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Understanding the Basis for Compulsory Licensing for Public Health Reasons

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Although they are critical for spurring innovation, intellectual property rights (IPRs) generally bestow some monopoly rights on the holder, which can be abused if market conditions permit. This is generally a major concern in the drug industry, where the production of drugs needed for controlling dangerous diseases is limited due to protection by IPR. One possible way of ensuring that there is improved access to an IPR-protected product is by granting a compulsory licence to other parties to produce the patented product under limited conditions. This briefing paper focuses on compulsory licensing for public health reasons. It discusses compulsory licensing, the various factors that are normally used to justify compulsory licensing and also discusses some examples in some select countries where compulsory licensing has been used for public health reasons.

Introduction

The fact that innovation can be encouraged through the assigning of IPRs to the innovator is hardly in dispute. Innovators can devote significant amounts of their budgets in exploring new and more economic ways of production if they are assured that they can at least be able to recoup the research costs through profit-inducing pricing, without other players entering the market. Such a need for intellectual property protection around the world is recognised under the WTO agreement on trade-related aspects of intellectual property rights (TRIPs) of 1995. The agreement has legal provisions underpinning IPRs in the world today[1].

While there is need for protecting intellectual property and allowing innovators to determine the trade terms, it should also be appreciated that IPRs grant the innovator monopoly rights, which can easily be abused or can easily result in problems of access of the protected products to vulnerable groups. Access to essential products and services, such as medicine for the treatment of life-threatening diseases, to vulnerable groups can not be guaranteed under a product protected by IPRs.

Thus, there is need for a correct balance between promotion of incentives for innovation and access to critical services to be struck. Article 31 of TRIPs gives room for flexibility in licensing procedures, to allow for developing countries to ensure access to critical services/products. Such a balance can be achieved through the granting of compulsory licensing[2].

Compulsory licensing provisions in the health industry under TRIPs were largely reaffirmed by the Doha Declaration on TRIPs and Public Health of 2001 (Doha Declaration) and the subsequent WTO 'Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health' in August 2003 (August 2003 Decision). The Doha Declaration itself had come under the background of the global HIV pandemic and the associated high cost of patented anti-retroviral (ARV) treatments. Many developing countries wanted confirmation whether the existing TRIPs provisions allowed enough flexibility to allow them to take measures to promote access to patented medicines. Thus, both meetings resulting in the Doha Declaration and the August 2003 Decision was mainly about a legal interpretation of the existing TRIPs provisions, rather than a new legislation[3].

Defining Compulsory Licensing

Compulsory licensing can be defined as a situation where government grants a licence for the production or distribution of a patented product to another individual or to itself, without the consent of the patent owner. It can, therefore, be regarded as a state-enforced involuntary contract between a willing buyer (user/manufacturer) and an unwilling seller (patent holder). Given that the patent owner does not have to give consent, the TRIPs agreement outlines some conditions under which a government can legally impose compulsory licensing, including, *inter-alia*, the following:

- The use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable

commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, except in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use;
- The scope and duration of such use shall be limited to the purpose for which it was authorised and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- Such use shall be non-exclusive, non-assignable (except with that part of the enterprise or goodwill which enjoys such use) and authorised predominantly for the supply of the domestic market of the member authorising such use;
- Authorisation for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorised, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur;
- Countries can issue compulsory licences to allow domestic companies to export pharmaceutical products to developing countries facing public health problems, but without the capacity to produce the patented products; and
- The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation[4].

Thus, Article 31 of the TRIPs, which sets out the framework for national laws on use without authorisation of the patent owner, largely forms the international legal backing for compulsory licensing. However, it is largely the Doha Declaration and the subsequent August 2003 Decision which confirmed and shed more light on the use of compulsory licensing *vis-à-vis* public health. Each member country also needs to have its own legislation, drafted consistently with the TRIPs, before it can start to apply compulsory licensing under TRIPs.

Why Compulsory Licensing?

There are several factors that justify the need for compulsory licensing. Generally, having a monopoly right to provide a product/service is always tempting for the right owner and this is sometimes followed by abuse of the right. Such abuse can take place in a number of ways, including excessive pricing, deliberate limited market access to give room for high pricing, applying selective marketing principles that compromise access and use of patent-induced monopoly right to block dynamic/ downstream innovation. Under such circumstances, countries, often under the recommendation of competition authorities, impose compulsory licensing to allow alternative manufacturing or distribution of the monopolised product.

Patent owners also have an incentive to limit market access, even if they do so without violating any competition law. In that regard, they can simply refuse to make the invention available for use by other dependent inventions, as a way of keeping the price high. There are also instances where the patent owner does not possess enough capacity to supply the whole country, or to meet the demand for the product. In such cases, the government may see the need to impose compulsory licensing for other manufacturers to reproduce the patented product, as long as it is deemed critical for the public.

Situations of national emergency can easily result, where a government finds itself faced with an unanticipated crisis, while its capacity to respond to the crisis in the interest of public protection is limited. This normally occurs in situations where a serious pandemic suddenly erupts or a situation threatening peace and stability arises.

The HIV/AIDS pandemic, where countries found themselves in a situation where the demand for anti-retroviral (ARV) treatment being severely outstripped by the available supply, and anthrax fears are good examples. In such a situation, the government might feel compelled to apply compulsory licensing for its local companies, either to manufacture the patented ARVs or to import them for distribution within the country from countries where the patent does not apply or where such products have been produced by way of compulsory licensing (which significantly reduce their prices).

The August 2003 Decision on the implementation of TRIPs allowed that, in addition to purposes of domestic use, countries can apply compulsory licensing to allow local companies to manufacture patented products for the purpose of exporting to developing countries facing critical shortages of the product, while having problems in importing directly from the patent owner. Many developing countries may fail to exercise their prerogative in applying compulsory licensing, simply because their local companies do not possess the capacity to manufacture the patented products. In such cases, the affected countries can identify companies in other countries with the capacity to produce and seek co-operation with the countries to allow compulsory licensing for exporting to them.

Impact of Compulsory Licensing on Innovation

It is important to note that while products such as medicines are expensive to develop, they are comparatively cheap to produce (Kommerskollegium, 2008). Thus, patent protection is required to prevent the cheap reproduction of invented products. The fact that compulsory licensing is given without the consent of the owner might, therefore, prejudice the owner of such privileges and reduce incentives for innovation. Compulsory licensing might result in lower prices for the generic product, this being a reflection of the fact that the new producer does not have to incur the research costs that have already been borne by the innovator. Thus,

there is an element of unfairness from the innovator's point of view and, if not done properly, compulsory licensing might discourage innovation.

This is also worsened by the fact that although the TRIPs Agreement provides for adequate compensation to the innovator in the event of issuance of a compulsory licence, the parameters to guide how such payment can be determined are not defined. The payment may not be fair to the patent owner, as it is generally the authorities in the country giving the compulsory license that decide whether the payment is adequate. Even though the TRIPs Agreement provides the patent owner the right to appeal payment decisions in that country as well, such a process may also imply significant legal expenses. This also bolsters the notion that compulsory licensing could be anti-innovation.

However, by looking at the frequency of compulsory licensing, it can be established that the damage to innovation may not be as pronounced as it might seem. They are relatively few countries in the world, particularly from the developing countries, that have applied compulsory licensing to date, despite having already adopted national legislation to legalise it. This could be because the procedure to apply compulsory licensing might be cumbersome, as the judicial and administrative procedure involved might even take nearly three years (Janodia *et al* (2006)). National laws dealing with compulsory licensing are also not immune to administrative loopholes likely to be challenged in court, thereby delaying the whole process.

In addition, products made from compulsory licensing are generally for those markets where patented products do not enter, either because of low income population who cannot afford or the whole country is poor, despite the fact that doctors prefer to prescribe branded (patented) drugs than generic drugs. This implies that the market share of the patented drugs are either not taken away or are minimally taken away as the drugs would not have been available in the country in the first place.

Compulsory Licensing under Selected Developing Countries

India

In India, the Patent Act, 1970, through amendments in 1999, 2002 and 2005, now provides an adequate legal framework to the Controller of Patents for the issuance of compulsory licensing[5]. Section 84 provides for compulsory license if reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price,[6] at least three years after the license has been patented. Section 84 (6) outlines the factors that the Controller has to take into account in deciding whether or not to issue the licence. Such factors include the following:

(i) The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;
(ii) The ability of the applicant to work the invention to the public advantage; and
(iii) The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted.

In addition to Section 84 of the Act, compulsory licensing is also provided for under Section 92 by the Central Government on national emergency grounds or in case of public non-commercial use. The Central Government is required to issue a notification in the Official Gazette to this effect, following which any person interested has to apply to the Controller for a licence.

In line with the August 2003 Decision, Section 92A of the Act now provides for the granting of compulsory licensing for exports. The Section provides for compulsory licensing for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for public health problems. However, the precondition is that a compulsory licence must have been granted by such country to allow importation of the patented pharmaceutical products from India.

The compulsory licensing provisions in India have not yet been fully utilised, despite some signs for its need. In 2005, for example, it was reported that the Indian Cabinet was considering issuing compulsory licenses to local generic companies under the 2005 Indian Patents Act which would have allowed them to produce copies of Roche's anti-influenza medicine, Tamiflu (oseltamivir), for the domestic market as well as for export. It is not yet public knowledge whether this has since been successfully done.

In January 2008, the *Business Standard*[7] reported that Natco Pharma filed an application for compulsory licensing for the manufacture of Roche's erlotinib (brand name Tarceva), which is used in the treatment of lung cancer, for export to Nepal (of about 30,000 tablets), offering Roche a five-percent royalty. The application was filed at the Controller General of Patents in September 15, 2007, and the outcome is still not yet publicised.

Zimbabwe

Section 31 of Patent Act (*Chapter* 26:03) of Zimbabwe provides for application for a compulsory licence to the Registrar on the grounds that reasonable requirements of the public with respect to the invention have not been met. Such an application can only be made at least after three years of the sealing of the patent, or four years from which application for the patent was lodged, whichever

period last expires. Factors to determine that 'reasonable requirements of the public' have not been satisfied include:

(i) if the patented invention, though capable of being worked in Zimbabwe, is not being worked therein on a commercial scale and there is no satisfactory reason for such non-working;
(ii) if the demand for the patented article in Zimbabwe is not being adequately met;
(iii) if the patentee has refused to grant a licence to others on reasonable terms, resulting in the trade or industry of Zimbabwe or the establishment of any new trade in Zimbabwe being prejudiced;
(iv) it is in the public interest that a licence or licences should be granted; and
(v) if the patent holder is prejudicing any trade by imposing unfair conditions.

Section 34 empowers State departments or any person authorised in writing by the Minister of Justice to make a patented product for the service of the State. Section 35 also allows for compulsory licensing during any period of national emergency, a period which means any period the Minister may declare by statutory instrument. Such emergency use includes:

(a) for the efficient prosecution of any war in which Zimbabwe may be engaged;
(b) for the maintenance of supplies and services essential to the life of the community;
(c) for securing a sufficiency of supplies and services essential to the well-being of the community; or for promoting the productivity of industry, commerce or agriculture;
(d) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade; and
(e) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Zimbabwe or any foreign country that is in grave distress as the result of war.

Zimbabwe is among the first developing countries to use compulsory licensing. A notice was issued by the Ministry of Justice, Legal and Parliamentary Affairs in 2002, which declared the HIV/AIDS pandemic a national emergency. The declaration sought to allow any person to apply to the Minister for permission to make or use any patented drug, including any ARV drugs, used in the treatment of HIV/AIDS related conditions, for six months. The declaration also allowed for the importation of any generic drug used to treat HIV/AIDS-related illnesses for the same period. At the expiry of the six months, the period was extended by a further five years.

In response to the declaration, Varichem Pharmaceuticals (Pvt) Ltd, a Zimbabwean registered company, was the first to obtain a license in 2003 and agreed to produce ARVs, while supplying three-quarters of its produced drugs to State-owned health institutions at price controlled terms determined by the Minister. Subsequently, another company, Datlabs, was authorised to import ARVs from Ranbaxy in India, while Omahn, an agent for the Indian manufacturer Cipla, has also been authorised to import Cipla products (Oh, C, 2006).

Zambia

The Patents Act (Chapter 400) of Zambia also has provisions on compulsory licensing. Section 37 allows any person to apply to the Registrar for a licence on the grounds that reasonable requirements of the public with respect to the invention in question have not or will not be satisfied. Just like Zimbabwe and India, such application can be made at least after three years of patent registration.

Section 38 empowers the High Court to order the granting of a compulsory licensing to an applicant where the patent is in respect of substances which can be used as, or used for the production of, food or medicine, or which can be used as part of a surgical or curative device. The High Court is expected to offer the licence on such terms that shall endeavour to secure that food, medicines and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent.

Section 40 has provisions allowing compulsory licensing for use of patented inventions for services of the State, while Section 41 provides for special provisions for compulsory licensing for State use during emergency.

The Zambian government has already made use of the compulsory licensing provisions of the Patent Act. In 2004, through the Ministry of Commerce, Trade and Industry, the Zambian government issued compulsory license No. CL 01/2004 to Pharco Ltd, a company incorporated in Zambia, in response to its application for the manufacture of ARVs. The licence was for the production of a triple compound of Lamivudine, Stavudine and Nevirapine, believed to be one of the most effective and economical anti-retroviral treatments, for which the three different international owners of such single drugs had failed to reach an agreement to produce the combination. Pharco proposed to produce the drugs under the names of Normavir 30 and Normavir 40[8].

Terms set by the compulsory license included the time period, which was set to be for five years ending July 31, 2009. The licence also explicitly prohibited the export of the products produced under the licence, while Pharco was to pay royalties to the patent holders not exceeding 2.5 percent of total turnover of the products at the end of each financial year.

South Africa

Section 55 and 56 of the Patent Act, 1978 (No. 57), of South Africa provides for compulsory licensing on the grounds of related patents and abuse of dominant

position, respectively. Similarly, the Act also empowers the compulsory acquisition of patent rights by the State in Chapter XIV of the Act[9]. In terms of Section 56, factors to be used to determine abuse of patent right include:

(a) when the invention is not being worked on a commercial scale or to an adequate extent after a period of three years from date of patent grant, without adequate reason;
(b) when the demand for the patented product is not being adequately met on reasonable terms;
(c) if the trade, industry or agriculture is being prejudiced by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms; and
(d) if the price of the product is excessive in relation to the price charged through the importation of the same product from countries where the patented article is manufactured by or under licence from the patent holder.

South Africa also offers another interesting case when the abuse of dominance provisions of the Competition Act, 1998, were used as a basis of forcing companies to issue licences to other players, without resorting to the Patent Act. In 2002, the Treatment Action Campaign registered a complaint with South Africa's Competition Commission against GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim, charging them with excessive pricing in respect of Ritonavir, Lamivudine, Ritonavir+Lamivudine and Nevirapine, which are ARV medicines. The Commission's investigations almost a year later resulted in the two pharmaceutical firms being found guilty of contravening the Competition Act of 1998. The Commission found the firms guilty of denying a competitor access to an essential facility, excessive pricing and engaging in an exclusionary act and referred the matter to the Competition Tribunal.

One of the respondents, GSK, conceded to a final settlement in December 2003, in whose terms GSK undertook to:

- extend a voluntary licence, which it had granted to Aspen Pharmacare in October 2001 in respect of the public sector, to include the private sector;
- grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare, based on reasonable criteria, which include registration with the Medicines Control Council and the meeting of safety and efficacy obligations;
- permit the licensees to export the relevant anti-retroviral drugs to sub-Saharan African countries;
- where the licensee does not have manufacturing capability in South Africa, GSK will permit the importation of the drugs for distribution in South Africa; and
- charge royalties of no more than five percent of the net sales of the relevant ARVs.

Indonesia

The Indonesian Law 14 of 2001 regarding Patents also provides for compulsory licensing. In terms of Article 74 of the Law, compulsory licence means a licence to implement a patent which has been granted based on a decision of the Directorate General based on an application. Article 75 provides that the application, which can be made by anyone after thirty six months from the date of the patent, can be made to the Directorate General on the grounds that the patent has not been implemented (or has been partially implemented) in the Republic of Indonesia by the patent holder or on the grounds that it has been implemented in a manner that contravenes public interest. The applicant must, however, have made efforts in a sufficient period of time to acquire a licence from the patent holder on normal terms and conditions and failed, while the Directorate General is of the opinion that the implementation is feasible and to the benefit of the majority of the society.

The Law also provides for the implementation of a patented product by the government itself or to another person approved by the government on behalf of the government on the grounds of defence and security of the State and for an urgent need for public interest (Article 99). However, the implementation of a patent by the government shall also be carried out with the provision of reasonable compensation to the patent holder.

Use of the compulsory licensing provisions has already been made in Indonesia. In 2004, a Presidential Decree regarding exploitation of patent by the government on ARV (No 83, 2004) was issued by the President in terms of the Law, pursuant to the urgent need to control HIV/AIDS epidemic in Indonesia, through provision of patented ARVs. The Decree provided for the production of Boehringer Ingelheim's patented Nevirapine and Biochem Pharma INC's Lamivudine for a period of seven and eight years, respectively, in Indonesia.

The Minister of Health was also tasked to appoint a Pharmaceutical Factory as the Patent exploiter for and on behalf of the government, upon which the government would give a 0.5 percent compensation fee of the net selling value of ARV Drugs to the Patent Holder[10]. This 2004 Decree was later amended in March 2007 to cover another ARV drug, Efavirenz, which had replaced Nevirapine as the first-line drug. Indonesia now uses Lamivudine, Efavirenz and Zidovudine (not considered for compulsory licensing as its patent had expired at the time) as the three first-line ARVs for its HIV/AIDS patients. PT Kimia Farma, a state-owned company, was appointed as the 'pharmaceutical factory' provided for in the Decree and now produces all the three drugs, Efavirenz, Lamivudine and Zidovudine[11].

Malaysia

The Patent Act, 1983 (Act 291), of Malaysia also has provisions for compulsory licensing. In terms of Section 49 of the Act, any person can apply to the Registrar for a compulsory licensing at least three years after the grant of the patent on the grounds that there is no production of the patented product in Malaysia, without any legitimate reason, or that there is production, but the products are being sold at unreasonably high prices or the products are failing to meet public demand, without any legitimate reason. The compulsory licence can, however, only be issued after the applicant has made efforts to get a voluntary licence from the patent holder under reasonable commercial terms and failed.

Section 84 of the Act also provides that the Minister may decide that the government, or a person designated by the government, should exploit the patent under conditions of national emergency or public interest issues, such as national security, nutrition, health or the development of other vital sectors of the national economy, as determined by the government so requires. The Section also provides for such a decision when a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive. Under such circumstances, the patent owner would be liable for compensation, arrived at taking into account the economic value or the need to correct anti-competitive practices.

The Malaysian government has already made use of the compulsory provisions of the Act. Using the provisions of Section 84, the Minister of Domestic Trade and Consumer Affairs, in 2003, issued a letter to Syarikat Megah Pharma & Vaccines (M), authorising the company to manufacture patented inventions for the following drugs:

i. Didanosine 100 mg tablets produced by Bristol-Myers Squibb;
ii. Didanosine 25 mg tablet produced by Bristol-Myers Squibb;
iii. Zidovudine 100 mg capsule produced by GlaxoSmithKline; and
iv. Lamivudine 150 mg + Zidovudine 300 mg tablet produced by GlaxoSmithKline.

The authorisation, however, was subject to some stringent conditions, which included that the licence was only valid for two years, commencing November 01 2003, and that the licence was only limited to authorisation to import the drugs from Cipla, an Indian company. The drugs were to be supplied only to government hospitals, where the government would determine the quantities to be imported, the terms and conditions of importation, as well as the prices of the products (the prices were listed in the letter). The brand name, shape and colouring of the tablets were to be differentiated from those of the patent holders, while the labelling should be under the name of the Ministry of Health[12].

Conclusion

Most of the developing countries have now adopted compulsory licensing provisions in their patent laws and have amended them accordingly, following the Doha Declaration. The grounds for compulsory licensing can arise from generally two sources, namely, from government initiatives and from applications by private players. It can also be established from the laws of developing countries discussed in the paper that the compulsory licensing provisions allow for both sources to be used for compulsory licensing, with provisions controlling compulsory licensing for government use being generally separated from the general provisions relating to the granting of compulsory licensing to private players.

It can, however, be established that the only ground that compulsory licensing is popular in developing countries is public health grounds. In all examples given above, the HIV/AIDS pandemic was the only ground used. In addition to the above countries, it can also be established that Thailand (2007), Brazil (2001), Ghana (2005) and Eritrea (2005) are also among the countries that invoked the provisions of compulsory licensing on public health grounds for the treatment of HIV/AIDS related conditions. There are still a lot of other life-threatening diseases[13] where similar efforts can still be made to ensure public safety.

Thus, private initiatives for compulsory licensing, despite being well articulated in the patent laws of most jurisdictions, are still to be utilised in developing countries. It goes, however, without saying that abuse of patent rights in its numerous dimensions is very prevalent in many developing economies. There is, therefore, some scope for more efforts to be made to encourage applications for compulsory licensing provisions whenever abuse occurs. Civil society organisations (CSOs) can play an important role in being watchdogs for cases that warrant compulsory licensing, to ensure public access to medicine.

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Endnotes

1 It is important to note that TRIPs only deals with trade-related issues of intellectual property, with the basic provisions on intellectual property being contained in a number of international agreements, most of which the World Intellectual Property Organisation (WIPO) monitors.

2 Parallel imports can also be used to ensure this balance. However, it is not the focus of this paper.

3 The August 2003 Decision, however, resulted in the amendment of paragraph 31 (f) of the TRIPs in 2005 to allow countries to issue compulsory licences for export of pharmaceutical products to developing countries facing public health problems.

4 Article 31 of TRIPs (as amended)

5 The 2005 Amendment, for example, brought in Section 92A with compulsory licensing provisions for exports, while the 2002 amendment brought in TRIPs flexibilities on compulsory licensing provisions.

6 Section 90 outlines factors that can be used to determine whether reasonable requirements of the public are satisfied.

7 http://www.business-standard.com/india/storypage.php?autono=310813

8 Cptech, at website http://lists.essential.org/pipermail/ip-health/2004-September/006959.html

9 Section 78 to 80 of the Act.

10 Cptech at website http://lists.essential.org/pipermail/ip-health/2004-December/007233.html

11 Intellectual Property Watch, 2007 at website http://www.ip-watch.org/weblog/index.php?p=841

12 http://www.cptech.org/ip/health/c/malaysia/arv-license.html

13 Other life-threatening diseases for which access to medication is threatened by pricing include lower respiratory infections, cancer, tuberculosis and malaria.

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