Designing National Regimes that Promote Public Health Objectives

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Abstract

The Agreement on Trade Related Aspects on Intellectual Property Rights, 1995, has introduced several mandatory changes to patent protection on pharmaceuticals that can affect health care and delivery in developing countries. The potential detrimental impacts of such IPR protection raise three major concerns for developing countries in the area of public health:

How can developing countries deal with price increases that can result from increased patent protection to ensure access to and availability of essential medicines in the future?

How can developing countries deal with any negative impacts that intellectual property rights may have on restricting their space for innovation and learning in the pharmaceutical sector?

If intellectual property rights are not sufficient incentives, what other instruments can developing countries look up to, in order to foster research into diseases of importance to their populations?

Given that IPRs form an integral part of technology policy, for a good technology policy that promotes the goal of public health, options within the IPR system are no doubt very important, but options outside the IPR system which help developing countries achieve their development objectives are equally important. The main focus of this paper is to explore options outside IPR regimes that can help achieve flexibility, such as parallel imports and compulsory licensing, in addition to many others in the realm of competition law and policy, for developing countries to be able to pursue technology policies that guarantee public health.

Key Words: Intellectual property rights, the TRIPS Agreement, Patents on Pharmaceuticals, pharmaceutical and biotechnological innovation, public health issues, developing countries, IPRs-competition policy nexus, economics of parallel imports, price discrimination, compulsory licensing, anti-competitive practices, economics of competition policy.

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1. INTRODUCTION

The Agreement on Trade Related Aspects of Intellectual Property Rights, 1995 (hereafter, the TRIPs Agreement) has introduced certain fortifying aspects to intellectual property protection in general and to pharmaceutical patents in particular that have become a subject of rampant controversy in recent years. These changes are contained in the Preamble, Articles 27(1), 27(3)(b), 28, 30 and 31 (a) to (f) of the Agreement (Correa, 2001). Consequently, Member Countries are obliged to provide patent protection to pharmaceutical patents for a period of twenty years (as opposed to the earlier 16 year period under the Paris Convention), allow for product patents and strengthen process patents, introduce patent protection to life forms (with some exceptions) and limit their authority to license the compulsory manufacturing of drugs.¹

Although the precise impacts of such increased intellectual property protection on developing countries is not clear and is heavily contested in literature, there is broader consensus that developing countries may end up bearing an unreasonable burden of the costs atleast in the short or mid-term.² Stronger intellectual property rights (hereafter, IPRs) on pharmaceutical products have the potential to seriously impact health care and delivery systems in developing countries in future due to three main reasons. Presently, the discussion on intellectual property rights and its impact on availability and accessibility of drugs restricted to few drugs that are on-patent and are relevant to developing countries.³ The controversies on AIDS drugs in several developing countries, such as South Africa and Brazil, has brought this issue to the forefront since these drugs are patented and of utmost necessity in developing countries. But the impact of such stronger intellectual property rights on health delivery in developing countries will start

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¹ As the WTO/WHO Report (2002) notes, the prescription of minimum standard of protection for patents makes the TRIPS Agreement stand in stark contrast to earlier international regimes of intellectual property. In providing for these minimum standards nationally, Member Countries are also obliged to ensure that no other laws and regulations or measures related to protection of public health and nutrition run contra to the provisions of the Agreement (see Article 8(1) of the TRIPS Agreement).

² In this context, see Maskus (2001), who after a survey of literature notes: “It is fair to say that the preponderance of conclusions is pessimistic about the net effects of drug patents on economic welfare in developing countries” (p. 7). The recent Royal Society report (2003) while noting similarly even recommends that developing countries should be allowed to refrain from implementing the TRIPs Agreement so long as the benefits do not outweigh the costs in their local contexts (p.5).

³ See the WHO’s Essential Medicines List, according to which a majority of the drugs that are essential for developing countries are off-patent.
becoming evident when more and more number of essential medicines will start to get patent protected.4

Secondly, the claim that increased intellectual property rights’ protection could lead to more investment into R & D in diseases of relevance for developing countries (Maskus, 2001, p.10) is questionable. There exists no conclusive empirical evidence that connects increased protection after the TRIPS Agreement to increase in R & D activity and more importantly, to the number of timely new drugs.5 In fact, according to recent estimates, the R & D investments within private sector on diseases of relevance to developing countries is minimal.6 Not only is there is very little R & D investment within western firms in diseases of importance to developing countries, but even firms in developing countries with sufficiently advanced pharmaceutical sectors, like India, choose to focus on diseases that predominantly affect the Western populace.7 Due to this, the inadequacy of intellectual property rights, which are mainly incentives for the private sector, in fostering investment into drugs for a set of people who cannot afford them is increasingly becoming evident.8

Lastly, there are concerns that stronger intellectual property protection on pharmaceuticals will obstruct developing countries from getting more competitive.9 The global pharmaceutical

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4 According to the WHO, this will be the case, since in the future, more and more essential medicines will be patent protected. In: WHO, Investing in Health: A survey of Findings of the Commission on Macroeconomics and Health, CMH Support Unit, 2003, p. 23.
5 There are several studies which try to gather evidence that strong protection stimulates innovative activity (see Kanwar and Evenson, 2001; Evenson, 1990, Sakakibara and Branstetter, 1999 among others). The data collected in these studies relates increased protection to higher innovative activity and some results – for example, the Sakakibara and Branstetter study – concludes in the case of Japan that the evidence of higher R & D after increased scope is not clear. The main issue – what is the optimal amount of protection that is required to stimulate socially desirable levels of pharmaceutical activity – is too complex an issue and has not been dealt with sufficiently until now.
6 A survey of 20 top grossing pharmaceutical companies worldwide revealed some activity in neglected diseases, but clearly indicated that the private sector involvement is minimal. In: The DND working group, “Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases” Medicins Sans Frontieres Access to Essential Medicines Campaign, September 2001, p. 8.
7 As Lanjouw and Cockburn (2001) show, a survey of Indian firms conducted in 1998 reveals that only 16% of their R & D was directed towards health problems prevailing in developing countries.
8 Lanjouw (2002), for example, expresses optimism on the basis that as a result of patent protection, firms will invest in a large variety of products that promise returns, and that these products, can by their sheer numbers be of value to the poor customers in developing countries (Lanjouw, 2002: 19). How far it is useful for customers in developing countries to have a wide range of fringe products but still lack the drugs to tackle their main health concerns and how much the benefits of having such products will offset the costs of increased intellectual property protection is questionable.
9 Note here that one needs to make a distinction between countries where IPRs can potentially spur knowledge creation and countries where the scientific infrastructure is so weak that this is far-fetched. It is within countries where the potential to use intellectual property as an incentive
industry has undergone a consolidation process in the last decade, resulting in the creation of a
global oligopoly that implies associated welfare losses in the long run. This makes the industry
fertile ground for anti-competitive practices such as price-fixing, collusion between
manufacturers and distributors and dealing in exclusive territories, among others. These
practices and the high risk and capital intensive nature of pharmaceutical research both act as
effective barriers to entry to new comers. Abuse of intellectual property rights by firms, to
augment their already strong market positions, worsen these effects.

Therefore, the major concerns for developing countries in the area of public health are as follows:

a) How can developing countries deal with price increases that can result from increased
patent protection to ensure access to and availability of essential medicines in the
future?

b) How can developing countries deal with any negative impacts that intellectual property
rights may have on restricting their space for innovation and learning in the
pharmaceutical sector?

c) If intellectual property rights are not sufficient incentives, what other instruments can
developing countries look up to, in order to foster research into diseases of importance
to their populations?

There has been much focus on finding ways to deal with these concerns by exploring flexibility
for developing countries within the TRIPs Agreement (see for example, Correa, 2003 for an
exhaustive analysis). This paper poses a different question: Are the solutions to these problems
to be restricted only to IPR regimes? Given that IPRs form an integral part of technology policy,
for a good technology policy that promotes the goal of public health, options within the IPR
system are no doubt very important, but options outside the IPR system which help developing
countries achieve their development objectives are equally important (see Barton, 2003). These
options, while interacting closely with IPR scope and the rights of IPR holders, may not be
directly a matter of IPR regulation, such as those related to competition policy (Correa, 2000b).
Identification and use of such flexible elements within or outside the IPR system could go a
long way in ensuring that a global regime for intellectual property rights does indeed benefit
developing countries atleast over the mid or long term. A closer look at the policy options that
developing countries have pursued in recent years – such as parallel imports and compulsory

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10 Note here that despite large scale mergers and acquisitions in this sector, the advent of
biotechnology has seen the emergence of smaller firms who share a symbiotic relationship with
the larger pharmaceutical houses. For more, see Tenkate and Laird (1999).
licensing - to deal with drug availability and affordability helps make the point better. The main focus of this paper is to explore the viability of such options as instruments of flexibility, in addition to many others in the realm of competition law and policy, for developing countries to be able to pursue technology policies that guarantee public health.

Owing to controversies sparked off by such attempts, notably the AIDS cases in Brazil and South Africa, the Doha Declaration on TRIPS and Public Health (WT/MIN(01)/DEC/W/2) has tried to clarify the scope of the TRIPS Agreement in relation to health issues. The Declaration sets out public health as one of the aims of the TRIPs Agreement and is been seen as a major step for developing countries towards securing flexibility in the use of intellectual property rights vis-à-vis health issues (McCalman, 2002, p.1). Truly enough, if the Declaration were taken seriously and implemented, it would open up several avenues for developing countries to deal flexibly with intellectual property rights issues in the realm of health. But given that the Declaration is not of a binding nature (Correa 2002, p. 40), there is a need to assess options available to introduce flexibility into IPR regimes in developing countries that can stand their own ground. For this, the main questions to be considered are: what are the costs imposed by mandatory minimum IPR protection on developing countries? The options being used to address some of these costs – such as parallel imports and compulsory licensing – are they in the larger interest of global trade? What other policy options are available to help developing countries get closer to harnessing any of the oft-advocated benefits of intellectual property protection in order to open up opportunities for innovation system building in pharmaceutical technologies?

To answer these questions, the chapter will set out with assessing the potential costs imposed by the TRIPs Agreement on developing countries in detail (section 2) for availability and affordability of drugs as well as learning and innovation. Section 2 showcases the concerns sparked off by increased IPR protection in pharmaceutical products and attempts to show that the main categories of costs that developing countries face are related to unresolved areas of conflict between IPRs and competition policy. Section 3 evaluates the controversial options of parallel imports and compulsory licensing from a legal and economic perspective. The analysis in this section clearly pins down parallel imports and compulsory licensing as two major competition law instruments, a conclusion that is supported by drawing parallels to European and American experiences and practices. Based on this, Section 4 derives some main elements of flexibility that developing countries should consider outside the TRIPs framework, in order to compliment those within the TRIPs framework, to enable flexible regimes that promote public health objectives at the national level. Section 5 presents the conclusions.

Throughout the chapter, while talking of repercussions on learning and innovation, a distinction is made between traditional pharmaceutical innovation using chemical synthesis and modern
biotechnological research, since the nature of innovation and consequences of strengthened patent protection for learning are different for both.
2. QUANTIFYING THE COSTS OF INCREASED INTELLECTUAL PROPERTY PROTECTION FOR DEVELOPING COUNTRIES

Both intellectual property law and competition policy try to achieve the aim of promoting innovation from two different perspectives. Whereas the former is based on the premise that an incentive to innovate requires the grant of temporary monopoly rights to the inventor (that restricts competition), the latter believes in elimination of all barriers to free competition in order to promote innovation.\(^\text{11}\) But this tension between the two disciplines has come to be viewed with time as something complimentary. Modern economic insights have revealed that not only can several forms of restrictions of competition have pro-competitive effects (Anderson, 1998, p. 657, 660), but also that competition law and policy can be a useful counterpart to deal with undesirable effects of strong intellectual property protection.\(^\text{12}\)

Talking of patents in particular, strength of patent protection is a sum total of the length of the patent and the breadth/scope of the patent (Gallini and Trebilcock, 1998, p. 19). Simply put, one can assume that the longer the patent life, the greater the expected rents and the broader the patent scope, the greater the market power conferred on the patent holder.\(^\text{13}\) Patent breadth/scope is defined as “how similar other innovations can be without infringing the original patent”,\(^\text{14}\) and it is generally the patent scope that determines the extent of monopoly that an inventor has over his creation (Dumont and Holmes, 2002, p. 152). This is why traditionally, restricting scope of protection has been seen as a way of balancing the static costs of intellectual property protection as against the dynamic gains of encouraging innovative activity (Glasgow, 2001, p. 230).\(^\text{15}\)


\(^{12}\) Literature on this point often makes a distinction between competition policy and competition law. The World Trade Organization defines competition policy as comprising of other measures in addition to competition law aimed at promoting competition in the national economy, such as sectoral regulations and privatization policies (see www.wto.org). This chapter considers the narrower construct of competition policy as used by Singh (2002).

\(^{13}\) Note here that in the case of patent life, longer life of a patent does not always translate into higher expected rents, since expected rents is also determined by how long it takes for a more superior technology to find its way into the market. See Scotchmer and Green, “Novelty and Disclosure in Patent law”, RAND Journal of Economics, Vol. 21, No. 1, Spring 1990, p. 131-146 at p. 131.


\(^{15}\) Gallini and Trebilcock note in this context that mainly due to this, economic models on this topic view patent scope and competition policy as perfect substitutes for one another. See Gallini and Trebilcock, 1998, p. 20.
In the general literature on the IPRs-competition policy nexus, it is a settled point by now that IPRs do not confer significant market power on holders of the rights (Anderson, 1998, p. 660). But to the extent that broader patent scope leads to further increasing market power, such patents are responsible for anti-competitive effects that result from the exercise of this power by firms. Specifically, in the case of pharmaceutical patents, permitting product patents to a given process patent is equivalent to extending patent scope, since it amounts to eliminating the possibility that the product be produced through a different process for a cheaper price. The excess market power that results from such broader patent scope can have two effects that demand attention. Increased market power conferred thereby can be used by firms to further restrict price competition through segmentation of markets (that promotes monopolistic pricing practices), exclusive dealing requirements (that can eliminate profits of newer competitors), tying up arrangements or collusion that can lead to leverage market power among or between markets and restrictive licensing practices (Gallini and Trebilcock, 1998). Firms may also attempt to use the excess market power accumulated through patents to control diffusion of newly created technologies that directly affect learning opportunities. The potential of stronger IPRs to create such effects in the pharmaceutical industry calls firstly, for an evaluation of such effects with available empirical evidence and secondly, for an assessment of the role that competition law and policy instruments could play in controlling such abuse of IPRs on pharmaceuticals (Glasgow, 2001).

2.1. Stronger IPRs Can Lead to Higher Drug Prices in Developing Countries

Whether introduction of product patents can lead to higher drug prices in developing countries ipso facto or whether there are specific factors that determine the rise in drug prices – these are both highly contested issues. There are many arguments in favour of product patents. It is claimed that since product patents ensure protection against cheap replication, they will act as better incentives for R & D, and that this will translate to higher investments in diseases of importance to developing countries (Maskus, 2001, p.10). The protection that product patents offer against cheap replication, it is said, will also ensure the availability larger number of patented drugs in developing countries (Maskus, 2001, p.11). Product patents will have no effect on the market for off-patent drugs. Based on this, a final argument made in support of product

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16 Note here that many of the anti-competitive practices discussed here may already exist, even without intellectual property rights. The focus of this section is on the extent to which these practices are more pronounced due to accumulation and/ or abuse of IPRs.
patents is that it will not lead to increase in drug prices in developing countries, since 95% of the
drugs on the WHO list of essential medicines are generics that are not patent protected.\(^{17}\)

On the other hand, the recent WTO/WHO report estimates that drug prices may be adversely
affected in developing countries due to “more stringent patent protection” (WTO/WHO, 2002:
16).\(^{18}\) Empirical evidence linking stringent intellectual property protection to higher drug prices
is hard to come by, but noteworthy in this context is the recent study released by Lucchini et al
(2003). Their study focussed on determinants of source prices of anti-retroviral drugs (ARVs) in
Brazil and 13 African countries. On the basis of their surveys, Lucchini et al (2003) note that:
“Our results clearly show that introduction of generic substitutes is influential for price decrease
and that patent protection in a country is associated with price increase.” (p. 201)\(^{19}\)

More generally, six main factors serve as indicators to predict the conditions under which
product patents can lead to a price rises in developing countries (Maskus, 2001 and Rozek and
Berkowitz, 1998).\(^{20}\) These are as follows:

- Structure of the local industry: There are several facets of the local drug industry that play a
critical role in determining whether product patents will lead to a rise in drug prices or not.

Two aspects of the domestic market that are critical in determining price rises are the nature
of competition (the kind of drugs being manufactured by the firms – whether they are
generic copies or not) and extent of competitiveness, measured in terms of the percentage of

\(^{17}\) For example, it is estimated that as of 1993, only 8.4% of the registered drugs sold in Indian
contained active ingredients patented in the developed world (Sherwood, 1994 cited in Maskus,
2001, p. 9). On the basis of this, surveys of the impact of product patents on developing
countries like India that have a strong generic drug industry have concluded that higher prices
may be unlikely (See Lanjouw, 1998).

\(^{18}\) Also note that the hypothesis that - since most essential medicines are not patent protected,
product patents will not affect their availability and affordability - stands in stark contrast to the
estimate presented by the WHO itself. The WHO recently noted that more and more essential
medicines are beginning to get patent protected. See WHO (2003), op. cit. footnote 4 p 23.

\(^{19}\) The data in this study was collected between 1996 to 2002and the African countries
considered included Congo, Botswana, Gabon, Nigeria, Senegal and Kenya, to ensure a good
mix of varying purchasing powers and HIV rates.

\(^{20}\) These six factors are based upon those derived by Rozek and Berkowitz (1998) and Maskus
(2001). Rozek and Berkowitz (1998) argued on the basis of their study that compared the impact
of intellectual property protection on drug prices in eleven developing countries that prices will
not automatically rise as a result of patent protection. They identified four main factors –
therapeutic competition, regulation of pharmaceutical prices, monopsony buyers and the actual
provision of the intellectual property laws – as critical in limiting the price rises associated with
intellectual property protection (Rozek and Berkowitz, 1998, p. 215). Here, two of Rozek’s and
Berkowitz’s factors – monopsony buyers and actual provisions of IP laws have been left out.
Maskus on the other hand, arrives upon four factors – market structure before and after the new
patent regime, demand elasticity, pricing regulations and competition policies – as key in
determining the impact of product patents on prices (see Maskus, 2001, p. 6-9).
the market that is captured by local firms and the extent of competitiveness amongst the local firms (Maskus, 2001, p. 9). If the domestic market is competitive, local firm strategies in the light of stronger intellectual property protection assumes importance. Local firms can either choose to confront international drug companies or to collaborate in order to survive in the light of external competition. India is a good example of confrontation by local firms (where, as Lanjouw (1998) notes, 12 out of 20 major firms are Indian and some of them are even subsidiaries of large MNCs that compete with foreign firms through production of cheaper copies of patented drugs), whereas Argentina is an example of collaboration. In Argentina, with the influx of foreign firms in the 1990s, the local firms chose to enter into co-production and co-marketing arrangements. This led to steeper increase in prices as against price increases in other Latin American countries, since the MNCs had no price competition to fear of within the Argentinean market. A third factor that affects price rise is the nature of products that the local firms produce. Even when there is a competitive local sector, introduction of product patents may not automatically lead to hike in drug prices, if the products being manufactured by the local industry are essentially those that are off patent (Maskus, 2001, p. 9). In such a case, despite the presence of a competitive local market and elastic demand, price increase after introduction of product patents is likely to be relatively small, since product patents will not affect the prices of off-patent drugs. But if the products are generic copies of drugs that are patent protected in other (developed) countries, then when the local country complies with the TRIPs Agreement, producing further generic versions of the drugs will no longer be possible. In such cases, it is possible to conclude that the more competitive the domestic market and the higher the share of generic products produced by local firms, the greater will be the price increase associated with the introduction of product patents (Nogues, 1993 cited in Maskus, 2001, p. 7).

- **Presence of therapeutic substitutes:** Since each patented product competes with other patented and off-patent products in a given therapeutic category, it has been proposed that stronger protection will not lead to higher introductory prices of drugs in the presence of therapeutic substitutes (Rozek and Berkowitz, 1998, 215-216). The South African AIDS case is a good example of the scale of the problem in cases where therapeutic substitutes do not exist. In this case, the government could not secure the supply of the three patented

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22 As Rozek and Berkowitz (1998) note, their study has examined the response of the pharmaceutical prices to changes in intellectual property protection. They do not examine the initial or launch prices of products introduced after intellectual property protection to determine if these prices would be lower in the absence of IP protection. They assume that in each category there is sufficient therapeutic competition as a result of which the IP protected products are forced to compete with lower priced alternatives and therefore cannot be launched at higher
drugs that formed part of the AIDS cocktail at prices affordable to HIV patients in South Africa. With no substitutes available in the therapeutic category in question, the government resorted to import generics of the same drugs that were available from Indian manufacturers for $1/3^{rd}$ of the price.

- **Demand elasticity** – In general, the term demand elasticity refers to the changes in quantity demand associated with changes in price. Demand is said to be highly price elastic when the demand of the product varies hugely with small changes in price. In developing countries, between 50-90% of the drugs are privately funded (WHO, 1999). Such markets, where the people have little or no medical insurance coverage and have to afford their medicines themselves, tend to exhibit demand functions that are highly price elastic, since the people are very sensitive to price rises.

- **Competition policy**: Of the three main effects of competition policy on creating social surplus, one clearly is that it “promotes price competition in product markets that use the new products and processes”, thereby lowering product prices (Gallini and Trebilcock, 1998, p. 22). Ensuring well-functioning product markets is a critical function of competition law and policy, whether in the presence or absence of therapeutic substitutes. In the presence of substitutes or generics, the role of competition law and policy will be to control collusion and other tie-up arrangements. In the absence of therapeutic substitutes, competition law and policy are extremely important to keep tabs on monopoly pricing leading to price rises and on license restrictions that may reduce potential competition in both product and technology markets (Anderson and Gallini, 1998, p. 25).

- **Price controls**: Most countries commonly impose ceilings on the prices that pharmaceutical firms can charge for their products. Such “price control” is usually set pursuant to the economic and social goals that countries wish to realize within their domestic contexts (Maskus, 2001). Whether domestic price control regulations are stringent or lax plays a significant role in the extent of price rise due to product patents.

- **Market segmentation**: Stronger patent protection, when coupled with the ability of the patent holder to segment and control markets through mechanisms such as a ban on parallel start prices (with the exception of true medicinal breakthroughs for which there wont be any substitutes).

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23 Price elasticity of demand is a measurement of the sensitivity of quantity demanded to price changes. See Pindyck and Rubinfeld, 1995, p. 29. Demand is elastic when a one unit increase in price (for instance, a 10% increase) leads to more than a 10% fall in demand, or the inverse: a 10% fall in price leads to more than a 10% increase in demand.

24 See Section 2.2 for a detailed discussion on this issue.

25 In this context, see Rozek and Berkowitz (1998, p. 215) who note in their study that a major reason for the price hike in Mexico in the 1990s was attributable to the relaxation of Mexico’s price control regulation.
imports is responsible for price rises. Such an ability to restrict competition often induces firms to resort to monopoly pricing even in a price discrimination scenario (Maskus, 2001, p. 7).

2.2. Stronger IPRs Can Affect Availability of Drugs

The classic availability versus affordability debate posits that the attempt to make drugs affordable by imposing higher price controls or encouraging parallel imports may lead to firms completely withdrawing from developing country markets. But the timely availability of drugs can also be affected by strategies of firms to abuse IPR protection to maintain their dominant market positions. Glasgow (2001) identifies five main ways that pharmaceutical firms employ to lengthen the patent life of their drugs in order to benefit from monopoly rents longer. These are: (a) using legislative provisions and loopholes to apply for a patent extension; (b) suing generic manufacturers for patent infringement; (c) merging with direct competitors as patent rights expire in an effort to continue the monopoly; (d) recombining drugs in slightly different ways to secure new patents and layering several patents on different aspects of the drug to secure perennial monopoly rights; and lastly, (e) using advertising and brand name development to increase the barrier to entry for generic drug manufacturers.

Buspirone is a good example for how firms use loopholes in legislative provisions to extend patents. Bristol-Myers Squibb has been charged with falsely listing a patent claim for Buspirone in the US FDA’s orange book (since a listing automatically delays FDA approval of a generic product by 30 days under US law). In the case of Hoechst Marion Roussel (now Aventis) and Andrx Corporation in 2001, the former sued the latter for patent infringement; such a lawsuit usually has the effect of preventing generic manufacturers from seeking for FDA approval (Glasgow, 2001, p. 240). Hoechst Marion Roussel (Aventis) had paid Andrx several million US dollars to delay the introduction of a generic version of the drug Cardizem CD (Lancet, 2002, p. 181). The Federal Trade Commission settled a similar case in 2000 between Abbott Laboratories and Geneva Pharmaceuticals over charges of payments to delay the introduction of generic versions of patented drugs. Firms also collude to price generics at costs higher than the

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26 For a detailed discussion of this issue, see Sections 3.1.3 and 3.1.4.
27 See footnote 19 and accompanying text in this context.
29 Lancet, p. 181.
30 As Glasgow (2001, p. 241) notes, the complaint alleged that Abbott paid Geneva $4.5 million per month to delay the generic version of Abbott’s brand name hypertension and prostrate drug, Hytrin which provided Abbott with sales as large as $452 million in 1998.
marginal production costs and/or to delay licensing. Civil charges for anti-competitive practices have been brought against Schering-Plough Corporation, Upsher-Smith Laboratories and American Home Products, on grounds that the companies entered into anti-competitive arrangements with the motive of delaying generic versions of a drug, K-Dur 20 potassium-chloride supplement.\textsuperscript{31}

Recombining drugs in slightly different ways to secure new patents is a real cause of concern for developing countries that expect drug prices to lower due to products going “off-patent” at any given point of time. According to the Report of the National Institute of Health Care and Medicines (NIHCM) of the USA (2002), firms demonstrate an increasing trend of recreating their own medicines, called Incrementally Modified Drugs (IMDs).\textsuperscript{32} According to the report, between 1989 to 2000, such IMDs constitute 54\% of all drugs patented and approved of by the FDA in the USA.\textsuperscript{33}

All these practices call into question some general assumptions that are made regarding the TRIPs Agreement, such as: will the expiry of many patents in important therapeutic categories really lead to domestic firms in developing countries producing price-effective generic drugs to compete with the original brand manufacturers? Or, will generic drugs, eventually be available at far cheaper costs? Do “biogenerics” really provide a promising venue for making affordable medicines for the developing world.\textsuperscript{34}

2.3 Extended Patent Breadth Can Have a Detrimental Impact on Innovation

Firms, in addition to acquiring broad patents covering entire areas of research (Barton, 1998 cited in Dumont and Holmes, 2002, p. 154), also possess the tendency to accumulate “sleeping patents” in order to preserve market shares (Gilbert and Newbery, 1982 cited in Kanwar and Evenson, 2001, p.5). There is also concern that firms use the excess market power accumulated

\textsuperscript{31} See Lancet, 2002, p. 181. Glasgow (2001) has extensively discussed the details of this case. Upsher-Smith, which initially applied for FDA approval to manufacture a generic version of the drug on which Shering-Plough had a patent until 2006, was sued for patent infringement by the latter. The two companies settled with Upsher agreeing not to sell the generic version until 2001 in return for licenses on five drugs from Schering for US $60 million. A similar arrangement was struck between American Home Products and Schering with the former agreeing not to manufacture generic versions in exchange for licenses on two drugs. See Glasgow, p. 239-240.

\textsuperscript{32} The report defines Incrementally Modified Drugs as “…(m)edicines that contain the same active ingredient as an approved product, but differ from the older medication as a result of changes made by the manufacturer.” See NIHCM Report, p. 5.

\textsuperscript{33} See Figure 3 on p. 7 of the report.

\textsuperscript{34} Schellekens and Ryff (2002) note that the first set of biopharmaceuticals is coming off patent in 2002. In this context, considerable optimism has been expressed that successful generic industries such as that in India can actively benefit from these products coming “off-patent” and develop their own “biogenerics” industry.
through patents to control diffusion of inventions and research results (Gallini and Trebilcock, 1998). This can have different impacts within the pharmaceutical industry, depending on whether it is traditional pharmaceutical innovation or biotechnology-based pharmaceutical research (characterized by cumulative innovation) that we are talking of.

In the case of traditional pharmaceutical research, broader patent scope can affect incremental imitative innovation (Dumont and Holmes, 2002, p. 152). For example, the case of India is a lucid example of weak patent protection leading to traditional incremental imitative innovation. This case lends strength to arguing that the latter impact too has to be considered more seriously since it can prevent a developing country to build capacity in this sector, as India did.  

In the case of biotechnological research, extended patent breadth can create impediments for learning and innovation (See Anderson, 1998, p. 669-673). In the main, it can lead to acquisitions of patents by firms, that translates into amassed market power and creates bargaining anomalies in licensing contracts (See Scotchmer, 1991; Chang, 1995 among others). This effect is particularly pronounced since biotechnological research cumulative in nature; access to earlier innovations and research tools is a precondition for further research (Scotchmer, 1991, 1999). Cumulativeness, thus denotes a dependency relationship between generations of innovations within a given technology. This dependency may assume any one of the following forms: later products can be improvements of earlier products or be cost effective for the production of earlier products; or they can be enabling technologies such as research tools that are required for further inventions (Cf. Scotchmer 1991, p. 1).

In such a research scenario, broader intellectual property protection can, instead of promoting innovative activities, limit access to knowledge that is necessary for society to indulge in innovative activity, by restricting access not only to inventions but also to research tools and processes. There is evidence of firms creating patent portfolios and holding up research in cases where progress is dependent on access to their inventions (Jaffe, 1999 cited in Dumont and Holmes, 2002, p. 154). That firms have already acquired strong patent rights covering not only inventions related to genes, but also genes and proteins themselves and fundamental research tools, apart from entire living organisms has deepened such concerns (Primo Braga and Fink, 1998, p. 550).

Another detrimental impact of stronger patent protection on innovation possibilities is in the way they are bought, licensed or used in joint venture arrangements. IPRs as firms assets are increasingly becoming the decisive factor for who has a joint venture with whom, instead of

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35 It is true that the achievements of India in this regard are not possible to be generalized, since there are many other countries, like Canada, where the same impact of encouraging a local generics industry was not to be seen. But given that India has been successful, this venue for building pharmaceutical capacity should not be foreclosed.
being just another matter in a joint venture agreement (Merges, 1998, p. 123-124). Accounts of firms buying IPRs or not licensing them with the sole purpose of thwarting competition are also numerous (Merges, 1998, p. 126-127).

These practices can have two different impacts: discouraging second generation innovations or increasing barriers to entry for newcomers, through exclusive/ restricting licensing of research tools and processes that may be very necessary to indulge in biotechnological research *per se*. But despite this potential, till date, there is very little empirical evidence of firms actually blocking technological progress in the pharmaceutical biotechnology sector using such tactics. One of the most recent studies by Walsh et al, finds little evidence of this. In their study, they note: “Notwithstanding concerns about the proliferation of IP on research inputs and about the ability of rights holders to limit access to upstream discoveries and promising research targets the problem was generally considered to be manageable…Many of our responding firms suggested that if a research tool was critical, they would buy access to it.” (p. 322-323)

To what extent this conclusion will hold for firms/research institutes in developing countries will depend on their ability to “buy” access to important research tools.

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36 See Heller and Eisenberg (1998, p. 700) for a discussion of the issues for further research that could emerge due to proliferation of patents on receptors, genetic fragments and research tools in biotechnology.

3.0 INTRODUCING FLEXIBILITY IN NATIONAL REGIMES: THE ROLE OF COMPETITION LAW AND POLICY

The pharmaceutical industry has long since offered an interesting case for anti-competitive practices, given its monopolistic/oligopolistic structure, discriminatory pricing practices and the importance of intellectual property as a market-leveraging instrument. Such practices call for the adoption of options of competition policy instruments that can curb abuse of IPRs into national regimes in developing countries (Correa, 2000, p. 9).

A survey of experience in the European Union and the USA reveals that facilitation of competition is an important disciplining factor in this industry. And such facilitation of competition has been made possible through several instruments of which parallel imports and compulsory licensing are prominent ones.

Yet promotion of parallel import practices by governments in developing countries to tackle issues of availability and affordability of medicines, despite being permissible under the TRIPS Agreement, have met with criticism on grounds that they amount to reducing social welfare of developing countries in the long run. Attempts to compulsory license the production of drugs have been opposed on other grounds - that they lead to lesser compliance with the TRIPs Agreement or on disagreement as to how certain terms such as “national emergency” listed out in Article 31 of the Agreement should be interpreted. This section will evaluate the arguments advanced for and against these options. The purpose is to derive results on the legality of these options within the TRIPs framework as well as to ascertain their potential as effective competition law instruments to deal with undesired effects of strengthened IPR protection.

3.1. Parallel Imports of Pharmaceuticals

Parallel imports or parallel trade in pharmaceuticals refers to “…(t)he process of importing patented drugs that are available more cheaply elsewhere into domestic markets.”

When the same goods are priced differently in different markets, it makes for profitable opportunities for arbitrage and leads to the emergence of parallel trade. As Maskus (2001, p.3)

38 Maskus, 2001, p. 11. Parallel importation regimes differ in country depending on the kind of intellectual property mechanism, i.e., patents, trade marks, etc. For example, Australia permits parallel imports only in the case of trade marked goods and grants patent holders the right to prevent them, if they wish to do so (see Maskus, 2001, p.4-6). For an analysis of the impact of parallel imports on different kinds of intellectual property rights, see Abbott, 1998.
notes, “parallel imports emerge where international price differences (expressed in a common currency) exceed the costs of transporting and selling goods across borders. Mainly because of this, parallel imports tend to equalize customer prices of identical goods in different markets, although differences might persist because of costs of transportation, tariffs, differing distribution regulations and taxes”.

Such differences in prices of drugs between markets can emerge and persist due to several reasons, the main ones being retail price discrimination and exchange rates.\textsuperscript{40}

- \textit{Retail Price Discrimination in the Pharmaceutical Industry}

The two main reasons that lead to retail price discrimination are discriminatory pricing and price controls, although several other factors, such as reference indexes and firms’ capacity to effectively segregate markets may also influence this. Pharmaceutical firms tend to indulge in discriminatory pricing that causes differences in prices of the same/similar drugs in different markets around the world. A preponderance of evidence suggests that such discriminatory pricing practices may not be based on a per-capita income basis (that is, people with lesser incomes are faced with lesser prices). They are rather are influenced by the firms’ capacities in the different markets to control profits and as a result are conditioned by factors such as the kind of competition, capacity to control parallel imports or exports.\textsuperscript{41}

Since the pricing practices of the pharmaceutical industry have direct bearing on public health, regulation of prices of drugs is a common practice in most jurisdictions worldwide. Price control/price regulations refers to governmental regulations that set the maximum prices that firms can charge for their products, to ensure that drug pricing is in keeping with the local social and economic reality. These factors, in turn, result in firms to price discriminate across geographical markets (Scherer, 1993, p. 108-109). Not only are drugs sold at different prices in developing and developed countries, the prices within the various developed and developing countries also differ significantly.

\footnote{Price discrimination occurs in many product markets, such as automobiles, computers, personal care products and so on. But the market for parallel imports is mainly to be seen in case of products that are light yet expensive.}

\footnote{Note here that Maskus (2001) discusses all these four reasons in detail. In this work, only the two major reasons are discussed. This is because of the view that vertical price inefficiencies and free riding on fixed distribution costs do not result in price differentials significant enough to make parallel imports a huge problem in the long run. This section does not also discuss the case where some developing countries, such as Brazil or South Africa, can presently parallel import generic versions of drugs from some other developing countries, such as India. This is because this issue of importation of generics to compete with patented products will cease to exist when developing countries, which show significant R&D prowess, become TRIPS compliant.}

\footnote{See empirical evidence presented by Maskus (2001) in this regard on p. 30-33.}
Price differences may also persist due to the tendency of some developed countries that have national health care systems to indulge in what is called Reference Based Pricing. Reference based pricing denotes a system of setting a price limit for active drug ingredients based on some feature, such as therapeutic effects or chemical structure, or price of other drugs containing the same active ingredient. It is a method of determining drug reimbursements within a therapeutic drug category, such as non-steroidal anti-inflammatory drugs to treat arthritis symptoms. When there are several different drugs of approximate therapeutic equivalence for treating the same disease or symptom, a drug payer can choose the cost of a specific drug as the reference and only reimburse other drugs up to the cost of the reference drug. The reference drug is often chosen on the basis of therapeutic efficacy. For example, in British Columbia, Canada, Cimetidine is the reference drug for treating gastric reflux. The amount that the government will pay for alternative new drugs for this indication, such as proton pump inhibitors, is limited to the price of Cimetidine. Reference based pricing, by setting the level of reimbursement, can help to lower the market price for new drugs, although pharmaceutical firms may still be free to set higher prices for their drugs. In this case, the patient must pay the difference between the level of reimbursement and the drug price.

Many national health systems also place limits on the level of reimbursement for breakthrough drugs that either offer a substantial therapeutic improvement over existing drugs for the same indication or which offer treatment for an indication for which no drugs were previously available. In some jurisdictions the level of reimbursement depends on a basket of prices in other similar markets. For Canada, this includes seven developed countries. Prices in developing countries are usually not considered.

- **Exchange Rates**

Due to frequent exchange rate variations in international trade, firms tend to set prices in different markets in such a way that the slight price changes do not affect profits by “setting local currency-prices that are specific to demand characteristics in each market” (Maskus, 2001, p. 17). Although not common, there may be situations where certain currency depreciations

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42 This paragraph is completely based on personal communication with Anthony Arundel, MERIT, University of Maastricht.


44 There does not seem to be consensus on this point. Maskus (2001) for instance, is of the opinion that reference based pricing has the potential to become a major issue between developed and developing countries mainly due to the tendency of firms to negotiate for the highest prices in developing countries, since prices that they can bargain for in developed countries depends on them (see Maskus, p. 10).
persist over a period large enough to create price differences that are significant. This makes parallel trade in these circumstances profitable enough an activity to indulge in.

3.1.1. The Legal Regime on Parallel Imports for Pharmaceuticals

Whether parallel imports are deemed legal or not depends upon how the question of Exhaustion of Rights is dealt with, in national jurisdictions. The concept, “exhaustion of rights” determines whether intellectual property holder’s rights include the control over the distribution of the good protected under intellectual property. Theoretically, there can be two different regimes of exhaustion - national or international. A regime of national exhaustion implies that the exclusive rights of the intellectual property rights holder are “exhausted” upon first sale within that country only, as a result, she can control/ exclude parallel imports from other countries into the local market. As Abbott notes rightly, “…(a) policy of national exhaustion amounts to allowing intellectual property rights holders within particular national or regional territories be entitled to restrict the importation of goods and services into those territories on the basis of local IPRs ownership even when the subject goods and services have been placed on the market outside the territory of importation with their consent” (Abbott, 1998, p. 608). A regime of international exhaustion, to the contrary, means that exclusive rights of intellectual property right owners to control distribution end when the first sale of the good takes place anywhere in the world. Therefore, she does not have the right to control parallel imports into the local market.

Article 6 of the TRIPs Agreement excludes the question of exhaustion of intellectual property rights from the purview of the Agreement. As a result, regulating parallel imports remains a question of national jurisdiction and all countries in the world have varied approaches to this question. Amongst developed countries, interestingly, the United States of America and the European Union both apply the first sale principle within their territories. This means that within the USA, when a product is sold in any state outside the distribution chain, it has the effect of exhausting the right of the intellectual property holder to control its movement. The same is true of the EU where the principle of regional exhaustion applies, wherein the sale of the product in any one of the EU states is deemed to exhaust the rights of the intellectual property holder. In both these jurisdictions, this is seen as an effective way of controlling market power and abuse of consumers that can arise from privately contracted exclusive territories.

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45 Article 6 of the TRIPs Agreement states: "For purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights."
46 This section on national approaches is based on information in Maskus (2001).
In the case of developing countries, although several of them ban parallel imports explicitly, recent trends reveal the enactment/amendment of laws aimed at encouraging parallel imports. A large reason for this is the public health situation in these countries and the belief that encouraging parallel imports will enable the influx of more affordable drugs into their local markets. The South African AIDS case, that triggered the debate on parallel imports, is an interesting example in this context. In this case, the pharmaceutical manufacturer’s association of South Africa initiated litigation on behalf of Glaxo Smithkline and two other companies that hold the patents to the three main drugs that form the AIDS cocktail, against a new law (the Medicines Amendment Act) that permitted parallel imports of generic substitutes of prescription drugs (in this case, AIDS drugs) from India and elsewhere (WHO/WTO Report 2002, p. 105-106). The Government, on its part, defended the law on grounds that such import led to the availability of drugs that formed part of the cocktail for around one third the price from Indian generic manufacturers at which the companies were selling it. Although the litigation was later on withdrawn due to fears of lack of success and adverse publicity (Dutfield, 2003, p.4), it has led to a spate of similar such laws in other developing countries.

The Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO in 2001 (WT/MIN(01)/DEC/W/2), has tried to clarify the legality of parallel imports by stating that Members have the right to adopt the principle of international exhaustion of rights and encourage parallel imports, if they wish to do so. According to paragraph 5(d) of the Declaration, “…(t)he effect of the provisions in the TRIPs Agreement ... is to leave each Member free to establish its own regime for exhaustion without challenge, subject to the MFN (Most Favourite Nation) and national treatment provisions of Articles 3 and 4.”

3.1.2 The Central Issue in Parallel Imports

As Abbott (1998, p. 608) rightly sums up, the main issue in parallel imports is: Is it efficient to extend the right of intellectual property owners to include the blocking of parallel imports of their goods and services between different national or regional territories? Or do the welfare losses of such a restriction on liberal trade outweigh the benefits of permitting intellectual property owners to do so? An assessment of the legal and economic literature on parallel imports reveals three main arguments in favour of and against permitting parallel imports.

3.1.2.1 Argument Against: Lower Welfare for Developing Economies

It is argued that a regime of parallel imports will eliminate the incentive of the producers to price discriminate, therefore making prices higher in developing countries. Pharmaceutical firms
fear that in a scenario of price discrimination, if parallel imports are permissible, this would lead to an influx of cheaper priced drugs from developing countries into developed markets, thereby cutting into their profits. This fear could prompt firms to adopt one single global price for a given drug or firms may choose to supply only to more profitable markets and drop out of the less profitable developing country markets altogether. In this way, an international regime of parallel imports will lower welfare of developing economies through higher prices and lower product availability (Maskus, 2001; Bale, 1998).

3.1.2.2 Argument Against: Lowers R&D Incentives of Firms

This argument is based on the same reasoning as above. Since parallel imports interfere with the ability of an intellectual property holder to price discriminate, maintain vertical control and thus limits license revenues, it is argued that it leads to a reduction in profits. This in turn is feared, will reduce R&D incentives of firms. It has also been suggested in literature that the ability of firms to price discriminate between markets should be complimented through supportive legislation, because such price discrimination is a very effective way of financing R & D.\footnote{See Danzon (2001) who argues that differential pricing, based on “Ramsey Pricing” principles, is the main mechanism to solve the potential conflict between patents, which are necessary to preserve incentives for research and affordability issues in developing countries. Ramsey pricing implies that prices are directly proportional to income levels and purchasing powers of people (See again, Danzon, 2001).} Promotion of parallel imports, in as much as it will prevent successful price discrimination can, according to this theory, hamper R & D financing.

3.1.2.3 Argument For: Cheaper Drugs and Competitive Effects

The most forceful argument in favour of parallel imports comes from a competition policy perspective. It is claimed that parallel imports have many competitive effects in developing countries. Whether or not parallel imports occur, the threat of parallel imports forces distributors to charge lower prices, thus keeping a check on monopolistic or oligopolistic pricing practices that firms will otherwise indulge in due to increased monopoly power in geographically divided markets. Furthermore, parallel imports, it is suggested, will get rid of all other problems associated with price discrimination, namely, vertical price controls, limited licensing and collusion between manufacturers and distributors.
3.1.3. Evaluating the Arguments for a Parallel Imports Ban

The most vociferous argument for a ban on parallel imports is that it allows for price discrimination and such discrimination is welfare enhancing.

Three main conditions must be satisfied for a seller to be able to price discriminate profitably (Scherer and Ross, 1990, p. 489): the seller has to have control over the price (a monopoly or an oligopoly); the seller has to be in a position to segregate his potential customers into different groups that have different elasticities of demand and therefore exhibit different reservation prices, and lastly, the seller has to be able to control opportunities of arbitrage; that is, resale of low priced goods to customers in the high price segment.

Economic theory generally recognizes three main forms of price discrimination depending on the capacity of the seller to segregate the groups for price discrimination purposes. In first degree or perfect discrimination, each unit is sold at its reservation price, so that every customer is exploited to the fullest extent. In such perfect discrimination, there is no consumer surplus since it is all appropriated as producer surplus (Scherer and Ross, 1990, p.490). In second-degree price discrimination; the discriminator is not able to set the price per customer, but he is able to divide the market into numerous blocks with differing reservation prices. Therefore, the seller charges each block its approximate reservation price, thereby expanding his output until there are no further blocks where the reservation price exceeds marginal cost (Ibid).

In third degree discrimination, the seller can divide customers into two or more independent groups, each of which has its own demand function reflecting quantities of good sold to the groups at the discriminatory prices. It pays for the seller to discriminate here as long as the groups have different demand elasticities at a common price. The pharmaceutical industry is a classic case of third degree price discrimination, where groups of customers identified on a geographical-cum-income level basis are discriminated to get the most out of each region.

3.1.3.1. Impact of Price Discrimination on Welfare

The ideal case is that of a perfect competitive market where price is equal to the marginal cost and the aggregate producer surplus and consumer surplus is the value created through the exchange of the goods. In a perfectly competitive market, the total surplus of consumers and producers is as large as possible. The direct contrast to this is the case of a monopoly where the total surplus shrinks due to the deadweight losses created by exercise of monopoly power.

Whether price discrimination is better than a simple monopoly or not depends on the kind of price discrimination in question. More specifically, it is possible that resources are allocated more efficiently under a discriminatory monopoly than under a simple monopoly in the case of
first and second-degree discrimination. In these two forms of discrimination, either the same amount of surplus is created as in a perfectly competitive market or at least a higher surplus than in a simple monopoly is created leading to lesser deadweight losses and increased allocative efficiency. But this surplus is always distributed in favour of the producer and away from the consumers.

The welfare effects of third degree discrimination are, in contrast, more ambiguous to estimate. Broadly speaking, there can be four different possibilities in third degree price discrimination, each having its own consequences for welfare.

1. **Linear Demand Functions in both markets:** This is the clearest case for prediction purposes. Where both or all markets have linear demand functions, price discrimination induces an increase in the deadweight losses when compared to a simple monopoly. This is because price discrimination allows the monopolist to cater to the marginal consumers in both markets but has no increase in the total surplus created, thereby reducing allocative efficiency.

2. **Linear or concave demand function in the low elasticity market and a convex demand function in the high elasticity market:** In such a case, price discrimination has a welfare enhancing effect due to an increase in the aggregate surplus.

3. **Stronger convexity in low elasticity market:** In this case too, there will be an increase in total surplus and therefore price discrimination will lead to an increase in welfare.

4. **Price discrimination leads to the serving of a market that would, under uniform pricing, not get served.**
   - Price discrimination can induce service to a market (“market opening”) that will not be served under a regime of price uniformity. By permitting the newer market to be served, price discrimination can lead to a Pareto welfare gain when marginal cost is a constant (Armstrong and Vickers, 1991).

From this it flows that beneficial effects can be realized only when specific conditions are satisfied, as set out by categories 2 and 3. How often the conditions set out in categories 2 and 3 above coincide in real life is hard to determine and therefore drawing any conclusions on the welfare enhancing effects of price discrimination in pharmaceuticals based on these categories may be misleading. At best, the beneficial effects of price discrimination in the case of pharmaceuticals are ambiguous.

It also seems that in the pharmaceutical market, the simple case with two linear demand curves is more prevalent, thus making the case for the detrimental impact of price discrimination. The
pharmaceutical industry also reveals a trend to alter prices to simply satisfy the market opening condition and set discriminatory prices (Armstrong and Vickers, 1991). As a result, usually, prices of drugs in the markets in developing countries are slightly lower than in developed countries making it highly unaffordable for most of the population. Given this, the Pareto welfare gain of price discrimination by allowing the service to more customers is also questionable.

3.1.3.2 The Impact of Parallel Imports on R & D Incentives
One has to be able to measure pharmaceutical price differences between countries and compare them, in order to be able to measure the potential impact of allowing parallel imports on reduced R&D incentives. But measuring pharmaceutical price differences and comparing them across countries is a hard task (see Danzon, 1997; Danzon and Chao, 2000, p. 160). This is probably why there are no studies on the R&D impacts of allowing/ banning parallel trade based on actual data (Maskus, 2001, p. 25). According to Maskus (2002), even assuming that such comparisons were possible and available, to measure precise effects of profits on original manufacturers one needs to take the structure of competition into account. And drawing conclusions on R & D incentives requires that such an exercise be performed on firms worldwide, which might not be practically feasible (Maskus, 2001, p. 25).

3.1.4 Conclusions on the Legality of Parallel Imports
To sum up, the impact of price discrimination on enhancing welfare of developing countries is ambiguous and there is no conclusive evidence on reduced R & D incentives due to parallel imports. Given the structure of the pharmaceutical industry, if parallel imports are permitted:

(a) In the case of a monopolist producer, the monopolist producer will choose one uniform price for the global market since he cannot control arbitrage. In such a case, the monopolist producer may most likely choose to withdraw from the developing country markets since it is more profitable for him to offer the good at the reservation price of the consumers in the higher price developed country markets.

(b) In the case of oligopolistic producers, all the results derived until now will hold well. The oligopolistic producers will also choose one uniform price since they too cannot control arbitrage and therefore the profits to be made through price discrimination will no longer exist. But in the oligopolistic case, parallel imports or the threat that they will occur, will induce more fierce competition because it will:
• reduce collusive practices and make it harder to create cartels
• eliminate oligopolistic practices at the distribution level
• help create larger markets and realize economies of scale, which is a very important underpinning of the WTO.

Thus, given this tangible positive effect of allowing parallel imports on competition in contrast to the ambiguous positive effects of banning it, it seems more efficient to allow parallel imports until the reverse can be proven by more empirical data. The EU policy on allowing parallel imports within EU countries also corroborates the view that parallel imports are an essential competition policy instrument (See Correa, 2002; Abbott, 1998; Dumont and Holmes, 2002). Within the scope allowed by Art. 81 of the Treaty of Rome that relates to anti-competitive practices and agreements, the European Court of Justice has used parallel imports as a competition policy principle in intra-community trade to prevent the use of IPRs to curtail segmentation of the community (UNCTAD, 2002, p. 8). There is no reason to assume why permitting could not achieve a similar effect within developing countries.

The negative impact that allowing parallel imports will have on developing countries in the case of monopolist suppliers who will then withdraw from the market will possibly have to be dealt with through other solutions. Mandating developing countries to simply ban parallel exports into developed countries can prevent the flooding of developed country markets by drugs exported out of cheaper-priced developing country markets.

3.2 Compulsory Licensing of Pharmaceuticals

Article 31 of the TRIPS Agreement restricts the ability of national governments to license the compulsory manufacture of drugs, except when certain specific circumstances are satisfied.

According to Article 31, the following conditions need to be fulfilled for the grant of a compulsory license:

• Such an authorization should be based on a consideration of individual merits (Art. 31(a));
• The proposed user should have made efforts over a reasonable period of time to secure a voluntary license on reasonable commercial terms, except in cases of national emergency, extreme urgency or public non-commercial use (Art. 31(b));

48 Consult the report for an extensive discussion on this issue.
49 Malueg and Schwartz (1993) propose a similar system where the world market is divided into regions based on income levels in which discriminatory pricing may be allowed but not within regions. But the main weakness of their model seems to be that it is based on a price discrimination model. See Malueg and Schwartz (1993), cited in Abbott (1998), p. 619.
• The scope and duration of the use should be limited to the purpose for which it was granted (Art. 31(c));
• Such a license should be non-exclusive (Art. 31(d));
• The use should be predominantly for domestic consumption (Art. 31(f));
• Such authorisation shall terminated when the circumstances that led to its grant cease to exist (Art. 31(g));
• the right holder will be paid adequate remuneration in the circumstances of each case, taking into account the economic valuation of the authorisation (Art. 31(h));
• The legal validity of the license and the remuneration will be subject to judicial or other forms of independent review (Art. 31(I)),
• Such a license can be issued to remedy anti-competitive behavior (Art. 31(k)).

But given that the terms used in Art. 31 are not defined by the TRIPs Agreement, there has been much disagreement between countries as to how “national emergency”, “extreme urgency” or “public non-commercial use” ought to be interpreted. Another issue that Article 31 raises concerns the interpretation of Article 31(f). Art. 31 (f) says that the compulsory manufacture of drugs thus achieved should be “predominantly” for use in the local market. Does this mean that one/ some developing countries who have secured the right to compulsory license an important drug can export it to other developing countries or LDCs who have a similar public health crisis and have no capacity whatsoever to locally manufacture the drug locally?

3.2.1. Interpreting Article 31 of the TRIPs Agreement
In addition to varying national interpretations of the terms of Article 31 of the TRIPs Agreement over the past few years, the Doha Declaration and on-going work under the Doha Agenda seeks to put some of the contentious issues in this areas to rest.

3.2.1.1. The Question of “National Emergency”
Differing standards have been invoked to define ‘national emergency’ in the past, as the cases of Brazil, Canada and USA on compulsory licensing reveal. In the Brazilian case, the USA brought a complaint against Article 68 of Brazil’s Industrial Property Law of 1996 in front of the WTO dispute settlement panel. Specifically in question was the legality of the provision that provided that a patent should be made subject to compulsory license if it was not “worked” locally. The US claimed that such a provision amounted to discrimination against patent holders who imported products into the Brazilian market as against those who produced it locally. Notably,
this provision and the imminent threat of compulsory licensing therein has been used by Brazil to get better terms of supply of HIV/AIDS drugs locally (WTO/WHO Report, 2002, p. 105). This dispute was settled bilaterally between the USA and Brazil in 2001, when Brazil agreed to hold talks with the US before Article 68 was applied to individual US pharmaceutical companies (Ibid).

The Canadian and the USA cases in the wake of the Anthrax scare stand in stark contrast to this. Owing to the Anthrax scares in the USA, the Canadian government decided in 2001 to override the patent that was held by Bayer AG for the drug Ciproflaxin (or Cipra) used to treat anthrax. On 17 October 2001, it signed a contract with Apotex, a generic manufacturer, for 1 million Ciproflaxin pills without issuing a compulsory license based on a “national emergency” and the USA too threatened to follow the Canadian case (Sridhar, 2001). This contract was cancelled later on, but it was mainly through these threats that both countries managed to negotiate large discounts on the patented price of the medicine (Abbott, 2002, p. 54).

The discrepancy in the way ‘national emergency’ has been perceived in the three cases has elicited concern and criticism in legal and political circles alike. The Doha Declaration has once again, in an attempt to clarify the terms used in Article 31, affirmed that member countries have the right to grant compulsory licenses and that public health crises can constitute a condition of “national emergency” (see Paragraph 5(6) of the Declaration; see Correa, 2002 for a detailed discussion). But how far this will help developing countries is not clear, given the uncertainties surrounding export of drugs produced through such licensing, or parallel imports and exports of drugs produced through compulsory licensing (see discussion in Sections 3.2.1.2 and 3.2.1.3 below).

3.2.1.2. Articles 30 and 31: Exporting Drugs Manufactured under Compulsory Licenses

Does the requirement under Art. 31(f) that compulsory manufacture of drugs be “predominantly” for use in the local market mean that one/ some developing countries who have secured the right to compulsory license an important drug can export it to other developing countries or LDCs who have a similar public health crisis and have no capacity whatsoever to locally manufacture the drug locally? 51

50 For example, the Canadian government cancelled the contract only upon Bayer’s assurance to deliver 1 million pills in case of an emergency to the Canadian government. See see V. Sridhar, “Perilious Patent”, Frontline, Vol. 18, Issue 24, December 7, 2001; see also Abbott (2002) for an extensive discussion on Ciproflaxin and the TRIPS provisions, p. 54-57.

51 It has been felt that Art. 31(f) will act as an intrinsic limitation to any developing country that may wish to export drugs produced through a compulsory license, since they are now to comply with the TRIPS Agreement. But the extension proposed to LDCs under the Doha Declaration to
Abbott (2002, p. 17) suggests that the word “predominantly” places a limitation on both the supply side and the demand side. On the supply side, developing countries that are in fact in a position to supply licensed drugs to other developing countries, which lack the production capabilities to do so, are constrained. On the demand side, the developing/least developed countries that possess no local manufacturing capacities are constrained from importing drugs manufactured under compulsory licenses, thereby foreclosing the only option that they have to ensure affordable drugs for their people (Ibid).

Article 30 of the Agreement, in this connection, provides certain exceptions to rights conferred. Article 30 reads as follows:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

Article 30 might be a way through which a developing country that has obtained the license to compulsory manufacture an essential drug may be able to provide for its export to another country in urgent need of the same, by enforcing a ‘limited exception’ to the patent holder’s rights, when it can be proven that the drugs manufactured by the former are much cheaper than the regular market price (Abbott, 2002, 24).

The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, (Decision No. WT/L/540 taken) by the WTO countries on 30 August 2003 has somewhat put this matter to rest. This decision waives countries’ obligations under Article 31(f) of the TRIPS Agreement, thereby allowing developing countries to export drugs made through compulsory licenses to other least developed countries that cannot manufacture them locally.

There are several qualifications to the nature of this Decision and the flexibility it allows developing countries. To begin with, WTO waivers are by nature, limited by time up to one year

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implement the TRIPS Agreement only by the year 2016 has now been agreed upon in the TRIPS Council at its June 2003 meeting. Therefore the TRIPs Council also agreed upon waiving the requirement that LDCs provide exclusive market rights for new drugs until 2016. This may very well mean that LDCs do have the discretion to import such drugs, since it will not clash with any exclusive rights that the pharmaceutical firms will have in their local contexts: See Abbott (2002).
only. The Decision makes it clear that the obligation of a developing country to produce predominantly for the local market will be waived if the importing country which is a least developed country/developing country seeking to import drugs manufactured under the said license: (a) proves the lack of local capacity to manufacture; (b) specifies the name and precise quantities of the drug required; and, (c) is faced with a case of a national emergency or other circumstances of extreme urgency or a case of public non-commercial use (see Paragraph 1(b) and 2(a)).

Secondly, the waiver granted under the Decision is also very limited. According to the Decision, the developing country (say India) that chooses to export the drugs to another needy developing/least developed country that has no local capacity (say Lesotho) to produce them has to take a compulsory license. But this license is only limited to Lesotho (see Paragraph 2(b) of the Decision). In order to be able to supply to another developing country, say Zambia, an application for a waiver has to be made all over again, proving the existence of a situation of a national emergency or a circumstance of extreme urgency.

These shortcomings seem to point out to the need for a permanent solution to the issue.

3.2.1.3. Parallel Imports of Compulsory Licensed Drugs

Another really problematic aspect in interpreting Articles 30 and 31 is the issue of parallel imports of compulsory licensed drugs. When a patent is licensed to a third party to manufacture the product, the first sale of the goods produced have the same effect as first sale by the patent holder herself. This, therefore, in a regime of international exhaustion (where parallel imports are allowed) will have the effect of exhausting the right of the patent holder to control further sale of transfer of the goods produced.

3.2.2. The Central Issue in Compulsory Licensing

As in the case of parallel imports, the legality of compulsory licensing is marred by differing viewpoints. Lower profits that might result from countries using compulsory licensing to negotiate lower prices of pharmaceutical drug supplies, or simply due to loss of revenue due to production by local firms are said to result in lowering R & D incentives for firms. The second argument advanced against compulsory licensing is that it would result in discrimination against the mandate of Article 27 (that prohibits discrimination as to field of technology) and therefore lesser compliance with the TRIPs Agreement. These arguments were put forth by

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52 Personal Communication, Prof. Correa, 06 September 2003.
pharmaceutical companies to defend their position in the Brazilian case on compulsory licensing discussed above.

Given that there is no concrete evidence of lower R & D incentives as a result of compulsory licensing, the central questions in compulsory licensing are: Does compulsory licensing run contrary to the stipulations of Article 27 of the TRIPs Agreement? And more importantly, does compulsory licensing serve any specific efficiency considerations that may outweigh the potential costs on R & D, if any?

3.2.3 Compulsory Licensing and its Importance for Developing Countries

Article 27(1) of the TRIPs Agreement mandates that patent rights should be enjoyable without discrimination as to the place of invention, field of technology and irrespective of whether products are imported or locally produced. A literal interpretation of Article 27(1) raises the question: If compulsory licensing rules are specifically applied to pharmaceutical patents, does this amount to “discrimination” as to field of technology?

Western experience reveals that compulsory licensing has been used as a competition policy tool and examples of such a balance can be found in legal provisions as well as case law in these countries. This, in turn, begs the question: under what circumstances is compulsory licensing being used as a competition policy instrument and does the scope, or even better, the need, for similar action exist in developing country contexts?

3.2.3.1. Assessing the Legality of Compulsory Licensing within Article 27, TRIPs

An authority on this point is the EU-Canada case (also known as the “Bolar” case),\(^{54}\) where the WTO panel upheld the predominance of Article 27(1) over Articles 30 and 31 of the TRIPS Agreement. The case concerned a section of the Canadian Patent Act regarding the “early working” or “bolar” exception; a permission that the patented invention could be used without the consent of the patent holder for testing purposes for the submission of data to get marketing approval for drugs (Correa, 2001, p. 3). But according to Correa (2001), the Panel prohibits only “discrimination” as to field of technology and not differentiation based on legitimate reasons (p. 9). And rules particularly applicable to pharmaceutical patents do not amount to “discrimination” as to field of technology, because discrimination as a term denotes unjustifiable adverse treatment only and not one that is it is based on a legitimate public health perspective (Abbott, 2002, p. 38).

\(^{53}\) This section is based on Abbott (2002) p. 41-43.
The Doha Declaration’s clarification that the TRIPS Agreement has to be interpreted in the light of public health lends enormous support such an interpretation. Furthermore, there are cases of developed countries where pharmaceutical products have been treated differentially on grounds of public health. Correa (2002) and Cotter (1999) both note the case of French patent law where the government may ask for compulsory licensing of a patent, if amongst other things, the patentee has not “worked” the patent within a specific amount of time or sold the product in quantities sufficient to satiate the French market, or for reasons of public health or the needs of the economy. In the light of all this, it seems quite appropriate to conclude that applying compulsory licensing to pharmaceuticals does not contravene the requirements of Article 27(1) of the TRIPS Agreement.

3.2.3.2. Assessing the Role of Compulsory Licensing in Promoting Learning and Research and in Ensuring Price Competition

Western anti-trust authorities have struggled to solve issues raised by accumulation of patents by firms such as coercive bargaining, hold-up effects, unfair terms in license agreements between firms that share research results, among others (see Section 2.2.3), through what has come to be known as the “essential facilities doctrine”. This doctrine simply means that when some invention is an essential facility for another invention, access should be allowed in the interests of promoting innovative activity and competition. Courts, both in the USA and the EU, have decreed the compulsory licensing of patents in cases where the doctrine was found applicable, irrespective of the field of technology in question.

Within the EU, Article 82 of the Treaty of Rome is the main provision that concerns itself with the abuse of dominant position. Article 82 contains a list of abuses that includes “limiting production markets or technical development to the prejudice of the customers” (UNCTAD, 2002, p. 8). Whereas the refusal to license is considered to be the prerogative of the IPR holder in general, Article 82 prohibits abusive conduct such as refusal to license in order to keep a secondary market to itself (Dumont and Holmes, 2002, p. 155). Mainly because of this, it has been felt that there is no real need for an “essential facilities” doctrine in EC competition law (Ibid.). But case law, especially after the Macgill case, reveals a strong integration of the doctrine into EC competition law. (UNCTAD, 2002, p. 10). In the Macgill case, the European Court of Justice held that “…(t)he refusal to license constituted an abuse in exceptional

54 See WT/DS160/R.
56 See Holmes and Dumont (2002), Cotter (1999), among others.
circumstances, because of the lack of actual or potential substitutes and the prevention of product innovation (contravening Art. 82), the abusive leveraging in a secondary market, and the lack of legitimate justification; a defence based upon the exercise of an IPR was expressly rejected and the IPR holder was denied the right to refuse the license” (UNCTAD, 2002, p. 10).

Other EC experience shows increasing use of licensing of intellectual property as a remedy in merger cases to remedy amongst other things, price distortions (Dumont and Holmes, 2002, p.157). Speaking only of the pharmaceutical industry, both the European Commission and the Federal Trade Commission of the USA have relied frequently on intellectual property licensing and provision of assistance to competitors to deal with issues of competition and price rises raised by undue market power (Ibid.).

In the USA, the essential facilities doctrine in conjunction with Section 2 of the Sherman Act would amount to preventing a monopolist from preventing others the access to a facility owned by him when the competitor’s inability to reasonably duplicate it can be proven and when its provision to the competitor is denied despite being feasible (Cotter, 1999, p. 232). Recent cases decided by the FTC reveal the growing tendency of the FTC to embrace the doctrine and to decree licensing as a solution.57

Even apart from the USA and the EU, such an obligation to grant compulsory licenses when competition is threatened is found in national laws of most developed countries (Dumont and Holmes, 2002, p. 155).58

57 See for example, cases discussed by Cotter in general and pharmaceutical merger cases discussed by Dumont and Holmes, 2002, p. 157, footnote 29 in particular. See also, Correa (2000) who notes that the USA has granted more than 100 such licenses for present and future patents (p. 95).
58 See footnote 53 and accompanying text for an example.
4.0 INTRODUCING FLEXIBILITY: LESSONS FOR DEVELOPING COUNTRIES

Until now, a large part of the debate on introducing flexibility in national IPR regimes has focussed upon options within the TRIPS Agreement. Whereas Article 8(1) offers a very important venue to national governments, there are several exogenous elements of flexibility that deserve attention.\(^{59}\) The foregoing analysis clearly points out to the importance of relying on competition policy and arguments based thereupon to extract such flexibility. Differential pricing and appropriate interpretations of Article 27(3)(b) and the criteria for patentability are other such elements.

4.1. Important Competition Law Elements That Help Extract Flexibility

As Gallini and Trebilcock (1998) note, an efficient competition policy that compliments IPRs should have three main effects of social surplus generated by innovative activity (p. 21-22): Firstly, it should provide ex-ante incentives to innovate, secondly, it should affect ex-post incentives to transfer new technologies and products and lastly it should promote price competition in product markets that use the new products and processes, thereby lowering prices. Using the potential of competition policy to generate these effects is critical to serve both concerns of developing countries: creating spaces for innovation in the realm of pharmaceuticals and ensuring availability and affordability of cheaper drugs.

4.1.1. Harnessing the Competition Policy-IPRs Nexus: Learning from Developed Countries

The analysis in Section 3 on efficiency considerations that play a role in both parallel imports as well as compulsory licensing reveal that both solutions can, if implemented in the right way, lead to positive results similar to that in the developed economies. Some important lessons that flow from the analysis as well as the survey of options used by developed countries are that:

\(^{59}\) Art. 8(1) allows that Members adopt measures important to protect public health and nutrition in their national regimes, so long as these measures do not go against or result in a lesser compliance with the TRIPs Agreement (Art. 8(2)).
• **Compulsory licensing can be for competition law purposes**

Licensing of intellectual property serves a very important role in the diffusion of technology and in price competition (Gallini and Trebilcock, 1998, p. 23). Whether the cases of price rises associated with pharmaceuticals in developing countries until now are all caused by anti-competitive behavior that can be rectified by compulsory licensing is not clear. What stands out, especially from the experience of developed countries, is that obligatory licensing is essential for developing countries to deal with most anti-competitive effects of broader patent protection. The legal basis for using compulsory licensing to deal with anti-competitive effects is contained in Article 31(k) of the TRIPS Agreement, countries should incorporate legal provisions in their national laws that recognize this friction and the need to rectify it.\(^{60}\) Although the TRIPs Agreement sets out precise conditions for grant of such licenses, the conditions can be interpreted flexibly (Correa, 1999, p. 18). Deriving and interpreting this set of legal conditions under which this might be made applicable by courts in cases of dispute, is of course, a tedious task, but case law in developed countries should be relied upon for this purpose.

Specifically to enable diffusion of technology, existing examples in biotechnology laws in the EU serve as fitting examples. Article 12(1) of the European Biotechnology Directive provides that a breeder can request for a compulsory license when she cannot exploit a plant variety for breeding purposes without infringing a patent (Correa, 1999, p. 18). A similar provision is present in the UK Plant Breeders Act mandating the licensing of patents for research purposes, where the licensee can prove its needs. Although recent evidence (see Walsh et al (2003) as discussed earlier) does not support hindered access to research tools and technologies, developing countries should consider incorporation of such provisions into their biotechnology laws.

• **Parallel imports are competition enhancing**

Parallel imports serve as an important competition policy instrument by ensuring price competition amongst various markets worldwide, especially when the increased global welfare from allowing discriminatory prices is not at all clear.\(^{61}\) This will, in fact, reinforce the goals of the WTO, since the “goods and services produced within the Members of the WTO system are expected to compete in each other’s markets on a head-to-head basis” (Abbott, 1998, p. 618).

\(^{60}\) See in this context, that some developing countries already have legal regimes that consider anti-competitive practices as a ground for the grant of compulsory licenses, such as Chile (1991), Argentina (1995) and the Andean Group (Decision 344, 1993). In: Correa (2000b), p. 9.

\(^{61}\) In this context, see Danzon (2001), who notes that: “Current drug prices for some on-patent drugs may appear inappropriately high, relative to income, in some low income countries. However, this is because current conditions do not encourage appropriate price differentials.
The conclusions of the First Report (final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation supports this view. The report, upon an institutional comparison of the EU and the WTO, concludes that the two are based on similar premises of creating common markets for trade in goods and services to enhance economic productivity, opening national markets to competition from goods and services produced anywhere within the system and elimination of all barriers to trade, among others. Thus, if the goals of the EU are served better by using parallel imports as an intra-community competition-enhancing tool, there seems to be no reason to believe that the same cannot be true of a global market.\textsuperscript{62}

- \textit{Enacting other competition rules is important to curb abuse of market power}

The role of effective competition policy is to curb market power, whether it arises from the accumulation of patents or otherwise and to ensure level playing fields. In addition to licensing and parallel imports, other competition law provisions are required to prevent abuse of market positions by pharmaceutical firms, such as collusion between retailers and distributors, collusion between manufacturers and generic producers, restrictive practices in the generics industry to prevent competition by non-branded producers and other forms of tie-ups that restrict entry of new comers in the markets. Developing countries require appropriate legal provisions that are tailor made to address these concerns in newly emerging technologies.

4.1.2. Options for Developing Countries

In the light of all this, there are some basic questions that developing country policy makers are confronted with today. Can competition policy provide a better way of dealing with the question of affordability and availability of drugs? The answer to this lies in the positive. Not only can competition policy help developing countries deal with affordability and availability issues better, it also offers a legitimate basis on which to access and build R & D efforts.

If this is the case, should this be an international agreement? As Singh and Dhumale (1999) note, developing countries have had little or no experience with competition policy because until liberalization, they were largely economies with considerable governmental control on industrial activities. As a result, it is estimated that until 1990 only 16 developing countries had some form of a competition policy and that it requires around ten years for a developing country to gather the expertise and implement a competition law framework (Singh, 2002, p.6-7, table

\textsuperscript{62} Thus the status quo is not a basis for judging the potential for differential pricing combined with patents.” (p. 1).
6). Given their inexpertness in this area, an interesting question is whether there should be an international competition policy agreement, that would run parallel to the TRIPs Agreement (Cottier, 1998). A common international competition policy agreement runs the same risk as with other agreements under the WTO – due to the numerous compromises that go into its creation, the agreement, in its final form, may not be flexible enough for developing countries to totally adapt it to their personal needs (Singh, 2002). Critical assessment of the activities of the WTO in the past few years (in the WTO’s Working Group’s analysis on competition policy) have concluded that the WTO’s work in this regard does not take into account the development perspective (Singh and Dhumale, 1999; Singh, 2002).

Development friendly competition policies necessary have to deal with problems of developing countries and therefore cannot be based directly on those prevalent in the developed countries (Singh, 2002). In general, for the concerns of developing countries to be fully taken into account, the focus of competition policy should be governed by (Cf. Singh and Dhumale, 1999, p. 1):

- dynamic and not static efficiency;
- concepts of “optimal degree of competition” that is required to promote long term growth and not the concept of maximum competition; and,
- creation of industrial and competition policy that work complimentary to each other;

Based on these general guidelines, developing countries have to devise and institute competition policies best suited to their domestic needs and environments.

4.2 Other Elements of Flexibility

Another element of flexibility proposed is that of differential pricing (See the WTO/ WHO Report, p. 16-17; Danzon, 2001). This refers to the possibility that prices of vital medicines are low enough in developing countries so that they remain affordable but the higher prices in developing countries continue to provide R & D incentives to firms (WTO/ WHO, p. 17).

Although there are other exhaustive accounts of how flexibility can be introduced within the TRIPs Agreement (see again, Correa 2003), one aspect that deserves special attention is the interpretation of patent requirements. For any invention to be granted a patent, three main criteria have to be met: novelty, inventive step and industrial application. Within these three criteria, the way ‘novelty’ is interpreted is critical in determining patent scope (Scotchmer and Green, 1990). But although Article 27 of the TRIPs Agreement sets out these requirements,

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since it does not define them in any way, they can be interpreted in a way so as to ensure flexibility (WTO/WHO, p. 43). Specifically, novelty can be interpreted strictly so as to limit certain forms of patents (Abbott, 2002, p. 46) and stricter interpretations of this criteria by patent offices in developing countries can be used to curb many of the issues of abuse of IPRs as identified earlier. The criterion of ‘novelty’ can also be used by developing countries to avoid granting patents on drugs recombined and presented in slightly different forms (as discussed in Section 2.2.2).
5.0 CONCLUDING REMARKS

This paper has tried to analyze the potential impacts of stronger intellectual property protection on health care and delivery systems in developing countries: on prices and availability of drugs as well as on learning opportunities. In the introduction, three major concerns for developing countries were laid out to be:

a) How can developing countries deal with price increases that can result from increased patent protection to ensure access to and availability of essential medicines in the future?

b) How can developing countries deal with any negative impacts that intellectual property rights may have on restricting their space for innovation and learning in the pharmaceutical sector?

c) If intellectual property rights are not sufficient incentives, what other instruments can developing countries look up to, in order to foster research into diseases of importance to their populations?

In finding answers to these questions, the focus has been on finding options for flexibility outside the IPR system that will help developing countries create technology policy best suited to public health needs. The main results of the analysis are as follows. Whereas the provision of stronger IPR protection to pharmaceuticals have a serious potential to impose costs on developing countries in the future, the potential benefits of stronger IPR protection will not accrue automatically. These have to be harnessed. Competition law and policy is one very important tool that needs to be in place to help developing countries reap the benefits as well as control the costs of monopoly protection. Appropriate competition policies will not only help curb increased prices of drugs, but also enhance learning possibilities. One effective competition policy instrument that can curb increased prices of drugs is parallel imports. If parallel imports are used within the EU and within the USA respectively for reasons of promoting competition, there is no reason why developing countries should be banned from doing the same. This action can be defended on the basis of the WTO Agreement, which seeks to promote competition between markets worldwide. Compulsory licensing can, in a similar way, serve both as an instrument to deal with public health crises, to ensure price competition and to ensure better access to inventions for research purposes, if the need so arises. Economics of competition policy and examples of case law from developed countries support this view of both, parallel
imports and compulsory licensing. Developing countries need to evolve technology policy frameworks within which the full potential of these instruments can be realized.

The analysis in this paper has contributed to the present discussions on this topic in two ways. By showing that the controversial options of parallel imports and compulsory licensing are powerful competition law instruments which either increase global welfare or leave it unaffected, while helping developing countries to deal with both – prices of drugs as well as innovation possibilities – it seeks to provide a neutral perspective on the debate. Secondly, it has shown that the search for flexibility (which is predominantly on provisions within the TRIPs Agreement) in national IPR systems has to expand to other aspects of national policy, such as competition policy, for developing countries to be able to pursue public health objectives. But competition policy cannot solve the third main concern that developing countries face, in the light of stronger intellectual property rights – that of finding alternate incentive instruments in order to foster research into diseases of importance to their populations. Optimally, such alternate incentives should not only promote research into neglected diseases (through a fund or a prize mechanism) but it should also cater to local capacity building needs, so that countries can, in the mid-term or long-term be hopeful of their own self-sufficiency. This issue, although critically important, has not been dealt with in this paper.

Although this paper has tried to highlight all issues in these areas, given the history and enormity of legal and economic literature on the interface between intellectual property and competition law and policy, and the efficiency implications of parallel imports and compulsory licensing, there is scope for in-depth analysis into each one of these areas.
6.0 BIBLIOGRAPHY


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