

COMPULSORY LICENSING AND THE ANTI-COMPETITIVE EFFECTS OF PATENTS FOR PHARMACEUTICAL PRODUCTS: FROM A DEVELOPING COUNTRIES' PERSPECTIVE

I. Introduction

Competition in the pharmaceuticals sector is inextricably linked to a range of issues related to intellectual property (IP) protection. Patents confer limited monopoly rights on pharmaceutical companies. Such monopoly rights are often misused. Companies abuse their dominant position by pricing their patented products at monopolistic profit-maximising levels. Companies also adopt strategies to frustrate entry by generic rivals such as through 'evergreening'. Given these difficulties in ensuring access to affordable medicines, especially in developing countries, the presence of competition in the market, particularly through generic products, is essential. Preventing entry of generics beyond the legitimate patent term is a competition concern. Measures such as compulsory licensing are called for in order to better regulate such anticompetitive practices, restore the competitive balance of the market, and ensure consumers' access to essential services, while respecting the principle of promoting innovation.

At the practical level, the global AIDS pandemic has highlighted the fact that millions of people in the developing world do not have access to the medicines. The high cost of patented anti-retroviral (ARV) treatments has drawn a lot of criticism about the relationship between patent protection and high drug prices. The difficulties developing countries experience in paying for new essential medicines has raised concerns about the effects of the 1995 World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which mandates global minimum standards for IP protection.

Such concerns began to get addressed by the Doha Declaration on TRIPS and Public Health of 2001 (widely known as "the Doha Public Health Declaration", hereinafter the "Declaration"), leading to the WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in August 2003 ("the August Decision"), and finally the amendment to the TRIPS Agreement in 2005 (which is yet to come into force). The Declaration affirmed the sovereign right of governments to take measures to protect public health, including the use of compulsory licensing and parallel importation, and allowed least developed countries (LDCs) not to grant or enforce pharmaceutical product patents until at least 2016. The August Decision and the amendment of the TRIPS Agreement that followed established a process, albeit cumbersome, allowing products manufactured under a compulsory license to be exported to countries without domestic production capacity. It has hardly been used in practice.

Between 2001 and end 2007, 52 developing and least-developed countries have issued compulsory licenses for production or import of generic versions of patented medicines, given effect to government use provisions, and/or implemented the non-enforcement of patents. Many countries have also used the flexibilities as leverage in price negotiations. The use of TRIPS flexibilities has been applied primarily to AIDS-related drugs, particularly ARVs. An exception is the recent case of Thailand, which issued government use orders for treatments for cardiovascular disease and cancer in 2007.

However, the scope and capacity of developing countries to make use of the TRIPS flexibilities is still limited in several ways. The response of the pharmaceutical industry to the use of these

flexibilities has only exacerbated the problem. TRIPS-plus provisions in free trade agreements, trade retaliation and political pressures have seriously impeded the full use of the flexibilities.

This paper will analyse the issue from a developing countries' perspective and examine whether compulsory licensing can still counter the various anticompetitive effects of pharmaceutical patents; and provide some recommendations on how to make it a more effective tool, especially in light of the current international discussions on competition policy.

Section II of the paper would provide an overview of compulsory licensing as a theoretical subject – definition, rationale, and how it is provided for in the legal system of various countries in the world. Some cases where compulsory licences have been granted due to the anticompetitive behaviours by patent holders would also be examined. Section III of the paper would examine the TRIPS Agreement, the Doha Declaration and the August Decision, and analyse how these provisions are being and could be more effectively applied in the context of compulsory licensing for patents over pharmaceutical products to address public health issues. Relevant cases would also be dealt with in this section. Section IV provides some recommendations for making compulsory licenses more of an effective tool by governments in developing countries to counter the anticompetitive effects of pharmaceutical patents.

II. Compulsory licensing

1. The interface between competition and intellectual property (IP) policies

Competition law (CL) and Intellectual Property Rights (IPRs) policies are bound together by the economics of innovation and an intricate web of legal rules that seek to balance the scope and effect of each policy.

IPRs protection is a policy tool meant to foster innovation, which benefits consumers through the development of new and improved goods and services, and spurs economic growth. It bestows on innovators the rights to legitimately exclude, for a limited period, other parties from the commercial use of innovative products and processes based on that new knowledge. In other words, innovators or IPRs holders are rewarded with a temporary monopoly by the law to recoup the costs incurred in the research and innovation process. As a result they earn rightful and reasonable profits, so that they have incentives to engage in further innovation.

Competition law, on the other hand, is essential in curbing market distortions, disciplining anticompetitive practices, preventing abuse of monopoly, inducing optimum allocation of resources and benefiting consumers with fair prices, wider choice and better qualities. It, therefore, ensures that the monopolistic power associated with IPRs is not excessively compounded or leveraged and extended to the detriment of competition. Besides, while seeking to protect competition and the competitive process, which in turn prods innovators to be the first in the market with a new product or service at a price and quality that consumers want, competition law underscores the importance of stimulating innovation as competitive inputs, and thus also works to enhance consumer welfare.

Indeed, the relationship between IPRs and competition law has been a complex and widely debated one. It is not just one of a balance between conflicting or complementary systems principles, but one of different levels of market regulation as well. Errors or systematic biases in the interpretation or application of one policy's rules can harm the other policy's

effectiveness. A challenge for both policies is to find the proper balance of competition and innovation protection.

Given the strong link between them, IPRs and competition laws have substantial interface in their regulation of various issues of the business world. Briefly, their interface can be seen from two main facets: (i) the impact of IPRs in shaping the disciplines of competition law, and (ii) the application of competition law on the post-grant use of IPRs.

IPRs policy can exert some restrictions on a pure prohibition of horizontal and vertical restraints by competition law, usually as an exemption. By economic virtue, where intellectual property is central to collective arrangements or joint ventures on the product markets, general antitrust principles will give way to considerations like transaction cost minimisation or pre-competitive cooperation. In this respect, IPRs policy acts as an institutional framework regulation for the proper operation of markets for intangible subject matter, and is therefore exempt from antitrust control. Competition law of most countries, therefore, expressly or implicitly exempts from their application the exclusive rights inherent in intellectual property protection granted by the state, which are considered to justify restrictions that would otherwise be subject to antitrust scrutiny.

On the other hand, “as a piece of individual property, IPRs are fully subject to general antitrust principles, because what is conferred upon its owner is precisely that autonomy of decision in competition and freedom of contracting according to individual preferences that results from any private property, no matter tangible or intangible, and that is the object of and connecting factor for restraints of competition”.¹ Competition law, thus, while having no impact on the very existence of IPRs, operates to contain the exercise of the property rights within the proper bounds and limits which are inherent in the exclusivity conferred by the ownership of intellectual assets. This is where one descends from lofty principles and broadly defined objectives to practical implementation, to deal with the tensions between the two policies, when the exercise of IPRs gives rise to some competition concerns because of the anticompetitive dimensions that it may embody. Broadly, IPRs-related competition issues include:

- Exclusionary terms in the licensing of IPRs; specifically the inclusion in licensing contracts of restrictive clauses such as territorial restraints, coercive package licensing, exclusive dealing arrangements, tying or grant-back requirements, conditions preventing challenges to validity etc.;
- Use of IPRs to reinforce or extend the abuse of dominant position on the market unlawfully;
- IPRs as an element of mergers and cooperative arrangements; and
- Refusal to deal.

2. Compulsory licensing of IPRs as an antitrust remedy

"A compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state...A survey of international intellectual property law

¹ Ullrich (2001), *Intellectual Property, Access to Information, and Antitrust: Harmony, Disharmony, and International harmonisation*, published in Dreyfuss, Zimmerman and First (ed.), “Expanding the Boundaries of Intellectual Property”, Oxford University Press, 2001, p.374

reveals that the three most prevalent compulsory licensing provisions are applicable where a dependent patent is being blocked, where a patent is not being worked, or where an invention relates to food or medicine. Additionally, compulsory licensing may be implemented as a remedy in antitrust or misuse situations, where the invention is important to national defence or where the entity acquiring the compulsory license is the sovereign.”² In these cases, the public interest in broader access to the patented invention is considered more important than the private interest of the right holder to fully exploit his exclusive rights. The designated third party should generally compensate the patent holder through payment of remuneration. Compulsory licenses do not deny patent holders the right to act against non-licensed parties.

With regard to the IPR/competition interface, compulsory licensing can be granted on the grounds of the existence of: (i) a refusal to license and (ii) anticompetitive exercises of IPRs by patent holders.

Refusal to deal as a ground for granting a compulsory license has been provided in many national laws, such as the patent laws of China, Argentina and Israel.

A widely accepted premise of IP law is that IP holders are under no obligation to license protected subject matter to others. This principle is generally held to be true even when a firm is in possession of a monopolistic position in a market as a result of its ownership of intellectual property. An early non-antitrust decision by the US Supreme Court stated that the ability to exclude competitors from the use of a new patent ‘may be said to have been of the very essence of the rights conferred by the patent, as it is the privilege of any owner of property to use or not use without question of motive.’³ On the other hand, from the perspective of IPR/competition law interface, there may be the question of whether such duty exists.

Courts in the EU and the US have at times held that refusals to license a patent violate competition law. However, in neither jurisdiction, though they are among the most advanced jurisdictions in terms of IP and competition law, have they provided clear direction as to whether a refusal to deal is anticompetitive where it involves intellectual property. The EU legal practice is sometimes even in favour of refusal to deal on the altar of expected benefits for innovation. Slightly different was the case of Brazil, where Article 21 of the Antitrust Law enlists the “non-exploitation or the inadequate use of intellectual property rights and technology of a company” as a strong indication that the free competition rules have been violated.

While the non-fraudulent acquisition of patent rights through government grant does not violate the antitrust laws; nor is it inherently illegal for a single party to accumulate patents, absent fraud or bad faith; antitrust jurisprudence does hold that when a party aggressively engages in accumulation, non-use, and enforcement of IPRs over the essential inputs in a particular market for the purpose of destroying competition in that market, it may be subject to antitrust liability. Thus, a duty to license this portfolio of rights might be found, or compulsory licensing might be imposed as a remedy to cure the violation.

² Arnold G.J (1993), *International Compulsory Licensing: The Rationales and The Reality*, PTC Research Foundation of the Franklin Pierce Law Center, IDEA: The Journal of Law and Technology. The situation has since changed in respect of food and medicine patents, as WTO members are obliged under TRIPS to provide patents in all fields of technology, including these two.

³ *Continental Bag Co. vs. Eastern Bag Co.*, 210. US 405 (1909)

In the United Kingdom and in other countries that have followed the model of UK legislation, before the coming into force of the WTO, refusal to deal may have led in all cases to a compulsory license when an export market was not being supplied, the working of any other patented invention which makes a substantial contribution was prevented or hindered, or the establishment or development of commercial or industrial activities in the country was unfairly prejudiced.⁴ This situation changed after the WTO came into force, and now the UK Patent Act, as amended in 2007, provides for two categories; a category applicable to WTO proprietors, where these grounds are no longer available, and others, where they are still available. Similarly, in South Africa, a license can be granted in the case of the refusal to grant a license on reasonable terms, where trade or industry or agriculture or the establishment of a new trade or industry in the country is prejudiced, and it is in the public interest that a license is granted.⁵

As regards anticompetitive practices, the Competition Act of Canada, for example, gives the Federal Court power to expunge trademarks, to license patents (including setting all terms and conditions), to void existing licenses and generally to abridge or nullify normal patent or trademark rights where the trademarks or patents have been used to injure trade or commerce unduly or to prevent or lessen competition unduly.⁶

Some Assorted Cases of Compulsory Licensing

The United States:

In general, the US position on compulsory licensing is that "compulsory licenses for the benefit of private competitors are not favoured by the tradition of America statute law, except as sanctions for actual violation of the antitrust laws."⁰

*US Federal Trade Commission (FTC) vs. Ciba – Geigy HO, Ciba – Geigy Corp., Chiron Corp., Sandoz Corp. and Novartis AG*⁰

The US FTC issued on 24 March 1997 a Decision and Order concerning the merger between Swiss companies Ciba-Geigy and Sandoz into Novartis. The combined entity would also control Chiron Corp., a biotechnology company. The FTC concluded that the merger would violate US antitrust laws, because the merged companies are current or potential competitors for several pharmaceutical, agrochemical and biotechnology products. The FTC required divestiture of several products, and ordered compulsory licenses of intellectual property rights for a number of other healthcare inventions. For example, Ciba-Geigy, Sandoz and Chiron were required to license a large portfolio of patents, data and know-how relating to HSV-tk products, haemophilia gene rights and other products to Rhone-Poulenc Rorer. The new merged entity and Chiron were also required to grant non-exclusive licenses to any interested party of patents and other rights relating to Cytokine products.

In the case of the non-exclusive Cytokine licenses (which involve gene therapy), and the Anderson gene therapy patent, the FTC specified that the royalties can be no greater than three per cent of the net sales price.

⁴ See Section 48.3.d of the UK Patent Act, as revised in 1977

⁵ See Section 56(2)(d), Patents Act No. 57 of 1978 of South Africa. This provision has been retained in the amendments carried out in 2002 as well.

⁶ See Section 32 of The Canadian Competition Act, RSC 1985, c C-34, as amended. Sub-section 3 thereof, prohibits issuance of an order by the Federal Court that is at variance with any treaty... with any other country respecting patents... to which Canada is a party, thereby nullifying possibility of use of this provision in the post-TRIPS era.,

Intergraph Corp. v. Intel Corp., 253 F.3d 695 (Fed. Cir. 2001)⁰

The case involves Intel, a firm that accounts for almost 80 % of the world's supply of microprocessors. Because Intel and others control key patents on Central Processing Unit (CPU) technology, barriers to entry in the industry are high. They are heightened further by important network and feedback effects due to the combination of Intel chips with the Windows Microsoft's operating system. In order to smoothen the incorporation of Intel's upcoming technologies into the complementary goods, Intel has implemented the practice of giving its main customers advance information about new and upcoming processor prototypes.

Intergraph, a producer of graphics workstations initiated the first case against Intel by suing the company and others for infringement on its CPU patents. Intel countered by removing Intergraph from the list of companies benefiting from advance notification of technical details about its forthcoming CPU's. What's more, the defendant threatened to discontinue the sale of microprocessors to the plaintiff if the latter carried on with its refusal to sell to it the patents it held on CPU technology. Intergraph won a preliminary injunction based on the argument that Intel's microprocessors and associated trade secrets were *essential facilities* under the antitrust laws. The court ordered Intel to deal with Intergraph under standard terms. The apparent implication was that the essential facilities doctrine, developed mainly to regulate access to essential physical equipment, applies to intangible assets.

However Intel appealed and won. The Federal Circuit Court held that Intel's refusal contravened neither antitrust nor patent laws. The Court held that two conditions required to make Intel's conduct unlawful were not met. First, Intel's microchips were not an *essential input* because other suppliers (AMD, Motorola, Sun, and IBM) were able to sell close substitutes. Second, the goal pursued by Intel's in refusing to sell was not to create a monopoly in the downstream market because the firm had no intention of entering into downstream activities.

The European Commission:

Magill⁰

The ECJ, in its decision of 6 April 1995, confirmed that Radio Telefis Eireann (RTE) and Independent Television Publications Limited (ITP), who were the only sources of basic information on programme scheduling, which is indispensable raw material for compiling a weekly television guide, could not rely on national copyright provisions to refuse to provide that information to third parties. Such a refusal, the Court held, in this case constituted the exercise of an intellectual property right beyond its specific subject matter and, thus, an abuse of a dominant position under Article 86 of the Treaty of Rome.

The court argued that RTE and ITP held a dominant position, because they were the only source in Ireland of the basic information necessary to produce weekly television programming guides and were thus in a position to reserve for themselves the secondary market for weekly television guides by excluding all competition from that market. The Court considered that, whilst refusal to grant a license in exercising an IPR is not of itself an abuse of a dominant position, it might be an abuse where special circumstances exist. Such circumstances included the lack of an actual or potential substitute for a weekly television guide, the existence of a specific, constant and regular demand for such a guide, and the fact that the refusal to grant a license to Magill to produce such a guide prevented the appearance of a new product on the market which RTE and ITP did not offer.

Developing Countries:

The general perception of developing nations is that that protection of intellectual property only serves to assist the developed nations in maintaining their economic power and international control. For developing nations, it is a commonly expressed thinking that their economic advancement is a goal, which if achieved, benefits all nations. Since knowledge is the common heritage of mankind, and since this knowledge would contribute to their economic development, some argue that the intellectual property of all nations should be provided to them at little or no cost. Therefore, developing countries are generally strong advocates of maintaining a system which allows compulsory licensing thereby limiting the scope of protection and rights available to foreign companies and individuals.

Sources:

A.Frost, *Legal Incidents of Non-Use of Patented Inventions Reconsidered*, 14 George Washington Law Review, 273, 435 (1945)

B.Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, T.R.A.D.E Working Papers No. 5, South Center, 1999

C.Encaoua & Hollander, *Competition policy and Innovation*, 2002

D.*Brief summary of ECJ's Magill Decision*, 6 April 1995, Joint Cases C-241/91 and C-242/91 P

The existence of anti-competitive practices is also considered a ground for the granting of compulsory licenses in the laws of Chile,⁷ Argentina,⁸ and the Andean Group countries,⁹ among others. In these cases, the anticompetitive rules are included in the patent laws themselves, an option that may be more practical and straightforward for countries with weak or no competition laws. So far, however, there is no evidence about the actual application of these provisions. In South Africa, a compulsory license can be granted if the demand for a protected product is being met by importation and the price charged by the patentee is "excessive in relation to the price charged therefore in countries where the patented article is manufactured by or under license from the patentee or his predecessor or successor in title".¹⁰

Compulsory Licensing under Patents Law of India

The Patent Act 1970 of India (Section 84, 90) provided for compulsory licensing of a patented invention to an interested person (only after the expiration of three years from the date of sealing of the patent) on the grounds:

- (i) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, which may be the consequence of:
 - inadequate manufacture in India or failure to grant licenses on reasonable terms, resulting in (1) prejudice to an existing trade or industry or its development, (2)

⁷ See Law No. 19.039 Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights (of 24 January 1991) of Chile

⁸ See Law No. 24.481 of 1995 on Patents and Utility Models (as amended by Law No. 24.572) (consolidated text approved by Decree No. 260/96 of March 20, 1996) of Argentina

⁹ See Article 61-69 of the Decision 486 of 2000 of the Andean Community of Nations on Common Intellectual Property Regime at <http://www.sice.oas.org/Trade/Junac/Decisiones/DEC486be.asp>

¹⁰ See Section 56(2)(e), Patents Act No. 57 of 1978 of South Africa

prejudice to the establishment of a new trade or industry in India, (3) prejudice to the trade or industry of any person or class of persons, (4) demand for the patented article not being met by local manufacture, (5) failure to develop an export market for the patented articles made in India, and (6) prejudice to the establishment of commercial activities in India;

- prejudice to the establishment or development of trade or industry in India in goods not protected by the patent arising from restrictive conditions imposed by the patentee;
- non-working of the patent in India on a commercial scale;
- demand for the patented article being met by importation from abroad; and
- commercial working of the patented invention in India being hindered or prevented by import of the patented articles from abroad.

(ii) that the patented invention is not available to the public at a reasonable price.

Since the coming into force of the WTO TRIPS Agreement, the Act has been amended three times. The Patents (Amendment) Act, 2002 replaced the old chapter on compulsory licensing. The Act now provides for compulsory license on the following grounds:

(a) The reasonable requirements of the public with respect to the patented invention have not been satisfied;

(b) The patented invention is not available to the public at a reasonably affordable price; and

(c) The patented invention is not worked in the territory of India.

The Indian law requires authorities to give regard to certain general considerations while granting compulsory licenses. These considerations, given in Section 83, include some directly relevant to the relationship between IP and competition law. They include, *inter alia* that patents are not granted merely to enable a patentee to enjoy a monopoly for the importation of the patented article; that the patentee does not abuse his rights including through resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and that patents are granted to make the benefits of the patented invention available at reasonably affordable prices to the public.

Section 84 specifies the grounds for applying for a compulsory license, which include public interest¹¹, affordability and working in India. Section 89 explains the general purposes of granting compulsory license as:

(i) That the patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;

(ii) That the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.

Section 90 of the Act also empowers the Controller to settle the terms and conditions for compulsory licences. Sections 92 (1) and 92 (3) enable the Central Government and the Controller, respectively, to deal with circumstances of national emergency or circumstance of extreme urgency related to public health crises by granting relevant compulsory licences.

Section 92A provides for compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. Thus, this section

¹¹ Public interest is further explained in greater detail in sub-section 7. From a competition perspective, any action or omission by the patentee that impedes commercial activity in India could be adjudged as against public interest.

is an "enabling provision" for export of pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector in certain exceptional circumstances, to address public health problems. Such country has either to grant compulsory license for importation or issue a notification for importation into that country.

The new amendment also requires an applicant for a compulsory license to prove that s/he approached the patentee with reasonable terms for a license. Similarly, where the patent holder imposes a condition for a grant-back, prevention of challenges to the validity of the patent is deemed to be against public interest.

Thus, many provisions in the Indian Patents Act facilitate competition while at the same time preserving the core exclusive rights of patent holders to commercially exploit their inventions and recoup their investment.

3. The likely anticompetitive effects of pharmaceutical patents

The global pharmaceutical industry is presently valued at approximately US\$400bn. Growth rates differ across nations, with developing countries like South Korea, Taiwan, India, etc, notching high growth in the range of 12-15% p.a. Countries can be classified into five categories, according to the stage of development of their pharmaceutical sector.¹² These categories are outlined in the following table:

The Structure of the Global Pharmaceutical Industry¹³

Level	Stage of development	Number of countries		
		<i>Industrial</i>	<i>Developing</i>	<i>Total</i>
5.	Sophisticated pharmaceutical industry with a significant research base	10	Nil	10
4.	Innovative capabilities	12	6 (Argentina, Brazil, China, India, Korea and Mexico)	18
3.	Those producing both therapeutic ingredients and finished products	6	7	13
2.	Those producing finished products only	2	87	89
1.	No pharmaceutical industry	1	59	60
	Total	31	159	190

The sophisticated, research-based part of the global pharmaceutical industry is highly concentrated in a handful of countries, notably the USA, the UK, Germany, and Switzerland,

¹² According to the classification of the World Trade Organisation (WTO) and the United Nations' Conference on Trade and Development (UNCTAD), there are in total 4 grades of development for the global pharmaceutical industry, which is similar to this classification.

¹³ Source: R. Ballance, J. Progan & H. Forstener, UNIDO, *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition & Policy* (1992), in K. Balusubramaniam, *Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives* (2001) (paper presented at Oxfam International Seminar on Intellectual Property and Development: What Future for the WTO TRIPS Agreement?, Brussels, March 20, 2001).

and is composed of just a few companies. Currently, there are fewer than 40 firms competing in highly lucrative drug markets. The pharmaceutical industry argues that long-term patent protection is essential because otherwise drug companies cannot afford to develop new medicines. These companies derive most of their profits from a small number of drugs. In fact, 75 percent of drug company profits come from 10 percent of drugs¹⁴. These figures point to the high level of concentration in the global pharmaceutical industry, even though respective domestic markets might be divided and segmented. M&As activities by multinational corporations (MNCs) (no matter where they are based or where the transaction actually take place) would have strong impacts on the competitive scenario in each country.

The exclusive rights conferred by patent protection over pharmaceutical products and the concentrated structure of the market, as mentioned above, by themselves do not constitute contraventions of competition law. However, they are quite likely to have anticompetitive effects. For example, generally having a monopoly right to provide a good or service is always tempting for the right owner and this is often 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 and applying selective marketing principles that compromise access.

In 2003, the South African Competition Commission found that GlaxoSmithKline South Africa and Boehringer Ingelheim have contravened the Competition Act 1998 by abusing their dominant positions in the anti-retroviral (ARV) drug market. Each of the firms had refused to license their patents in return for a reasonable royalty. In particular, the Commission found that the firms denied a competitor access to an essential facility, set excessive prices, and engaged in an exclusionary act. Finally, the companies had decided for out-of-court settlement, after the case was referred to the Competition Tribunal.

In another example, in 2007, some US pharmaceutical retailers have accused drug maker Abbott Laboratories of leveraging its monopoly position over an HIV drug patent called Norvir, to inflate the cost of the drug by almost 400 per cent over the last four years to offset losses due to increased competition for other HIV-related drug it makes. Although Norvir can be used alone, it is typically a component drug used to boost the effectiveness of other HIV inhibitors, including Kaletra, another Abbott brand. Several rival producers use Norvir, which is the only drug of its kind, to supplement their drugs. When competitors to Kaletra began gaining market share, Abbott charged them more for Norvir to offset its losses and regain market position.

Patent holders could also abuse their rights to block dynamic or downstream innovation, or entry of generic rivals. For example, in June 2005, the European Commission (EC) imposed a 60-million *euros* fine on AstraZeneca for misusing national patent systems and national procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug Losec. Subsequently, in January 15, 2008, the EC disclosed that it had launched a "sector inquiry" into the pharmaceutical industry, including unannounced inspections known as "dawn raids." The EC stated that it had launched the sector inquiry because it was concerned that fewer new drugs were being brought to market, and that the entry of generic drugs appeared to be delayed. The EC noted that while 40 new drugs were introduced per year by drug companies between 1995 and 1999, that average fell to 28 between 2000 and 2004. The EC also stated that it was considering several potential competitive issues: agreements between pharmaceutical companies, such as patent litigation settlements; and the

¹⁴ Nanda, Nitya and Ritu Lodha (2002): 'Making Essential Medicine Affordable to the Poor', *Wisconsin International Law Journal*, Vol 20, No 3.

creation of barriers to entry through the misuse of patent rights, vexatious litigation, and abuse of the regulatory process or other means.

III. Compulsory licensing and the TRIPS

At an international level, the concept of compulsory license was first recognised and provided for vide Article 5A the Paris Convention of 1967¹⁵. The convention specifically mentioned that the member countries have *right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of exclusive rights conferred by patent*. However, with the advent of the WTO, compulsory license is now dealt in the TRIPS Agreement, and the relevant parts of the Paris Convention are inscribed into the TRIPS Agreement¹⁶. The TRIPS Agreement and the Paris Convention for the Protection of Industrial property¹⁷ do not limit the grounds for application of compulsory licenses by member States.

The TRIPS Agreement only lays down the conditions which have to be respected in granting and working of a compulsory license. These conditions basically require the license to be given only after negotiations with the patent owner for authorised use on reasonable terms have failed, and should last only until the ground for such grant subsists. This condition of prior negotiations can also be waived in situations of ‘national emergency’, ‘other circumstances of extreme urgency’, ‘public non-commercial use’ and ‘anti-competitive practices’, but the patent owner has to be informed.

Article 31 of TRIPS outlines conditions under which a government can legally impose compulsory licensing, including the following, which are relevant for this paper:

- The use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, 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 authorized;
- Such use shall be non-exclusive, non-assignable (except with that part of the enterprise or goodwill which enjoys such use) and authorized predominantly for the supply of the domestic market of the Member authorizing such use;

¹⁵ Choudhary, D.N., *Evolution of Patent Laws, “Developing Countries’ Perspective”* (1st Ed.) Capital Publishing House, New Delhi, Pg 139

¹⁶ ARTICLE 2 OF THE TRIPS AGREEMENT.

¹⁷ See the Paris Convention 1883 as amended by the Stockholm Act of 1967. at http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html

- Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur;
- the requirement for prior efforts to seek authorisation and for producing predominantly for domestic use may be waived in cases where the compulsory license is permitted in order to remedy an anti-competitive practice; and
- Compulsory license can extend to dependant patents with conditions.

In the run-up to the Doha Ministerial Conference of the WTO in 2001, access to medicine and potential limitations imposed by the TRIPS Agreement and particularly its Art.31 on such access, were focal points of discussion. The reason for the pressing need to facilitate access to essential drugs for combating the spread of HIV/AIDS in developing countries, in particular in Africa, led to strong public pressure to introduce more flexibilities in the TRIPS Agreement. Following lawsuits by 40 pharmaceutical companies objecting to the South African Medicines Act¹⁸ and subsequent WTO consultations initiated by the United States against Brazil challenging provisions on local working of patents,¹⁹ an unprecedented campaign was launched by non-governmental organisations against the research-based pharmaceutical industry and the WTO at large, which was seconded by developing countries and other international organisations.

These various pressures coupled with debate on essential drugs questioned the suitability of the minimum standard of protection that TRIPS obliges WTO members to put in place, for such a diverse world with different socio-economic conditions. The discussion ultimately led to the Declaration on TRIPS Agreement and Public Health, 2001. The Declaration specifically mentioned the right to grant compulsory licenses and the freedom to determine grounds upon which such licenses can be granted. It also clarified that public health crises including those related to HIV/AIDS, malaria, tuberculosis, and other epidemic etc may represent a national

¹⁸ During the 1990s, South Africa was severely affected by the global HIV epidemic. Of 39 million South Africans, nine million were estimated to be infected by the HIV virus. And the cost for medication treating HIV was found greatly unaffordable for most of the affected population. In response to this crisis, the South African legislature passed the Medicines and Related Substances Control Act Amendment 90 of 1997. The amendment permitted the use of importation of low-cost pharmaceutical drugs intended for poorer countries, compulsory licensing, and the use of generic drug substitutions for patented medicines. The measure provoked forty pharmaceutical companies and the South African Pharmaceutical Manufacturers Association to sue the South African government to block the amendment from coming into force. The drug firms alleged that the new amendment violated the TRIPS agreement (of which South Africa is a signatory) and contradicted South Africa's own patent law. After a lot tensions between the US government (who was backing up the pharmaceutical companies) and the South African one, joint in later by the EU in favour of the stand taken by the US, the case was brought to the court room in May 2000. Huge public outrage all over the world and the companies' weak legal position forced them to withdraw unconditionally in April 2001. See Robert C. Bird, *Developing Nations and the Compulsory License: Maximising access to essential medicines while minimising investment side effects*, in *Journal of Law, Medicine & Ethics*, 2009 *inter alia*.

¹⁹ In 1997, Brazil passed a broad compulsory licensing statute that would permit compulsory licensing of any patent right unless the patent holder manufactured the subject of the patent in Brazil within three years from when the patent was granted. (The Intellectual Property Law of Brazil, effective as of May 15, 1997, at art. 68, is available at <<http://www.araripe.com.br/law9279eng.htm>> The United States brought a complaint before the WTO Dispute Settlement Body in February 2001, alleging that the law violated TRIPS because it discriminated between patents as to the place of their invention and use. Brazil quickly retaliated by filing its own complaint before the WTO challenging portions of the US code requiring that products made with certain government-supported funding be manufactured in the United States. See S. A. Mota, *TRIPS: Ten Years of Disputes at the WTO*, in the *Computer Law Review and Technology Journal*, no. 1 (2005):455-478.

emergency or other circumstances of extreme emergency. The Declaration reaffirmed the flexibilities available under TRIPS Agreement, and proclaimed: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.... We affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all."

The Declaration also suggested that the General Council should find solution to the problem of those WTO member countries that do not have domestic manufacturing capacity and in the pharmaceutical sector could face difficulties in making effective use of the provisions of compulsory licensing, which required compulsory licences to be used primarily for the domestic market. In August 2003, subsequent negotiations within the TRIPS Council resulted in the adoption of the so-called Doha Waiver on essential drugs, the decision on *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*.²⁰ Subsequent negotiations prepared the ground for inserting the substance of the Waiver into the TRIPS Agreement, thus bringing about a permanent regime of *lex specialis* on access to essential drugs in the TRIPS System of intellectual property protection. However, it is abundantly clear that this amendment was limited to waiving the condition of predominantly domestic manufacture of compulsorily licensed patented products and that it was carried out with a very narrow policy perspective, *i.e.* only taking into consideration those member countries that had patented drugs available at their disposal but lacked manufacturing capabilities. Thus larger issues related to competition vis-à-vis TRIPS agreement are not being addressed by the ongoing Doha negotiations.

This is further confirmed by the fact that as of date there has been only one notification under the system created by this *lex specialis*, that by Rwanda in 2007²¹, and even that has not actually seen any increase in availability of affordable medicines. In fact, not a single developing country has notified itself as 'an eligible importing member' so far. In fact, as one author argues, it is food for thought for those who advocate legal or institutional changes in the WTO as a panacea for problems in global trade. Indeed, overly legalistic approaches to entrenched social, political and economic problems, which are the hallmark of many academics and international lawyers, may be a significant cause for the purported solution so far failing to fulfil its promise.²²

Therefore, it may be worth examining the several other provisions in the TRIPS Agreement which provide enough flexibility to member countries to better utilize it to their own advantage. The objectives of the Agreement in Article 7 set down a subtle balance between the requirement to compensate inventors and the demand for dissemination of technology. Again, the principles of the Agreement in Article 8 provide that members may adopt the necessary measures to protect public health and nutrition provided such measures are consistent with the provisions of TRIPS including compulsory licensing.

²⁰ WT/L/540 (2 September 2003), including chairman's statement.

²¹ At http://docsonline.wto.org/imrd/gen_searchResult.asp?RN=0&searchtype=browse&q1=%28+%40meta%5FSymbol+IP%FCN%FC9%FC%2A+%29+&language=1, on the WTO webpage dedicated to such notifications, accessed last on 14 October 2009.

²² Adam McBeth, Faculty of Law, Monash University, in Research paper No. 2006/35 dated 7 December 2007; *When Nobody Comes to the Party: Why have No States Used the WTO Scheme for Compulsory Licenses for Essential Medicines?*; available with the authors.

Notably, the TRIPS Agreement does not provide any disciplines on exhaustion²³, which could be useful to rein in the practice of parallel trade in the pharmaceutical industry.

The TRIPS Agreement contains some very precise provisions concerning competition law. They allow fair use²⁴ and the possibility of compulsory licensing²⁵ or the granting of dependent patents²⁶, i.e. the granting of a right by public authorities, and against the will of a patent owner, in order to make use of a patent to the extent necessary to develop a new product. In practice the fair use provision allows countries to permit limited use of innovation achievements for private and non-commercial purposes, for example in research and/or experiments. The facility of compulsory license allows countries to create involuntary agreements between patent owners and the government or its contractors to serve specific public interest needs.

Further, Article 40 provides considerable discretion to Members in curtailing licensing practices or conditions that may constitute an abuse of IPRs and have an adverse effect on competition. The three examples of potentially abusive licensing practices in the article include exclusive grant-back conditions, conditions preventing challenges to validity, and coercive package licensing. Careful reading of the Article could cover many potential abuses of IPRs.

Thus there is sufficient policy space in the TRIPS Agreement which member countries can utilize in formulating their domestic laws. Some of the member countries have been successfully utilizing this policy space in public interest, whether through legislation or jurisprudence. To cite an example: in India, in case of Roche (A Swiss patented drug manufacturing company) vs. Cipla (an Indian generic drug manufacturing company), Roche dragged Cipla to the Delhi High court, alleging that Cipla infringed their patent rights over Tarceva, an anti cancer drug (sold as "Tarceva"). The judge, Justice Ravindra Bhat, refused to grant an interim injunction on the ground that since Cipla was selling the drug at one-third of the price of Roche, an injunction would have meant lack of affordable access for a large number of cancer patients in India. Therefore, "public interest" demanded that no injunction (restraining order) be granted. Roche then appealed to the Division Bench²⁷, whose order proved much more detrimental for Roche. Not only did the appellate bench uphold the key findings of the trial judge, it went on to impose costs on Roche for suppression of material patent information. It also went on to find that Roche had not established a prima facie case of infringement, since the patent in question did not seem to be implicated by Cipla's generic product. This was first ever order in the history of Indian Patents Act that an order was granted on the ground of public interest. Similarly, the Madras High Court in India dismissed Novartis petitions which challenged the provision of section 3(d)²⁸ thereby preventing enforcement of what the activists call as the ever greening or spurious patenting.

Other developing countries who have used flexibilities under the TRIPS Agreement or harnessed provision of compulsory licensing are Zimbabwe, Zambia, South Africa, Indonesia etc. Thus it is clear that it is the TRIPS Agreement contains sufficient policy space that can be harnessed by member countries in formulating their domestic laws and curb anticompetitive practices, etc by using public interest clause.

²³ Article 6, TRIPS Agreement

²⁴ Article 30, TRIPS Agreement

²⁵ Article 31, TRIPS Agreement

²⁶ Article 31 (l) and 34, TRIPS Agreement

²⁷ Refer Roche ltd & another Vs Cipla ltd, FAO (O.S.) No. 188/2008

²⁸ Section 3(d) Indian Patents Act, 2005, forbids the patenting of derivative forms of known substances unless they are substantially more effective than the known substance.

How compulsory licensing provisions are used in developing countries

Zimbabwe

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 antiretroviral (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.²⁹

Zambia

The Zambian government has also made use of the compulsory licensing provisions of its 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 license 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*.³⁰

Indonesia

Use of the compulsory licensing provisions has also been made in Indonesia. In 2004, a Presidential Decree regarding exploitation of patent by the government on anti retroviral drugs (No 83, 2004) was issued by the President in terms of the Patent Law of the country, 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% compensation fee of the net selling value of anti-retroviral drugs to the patent holder³¹. 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

²⁹ Oh, Cecilia (2006), *Compulsory licences: recent experiences in developing countries*, in the Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, pp.22–36

³⁰ Cptech, at website <http://lists.essential.org/pipermail/ip-health/2004-September/006959.html>

³¹ Cptech at website <http://lists.essential.org/pipermail/ip-health/2004-December/007233.html>

produces all the three drugs, *efavirenz*, *lamivudine* and *zidovudine*.³²

Malaysia

The Malaysian government has also already made use of the compulsory provisions of its Patent 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 100mg tablets produced by Bristol-Myers Squibb;
- ii. Didanosine 25mg tablet produced by Bristol-Myers Squibb;
- iii. Zidovudine 100 mg capsule produced by GlaxoSmithKline; and
- iv. Lamivudine 150mg + Zidovudine 300mg tablet produced by GlaxoSmithKline.

The authorisation however was subject to some stringent conditions which included that the license was only valid for two years commencing November 1 2003, and that the license 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 Health³³.

Source: CUTS (*upcoming*), *Understanding the Basics of Compulsory Licensing in Public Health*, Jaipur, India.

However, developing countries that make use of these flexibilities are scrutinised more strictly in comparison to past compulsory licensing practices by Western European countries, Canada and the US. Between 2001 and end of 2007, only 52 developing and least-developed countries have issued post-Doha compulsory licenses, giving effect to government use provisions or implemented the non-enforcement of patents. And in some cases, such as the recent ones in Thailand,³⁴ and Brazil,³⁵ the pharmaceutical industry has reacted quite strongly against the governments' efforts to bring drug prices down³⁶.

³² Intellectual Property Watch, 2007 at website <http://www.ip-watch.org/weblog/index.php?p=841>

³³ <http://www.cptech.org/ip/health/c/malaysia/arv-license.html>

³⁴ Citing the high drug prices and its obligation to provide access to essential medicines, Thailand issued government use (GU) orders for three drugs on the national essential medicines list: *efavirenz* (November 2006), *lopinavir/ritonavir* (January 2007), and *clopidogrel*, a heart disease drug marketed as Plavix by BMS (January 2007). The patent holders were entitled to a royalty of 0.5% of the total sales of the generic product. The GU authorised the Governmental Pharmaceutical Organisation (a Thai State-owned enterprise) to import or produce generic versions of these products for non-commercial use in the public health sector. Initially the GU was used for importation.

³⁵ On 4 May 2007, Brazil issued a compulsory license that would allow for the import and production of generic versions of *efavirenz*. Despite numerous threats in the past, Brazil had never actually issued a compulsory license for an AIDS drug. Before the compulsory licensing, Brazil had been paying US\$580 per patient/year for *efavirenz*, which comprised about 18% of the ARV budget that year. As a result of the compulsory licensing, the price will come down to US\$165 per patient/year, a considerably lower price than Brazil had been able to obtain through negotiations.

³⁶ The case of the Thai government use orders is of particular interest because of the fierce responses it provoked from the media, politicians, pharmaceutical companies and their lobby groups. In July 2007, the EU

Besides, it is unclear whether developing countries, through legislation or jurisprudence, have used TRIPS flexibilities specifically to enforce competition in cases of abuse of patent rights³⁷. Developed countries have treated intellectual property rights generally and rights of pharmaceutical patent owners in particular with kid gloves, generally rejecting all claims of competitive efficiency until after the expiry of the patent. Even then, the courts in developed countries have been circumspect in finding flexibilities in legislation that may enthrone competition in this sector. The most recent example is the decision by the ECJ on October 06, 2009, in overturning the decision of the European Commission which found parallel trade and price differentiation practice of GSK in Spain as ‘an export ban’ and hence anti-competitive. The ECJ ruled that this parallel trade practice was not a restriction of competition, and goes on to distinguish the pharmaceutical sector on the ground that competition by innovation is fierce in this sector and that competition on price exists after patent expiry and the arrival of generic medicines³⁸.

IV. Conclusions

It is clear from the discussion above that the TRIPS Agreement does provide room for creative uses of competition law to check the potential imbalances that may arise in intellectual property rights system. The source of debate and disputes so far, however, has always been the manner in which member States fashioned their intellectual property laws, especially with regards to patents and how compulsory licences may be granted. While it is in the interests of the poor consumers in developing countries that these conditions are broad and open-ended, interest groups such as pharmaceutical manufacturers do have valid points when they demand that innovators are sufficiently protected and rewarded, so as not to discourage R&D and investment. Sometimes, licenses might be derailed into trade protection measures for local interests. And most importantly, such licenses may not achieve their intended purpose — to improve access of pharmaceutical drugs to low-cost consumers. Thus, balanced decisions are required and consultation with affected parties is a must.

Anti-competitive practices in the pharmaceutical sector may be categorised into primarily three classes: breaches related to intellectual property rights (IPRs); abuse of competition norms arising from mergers and acquisitions (M&As); and collusive and other anti-competitive practices³⁹. This paper focused on the first, specifically how pharmaceutical patents might have or be abused to create anticompetitive bottlenecks. In such cases, use of compulsory licensing

Trade Commissioner Peter Mandelson wrote to the Thai Minister of Commerce to complain about Thailand’s government use orders. Abbott responded to the GU on its drug *lopinavir/ritonavir* by withdrawing all new drug applications from the Thai Food and Drug Administration, including the much needed heat-stable version of *lopinavir/ritonavir*. An international media campaign portrayed the Thai government as a pirating military junta that showed no regard for property rights. In a series of editorials, the *Wall Street Journal* characterized Thailand’s actions as a ‘seizure of foreign drug patents’ and a ‘frontal attack on property rights’, and called those who supported Thailand ‘anti-patent hooligans’. A conservative lobby group, USA for Innovation, in full-page ads in US newspapers called on the White House and Congress to ‘take retaliatory action in the form of trade or economic sanctions or the removal of military aid’. See Ellen Hoen, *The Global Politics of Pharmaceutical Monopoly Power*, AMB Publishers, 2009 for more details.

³⁷ Such examples exist in developed countries, like those related to enforcing competition in tied products by the technology industry (Microsoft cases in Europe, for example) but in the pharmaceutical sector even those are rare.

³⁸ Please refer <http://www.europeanvoice.com/article/2009/10/commission-told-to-review-glaxo-case/66049.aspx#>, accessed on October 15, 2009

³⁹ <http://www.cuts-ccier.org/pdf/CCIER-3-2008.pdf>

is instrumental in restoring the balance and bringing the fruits of innovation to the wider public. However, given the inadequate use of the provision of compulsory license by developing countries, and the difficulties faced by developing countries in making use of the TRIPS flexibilities, in particular the amendment of the TRIPS Agreement for use of compulsory licenses in cases where there are no domestic manufacturing facilities, the other options could be suitably explored so as to attain proper balance between the IP and competition needs in the pharmaceutical sector in developing countries.

Developed countries generally tend to consider that innovation plays a crucial role in the enforcement of anti-trust laws against monopolies, particularly where patents are involved, and more particularly in the case of the pharmaceutical sector where IP protection is critical to innovation. For developing countries, as we have seen in the South African saga that preceded the Doha Declaration on TRIPS and Health and more recently in the Roche *vs.* Cipla case in India, public interest may trounce IP rights based on existing flexibilities in the international IP regime. That is not a sufficient step to ensure a happy convergence between IP and competition policies in developing countries according to authors. An overly IP-protective domestic policy may not lead to desired competition. As we have seen in the lack of use of the flexibilities introduced in the TRIPS Agreement for those lacking domestic manufacturing facilities, a more rigorous application of competition principles in cases involving IP rights is desirable.

It is, therefore, recommended that it would be more appropriate to give the competition authorities in developing countries the responsibility of granting compulsory licences in consultation with the patent office, rather than the other way around. This recommendation is in agreement with the policy of mandatory price negotiations of patented drugs before the grant of marketing approval followed by many developing countries. Besides, bureaucratic delays in granting compulsory licenses in developing countries should also be removed. It is recommended that while framing guidelines in this respect, developing countries may look at the experiences of other countries, which follow similar practices, such as Canada, France, Germany, Italy, Japan, and the UK.

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