdted6_en.pdf

Summary: The study provides two specific cases in the context of the Montreal Protocol of the acute problems faced by Indian firms in their attempts to access technology from suppliers holding patents.

One case concerned an Indian company seeking access to HFC 134a (a substitute for chlorofluorocarbon), an ozone depleting substance used in refrigerators and air conditioners. The patent holder, a transnational company producing HFC 134a quoted US\$25 million for allowing access to the technology and proposed that the Indian firm either allow the supplier to take majority ownership in a

joint venture that would be set up, or that the Indian firm agrees to export restrictions on HFC 134a produced in India. Both options were unacceptable to the Indian firm. The price was also unrealistically high as the technology fee was estimated to be between \$2-\$8 million.

In another case Indian firms that tried to acquire technology to substitute ozone-depleting substance halon (used in fire extinguishers and other products) found that the patent owner was not interested in licensing the technology to wholly owned companies. The patent holder was interested only in joint ventures where it could hold a majority share.

2.5 Resource: Korean Trade Promotion Agency “The Republic Of Korea And The Montreal Protocol”, in Veena Jha and Ulrich Hoffmann (Eds.), Achieving Objectives of Multilateral Environmental Agreements: a Package of Trade Measures and Positive Measures. Elucidated by Results of Developing Country Case Studies, UNCTAD/ITCD/ TED/6, Geneva

Available at: http://unctad.org/en/Docs/itcdted6_en.pdf

Summary: The study presents the Korean experience with respect to the Montreal Protocol and particularly looks at its experience as a producer of ozone-depleting substances (ODS). It states that the issues relating to technology transfer for the production of alternatives to ODS are of vital importance. In this context, the case study specifically outlines the barriers posed by intellectual property to the transfer of alternative technologies.

Extracts See Case Study 4 The Republic Of Korea and the Montreal Protocol (Page 62)

“Most of the current applications for patent rights in the context of CFCs, have been submitted to the Patents office in Korea by foreign firms, are mainly to patent technology for the production of HCFC-141b and HFC-134a. Most of these applications are for process patents relating to agents or synthesis conditions and will expire only after the phaseout deadline for Korea, implying that the local producers of HCFC-141b and HFC-134a will have to pay heavy royalties for their use during their phaseout.”

“The experience so far bears out the fact that the rates of royalty demanded by technology owners for using patented technologies are very high. In the opinion of Korean firms, the exorbitant high royalties are an expression of a lack of intention to transfer the alternative technology on the part of technology owners.”

“In addition to the high prices to be paid for acquiring alternative technology, Korean businesses are also at a disadvantage due to the various unfavorable conditions to Korea in a technology transfer agreement with their foreign partner. Among 168 Japanese technologies introduced into Korea in 1994, 15 (8.9%) were not allowed to be consigned to a third party, and 13 (7.7%) were granted on a non-exclusive basis and on the condition that improved technologies should be shared between two parties during the contract period. Seven (4.2%) were prohibited to be used for export products and 3 (1.8%) were granted on the condition that the licensee not deal in competitive products or technologies. Among the 209 US technologies introduced to Korea in the same year, 16 (7.7%) were conditional upon the sharing of the improved technologies, 12 (5.7%) were granted on a non-exclusive basis and 10 (4.8%) were not allowed to be consigned to a third party. These conditions have been reported to inhibit the effective transfer of technology, and have been considered unreasonable at times by Korean firms.”

“Although there is the option of applying for a compulsory license in TRIPs, in case the owners of

patented technologies refuse to transfer their technologies, this recourse is generally very time consuming due to many stringent procedures and conditions. For instance, if the technology for the primary alternative substance (for example, HCFC) is required for the production of the secondary alternative (for instance, HFC), the country could resort to the compulsory licensing. One of the requirements for this procedure is that the invention claimed in the second patent (HFC technology) should involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent (HCFC technology). However, there are no specific guidelines for defining “important technical advance” or “considerable economic significance.” Therefore, in practical terms, it is difficult to utilize the compulsory licence clause of the TRIPs Agreement, especially for SMEs who have limited negotiating abilities. Thus, to improve the prospects of a technology transfer, the varied and stringent conditions for the compulsory license described in article 31 would have to be modified.”

“In addition, the presence of these patents makes the process of indigenous technology development more difficult. Generally, those who have developed a technology tend to apply for the widest possible protection of it under the patent rights system. As a result, if a local business wishes to develop an alternative substance, it has to ensure that its technology does not conflict with any existing.”

2.6 **Resource: Ockwell, David (2008). *UK-India Collaboration to Overcome Barriers to the Transfer of Low Carbon Energy Technology: Phase 2: Intellectual property rights and low carbon technology transfer to developing countries – a review of the evidence to date.* Sussex Energy Group, Freeman Centre, University of Sussex, Brighton; TERI India Habitat Centre; Institute of Development Studies, University of Sussex, UK.**

Summary: The study looked at Light Emitting Diode (LED) lighting technology and the main barriers that India faced in the transfer of such technology. On IPRs, the study concludes: “Another barrier relates to the IPR issue associated with LED manufacturing. It is a highly protected technology. As there are various processes involved in manufacturing LED chips, each process is patented and requires huge investment. At present, the cost of investing in both chip manufacturing and resolving IPR issues is substantially high compared to importing the chips.”

The study also indicates significant IPR issues faced by Indian manufacturers in biomass technology and in manufacturing hybrid vehicles since there are many patents associated with the equipment and technologies. On “biomass technology” the study found that IPRs, though it is “not a very important issue” in this sector in the context of India, has created “some friction between the European and Indian manufacturers of briquetting machines” as “small-scale industries such as briquetting machine manufacturers are typically ‘copycat’ businesses based on reverse engineering...” The study also recognises that Europe is dominant in biomass fuel of pellets and not briquettes, thus it concludes that “The growth of the pellet market in Europe has some implications for technology transfer to developing countries like India”.

On hybrid vehicles the study found that found that companies in developed countries hold commercially viable technologies for hybrid vehicles. The study also found that “there may be IPR issues associated with imitating patented hybrid drive-trains” since “companies such as Toyota, General Motors and BAE have strict patents relating to their hybrid drive-trains”. The study also reviewed 3 studies on the issue of IPRs in the context of low carbon technology transfer and concluded: “Developing country firms were generally not observed to have access to the most cutting edge technologies within the sectors examined”.

2.7 Resource: Barton, John H. (2007), *Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis of Solar Photovoltaic, Biofuels and Wind Technologies*. ICTSD Trade and Sustainable Energy Series Issue Paper No. 2. Geneva, Switzerland: International Centre for Trade and Sustainable Development.

Available at: http://www.ictsd.org/downloads/2008/11/intellectual-property-and-access-to-clean-energy-technologies-in-developing-countries_barton_ictsd-2007.pdf

Summary: The study on three sectors (solar photovoltaic, biofuels and wind technology) found that despite patents being prevalent in these sectors, competition between the various types of energy kept prices and costs relatively low. However his study did not rule out IPRs being a possible barrier, and he warns of “serious plausible patent issues likely to arise from the new technologies” and the risk of broad patents which may complicate the development of new, more efficient or less expensive technologies, as well as anti-competitive practices if the small number of suppliers cooperate to violate competition-law principles. On Barton’s study, Ockwell (2008) states: “It is notable that for all of the case studies he examines, uncertainty is expressed as to the likelihood of developing country firms gaining access to the most advanced technologies in these industries”.

In the case of photovoltaic technology, Barton suggests that access to the newer thin-film technologies (which is subject to much more extensive patenting than the older silicon-slice technology) is likely to be difficult. Similarly patent holders of new methods, enzymes or micro-organisms important in the case of biofuels may be hesitant to make these technologies available to developing country firms. Barton also identifies wind technologies as an area where existing industrial leaders are hesitant to share their leading technology for fear of creating competitors.

3. AGRICULTURE AND BIOTECHNOLOGY

3.1 Resource: American Patent Policy, Biotechnology, and African Agriculture, Chapter 5, *Impact of U.S. Patents and Patent Policy and the Case for Change*

Available at: <http://www.rff.org/rff/Documents/RFF-RPT-Patent-Ch4-7.pdf>

Summary: The Chapter assesses how U.S.-issued patents have enveloped agricultural biotechnology and how U.S. patent policy addresses access to patented technologies domestically and attempts to shape patent practices internationally. In brief, U.S. patent policy has resulted in a patent thicket surrounding biotechnology, most of the policy tools that are potentially available to promote broad dissemination and use of patented biotechnologies have not been applied, and the United States is promoting policies internationally that would reduce the flexibility of developing countries to adopt patent systems tailored to their local innovation and development needs.

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“The direct legal impact of U.S. patents can also reach researchers working in developing countries if they are working on applications of biotechnology to crops that are intended to be exported to the United States, even on a limited basis. The importation into the United States of a crop produced with a U.S.-patented technology would constitute an infringement of the patent, unless the use is licensed. Because researchers and research institutions in developing countries frequently lack the skills and resources required to manage their way through the patent thicket, the possibility that a crop will be exported to the United States—where applicable patents may exist – is a legal obstacle and a disincentive for developing country researchers to use US patented technologies”

Overall, these indirect impacts of U.S. patent law, combined with the large number of patents in the patent thicket surrounding biotechnology, are a deterrent to the development of biotechnology applications by researchers in developing country institutions”.

3.2 **Resource: Seed Giants vs. US Farmers, A Report by the Centre for Food Safety & Save Our Seeds (2013)**

Available at: http://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf

Summary: This report recounts the history of seed and plant breeding and intellectual property policies in the U.S. and outlines how the current intellectual property regime has resulted in seed industry consolidation, rising seed prices, loss of germplasm diversity, and the strangling of scientific inquiry. It then documents lawsuits and threats of lawsuits by the largest agrichemical companies in the world against U.S. farmers for alleged infringement of seed patents.

This report shows how monopoly control over agriculture related technology (e.g. seeds, genes) allows multinational companies such as Monsanto to prevent farmers from continuing practices such as saving and reusing of seeds, breeding new varieties that are fundamental for promoting agrobiodiversity and sustainable agriculture.

4. PHARMACEUTICAL & MEDICAL TECHNOLOGIES

The cases below 4.1-4.4, show how patents are a barrier to the transfer of pharmaceutical/medical technologies as patent holders abuse their dominant market position as well as measures taken by countries to address this problem.

4.1 Italy

The Italian Competition Authority decided on 21 March 2007 that the Merck Group will be obliged 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 expiration of Merck’s exclusive rights. Finasteride is used in the treatment of hypertrophy of the prostate as well as male pattern hair loss.

The investigation started in February 2005 when the Authority began looking into Merck’s refusal to give certain companies licenses to produce ingredients of its medicines so that they could sell them in countries which were not patent protected.

According to a 26 March 2007 press release by the Authority, the "corporation's commitment to remove an obstacle to the production in Italy of Finasteride and a generic version of related pharmaceuticals, among the most important drugs used in the treatment of hypertrophy of the prostate, will encourage greater competition in this market and may lead to significant reductions in retail prices and in costs for the National Health System in Italy and in other European countries."

The press release added that "This ruling needs to be seen in the wider context of the Authority's efforts to encourage businesses to adopt commitments aimed at improving market conditions, competition and consumer choice. In the pharmaceuticals sector, in particular, the Antitrust Authority's initiative is aimed at encouraging more widespread use of generic products, taking advantage of notifications from the Italian Office of Patents and Trademarks within the Ministry of Economic Development which are based on regulations governing patents in this sector."

Previously, in two other cases relating to pharmaceuticals, the Italian Competition Authority also reached similar conclusions.

The first case involves a GSK (Glaxo Smith Kline) product used to treat migraine headaches. On 23 February 2005, the Competition Authority began investigating (under Article 82 of the European Community Treaty) the alleged anti-competitive behaviour of Glaxo Group Limited, when it refused to grant a licence to Fabbrica Italiana Sintetici SpA (FIS), a chemical company that produces active ingredients for the manufacturing in Italy of sumatriptan succinate and for the commercialisation of that ingredient in other EC countries where the relevant patent has or will have expired.

The competition authority decided that Glaxo was abusing its dominant position by refusing to grant third parties the licence to produce the sumatriptan succinate active ingredient (although the patent was to expire soon). If a licence was granted by Glaxo, the generic product would be able to enter the market as soon as the patent expired. However, if no licence was granted, then the generic company would take longer to enter the market since the proceedings to obtain authorisation to commercialise pharmaceutical products in EU member states normally takes a long time.

According to Luciano Vasques from Studio Legale Agnoli Bernardi e Associati in an article titled 'Dominance in Italy' featured in *Global Competition Review*, Italian law provides that third parties wishing to produce and commercialise medical products outside Italy using products that are still under patent protection in Italy (but not in other EU countries), may start to negotiate with the patent owner in proceedings initiated before the Ministry of Productive Activities to obtain an export licence. According to the law (DM 10/2002), the request for the export licence should be submitted to the Italian Patent and Trademark Office.

If no agreement is reached among the parties concerned, the Ministry shall help the parties reach an agreement. However, if the intervention does not lead to any positive result, the Ministry will transmit a copy of the file of the proceedings to the Competition Authority.

Such a settlement was not accepted by Glaxo, which led to an investigation by the Competition Authority. Glaxo however took remedial actions, which led the Competition Authority to state that Glaxo's remedial actions put a stop to improper conduct, preventing delays in bringing generic medicines to market.

It is important to note that Glaxo's original refusal to deal was seen by the Authority as an abuse of dominant position. The Authority stated that a refusal to deal of a patent holder is illegal if the holder is a dominant firm and if the refusal could impede or delay access to a competitor, even one in a different geographic market.

The second case involves an antibiotic whose patent is owned by the drug firm Merck. Merck had an industrial patent in Italy giving it exclusive rights to the sale of a pharmaceutical product "Tienam" (an antibiotic intended for the treatment of particularly serious infections, most often contracted in hospitals) based on the active ingredient Imipenem Cilastatina.

In 2005, the Competition Authority found evidence of possible abuse of dominant position by Merck as it refused to grant a licence for the production in Italy of Imipenem Cilastatina to be exported for the manufacture of generic pharmaceuticals in countries not covered by patents. The Italian Competition Authority decided to order an interim measure on Merck & Co. Inc., a company of the pharmaceuticals group Merck, based on EU competition law.

Its decision obliged Merck to allow by granting a licence, the manufacture and warehousing in Italy of the active ingredient Imipenem Cilastatina. This would permit chemical companies having plants in Italy to be already in a position, at the completion of the proceedings, to export the product in question to European countries where Merck has already lost all patent rights, in advance of the arrival in those markets of generic drugs, which will compete with Merck's Tienam product.

These are some cases in which the Italian Competition Authority had to assess the abusive nature of unjustified refusals to grant licences by the patent holder, which were necessary for the production of active ingredients in quantities sufficient to allow wide distribution of generic drugs, to the benefit of competition and consequently of consumers.

4.2 Thailand

On 29 November 2006 Thailand's Ministry of Public Health announced a five-year government use authorization (as found in TRIPS Article 31(b)) for the importation and the domestic manufacture of Efavirenz which is used for HIV/AIDS treatment. On January 25, 2007 the Government of Thailand announced two additional compulsory licenses on patents for the AIDS drug Kaletra (LPV+RTV) and the heart disease drug Plavix (clopidogrel bisulfate). Four other compulsory licenses were granted in January 2008 for cancer drugs, letrozole, docetaxel, erlotinib, and imatinib (which are used in the treatment of breast and lung cancers, gastrointestinal stomach tumor (GIST) and leukaemia)

These licenses were issued only after extensive negotiations with the patent holder. However due to the onerous demands of the patent holders including their reluctance to reduce the price of the pharmaceutical technology to that which is reasonable and affordable, Thailand decided to proceed with the issuance of compulsory licenses. Without affordable pharmaceutical technology, Thailand would have been unable to provide treatment for patients that require it.

4.3 Brazil

On May 4, 2007, Brazil granted for public interest and non-commercial use (through a presidential decree no 6,108) a compulsory license for the drug Efavirenz which is used for the treatment of HIV/AIDS. Specifically, the compulsory license allowed the government to import the generic version of Efavirenz from India (at US\$0.46 a pill) and, possibly, start domestic manufacturing later. The compulsory license included a validity period of five years and 1.5 percent royalties to the patent holder as remuneration. Efavirenz was the most used imported ARV in AIDS treatment in Brazil.

According to a summary of a presentation by an official from the Brazilian Ministry of Health⁴: "Previous to the decree the Government held 16 meetings with the patent holder Merck, seeking to negotiate a price reduction for the 2007 supply of the drug. During the negotiations Merck proposed a technology transfer to the pharmaceutical manufacturer Farmanguinhos (an entity that is part of the Oswaldo Cruz Foundation of the Government of Brazil) after 2010, a date close to the expiry of the patent of the drug. Amongst others, the proposal also included a two percent price reduction; furthermore a provision, that for the time period prior to the technology transfer Farmanguinhos should purchase the drug supply from Merck, and should perform packaging and labeling activities."

This proposal was considered to be insufficient to meet the national interests in the HIV/AIDS

⁴ <http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/>

treatment policy. Brazil’s request for a significant price reduction comparable to the amount charged in Thailand was refused by Merck and the CL was issued.

According to the presentation by an official from the Brazilian Ministry of Health⁵, - due to lack of further technical information Farmanguinhos used the patent specification for the reproduction process. The disclosure of the patented invention was found to be insufficient and did not enable the generic company to replicate a generic form of the drug. Farmanguinhos had to perform its own research activities in order to reverse engineer the product and to import small quantities of efavirenz from India; a preliminary injunction filed by Merck to stop the importation was rejected by the Brazilian courts.

4.4. Compulsory Licences

The issuance of compulsory licenses on pharmaceutical patents by a number of developing countries highlights the evidence that patents can be an impediment to the transfer of technology. By charging monopoly prices and/or imposing unreasonable and onerous conditions for the use of the patented technology, patent holders prevent third parties from using and/or manufacturing the patented medical technology, often resulting in devastating consequences for the patients. To facilitate access to critical pharmaceutical and medical technologies, governments often have to step in by issuing compulsory licenses to overcome the patent barrier. Table 1 contains a list of compulsory licenses issued by governments. Details on some of the issued CLs have been provided above.

Table 1: Examples of Compulsory Licenses issued by Developing Countries

Year	Country	Pharmaceutical Product
2002	Zimbabwe	Any drug used for the treatment of HIV/AIDS
2003	Malaysia	ARVs: didanosine, zidovudine, lamivudine and zidovudine combination
2004	Indonesia	ARVs: lamivudine and nevirapine
2004	Mozambique	ARVs: lamivudine, stavudine and nevirapine
2004	Zambia	ARVs: lamivudine, stavudine and nevirapine
2005	Ghana	ARVs
2006	Thailand	ARV: efavirenz
2007	Brazil	ARV: efavirenz
2007	Indonesia	ARVs: efavirenz, lamivudine and nevirapine
2007	Thailand	ARVs and cardiovascular: lopinavir/ritonavir and clopidogrel
2008	Thailand	Cancer treatments: letrozole , docetaxel, erlotinib and imatinib
2010	Ecuador	ARVs: ritonavir/lopinavir

⁵ <http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/>

2012	Indonesia	Seven ARVs + Hep B: efavirenz , abacavir, didanosine, Combination lopinavir, ritonavir , tenofovir, Combination of tenofovir and emtricitabine and Combination of tenofovir, emtricitabine and efavirenz
2012	Ecuador	ARVs: abacavir/lamivudine(ARVs)
2012	India	kidney and liver cancer: sorafenib tosylate

The following studies and papers provide information on the issuance of the abovementioned CLs.

- (a) Khor, Martin, Patents, Compulsory Licenses and Access to Medicines: Some Recent Experiences, Third World Network (Pg 11) <http://www.twinside.org.sg/title2/IPR/pdf/ipr10.pdf>
- (b) <http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/>
- (c) Italy compels pharmaceutical companies to issue licenses. See http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.040701.htm
- (d) Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, The Ministry of Public Health and The National Health Security Office, February 2007.
- (e) The 10 burning questions regarding the Government Use of Patents on the four anti-cancer drugs in Thailand By The Ministry of Public Health And The National Health Security Office Thailand February 2008

4.5 Voluntary Licenses

Voluntary licenses (VLs) are the preferred method by originator pharmaceutical companies to expand operations with generic manufacturers and to sell medicines. They are seen as a tool to overcome the patent barrier and to facilitate access. However these same VLs raise serious concerns – the lack of transparency with regard to the content of the VLs and the restrictive provisions that are included in the licenses hinder access to and use of the patented medical/pharmaceutical technologies.

A worrying trend emerging in voluntary licenses in the pharmaceutical sector is that these VLs generally tend to be for the benefit of least developed and sub-Saharan Africa countries and generally exclude middle-income countries (with the notable exception of India, which is sometimes included), many of which have the potential to manufacture the patented medical technology.

VLs negotiated under the Medicines Patent Pool are publicly disclosed and include a high number of countries in the licence although many middle-income countries have been excluded. For example in 2011 Gilead signed an agreement with MPP authorizing only companies in India to manufacture certain ARV products. Manufacturers from other countries were not allowed to manufacture the ARV products. Further, drugs produced under the agreement can only be supplied to 103 territories listed in the agreement. Countries such as China, Brazil, Ukraine, Sri Lanka, and Indonesia are excluded from the agreement.

This is a clear example of how a right holder enabled by the patent system, uses its monopoly control over key medical/pharmaceutical technologies to decide which countries should be allowed to have access to its patented technology and to manufacture affordable products and which countries should be prevented from using the technology, and thus denied access to affordable pharmaceutical technology.

It is also worth noting that many companies holding patents on key medicines have refused to enter negotiations, or have not concluded licensing agreements with favourable terms and conditions with the MPP.

The 16th Edition of Untangling the Web of Antiretroviral Price Reductions by the MSF Access Campaign contains more information on voluntary licenses and conditions contained in the licenses.⁶

5. OTHER TECHNOLOGIES

5.1. India: Ericsson- Micromax

Source: <http://www.hindustantimes.com/business-news/competition-commission-to-probe-ericsson-on-micromax-complaint/article1-1156424.aspx>

Summary: The Competition Commission of India (CCI) has ordered investigation after finding prima-facie evidence of Telefonaktiebolaget LM Ericsson indulging in unfair trade practices in November 2013. Handset maker Micromax had complained that Sweden-based Ericsson was demanding unfair, discriminatory and exorbitant royalty for its GSM technology-related patents.

According to the CCI order, Ericsson is dominant in the market of GSM and CDMA (telecom technology standards) in India and holds large number of such patents. Ericsson has 33,000 patents to its credit, with 400 of these granted in India. The company was the largest holder of SEPs (Standard Essential Patents) for mobile communications technologies like 2G as well as 3G and 4G, used mainly used for smart phones and tablets. The Commission noted that since Ericsson held these SEPs and there was no other alternate technology in the market, the telecom equipment firm "enjoys complete dominance over its present and prospective licensees in the relevant product market".

The Commission observed that allegations regarding royalty rates make it clear that the practices adopted by the Ericsson were discriminatory as well as contrary to FRAND (Fair, Reasonable and Non Discriminatory) terms. "The Opposite Party seemed to be acting contrary to the FRAND terms by imposing royalties linked with cost of product of user for its patents," the order said.

This is a clear example of where restrictive licensing practices such as high royalty rates, which stem from patent ownership can pose a barrier for a local enterprise to make use of certain technology.

⁶ See http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf