intellectual property and access to medicines: papers and perspectives

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Foreword

In response to requests to support countries' efforts toward capacity-building in the area of intellectual property and public health, the WHO Regional Office for Africa and the WHO Regional Office for South-East Asia have conducted a course entitled "Towards an Intellectual Property Regime that Protects Public Health". This course was held on 22-27 June 2009 in Cape Town, South Africa and on 6-10 July 2009 in Bangalore, India.

This volume contains a selection of the papers used in these courses. Its publication is intended to facilitate the conducting of further courses on the implications of intellectual property rights on access to medicines. However, it can also be used as a reference for readers who, having already acquired an understanding of the basic concepts in this field, would like to gain a deeper understanding of the issues.

The compilation, like the course on which it is based, aims to support efforts to build capacity in the application and management of intellectual property in a manner oriented toward the public health needs and priorities of developing countries, as mandated by the Global Strategy and Plan of Action on public health, innovation and intellectual property, adopted by the World Health Assembly in 2008.

These papers explore the principal issues in intellectual property as it relates to public health. They are comprehensive, though not exhaustive, as the field is a constantly evolving one. They do attempt to address various perspectives of interest to readers concerned with public health.

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Abbreviations and acronyms

AIDS	acquired immunodeficiency syndrome
ARVs	antiretrovirals
BD	Bayh-Dole (Act)
BITs	bilateral investment treaties
BMC	Biodiversity Management Committees (India)
CBD	Convention on Biological Diversity
CPAA	Cancer Patients Aid Association (India)
DHHS	Department of Health and Human Services (United States)
DNA	deoxyribonucleic acid
DRA	drug regulatory authority
DSB	Dispute Settlement Body (of the WTO)
EFTA	European Free Trade Association
EU	European Union
FTA	free trade agreements
GATT	General Agreement on Tariffs and Trade
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GPO	Government Pharmaceutical Organization (Thailand)
HIV	human immunodeficiency virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IDCs	innovative developing countries
IP	intellectual property
IPR	intellectual property rights
LDC	least developed country
MFN	most favored nation
NBA	National Biodiversity Authority
NIH	National Institutes of Health (United States)
MOH	Ministry of Health
MSF	Médecins Sans Frontières
NCE	new chemical entities
NGO	nongovernmental organization
PCT	Patent Cooperation Treaty
PIC	prior informed consent
R&D	research and development

SMEs	small and medium enterprises
SPLT	Substantive Patent Law Treaty
TAC	Treatment Action Campaign (South Africa)
TKDL	Traditional Knowledge Digital Library
TRIPS	(Agreement on) Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UDHR	Universal Declaration of Human Rights
USTR	United States Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

paper 1

Trade agreements, intellectual property and access to medicines: An introduction

Germán Velásquez

Sustainability of health insurance in the field of medicines

One in three people in the world has no regular access to medicines, and three out of four live in developing countries that account for only 8% of global pharmaceutical sales.[1] Of the 10 million children under five who die each year, 80% could be saved if they had access to essential medicines. But the technical and financial capacity to manufacture these medicines exists.

The cost of pharmaceutical drugs is already a desperate problem for developing countries, but during the next two decades the situation could worsen if solutions are not found. Access to medicines is a pressing, global issue, closely linked to trade and intellectual property issues. We do not know how long the health systems of industrialized countries can continue to meet the increasing cost of reimbursements given the emergence, for example, of very costly new drugs to treat such widespread conditions as cardiovascular diseases or cancer, treatments that will be developed and patented on the basis of research into the human genome—even though this research is publicly funded.[2]

In the United States, experts estimate that national expenditure on health care will increase faster than GDP; health costs will rise from 15.3% of GDP in 2003 to 18.7% in 2014.[3] Over the same period expenditure on pharmaceuticals will treble, reaching US$ 414 billion in 2014. Private insurers will therefore have to choose between reducing benefits and increasing contributions. The gap will widen between people who are able to finance their own health care and those with reduced coverage. Many European

countries are already devoting a higher percentage of their health spending to drugs than the United States, where the figure is 12.48%. In Germany the figure is 15.2%, in Spain 22.8%,[4] in Finland 16.3%, in France 16.6% and in Italy 20.1%. The same trend can be seen in other developed countries: in Canada the cost of medicines represented 17.7% of the health budget in 2005 compared with 11% 15 years earlier.[5] The same is true in Japan. To put this in perspective, a decade ago, no industrialized country spent more than 10% of its health budget on medicines.

Globalization of intellectual property

Since the World Trade Organization (WTO) was set up in 1995, the debate on the cost of medicines has centred around the possible impact of TRIPS, the Agreement on Trade-Related Aspects of Intellectual Property Rights. In 1998 WHO published a report citing the Agreement's possible effects on access to drugs.[6] That report and the concerns of many developing countries were soon supported by awareness campaigns mounted by Médecins sans Frontières (MSF), Oxfam and Farmacéuticos Mundi.

When South Africa tried to take advantage of the flexibilities embodied in TRIPS, 39 drug companies took the South African Government to court in 2000 to challenge the pharmaceutical legislation. After an intense international campaign backing the South African Government and strong pressure from South African civil society—especially the Treatment Action Campaign[7]—the issue finally was discussed in the WTO on 20 June 2001. Subsequently, the Doha Declaration was drawn up in November 2001, which confirmed that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".[8]

The argument for generalizing the application of patents (of a minimum duration of 20 years) is that it is essential to allow private drug companies to continue their research; research is expensive, but will be funded through patents. Guaranteeing a monopoly for the drug companies enables them to keep their prices high, which will allow them to continue their research and develop new products. Yet those same high prices prevent most people who need new products from obtaining them. From a public health perspective, it is vital that these drugs be made available to save lives as soon as they have been developed.

Research and development is mostly done by the private sector, and depends on the potential market for the product, not the health needs of the poorest people. Over the past 20 years, there has been almost no drug research related to diseases or epidemics that afflict millions in developing

countries, such as Chagas disease, leishmaniasis, schistosomiasis or narcolepsy.

TRIPS contains mechanisms that allow countries to make certain medicines widely available and affordable, in the interest of public health—even if the medicines are under patent. At Doha in November 2001, the WTO General Council was asked to find an "expeditious" solution to the so-called TRIPS "paragraph 6 problem"; that is, to ascertain how countries with insufficient manufacturing capacity in the pharmaceutical sector could make use of "compulsory licenses", the legal mechanism built into the Agreement that in some cases can be used to circumvent the monopoly conferred by patents.

For five years, the Doha process pitted health against trade. The debate centred on which came first and what exceptions should be made. It is now realized that the right to health and the expansion of trade are different issues. Promoting the right to health involves guaranteeing the right to benefit from technological advances and a recognition of the human rights principles embodied in many international treaties and accepted by most states.

In 2006, the WHO report on *Public health, innovation and intellectual property rights* stated that "the TRIPS Agreement allows countries a considerable degree of freedom in how they implement their patent laws, subject to meeting its minimum standards including the criteria for patentability laid down in TRIPS. Since the benefits and costs of patents are unevenly distributed across countries, according to their level of development and scientific and technological capacity, countries may devise their patent systems to seek the best balance, in their own circumstances, between benefits and costs. Thus developing countries may determine in their own ways the definition of an invention, the criteria for judging patentability, the rights conferred on patent owners and what exceptions to patentability are permitted".[9]

Avoidable deaths

The HIV/AIDS epidemic began in the early 1980s. Now, almost 10 years after the first antiretroviral drugs appeared on the market, 99% of those able to access them live in developed countries. And of the 9 million people whom WHO, UNICEF and UNAIDS estimate in their 2008 report should be receiving treatment, just 3 million had access to therapy at the end of 2007.

The question naturally arises as to how countries can use the TRIPS flexibilities to increase access to these life-saving drugs. But seven years after Doha, the "paragraph 6 solution" had still not been ratified by WTO Members, who decided to extend the deadline for ratification of a proposed

procedure until the end of 2009. Cost is not the sole factor in access, of course. Other crucial elements include the rational selection of drugs authorized for sale in particular countries; the existence of funding mechanisms; and the maintenance and development of reliable health-care systems and infrastructure. However, the issue of costs must be resolved first of all.

Significant agreements have been made in recent years to reduce the cost of antiretrovirals in developing countries. For example, the Accelerating Access Initiative helped make it possible to cut the annual cost per patient from US$ 12 000 in 2000 to US$ 140 in 2008. It was launched in May 2000 by UNAIDS, in partnership with several UN agencies and five drug companies. Over three years, 80 countries expressed an interest; 39 have developed action plans, but only 19 have actually concluded agreements with the companies. The number of patients covered and the duration of these discounts is not known.[10] Set up in April 2001 at the initiative of the then-United Nations Secretary-General Kofi Annan, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) has received about US$ 10 billion over seven years, whereas its *annual* funding requirements were originally estimated at US$ 12 billion. Even if the shortcomings of such initiatives could be addressed, they do not represent a long-term solution for developing or for developed countries. It is not feasible for the cost of drugs to continue to rise exponentially, outstripping the rest of the economy. Drug companies, including the main private companies, government-owned companies and NGOs, are collaborating on the International AIDS Vaccine Initiative (IAVI), and it is to be hoped that this initiative produces results soon. But the vaccine must be made available to as many people as possible, as quickly as possible and at the lowest possible cost.

Generally speaking, the rules of trade should contribute to the well-being of society. They should never be an obstacle excluding a large section of society from the benefits that trade confers. Access to a health-care system, perceived as a fundamental right, is also a collective right that must be proactively protected by the public authorities. After Doha, it is clear that if medicines are considered as being like other merchandise, health will always be subject to the market, with remedies and treatments available only to those with enough purchasing power.

New proposals

Essential drugs must be considered a global public good. This raises fundamental questions. Can a global public good be patentable, so that only a few have a monopoly over it to the disadvantage of millions? Can a drug that makes it possible to exercise a fundamental right (to health) be bound by rules that thwart universal access for 20 years? How can research and development of new pharmaceuticals be organized to ensure that they

are immediately accessible to all who need them? How can the society of tomorrow guarantee the manufacture of these drugs on a global scale?

What sort of mechanism could reconcile the goals of public health, profit motives, and the rules of trade? Dr James Orbinski (awarded the Nobel Peace Prize in 1999 on behalf of MSF) has suggested a tax on international drug sales to fund a public body responsible for research. A complementary approach would be to "ringfence" a portion of national taxes on tobacco for an international public fund, which would enable developing countries to take part in medical R&D (and ensure research into tropical diseases). Still other approaches could be devised. The central point is that concerted effort is needed to develop solutions that will enable scientists to research, industrialists to manufacture and patients to be treated on a sustainable basis.

Some maintain that WHO "as the only legally mandated international governmental agency responsible for global health (…) should work towards establishing an essential research and development agenda" for future medicines considered as a public good.[11] In fact WHO has taken a number of steps related to the nexus of innovation, access and intellectual property rights. In 2006, in response to the report of the Commission on Intellectual Property Rights, Innovation and Public Health,[12] the World Health Assembly agreed to the establishment of an intergovernmental working group to draw up a global strategy and plan of action which, on the basis of the recommendations made by the Commission, should be capable of promoting innovation in accordance with public health priorities.[13] In 2007, the Director-General established the WHO Secretariat for Public Health, Innovation and Intellectual Property.

Then, at its May 2008 session, the World Health Assembly approved a global strategy on public health, innovation and intellectual property, drafted by an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The global strategy adds to the mandate given by several earlier WHA resolutions on World Health Organization involvement in issues related to intellectual property and public health.

Many hope that the IGWG and the global strategy will be a step towards repositioning health at the centre of all pharmaceutical research and development and promotion of access to pharmaceuticals.

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

Resolution WHA 61.21 on "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property", was the outcome of two years

of difficult and complex negotiations and represents an important step in that it seeks to address both access and innovation.

The global strategy recognizes that existing initiatives to increase access to health products are not sufficient; more than one third of the world's population does not have regular access to medicines. Current initiatives include efforts by Members States, the pharmaceutical industry, charitable foundations and nongovernmental organizations to develop new products against diseases affecting developing countries and to increase access to existing medicines. More needs to be done, however, in order to achieve the Millennium Development Goals for health.

According to the global strategy, proposals should be developed to explore a range of incentive mechanisms for research and development. The global strategy furthermore recalls that the report of the Commission on intellectual property and Public Health provides an analysis of the problems and makes recommendations that form a basis for future action.

The global strategy specifically recognizes that "The price of medicines is one of the factors that can impede access to treatment". It also acknowledges that intellectual property rights do not provide sufficient incentive to meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.

The global strategy quotes Article 7 of TRIPS, which states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner condusive to social and economic welfare, and to a balance of rights and obligations".

The strategy mentions that "international intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities".

The global strategy aims to promote new thinking on innovation and access to medicines. It will, *inter alia*, encourage and support the application and management of IP in such a way as to maximize health-related innovation, as well as to explore and implement possible incentive schemes for R&D. The global strategy also recognizes in its principles that public policies to promote competition can increase affordability of medicines.

Intellectual property rights in the global strategy

The global strategy lists numerous actions, ranging from identifying research gaps to strengthening the WHO prequalification programme and encouraging investment in the health-delivery infrastructure. Particularly relevant for discussions on IPR and public health is element 5 of the global strategy, on the application and management of intellectual property. It lists a number of necessary actions, including:

- to strengthen education and training in the application and management of intellectual property from a public health perspective;
- to facilitate access to user-friendly global databases with information on the status of health-related patents;
- to provide technical support, including to policy processes, to countries that intend to make use of the flexibilities contained in TRIPS in order to promote access to pharmaceutical products; and
- to explore and promote a range of incentive schemes for research and development including addressing the de-linking of the cost of R&D and the price of health products.

The papers in this compilation seek to contribute to training in the application and management of intellectual property from a public health perspective through the provision of background information and by sharing country experiences, as envisaged by the global strategy.

New beginning or unfinished business?

When the concept of essential medicines was launched in 1977, the only stakeholders were ministries of health and WHO. More than 30 years on, the field is now crowded: UNICEF, UNCTAD, UNDP, UNAIDS, WHO collaborating centres, the World Bank, regional development banks, the Global Fund, the Bill and Melinda Gates Foundation, the Clinton Foundation, the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Drug Facility (GDF), UNITAID, for-profit or not-for-profit NGOs, more than 80 public- and private-sector initiatives, donations from industry, etc. Many of these new stakeholders have considerable financial resources, up to 100 times WHO's budget in the field of medicines.

Given the multiplicity of stakeholders, coordination has become complicated and the conditions attaching to aid that are imposed on developing countries have multiplied. For example, if a country is to qualify for PEPFAR assistance in order to finance and procure medicines, it must give priority to products from US pharmaceutical companies, and if it accepts financial support from

the Global Fund, the government must procure products that have been prequalified by WHO.

We may surmise, with Laurie Garrett, that while more money is being directed toward pressing health challenges than ever before, because of limited and uncoordinated efforts there is a grave danger that the current age of generosity could actually make things worse on the ground.[14] And of course, giving aid to provide medicines to developing countries is a different thing from revising the rules and policies with a pro-poor and pro-health emphasis so that medicines will be more affordable and accessible in the future. To ameliorate a situation and to reform the conditions that led to it are different goals. Thus, it may be that the various parties concerned with access, innovation and IP are not only pursuing different strategies; they may be pursuing different things. Perhaps this is partly why the negotiations surrounding these issues are so complex. This volume of papers has an educational rather than a normative function; its purpose is to clarify the issues and concepts, which is a prerequisite for future thinking and policy interventions on the subject.

Certain themes have underpinned the essential medicines concept for the past 30 years, i.e. national medicines policies, selection of medicines, transparency with regard to pricing, information and ethical promotion, alerts regarding "new" pharmaceuticals that might be ineffective or dangerous, and the right of governments to have recourse to the flexibilities provided for in the TRIPS Agreement. Looking to the future, it is likely that the essential medicines concept will evolve in relation to the concerns of the twenty-first century, in terms of social security schemes and a focus on justice (rather than charity), public goods and human rights.

References and endnotes

1. WHO, "Equitable access to essential medicines", *WHO Policy perspectives on Medicines*, No. 8, Geneva: WHO, 2004, p. 1.
2. See John Sulston, "Heritage of humanity", *Le Monde diplomatique*, English language edition, December 2002.
3. Stephen Heffler, Sheila Smith, Greg Won et al., "Health Spending Projections for 2004-2014", *Health Affairs*, 23 February 2005, http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.74/DCI (7/2008).
4. For Spain specifically, see P. Recio Arias et al., *Elementos de perspective ante el Plan estatégico de política farmacéutica*, Seville, CONCITEC, 2005.
5. Organisation for Economic Co-operation and Development, *OECD Health Data* 2007, Paris, OECD 2008.
6. G. Velásquez and P. Boulet, *Globalization and Access to Drugs. Implications of the WTO/TRIPS Agreement*, World Health Organization, Geneva, 1999.

7. See Philippe Rivière, "South Africa's Aids apartheid", *Le Monde diplomatique*, English language edition, August 2002.
8. Declaration on The TRIPS Agreement And Public Health, 20 November 2001, WT/MIN(01)/DEC/2.
9. Commission on International Property Rights, Innovation and Public Health, *Public health, innovation and intellectual property rights*, Geneva, p. 21.
10. C. Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China. Considerations for Access to Medicines*, London, DFID, 2004.
11. Médecins sans Frontières, *Recherche médicale en panne pour les maladies des plus pauvres*, Geneva, MSF, 2001.
12. WHO, *Public Health, Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, Geneva: WHO, 2006.
13. WHA, *Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action*, 2006, WHA59.24.
14. L. Garrett, "The Challenges of Global Health", *Foreign Affairs*, vol. 86, nº 1, 2007, pp. 14-38.

paper 2

Intellectual property rights and public health: the general context and main TRIPS-compliant flexibilities *

Carlos M. Correa

Members of the World Trade Organization (WTO) may adopt different measures in order to foster competition, as long as these are compatible with the obligations deriving from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Some of these measures are reviewed briefly below. Of particular importance is the possibility of defining the criteria for patentability in a manner consistent with the protection of public health.

Among other measures that developing countries may adopt, some tend to only or mainly foster price competition and access to protected products. This, in particular, is the case of parallel imports, some exceptions to patent rights (such as the "Bolar" exception), the granting of certain types of compulsory licences (e.g. in case of emergencies, or anti-competitive practices), and the protection, in compliance with the concept of unfair competition, of the test data provided to health authorities for the marketing approval of pharmaceutical products (see paper 10.1 and 10.2).

Other measures may be required in order to foster technology transfer. For example, compulsory licences for public use may be used—as the United States has often done—to obtain access to critical technologies.[1] Compulsory licences granted due to lack of local exploitation of a patented product have generally been considered as an important means of technology transfer, despite the fact that very few licences of this kind have been granted in

* This paper is partially based on a study prepared by the author for the United Nations Development Programme (UNDP), which was published as "The TRIPS Agreement: how much room for maneuver?", Journal of Human Development, 2001; 2(1): 59-77.

developing countries, and that the patent-holder is generally not obliged to transfer the know-how required to efficiently use the patented invention.[2]

Finally, certain measures may be adopted essentially in order to stimulate innovation. This is the case, for example, with the experimental use exception (discussed below) which is particularly important for those sectors where incremental innovation is significant.

Patentability standards

One of the main flexibilities of the TRIPS Agreement in the area of patents is the freedom left to WTO members to define what an invention is. Thus, they may differentiate "discoveries" from "inventions" and exclude the former from protection. Hence, there is no obligation under TRIPS to grant patents, for instance, over genes and over other substances found in nature.

In addition, Article 27.1 of the Agreement prescribes that patents shall be available for any invention "provided that they are new, involve an inventive step and are capable of industrial application", but does not contain any specification about the precise way in which these criteria are to be applied.

As a result, WTO members are not constrained to apply a particular concept of novelty. While most countries adhere to the concept of universal novelty, the Agreement is flexible enough to permit, for instance, the United States to maintain a mixed standard of novelty (universal/local) depending on whether the disclosure of the invention has taken place within or outside the territory of the United States [35 U.S.C Section 102 (a)].[3]

Defining "inventive step/non-obviousness" is critical, as it determines the level of technical contribution required to obtain a patent. Since the TRIPS Agreement does not define this concept, WTO Member States are free to determine whether they want a system under which a myriad of minor, incremental developments are patentable, as is currently the case in the United States,[4] or rather opt for a system that rewards only genuine departures from the prior art. From a public health perspective, the latter approach is the one advisable for developing countries, in order to avoid a proliferation of patents that may unduly restrain innovation and competition.

Such a proliferation is of particular significance in the pharmaceutical field. Deliberate strategies applied by large pharmaceutical companies aim at blocking or delaying competition through the patenting of derivatives or variants of existing products or their method of use, such as formulations, dosages, salts, esters, ethers, polymorphs, metabolites, isomers, and

combinations. A recent report by the European Commission, for instance, found an extensive misuse of patents relating to pharmaceuticals:

Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines. In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States. Despite the lower number of underlying patent families based on EPO applications, looking from a commercial perspective, a challenger may, in the absence of a Community patent, need to analyse and possibly confront the sum of all existing patents and pending patent applications in those Member States in which the generic company wishes to enter.[5]

While patentability criteria may be set out in regulations or guidelines issued by the patent office, Section 3(d) of the Indian Patent Act, as amended in 2005, provides an example of the incorporation of detailed criteria into the law itself.[6] From a public health perspective, it has been suggested that patents should not be granted where the claimed subject matter consists of polymorphs, isomers, active metabolites, dosages or new indications of known medicines, and that patent applications should normally be rejected (due to lack of inventive step) where salts, ethers, esters or formulations are claimed.[7]

Parallel imports

Article 6 of the TRIPS Agreement recognizes the possibility of legally justifying parallel imports[8] on the basis of the principle of "exhaustion of rights". This principle was elaborated in the framework of the European integration in order to avoid market fragmentation and discriminatory price fixing practices by rights-holders within the Community.

The doctrine of international exhaustion—which justifies parallel imports from any country—has been applied with respect to industrial property titles (e.g. patents and trademarks) as well as copyrights (see Graz, 1988). It is based on the concept that the right-holder does not have the right to control the use or resale of the goods he has introduced in the market or that he has allowed a licensee to market. According to a broad version of this doctrine, the holder's consent would not be required in the exporting country; it would be sufficient to determine if the product entered the market legally (e.g. via a compulsory licence).

In many countries, in particular those under a common law system, the doctrine is based on the existence of an implied licence under which the buyer of a patented product (and those claiming rights through him/her) is free to deal with the product as if it were not patented. The sale of a patented product, unless otherwise indicated, entitles the buyer, with respect to said product, to exercise all the normal rights of a patent-holder, including the right to resell (Cornish, 1998, p. 200; Omaji, 1997, pp. 565-566).

The doctrine of exhaustion of intellectual property rights is not subject to any right-holder's act, but is automatic. In continental Europe, the inventor is deemed to have been rewarded through the first sale or distribution of the product. The equivalent to this doctrine in the United States is known as the "first-sale doctrine" (Yusuf and Moncayo von Hase, 1992, pp. 117-119).

The doctrine of exhaustion of intellectual property rights was originally restricted to the domestic market. However, in the European Community (EC) this doctrine has been extended by decisions of the European Court of Justice to the entire EC market, in order to avoid the fragmentation that the application of import bans in each jurisdiction could cause. The EC exhaustion doctrine has been applied with respect to different types of intellectual property, including copyrights. In the patent field, the validity of the doctrine has been sustained even in cases where the exporting EC country did not provide for patent protection (see, in particular, the decision of the European Court of Justice in *Merck vs. Stephar*, case 187/80, and the more recent decisions in *Merck vs. Primecrown* and *Beecham vs. Europharm*).[9]

While the EC adopted a principle of regional exhaustion of rights, other countries decided to apply the same principle, but at an international level. This means that, whichever the exporting country may be, the intellectual property rights holder does not have the right to prohibit parallel imports of a product that was put on the market in the said country, whether with his/her consent or through other legal means.

By contrast, applying the exhaustion of rights doctrine exclusively on a domestic scale (which means parallel importation is not allowed) has a protectionist effect since a ban on parallel imports avoids foreign competition. Since the holder has been rewarded through the first sale of the product in the country of origin, a ban on parallel imports is not required to guarantee intellectual property rights compliance (Yusuf and Moncayo von Hase, 1992, p. 128).

Parallel imports are not a means of disregarding a patent-holder's rights to payment (which he receives through the product's first sale), but to ensure that patents work to "the mutual advantage of producers and users of technological knowledge" (Article 7 of the TRIPS Agreement) within a global economy.

The recognition in the TRIPS Agreement of the principle of international exhaustion may be considered as a logical result of the economic globalization process. Thanks to the progress in transportation and communications and the steady reduction of tariff and non-tariff barriers on a worldwide scale, the boundaries of "domestic" markets are vanishing. From an economic point of view, parallel imports may contribute to the competitiveness of local companies, which may be jeopardized if they are obliged to buy solely from a local distributor whose prices may higher than those charged elsewhere. Equally, the consumer's interests may be better served if the right to purchase legitimate products from lower-priced sources—domestic or foreign—is recognized. Parallel imports may lower prices and encourage rights-holders to establish themselves locally in the country where their products are being imported in order to monitor the market and adjust their market strategies to changing conditions (Reichman, 1993, p. 7).

The doctrine of international exhaustion of intellectual property rights has been applied in two important cases by the Japanese courts. The High Court of Tokyo held, in the case of *Jap Auto Products Kabushiki Kaisha & Anor vs. BBS Kraftfahrzeug Tecynik A.G* (1994), that the parallel imports of automobile parts purchased in Germany did not violate patents granted to BBS in Japan. And in the *Aluminium Wheels* case, the High Court of Tokyo sustained, in July 1997, that Article 4bis of the Paris Convention ("Independence of the patents for the same invention in several countries") did not apply in Japan, and that parallel imports were a matter of domestic policy in each country.

In the United States, parallel imports are generally permitted, in the absence of binding contractual restrictions (Barrett, 2000, p. 984). A decision by the United States Supreme Court of 9 March 1998 confirmed the principle of international exhaustion of rights with regard to the importation of copyrighted items sold in the "grey market" (*Quality King Distributors Inc. vs. L'Anza Research International Inc.*).[10] In other countries, the international exhaustion of intellectual property rights has been accepted, at least with regard to trademarks and copyrights. This is the case, for example, of Australia (Omaji, 1997) and New Zealand (in relation to copyrights).

The United States questioned Section 15C of the South African Medicines and Related Substances Control Act (1997), which stipulates that "the Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public" and, in particular, the conditions under which any medicine put on the market by the patent-holder, or with its consent, may be imported by a third party in South Africa.

Despite the legality of South African law within the context of the TRIPS Agreement, the United States Government and the pharmaceutical industry

put enormous pressure on the South African Government to eliminate such measures, among others by including South Africa on the list of the "Special 301 Section" of the US Trade Act[11] in December 1999. With the support of several NGOs (in particular those concerned by the dramatic increase of HIV/AIDS prevalence rates in South Africa), the Government of South Africa resisted those pressures.[12]

The application of the principle of international exhaustion of rights in the public health sector may be of particular importance. Allowing a (patented) medicine to be imported from a country where it is sold cheaper than in the importing country may benefit a large number of patients and increase access to this product. Meanwhile the patent-holder receives payment for the patented invention in the country where the product was originally sold. The acceptance of parallel imports may therefore be considered as one of the measures compatible with the TRIPS Agreement that WTO member countries may explicitly use to protect public health (Section 1 of Article 8 of the Agreement). This was expressly stated in the "Declaration on the TRIPS Agreement and Public Health"[13] (the "Doha Declaration"), adopted at the Fourth World Trade Organization (WTO) Ministerial Conference in November 2001.

Exceptions to patent rights

Exceptions to patent rights may include the use of an invention for experimental, educational and research purposes, as well as for use prior to the granting of a patent. Other exceptions may be based on other public interest reasons, such as public health or the protection of the environment.

Article 30 of the TRIPS Agreement defines, in very general terms, the exceptions that members may allow.[14] It leaves a substantial margin of freedom for national laws to define the type and scope of possible exceptions to patent-holders' exclusive rights. On the basis of comparative law, different types of exceptions may be provided for within the scope of Article 30, such as:

- acts for private purposes, on a noncommercial scale or for noncommercial purposes;
- use of the invention for research;
- use of the invention for teaching purposes;
- experimentation on the invention to evaluate or improve it;
- preparation of medicines under individual prescriptions;
- experiments made for the purpose of seeking regulatory approval for marketing of a generic version of the product after the expiration of a patent;
- use of an invention by a third party that has used it in good faith prior to the patent application date.

Some of these exceptions are particularly important within the context of technological policies, such as the "experimental use" exception, and to promote competition and access to medicines, such as the so-called "Bolar" exception. These exceptions are considered below.

Experimental use exception

Exceptions relating to research and experimentation on a patented invention may be an important tool to create a favorable context for innovation. The adoption of an experimental use exception may permit innovation based on existing inventions as well as assessing an invention in order to request a licence or for other legitimate purposes, such as to check whether the disclosure of the invention is sufficient for reproducing it.

In some countries, such as the United States (Wegner, 1994, p. 267), experimentation and research without the authorization of the patent-holder is permitted for scientific purposes only. In some countries, including some European countries, experimentation on an invention is also allowed for commercial purposes. The Community Patent Convention, for instance, provides that there is no infringement in case of "acts done for experimental purposes relating to the subject-matter of the patented invention" (Article 27.b). Jurisprudence on the experimental use exception in European countries—all of which relates to pharmaceutical or agrochemical products—has accepted that it covers research conducted to obtain more information about a product (provided that it is not made solely to convince licensing authorities or customers of the virtues of an alternative product) or to obtain further information as to the uses of a product and its possible side-effects and other consequences resulting from its use (Cornish, 1998, p.736).

Most developing countries apparently have not explicitly used the flexibility permitted by the TRIPS Agreement to formulate an experimental use exception, or a "Bolar" exception.

The "Bolar" exception[15]

Another important exception, first introduced by the United States, deals with the use of an invention relating to a pharmaceutical product to conduct tests and obtain approval from the health authority before the expiration of the patent, for commercialization of a generic version immediately after the expiration of the patent. Australia, Canada, Israel and the United States, among other countries, have incorporated this exception through laws or jurisprudence.[16] In exchange for this permission, some countries have authorized the term of a patent to be extended for an additional period.

The US Drug Price Competition and Patent Term Restoration Act of 1984 permits testing to establish the bio-equivalence of generic products

before the expiration of the relevant patent. The purpose of this exception is to help generic medicine producers to place their products on the market as soon as a patent expires, and thereby allow consumers to obtain medicines at much lower prices immediately thereafter. In exchange for this exception to exclusive patent rights, the patent term of the original medicine could be extended up to five years.

Canada also adopted a "Bolar" type provision in 1991, explicitly allowing a third party to produce and stockpile the product for release on the market immediately after the expiration of the patent. This exception, particularly if not linked to an extension of the patent term (as for instance in Argentina and Canada), fosters the development of a generic pharmaceutical industry and allows consumers to obtain access to medicines at lower prices as soon as the patent expires.

The consistency of the "Bolar" exception with the TRIPS Agreement was analysed in a case decided in the framework of the WTO. In November 1998, the European Communities and their Member States requested the WTO Dispute Settlement Body (DSB) to establish a panel to examine the consistency of the Bolar provisions in the Canadian Patent Act with Canada's obligations under the TRIPS Agreement. In March 2000, the WTO panel concluded that Canada was not in violation of TRIPS in terms of its practice of allowing the development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the consent of the patent-holder. However, Canada was found to be acting inconsistently with TRIPS in terms of its practice of allowing a third party to manufacture and stockpile pharmaceutical products during the six months immediately prior to the expiry of the 20-year patent term (WTO WT/DS114/R).

The admission of an exception for initiating approval procedures for generic medicines (and, in some cases, agrochemicals) before the expiration of a patent seems to have gained growing support. This exception does not need to be linked to an extension of the patent's period of validity to be consistent with the TRIPS Agreement requirements.

Compulsory licences

A compulsory license is an authorization granted by the government for the use by a third party of a patent or other intellectual property right without the consent of the rights-holder.

Article 31 of the TRIPS Agreement expressly allows the granting of compulsory licenses on patents under certain conditions. No specification is made in the Agreement, however, on the *grounds* under which such licenses can be granted. A particular, but not exhaustive, reference is made

to the cases of national emergency or extreme urgency, dependency of patents, licenses for public noncommercial use, and licenses to remedy anti-competitive practices. National laws can, however, provide for the granting of such licenses whenever the title-holder refuses to grant a voluntary license "on reasonable commercial terms" (Article 31.a) (see WTO, 1995) and for other reasons, such as public health or public interests at large.

But while TRIPS does not limit the grounds for compulsory licensing,[17] it does impose conditions regarding the procedures to be followed; for example, the beneficiary of the compulsory license should first have tried to obtain a voluntary license from the patent holder on reasonable terms and conditions (Article 31(b) of TRIPS), and should pay "adequate remuneration" to the patent-holder (Article 31(h)). It should be noted that in some cases—for instance, emergency and public noncommercial use—there is no need for such a prior request for a voluntary license. Licences to remedy anti-competitive practices are subject to a special treatment with regard to the remuneration to be paid.

The TRIPS Agreement also allows for compulsory licences in cases of lack of or insufficient exploitation. Article 27.1 of the Agreement stipulates that "patent rights [shall be] enjoyable without discrimination . . . whether products are imported or locally produced". Although this has been understood as prohibiting any obligation to locally use a patented invention, this interpretation is not based on a literal reading of the provision, as would be mandated by the Vienna Convention on the Law of the Treaties (Article 31). The Preamble of the Agreement, as well as Articles 7 and 8, make it clear that one of the objectives of the Agreement is to promote technology transfer, which may be ensured in some circumstances by means of compulsory licences due to lack of exploitation. The interpretation of this Article[18] is likely to be finally settled under WTO procedures if a dispute thereon arises between WTO members.[19]

Most countries in the world—including developed countries—provided for different modalities of compulsory licenses before the adoption of the TRIPS Agreement (Correa and Bergel, 1996). Such provisions have been retained or expanded thereafter. The United States has made extensive use of these licenses.

With regard to the granting of compulsory licences to deal with anti-competitive practices in the Unites States, Scherer has noted that "compulsory patent licensing has been used as a remedy in more than 100 antitrust case settlements, including cases involving meprobamate, the antibiotics tetracycline and griseofulvin, synthetic steroids, and most recently, several basic biotechnology patents owned by Ciba-Geigy and Sandoz, which merged to form Novartis. My own statistical analysis of the most important compulsory

licensing decrees has found that the settlements had no discernible negative effect on the subject companies' subsequent R&D expenditures, although they probably did lead to greater secrecy in lieu of patenting" (Scherer, 1999, p. 12). The United States has also made an extensive use of compulsory licences for government use, in a manner that has led to complaints by the European Union.[20]

Despite the legitimacy of compulsory licences, some countries that have provided for them in their legislation have faced the threat of unilateral retaliations, or the suspension of aid, by certain developed countries. Of particular interest was the dispute between a number of pharmaceutical companies, supported by the US Government, and South Africa in relation to South African legislation aimed at allowing parallel imports and compulsory licences for medicines.[21] As in the case of parallel imports, the Doha Declaration has clearly confirmed that member countries have the authority to decide when and why to grant compulsory licences.

Conclusion

The new rules for intellectual property rights, as contained in the TRIPS Agreement, provide for greater uniformity of national legislation and practices related to intellectual property rights. But the TRIPS Agreement is not a "uniform law". TRIPS leaves certain flexibilities for WTO member countries to adopt different legislative policies in some respects. Such flexibilities may be used, in particular, in order to adopt pro-competitive measures that may, as described previously, facilitate the dissemination of innovations and, especially, ensure access to medicines. While some countries have already incorporated compulsory licenses, parallel imports, the "Bolar" exception and other flexibilities in their legislation, others that have not yet done so should act promptly in order to ensure that such measures are available to protect, as necessary, public health.

References

1. Barrett, Margaret (2000), "The United States doctrine of exhaustion: parallel imports of patented goods", Northern Kentucky Law Review, vol. 27, No. 5.
2. Bond, Patrick, (1999), "Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians", *International Journal of Health Services*.
3. Cook, Trevor (1997), "Pharmaceutical patents and the generic sector in Europe", Patent World, February.
4. Cornish, W., (1989), *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, Sweet & Maxwell, London.
5. Cornish, W., (1998), "Experimental Use of Patented Inventions in European Community States", IIC, vol. 29, No.7.

6. Correa, Carlos (1999), "Intellectual property rights and the use of compulsory licenses: options for developing countries", South Centre, Geneva.
7. Correa, Carlos (2000), "Emerging trends: new patterns of technology transfer", in Patel, S., Roffe, P. and Yusuf, A, (Editors), *International technology transfer. The origins and aftermath of the United nations Negotiations on a draft Code of Conduct*, Kluwer Law International, The Hague.
8. Correa Carlos (2007), *Guidelines for the examination of pharmaceutical patents: developing a public health perspective, Working Paper*, Geneva: ICTSD, UNCTAD, UNDP and WHO. Available at www.ictsd.org.
9. Correa, Carlos and Bergel, Salvador, (1996), *Patentes y Competencia*, Rubinzal-Culzoni, Santa Fe.
10. Correa, Carlos and Musungu, Sisule (2002) The WIPO Patent Agenda: the risks for developing countries, Working Paper No. 12, South Centre, Geneva.
11. European Commission, (1997), Report on United States Barriers to Trade and Investment.
12. Fugate, W. (1991), *Foreign commerce and antirust laws*, 4 ed., Little Brown and Co.
13. Geuze. M. and Wager, H, (1999), "WTO Dispute Settlement Practice Relating to the TRIPS Agreement", *Journal of International Economic Law*, No. 2.
14. Graz, Dominique (1988), *Propriété Intellectuelle et libre circulation des marchandises*, Libriarie Droz, Geneva.
15. Hoekman, Bernard y Kostecki, Michel (1997) *The Political Economy of the World Trading System. From GATT to WTO*, Oxford, Oxford University Press.
16. Jackson, John, (2000), *The jurisprudence of GATT & the WTO*, Cambridge University Press, Cambridge.
17. Marceau, Gabrielle and Pedersen, Peter, (1999), "Is the WTO Open and Transparent? A Discussion of the Relationship of the WTO with Non-governmental Organisations and Civil Society´s Claims for more Transparency and Public Participation", *Journal of World Trade*, vol. 33, No.1.
18. NERA (National Economic Research Associates), (1998), *Policy relating to generic medicines in the OECD. Final report for the European Commission*, December, London.
19. OECD, *Technology and the Economy. The key relationships*, Paris, 1992.
20. Omaji, Paul, (1997), "Infringement by Unauthorised Importation under Australia Intellectual Property Laws", EIPR.
21. Pugatch, Meir P. (2004), *Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access*, paper presented at the ICTSD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, 12-16 October.
22. Reichman, J. (1993), *Implications of the draft TRIPS Agreement for developing countries as competitors in an integrated world market*, UNCTAD, Geneva.
23. Reichman, J and Hasenzahl, C. (2002), *Non-Voluntary licensing of Patented Inventions: Historical Perspectives, Legal Framework under TRIPS, and an*

Overview of the Practice in Canada and the United States of America, UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development (Issue Paper No. 5, 2003) Geneva, available at http://ictsd.org/i/publications/11764/.

24. Scherer, F. (1999), "The patent system and innovation in pharmaceuticals", ponencia presentada ante el "Colloque de Toulouse: Brevets pharmaceutiques, innovations et santé publique", Toulouse, 28-30 January.
25. Schott, Jeffrey J., (1994), *The Uruguay Round. An Assessment*, Institute for International Economics, Washington, D.C.
26. Sell, Susan (2003) Private Power, Public Law: The Globalization of Intellectual Property Rights, Cambridge University Press, Cambridge, 2003.
27. Skolnikoff, E. (1993), "New international trends affecting science and technology", *Science and Public Policy*, vol. 2 No. 3.
28. South Centre, (1995), *The Uruguay Round. Intellectual Property Rights Regime. Implications for Developing Countries*, Cartagena.
29. UNDP (1999), *Human Development Report*, Nueva York.
30. Wegner, Harold (1994), *Patent law in biotechnology, chemicals & pharmaceuticals*, Stockton Press, Nueva York.
31. WTO (1995), "Environment and TRIPS", WT/CTE/W/8, Geneva.
32. Yusuf, Abdulqawi and Moncayo von Hase, Andrés, (1992), "Intellectual Property Protection and International Trade-Exhaustion of Rights Revisited", *World Competition*, vol.16, No.1, Geneva.

Endnotes

1. See, e.g., Jerome H. Reichman and Hasenzahl (2002).
2. See, however, in Correa, 1999, some decisions in the United States that required the patent holder to transfer the relevant know-how.
3. The USA has held at the Council for TRIPS that in the TRIPS Agreement there was 'no prescription as to how WTO Members define what inventions are to be considered "new" within their domestic systems' and, hence, that its legislation was 'perfectly consistent with the provisions of the TRIPS Agreement'. See document IP/Q3/USA/1, May 1, 1998.
4. See, e.g., Jaffe, Adam B. and Lerner, Josh (2004), *Innovation and Its Discontents: how our broken patent system is endangering innovation and progress, and what to do about it*, Princeton University Press.
5. European Commission (2009), *Executive Summary of the Pharmaceutical Sector Inquiry Report*, p, 10, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf
6. Section 3(d) provides that the following shall not be treated as an invention within the meaning of the Act: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

7. See Correa (2007). See also paper 5.
8. "Parallel imports" take place when a product is imported into a country without the authorization of the rights-holder or his licensees provided that the products entered the foreign market in a legitimate manner. This concept does not include the importation of counterfeited products.
9. ECJ, December 5 1996, joined cases C-267/95 and C 268/95 *Merck vs. Primecrown and Beecham Group vs. Europharm.*
10. The United States Congress passed a law in 2001 authorizing parallel importation of medicines into the United States for cases where a product was being re-imported into the United States (United States *Agriculture, rural development, food and drug administration, and related agencies appropriations Act, 2001*).
11. This section allows the US Government to apply trade retaliations against countries that, in accordance with the US Trade Representative's assessment, does not adequately protect intellectual property rights.
12. On 10 March 2000, President Clinton issued a Decree that instructed the adoption of a flexible policy on HIV/AIDS and the TRIPS Agreement for Sub-Saharan Africa.
13. Document WT/MIN(01)/DEC/2.
14. More specific proposals were formulated during the Uruguay Round of negotiations (e.g. the CEE proposal contained in document MTN.GNG/NG11/W/26 of July 7 1988) but they were not included in the final text.
15. This exception was named "Bolar" from the case tried by the United States courts in *Roche Products Inc. vs. Bolar Pharmaceutical Co.* (733 F. 2d. 858, Fed. Cir., cert. denied 469 US 856, 1984), in which the exception issue was raised. The court denied Bolar the right to initiate the approval request procedures before the *Food and Drug Administration* prior to the patent's expiration.
16. In some European countries, the ·exception based on the statutory review was gradually accepted by the jurisprudence on the basis of the already-mentioned right of a third party has to undertake experimentation without the authorization of the patent-holder (Cook, 1997; NERA, 1998). The exception was formally accepted by the European Parliament in 2004.
17. The only case in which the Agreement does restrict the freedom to determine the grounds for compulsory licences relates to "semi-conductor technology", which can only be subject to compulsory licences for public noncommercial use and to remedy anti-competitive practices.
18. Article 5A of the Paris Convention for the Protection of Industrial Property explicitly allows contracting parties to grant compulsory licenses to remedy abuses,

including lack of working. In addition, correctly interpreted, Article 28 of the TRIPS Agreement only confers negative rights; this means that the reference in Article 27.1 of said Agreement to locally produced or imported products can only allude to infringing products of third parties and not to products manufactured or imported by the patent owner.

19. The United States requested a panel against Brazil under the WTO's Dispute Settlement Agreement in relation to the Brazilian provision (Article 68 of the Industrial Property Law) on compulsory licenses for cases of non-exploitation. However, the complaint was withdrawn before the panel was constituted.
20. See European Commission, 1997.
21. See Sell (2003).

paper 3

Introduction to patent law*

Sudhir Krishnaswamy

This paper introduces the basic elements of patent law and reviews the core legal concepts and essential vocabulary in patent law necessary to ensure an understanding of the legal fundamentals in this area of law. It provides a foundation for the papers that follow, which examine discrete aspects of patent law in greater detail.

The paper is organized into three sections. The first section looks at the sources of patent law, its general scope and application and the subject matter to which it applies. The next section examines three key criteria (novelty, inventive step and industrial applicability) that any invention has to satisfy in order to secure a patent. The concluding section examines the procedure by which a patent application is made, prosecuted and granted.

Sources of patent law

A patent is the grant of an exclusive right to an invention, which ensures that no other person may make, use, distribute or sell the patented product or use the patented process. The invention may relate to either a process or product (or both) in any field of technology, barring those expressly excluded by the patent laws of a country.

A patent grants the patent owner a negative right to prevent others from using the invention in particular ways. This does not mean that the patent owner has the positive right to market his invention. Often there are hurdles, both technological and regulatory, to be overcome before a patented invention can be marketed. However, where patented inventions have a market, the patent confers valuable rights which the patent owner may exercise personally or may assign or transfer by succession or licence.

* Ms Suchita Saigal contributed significantly to the research and writing of this article.

The exclusive rights granted to the owner of a patent include the right to prevent third parties not authorized by the patent owner from:

(1) making the invention;

(2) using the invention;

(3) offering for sale and marketing the invention; or

(4) importing the invention for any of the above mentioned purposes.

The distinction between a process and product patent is critical to a discussion of pharmaceutical patents and public health. A product patent protects a material thing or substance. This thing or substance may for example be a new chemical substance (often referred to as a "new chemical entity") or a new machine or apparatus. A product patent means that no one may make the product without the authorization of the patent holder. Thus, the scope of protection is wide in the case of a product patent.

A process patent protects the manner in which a particular output is achieved.[1] For example, where a pharmaceutical substance is already known, inventive activity may result in a new method to produce the substance more efficiently or less expensively. The known pharmaceutical substance may or may not be covered by an existing patent. Nevertheless, a patent may protect the new and more efficient procedure developed by the inventor. In case of a process patent, third parties may not use the patented process without authorization—but they cannot be prevented from using a different process to obtain the same result. Maintaining the distinction between product and process patent claims is critical to ensuring continuing innovation in the pharmaceutical industry and access to affordable medicines.

Historically, many countries adopted a policy and legal framework that did not grant product patents in the field of pharmaceuticals, foods, chemicals and fertilizers. Such policies facilitated the development of a domestic generic drug industry in countries such as India. The TRIPS Agreement[2] mandatorily requires the adoption of product patents in all fields of technology. Several countries including India have amended their patent law to ensure compliance with this requirement; hence it is critical to understand how process and product patent claims operate in tandem.

There is a significant body of literature that examines whether the grant of a patent is justifiable philosophically or as a matter of economic policy. However, most courts assume that some such justification is available. The Indian Supreme Court in the case of *Bishwanath Prasad Radhey Shyam* v. *Hindustan Metal Industries*,[3] held that "the object of patent law is to encourage scientific research, new technology and industrial progress. Grant

of exclusive privileges to own, use or sell the method or the product patented for a limited period, stimulates new inventions of commercial utility. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which after expiry of the fixed period of the monopoly, passes into the public domain."[4] Recent contributions to the academic debate on the justification for patent law doubt whether patents are necessary for economic development[5] and whether patents promote and sustain innovation.[6] Ironically, the growing academic scepticism about the role of patent law in promoting the public good has been accompanied by a dramatic expansion of the scope of patentability and the rights of patent holders.

The sources of patent law are the national laws on the subject and the relevant international patent law. The Paris Convention 1967,[7] as revised and amended, introduced the rules of national treatment, priority and some common rules relating to compulsory licenses into patent law. The Patent Cooperation Treaty 1970 introduced a procedure whereby an applicant could make a single application in several countries simultaneously. The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994[8] sets common substantive standards regarding patentable subject matter, criteria of patentability, scope of rights granted to inventors and the manner of their enforcement. Most recently the Patent Law Treaty 2000 sets out the formalities in the application procedure that may be required by parties. There are ongoing negotiations in relation to a Substantive Patent Law Treaty (SPLT).[9]

Despite this body of international law on patents it is important to reiterate that a patent is granted by a national authority acting under the authority of national law. Hence, in order to understand specific patent regimes, one must identify the laws that apply to the grant and exercise of patents in the concerned jurisdiction. In India the Patents Act, 1970 (as amended to date; hereafter the Act) and Patent Rules, 2003 constitute the legal framework that governs the grant and exercise of patents. The rest of this paper is confined to the analysis of the relevant Indian legal materials, for the purpose of illustration.

The criteria of patentability

For a patent to be granted, the applicant must show that there is an invention which satisfies the criteria set out under the Act. An "invention" is a *new product* or *process* involving an *inventive step* and [being] *capable of industrial application*.[10] Hence products and processes may qualify as inventions if the three criteria of novelty, inventive step (also referred to as non-obviousness), and industrial application are satisfied and the subject matter of the invention does not fall under one of the statutory exceptions.[11] The paper will examine

each of these criteria in turn and begin with a discussion on subject matter in the next section.

Subject matter

In order to secure a patent the subject matter of an invention should be patentable. Article 27 of the TRIPS Agreement deals with the patentability of subject matter and makes three exclusions in relation to pharmaceutical products:

(a) Subject matter, the commercial exploitation of which is prevented in order to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[12]

(b) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

(c) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.[13]

Sections 3 and 4 of the Patents Act deal with patentable subject matter. It is difficult to identify a single principle which justifies the varied exclusions from patentable subject matter set out in Section 3. The invention may be excluded for being contrary to public order or morality or being a mere discovery of a natural law.[14] Given the breadth of these exclusions, this paper will examine only one such exclusion in detail below.

Section 3(d) renders "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of a new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant", not to be classed as an invention under the Act.

The validity of this provision was challenged by Novartis AG on two grounds: first for non-compliance with the relevant provisions of the TRIPS Agreement, and second, for utilizing a vague and arbitrary standard that offered no guidance to the patent office and therefore violated the constitutional guarantee of equal protection. The court declined to go into the first challenge, related to TRIPS compliance, as it concluded that international legal rules did not apply in domestic litigation. The court rejected the second challenge and held that enhanced efficacy was a reasonable basis to make a distinction between inventions that would be granted patents and those that would be denied patents. By sustaining the constitutional validity of

section 3(d) the Madras High Court maintains the broad scope of Section 3 exceptions.

This section concludes with a couple of general observations about the nature of subject matter exceptions in section 3. Section 3 lists non-patentable subject matter in an exclusive and not inclusive manner.[15] However, each sub-clause is phrased in a general manner and may be interpreted broadly. Further, not all exclusions are absolute—a computer program *per se* is not patentable, but if embedded in a machine or chip, it may be patented. The next section will consider the first of the three criteria that an invention must satisfy to be granted a patent.

Novelty

In order to be patentable, a new product or process must satisfy the criteria of novelty, non-obviousness and industrial applicability. Section 2(1)(j) of the Act defines an invention to include the element of novelty by specifying that it should be a "new" product or a new process. Section 2(1)(l) of the Act goes further and defines a "new invention" as any invention or technology that has not been "anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing the patent application with complete specification, i.e., the subject mater has not fallen in the public domain and does not form part of the state of art." Novelty is set out in different and more elaborate terms in the provisions relating to examination[16] and opposition[17] prior to the grant of the patent, and in the provision on revocation[18] of a patent that has been granted.

The Indian courts have emphatically cited from Halsbury's Laws of England to explain that: "To anticipate a patent, a prior publication or activity must contain the whole of the invention impugned; … In other words, the anticipation must be such as to describe, or be an infringement of the claim attacked."[19] This proposition emphasizes the strongest manner in which an invention may be anticipated: if a single source of prior art contains all elements of the claimed invention.[20]

Anticipation of an invention is judged against the existing state of knowledge in the particular field i.e., the prior art. In Indian law, prior art means prior public knowledge or prior public use in India before the priority date of the claim, or prior publication in India or elsewhere in any document. Anticipation by prior public use and prior public knowledge is limited to such prior use and knowledge in India. The Indian law, like US law on the subject, seems to adopt a mixed novelty standard where prior use or knowledge is determined by a local enquiry whereas prior publication is a subject of global enquiry. Thus, if an invention is publicly used in the United Kingdom, such

use will not amount to prior use for the purposes of patenting that invention in India. There is an exception to this rule in Section 25(1)(k), which relates to the invention being anticipated, *orally* or otherwise (including use) by knowledge available within any local or indigenous community in India or *elsewhere*. On the other hand, anticipation by publication has an absolute novelty standard, i.e., the invention should be novel and not be anticipated by prior publication anywhere in the world. By contrast, the European Patent Convention 1973 and the United Kingdom Patents Act 1977 adopt an absolute or universal novelty standard, where an invention is considered novel only if it is not known, used or published anywhere in the world. Furthermore, as regards anticipation by prior public knowledge and prior publication, it should be noted that for such information to form a part of the state of the art there is no need for the information to be put to actual use. The mere fact that it was available and capable of being used by the public (that is, an unrestricted group of people) is sufficient.[21]

Non-obviousness

Further, a patent may be refused[22], opposed[23] or revoked[24] where the invention claimed is obvious to a person skilled in the art either because it does not involve a technical advance compared to the existing knowledge or does not have an economic significance or both. The process to be followed by the Patent Office to determine the existence of an inventive step has been accounted for in the Draft Manual of Patent Practice and Procedure, 2008. Though the manual is in draft form and faces several objections it offers some insight into the manner in which a patent examiner may determine the non-obviousness of an invention:[25]

(a) Determining scope and content of the prior art to which the invention pertains;

(b) Assessing the technical result (or effect) and economic value achieved by the claimed invention;

(c) Assessing differences between the relevant prior art and the claimed invention

(d) Defining the technical problem to be solved as the object of the invention to achieve the result;

(e) Final determination of non-obviousness, which is made by deciding whether a person of ordinary skill could bridge the differences between the relevant prior art and the claims at issue.

Unlike other areas of patent law in India where precedent is lacking, the Supreme Court of India has explained the concept of inventive step in *Bishwanath Prasad* v. *H. M. Industries*.[26] The Court stated that, "Obviousness has to be strictly and objectively judged. The question to be asked is...

Whether the alleged discovery lies so much out of the track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known."[27]

Determining whether there is or is not an inventive step is a mixed question involving both law and fact. That a routine development is *not* inventive may often be obvious; however, what is not so clear is the point at which "inventiveness" begins. This involves making a judgment that sets some limits around obviousness. One approach has been to consider obvious (and hence non-inventive) a development that a person with some knowledge of the field in question (in this case, pharmaceutical chemistry) would be able to achieve without any additional inventive step going beyond the application of ordinary skill in the trade.

The novelty and non-obviousness tests evaluate an invention against a common background of the prior art. However, the non-obviousness requirement involves more rigorous and complex scrutiny than novelty. While novelty requires that the claimed invention should not be previously disclosed by any prior art source, the non-obviousness criterion requires that the invention is not previously disclosed by the specific prior art sources, and attains a level of inventiveness that places a distance between the claimed invention and the prior art sources taken together. The difference between novelty and non-obviousness is that the former requires an invention to be merely different from the information disclosed earlier whereas the latter requires a qualitative improvement creative enough to warrant a monopoly.[28] The aim of this inventive step criteria is to distinguish between minor improvements to prior art and inventions that actually add significantly to prior art. This distinction prevents the grant of monopoly rights to minor improvements and to inventions that implicitly exist in the public domain.

Article 27 of the TRIPS Agreement lists the requirement of non-obviousness or inventive step, as does Section 2(1)(j) of the Act. Section 2(1)(ja) of the Act goes further and defines the concept of "inventive step" to mean a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and *that makes the invention not obvious to a person skilled in the art*. This provision has given rise to a debate on whether mere economic significance of a claimed invention, in the absence of any technical advance, constitutes an inventive step.

V.J. Taraporewala argues that as economic significance is mentioned as an independent ingredient for what an inventive step means, if satisfied, the claimed invention need not also have technical advance as compared

to the existing knowledge.[29] Shamnad Basheer argues that the introduction of economic significance makes the provision confusing and may possibly result in an interpretation that puts an onus on the applicant to show economic significance *in addition* to technical advance, which unnecessarily duplicates the utility analysis discussed below.[30] This debate on whether technical advance and economic significance should be read conjunctively or disjunctively pays inadequate attention to the second part of section 2(1)(ja).

The first part of the section requires that the invention demonstrates a technical advance or economic significance. The second part of the section requires that this advance or significance "makes the invention not obvious to a person skilled in the art." Hence, it appears that the second part is the operative part of the section and the invention must ultimately show "non-obviousness" to a person skilled in the art.[31] In conclusion, it may be noted that technical advance or economic significance do not control the application of this section.

Capable of industrial application

The third criterion that an invention must satisfy in order to be granted a patent is that it "must be capable of industrial application".[32] Section 2(1)(ac) defines "capable of industrial application" in relation to an invention to mean that the invention must be capable of being made or used in an industry. This is relevant at the stage of examination for granting a patent and is also a ground for revocation of the patent under Section 64(1)(g). The requirement that an invention should be capable of industrial application is also mandated by Article 27(1) of the TRIPS Agreement.

The phrase "capable of industrial application" implies usefulness or utility.[33] An invention that is new and also non-obvious but cannot be put to any use by mankind cannot be patented. However, the non-working of a patent *per se* is not equated to non-usefulness as a patent can be granted for an invention that is "capable of industrial application".[34] The claims must be in priniciple practical and useful and not merely aesthetic or theoretical. This utility requirement allows the invention to be confined to its proper sphere and avoid the patenting of ideas at a premature stage before potential uses have been identified.[35]

The question that arises for consideration often pertains to the quantum of utility required to support the patent. There must be a promise in the specification that a definite degree of advantage would result from the use of the invention, even if this is very small. In other words the new invention must "give the public a useful choice".[36] As stated in Halsbury's Laws of

England, "not useful" in patent law means that the invention will not work, either in the sense that it will not operate at all or more broadly, that it will not do what the specification promises that it will do. If the invention will give the result promised at all, the objection on the ground of want of utility must fail. Terrell states that the protection is purchased by the promise of results, and that it does not, and ought not, to survive "the proved failure" of the promise to produce the results.[37]

Procedure for filing for a patent

So far, this paper has set out the substantive law that governs the grant of a patent in India. This section briefly sketches out the procedures by which a patent may be filed under the Indian law. Invariably the quality and quantity of patents granted in any legal system is a function of the substantive criteria that an invention must satisfy, as well as the procedural scrutiny to which it is subjected. This section describes the procedures adopted in Indian law, which include an elaborate pre-grant opposition process that arguably improves patent quality.

The procedure for obtaining a patent may include the following steps:[38]

(1) Submission of application

(2) Examination of application

(3) Advertisement of acceptance of complete specification (publication of the application)

(4) Opposition to grant of patent to the applicant

(5) Hearing of the parties

(6) Grant and sealing of the patent

(1) Submission of application

The Indian law adopts the first-to-apply (or first-to-file) system and Section 6 of the Act states that the true and first inventor, his assignee or legal representative may make an application. The true and first inventor is the person who is the first to convert the ideas and scientific principles into a working invention. Section 2(1)(y) of the Patents Act clearly states that the true and first inventor does not include either the first importer of an invention into India, or a person to whom an invention is first communicated from outside India. In the event that an assignee is filing an application for a patent over an invention, the assignee is required to give proof of a valid existing assignment. Moreover, the assignee has to name the first and

true inventor, and give a declaration that that person is the true and first inventor of the said invention.[39] The application may be made either alone or jointly with another person.[40]

The general rule is that inventions made by an employee during the course of employment would be patentable by the employer unless there is a contract to the contrary. However, since there are opinions to the contrary, it is common practice is to have specific contractual provisions relating to ownership of inventions invented during the course of employment by an employee and any ownership disputes which arise subsequently are decided in accordance with the contract.[41]

Under Indian law, section 7(1) of the Patents Act provides that only one application can be made for one invention and it has to be made in the prescribed form and filed in the Patent Office. Section 7(1A) provides for applications for international patent under the Patent Cooperation Treaty designating India to be deemed to be an application filed under the Patents Act, 1970. An application made as a single international application in one of the receiving offices will have the right of priority from the date of filing.[42]

Every application must be accompanied by a specification which is a technical document describing the invention. The purpose of filing a specification is to make the invention available to the public and to allow the examiner to assess whether it satisfies the substantive requirements of the Act. The specification, whether provisional or complete, is to be made in Form-2 prescribed under the Patent Rules, 2003 and must follow the guidelines set out in section 10 of the Act. A provisional specification is one which gives the initial description of an invention when the application is filed. A complete specification has to give full and sufficient detail of an invention in such a manner that a person skilled in the art can use the invention when he reads such a description. Every specification should include the title, full and particular description of the invention, disclosure of the best method of performing the invention, claims, drawings (if required) and declaration as to inventorship. If the complete specification does not sufficiently or clearly describe the invention or the method by which it should be performed this can be grounds of opposition proceedings under section 25(1)(g).

(2) Examination of application

The examination of the application involves the enquiry into the following aspects:[43]

- Whether the application complies with the requirements of the Act and Rules;

- Whether there exists any lawful ground of objection to the patent; and
- Whether the invention has already been published or claimed by any other person.

Section 11B of the Act clearly states that no application for a patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period. Once a request for examination is made under section 12 the application, specification and other documents are referred by the Controller of Patents to an examiner for making a report regarding these matters. After the examination the examiner submits a report to the Controller of Patents.

The guidelines for conducting the search are provided for in Section 13 of the Act. Simply put, the Examiner makes a search in the publications, specifications or other documents of prior applications and specifications of patents already granted, to see whether the same invention has already been published or claimed or is the subject matter of existing or expired patents.[44]

(3) Publication of complete specification

While the patent application is not disclosed in full in the initial application phase, it is published after the designated period or on the request of the applicant. The purpose of publication is to let the general public know that the applicant claims to be the true and first inventor of the invention and anybody who seeks to oppose the applicant's claim may do so.[45]

(4) Opposition to grant of patent to the applicant

Any person may oppose the grant of a patent anytime after the publication and before the grant of the patent. In order to oppose a patent, the opposition must be submitted in writing and must show that: the person applying for the patent is ineligible to do so; that the invention is previously disclosed; that the invention is obvious; that the specification does not sufficiently or clearly disclose the invention or the method by which it is to be performed; the invention uses biological material and does not disclose its geographical origin or source and finally if the invention is previously disclosed by traditional knowledge in India or outside.

The elaborate range of grounds on which applications may be opposed has promoted a significant opposition practice in areas such as pharmaceutical patents. The courts have clarified the scope and process of patent oppositions in some detail. As many other jurisdictions have not provided for a pre-grant

opposition process the Indian experience offers considerable insights into the value of such a procedure.

(5) Hearing of the parties

When the Controller receives an application of opposition, the Controller forwards a copy of the notice to the applicant who may file his reply statement within three months from the date of receipt of the copy of the notice. Thereafter, the Controller shall hear the parties and taking into account any evidence in support of their respective stands furnished by the parties, arrive at his decision.

(6) Grant and sealing of the patent

Where, after substantive examination, the application for a patent is found to be in compliance with the provisions of the Act and the Controller has not refused it either with or without any opposition proceedings, the patent shall be granted as expeditiously as possible. The grant of a patent shall confer on the patentee the rights set our section 48 subject to some limitations set out in section 47. Nevertheless, the patent may be opposed within a one-year period from grant by any interested person by opposing before the Controller on the grounds listed in section 25(2). A patent may be revoked on a petition by any interested person before the Appellate Board or by the High Court entertaining a counter claim in a suit for infringement on the various grounds set out in section 64.[46]

References and endnotes

1. WR Cornish *Intellectual Property* (Sweet and Maxwell London 1999 4th ed) 169.
2. Article 27(1) TRIPS Agreement 2004.
3. (1979) 2 SCC 511.
4. Ibid., paragraph 17.
5. FM Scherer *Political Economy of Patent Policy Reform in the United States*. http://ssrn.org/abstract=963136
6. W Cohen and S Merill *Patents in the Knowledge-Based Economy* (National Research Council 2003)
7. The Paris Convention is the first major international agreement relating to the protection of industrial property rights, including patents, providing for, in particular, national treatment, the right of priority and a number of common rules.
8. The TRIPS Agreement incorporates the major principles of the Paris Convention, 1967 but establishes new minimum standards of protection to be adopted by all contracting parties
9. The Substantive Patent Law Treaty is a proposed international patent law treaty aimed at harmonizing substantive points of patent law. The SPLT aims at

harmonising substantive requirements such as novelty, inventive step and non-obviousness, industrial applicability and utility, as well as sufficient disclosure, unity of invention, or claim drafting and interpretation.

10. Section 2(1)(j) Patents Act, 1970 which follows Article 27 of the TRIPS Agreement 1994.
11. FA Khader The Law of Patents (Lexis Nexis New Delhi 2007) 32.
12. Article 27(2) TRIPS Agreement.
13. Refer to Article 27(3) of the TRIPS Agreement.
14. FA Khader The Law of Patents (Lexis Nexis New Delhi 2007) 42.
15. FA Khader The Law of Patents (Lexis Nexis New Delhi 2007).
16. Section 13 Patents Act 1970.
17. Section 25(1) Patents Act 1970.
18. Section 64 Patents Act 1970.
19. *Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning a Corporation etc.* v. *Unichem Laboratories and Ors* AIR 1969 Bom 255 (Para 15).
20. BL Wadhera, Law relating to Patents, Copyright, Trade Marks, Designs and Geographical Indications (Universal Publishers, 3rd ed, New Delhi) 7.
21. For a discussion on anticipation in the Indian Patent law FA Khader The Law of Patents (Lexis Nexis New Delhi 2007) 477.
22. Section 18 Patents Act 1970.
23. Section 25 (1) (e) Patents Act 1970.
24. Section 64(1) (f) Patents Act 1970.
25. Draft Manual of Patent Policy and Practice 2008 (Patent Office) 39.
26. *Bishwanath Prasad Radhey Shyam* v. *Hindustan Metal Industries*, (1979) 2 SCC 511.
27. Ibid., paragraph 26.
28. Lionel Bently and Brad Sherman, *Intellectual Property Law*, 2000, p. 413.
29. Refer to V.J. Taraporewala, *Law of Intellectual Property* (Mumbai: V.J. Taraporewala, 2005) at 57-58.
30. S Basheer *India's Tryst with TRIPS: The Patents Amendment Act 2005* 1 IJLT 15 (2005) 21-23.
31. I thank the anonymous reviewer of this article who hinted at this plausible interpretation.
32. Section 2(1)(j) of the Patents Act 1970.
33. FA Khader The Law of Patents (Lexis Nexis New Delhi 2007) 37.
34. FA Khader The Law of Patents (Lexis Nexis New Delhi 2007) 535.
35. *Halliburton Energy Services Inc.* v. *Smith International (North Sea) Ltd.*, (2006) RPC 2, para 216.
36. *Welsbach Incandescent Gas Light Co. Ltd.* v. *New Incandescent (Sunlight Patent) Gas Lighting Co.*, (1900) 17 RPC 237.
37. Terrell, at page 99.

38. BL Wadhera, Law relating to Patents, Copyright, Trade Marks, Designs and Geographical Indications (Universal Publishers, 3rd ed, New Delhi) 18.
39. Refer to Section 7(3) of the Indian Patents Act, 1970.
40. Refer to Section 6(2) of the Indian Patents act, 1970.
41. For a detailed discussion on this topic refer to FA Khader The Law of Patents (Lexis Nexis New Delhi 2007) 189 - 193.
42. Articles 8 and 10, Patent Cooperation Treaty.
43. Refer to Section 12(1) of the Indian Patent Act, 1970.
44. BL Wadhera, Law relating to Patents, Copyright, Trade Marks, Designs and Geographical Indications (Universal Publishers, 3rd ed, New Delhi) 23.
45. BL Wadhera, Law relating to Patents, Copyright, Trade Marks, Designs and Geographical Indications (Universal Publishers, 3rd ed, New Delhi) 24.
46. Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries, (1979) 2 SCC 511.

paper 4

Patentability standards: When is an invention patentable?*

Carlos M. Correa

Introduction

The patent system was devised in order to reward inventiveness, encourage technical progress and foster the dissemination of innovations. The restriction of the free movement of ideas that the granting of a patent entails has been justified under different theories, such as natural rights, moral reward, incentive to innovation. The idea that patents are necessary to allow the investor/inventor to recoup the investment in research and development (R&D) dominates current debates as well as the case law of many countries.[1]

Though the development of numerous contributions to technology have been closely linked to the possibility of obtaining exclusive rights to exploit inventions,[2] the patent system today is far from fulfilling its intended objectives. The expansion of the subject matter of patentability—what actually can be patented—from inanimate things to life forms, the admission of broad claims encompassing vast fields of technology, the dilution of the patentability requirements, and shortcomings in the examination process have led to a profound distortion of the system.[3] There is a proliferation of patent applications and grants, in great part motivated by a variety of defensive and offensive patenting strategies.[4] Under these conditions, patents tend to maximize the monopolization of technologies while minimizing the diffusion of innovations.[5]

One increasingly widespread view is that the patents system is in crisis,[6] and that its role in promoting innovation is less substantial than usually claimed.[7] Patents may even stifle the very innovation they are supposed to foster. The National Academies of Sciences of the United States have taken up the criticism leveled by many academics and sectors of industry and

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have expressed their concern about the lax application of the patentability standards,[8] especially as regards non-obviousness and usefulness, in the examination of patents, resulting in many overly broad[9] or "low quality" patents.[10]

Even the users and main beneficiaries of the patent system have become increasingly critical. A survey conducted among large companies (with annual revenues exceeding US$10 billion) by the Intellectual Property Owners Association (IPO) in August 2005 showed that its corporate members "perceive the quality of patents granted by the U.S. Patent and Trademark Office to be less than satisfactory. Over half of respondents, 51.3 per cent, rated the quality of patents issued in the U.S. today as less than satisfactory or poor (47.5 per cent less than satisfactory and 3.8 per cent poor). Those rating quality more than satisfactory or outstanding were 8.8 per cent of all respondents (8.8 per cent more than satisfactory and 0 per cent outstanding). Respondents' prognosis for the future was not encouraging. Over two-thirds of respondents said they would be spending more, not less, on patent litigation over the coming years".[11]

The efficacy of the patent system for ensuring a satisfactory rate of innovation at the lowest social cost is in serious doubt. A basic question in developed countries is how to ensure that patents actually encourage innovation, rather than unduly limit competition and hold back innovation.[12] As incremental innovations prevail in most sectors (including biomedicine), the patent system has increasingly moved away from its objective of stimulating genuine "invention" towards a system for the protection of investment in incremental innovation, whether truly inventive or not. For some analysts, "the time has come not for marginal changes but for wide-open thinking about designing a new system from the ground up" (Thurow, 1997).

Determination of the patentability standards

Article 27.1 of the TRIPS Agreement indicates the standards that an invention should meet to be granted, but leaves WTO members considerable leeway to determine the criteria for their application. In fact, these criteria vary considerably across countries.

In practice, the concept of "novelty" is narrowly construed by patent offices, requiring an almost "photographic" disclosure of the invention in a single prior document in order to consider that novelty does not exist. For experienced patent applicants, overcoming novelty barriers is just a matter of clever design of patent applications. Important issues are raised, among others, in cases where an invention is not found *expressis verbis* in a document but may be derived therefrom, and where an invention is

selected from a family of products already disclosed (the so-called "selection inventions").[13]

WTO members, however, are not constrained to apply a particular concept of novelty. This has permitted, for instance, the United States to maintain a dual standard depending on whether the disclosure of the invention has taken place within or outside the territory of the United States (35 U.S.C Section 102 (a)).[14] The United States held in this regard that in the TRIPS Agreement there was "no prescription as to how WTO Members define what inventions are to be considered 'new' within their domestic systems" and, hence, that its legislation was "perfectly consistent with the provisions of the TRIPS Agreement".[15]

Defining "non-obviousness/inventive step" is one of the most critical aspects of a patent regime, as it determines the level of technical contribution required to obtain a patent. As the TRIPS Agreement does not define this concept, member countries are free to determine whether they want a system under which a myriad of minor, incremental, developments are patentable,[16] or one aimed at rewarding substantive departures from the prior art. The original proposal of the Substantive Patent Law Treaty (SPLT) opted for the first approach. The draft regulations of the SPLT proposed a broad definition that imposes a low standard for determining inventive step.[17] The claimed invention would be assessed, in terms of inventiveness, against the general knowledge of an ordinary skilled person, and not against specialized knowledge in a particular field of technology.

Such a low standard corresponds to the current administrative and judicial practice in the United States, but the level of inventiveness was not always the same in that country; it changed over time as the patent office and courts adopted a more or less favorable attitude to patents. Chisum and Jacobs (1995, p. 2-14/2-15) recall an early precedent wherein Justice Bradley stated that "[I]t was never the object [of the patent laws] to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures" (*Atlantic Works v. Brady, 107 U.S. (17 Otto) 192, 1883*). Fifty years later, Justice Douglas stated that a new device, to be patentable, "must reveal the flash of creative genius" (*Cuno Engineering Corp., 314 U.S. 84, 51 U.S.P.Q. 1, 1941*), while in another case the Court considered that a combination of old mechanical elements was patentable only if it showed "unusual or surprising consequences" (*Great Atlantic & Pacific Tea Co. v. Supermarket equipment Co., 340 U.S. 147, 87 U.S.P.Q. 303, 950*). The US Supreme Court's requirement of non-obviousness was so high that Justice Jackson complained, in dissent, "that the only patent that is valid is one which this Court has not been able to get its hands on" (*Jungersen v. Ostby & Barton Co., 335 U.S. 560, 80 U.S.P.Q. 32 (1949)*

dissenting opinion). The concept of invention elaborated in these cases is in sharp contrast with that currently applied by the US Court of Appeals for the Federal Circuit specialized in intellectual property matters.[18]

However, a recent decision by the Supreme Court[19]—where it stated that "a person of ordinary skill is also a person of ordinary creativity, not an automaton"—suggests the Court's intention to restore a higher standard of non-obviousness.[20]

Finally, while most countries apply a standard of "industrial applicability", the United States and a few other countries rely on the much broader concept of "utility". A strict application of the industrial applicability standard would allow patents on the second indications of pharmaceutical products—as well as other methods that do not lead to an industrial product—to be refused.

Adapting patent law to innovation systems

Patents are granted to promote innovation. The formulation of a patent law, hence, should not be dissociated (as is generally the case) from the characteristics of the innovation system of the relevant country.[21] This relationship has been generally ignored in the technical assistance provided through bilateral or multilateral programmes. Advice has been generally given on the basis of "model laws" that make no distinction according to the degree of sophistication of the local innovation system.

Interestingly, there is only one provision in the TRIPS Agreement where the relationship between the protection of intellectual property and technological capacity is mentioned. Paragraph 1 of Article 66 ("Least-Developed Country Members") provides that

> In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

The wording of this provision suggests[22] that in order to develop a "viable technological base" LDCs need a flexible intellectual property system—that is, less protection of intellectual property than that required under the Agreement. This is in sharp contrast to the main argument of the proponents of the TRIPS Agreement, which is that more intellectual property protection would lead to more innovation. It is also in line with developing

countries' demand for more flexibility and policy space to develop their own technological capacities.

In most developing countries the innovation systems are fragmented and weak, and overwhelmingly depend on innovations made abroad. In many countries, which have followed the "linear model" of scientific and technological development, the public sector modestly invests in scientific activities—generally focused on subjects of research of interest to developed countries—while the private sector involvement in research and development is low or nonexistent. Domestic firms generally follow "imitative" or "dependent" technological strategies, usually relying on external sources of innovation, such as suppliers, customers and competitors, and at best generate "minor" or "incremental" innovations[23] derived from the routine exploitation of existing technologies.

However, there are growing differences among developing countries. Some developing countries (such as Brazil, China and India) that are more scientifically advanced than others are starting to reap benefits from decades of investment in education, research infrastructure and manufacturing capacity. These countries, which have been termed "innovative developing countries" (IDCs) in recent literature,[24] invest relatively more in R&D than other developing countries; there is a greater involvement of the private sector; and the interactions between public institutions and private companies and with innovation agents in developed countries are more frequent.

Adapting the patent system to these various situations is not a simple task. The considerations relevant to an IDC may well be different from those relevant to less technologically advanced countries. These differences, however, should not be overstated since, on the one hand, developing countries, including IDCs, are equally vulnerable to patent strategies of large companies from developed countries and, on the other, a large portion of the population in those countries live in poverty, and will bear the costs of restrictive patent systems in terms of reduced access to essential goods, such as medicines and chemical products for agriculture.

An example of adaptation of the patent law to local conditions is provided by the amendment, in 2005, of the Indian Patents Act. In order to prevent the so-called "evergreening" of pharmaceutical patents,[25] which delays or impedes competition of generic products, a specific provision was introduced, tightening the inventive step requirement as applied to new forms or modifications of existing products. This section (Section 3(d)) stipulates that the following shall not be treated as an invention within the meaning of the act:

> . . . the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> *Explanation*.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Although this is an important example, the broader question is how to frame the patent system in a country where the innovations generally relate to minor/incremental technical changes. At first sight, such innovations may be regarded as outside the patent system, and a different set of measures to promote them would seem to be called for.

Contrary to what might be thought, however, patents are not granted solely for new or significant improvements of existing technologies. In fact, the largest part of R&D undertaken (by large and small firms) is devoted to the improvement on and further refinement and patenting of existing technologies.[26] Though not all types of incremental innovation may be eligible for patent protection, many actually get it.

Inventions marked by considerable originality[27] do not occur frequently, even in highly intensive R&D industries. For instance, while in the pharmaceutical sector only a small number of "new chemical entities" (i.e. not pre-existing molecules) are patented and approved for commercialization each year,[28] thousands of patents are applied for—and granted—covering processes of manufacture, different crystal forms or formulations, new indications and other aspects of or modifications to existing pharmaceutical products. There is also a great deal of emulation of successful drugs by rival companies,[29] leading to the development of "me-too" drugs. Nearly half of the new drugs approved for use in the United States in the 1990s did not offer important clinical improvements.[30] A study done in Canada on 1147 drugs patented between 1990 and 2003, including derivatives of existing medicines, revealed that 1005 of such drugs (87%) did not provide a "substantial improvement over existing drug products".[31]

The application of low standards of patentability may, in practice, subject to private control both genuine inventions and minor or incremental innovations occur. It might be argued that, as patents might cover both major and minor innovations, a patent regime based on a low inventive threshold could be

functional for the incremental innovations prevailing in developing countries. This would make it unnecessary to adopt other measures to promote the type of incremental innovations that prevail in those countries.

In some countries, such as the United Kingdom, it has been deemed preferable to include provisions in the patent law that allow the patent office a great degree of flexibility in applying the patentability standards, rather than establishing a separate type of protection for small or minor inventions.[32] This is also, de facto, the case in the United States, where a large number of patents with low or minimal inventive step are granted.

This expansive approach on patentability, however, may have negative consequences. On the one hand, as exemplified by the case of pharmaceuticals, large firms with experienced patent lawyers are much better prepared, financially and technically, to exploit a patent regime with a low patentability threshold than domestic firms, and there is a risk of blocking innovation and competition rather than promoting it. In addition, the public will be bound to pay monopoly prices for access to knowledge and products that should be, and should remain, in the public domain.

On the other, the cost of acquisition and, particularly, exercise of patent rights is too high for most local innovators, which are generally small and medium enterprises (SMEs). While SMEs could opt in many cases to seek patent protection, they must bear the costs of filing, registration and maintenance. If there is litigation (either to enforce the patent against infringers or to defend it from validity challenges), victory in courts is not assured, damage claims by competitors may be high and litigation costs can be prohibitive.

Another approach adopted by some countries for the promotion of innovations that may not meet a high standard of inventive step is to provide for the registration of utility models, also known as "petty patents". [33] These may be useful to protect minor or incremental innovations, particularly in the mechanical field. The main differences with patents, as described by WIPO, are the following:[34]

- The requirements for acquiring a utility model are less stringent than for patents. While the requirement of "novelty" is always to be met, that of "inventive step" or "non-obviousness" may be much lower or absent altogether. In practice, protection for utility models is often sought for innovations of an incremental character.
- The term of protection for utility models is shorter than for patents and varies from country to country (usually between 7 and 10 years without the possibility of extension or renewal).
- In most countries where utility model protection is available, patent offices do not examine applications as to substance prior

to registration. This means that the registration process is often significantly simpler and faster, taking, on average, six months.

- Utility models are much cheaper to obtain and to maintain.
- In most countries, utility model protection can only be obtained for certain fields of technology and only for products but not for processes.[35]

Utility model protection is simpler and may be more accessible to domestic companies than patents. The enforcement of the rights conferred may, however, raise the same problems as patents, since litigation will again be costly and of uncertain outcome. The lack of substantive examination might be an advantage, but the risk of exercising the exclusive rights against third parties without a prior scrutiny of compliance with the eligibility requirements is also highly risky.

In Australia, Petty Patents, which were introduced in 1979 mainly to protect functional designs, were replaced in 2000 by "innovation patents".[36] The new law weakened the requirement of "inventive step" and replaced it with an "innovative step", defined as follows:

> An invention is to be taken to involve an innovative step when compared with the prior art base unless the invention would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, only vary from the kinds of information set out in subsection (5) in ways that make no substantial contribution to the working of the invention (Sec. 7(4) of the Australian Patents Act).

The subject matter covered by the Australian innovation patents is the same as under conventional patents, except for plants and animals, or biological processes for the generation of plants and animals.[37]

It is important to note that utility models generally apply in respect of mechanical innovations only. Since such models are not covered by the TRIPS Agreement, WTO members may exclude pharmaceutical innovations from this type of protection. This would be, in fact, the advisable approach, as the use of utility models for pharmaceuticals might encourage "evergreening" practices.

Conclusion

The TRIPS Agreement leaves developing countries considerable room to determine some basic aspects of their patent regimes, such as defining the standards of patentability. In order to adapt such regimes to developing countries' needs and objectives, the nature and characteristics of the local

innovative process must be carefully considered.[38] While in some developed countries—notably the United States—the patentability standards have been relaxed in order to capture a growing number of incremental innovations, developing countries may get little benefit from this approach. Given the public policy implications of granting patent rights, particularly in the area of public health, and the asymmetries in the capacity of foreign and local companies to claim such rights, developing countries' needs can best be served by a system under which patent rights are confined to inventions that are susceptible of industrial application, and which meet universal novelty and strict inventiveness standards.

References

1. Archibugi D. and Malaman, Roberto (1991), "Il brevetto come strumento di appropriazione dell'attività inventiva e innovativa: 1'insegnamento delle indagini empiriche", en Malaman, Roberto, (1991), Brevetto e politica dell' innovazione. Organizzazione a funzioni dell' Ufficio Brevetti, 11 Mulino, Bologna.
2. Canadian Intellectual Property Office (1994), A Guide to Patents, Publications Centre Communications Branch, Industry Canada, Ottawa.
3. Cooper, Christopher (2004), Patently absurd. The most ridiculous devices ever invented, Barnes and Noble, London.
4. Federal Trade Commission (FTC) (2003), To promote innovation: the proper balance of competition and patent law policy, available at htpp://www.ftc.gov
5. Foray, Dominique (1995), Production and distribution of knowledge in the new systems of innovation: the role of intellectual property rights, STI, N°16.
6. Galhardi, Regina, (1994), Small High Technology Firms in Developing Countries, Avebury, Aldershot.
7. Granstrand, Ove, (1999), The economics and management of intellectual property. Towards intellectual capitalism, EE, Northampton.
8. Grubb, Philip, (1999), Patents for chemicals, pharmaceuticals and biotechnology. Fundamentals of global law, practice and strategy, Clarendon Press, Oxford.
9. Gutterman, Alan, (1997), Innovation and competition policy: a comparative study of regulation of patent licensing and collaborative research & development in the United States and the European Community, Kluwer Law International, London.
10. Jaffe, Adam B. and Lerner, Josh (2004), *Innovation and Its Discontents : How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Princeton University Press.
11. Landes W., and Posner, R. (2003), The economic structure of intellectual property law, The Belkup Press of Harvard University Press, Cambridge.
12. Leveque F. and Meniere, Y. (2003), Economie de la propriété intellectuelle, La Découverte, Paris.
13. Levin, R.C.; Klevorick, A.K.; Nelson, R.R. and Winter, S.G., (1987), "Appropriating the Returns from Industrial Research and Development", Brookings Papers on Economic Activity, No.3.

14. Llewelyn, Margaret, (1996), "Protecting Innovation within the European Union: The Proposals for a Community Utility Model System", in Webster, Andrew and Packer, Kathryn, (Eds.), Innovation and the Intellectual Property System, Kluwer Law International, London/The Hague/Boston.
15. Mazzoleni, Roberto and Nelson, Richard, (1998), "The benefits and costs of strong patent protection: a contribution to the current debate", Research Policy, No. 27.
16. Merges, Robert and Nelson, Richard, (1996), "On limiting or encouraging rivalry in technical progress: the effect of patent-scope decisions", in The Sources of economic Growth, Harvard university press, Cambridge/London.
17. Morel, Carlos, Tara Acharya, Denis Broun, Ajit Dangi,Christopher Elias, N. K. Ganguly, Charles A. Gardner, R. K. Gupta, Jane Haycock, Anthony D. Heher, Peter J. Hotez, Hannah E. Kettler, Gerald T. Keusch,Anatole F. Krattiger, Fernando T. Kreutz, Sanjaya Lall, Keun Lee, Richard Mahoney, Adolfo Martinez-Palomo, R. A. Mashelkar, Stephen A. Matlin, Mandi Mzimba, Joachim Oehler, Robert G. Ridley, Pramilla Senanayake, Peter Singer, and Mikyung Yun, (2005). 'Health Innovation Networks to Help Developing Countries Address Neglected Diseases, SCIENCE Vol. 309, 15 JULY.
18. Morgan, S, Bassett, K, Wright, J. Evans, R., Barer, M., Caetano, P., and Black, C.,' "Breakthrough" drugs and growth in expenditure on prescription drugs in Canada,' BMJ, available at doi:10.1136/bmj.38582.703866.AE (published 2 September 2005.
19. National Academies of Science (2003), Patents in the Knowledge-Based Economy, Washington D.C.
20. Oxfam (2000), Cut the Cost. Fatal Side Effects:Medicine. Patents Under the Microscope, Oxford.
21. Scherer, F.M., (1987), 'Comment' on R.E. Evenson, ' International Invention: Implications for Technology Market Analysis ', In Zvi Griliches, ed. R&D, Patents, and Productivity, University of Chicago and National Bureau of Economic Research, Chicago,
22. Steil, Benn, Victor, David and Nelson, Richard (2002) Technological Innovation & Economic Performance, A council on Foreign relations Book; Princeton Univeristy Press, Princeton and Oxford.

Endnotes

1. See, e.g., Gutterman, 1997.
2. See, e.g., Archibugi and Malaman, 1991.
3. See, e.g, Jaffe and Lerner, 2004; OECD (2004);
4. See, e.g., Granstrand, 1999.
5. On the economics of intellectual property, see, e.g., Leveque and Meniere, 2003.
6. See, e.g., Foray, 1995.
7. See, e.g, the analysis in Landes and Posner, 2003; see also Levin, Klevorick, Nelson and Winter, 1997.

8. See, National Academies of Science, 2003.
9. See, e.g., Mazzoleni and Nelson, 1998.
10. See some examples in Cooper, 2004.
11. Patent Litigation Costing More, PR Newswire (press release), New York - Sep 13, 2005.
12. See, e.g, Federal Trade Commission, 2003; Samuelson, 2004.
13. See, e.g., Grubb, 1999.
14. According to this section "A person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States...".
15. See document IP/Q3/USA/1, May 1, 1998.
16. Scherer noted almost two decades ago: "As the bleary-eyed reviewer of some 15,000 patent abstracts in connection with research… I was struck by how narrowly incremental (adaptive?) most "inventions" are" (Scherer, 1987, p 124).
17. See SCP/9/8 Prov. para. 102
18. See Jaffe and Lerner, 2004.
19. Supreme Court of the USA, *KSR International Co. v. Teleflex, Inc., Supreme Court Reporter*, vol. 127, p. 1742.
20. The Supreme Court relied on its previous jurisprudence, particularly on the tests developed in Graham v. John Deere Co. (383 U.S. 1, 1966).
21. For an analysis of intellectual property regimes in the context of different innovation systems, see Steil, Victor, and Nelson, 2002.
22. See also the Preamble of the TRIPS Agreement.
23. These are successive improvements upon existing products and processes which bring out increases in technical efficiency or/and improvements in quality (Galhardi, 1994, p. 49).
24. Morel et al., 2005, p. 401.
25. "Evergreening" refers to the acquisition of new patents over formulations, dosages, etc of existing drugs in order to exclude or limit, beyond the term of the original patent, generic competition with regard to a drug.
26. According to a Guide of the Canadian Intellectual Property Office, for instance, 90% of all patented inventions were minor improvements on existing patented devices (Canadian Intellectual Property Office, 1994).
27. See Merges and Nelson, 1996, p. 128.
28. Between 1975 and 1996 only 1223 new chemical entities were developed (WHO, 2001).
29. Casadio Tarabusi and Graham, 1998, p. 78.
30. Oxfam, 2000, p. 26.
31. Morgan, Bassett, Wright, Evans, Barer, Caetano, Black, 2005.
32. Llewelyn, 1996, p. 195.

33. Utility model protection is granted in Argentina, Armenia, Austria, Belarus, Belgium, Bulgaria, China, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Hungary, Ireland, Italy, Japan, Kazakhstan, Kenya, Kyrgyzstan, Malaysia, Mexico, Netherlands, members of the African Organization of Intellectual Property (OAPI), Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Maldova, Russian Federation, Slovakia, Spain, Tajikistan, Trinidad & Tobago, Turkey, Ukraine, Uruguay and Uzbekistan.
34. WIPO at www.wipo.org/sme/en/ip_business/utility_models/
35. Utility models generally apply to mechanical innovations. In Germany, however, they can also be acquired with regard to chemical and pharmaceutical products.
36. See "The Innovation Patent Bill" of 29 June, 2000 effective on 24 May, 2001.
37. This exclusion does not apply if the invention is a microbiological process or a product of such a process.
38. Another dimension to be considered, which has not been examined in this paper is, of course, the *costs* that patents create to competitors and consumers due to the limits that they impose on the diffusion of innovations and the prices, above marginal costs, that may be charged.

paper 5

Excerpts from "guidelines for the examination of pharmaceutical patents"*

Carlos M. Correa

The guidelines summarized in this paper are intended to be a contribution to the improvement of transparency and efficiency of the patent system for pharmaceuticals, particularly in developing countries. They should be understood in the context of two major issues:

(1) The accessibility of medicines to the world's population as a key element of public health policy; and

(2) Innovation as an essential prerequisite for the existence of medicines.

Given the substantial effects that patents can have on competition and, hence, prices of medicines, the criteria that are applied to examine and grant pharmaceutical patents are extremely relevant for public health policies, and not only a matter of concern for patent and industrial policy. Policy-makers in the health area, as well as patent examiners, should be aware that decisions relating to the grant of a patent (which is generally presumed valid until proven to the contrary) can directly affect the health and lives of the people of the country where the patent is granted and enforced.

The purpose of this paper is to provide a set of general guidelines for the assessment of some of the common types of pharmaceutical patent claims. It responds to growing concerns in different circles about the proliferation of patents that protect minor, and in some cases obvious, variants of existing drugs or processes (such as changes in the drug formulation, salts, esters, ethers, isomers, polymorphs of known molecules, combinations of a known

* The full document *Guidelines for the examination of pharmaceutical patents: developing a public health perspective,* Working Paper, Geneva: WHO, ICTSD, UNCTAD, UNDP is available at http://ictsd.org/i/publications/11393/. The full document contains examples that illustrate the issues raised.

drug with other known drugs) while the number of new chemical entities of pharmaceutical use is declining.

The paper contains recommendations to assess different categories of patent claims for pharmaceutical products and processes. They do not suggest the application of a new requirement of patentability, but rather to take into account, in applying the ordinary requirements of novelty, inventive step and industrial applicability (or utility), specific considerations relating to innovation in pharmaceuticals.

Dosages/doses

Some patent applications claim inventions consisting of the dosage for administration to patients of an existing product, including paediatric dosages. Although drafted as product claims, these claims have the same effect as claims over methods for medical treatment,[1] as the subject matter is not a product or process but the way in which a product is therapeutically used.

Changes in dosages would rarely be of an inventive nature and may be considered as not meeting the industrial applicability standard, since the invention would only have effects on the body and not technical effects.

Recommendation:

New doses of known products for the same or a different indication do not constitute inventions, particularly (but not only) in countries where methods of medical treatment are not patentable as such.

Salts, ethers and esters

Frequently, pharmaceutical patents protect new salts of known active ingredients. Salts are normally formed to increase stability or solubility of the drug. It is common knowledge in the pharmaceutical field that salts result in different solubility and, therefore, in different bioavailability. If an active ingredient is an acid or base, then any chemistry student knows how to make a salt, and can make predictions about its likely physicochemical properties.

There may be exceptional cases in which new salts present unexpected advantages in properties as compared to what is in the prior art. Such advantages should be supported by information about the results of appropriate tests incorporated into the patent specifications.

The processes for forming salts are normally obvious to a person trained in the field. There may be very exceptional cases where forming a salt (for instance, with optimal crystalline characteristics) of complex molecules

requires special skills and may be eventually patentable as a process. However, the complexity of a process does not provide sufficient ground for claiming inventive step.

Similarly, ethers as well as esters of known alcohols, although fundamentally different from salts,[2] are generally subject to the same objection of obviousness.

Any special claims made by an applicant regarding, for instance, a faster therapeutic response of a new salt, should be supported by clinical data that demonstrate this effect. The more special the claims that are made, the more data should be required to examine the viability of the application. It is critical that the new data be properly assessed. Health regulatory authorities have the appropriate expertise in these matters; hence, an articulated cooperation with patent offices in examining these applications might facilitate the task of the patent offices and improve the quality of their decisions.

Recommendation:

New salts, ethers, esters and other forms of existing pharmaceutical products can generally be obtained with ordinary skills and are not inventive. This may not apply, exceptionally, when tests, appropriately conducted and described in the specifications, demonstrate unexpected advantages in properties as compared to what was in the prior art.

Polymorphs

Some therapeutically active ingredients present polymorphic forms, that is, they may exist in different physical forms (as amorphous solid and/or in different crystalline forms), which may have different properties more or less pharmaceutically significant (such as solubility and therefore bioavailability). Polymorphism is a natural property: polymorphs are not "created" or "invented"; they are discovered normally as part of routine experimentation related to drug formulation. They result from the conditions under which a compound is obtained.[3] Any compound that presents polymorphism will naturally tend to its more stable form,[4] even without any human intervention.

The significance of different polymorphs lies almost entirely in their relative rate of dissolution (in theory the extent of dissolution can be affected too, but this is rarely of practical significance). Occasionally there is an effect on long-term stability if the most stable polymorph had not been selected for development in the first place. The practical effect of changing the polymorph is, consequently, on the dissolution rate of the finished product and, potentially, an effect on bioavailability, or a change in the long-term stability profile. There could also be in some cases manufacturing advantages

in choosing a particular polymorph. However, there is no question of an effect on safety or efficacy, since the active ingredient is the same.

Polymorphs can be deemed within the prior art—and therefore non-patentable—if they are inevitably obtainable following the process of the basic patent on the active ingredient. Moreover, the possibility of discovering different crystals is obvious when polymorphism is found.

Solvates, including hydrates, are to be deemed polymorphs according to the International Conference of Harmonization (ICH) of 1999.[5] Hydrates/solvates will rarely be inventive, as they are obvious to produce in most situations. Hence, claims relating to changes in the content of water in known molecules (forming mono-hydrates, bi-hydrates, etc.) should generally be considered non-inventive and not patentable.

For most solvates and polymorphs, like for new salt forms, only data on quality and, where required, bioequivalence are needed, that is, no more data than for the approval of a generic product. This is the reason why in many jurisdictions these variants of a substance are deemed to be the "same" substance for health regulatory purposes.

Recommendation:

Polymorphism is an intrinsic property of matter in its solid state. Polymorphs are not created, but found. Patent offices should be aware of the possible unjustified extension of the term of protection arising from the successive patenting of the active ingredient and its polymorphs, including hydrates/solvates. Processes to obtain polymorphs may be patentable in some cases if they are novel and meet the inventive step standard.

Markush claims

So-called "Markush claims" refer to a chemical structure with multiple functionally equivalent chemical entities allowed in one or more parts of the compound. Markush claims may include a vast number (sometimes millions) of possible compounds. They may be used to obtain a wide patent coverage including a large number of compounds whose properties have not been tested, but only theoretically inferred from the equivalence with other compounds within the claim. Hence, the acceptance of Markush claims generates rights over an extremely broad set of compounds without prior testing or experimentation.

In addition to the ordinary issues relating to the patentability requirements, the consideration of Markush claims raises issues of disclosure

and enablement, since the patent applicant has effectively obtained only a few of the possible elements of the group. Given that a search of prior art for millions of compounds is virtually impossible, the search of the patent office and the corresponding patent grant should be limited to what has been actually assessed and supported by the examples provided in the specification.

Recommendation:

Claims covering a large range of compounds should not be allowed. Patent offices should require patent applicants to provide sufficient information, such as fusion point, Infrared Absorption Spectrum (IR) or Nuclear Magnetic Resonance (NMR), obtained through true testing and experimentation to enable the reproduction by the disclosed method of each embodiment of the invention for which protection is sought. Claims of limited scope could be granted if evidence is provided at least that, with the substitution of any member within the same family class, the same disclosed result would be obtained. The coverage of the patent should be limited to what is actually enabled by the disclosure in the specification.

Selection patents

A "selection patent" is a patent under which a single element or a small segment within a large known group is "selected" and independently claimed based on a particular feature not mentioned in the large group. A "selection invention" may be applied for, for instance, when a range of products characterized as having *n*-carbon atoms has been patented, and later on a patent on a specific range (e.g. C_1-C_4) is claimed.

If a large group of elements is patented, the patent owner may use the selection patent to extend the term of protection for the selected subset beyond the expiration of the original patent.[6] While accepted in some jurisdictions when the selected elements possess a surprising advantage, selection patents have been denied when the supposed advantage is a property shared by all or nearly all the large group.

If a previous patent contains, for instance, a Markush-type claim with a large number of possible compounds without a detailed disclosure, and the compounds claimed in a subsequent patent are not found by simple experiments and show an unexpected advantage, far enough away from the completely disclosed compounds in the previous patent, an issue of inventive step will essentially arise in considering the patentability of the selection.

Recommendation:

As a general rule, selection patents should not be granted if the selected components have already been disclosed or claimed and, hence, lack novelty.[7] If unexpected advantages of existing products were deemed patentable under the applicable law, the patentability of a selection could be considered when an inventive step is present.[8]

Analogy processes

"Analogy processes" are manufacturing processes that are not by themselves novel or inventive, which are used for the preparation of new or inventive but unpatented compounds. The doctrine of analogy processes expands the possibility of appropriation of knowledge in the public domain. A different situation arises when a compound has to be produced by a large number of consecutive steps (chemical reactions). It may be inventive to produce this compound by another much more efficient route (comprising less steps), even if these individual chemical reactions as such were known for other compounds.

Recommendation:

Non-novel or obvious pharmaceutical processes, regardless of whether the starting materials, intermediaries or the end product are novel or inventive, should be considered not patentable as such.

Enantiomers

Enantiomers (or optical isomers)[9] behave in relation to one another as an image does to its mirror image. In organic chemistry, enantiomers spontaneously occur, for example, in compounds that comprise a carbon atom with four different substituents.[10] This property has been exploited in the patent field by often claiming, first, the "racemic" mixture of both enantiomers, and later claiming rights over the most active enantiomer, thus evergreening the originally obtained protection.

It is routine to test whether one or the other enantiomer in isolation is more active than the racemic mixture of both, as it is expected that one optical isomer will typically have much higher activity than the other, so that superior activity for at least one of the isomers as compared to the racemate is to be expected.[11] When the chemical formula of a compound with enantiomers is disclosed, the novelty of the latter is also lost as the formula necessarily reveals the existence of the enantiomers.[12]

Recommendation:

Single enantiomers should generally not be deemed patentable when the racemic mixture was known. However, processes for the obtention of enantiomers, if novel and inventive, may be patentable.

Active metabolites and prodrugs

In some cases, pharmaceutical compounds generate an active metabolite, which is the product of the compound's metabolism in the body.[13] Metabolites are derivatives from the active ingredients that are produced in the body, and cannot be deemed as "created" or "invented". However, active metabolites can have different safety and efficacy profiles to those of the parent molecule.[14]

On the other hand, when metabolized in the body, inactive compounds (called "prodrugs") can produce a therapeutically active ingredient.[15] In some cases, patent claims cover a drug and its prodrug/s.[16] In situations where the active ingredient is not patented, a patent over a prodrug as such may extend control by the patentee over the market of the active ingredient that is metabolized. A prodrug may be regarded as the original drug "in disguise".

One possible way of dealing with patents over prodrugs—which may be novel and inventive in some cases—is to allow them when the patentability standards are met, provided that the active ingredient is properly disclaimed (that is, excluded from the patent claims).

Recommendation:

(a) Active metabolites of drugs should generally not be deemed patentable separately from the active ingredient from which they are derived.

(b) Patents over prodrugs, if granted, should disclaim the active ingredient as such, if previously disclosed or otherwise non-patentable. Like other subject matter claimed in a patent, a prodrug should be sufficiently supported by the information provided in the specifications. In addition, evidence may be required that the prodrug is inactive or less active than the compound to be released, that the generation of the active compound ensures an effective level of the drug and that it minimizes the direct metabolism of the prodrug as well as the gradual inactivity of the drug.

Method of treatment

Some patents claim methods of treatment, including prophylaxis, cure, relief of pain, diagnosis or surgical methods. These claims do not cover a product per se, but the way in which it is used in order to obtain certain effects.

In many cases, a method of treatment claim is not apparent at first sight since reference may be made, for instance, to compositions that are not characterized by their chemical structure or intrinsic characteristics but by their dosage or form of administration. It is important, hence, to carefully examine the claims in order to identify and appropriately deal with cases in which under the appearance of product claims, it is a method of treatment that is actually disclosed.

The TRIPS Agreement (Article 27.2) explicitly allows members to exclude therapeutic, diagnostic and surgical methods from patent protection, and many countries do follow this approach. If such exclusion has been provided for, claims describing such methods or claims that are equivalent thereto should be refused.

Even in the absence of a specific exclusion from patentability, such methods should be deemed not patentable in countries where the standard of industrial applicability applies, since they only produce effects on the body and have no industrial application.[17] The same would apply to the case of cosmetic methods.

In cases where aspects of a therapeutic method are indistinguishable from a non-therapeutic method (for instance a method for cleaning teeth), the method may be considered therapeutic and, hence, non-patentable.

Recommendation:

Methods of treatment, including for prevention, diagnosis or prophylaxis should be deemed non-patentable where industrial applicability is required as a condition for patentability (including in cases where the patentability of such methods is not expressly excluded).

Use claims, including second indications

Patenting of the medical use of a product, including first and second indications[18] of a known medicinal product, has become common practice in the pharmaceutical field. According to a literal interpretation of the TRIPS Agreement,[19] which only obliges to grant patents over products and processes, members are under no obligation to grant use claims, including second indications.

Second indications are accepted in some countries when framed in accordance with the so-called "Swiss" claims.[20] However, the patenting of a new use of a known product including, in particular, second indications, expands the scope of protection inconsistently with the novelty requirement. In addition to the lack of novelty, there are other possible objections to the patentability of second indications:

- there is no industrial applicability, since what is new is an identified effect on the body, not the product as such or its method of manufacture;
- a patent covering the second medical indication of a known product is substantially equivalent to a patent over a method of therapeutic treatment.

Recommendation:

Claims relating to the use, including the second indication, of a known pharmaceutical product can be refused, *inter alia*, on grounds of lack of novelty and industrial applicability.

Endnotes

1. A method of medical treatment (or therapeutic method) is a set of steps that may include the administration of a medicine, applied to the human (or animal) body to treat or cure a disease.
2. Salt forms can affect stability, dissolution rate and manufacturing properties (e.g. powder flow in a hopper). Esters and ethers are generally more lipid-soluble than are salts, thus altering tissue penetrability and sometimes rate of release (for example, steroids have quite different topical potencies when administered as esters). In some cases, the use of esters may confer an advantage in terms of safety and efficacy.
3. The usual process for finding new polymorphs is to recrystallize the active pharmaceutical ingredient from different solvents, or under different recrystallization conditions such as temperature or rate of stirring.
4. Many polymorphs are metastable, that is they have short-term stability, which reduces their utility from a manufacturing and storage perspective. An ordinary skilled chemist who develops a new substance for pharmaceutical use will normally seek to identify the most stable polymorph.
5. "Polymorphic forms: Some new drug substances exist in different crystalline forms which differ in their physical properties. Polymorphism may also include solvation or hydration products (also known as pseudopolymorphs) and amorphous forms. Differences in these forms could, in some cases, affect the quality or performance of the new drug products. In cases where differences exist which have been shown to affect drug product performance, bioavailability or stability, then the appropriate solid state should be specified" (*Specifications: Test Procedures & Acceptance. Criteria for New Drug Substances and New Drug Products: Chemical substances,* Q6A, ICH 1999).

6. However, a selection patent may be applied for by a third party, and not necessarily by the owner of the original patent. This may raise issues of patent dependency and eventually trigger the application of compulsory licenses. See Article 31(l) of the TRIPS Agreement.
7. When a prior claim or document in the prior art includes a range, for instance, in the form of C_1-C_4 or 50° to 75° of temperature, all the comprised possibilities (e.g. C_2 and C_3; 60° of temperature) should be deemed disclosed and, hence, not patentable as a "selection".
8. The patentability of a selection will proceed in this case if an exception to the strict principles of novelty were allowed under the applicable law.
9. Enantiomers are "stereoisomers whose mirror images cannot be superimposed. Enantiomers have identical physical and chemical properties except that they rotate the plane of polarized light in opposite directions and behave differently in a chiral environment". "'Stereoisomers' are compounds made up of the same atoms bonded in the same sequence but having different orientations in space.[….]". See http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/stereo_e.pdf.
10. During the synthesis of asymmetric molecules equal amounts of enantiomeric pairs will always form, except when one of the starting materials or reagents is itself a single enantiomer. In other words, unequal amounts of enantiomers will form only if the chemist deliberately selects starting materials or reagents that are single enantiomers.
11. For instance, esomeprazole is the *S-enantiomer* of *omeprazole*. Improved efficacy of this single enantiomer over the racemic mixture of omeprazole has been claimed. Another example is citalopram and escitalopram.
12. An enantiomer might have in some cases useful properties that are not the same as those of the racemate, which useful properties could not have been predicted but were masked in the racemate by the other enantiomer. It will depend on the applicable national law whether the identification of such properties could provide the basis for obtaining a patent or whether it would be considered a non-patentable discovery or anticipated in the prior art.
13. An example is nelfinavir and its active metabolite M8.
14. When an active metabolite of an existing product is registered with the health authority in its own right, it is possible that a full set of new safety and efficacy data will be required, similar to that which was generated for the parent compound. There are cases where an active metabolite has been registered for a different indication to that of the parent drug (for example, the primary indication for temazepam, an active metabolite of diazepam, is as a hypnotic whereas the primary indication for diazepam itself is anxiety).
15. Some examples are the following: enalapril is converted by esterase to the active enalaprilat; valaciclovir is converted by esterase to the active aciclovir; levodopa is converted by DOPA decarboxylase to the active dopamine; fosamprenavir calcium is a prodrug of the protease inhibitor and antiretroviral drug amprenavir.
16. In some cases, the prodrug might have benefits in terms of being more readily administered than the active compound.

17. The medical profession is not an industry, as stated in a landmark decision by the German Federal Supreme Court in *Operation for baldness* (38 BGHZ 313, 1968 GRUR 142).
18. A well-known example of a "second indication" patent relates to sildenafil citrate. Another example is zidovudine, developed as an anticancer drug and then covered by patent as a HIV drug.
19. As required by the Vienna Convention on the Law of the Treaties.
20. The formulation of these claims, deemed to have been first introduced by the Swiss patent office, is of the type "use of *x* for the manufacture of product *y* to treat disease z".

paper 6

TRIPS flexibilities: the case of India

Dr N.S. Gopalakrishnan

Introduction

Protection of public health was one of India's major concerns when the TRIPS Agreement was being negotiated. The Patents Act, 1970 did not provide for product patents for inventions relating to medicines. The duration of protection of process patents for medicines was also limited to a maximum of seven years. This conscious policy choice adopted in India's Patent Act yielded positive results over a period of three decades in building a good industrial infrastructure for manufacturing generic medicines, while also to keeping the price of essential drugs at a relatively low level. During the final stages of negotiations that resulted in the TRIPS Agreement, India attempted to ensure that TRIPS provisions would not substantially affect the public health needs of the large sections of the population that are below the poverty line. Subsequently, India made conscious efforts to incorporate the flexibilities available in TRIPS and the Doha Declaration when India amended the Patents Act in 1999, 2002 and 2005. This paper is an attempt to briefly explain how India used the flexibilities relating to public health.

Introduction of product patents

The major policy decision India took in the implementation of the TRIPS obligations relating to public health was to delay the introduction of product patent protection for new inventions relating to pharmaceutical products till 2005, using the flexibility under Article 65 of the TRIPS Agreement. But one of the immediate obligations after the coming into force of the TRIPS Agreement was to provide transitional protection as mandated in Article 70.8 to new inventions relating to pharmaceutical products. Though in 1996 India introduced an amendment to provide exclusive marketing rights to pipeline products, this was unsuccessful since there was no political support. India's failure to implement its obligations under Article 70.8 resulted in

the first WTO dispute on the TRIPS Agreement. The WTO Panel decision[1] led to the first amendment to the Patents Act in 1999, carrying out the obligation to implement pipeline protection for new inventions in the field of pharmaceuticals. Product patent protection for pharmaceuticals was introduced in India only in 2005.

Patentable subject matter

The unique feature of the Indian Patents Act is the attempt to carefully carve out the subject matter eligible for patent protection. The policy adopted is to limit the award of patent protection through strict standards of patentability. While elaborate definitions are included for the three basic requirements of patentability, i.e. "novelty", "inventive step" and "capable of industrial application", Section 3 of the Act contains express provisions to exclude certain inventions from patent protection. Though these provisions are not specific to any field of technology, some of them are very relevant to the protection of inventions relating to pharmaceuticals. If one examines Article 27 of the TRIPS Agreement it is evident that the obligation of a Member State is only to provide product or process patent protection to inventions that "are new, involve an inventive step and are capable of industrial application". There is also a requirement not to discriminate based on the field of technology. Thus, product patents have to be available for new pharmaceutical products. It is to be noted that even though the three tests (novelty, inventive step and industrial applicability) are included in the TRIPS Agreement, there is no definition laying down the standards to be followed in applying these tests. This policy space is utilized by India to prevent "evergreening" of pharmaceutical patents resulting in long-term monopoly on some products. This is achieved by giving legislative guidance indicating the standards to be followed in identifying the inventions for patent protection. The standards for "inventive step" constitute the most important element in preventing evergreening. The Act defines inventive step to include a "technical advance" or "economic significance" or both, and demands that the invention is "not obvious to a person skilled in the art". The requirement for a "technical advance" could be construed to exclude incremental innovations that are of an insignificant nature. This is further substantiated with the specific exclusion of certain inventions from patent protection in Section 3. In the context of public health, the notable exclusions relate to "new use of a known substance",[2] "admixture resulting only in aggregation of properties of the components",[3] "mere arrangement or re-arrangement"[4] and methods of treatment. If one reads all these provisions together, it is clear that the standard of inventive step is high and that the legislative intent is to exclude petty inventions from the scope of patent protection.

The changes made in Section 3(d) of the Act, particularly the exclusion of a new form of a known substance from patentability, attracted much debate and litigation in India. It was alleged, in the *Novartis case* before the Madras High Court, that this provision is in violation of India's TRIPS obligations. The court, however, refused to examine this issue, which it considered to be outside its jurisdiction. It was also alleged that this provision may have a potential negative impact on indigenous innovation.[5] If one examines Section 3(d) in detail, it is evident that the provision excludes the mere discovery of new forms (derivatives) of known substances from patentability unless they result in the enhancement of known efficacy of the substance. The explanation further clarifies that the "efficacy" requirement relates to substances that "differ significantly in properties with regard to efficacy". This restriction is aimed at preventing evergreening. There is much debate with respect to the scope of the term "efficacy". In the *Novartis case*,[6] it was alleged that this term is not properly defined and that insufficient guidelines are provided for its interpretation.[7] The petitioner also criticised the explanation to the provision along the same lines. Rejecting this argument, the Court held:

> The argument that the amended section must be held to be bad in Law since for want of guidelines it gives scope to the Statutory Authority to exercise its power arbitrarily, has to be necessarily rejected since, we find that there are in-built materials in the amended section and the Explanation itself, which would control/guide the discretion to be exercised by the Statutory Authority.[8]

The Court further observed that the amended Section does not suffer from vagueness, ambiguity or arbitrariness. In reaching this conclusion the Court interpreted "efficacy" to mean "the ability of a drug to produce the desired therapeutic effect". The Court interpreted "therapeutic" in the following manner:

> Darland's Medical Dictionary defines the expression "efficacy" in the field of Pharmacology as "the ability of a drug to produce the desired therapeutic effect" and "efficacy" is independent of potency of the drug. Dictionary meaning of "Therapeutic", is healing of disease—having a good effect on the body. Going by the meaning for the word "efficacy" and "therapeutic" extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease / having a good effect on the body. In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though [+] preceded by research,—we state—for any Patent applicant to place on record what is the therapeutic effect/efficacy of a known

substance and what is the enhancement in that known efficacy. The amended section not only covers the field of pharmacology but also the other fields. As we could see from the amended section, it is made applicable to even machine, apparatus or known process with a rider that mere use of a known process is not an invention unless such a known process results in a new product or employs at least one new reactant. Therefore the amended section is a comprehensive provision covering all fields of technology, including the field of pharmacology. In our opinion, the explanation would come in aid only to understand what is meant by the expression "resulting in the enhancement of a known efficacy" in the amended section and therefore we have no doubt at all that the Explanation would operate only when discovery is made in the pharmacology field.[9]

The Court concluded:

> Scientifically it is possible to show with certainty what are the properties of a "substance". Therefore when the Explanation to the amended section says that any derivatives must differ significantly in properties with regard to efficacy, it only means that the derivatives should contain such properties which are significantly different with regard to efficacy to the substance from which the derivative is made. Therefore in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the Patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy.[10]

The Draft Manual of Patent Procedure and Practice 2008 quotes from the Madras High Court decision in the *Novartis case* to explain the term "efficacy".[11]

It may be noted that while most Indian pharmaceutical companies are opposing patent extensions through evergreening, and are insisting on strict criteria for patentability, some multinational companies argue that patenting of incremental improvements–such as derivatives of known substances of the type listed in Section 3(d)–would help Indian industries to grow.[12] However, in adopting patentability standards development interests, which include the physical well-being and health of its people, should be an equally strong concern for every country, along with concern for industrial development. Therefore, allowing patent protection for incrementally modified drugs, even for the sake of encouraging the development of the indigenous industry,

may be outweighed by the need to provide access to pharmaceuticals at an affordable cost. It may be noted that there also are studies in the United States and Europe that support the approach of avoiding patenting of incremental innovations, at least in these fields, and that suggest that high patentability standards are desirable.[13]

Pre-grant and post-grant opposition

One of the important measures to facilitate access to medicines is to ensure that the patent office will not grant patents to minor inventions that do not satisfy statutory requirements. The right to oppose a patent application before it is granted—pre-grant opposition—and oppose it after grant—post-grant opposition—are both present in Indian law. Regarding pre-grant opposition, the law allows "any person" to file an opposition to an application for a patent after its publication and prior to grant. The law identifies a number of grounds for opposition, such as wrongful obtaining of the invention by the applicant, prior publication of the claims in India or elsewhere, public knowledge about the invention prior to the application, invention already claimed in another application, non-fulfillment of patentability standards, insufficient disclosure, non-disclosure or wrongful disclosure of source or geographical origin of biological material used for the invention, or that the invention is anticipated by traditional knowledge. The purpose of this provision is to enable any person, including public interest groups, to take steps to prevent the granting of patents over inventions that do not merit patent protection. It is important to note that the pre-grant opposition procedure is being used by rival industries as well as vigilant consumer groups.[14] The Madras High Court in *Indian Network for People living with HIV/AIDS v. Union of India*[15] held that the person filing the pre-grant opposition has the right to be heard by the Controller before disposing the application and deciding to grant the patent. The Court stressed the importance of the public interest in the pre-grant opposition procedure and held:

> The petitioners in this writ petition are asserting their rights and voicing their concern on a broad public interest angle. So it cannot be said if their right is denied they will not suffer any prejudice by denial of an opportunity of hearing them to establish their rights. A right is a legally protected interest. Therefore when law consciously confers a right on a person to object at a pre-grant stage that right must be protected in the way it has been granted, namely the right to object with a right of hearing. For a Court to dilute the said right on the basis of an interpretative process and by looking at it from a narrow angle, would, in our judgment, be a travesty of justice.[16]

It may be noted that only a "person interested"[17] is allowed to file a post-grant opposition. The "person interested" is defined in the Act to include "a person engaged in, or in promoting, research in the same field as that to which the invention relates". As per the law, the application must be filed within one year of publishing the grant of the patent. The grounds of opposition are similar to those of a pre-grant opposition. Examining the scope of this Section and distinguishing it from the provision dealing with pre-grant opposition, the Supreme Court in *J. Mitra v. Asst. Controller of Patent and Design*[18] observed:

> There is, however, a radical shift due to the incorporation of Section 25(2) where an interested party is granted a right to challenge the patent after its grant. The ground of challenge under Section 25(1) is identical to Section 25(2) of the said 1970 Act. However, Section 25(1) is wider than Section 25(2) as the later is available only to a "person aggrieved". The main difference between Section 25(1) and Section 25(2), as brought out by Patent (Amendment) Act, 2005, is that even after a patent is granted, a "post-grant opposition" can be filed under Section 25(2) for a period of one year. The reason is obvious. In relation to patent that are of recent origin, a higher scrutiny is necessary. This is the main rational underlying Section 25(2) of the said 1970 Act….[19]

These judgments are indicative of the judicial recognition of the legislative intent to protect the public interest while granting patents. It is expected that these provisions will be used effectively in case of patents relating to pharmaceuticals to promote access to medicines. There are a number of pre-grant oppositions that have been filed to prevent evergreening, and also to prevent monopoly rights from being granted in India over inventions that are already in the public domain in other countries.

Parallel import

India introduced provisions facilitating parallel import; it is believed this will act as a market mechanism to facilitate access to patented products at affordable cost. Section 107A (b)[20] was included in the Act to facilitate import of products patented in India from other countries. This provision puts limitations on the rights of the owner of the patent to restrict the movement of the product from one country to another once it is legally manufactured and sold in the market. The idea of this provision is to allow the circulation of products legally manufactured in another country into the Indian market while the patent is still in force in India through distributors not authorized by the owner of patent. Thus, even though the owner of the patent may supply the Indian market (either through local manufacture or through importation), still, Section 107 A (b) authorizes any other person in India to import and distribute the products in India. This is permissible

as long as the product is purchased from a manufacturer in a third country who has legally manufactured the product in that country. This is irrespective of the territorial limit for the sale of products included in the conditions of the licence by the owner of the patent (in case the product is patented in that third country) on the manufacturer in the third country. This freedom is evident from the phrase "who is duly authorized under the law to produce and sell or distribute the product". [21] This language, which was included in the section by the 2005 amendment, is broad in scope. It permits importation of products patented in India even from countries not recognizing a patent for that invention. The word "patented product", used in this section, only means the product is patented in India, and not in the country from where the product is imported. This is clear since the exclusion from infringement is evidently of the patent granted in India. Similarly, the word "law" used in this section is the law applicable in the country from which the product is imported and not the Indian law.

Thus, the principle of exhaustion has been interpreted from the point of view of the public interest; the Indian provision is structured to take full advantage of the flexibility available under the TRIPS Agreement (see also paper 2) to make the patented products available to the Indian public at the cheapest possible price.

Compulsory licence

Compulsory licensing provisions can be used to expand access and to prevent ownership of an intellectual property right from resulting in abuse of a monopoly. The patent system will provide maximum benefit to a country in case the patented invention is worked in the country by actual manufacture and distribution.[22] This will enable not only the development of the industry and progress of science and technology, but also ensure availability of products for local needs. In the early stages of the development of the patent system, patents were revoked on the ground that the patented invention was not worked in the country. India has made use not only of the flexibilities available in the TRIPS Agreement, but also has implemented the changes requested by the WTO Ministerial Conference in its Doha Declaration and the proposed amendment to the TRIPS Agreement.[23] Thus, India has created different types of compulsory licences. Still, some hold the view that the complete flexibilities available were not properly exploited/utilized by India.[24]

The compulsory licensing provisions available under the Indian Patent Act could be broadly classified into (a) general compulsory licensing provisions; (b) a provision relating to pharmaceutical patents in case of emergency; and (c) a licence to export pharmaceuticals to countries with insufficient manufacturing capabilities. The grounds on which a general compulsory licence can be requested by an interested person after the expiry of three

years from the granting of a patent are: (a) the reasonable requirements of the public have not been satisfied; (b) the patented invention is not available to the public at a reasonably affordable price; or (c) the invention is not worked in the territory of India.[25] With regard to the first category of compulsory licenses, the section also explains the circumstances that result in *not* satisfying the reasonable requirement of the public.[26] The reasonable requirement of the public would include: protection of existing trade and industry, development of new industrial activities, promotion of export, availability of the product at an affordable price, prevention of unreasonable terms—such as exclusive grant-back requirements, or prevention of patent challenges—in voluntary licences,[27] and exploitation of the market based only on import.

The second category of compulsory licence relates to situations of national emergency.[28] The provision takes advantage of the special provision in this regard in Article 31 of the TRIPS Agreement. According to this provision, in circumstances of national emergency or in circumstances of extreme urgency or in case of public noncommercial use, if the government is satisfied that in respect of any patent it is necessary that a compulsory licence should be granted at any time after the sealing of the patent, it may make a declaration to that effect by a notification in the official gazette. This provision is different from that of the general compulsory licence provision mainly because of the waving of the three-year period before a compulsory licence can be issued.[29] What is needed in this case is a government notification of the patents that fall under this circumstance. Once the notification is made, the controller can issue the licence.

The third type of compulsory licence is structured based on paragraph 6 of the Doha Declaration.[30] This was introduced in 2005, by inserting Section 92A, to facilitate manufacture and export of patented pharmaceutical products to countries having insufficient or no manufacturing capabilities.[31] This provision is in line with the requirement under paragraph 6 of the Doha Declaration and the various conditions stipulated in this regard. It is clarified in the provision that "pharmaceutical product" would include not only patented products and processes but also ingredients necessary for their manufacture and the diagnostic kits required for their use. It may be noted that there is no provision regarding the precautions to be taken such as labelling standards to prevent the products from being diverted to other markets. However, the broad powers given to the controller to specify the terms and conditions of such licenses may be used to achieve this.

The effectiveness of compulsory licences in preventing abuse of monopoly and safeguarding the public interest (such as access to affordable products, transfer of technology and improvement of existing industry) depends largely on the presence of interested parties—industrialists with adequate capital

and technology—to manufacture the product. The procedures for issuing the compulsory licence should preferably be time-bound and less cumbersome so that there are adequate incentives for parties to apply. Preferably, the compulsory licensing procedures would also induce the owner of a patent to grant licences voluntarily, on reasonable terms, rather than trying to delay this by using procedural benefits/loopholes/ambiguities and litigation strategies.

Exceptions

One of the important exceptions included in Section 107 A of the Act is to facilitate the use of the patented invention for producing information necessary to obtain marketing approval. Known as the Bolar Exception, this regulatory provision permits activities necessary for the development and submission of information required by the authorities for approval of a generic version of a patented medicine.[32] This provision will enable generic manufacturers to conduct research in order to generate this information during the patent term, so that they can start manufacturing and distributing their product as soon as the patent term has expired.

Enforcement and temporary injunctions

Recently, there have been a number of cases in which the validity of a patent was challenged. It is important to note that the majority of the litigations on patent validity relate to pharmaceutical patents.[33] An important issue that came up before the courts in these cases relates to the grounds on which temporary injunctions could be granted to the owner of patents when the validity of a patent is challenged before the court in an infringement suit. In these litigations, the judiciary has considered the public interest in access to medicines as an important factor when deciding whether or not to grant a temporary injunction. This is well articulated by the Delhi High Court in *F. Hoffman-La Roche Ltd., v. Cipla Ltd.*[34] The Court, while rejecting the application from Roche for a temporary injunction preventing Cipla from manufacturing and selling at very low price the generic version of the cancer drug erlotinib, observed:

> Therefore, this Court is of the opinion that as between the two competing public interests, that is, the public interest in granting injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant's product which may lead to shortening of

lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus irreparable injury would be caused if the injunction sought for is granted.[35]

Conclusions

The above brief analysis describes the attempt made by India to create a patent system keeping in mind the public interest and using the flexibilities available in the TRIPS Agreement. The Indian legislation appears to use the patent system to encourage industrial activity while keeping in mind the larger public interest of access to patented products at affordable prices. In case of the pharmaceutical sector, India has the industrial capability to produce generic drugs at affordable cost, not only to cover the needs of India but also those of other countries. The legislative intention is also to ensure that the industry uses the new provisions to grow further in order to become a creative industry. The impact of the amended Patents Act will largely depend on how the law is going to be implemented by the Patent Office and interpreted by the judiciary. Thus far, the interpretation of the Patents Act has been favourable to the public interest. A clear indication of this is the rejection of several patent applications for pharmaceuticals on the basis of Section 3(d) of the Act. Decisions of the Indian High Court to deny temporary injunctions in cases of alleged infringement of pharmaceutical patents because of the public interest of access to life-saving medicines also reflect this view of the legislative intent. If this trend continues, India may develop a patent system that balances the protection of intellectual property rights with the public interest, which could become a model for other counties to follow.

Endnotes

1. *India - patent protection for pharmaceutical and agricultural chemical products,* Report of the Panel, WT/DS50/R, World Trade Organization, 1997.
2. Section 3(d) reads: "The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. *Explanation:* For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."
3. Section 3(e) reads: "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance".

4. Section 3(f) reads: "the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way".
5. *Novartis AG v. Union of India*, W.P. Nos.24759 and 24760 of 2006 decided on 06.08.2007 (Madras High Court).
6. *Ibid*.
7. It was argued by the petitioner that: "Under the amended section, the patent applicant is required to show that the invention has enhanced efficacy of the known substance. Though the efficacy of a known substance may be well known, yet, unless there are some guidelines in the amended section itself to understand the expression 'enhancement of the known efficacy' namely, what would be treated as 'enhanced efficacy', an uncontrolled discretion is given to the Patent Controller to apply his own standards, which may not be uniform, in deciding whether there is enhancement of the known efficacy of that substance. Such wide discretion vested with a Statutory Authority without any guidelines to follow, would result in arbitrary exercise of power. In other words, the Patent Controller may be in a position to decide any case, based on his whims and fancies namely, whether there is enhancement in the known efficacy or not. On this short ground, the section must be held to be violative of Article 14 of the Constitution of India." *Ibid.,* Para 3.
8. *Ibid.*, Para 16.
9. *Ibid.,* para 13.
10. *Ibid.,* para 13.
11. See the *Draft Manual of Patent Procedure and Practice* (2008) para 4.5.6.
12. Janice Mueller, "The Tiger Awakens: The Tumultous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation" Vol. 68 *University of Pittsburgh Law Review* 491 (2007), p. 551, 556. The author quotes from an interview with the Director of Corporate Affairs, Pfizer India, New Delhi on Nov 15, 2005.
13. See *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,* Report of the US Federal Trade Commission, 2003. Also see Scenarios for Future, European Patent Office, 2007 at p. 89.
14. For a detailed analysis of the practical working of the pre-grant opposition provision in Indian patent law, see Jancie Mueller, "The Tiger Awakens: The Tumultous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation" *68 University of Pittsburgh Law Review* 491 (2007), at pp. 570-572.
15. MANU/TN/1217/2008
16. *Ibid*. at para. 33.
17. "Person interested" is defined under Section 2 (1) (t) to include "a person engaged in, or in promoting, research in the same field as that to which the invention relates".
18. MANU/SC/3435/2008.
19. *Ibid*. at p. 3448.
20. Section 107A (b) reads: "importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product shall not be considered as an infringement of patent rights". This clearly indicates that India has opted for the international exhaustion principle.

21. Section 107A (b) reads: "importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product shall not be considered as an infringement of patent rights".
22. The working of a patent means the commercial exploitation of the invention embodied in the patent.
23. Article 31 bis.
24. Biswajith Dhar and Gopakumar, *op.cit*., at pp. 21-24.
25. See Section 84 (1).
26. See Section 84(7).
27. This ground makes use of the flexibility available in Articles 31 (k) and 40.
28. Section 92.
29. See Section 92(1).
30. WT/MIN(01)/DEC/2
31. Section 92A reads: (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

    (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

    (3) the provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.

    Explanation – For the purpose of this section, "pharmaceutical products" means any patented product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.
32. Section 107A (a) reads: "For the purpose of this Act, - (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; — shall not be considered as an infringement of patent rights"
33. *Cadila Pharmaceuticals Ltd., v. Instacare Laboratouries Pvt. Ltd.* 2001 PTC 472 (Guj), *Novartis AG v. Mehar Pharma,* 2005 (30) PTC 160 (Bom.), *Wockhardt Ltd., v. Hetero Drugs Ltd.*, 2006 (32) PTC 65 (Mad) (DB), *Bilcare Ltd., v. Amartara Pvt. Ltd.,* 2007 (34) PTC 419 (Del) and *Bilcare Ltd. v. Supreme Industries Ltd.,* 2007 (34) PTC 444 (Del).
34. 2008 (37) PTC 71 (Del.).
35. *Ibid.* at p. 108, *per* Justice S. Ravindra Bhat.

paper 7

Implementation of the WTO decision on paragraph 6 of the Doha declaration on the TRIPS agreement and public health*

Carlos M. Correa

Introduction

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,[1] adopted at the Fourth World Trade Organization (WTO) Ministerial Conference (9–14 November 2001), instructed the WTO Council for TRIPS (Trade-Related Aspects of Intellectual Property Rights) to address how WTO Members lacking or with insufficient manufacturing capacities in pharmaceuticals can make effective use of compulsory licensing. While these countries may issue compulsory licences to import generic versions of patent-protected medicines, TRIPS rules impose constraints on the ability of countries to authorize exports of such products. Paragraph 6 promised a solution to the export problem caused by these constraints.

The problem is that, as product patents for pharmaceuticals become enforceable in accordance with the TRIPS Agreement,[2] countries with industrial and export capacity will face legal obstacles to produce and export cheap generic copies of patented medicines. If a product is deemed covered in an exporting country by the exclusive rights granted to the patent owner, production for export could take place under a compulsory licence.[3] However, the TRIPS Agreement establishes that, unless a compulsory licence is granted to remedy anti-competitive practices (Article 31 (k)), it must "predominantly" supply the licensee's domestic market (Article 31 (f)). As a result of these legal constraints, and although countries without sufficient manufacturing capacity in pharmaceuticals could issue a compulsory licence

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for the importation of products they cannot manufacture, they will not be able to find export sources of affordable new medicines.

The WTO Decision of 30 August 2003 "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" is intended to address this problem by establishing a procedure that allows exporting countries to waive the requirement (of TRIPS Article 31(f)) that a compulsory license should be "predominantly for the supply of the domestic market". This paper examines the ways in which the Decision can be implemented in prospective importing and exporting countries.

Legal status of the Decision and amendment of national laws

The Decision adopted by the WTO General Council implements interim waivers with regard to the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement. This waiver shall terminate on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for a Member. The Decision does not affect the use of the flexibilities allowed by the TRIPS Agreement, including the adoption of other avenues to facilitate the export and importation of cheaper pharmaceutical products, such as on the basis of Article 30 of the TRIPS Agreement.

A WTO waiver means that a member shall not initiate a complaint against another member if the latter acted under the terms of the adopted waiver. However, to the extent that a member's national law is not revised to implement the terms of the waiver, patent owners may invoke provisions in the national law to block the export of a patented drug by other companies. Whether generic drug makers will actually be able to export under the terms of the Decision, therefore, will depend on the extent to which national laws allow for it.

The Decision does not waive the application of Article 31 (b) of the TRIPS Agreement, which requires that before a compulsory licence is granted, the licence applicants must have made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and within a reasonable period of time. This requirement may be waived by national law in the case of a national emergency or other urgent circumstances or in cases of public non-commercial use. Compulsory licences are granted under grounds specified in national laws. The supply of export markets is not an accepted ground in most national laws. Moreover, Article 31 (f) of the TRIPS Agreement requires that compulsory licences be issued "predominantly" for the domestic market. National laws in exporting countries may have to be

amended in order to permit paragraph 6 compulsory licences exclusively to supply a foreign country.

The need to apply the Decision will arise when the patent owner does not agree to supply a patented pharmaceutical product to a country with insufficient or no manufacturing capacity in pharmaceuticals, at an affordable price or under other suitable conditions. Whatever humanitarian reasons[4] underpin the country's demand for a given pharmaceutical product, nothing in the system adopted through the Decision compels the patent owner to supply it or to forego the owner's rights under national laws.

In this context, the patent owner may eventually exercise his right to appeal a decision granting a compulsory licence—in both the importing and exporting country. In some countries, such appeals may not suspend the immediate execution of the compulsory licence. In others, this may not be the case,[5] and the patent owner may obtain an injunction and thereby delay exports or imports under the compulsory licence until a final administrative or judicial decision is taken. National patent laws, hence, may have to be amended if there is to be an effective and rapid application of the Decision to address public health needs, particularly in cases of national emergency or urgency. In undertaking such an amendment, prospective exporting and importing countries should both consider establishing a short period for fulfilling the obligation under Article 31 (b) of the TRIPS Agreement[6] for a prior negotiation with the patent owner.[7]

In order to use the Decision, the law in the importing country must provide for compulsory licences under which imports can be made to address public health needs, and the law in the exporting country must allow for exports in cases (not covered by Article 31 (k) of the TRIPS Agreement) where production is predominantly for export markets. The national law in the importing country should also permit the implementation of the waiver of Article 31 (h) regarding compensation to the patent owner when products are being imported pursuant to the Decision.

Implementation of the Decision may not only require making specific changes to national laws, but also that countries avoid assuming TRIPS-plus obligations under bilateral or regional treaties. The implications of these obligations are quite significant, and may delay introduction of generic products, even where compulsory licences are issued. In this context it is to be noted that the Decision creates international obligations that must be complied with in good faith.[8]

In sum, WTO members should review their domestic laws in order to determine what amendments are required in order to implement the Decision, and undertake the necessary legal adaptations. Such review should consider the procedures for granting compulsory licences, in order to ensure their timely granting and that their execution could not be prevented by appeals or other legal actions.

Circumstances in which the Decision may be used

The Decision will apply when the required pharmaceutical products are patented, at least in the exporting country. The application of the Decision may require the granting of compulsory licences on a set of patents, not just on a single patent. Given the territoriality of the patent system and the fact that the same patents are not necessarily applied for and obtained in all countries, and that the scope of the approved claims (with regard to the same invention) may also vary from country to country, the set of patents to be subject to compulsory licences may not be exactly the same in the exporting and importing countries. In addition, it will be necessary to determine whether the relevant patents are in force. Importing and exporting countries alike may overcome these problems by specifying that the compulsory licences apply to all patents on the product, its processes of manufacture and its uses.[9]

The Decision may apply either when a patent covers a product or a manufacturing process. It applies to products "of the pharmaceutical sector" in general and includes "active ingredients necessary for its manufacture", pharmaceutical formulations or the process for their manufacture. The Decision also clarifies that "diagnostic kits needed for its use would be included". This wording may be interpreted as including reagents, diagnosis and monitoring kits. Moreover, as the negotiation of the Decision made clear, it applies to pharmaceutical products for any disease.

The Decision may be applied when:

(a) the required pharmaceutical product is subject to one or more patents validly in force in the exporting country;

(b) the relevant patents are not subject in the exporting country to a compulsory licence to remedy anti-competitive practices that allows the licensee to export (Article 31 (k) of the TRIPS Agreement, in which case Article 31 (f) does not apply, and there is no need to employ the Decision waiver). Similarly, if a compulsory licence has been issued under which the licensee is predominantly supplying the domestic market, the licensee may supply an importing country with the non-predominant share of its production, and therefore without resort to the Decision waiver.

If the required pharmaceutical product, or the process for its manufacture, is not patented in the importing country or the patent has expired or been revoked, there is no need to grant a compulsory licence in the importing country. But the Decision applies in order to allow the granting of such a licence in the exporting country.

If the product or process for its manufacture is patented in the importing country, then the importing country must issue a compulsory licence pursuant to the special conditions set forth in the Decision. A particular case may arise in least developed countries (LDCs), which can delay the recognition of pharmaceutical patents until 2016. This means that LDCs may consider pharmaceutical patents as non-enforceable until that date. If, despite this possibility, patents on needed pharmaceutical products are enforced, they can still grant compulsory licences as per the terms of the Decision.

The Decision will not apply if the relevant product is off-patent in the exporting country, since a waiver of Article 31 (f) is not required. In this case, and if the product were patented in the importing country, a compulsory licence should only be granted in the importing country, under the ordinary terms allowed by the national law. There would be no need to comply with the special conditions established by the Decision.

The Decision can be used for importation by:

(a) Any least developed country member. The only qualification is that the LDC must be a WTO member.

(b) Any other member that has made a notification to the Council for TRIPS of its intention to use the system as an importer.

LDCs can use the system to import pharmaceutical products under a compulsory licence granted according to any of the grounds authorized by their national laws. Eligible importing members may grant compulsory licences to foster the development of capacity in their pharmaceutical industry as a sustainable way to address their public health problems, for instance by importing active ingredients under the Decision for the local formulation of medicines. Further, prospective suppliers of pharmaceutical products under the Decision include private companies, notably from countries where a strong generics industry has developed. Such companies will not make the needed investments nor bear the opportunity costs of supplying products under the Decision, unless they are able to obtain some commercial benefit.

Compulsory licence in the importing country

Implementation of the Decision involves two kinds of notifications to the Council for TRIPS: a general notification about the intention to be an eligible importing member, and a specific notification about the products, quantities,

and so on that the country intends to import.[10] The notifications are for the sake of transparency and information only, and do not amount to requests for authorization.

The first notification is about the intention of a member to use the Decision, and not about its actual use. It is not a requirement for LDCs, however, which automatically qualify as eligible importing members. The notification may be unqualified, when the member does not declare any limitations to its potential use of the system, or it may be qualified, when the member voluntarily states that it will only use the system in a limited way. There is nothing in the Decision preventing a member from changing, at any time, the terms of its notification. The effect of the notification is declaratory only; this means that neither the Council for TRIPS nor any other WTO body is entitled to review, approve or reject a notification and the specific terms under which it is made.

Under the second notification, the would-be importing country is bound to notify the Council for TRIPS of:

(i) The names of the needed product(s)—the generic names of the required pharmaceuticals are to be mentioned.

(ii) The "expected quantities": the notified quantities may not exactly correspond to the quantity of product finally requested or purchased. However, importing countries should carefully assess the quantities needed since, as mentioned below, the corresponding compulsory licence in the exporting country can be granted only for a specified amount.

The obligation to specify the expected quantity only applies to the notification. It does not refer to the specific terms of the compulsory licence. A situation may arise in which the notified "expected" quantities may not correspond to the quantities effectively imported. This discrepancy would not affect the right to import, so long as the compulsory licence was not limited to the amounts specified in the TRIPS Council notification.

Moreover, there is no obligation on the importing country to determine a specific timeframe in which importation would take place.

(iii) Lack of manufacturing capacity: the requirement of establishing the lack of or insufficient manufacturing capacity does not apply to LDCs. For other countries, insufficient or no manufacturing capacity is not to be assessed in general, but for the particular pharmaceutical product(s) required. The assessment of the existence of manufacturing capacity should not be limited to technical aspects. The Decision does not determine particular criteria or methods to establish the lack of or insufficient capacity. This is a matter

of self-assessment,[11] the outcome of which cannot be challenged by another member and cannot be subject to review, reversed or rejected by the Council for TRIPS.

(iv) Granting of compulsory licence: where a pharmaceutical product is patented in its territory, the importing country must notify the Council for TRIPS that it has granted or intends to grant a compulsory licence. It would be sufficient to notify the Council that the competent authority intends to grant a compulsory licence. The only condition imposed on the compulsory licence to be granted is that it be "in accordance with Article 31 of the TRIPS Agreement".[12]

The grant of a compulsory license in the importing country before or after notification may be for an unlimited quantity, as long the patent is in force, and without compensation.

In addition, there is no obligation in the importing country to provide compensation to the patent holder. However, the Decision does not waive the obligation of Article 31 (b) of the TRIPS Agreement for prior negotiation with the patent holder. Nevertheless, the importing country (as well as the exporting country) may apply the system on the basis of an authorization for *public non-commercial use*. For such use, the obligation for prior negotiation is waived.

The notification will be made publicly available by the WTO Secretariat through a page on the WTO web site dedicated to the Decision. If the notification was made before the granting of the compulsory licence by the importing country, there is no need to make another notification after grant of the licence.

Compulsory licence in the exporting country

The Decision requires the exporting country to grant a compulsory licence. It does not waive the Article 31 (b) requirement that, prior to issuance of a compulsory licence, a request for a voluntary licence be made to the patent owner.[13] If the request for the voluntary licence is unsuccessful, the interested supplier would have to apply for a compulsory licence under the applicable national rules. The competent national authority would have to decide on the application and determine the remuneration to be paid. The patent owner may appeal the government's decision to grant a compulsory licence.

The compulsory licence must be granted only to produce and export "the amount necessary to meet the needs of the eligible importing Member(s)". In addition, the entirety of the production under licence shall be exported to the Member(s) that has notified its needs to the Council for TRIPS. The "needs" are established by the importing country and may be established

on the basis of several criteria, depending on the degree to which the needs of the eligible importing country can be determined upfront.

In order to avoid the transaction costs and delays involved in obtaining a compulsory licence, it might be possible to consider the granting of an amendable compulsory licence that expands the quantity to be supplied based on subsequent requests notified by the importing country/countries.

The Decision requires that the products to be supplied under the Decision be clearly identified "through specific labelling or marking". The purpose of the label or mark is to make the products identifiable in case there is diversion to other markets. Products should not only be identifiable but also distinguishable, presumably from the branded products. This is to be achieved, according to the Decision, through special packaging and/or the colouring/shaping of the products themselves. It will be up to the supplier to choose whether to distinguish through packaging, colouring or shaping. The obligation to distinguish the products is not absolute. Exporters do not need to distinguish the products when doing so (i) is not feasible, or (ii) will have a significant impact on price.

The supplier should post on a Web site certain information before shipment begins. The information must include (i) the quantities being supplied to each destination, and (ii) the distinguishing features of the product(s). In addition to the supplier's notification, the exporting country must notify the Council for TRIPS of the grant of the licence. As in the case of the notification by the importing country, this notification does not need to be approved by any WTO body (footnote 8 of the Decision). The notification will be made available publicly by the WTO Secretariat through a page on the WTO web site dedicated to the Decision.

The exporting country's notification must contain the following:

- the name and address of the licensee;
- the product(s) for which the licence has been granted;
- the quantity/quantities for which it has been granted;
- the country/countries to which the product(s) will be supplied;
- the duration of the licence;
- the address of the Web site where the supplier will post the information referred to in paragraph 2 (b)(iii) of the Decision.

A single compulsory licence may cover the production for and export to more than one country. Several importing countries may in fact pool their purchasing power for a set of pharmaceutical products, in order to obtain better prices. The duration of the compulsory licence is to be determined by the exporting country's government.

Anti-diversion measures

The decision requires that eligible importing members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.

It will be the prerogative of the importing country to determine what is:

- reasonable, within its means;
- proportionate to its administrative capacities; and
- proportionate to the risk of trade diversion.

Other issues to be considered

A dissatisfied patent owner may use the legal mechanisms available under the laws of the importing and/or exporting country to challenge the compulsory licence, the compensation to be paid (in the exporting country) or other aspects of the transactions made under the Decision. Depending on national law, the review need not suspend the execution of the licence.

For the purpose of registration of products with the health authority in the importing country, proof of bioequivalence and bioavailability may be required by national law. If, in the importing country, data exclusivity is granted with regard to data submitted for the registration of medicines, the data holder's authorization would be required, unless the use of such data is included[14] in the CL.[15] Under the data exclusivity terms, if a compulsory licence were granted in a country to import a pharmaceutical product, a generic company would have to develop on its own all the test data as required for approval.

This is a very lengthy, costly, duplicative and wasteful process given that the data have already been generated by a brand-name company, and will create an enormous obstacle to the use of the Decision. Moreover, "linkage" between patent protection and marketing approval seems to erect an almost insurmountable barrier to the execution of a compulsory licence or government non-commercial use, since the compulsory licensee or government would be authorized to use the patented invention but not to obtain the regulatory approval to make it available.

Suspension of the system

Since it is the importing county itself that determines insufficient capacity, and the Council for TRIPS has no power to review this determination, it is logical to interpret that the importing country should also make the determination that capacity has become sufficient. Given that lack or insufficient capacity

is to be established per product, and that compulsory licences are issued to import a specified quantity of a needed pharmaceutical product(s), the determination that capacity has become sufficient would not affect the future use of the system with regard to other product(s).

Conclusions

The WTO General Council Decision allows Member countries to grant compulsory licences for the export of pharmaceutical products without the restriction established by Article 31 (f) of the TRIPS Agreement, and permits the importing country not to provide compensation to the patent owner where a compulsory licence is granted. The Decision may also be applied on the basis of government non-commercial use, an avenue that in many instances may be quicker, simpler and more effective than the granting of a compulsory licence.

In addition to the steps and procedures stipulated by the Decision, legislative changes are likely to be necessary in both the exporting and importing countries in order to implement the Decision. The conditions under which a compulsory licence can be obtained will influence the speed and cost of making the system operative.

Finally, countries willing to use the Decision should ensure that legal obstacles are not erected through data exclusivity obligations, the "linkage" between product patents and drug registration, or through other regulations.

Endnotes

1. WT/MIN(01)/DEC/2, 20 November 2001, hereinafter "the Doha Declaration".
2. By 2005 at the latest, all WTO Members (except least developed countries) must provide patent protection for pharmaceutical products.
3. Production for export, however, may be deemed admissible under Article 30 of the TRIPS Agreement. See, e.g. Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, 2002, available on the Internet at www.iprcommission.org; Correa C, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Geneva, WHO, Health Economics and Drugs, EDM Series No. 12, 2002.
4. See the Statement by the Chair of the General Council accompanying the Decision.
5. The experience of the Philippines is illustrative in this regard. One hundred and twenty petitions for compulsory licences were filed under the old Philippine patent law, out of which 51 compulsory licences were granted. However, the beneficiary companies were unable to market the products due to appellate proceedings that delayed the execution of the decision. The delay in the proceedings also led to the dismissal of 23 applications. Fourteen petitions were also dismissed due to a compromise agreement between the parties. Eight petitions were dismissed because the patent expired while the petitions were still pending. The

only compulsory licence granted after the new Philippine Intellectual Property Code took effect on 1 January 1998 was a compulsory licence petition filed on 8 December 1991 when the old patent law was in effect. This petition was finally granted on 19 December 2001, i.e. after a period of ten years. The rest of the petitions filed under the old Philippine patent law are still pending (communication from Susan Villanueva, College of law, Philippines, 26 September 2003, on file with the author).

6. Since prior efforts to obtain a compulsory licence would have to be made, in some cases, both in the importing and exporting country, and given the need to provide a rapid response, coordination on this matter may be envisaged between the two countries.

7. Canadian Bill C–9 requires the applicant of the compulsory licence to provide a declaration showing that at least thirty days before filing the application it sought a voluntary licence from the patent owner on reasonable terms and that his effort were unsuccessful (Section 21.04.3 (c)).

8. See Vienna Convention on the Law of Treaties (Article 26).

9. See, e.g. the notice of authorization for the exploitation of patented inventions issued by the Government of Malaysia on 29 October 2003 relating to didanosine, zidovudine and lamivudine, and the compulsory licence granted by the Government of Mozambique (No. 01/MIC/04) in May 2004.

10. Except as required by Article 31 (b), where applicable, there is no obligation to notify the patent owner about the intention to grant a compulsory licence and the conditions thereof. Likewise, there is no obligation to offer the patent owner the option to supply the required products under the terms and conditions established for the compulsory licence, as proposed in Canadian Bill C–56 (2003).

11. Vandoren, Van Eeckhaute, op. cit., p. 785.

12. A question may be raised as to whether this condition means that a compulsory licence may be granted to import pharmaceutical products under Article 31 even in cases where the national legislation does not provide for such grant or for the execution of the licence through importation. The adopted waiver means that a Member country will not have the right to complain against another Member not complying with Article 31 (f) or (h) but would not prevent, in principle, the patent owner from interfering with the granting of a compulsory licence if inconsistent with national law.

13. As previously mentioned, it may be argued that the exporting country is entitled to consider the situation in the importing country as an emergency, or to recognize public non-commercial use, thus waiving the obligation for prior negotiations as required by Article 31 (b) of the TRIPS Agreement. This possibility would speed up the application of the system.

14. There are precedents of this kind in the USA. See Correa, C (1999), *Intellectual property rights and the use of compulsory licenses: options for developing countries*, Trade-Related Agenda, Development and Equity, Working Paper No. 5, Geneva, South Centre, 1999, p.16.

15. Provisions allowing the use of data in cases of the granting of a compulsory licence may need to be incorporated into national laws, in order to prevent legal challenges that could otherwise block the exploitation of the licence.

paper 8

Patents, compulsory licences and access to medicines: some recent experiences*

Martin Khor

Background

Access to medicines, which is part of the human right to health, has emerged as a major public health issue, especially with the impact of patents on the prices of drugs. The patenting of medicines has become more prevalent after the establishment of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in the World Trade Organization (WTO) in 1995. That Agreement made it compulsory for WTO Member States to include medicines in their regime for product and process patents.

In recent years, public health and development organizations have highlighted how the monopoly granted by patents enabled the maintenance of excessive prices of medicines for HIV/AIDS. The cost of treating a patient with patented drugs was US$ 10 000–15 000 a year in developed countries, whereas some producers in developing countries were able to provide generic versions for as low as US$ 300 per year. The cost of the generic drugs has now dropped to US$ 100–150. If developing countries are able to make or import these generic drugs at lower cost, that would significantly increase access to medicines.

While mandating that WTO members have to allow patenting of medicines, the TRIPS Agreement does contain flexibilities. For example, if patented drugs cost too much, the government authorities can take measures such as issuing a compulsory licence to an agency or company to manufacture

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or import a generic version of that patented drug, which can then be made more widely available to patients and at a cheaper price.

At the WTO's Ministerial Conference in Doha in 2001, the Doha Declaration on the TRIPS Agreement and Public Health was adopted as a response to public concerns. The Declaration reaffirmed and clarified the flexibilities available under the TRIPS Agreement, and proclaimed: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health …. [W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." The Declaration spells out several flexibilities that WTO members can use, such as the right to grant compulsory licences and the freedom to determine the grounds for their issuance.

Two important and influential studies that emphasize the crucial importance of TRIPS flexibilities for developing countries are:

- "Integrating Intellectual Property Rights and Development Policy – Report of the Commission on Intellectual Property Rights", established by the United Kingdom (2002);[1] and
- "Public health, innovation and intellectual property rights" – Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) (2006).[2]

These two commissions were made up of international experts on intellectual property, development and public health.

If the Doha Declaration is to benefit HIV/AIDS patients and those afflicted with other ailments in developing countries, these countries will have to establish appropriate provisions in their national patent legislation by using the flexibilities in the TRIPS Agreement. They also need to formulate and implement national policies aimed at providing access to medicines for all. In doing so, they would be operationalizing, at the national level, the aims of the Doha Declaration. If such laws and policies are not introduced, the gains made at the international level through the Declaration will not translate into actual benefits for patients.

In other words, while in recent years the goal of access to medicines has been significantly pursued at the international level, action is now equally or even more important at the national level, where policy-makers should focus on policy and practical measures to get medicines to poor patients.

National public health measures that are TRIPS-consistent

Governments can employ a range of policy measures to facilitate access to affordable medicines, including the following:

Importing drugs

A country can import a generic version of a patented drug by issuing a *compulsory licence* to a company or agency to import the drug, and the government has the freedom to determine the grounds upon which such licences are given. The imported drug can be from a country in which the drug is not patented, or in which the drug is patented (in which case the exporting country also has to issue a compulsory licence). The applicant has first to negotiate to obtain a voluntary licence from the patent holder (except in cases of public non-commercial use, situations of extreme urgency and national emergency), and if that fails, then a compulsory licence can be granted. Adequate compensation has to be paid to the patent holder.

A generic version of the patented drug can also be imported for "public non-commercial use" by the government. Under this "*government use*" procedure, the prior consent of or negotiations with the patent holder are not required, but adequate compensation has to be paid. This method is suitable if the imported drug is to be used by the government.

There can also be "*parallel importation*", which refers to the import and resale in a country without the consent of the patent holder of a patented product that has been legitimately put on the market of another country (the exporting country) at lower cost. It is a very important tool enabling access to affordable medicines because there are still substantial price differences for pharmaceutical products in different markets. Parallel importation is allowed under Article 6 of the TRIPS Agreement (on "exhaustion" of intellectual property rights), and the Doha Declaration affirms this by stating that each WTO member is "free to establish its own regime for such exhaustion without challenge". There is no need for an importer to obtain a compulsory licence or to pay compensation to the patent holder (see also paper 2).

Local manufacture

If a drug is patented in a country, generic versions of the drug can be locally manufactured by a local company or agency that has been granted a compulsory licence. The applicant has to have negotiated with the patent holder for a voluntary licence, and failed to obtain such a licence, before applying for a compulsory licence. This requirement does not apply, however,

if the compulsory licence is issued on grounds of public non-commercial use, for national emergency or situations of extreme urgency, or to remedy anti-competitive practices. Compensation has to be paid.

The government can also assign to a public or private agency the right to locally manufacture a patented product without the patent holder's permission, provided it is used for a public non-commercial purpose. Compensation has to be paid.

Export, including to countries with inadequate manufacturing capacity

A local producer of generic versions of patented products under a compulsory licence or government-use provision may export a portion of its output. However, Article 31(f) of the TRIPS Agreement requires that this production be "predominantly for the supply of the domestic market", and thus there is a limit to the amount that can be exported. This restriction does not apply when the compulsory licence is granted to correct anti-competitive practices.

The restriction on export quantity has posed a problem for developing countries with insufficient or no drug manufacturing capacities, as they may find it difficult to import the required medicines because the exporting countries face a limit on how much of the medicine they can supply to them.

The Doha Declaration recognized that this problem could affect access to medicines, and mandated the WTO to find an "expeditious solution". After lengthy negotiations, the WTO's governing General Council in August 2003 adopted a decision on a "temporary solution" in the form of an interim waiver to the Article 31(f) restriction, such that countries producing generic versions of patented products under a compulsory licence would be allowed to export the products to eligible importing countries without having to limit the exported amount.

However, the decision also obliges importing and exporting countries that wish to make use of the waiver to undertake several measures and fulfill several conditions. It has been pointed out by some experts and nongovernmental organizations (NGOs) that these measures and conditions are difficult for the concerned companies and governments to comply with.

In addition, there are further requirements under a "Chairperson's Statement" linked to the decision, such as that the system should be used in good faith and not pursue a commercial policy objective, and members concerned about how the decision is implemented can bring matters for review in the WTO's TRIPS Council.

As the waiver and the conditions for its use are only an "interim solution", the WTO has mandated the pursuit of a "permanent solution" to this problem. In December 2005, the WTO General Council adopted a set of amendments to the TRIPS Agreement that was basically a reiteration of the August 2003 "interim solution". This amendment will come into force only when it has been ratified by a sufficient number of countries. As of June 2009, this number had not yet been reached. Thus, the "interim solution" of August 2003 is still in force.

Conclusion

Patents can and often do affect the access of patients (especially the poor) to medicines. The TRIPS Agreement also affects the space available to developing-country members of the WTO to formulate drug patent policies of their choice.

However, despite these limitations, developing countries can take full advantage of the measures that are permitted by the TRIPS Agreement, in pursuit of the goal of promoting access to medicines for all.

In order to exercise their right to use these flexibilities "to the full" (in the words of the Doha Declaration), developing countries can study the policy options available to them and introduce the appropriate laws and concrete measures. In the longer term, revisions to the TRIPS Agreement may also be desirable, in order that the existing flexibilities be expanded to meet the needs of patients and consumers. As lives are at stake, both the shorter- and longer-term tasks are urgent.

Use of TRIPS flexibilities: Some recent experiences

Implementation of the flexibilities in the TRIPS Agreement is vital if a country is to achieve the objectives and abide by the principles outlined in the Agreement. Article 7 of the Agreement unequivocally expresses the "objective" of protection and enforcement of intellectual property rights as contributing "to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

Article 8 (on "principles") recognizes that IP right-holders can abuse the rights granted to them and/or resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology, and that governments may need to take "appropriate measures" consistent with the TRIPS Agreement to prevent this from happening. It also recognizes that governments may "adopt measures necessary to protect public health and

nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with" the TRIPS Agreement.

Before the TRIPS Agreement came into force, several developed countries had on many occasions made use of compulsory licences. But in comparison, few developing countries have implemented TRIPS flexibilities. This is due to a variety of reasons, e.g., lack of awareness or understanding about the available flexibilities, lack of legal expertise on IP-related issues (in particular with a pro-development perspective) in government departments, inappropriate or inadequate TRIPS flexibilities in the national laws and, finally, pressure from developed-country governments and industry, in particular the multinational pharmaceutical industry, not to use these flexibilities.

An example of such pressure was seen in 2001 when 39 pharmaceutical companies brought an action against the South African Government for amendments it wished to make to its law (Medicines and Related Substances Control Amendment Act No. 90 of 1997) to incorporate provisions on compulsory licensing and parallel importation to increase access to affordable medicines. Later the industry withdrew the suit after it faced severe criticism nationally and globally.

It was criticism of the effects of patents on prices that led to the adoption of the Doha Declaration in 2001. As stated above, the Declaration recognized "that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" and affirmed that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".

Furthermore, the Declaration reaffirmed "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose". Since the adoption of the Doha Declaration, many more developing countries have exercised their rights and made use of the available flexibilities to increase access to affordable medicines, despite the continuing pressure. The initial focus was on antiretroviral medicines for HIV/AIDS treatment, but the scope has now been expanded to other much-needed medicines.

Below are examples of the use of TRIPS flexibilities by developing countries. The recent use of compulsory licences in Italy and the United States is also highlighted.

Malaysia

In 2003, Malaysia became the first country in Asia to issue a government-use authorization after the adoption of the Doha Declaration. The health authorities initiated the measure after considering various options (i.e., compulsory licensing and government-use authorization) and after consultations with other government departments.

The government-use authorization was for the import of generic versions of patented antiretrovirals or ARVs (to treat AIDS) from the Indian company Cipla for use in government hospitals and clinics.

The patented ARVs were didanosine (ddI) 100 mg tablet (patent holder: Bristol-Myers Squibb); didanosine 25 mg tablet (patent holder: Bristol-Myers Squibb); zidovudine (AZT) 100 mg capsule (patent holder: GlaxoSmithKline); lamivudine 150 mg + zidovudine 300 mg tablet (Combivir; patent holder: GlaxoSmithKline).

The authorization, which was for a period of two years beginning 1 November 2003, was obtained from the Ministry of Domestic Trade and Consumer Affairs (DTCA) for the import of AZT, ddI and Combivir. The government-use authorization was initiated by the Ministry of Health (MOH) and the licence was issued by the DTCA. In November 2002, the MOH had presented a paper to the Malaysian Cabinet with a recommendation to import generic ARV drugs, under a section in the Patents Act that allowed the Minister to exploit a patented invention where it is required by the public interest. The cabinet approved the import on the basis of this provision. As a result of the government-use authorization, the average cost of MOH treatment per patient per month dropped significantly from 2001 (before the government-use authorization) to 2004, as can be seen from Table 1. Also as a result of the exercise of the right of government use, the patent holders dropped their own prices, leading to considerable reduction in the cost of treatment, as seen in Table 1.

Table 1: Comparison of cost of treatment per patient per month after import of generic ARVs under a government-use authorization in Malaysia

Treatment	2001 price for patented ARV (US$)	2004 price for patented ARV (US$)	2004 price for generic ARV (US$)	Percentage of cost reduction
stavudine + didanosine + nevirapine	261.44	197.10	45.32	83%
combination of zidovudine and lamivudine + efavirenz	362.63	136.34	115.14	68%

Source: Ministry of Health, Malaysia.

The much lower cost encouraged the MOH to consider free treatment for more people who needed treatment. Previously, free treatment had only been provided to a few select categories of patients. In addition, the number of patients that could be treated in government hospitals and clinics increased from 1500 to 4000, according to the MOH. In June 2004, the MOH began prescribing the imported generic medicines, which were distributed through government hospitals.

According to news reports, there are 59 000 people in Malaysia infected with HIV, but only 6000 have gone for follow-up treatment in government hospitals; until a few years ago, only 1500 of the estimated 4000 HIV-positive people on the verge of developing full-blown AIDS were receiving treatment (*Sunday Star*, 4 July 2004).

The MOH proposed to the patent holders a remuneration level of 4% of the value of stocks actually delivered. As of February 2006, it was reported that the patent holders had not shown interest in claiming the offered compensation.

Indonesia

Indonesia became the second Asian country in the post-Doha Declaration period to issue a government-use authorization. On 5 October 2004 a Presidential Decree was issued in accordance with Article 5 of the Indonesian Government Regulation No. 27 of 2004 regarding the Mechanism of Patent Exploitation by the Government. This was in light of "the urgent need of the community in the effort to control the HIV/AIDS epidemic".

The Presidential Decree No. 83 of 2004 Regarding Exploitation of Patent by the Government on Antiretroviral Drugs empowered the Minister of Health to appoint a "pharmaceutical factory" as the patent exploiter on behalf of the government, taking into account the recommendations from the head of the National Drug and Food Authority. The two ARVs in question are nevirapine and lamivudine and the authorization covers the remaining patent protection term.

The decree also set the "compensation fee" to the patent holder at 0.5% of the net selling value of the ARVs concerned. According to an interview with a staff member at the Indonesian Patent Directorate, the patent holder has not provided any comments on the release of the Presidential Decree.

Local production has resulted in cheaper ARVs in government hospitals, as seen in Table 2.

Patients who need the ARVs can now get free or partly subsidized medicines from the hospital. The price per package per month for the first-line fixed dose combination (lamivudine, zidovudine and nevirapine) produced by Kimia Farma, the authorized generic manufacturer, is US$ 38. The government provides a subsidy of US$ 20 per month, so patients pay only US$ 18 per month.

In comparison, the price of lamivudine produced by GlaxoSmithKline is about US$ 290 per 60 tablets; for nevirapine produced by Boehringer Ingelheim, the cost is US$ 96 per 60 tablets. Table 2 provides a summary of the relevant ARV prices compared with prices of patented equivalents in 2000 as a baseline.

Table 2: Indonesia: Prices of patented ARVs compared with prices of the generic version

ARVs	Price of patented ARV before 2000 (per 60 tablets) (US$)	Price of patented ARV after 2000 (per 60 tablets) (US$)	Price of generic ARV after government-use authorization (per 60 tablets) (US$)
Lamivudine + zidovudine + nevirapine	800-1000	600	18-65*
Lamivudine (3TC)	NA	290-330**	28
Nevirapine (Viramune)	NA	96	28
Lamivudine + zidovudine (Combivir)	NA	400	48.60

Source: Lutfiyah and Hira (2006). Data obtained through interview with PT Kimia Farma, the Indonesian generic manufacturer. *Note:* The brand names of the patented ARVs are in brackets.

* The range of subsidized and full-cost prices that patients have to pay.

** The price range in different pharmacies. Indonesia does not have price control on medicines and therefore pharmacies and hospitals charge different prices.

But according to the Working Group on HIV/AIDS of the Faculty of Medicine, University of Indonesia (Pokdisus), the price of patented ARVs has not decreased substantially even though the generic drugs are in the market. Almost all the PLWHA (people living with HIV/AIDS) treated under the Pokdisus programme have turned to generic drugs. Pokdisus currently provides about 2000 persons with free generic ARVs sourced from domestic production under the government-use decree.

In early 2007, the Indonesian Government issued *Presidential Decree No. 6/2007 on Revision of the Presidential Decree No. 83/2004 on Implementation of Patent by the Government for Anti Retroviral Drugs*. This was in recognition

of the need "to increase the number of ARVs whose patents are to be implemented by the government in order to enhance access to ARVs".

The decree added efavirenz to the other two ARVs listed in the previous decree. The patent holder is Merck & Co. Inc., and the duration for the patent implementation is until the patent period expires on 7 August 2013.

Thailand

On 29 November 2006 Thailand's Ministry of Public Health announced a five-year government-use authorization for the domestic manufacture of efavirenz. This drug is recommended by the World Health Organization for HIV/AIDS treatment and is commonly used and considered by doctors as one of the best components for first-line therapy because it results in fewer side-effects and is more suitable for those coinfected with other diseases such as tuberculosis or liver infections. Although the drug has been in the market for many years, it still remains very expensive.

Originally developed by DuPont Pharma, the medicine is now marketed by Bristol-Myers Squibb. However, Merck, another pharmaceutical giant, has marketing licence rights in a number of countries including Thailand and China.

The government-use authorization was issued by virtue of Section 51 of Thailand's Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), which states that any ministry, bureau or department of the government may, by themselves or through others, exercise the compulsory-licensing right "in order to carry out any service for public consumption or which is of vital importance to the defence of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service".

The authorization grants the Government Pharmaceutical Organization (GPO) of Thailand, a government-linked pharmaceutical manufacturer, the authority to exercise the rights under the Act.

A royalty fee of 0.5% of the GPO's total sale value of the imported or locally produced efavirenz would be paid to the patent holder.

The authorization took effect immediately following the announcement and the GPO was expected to start mass production of a generic version of the drug by mid-2007. In the meantime, imports of generic efavirenz from India under the same authorization were to start. This importation of the

generic version from India was expected to reduce the cost of the drug for treatment to US$ 22 per month from US$ 41 per month (the price of the patented product). The cost of the locally produced drug was also expected to reduce the price to about half that of Merck's product.

Minister of Public Health Dr Mongkol na Songkhla told the national daily newspaper *The Nation* that there were about 500 000 HIV-infected people who needed antiretroviral treatment, yet only about 100 000 had access to the drugs because of the high prices as well as insufficient budgets. "Of course, the company [patent holder/licensee] will do something to oppose this but we're doing everything according to not only the country's law, but also international law", said Mongkol in the news report.

The Thai Network of People Living with HIV/AIDS (TNP+) and other HIV/AIDS activists hailed the Thai Government's decision. They have been at the forefront of efforts to advocate for the government to use the flexibilities in the TRIPS Agreement.

In issuing a licence to temporarily override the patent barrier to enable the GPO to first import, and then locally manufacture, generic efavirenz, Thailand has strengthened its policy to ensure access to affordable HIV/AIDS medicines. This move allows more patients to switch from the current triple therapy (which could result in serious side-effects) to efavirenz. Eventually, if the cost of efavirenz were to drop further, the Thai Government hoped to replace the triple-therapy formulation with an efavirenz-based one for all patients, according to Dr Suwit Wibulpolprasert, Senior Adviser on Health Economics to the Thai Ministry of Public Health, in an interview with the international medical humanitarian aid organization Médecins Sans Frontières (MSF).

Following Thailand's decision, commercial pressures were placed on the government. There was also, however, widespread support from international health networks and organizations, including MSF and the Consumer Project on Technology, which wrote to the US Government calling on it not to put pressure on the Thai Government. About 22 members of the US House of Representatives also sent a letter to US Trade Representative (USTR) Susan Schwab asking the USTR not to interfere in Thailand's decision to issue the government-use licence on efavirenz.

In January 2007, compulsory licensing for government use was authorized for the GPO to manufacture a lopinavir+ritonavir combination (a second-line ARV) and clopidogrel (for coronary illness). This was the first time a developing country issued a non-ARV compulsory licence.

The benefits are clear. The price of efavirenz was reduced by more than 7 times, lopinavir/ritonavir by 3 times and clopidogrel by 50 times, while the cost of the anti-cancer drug docetaxel was reduced by 24 times and letrozole by 70 times (see Table 3). As a result, access to essential ARVs increased significantly. The prices of the patented drugs also decreased due to the competition from the generic versions, but these are still very high.

Table 3: Comparison of prices before and after the government use authorization

Medicines	Price (US$)			
	Patented drugs before GU	Patented drugs after GU	Generic drug	Percentage of cost/price reduction
efavirenz	58/month	24/month	7.5/month	87%
lopinavir/ ritonavir	1800/year	1,000/year	600/yr	67%
clopidogrel	3	1.3	0.06	98%
docetaxel	900	450	37	96%
letrozole	7	2.2	0.1	98%

Source: Dr. Suwit Wibulpolprasert, Ministry of Public Health, Thailand.

Zimbabwe

In 2002, in view of the HIV/AIDS pandemic affecting Zimbabwe, a notice of "Declaration of Period of Emergency (HIV/AIDS)" was issued by the Minister of Justice, Legal and Parliamentary Affairs for a period of six months.

The notice was intended to allow the state or a person authorized by the minister to:

(a) Make or use any patented drug including any antiretroviral drug; and

(b) Import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.

The period of emergency was extended to 31 December 2008 in a Statutory Instrument 32 of 2003. During this period the state or any person authorized by the Minister of Justice would be able to manufacture or use patented medicines or import any generic medicines used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.

Varichem Pharmaceuticals (Private) Limited, a Zimbabwean generic company, applied under Section 34 of the Patents Act for the authority to make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the state.

Following the application, the Minister of Justice, Legal and Parliamentary Affairs in April 2003 granted Varichem the authority to "produce ARVs or

HIV/AIDS related drugs and supply three quarters of its produced drugs to State-owned health institutions". The licence that was issued also states that the prices of the drugs shall be fixed subject to price control mechanisms that are to be determined by the minister.

According to a Varichem representative, the company produced its first ARV in October 2003 and it has seven generic versions of ARV medicines on the market (i.e., Combivir, nevirapine (200mg tablets), Stalanev-40 (fixed dose combination comprising stavudine 40mg, lamivudine 150mg and nevirapine 200mg), Stalanev30 (stavudine 30mg, lamivudine 150mg and nevirapine 200mg), stavudine (30mg capsules), stavudine (40mg capsules) and lamivudine (150mg tablets)).

Ghana

In October 2005, the Government of Ghana issued a government-use order to import (from selected generic pharmaceutical companies in India) generic versions of selected ARVs that are patented in Ghana. The HIV/AIDS drugs are to be used to treat people without commercial purpose and are for government use, according to the Ministry of Health. According to an official source, the cost of the ARVs dropped more than 50%, from US$ 495 to US$ 235 for one year's treatment.

Brazil[3]

The Brazilian President, Luiz Inácio Lula da Silva, on 4 May 2007 signed a decree sanctioning the compulsory licensing of the antiretroviral drug efavirenz. The ARV was declared to be of "public interest" in an ordinance issued by the Minister of Health on 24 April 2007. Brazil has stated that its decision is in "absolute compliance with international requirements and with Brazilian legislation".

The patent holder, Merck, was given time in which to make a new proposal on the price it would charge for the ARV. Merck offered the ARV to Brazil at a 30% discount on the current price of US$ 1.59 per tablet (i.e. at US$ 1.11 per tablet) but the Brazil MOH reports that it could obtain the product elsewhere for US$0.45 per tablet.

Efavirenz is the most-used imported ARV in AIDS treatment in Brazil. Currently, 38% of AIDS patients take efavirenz as part of their treatment scheme. Brazil's National STD and AIDS Programme estimated that by the end of 2007, 75 000 of Brazil's 200 000 AIDS patients would be taking the ARV.

The annual cost per patient is equivalent to US$ 580, representing budgeted expenditure of US$ 42.9 million for the year 2007. The prices

charged for the generic product result in an annual cost per patient that varies between US$ 163.22 and US$ 166.36. Based on these amounts, under compulsory licensing, expenditure reduction in 2007 would be around US$ 30 million. Savings by the year 2012 of US$ 236.8 million are estimated, at which time the efavirenz patent expires.

News posted on 4 May 2007 on the website of the Brazil National STD and AIDS programme (at www.aids.gov.br) gives the following background on the negotiations with drug companies on other drugs:

"In August 2001, the then Minister of Health, José Serra, requested the compulsory licensing of the nelfinavir patent (made by Roche). The decision was taken following nine months of negotiations with the laboratory. However, on the same day as the announcement was made, the Minister further announced that the process had been interrupted. This happened because Roche agreed to reduce the price of the drug by 40%."

"In December 2003, Health Minister Humberto Costa announced that compulsory licensing could be adopted for the production of nelfinavir in Brazil. On that occasion, Humberto Costa explained that he expected to negotiate with Roche, but that compulsory licensing would be decreed if necessary. In January 2004 the Health Minister was successful in obtaining a price reduction for five drugs: nelfinavir, lopinavir, efavirenz, tenofovir and atazanavir. The agreement resulted in a 37% reduction in the prices previously paid for these antiretroviral drugs."

"In June 2005, the President of the Republic, Luiz Inácio Lula da Silva, and the Minister of Health, Humberto Costa, signed a declaration of public interest in relation to the antiretroviral drug Kaletra (lopinavir + ritonavir), made by Abbott Laboratories. In July of the same year, the Minister of Health issued a statement on the conclusion of the negotiations with Abbott, which ensured a reduced price for the drug for six years, access to the new Kaletra formulation (known as Meltrex) and the transfer of the technology for the formulation of lopinavir + ritonavir. The laboratory agreed to reduce the unit price of Kaletra capsules from US$ 1.17 to US$ 0.63 each, with effect from March 2006, representing a saving of US$ 339.5 million between 2006 and 2011."

The United States

Cases involving government use under 28 USC 1498

28 USC 1498 is the law on the use of patents or copyrights, when the use is by or for the government. Under this law the US Government does not have to seek a license or negotiate for use of a patent or copyright. Any

federal employee can use or authorize the use of a patent or a copyright. The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government to prevent the use. Use by any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement.

In 2001, then Department of Health and Human Services (DHHS) Secretary Tommy Thompson used the "threat" to invoke 28 USC 1498 to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack.[4]

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

Cases involving merger reviews

In 2002, the US Federal Trade Commission (FTC) ordered[6] a compulsory cross-licence of the Immunex tumor necrosis factor ("TNF") patent, to Serono, including the "freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States". Permission was given to export, which is permitted by Article 31.k of the TRIPS Agreement. In this case, the compulsory cross-licence allows a Swiss firm to compete with the US patent owner.

In 2005, the FTC ordered a compulsory licence of Guidant's intellectual property surrounding the RX delivery system for drug-eluting stents (DES) as a condition of Guidant's acquisition by either Johnson & Johnson or Boston Scientific.[7] Boston Scientific, which eventually won the bidding to acquire Guidant, was required to licence DES patents to a potential entrant, Abbott.

Italy

Merck antibiotic *(Imipenem Cilastatina)* patents

On 23 February 2005, the Italian Competition Authority (Autorità garante della concorrenza e del mercato–AGCM) opened an investigation into abuses of a dominant position by refusals to licence rights to active pharmaceutical

ingredients by two large pharmaceutical companies—GlaxoSmithKline and Merck & Co Inc. (Cases A363 and A364).

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

Glaxo patents on migraine drug

On 8 February 2006, the AGCM closed the investigation into the Glaxo Group's refusal to grant a licence to Fabbrica Italiana Sintetici SpA (FIS), a chemical company, for the manufacture in Italy of an active ingredient, *Sumatriptan Succinate*, used in the production of migraine medicines.

According to the AGCM press release, "To remedy the earlier refusal to license, Glaxo granted the licences originally requested by FIS, but also set conditions such as to allow the time to be made up which had been lost because of the original refusal. Those conditions include the granting of a number of additional procedural licences, whereby Glaxo has allowed FIS to save the time otherwise required to research and test an efficient manufacturing process for *Sumatriptan Succinate*. FIS will thus be enabled to offer the active ingredient to manufacturers of generics as early as if Glaxo had never refused the original request for a licence."[8]

The AGCM sought to prevent delays in bringing generic pharmaceuticals to market, thus paving the way for substantial price reductions. FIS initially used the compulsory license entirely for the export market, supplying generic firms that were selling products in markets outside of Italy (such as Spain), where the patents had expired. It did so outside of the framework of the WTO 30 August 2003 Decision on exports of medicines manufactured under a compulsory license, which Spain and other EU members had "opted out" of as an importer. This was possible in part because TRIPS waives all restrictions on exports in cases where the licenses were issued to remedy anti-competitive practices.

Merck patents on prostate and male-pattern baldness drug

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

Table 4: some recent cases of compulsory licensing

Country	Type of Compulsory Licence (CL)	Reason	"Adequate Remuneration"
Malaysia	CL to local company to import for use in public hospitals	Government use	Offer 4% to patent holder
Mozambique	CL to Pharco Mocambique Lda for local manufacture	Condition of national emergency and extreme urgency	Not to exceed 2% of sales
Zambia	CL to Pharco Ltd for local manufacture	Condition of national emergency and extreme urgency	Not to exceed 2.5% of the total turnover of the products
Indonesia	Licence for Ministry of Health to appoint a pharmaceutical factory as patent exploiter	Government use	Compensation fee of 0.5% of the net selling value of the ARVs to the patent holder
Zimbabwe	CL to Varichem to exploit patent	Emergency	
Thailand	CL to Government Pharmaceutical Organization to manufacture efavirenz	Government use	0.5% of the sale price of the generics to patent holder
Ghana	CL to import generic ARVs	Government use	
Brazil	CL to manufacture efavirenz	Government use	
United States	CL to Swiss company to research, manufacture and sell in the US products using Immunex tumor necrosis factor patent (exports also permitted); CL on intellectual property surrounding the RX delivery system for Drug-Eluting Stents	To correct anti-competitive practices	
Italy	CL to manufacture active ingredients: *Imipenem Cilastatina* used in antibiotics; *Sumatriptan Succinate*, used in the production of migraine medicines; *Finasteride* used in products to treat hypertrophy of the prostate, cancer of the prostrate, and male-pattern baldness.	To correct anti-competitive practices	

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Chee Yoke Ling updated the paper.

References

1. Chee Yoke Ling (2006a). "Thailand uses compulsory licence for cheaper AIDS drug", Third World Resurgence, No. 196, December.
2. Chee Yoke Ling (2006b). "Malaysia: 'Government use' route to importing generic medicines", Third World Resurgence, No. 196, December.
3. Khor, Martin (2004). "Patents and Access to Medicines: What Can be Done at National Level", Third World Network Briefing Paper 23.
4. Khor, Martin (2007). "Bilateral FTAs: Overview of Elements, Nature and Implications for Developing Countries".
5. Love, J (2007). "Recent examples of the use of compulsory licenses on patents", Knowledge Ecology International Research Note 2007:2,
6. Lutfiyah Hanim and Hira Jhamtani (2006). "Indonesia: Manufacturing generic AIDS medicines under the 'government use' approach", Third World Resurgence, No. 196, December.
7. Médecins Sans Frontières (2004). "Access to Medicines at Risk Across the Globe".
8. Musungu, Sisule and Cecilia Oh (2006). The Use of Flexibilities in TRIPS by Developing Countries, Geneva: South Centre and World Health Organization.
9. Sangeeta Shashikant (2007a). "Implementing TRIPS Flexibilities".
10. Sangeeta Shashikant (2007b). TWN IP Information dated 8 May 2007
11. Smith, Sanya (2007). "Thai Human Rights Commission attacks FTA with US", South-North Development Monitor (SUNS), No. 6176, 25 January.

Endnotes

1. www.iprcommission.org.
2. http://www.who.int/intellectualproperty/documents/thereport/CHPublicHealthReport.pdf
3. For the official Brazilian Government decree see: http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29717
4. For more information: http://www.cptech.org/ip/health/cl/cipro/
5. See video excerpts from November 8, 2005 Hearings of the Subcommittee on Health of the House Committee on Energy and Commerce, http://www.cptech.org/ip/health/tamiflu/hearingexcerpts11082005.html
6. For more information: http://www.ftc.gov/opa/2002/07/amgen.htm
7. For more information: http://www.ftc.gov/opa/2006/04/bostonscigui.htm
8. AGCM. 21 February 2006. PRESS RELEASE: Pharmaceuticals: Antitrust says Glaxo has made amends and abuse of dominant position discontinued Granting of licence opens way for manufacture of generic migraine drugs. PROCEEDING reference n. A363, case GLAXO-PRINCIPI ATTIVI.

paper 9

Challenging pharmaceutical patents: the case of India

Chan Park

Introduction

There is mounting evidence that overly broad patent protection on pharmaceuticals is hindering access to affordable generic medicines.[1] Originator pharmaceutical companies regularly seek and obtain patent protection on a variety of secondary features or minor variants of a pharmaceutical product.[2,3] Often these patent applications are filed for and granted long after the patent on the active molecule has been granted (if such a patent exists at all). Thus, the effect of these subsequent secondary patents is often to effectively extend the monopoly period of the originator company beyond the 20-year period conferred by the original patent for the active molecule (or to confer patent protection over what had been an unpatented molecule).

As has been already noted, the adoption and application of more rigorous standards during the examination process has the potential to drastically reduce the number of secondary pharmaceutical patents.[3] For instance, adopting a robust distinction between an "invention" and a "discovery" (and granting patent protection only for the former) could potentially preclude the patenting of polymorphs or other crystalline forms of known pharmaceutical substances.[4] Additionally, adopting a robust exclusion for new uses and "method of treatment" claims could preclude the patenting of new uses of already-known substances.[5] Finally, adopting strict standards for novelty, inventive step and industrial applicability could ensure that many of the most common secondary pharmaceutical patent applications (e.g., patents on salts, formulations, enantiomers, combinations etc.) are not granted by the patent office.[6]

All of the above safeguards are important in adopting a set of patent criteria that is sensitive to public health needs. However, even with the strictest standards, there is no guarantee that patent offices will consistently and

rigorously apply them to ensure that questionable patents are not granted. There are several possible reasons for this. One potential reason is that patent examiners—particularly in developing countries—simply do not have the necessary resources to undertake a thorough and rigorous examination of every patent application.[7] Even in the United States, where the Patent and Trademark Office (USPTO) employs upwards of 3000 patent examiners, there have been complaints that the USPTO is understaffed and underfunded, and that examiners are given inadequate time to examine each patent application and make a determination.[8] The situation in developing countries may be worse. Even India, a developing country with a comparatively high level of funding and expertise with respect to patent examination, reported having a total of only 198 patent examiners and controllers to deal with nearly 29 000 applications filed in 2006-2007.[9] South Africa, by contrast, foregoes the substantive examination process altogether, and the lack of a sufficiently qualified pool of examiners to perform examinations is cited as a key reason for the continuation of this practice.[10]

Thus, even the best-staffed and most generously funded patent offices may issue patents of dubious validity. In the United States, for instance, one study estimates that 45% of all patents that are fully litigated are ultimately found to be invalid.[11] Questionable patents, once issued, can generally be invalidated through litigation, but such court proceedings are usually extremely lengthy and can be prohibitively expensive.[12] Moreover, even a questionable patent can be used as a tool to unreasonably delay the entry of generic competitors. By asserting questionable patents in infringement proceedings, originator companies have successfully obtained court-issued injunctions that delay the entry of generic competitors pending the completion of the infringement proceedings, which can last for years.[13]

Patent oppositions as a tool for improving patent quality

One of the options available to countries to both improve patent quality and lower the transaction costs of adjudicating patent challenges is to allow for third parties to challenge the grant of patents—either before the patent is granted, after the patent is granted, or both—in expedited administrative proceedings. The TRIPS Agreement is silent with respect to the opposition proceedings countries may implement in their patent law, and countries have considerable freedom to tailor their opposition proceedings to suit their national interests.

The United States, for example, does not allow for opposition proceedings prior to the grant of the patent, but allows for an administrative post-grant "reexamination" procedure.[14] In contrast, Thailand allows for a pre-grant opposition to be filed within 90 days of the publication of the patent application.[15] India, which has relatively liberal provisions for opposition,

provides for both pre- and post-grant opposition procedures. In India, a pre-grant opposition may be made at any time after publication of the patent application but prior to the grant, and a post-grant opposition may be filed up to one year after publication of the grant of the patent.[16] A summary of the opposition provisions in selected countries in Asia is provided in Table 1.

Table 1: Summary of opposition provisions in selected Asian countries*

Country	Pre-grant?	Post-grant?
Bangladesh	Yes—any person may, within four months after publication of acceptance, give notice of opposition; but only on limited grounds (sec. 9)	No
Bhutan	No	Yes—any "interested person" can petition registrar or court any time after grant (sec. 16)
Cambodia	No	No
China	No	Yes—"any entity or individual" may oppose, any time after grant (Art. 45)
India	Yes—any person may oppose, any time after publication but before grant (sec. 25(1))	Yes—any "person interested" may give notice of opposition, up to one year after publication of grant of patent (sec. 25(2))
Indonesia	Yes—any person may submit written opinion and/ or objection, any time after publication period (6 months) (Art. 45)	No
Nepal	No	Yes—"anyone" can file an objection within 35 days of "seeing or copying" the patent (sec 7A).
Thailand	Yes—any person may oppose, up to 90 days after publication (sec. 31)	No

* Please note that the information in this table is in some cases based on an unofficial translation of the law; moreover, laws may be amended subsequent to this publication. Thus, the table has indicative value only.

As the foregoing demonstrates, there is substantial variance among countries in the form and scope of the opposition proceedings allowed. As TRIPS imposes no obligations on countries with respect to the permissible forms of opposition proceedings, countries are free to formulate a regime that best suits their needs. For instance, countries may choose to restrict opposition proceedings to a limited class of actors (e.g., direct competitors of the patentee), or have more liberal proceedings in which any "person," including civil society groups, may participate in the opposition process. Notably, the active participation of civil society groups in opposition

proceedings has resulted in the invalidation or rejection of patents and patent applications on a number of key medicines; this has been important from the perspective of public health in the developing world.

The first instance in which civil society groups successfully challenged a patent on an essential medicine was in Thailand. Thai civil society groups in 2001 were able to successfully challenge the grant of a patent by the Thai Patent Office on the antiretroviral medicine didanosine.[17] Despite the patent holder's contention that civil society groups lacked the legal standing to bring a patent challenge, the Thai authorities allowed the challenge to be maintained, citing the Doha Declaration: "Since the TRIPS Agreement must be interpreted and implemented so as to promote and support access to medicines for the people as a whole and since those suffering from HIV/AIDS can be injured by a patent blocking access to affordable medicines … they had the right to challenge the patent."[18]

Following on the success of Thai civil society groups in challenging the didanosine patent, civil society groups in countries such as Brazil, China and India have filed their own oppositions to patents on essential medicines.[19] India in particular has seen a large number of patent oppositions filed, both by civil society groups and generic companies, making full use of the pre- and post-grant opposition proceedings available under Indian law.

Patent oppositions in India: a case study

When India amended its law in 2005 to comply with its TRIPS obligations, it included some unique provisions designed to ensure that patent protection on pharmaceuticals did not impede access to affordable generic medicines. One key provision was Section 3(d) of the Patents Act, which was amended to reduce the number of secondary patents for pharmaceuticals. It states that the following is not an invention:

> (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> *Explanation:* For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Thus, any derivative of an already existing drug would not be eligible for a patent in India unless the patent applicant could demonstrate that the derivative form of the drug resulted in making the drug more effective.

From the parliamentary debates surrounding the amendments, it is clear that the essential purpose of this provision was to prevent "evergreening," a term often used to refer to practices in which the entry of generic medicines is delayed through obtaining and asserting secondary patents on existing medicines. In response to several members of Parliament voicing their concerns regarding the effect of patent protection on access to affordable medicines, the then-Commerce Minister of India, Kamal Nath, replied:

> In regard to evergreening, I just want to read out section 3(d) which says that a mere discovery of a new property or a new use for a known substance or the mere use of a known process in a new product—these are exceptions, these will not be granted any patent—and substances obtained by a mere ad-mixture resulting only in aggregation of properties of the components thereof or, processes of producing such substances will not be given patents. There is no question of evergreening.[20]

In addition to Section 3(d), which, on its face, precludes the patenting of a wide array of secondary pharmaceutical "improvements", Indian law retained a number of other exclusions that could potentially also have significance in the pharmaceutical context. These include excluding "the mere discovery of a scientific principle …or discovery of any living thing or non-living substance occurring in nature",[21] substances obtained by the "mere admixture resulting only in the aggregation of properties of the components thereof",[22] and "any process for the medicinal …treatment of human beings".[23] Although these additional provisions are not necessarily unique to Indian patent law, the robust application of all these provisions across a wide variety of pharmaceutical contexts has the potential to make Indian law uniquely progressive in incorporating public health concerns into its patent policy.

The Novartis case

In addition to the existence of the broad substantive safeguards that were put in place in Indian patent law, the presence of the key procedural safeguard of opposition proceedings has arguably been equally significant in the shaping of India's post-TRIPS landscape in relation to access to medicines. As mentioned, Indian law provides that "any person" (including civil society groups) may file a pre-grant opposition against a pending patent application.

The opportunity to test both the procedural and substantive safeguards came soon after the enactment of India's 2005 amendments, when a patent

application relating to imatinib mesylate came up for examination in the Indian Patent Office. Imatinib mesylate, marketed as Glivec/Gleevec by Novartis, had already been the subject of some controversy in India, as Novartis had previously obtained injunctions against several Indian generic manufacturers from selling their versions of this anti-cancer drug. The price differential was significant: while Novartis at the time sold its version at a cost of approximately US$ 2500 per person per month, the Indian companies sold their equivalent generic versions as low as one-tenth the cost.

Concerned about the continued availability of more affordable versions of this lifesaving cancer drug, a patients group, the Cancer Patients Aid Association (CPAA), along with a number of Indian generic manufacturers, filed a pre-grant opposition against Novartis's application in late 2005. Novartis's application for imatinib mesylate was a key early test of Section 3(d), as the application concerned a specific crystalline salt form of the active molecule, imatinib. The CPAA argued, and the Indian Patent Office agreed, that the application was for a new form (i.e., the crystalline salt form) of a known substance (i.e., imatinib), and thus fell under Section 3(d)'s exclusion. Finding insufficient evidence that the crystalline form exhibited any significant enhancement of the active substance's efficacy, the patent office denied this application.[24]

Novartis subsequently appealed the patent office's rejection. In addition, Novartis challenged the validity of Section 3(d), claiming that it was inconsistent with India's TRIPS obligations and that it was invalid under the Indian Constitution. The Madras High Court, in upholding the validity of Section 3(d), noted that it had borne in mind the object of Section 3(d), namely, "to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens".[25]

In upholding the validity of Section 3(d) against constitutional challenge, the court had occasion to provide some guidance as to what the term "efficacy" means:

> The position therefore is, if the discovery of a new form of a known substance must be treated as an invention, then the patent applicant should show that the substance so discovered has a better therapeutic effect. Darland's Medical Dictionary defines the expression "efficacy" in the field of pharmacology as "the ability of a drug to produce the desired therapeutic effect" and "efficacy" is independent of the potency of the drug…. In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the [known substance] and what is the difference between the therapeutic effect of the [known substance] and the drug in respect of which patent is asked for. Therefore it is a

simple exercise … for any patent applicant to place on record what is the therapeutic effect/efficacy of a known substance and what is the enhancement in that known efficacy.[26]

Thus, for a derivative patent to be granted in India, the applicant bears the burden of showing that the derivative of the known substance results in an enhancement of therapeutic efficacy. Further, under the prevailing interpretation of Section 3(d) as laid down by the Madras High Court, improvements to already known substances that merely make the drug easier to manufacture, or more convenient to administer, or results in improved storage capabilities, would not be patentable under Section 3(d).

The landmark Novartis judgment, in which an Indian court for the first time expressly recognized the need to balance patent protection with the government's duty "to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens", was equally the result of India's substantive safeguards (i.e., making new forms of known medicines harder to patent) and its procedural safeguards (i.e., allowing the public an opportunity to oppose patent applications). By allowing generic competitors as well as concerned civil society groups to participate in the patent examination process, the pre-grant opposition procedure paved the way for such groups to advocate for a rigorous interpretation of Section 3(d) which can prevent the granting of secondary pharmaceutical patents. In the wake of this success, civil society groups have filed both pre- and post-grant oppositions against a number of pending applications and granted patents.

Developments after the Novartis case

Since the Novartis judgment was issued in 2007, there have been a number of developments that help illustrate the importance, as well as the limitations, of the opposition process as a tool to ensure patent quality.

A recent decision by the Indian Patent Office, in response to a pre-grant opposition filed by the Indian Network for People Living with HIV/AIDS (INP+), rejected the patent application of Boehringer Ingelheim (BI) relating to a paediatric formulation of nevirapine, a critical first-line AIDS medicine. In considering the patent opposition, the patent office cited to the Madras High Court's judgment in the Novartis case, and agreed with the opponents that it needed to "give a strict interpretation of patentability criteria, as decision …thereof shall affect the fate of people suffering from HIV/AIDS for want of essential medicine".[27] Applying these strict criteria, the patent office concluded that BI's application, which covered a pharmaceutical composition of a specific crystal form of nevirapine along with a variety of common inactive pharmaceutical ingredients, could not be considered an

invention under Indian law under both Sections 3(d) and 3(e); the latter excludes "mere admixtures" from patentability.

As the case of nevirapine indicates, the substantive safeguards included in Indian law, when vigorously applied, can be extremely effective in preventing the grant of many types of secondary patents. In theory, the prime responsibility for ensuring that such safeguards are applied correctly lies with the patent office, regardless of whether an opposition has been filed or not. However, it is far from clear that the higher standards created by Section 3(d) are being applied in a uniform manner.

For instance, the patent office recently granted a patent on an application entitled "A Crystalline Form of a Compound of Formula I" (Application No. 447/MUM/2000; Patent No. 201140) that claims nothing more than a particular crystalline form of an existing drug. The specification expressly states that the sole benefit of these crystal forms is that they "possess unexpected physical properties *which facilitate the manufacture of dosage forms of the compound*" (emphasis added). As such, according to the patent applicant's own admissions, the "new form" of a known substance did nothing to improve the drug's efficacy, but merely facilitated the drug's manufacture. However, despite the applicant's own admission of its failure to meet the enhanced efficacy requirements of Section 3(d), this patent was granted.

There have been other indications that the patent offices are not consistently applying the public health safeguards in Indian law. Indeed, in one reported instance, the Indian Patent Office was found to have granted a number of patent claims that had been specifically rejected as not patentable by the USPTO, which operates under far more liberal patent criteria than does India.[28]

As mentioned earlier, the existence of rigorous patentability standards cannot fully ensure that patent offices never grant questionable patents. Given the realities of resource constraints that many developing country patent offices operate under, some questionable patents are likely to be granted, despite the existence of strict patentability standards. Adopting liberal patent opposition procedures that allow for various actors to participate in the examination process has been shown (in Brazil, India and Thailand) to help ensure that questionable patents on essential medicines are not granted. However, the filing of oppositions against individual patent applications is resource-intensive and requires legal and pharmaceutical expertise that may not be available in all countries. Nevertheless, allowing for the participation of non-traditional actors in opposition proceedings can help a country evolve a patent policy that is responsive to public health considerations.

References

1. Correa, Carlos (2009), The Push for Stronger Enforcement Rules: Implications for Developing Countries, ICTSD, Geneva.
2. Correa, Carlos (2007), Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective, Working Paper, WHO-ICTSD-UNCTAD, Geneva.
3. European Commission (2009), Pharmaceutical Sector Inquiry, Final Report, DG Competition Staff
4. Government of India, Patent Office Annual Report, 2006-2007, New Delhi.
5. Lemley, Mark (1998), Empirical Evidence on the Validity of Litigated Patents, 26 AIPLA Q. J. 185.
6. Love, James (2001), *Compulsory Licensing: Models For State Practice In Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord*, Consumer Project on Technology, Washington, D.C.
7. 't Hoen, Ellen (2009), *The Global Politics of Pharmaceutical Monopoly Power*, AMB Publishers, Diemen, the Netherlands.
8. Unnikrishnan, C.H. (2008), "Patent Denied in US, but Granted in India," *Mint*, 15 January 2008.
9. United States Federal Trade Commission (2003), To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, Washington, D.C.
10. United States Federal Trade Commission (2002), Generic Drug Entry Prior to Patent Expiration: An FTC Study, Washington, D.C.

Endnotes

1. See, e.g., USFTC (2002), European Commission (2009), Correa (2009).
2. European Commission (2009).
3. Correa (2007).
4. Ibid.
5. Ibid.
6. Ibid.
7. See USFTC (2003).
8. Ibid. at Ch. 5, p. 4.
9. India Patent Office Annual Report, 2006-2007.
10. Interview with MacDonald Netshitenze, South Africa Department of Trade and Industry, 10 October 2007, notes of interview on file with author.
11. Lemley (1998).
12. See Love (2001).
13. See Correa (2009).
14. See 35 U.S.C. § 302 (ex parte reexamination) and § 311 (inter partes reexamination).

15. Thailand Patent Act, Section 31.
16. India Patents Act, Section 25(1)-(2).
17. MSF 2003.
18. Ibid.
19. 't Hoen (2009).
20. India Lok Sabha debates (2005).
21. India Patents Act, Section 3(c).
22. Ibid, Section 3(e).
23. Ibid., Section 3(i).
24. *See Cancer Patients Aid Association v. Novartis AG*, Decision of the Chennai Patent Office, 25 January 2006. Novartis has subsequently appealed the decision of the Chennai Patent Office, and its outcome is currently pending before the Intellectual Property Appellate Board.
25. *Novartis v. Union of India and others*, (2007) 4 MLJ 1153. The Madras High Court declined to issue a ruling on the issue of Section 3(d)'s TRIPS-compliance, as it held that a domestic court lacked authority under Indian law to strike down a statute as inconsistent with India's international obligations.
26. Ibid.
27. *Indian Network for People Living with HIV/AIDS v. Boehringer Ingelheim*, Decision of the Delhi Patent Office.
28. Unnikrishnan (2008).

paper 10

Monopolizing clinical trial data: implications and trends*

Karin Timmermans

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement, Box 1) has to a large extent harmonized standards for intellectual property rights, including patents. For many countries, the TRIPS standards were higher than their previous standards. For example, TRIPS obliges countries to allow patenting of pharmaceuticals and imposes a minimum duration of 20 years for patents. Before TRIPS entered into force, a number of (developing) countries either did not grant patents for medicines, or had a shorter patent term. Since generic medicines can only be marketed in the absence of a patent or after its expiry, the implementation of TRIPS in those countries means it will take longer before generic versions of new medicines can enter the market. The TRIPS Agreement has therefore been criticized for its anticipated detrimental effect on access to medicines, especially in developing countries.

But while much of the debate on TRIPS, intellectual property rights, and access to medicines has focused on patents (Box 2), largely outside the limelight the rather abstract notion of data exclusivity has quietly been introduced and promoted. *Data exclusivity* refers to the granting of exclusive rights over the data required for registration of pharmaceuticals, notably the clinical and preclinical trial data. Data exclusivity, too, can jeopardize access to medicines and negatively affect public health. This article tries to demystify the concept and implications of "data exclusivity," and to provide an overview of current trends.

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Box 1: TRIPS and TRIPS-plus

The TRIPS Agreement harmonizes standards for various types of intellectual property rights, such as copyrights, patents, and trademarks. TRIPS is an integral part of the WTO Agreements, which create binding obligations among WTO member countries. TRIPS is subject to the WTO's dispute settlement mechanism, which may—as a last resort—allow WTO member countries to apply trade sanctions against a noncompliant country. This is a powerful enforcement mechanism, especially vis-à- vis developing countries, which can usually ill afford to be faced with trade sanctions.

Meanwhile, intellectual property protection that surpasses the standards and requirements of the TRIPS Agreement is often referred to as "TRIPS-plus." There are many different TRIPS-plus provisions. For example, patent term extensions enable prolongation of the patent term beyond the 20 years required by TRIPS, under certain circumstances. Data exclusivity and "linkage" (see text) are other TRIPS-plus provisions. These TRIPS-plus provisions all delay or hamper generic competition.

Box 2: Patents, registration, and marketing of medicines

The pharmaceutical market is highly regulated. Two sets of laws and regulations play a crucial role in shaping this market: the intellectual property laws and the laws and regulations pertaining to drug registration. Intellectual property rights, especially patents, confer negative rights: if a particular medicine is under patent, the patent holder can prevent others from producing or selling (generic versions of) that medicine in the country concerned. But a patent does not give the patent holder the right to put that medicine on the market. In order to be allowed on the market, a medicine has to be registered by the national drug regulatory authority.

Moreover, a patent applies to an invention, not to a medicine per se. Patents can be granted for instance for a new chemical entity, a production process, or a particular formulation. Thus, a single medicine can be covered by more than one patent. Some patents (notably those on the chemical entity) completely block generics. But in other cases it may be possible to produce a generic version without infringing the patent, e.g., a tablet would not infringe a patent that only covers liquid dosage forms.

Scrutinizing TRIPS

It has at times been argued that a relatively obscure clause in the TRIPS Agreement—namely its Article 39.3—requires countries to implement data exclusivity [1,2]. However, careful reading of the Article does not warrant this conclusion. Article 39.3 essentially demands that undisclosed registration data about new chemical entities be protected against unfair commercial use and against disclosure. Thus, in line with standard regulatory practice, authorities may not publish or share such data—though, importantly, TRIPS does not prevent disclosure when it is necessary to protect the public.

Discussions about data exclusivity, however, gravitate around the interpretation of "unfair commercial use" of registration data. Before registering a pharmaceutical product and allowing it on the market, regulatory authorities verify its quality, safety, and efficacy. In the case of a new medicine, safety and efficacy are established via preclinical and clinical trials; hence submission of the trial data is an important prerequisite for registration.

Meanwhile, in order to obtain marketing authorization for their products, generic manufacturers have to submit their own data on quality. In addition, they usually have to demonstrate that their product is chemically and biologically equivalent to the original. When those requirements are satisfied, the regulatory authority will normally assume that the efficacy and safety profiles of both products are the same, and on that basis allow marketing of the generic. Thus, while it could be argued that generic manufacturers indirectly rely on the originator's safety and efficacy data, such manufacturers do not use the originator's data—in fact they do not even have access to them.

The regulatory body relies on the originator's data, but normally does not actually use or revisit them. Moreover, even if the regulatory body would use those data, this would not be commercial use—though such use could, indirectly, have commercial implications. Finally, it does not seem justified to suddenly label longstanding regulatory practices as "unfair."

Recently the independent Commission on Intellectual Property Rights, Innovation and Public Health, established by the World Health Organization, also found that Article 39.3 does not create property rights over registration data, nor does it amount to data exclusivity [3]. This interpretation is further supported by the Article's negotiating history [4].

Exclusivity examined

Although data exclusivity is not mandated by TRIPS, the European Union (EU), the United States, and a few other countries have chosen to provide

for data exclusivity domestically, and are encouraging other countries to follow suit [2,5]. Therefore it is important to be aware of its implications.

Data exclusivity essentially prevents regulatory authorities from relying on data submitted by originator companies in order to register a generic product. By implication, as long as the exclusivity lasts, generic producers would have to submit their own safety and efficacy data. This would oblige them to repeat clinical and preclinical trials— something that takes time and that they usually cannot afford. But more importantly, the repetition of clinical trials raises serious ethical questions, since it would imply withholding medicines that are already known to be effective from some patients (the control group), solely for commercial purposes. It is unlikely that withholding medicines in this way this would pass the scrutiny of ethical review committees, which renders it de facto impossible for generic companies to repeat the clinical trials.

Alternatively, generic manufacturers would have to postpone the launch of their product until the end of the exclusivity period. Thus, data exclusivity can delay generic competition and the ensuing price reductions.

From the perspective of public health and enhancing access to medicines, another troublesome feature of data exclusivity is its potential interference with a compulsory license. A compulsory license is a license, granted by the government (without the agreement of the patent holder) to allow third parties to produce generic versions of a product that is still under patent. Compulsory licensing is an important safeguard-mechanism in TRIPS. Yet data exclusivity could prevent the registration—and hence the actual sale and use—of generics produced under a compulsory license (see Box 3) [6].

The duration of data exclusivity is usually shorter than patent protection; therefore data exclusivity is most relevant when a product has not been patented in a particular country, or when patents can be challenged or circumvented (Box 4).

It is also relevant when a new use or indication is found for an existing medicine whose patent has expired, or is about to expire, since, in order to obtain permission to market a drug for a novel indication, new clinical trial data need to be submitted to the regulatory authority. Registration for a new indication could trigger a new period of exclusivity. Meanwhile, patent laws may not permit the patenting of such a "new indication" (although this is allowed in some jurisdictions). Thus, data exclusivity acquires considerable commercial significance against the backdrop of disappointing levels of discovery and development of new drugs [7–9] and of the struggle by drug companies to extend exclusivity of their top-selling products. According to one commentator: "Drug companies have learned that when they can't

create a new drug to treat an existing illness, they can create a new illness to treat with existing drugs" [10]. Data exclusivity, in other words, provides a mechanism that can be used to stave off generic competition.

Box 3: Avian flu and data exclusivity in Europe

In the face of a possible pandemic of avian flu, combined with insufficient stockpiles of the "flu drug" oseltamivir and a global demand that was significantly exceeding the production capacity, questions have been raised in the EU about the role of generic production. The laws of EU Member States contain provisions for compulsory licensing, which could be used to allow production of a generic version of a patented medicine. But European legislation does not provide for exceptions to the data exclusivity period following registration of a new medicine.

Thus, even if a compulsory license were issued during that period, generic production and marketing would not be allowed, unless the manufacturer conducted its own preclinical tests and clinical trials. Alternatively, the originator would have to agree to the generic competitor's reliance on its data. European officials have stated that they can not waive these requirements, not even in the case of an emergency or outbreak [52].

Box 4: Affecting access to antiretrovirals

In China, one of the key first-line antiretrovirals for treatment of HIV/AIDS is protected by process patents, which can be circumvented. There is no molecular patent that would completely block generic production, and Chinese manufacturers reportedly are producing the active pharmaceutical ingredient (or raw material) for export. But because of "administrative protection" (the Chinese equivalent of data exclusivity), these companies are not allowed to market the final product (tablets) to patients inside China that need them [53].

Meanwhile in Guatemala, where most antiretrovirals are not under patent, Médecins Sans Frontières is treating AIDS patients mostly with generic medicines. Their considerably lower prices (5%–50% of the price of originator products) have made it possible to expand access to first line treatment. However, Médecins Sans Frontières has expressed concern that recently enacted data exclusivity provisions will preclude the use of generic versions of newer antiretrovirals such as atazanavir, and could thus render second-line treatment unaffordable [54,55].

Options for damage control

Faced with incessant demands, some countries have opted to provide data exclusivity, while trying to mitigate its negative impact on their domestic industries and on access to medicines. They have devised several strategies for damage control.

- *Limiting the duration of data exclusivity, and/or specifying that data exclusivity cannot extend beyond the patent term.* The latter strategy was, until recently, explicitly provided for under EU regulations, and was implemented by Greece, Portugal, and Spain [11,12].
- *Limiting the scope of data exclusivity.* This can be done by specifying explicitly that data exclusivity will only apply to new chemical entities and will not extend to new indications or different formulations of existing medicines. This strategy has been adopted by Egypt and Chile [13,14].
- *Imposing quick registration of a medicine.* Chile has drafted regulations specifying that failure to register a new medicine in Chile within one year after obtaining the first global marketing authorization will disqualify it for data exclusivity [14].
- *Creating procedures for "compulsory licensing" of the data that fall under the exclusive rights.* This strategy draws on US practices in case of mergers [6] and on the examples of Costa Rica and Brazil [13].
- *Enabling health authorities to waive data exclusivity when it is deemed in the interest of public health or of specific patients to do so.* This strategy is analogous to the registration waivers or "compassionate use" provisions that often figure in national rules on drug registration—Colombia reportedly takes this line [13]. Waiving data exclusivity is also the approach followed by the EU in the case that a compulsory license is issued to allow the production of generic pharmaceuticals for export to countries that lack production capacity [15].

In other cases, regulators do not rely on the originator's confidential safety and efficacy data when registering a generic medicine. Instead, they rely on published data or on foreign registration of the medicine concerned—Argentina for instance has been said to use the latter approach [1]. In fact, referring to or relying on foreign registration is a longstanding, recommended practice, especially for regulatory authorities with limited (human) resources [16–20].

Finally, there have been proposals to allow use of clinical trial data by generic competitors on a cost-sharing basis. Cost-sharing would prevent the creation of new monopoly rights, but instead enable competition in return for a fair, and probably modest, compensation to the originator of the data [13].

Bilateral agreements: preemptive strikes?

Meanwhile, on the trade front, countries are increasingly turning to bilateral and regional free trade negotiations. At the instigation of their well-established pharmaceutical industry [21–23], some developed countries are using these negotiations to obtain protection for intellectual property that goes significantly beyond the TRIPS standards. Data exclusivity figures prominently among those "TRIPS-plus" requirements (Box 1).

A comparison of bilateral free trade agreements (FTAs) that have been concluded in recent years between the US and an array of other countries demonstrates a worrisome trend: the requirements for data exclusivity are progressively getting tighter (Table 1). FTAs also increasingly preclude the use of the strategies for damage control discussed above. In line with the tendency to seek ever more detailed and stringent data exclusivity concessions in FTAs, shown in Table 1, Thailand reportedly is facing extensive demands in this area during its bilateral trade negotiations with the US [24–26]. Moreover, Thailand risks being faced with similar demands during concurrent negotiations with the European Free Trade Association (EFTA) [27].This risk is not imaginary, since the EFTA has already concluded several other free trade agreements that contain "TRIPS-plus" pro-visions, including data exclusivity [28–30].

Table 1: Overview of data exclusivity provisions in recent US FTAs

Exclusivity provisions include/ apply to:	2000	April – Sept. 2003			May – Sept. 2004				Jan.-April 2006	
	Vietnam	Laos	Singapore	Chile	Australia	Morocco	CAFTA	Bahrein	Oman	Peru
New chemical entities (NCEs)	(+)	+	+	+	+	+	+	+	+	+
New indications	(+)	(+)	(+)		+	+		+	+	
When relying on foreign registration			+		+	+	+	+	+	+
When relying on disclosed data			+			+		+	+	+
Exclusivity period can surpass patent term			+		+			+	+	+
'Local' definition of NCE to be used					+	+	+	+	+	+
Imposing quick registration prohibited							+			+

Symbols: + means the FTA imposes this particular requirement or condition; (+) means the language is ambiguous but may impose the requirement.

Data are based on the author's assessment; they do not represent a legally binding or final interpretation.

Time periods refer to the date on which the texts were finalized, not to the ratification or entry into force of the respective agreements.

CAFTA: Central American Free Trade Agreement

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Perhaps even more disturbing are suspicions that the EU may be attempting to include requirements for European-style data exclusivity in its Economic Partnership Agreements [31,32]; the EU already expects data exclusivity from new and aspirant Member States [33,34]. EU-style data exclusivity lasts longer and hence could impede access to medicines even more seriously than US-type provisions (Box 5).

Box 5: Data exclusivity in the EU versus US

In the EU, data exclusivity for a new medicinal product lasts for eight years and is followed by two years of market exclusivity. During the latter period, regulatory authorities can accept and evaluate the registration dossier of a generic version of the same product, though marketing can only commence at the end of the entire ten year exclusivity period. These ten years can be extended by one year if, during the first eight years of the exclusivity period, the product has been registered for one or more new indications for which it is believed to be of "significant clinical benefit" [56]. Meanwhile, in the US, data exclusivity lasts five years for products with a new active ingredient, and three years for a new indication of a known product [57]. However, in the US, multiple extensions appear to be possible, while EU regulations allow only a single extension.

Blurring the boundaries

The boundaries between the registration system and the intellectual property system are further blurred by requirements that the regulatory authority should withhold registration of generic versions of patented drugs. This is often referred to as "linkage." Currently generic companies are free to make their own assessment as to whether a patent would stand up to legal scrutiny; when they consider a patent weak, generic manufacturers may decide to enter the market regardless.

"Linkage" renders the regulatory authority de facto responsible for enforcing pharmaceutical patents. When implementing it, regulators—having neither the expertise, the resources, nor the mandate to assess the validity of a patent—will probably enforce any and all patents. This is problematic; in the US, generic companies have regularly prevailed in pharmaceutical patent infringement cases [35], meaning that in those cases the patent was either not infringed or not valid.

Thus, making registration conditional upon the absence of a patent will create additional barriers for generic manufacturers. It will also redouble the incentives for "evergreening": the practice of filing additional and at

times frivolous patents on minor improvements, or even simply on particular features of existing medicines, in an effort to keep generic competition at bay. Unfortunately—though perhaps not surprisingly—virtually all recent bilateral FTAs concluded by the US contain clauses mandating "linkage" between registration and patent status.

Accidents on accession?

As if the above is not troubling enough, another worrisome trend has started to emerge: "TRIPS-plus" requirements are being imposed during World Trade Organization (WTO) accession negotiations. While initially appearing to be an incident unique to the accession of China [36], more recently, acceptance of tightly worded provisions on data exclusivity seems to have become a rather routine precondition for aspiring WTO members.

The first indication that this precondition was becoming more common was the reference to data exclusivity during Cambodia's accession [37]. The alarm bells that sounded when this fact became known [38-40] apparently were heard, and during the formal acceptance of Cambodia's WTO membership, reference was made to the Doha Declaration on the TRIPS Agreement and Public Health [41], by virtue of which Cambodia would be able to defer the implementation of data protection.

But all this was quickly forgotten thereafter; similar "TRIPS-plus" commitments have surfaced during the recent accession of Tonga [42]. Data exclusivity has also been raised during the accessions of Saudi Arabia and Vietnam [43,44], and there are reports and fears that "TRIPS-plus" concessions are being asked of Russia [45], which is actively negotiating its way into the WTO.

Moreover, there appears to be little mercy for the small or the weak: the accession documents of Cambodia (a least-developed country) and Tonga (a small pacific island nation) not only contain obligations with regard to data exclusivity, but also explicitly impose "linkage"—a feature that thus far is unique to the accession of small or least-developed countries.

Stemming the tide?

Table 1 shows how FTAs are increasingly used to micromanage other countries' domestic policies. WTO accession negotiations risk becoming an extension of this strategy. These trends beg the question of what competition in the pharmaceutical sector will look like in the future, and create serious concerns about the prospects for access to medicines, especially in developing countries.

But maybe all is not yet lost. The Southern African Customs Union has not yet caved in to "TRIPS-plus" demands in bilateral negotiations with both the US and EFTA [46–51]. Meanwhile, the emerging trend of making use of WTO accession negotiations to advance the "TRIPS-plus" agenda—which goes against the spirit of the Doha Declaration on TRIPS and Public Health—can probably still be nipped in the bud, if current WTO members recognize what is happening and take a common stance against the few demanders.

But more countries should resist demands that monopolize the use of clinical trial data and blur the boundaries between the intellectual property regime and regulatory requirements for pharmaceuticals. And the health sector should pay more attention to these developments outside its immediate purview, wake up to the far-reaching implications of these developments, and voice its concerns more widely and more effectively. Failing that, the battle for access to medicines will be lost on these new and little-known fronts.

References

1. International Federation of Pharmaceutical Manufacturers and Associations (2000) Encouragement of new clinical drug development: The role of data exclusivity. Geneva: International Federation of Pharmaceutical Manufacturers and Associations.
2. US Trade Representative (2004) Special 301 report. Washington (D. C.): Office of the United States Trade Representative.
3. Commission on Intellectual Property Rights, Innovation and Public Health (2006) Public health, innovation and intellectual property rights. Geneva: World Health Organization.
4. Correa CM (2002) Protection of data submitted for the registration of pharmaceuticals: Implementing the standards of the TRIPS Agreement. Geneva: South Centre/World Health Organization.
5. European Commission (2003) Notice of initiation of an examination procedure concerning obstacles to trade within the meaning of Council Regulation (EC) No 3286/94, consisting of measures imposed and practices followed by the Republic of Turkey affecting trade in pharmaceutical products. Official Journal of the European Union.
6. Correa CM (2006) Protecting test data for pharmaceutical and agrochemical products under free trade agreements. In: Roffe P, Tansey G, Vivas-Eugui D, editors. Negotiating health. London: EarthScan/International Centre for Trade and Sustainable Development.
7. Angell M (2000) The pharmaceutical industry—To whom is it accountable? New Engl J Med 342: 1902–1904.
8. US Food and Drug Administration (2004) Innovation or stagnation: Challenge and opportunity on the critical path to new medical products. Rockville (MD): US Food and Drug Administration. Available: http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf. Accessed 9 January 2007.

9. Harris G (2000 July 6) Drug firms, stymied in the lab, become marketing machines. The Wall Street Journal.
10. Thompson N (2002 October 7) Drug abuse: Where have all the new meds gone? The New Republic.
11. European Parliament (2001) Directive 2001/83/EC of the European Parliament and of the council of 6 November 2001 on the community code relating to medicinal products for human use. Official Journal of the European Communities.
12. Ranson P (2003) Data protection in the pharmaceutical industry. J Gen Med 1: 48–56.
13. Weissman R (2006) Public health-friendly options for protecting pharmaceutical registration data. Int J Intellect Prop Manage 1: 113–130.
14. Government of Chile (2005) Industrial Property Law No 19.039 modified by Law 19.996.
15. European Parliament (2006) Regulation (EC) No 816/2006 of the European Parliament and of the council of 17 May 2006 on compulsory licensing of patents relating to the manufacturing of pharmaceutical products for export to countries with public health problems. Official Journal of the European Communities.
16. World Health Organization (1988) Guidelines for developing national drug policies. Geneva: World Health Organization.
17. World Health Organization (1990) WHO expert committee on specifications for pharmaceutical preparations. Thirty-first report. Technical report series no 790. Geneva: World Health Organization.
18. World Health Organization (1995) Report of the expert committee on national drug policies. Geneva: World Health Organization.
19. World Health Organization (1999) Effective drug regulation: What can countries do? Geneva: World Health Organization.
20. Management Sciences for Health, World Health Organization (1997) Managing drug supply. West Hartford (CT): Kumarian Press.
21. Drahos P (2001) BITS and BIPS: Bilateralism in intellectual property. J World Intellect Prop 4: 791–808.
22. Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFA-3) (2003) The US–Chile Free Trade Agreement (FTA): The intellectual property provisions, 28 February.
23. Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFA-3) (2004) The US–Central American Free Trade Agreement (FTA): The intellectual property provisions, 12 March.
24. Bilaterals.org (2006) IPR text proposed by US to Thailand. Available: http://www.bilaterals.org/article.php3?id_article=3677. Accessed 10 January 2007.
25. Ten Kate D (2006 January 5) IPR debate centers on cheap drugs. International Herald Tribune–Thai Day, Bangkok.
26. Ten Kate D (2006 January 13) Mounting opposition to FTA drug rules. International Herald Tribune–Thai Day, Bangkok.
27. Berne Declaration, Focus on the Global South (2006) NGOs urge EFTA countries not to endanger public health, food security and development in Thailand. Available: http://www.evb.ch/en/p25010565.html. Accessed 10 January 2007.

28. Governments of the EFTA and Chile (2003) Free Trade Agreement between the EFTA States and the Republic of Chile, Annex XII. Kristiansand.
29. Governments of the EFTA and Lebanon (2004) Free Trade Agreement between the EFTA States and the Republic of Lebanon, Annex V. Montreux.
30. Reinhard J (2004) Deprive Doha of all substance: How through bilateral agreements EFTA States impose to developing countries intellectual property rules on medicines that are beyond the WTO obligations and that restrict access to medicines. Available: http://www.evb.ch/en/p25009517.html. Accessed 10 January 2007.
31. Hormeku T (2005) Data exclusivity: How the EU could use EPAs to undermine access to affordable medicines. Third World Network–Africa. Available: http://twnafrica.org/news_detail.asp?twnID=788. Accessed 10 January 2007.
32. Pugatch MP (2005) Data exclusivity: Implications for developing countries. Bridges 9: 21–22.
33. Commission of the European Communities (2001) 2001 Regular report on Hungary's progress towards accession. Brussels: Commission of the European Communities.
34. Commission of the European Communities (2004) 2004 Regular report on Turkey's progress towards accession. Brussels: Commission of the European Communities.
35. Federal Trade Commission (2002) Generic drug entry prior to patent expiration: An FTC study. Washington (D. C.): Federal Trade Commission.
36. World Trade Organization (2001) Report of the working party on the accession of China. Document WT/MIN(01)/3. Geneva: World Trade Organization.
37. World Trade Organization (2003) Report of the working party on the accession of Cambodia. Document WT/ACC/KHM/21. Geneva: World Trade Organization.
38. Cropley E (2003 September 9) Oxfam, MSF say Cambodia railroaded in WTO talks. Reuters (Phnom Penh).
39. Mayne R (2003) Oxfam note on Cambodia's WTO accession. IP-health.
40. Oxfam (2003) Cambodia's accession to the WTO: How the law of the jungle is applied to one of the world's poorest countries. Oxfam International.
41. Yerxa R (2003) Statement on behalf of the working party on the accession of Cambodia. Available: http://www.wto.org/english/thewto_e/minist_e/min03_e/min03_11sept_e.htm. Accessed 19 March 2004.
42. World Trade Organization (2005) Report of the working party on the accession of Tonga to the World Trade Organization. Document WT/ACC/TON/17, WT/MIN(05)/4. Geneva: World Trade Organization.
43. World Trade Organization (2005). Report of the working party on the accession of the Kingdom of Saudi Arabia to the World Trade Organization. Documents WT/ACC/SAU/61. Geneva: World Trade Organization.
44. World Trade Organization (2006) Report of the working party on the accession of Viet Nam. Document WT/ACC/VNM/48. Geneva: World Trade Organization.

45. New W (2005) Official: In WTO talks, US pushes Russia to restrictive TRIPS standard. Intellect Prop Watch 2: 4–5.

46. Lourens C (2004 November 23) SA near to clinching another trade deal. Business Day (Johan-nesburg). Available: http://allafrica.com/stories/200411230170.html. Accessed 10 January 2007

47. Mnyanda L (2004 September 19) Trade talks grind to a halt. Sunday Times (Johannesburg). Avai-lable: http://www.aegis.com/news/suntimes/2004/ST040913.html. Accessed 10 January 2007.

48. International Centre for Trade and Sustainable Development (2005) US–SACU talks underway again. Bridges Weekly Trade News Digest 9: 5.

49. Treatment Action Campaign, Berne Declaration (2005) Southern African countries have taken a firm stand against EFTA demands on intellectual property rights in free trade agreement. Available: http://www.evb.ch/index.cfm?page_id=3473. Accessed 10 January 2007.

50. Editorial (2006 April 21) US drops FTA with SACU, starts trade and investment work program. Inside U.S. Trade.

51. Editorial (2006 April 21) US, SACU trade talks proves far-fetched. Namibia Economist. Available: http://allafrica.com/stories/200604210389.html. Accessed 10 January 2007.

52. Terberger M (2006) Tamiflu applications and data exclusivity in an emergency compulsory license situation. Letter to the European Generic Medicines Association. Brussels: Enterprise and Industry Directorate-General, European Commission.

53. Grace C (2005) Update on China and India and access to medicines. Briefing paper. London: Department for International Development (DFID) Health Resource Centre.

54. Médecins Sans Frontières (2005) Data exclusivity and access to medicines in Guatemala. Briefing note. Guatemala/USA: Médecins Sans Frontières.

55. Médecins Sans Frontières (2003) Open letter to Ambassador Robert Zoellick. Available: http://www.doctorswithoutborders.org/publications/openletters/tozoellick_10-15-2003.cfm. Accessed 13 January 2007.

56. European Parliament (2004) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, amending Directive 2001/83/EC on the community code relating to medicinal products for human use. Official Journal of the European Union.

57. Government of the United States (1994) 21 US Code, § 355(j).

paper 11

Protection of data submitted for the registration of pharmaceutical products: TRIPS requirements and "TRIPS-PLUS" provisions

Carlos M. Correa

Introduction

One component of all public health policies that requires careful consideration is related to the conditions for the registration of pharmaceutical products. These products must, of course, satisfy certain efficacy and safety criteria. National authorities usually require, as a condition for registering new products, that data related to efficacy and safety be provided. The legal protection of this data, in particular with regard to the use that is made of such data when dealing with subsequent applications for registration of similar medicines, has caused different approaches to be adopted, and has generated great controversy.

Article 39.3 of the TRIPS Agreement, which raises the issue of data protection, leaves member countries considerable room to maneuver in implementing the obligation to protect such data against "unfair commercial use". The Agreement stipulates the protection of "undisclosed data" as a measure against unfair competition in accordance with the provisions of Article 10bis of the Paris Convention. The Agreement avoids considering undisclosed data as "property", and does not oblige granting the owner of the data "exclusive" rights.

According to Article 39.3, the element that is subject to protection is undisclosed test data, i.e. the result of tests carried out by the manufacturers of brand-name medicines in order to prove the product's efficacy and safety, so long as these data have not been made public. These data are obtained by applying standard protocols to certain chemical substances; they are not a creative contribution. The TRIPS Agreement recognizes this, and therefore provides protection only for data that are the result of "a considerable effort". The underlying concept is not that of protecting a creation, but that

of protecting an *investment*. In addition, the TRIPS Agreement only requires this protection for *new chemical entities*. This protection is not required for a new dosage form or for a new use of a known product.

Protection is granted against all "unfair commercial use" of the protected data in question. This means that a third party could be prohibited from using the results of the tests carried out by another company as a basis for submitting an independent application for commercial approval if the respective data have been obtained through dishonest commercial practices. This party could obviously prepare the data and the information independently, or obtain them from other sources. However, duplicating tests to obtain already-known results is, undoubtedly, questionable in terms of cost-benefit. Article 39.3 also allows any competent national authority to use the data previously submitted by the originator to evaluate second and future applications regarding the same medicine since this does not entail an "unfair commercial use".

In some jurisdictions—in the United States and the European Union for example—additional protection beyond what is required by TRIPS is granted to data submitted for registration. In the United States, the brand-name medicines manufacturer is granted a five-year period of exclusivity to use this information.[1] In the European Union, following a recent regulatory reform, this period can be up to 11 years. During the data exclusivity period, a subsequent applicant may not base his application on the first registration's data; consequently, he cannot register a generic equivalent unless he produces his own clinical data.

But this is not the concept contained in the TRIPS Agreement, which does not require granting exclusive rights. According to the standard contained in the Agreement, national authorities may (in order to approve subsequent applications for example) base their approvals on a registration in a third country that applies strict health standards,[2] or on data already in their possession,[3] so long as the products' equivalence ("similarity") can be proven.

In summary, according to the TRIPS Agreement, countries can decide how they wish to regulate the protection of undisclosed data that is submitted for pharmaceutical product registration. *Article 39.3 does not create property rights or exclusive rights with regard to test data*.[4]

Does registration through abridged procedures constitute undue use of another's efforts?

An important question is whether a person or entity who applies for and obtains registration of a generic pharmaceutical product through an abridged

procedure is making *undue* use of the effort of the company that first registered the product (since the latter performed clinical and pre-clinical tests which the former doesn't have to redo).

It should be noted that a company which applies for registration through an abridged procedure does not necessarily have to access or *use* the data (the results of pre-clinical and/or clinical tests) submitted by the first company when registering a medicine. It is the health authority that, by *reference* to the first product, relies on the data. However, can the argument be sustained that this registration supposes the *use of another's effort,* which the law should prohibit? Or, in other words, can such act be reprehended, *in itself*, as an act of unfair competition?

Companies follow attentively what their competitors do and, within the framework of commercial and industrial freedom, attempt to use all the means they can to increase the number of their own customers. If *all* use of another's effort were to be considered as legally prohibited, the market economy, as we know it today, would cease to function. In fact, the dynamics of competition suppose that all economic agents will attempt to take advantage of their competitors' efforts, which would certainly not be illegitimate, unless they were to engage in illegal or morally reprehensible behaviours which could be considered as "unfair".

Ideas and investments made by a company often give clues and open the way for others to obtain economic advantages. Economic theory has analysed this phenomenon in depth; it simply reflects what is technically called "positive externalities". Thus, when a company shows that a certain disease can be treated with a particular kind of medicine (e.g. Smith Kline and French's cimetidine), others immediately search for competing medicines (e.g. Glaxo's ranitidine), benefiting enormously from the information generated by the pioneer company. When a company identifies a "niche" market, it also opens the eyes of competitors, who will—unless there is an intellectual property right or other barrier that excludes them—sooner or later compete in that market.

In this sense, Kamperman Sanders notes that

> ... the mere fact that another's achievement is being exploited does not call for any impediment on the basis of unfair competition provisions. *On the contrary, appropriating and building on others' achievements is the cornerstone of cultural and economic development.* The axiom of freedom to copy epitomizes the principles of the free market system (Kamperman Sanders, 1997). [emphasis added]

The law condemns taking advantage of another's efforts when it is the result of an illegal act, or of an act which, although legal, is dishonest or unfair.

In other words, what the law condemns is not the *effect* of a commercial behaviour (reducing a competitor's market share), but the *manner* in which such effect is obtained.

When describing the nature of competition, Stephen Ladas, a recognized authority on industrial property matters, pointed out that:

> It is an undeniable fact of modern business life that successful manufacturers or traders have to cope with the danger of having the goodwill of their businesses, their connection with the purchasing public, interfered with by competitors ... In a competitive economy it is to be expected that each manufacturer or trader necessarily seeks to maintain and improve his market position by obtaining the benefit of a public demand, even though this demand be created by other manufacturers or traders ...
>
> ... Where does lawful competition end and unlawful competition begin? The fact that a competitor may derive a profit from his act of competition or cause monetary loss to another is not, in itself, unlawful. The dictum "no one should reap where he has not sown" requires delicate application. Progress would be paralyzed and monopoly would become general if we should attempt to prevent persons from using the work or experience of others. We must encourage people in the same trade or industry to compete for the custom of the public on the most favorable terms. The issue is whether the means employed in such competition are fair and lawful. An act may lack in tact or taste but not be dishonest (Ladas, 1975, p.1676-1677; 1689).

There is no discipline in comparative law which punishes the use of another's effort *as such*. As a result, in a situation where someone makes use of another's effort, there is nothing to determine whether it is legal or not. To make that determination, it is necessary to assess *how* the use took place, in other words to characterize the behaviour within the applicable legal framework—in this case, that which regulates unfair competition.

Unfair competition

The unfair competition discipline has evolved, in particular in countries with continental European legal roots, toward judging the *mode* in which competition is taking place and not the competition itself. The ultimate objective of unfair competition legislation is to ensure the competitive operation of the market (Bercovitz, 2000), by ensuring that competition is based on commercially honest practices. The purpose is not to protect a share of the market for any of the competitors, because successful competition

always reduces the market share of some competitor, and this is a natural feature of the market system's normal operation.

Although there is a connection between the defense of competition, or antitrust law, and unfair competition, these are in fact two clearly differentiated disciplines (Portellano Diez, 1995, p. 131). The purpose of the former is to punish anti-competitive practices, i.e. those which tend to *exclude* a competitor, for example through monopolistic and oligopolistic behaviours and other means that could prevent, restrict, distort or limit the enjoyment of economic freedom. As a result, *antitrust law will not be applicable when the effect of an action on the market increases competition.*

Unfair competition, on the other hand, applies when competition is not restrained but does increase (for example by the introduction of a product that competes with a product that already exists on the market) if this competition is exercised through an unfair commercial practice. In other words, this discipline does not punish competition or its impact (e.g. fall of a competitor's market share), but it does punish the *mode* in which competition is practised.

An "unfair" commercial practice is a *dishonest* practice (see, for example, Henning-Bodewig, 1999, p. 177).

The common meaning of "unfair" is "not equitable or honest or impartial or according to rules". [5] This qualification derives from the Paris Convention (Article 10*bis*), applicable to all WTO member countries, which defines unfair competition as "contrary to honest practices" in commercial or industrial matters. Article 39.2 of the TRIPS Agreement contains this same concept, which is developed in Article 10*bis* of the Paris Convention.

The WIPO Model Provisions on the Protection against Unfair Competition also confirm that the "decisive criterion" is that the action be "contrary to honest practices", as this notion is interpreted by the legal authorities of the corresponding country (WIPO, 1996, p. 6).

In conclusion, in order to uphold that a conduct within the framework of a competitive relation is *unfair*, it must be commercially dishonest.

The decision as to whether a practice is honest or not is a strictly territorial question. There is no universally accepted, uniform standard in this respect; even within Europe there is no consensus as to when a practice is dishonest, since this assessment depends on the vision of the specific country where protection is being claimed (see Henning-Bodewig, 1999, p. 177).

The "unfair" concept is relative to the values of a specific society at a given time. It differs from state to state, and this variation is in fact one

of the premises on which the unfair competition discipline is based. There is no absolute universal rule to decide when certain practices should be considered unfair. Ladas writes that

> Morality, which is the source of the law of unfair competition, is a simple notion in theory only. In fact it reflects customs and habits anchored in the spirit of a particular community. There is no clearly objective standard of feeling, instincts, or attitudes toward a certain conduct. Therefore, specific prescriptions involving uniform evaluation of certain acts are extremely difficult.
>
> The pressures existing in the various countries for the suppression of acts of unfair competition differ greatly. Generally, the development of law of unfair competition depends on active and intense competition in the marketplace by competing enterprises. The pressure of conflicting interests is what leads to the establishment of clear rules of law. This pressure is not uniform in all countries and indeed it is evolving continuously. (Ladas, 1975, p.1685-1686).

Ladas concludes that "We look for a standard by which we may judge the act complained of. This is an objective standard: the honest practices in the course of trade in the particular community and at the particular time" (Ladas, 1975, p.1689). This remark shows that qualifying a practice as unfair cannot be arbitrary, subject to the personal criterion of the administrative or legal authority judging a concrete case. It must be the result of an objective appreciation of what society considers to be dishonest or immoral.

Given the diversity with which societies assess behaviours, it is possible that different countries judge certain situations differently depending on their values and competitive advantages. Can the conduct of an entity that obtains a health registration through an abridged procedure, which is to say based on the prior existence of the registration of another similar product, be considered as dishonest or immoral, since that entity does not have to conduct the pre-clinical and/or clinical tests that the first had to conduct in order to register the product?

Naturally, the answer to this question will depend on the moral assessment of this conduct in each country. Most of the world's countries accept abridged registration procedures in order to promote the competition of "generic" products. In the United States, for example, abridged registration is admitted for agrochemical products (under the Federal Insecticide, Fungicide and Rodenticide Act–FIFRA), even without the consent of whoever first submitted the data, merely against the payment of an amount which, should the parties involved disagree, is set by a judge. On the other hand, the protection of data submitted for the registration of medicines was implemented in the United

States via a *sui generis* system consisting also of a period of exclusive use in order to protect the *investment* necessary for developing such medicines. However, none of these *sui generis* systems is founded on considering the use of the data by third parties as a dishonest or immoral action, but rather on practical reasons related to the development of the country's agrochemical and pharmaceutical industries (with regard to the scope of these systems, refer to Cook, 2000).

Such a *sui generis* system was not included in the TRIPS Agreement, according to which industrial secrets and data submitted for the registration of pharmaceutical or agrochemical products were regulated only under the unfair competition discipline (see Article 39.1 of the TRIPS Agreement).

Many national legislations promote an abridged registration procedure, because it fosters competition in a critical, socially important sector such as that of public health. Additionally, such a procedure

(1) is normally performed without using the data presented by the first party to register and consequently without infringing intellectual property rights;

(2) can only be performed in compliance with laws that stipulate it, in other words, under the protection of specific administrative standards.

Indeed, in the abridged pharmaceutical product registration system, the applicant does not have access to company secrets belonging to the holder of the original registration of a similar or "reference" product. The health authorities only check the similarity or equivalence of the "generic" product with the previously registered product. Also, this procedure can only be performed if there is no patent in force, since the patent holder would otherwise benefit from a *ius prohibendi* to exclude the competitor. In other words, there is no infringement of intellectual property rights. Such registration can only take place if the law provides for it.

The law reflects what society considers to be moral. Someone who makes use of the prerogative granted by the law cannot be guilty of unfair practices, so if an abridged registration procedure is legal, pursuing it cannot be unfair or immoral.

Finally, to argue that an abridged registration procedure is a form of unfair competition (unless authorized by who originally submitted the respective test data) would imply *the end of generic medicines supply*. It would also undermine the use of generics in the interest of public health adopted by countries such as Argentina, Brazil, Canada, Venezuela and many others.

Indeed, by definition, generic medicine manufacturers do not repeat the efficacy and safety tests of already-known products, allowing them to sell these products at lower prices and thus benefiting patients and responding to the basic interests of public health policies with regard to access to medicines. Since the manufacturer of generics does not repeat the efficacy and safety tests, the hypothetical interpretation that any registration via the abridged procedure represents undue use of another's efforts (unless their consent had been obtained) would in fact ensure an indefinite monopoly over the product to the original developer. This result would have no precedent in the world and would be very dangerous for public health in any country.

The availability of generics is fundamental from a public health perspective, since it is well known that competition from generics causes medicine prices to fall dramatically. This has been confirmed repeatedly, and many countries apply deliberate policies tending to have these products arrive as early as possible (WHO, 1988, p. 31).

It is difficult to consider as dishonest or unfair a conduct which, respectful of third party intellectual property rights, and compliant with a specific regulation, makes use of an abridged procedure to provide greater competition to the pharmaceutical market, clearly benefiting public health.

The World Health Organization has set as an international standard that regulatory authorities, in order to improve generic medicines, should request documentation that demonstrates that the product has been manufactured according to GMP (good manufacturing practices) and meets the applicable quality standards. They should also provide information regarding the general characteristics of the product and the patient information leaflet, and demonstrate therapeutic equivalence. Only for "innovative" products, in other words those products that are being marketed for the first time in the world, is it necessary in addition to present efficacy and safety studies.

Finally, it should be noted that the unnecessary repetition of tests on human beings to replicate already available results is unethical. This would be contrary to the Helsinki Declaration for the Conduct of Clinical Research (available at www.bioscience.org/guides/declhels.htm), whose recommendations are quoted and guide the regulations regarding clinical tests throughout the world, including the FDA from the United States and the European Medicines Agency (EMEA).[6]

References

1. Bercovitz, Alberto, 2000, "La competencia desleal", Palacios L., Antonio y Antequera H., Ricardo (Eds.), Propiedad Intelectual. Temas Relevantes en el Escenario Internacional, Proyecto Propiedad Intelectual SIECA-USAID, Guatemala.

2. Henning-Bodewig, F., 1999, "International protection against unfair competition- Art. 10bis Paris Convention, TRIPS and WIPO Model Provisions", IIC. Vol. 30, Nº 2.
3. Cook, Trevor, 2000, Special Report: The protection of regulatory data in the pharmaceutical and other sectors, Sweet & Maxwell, London.
4. Kamperman Sanders, Anselm, 1997, Unfair competition Law, Clarendon Press, Oxford.
5. Ladas, Stephen, 1975, Patents, Trademarks, and Related Rights. National and International Protection, Vol. III, Cambridge.
6. Portellano Diez, Pedro, 1995, "La Imitación en el Derecho de la Competencia Desleal", Civitas, Madrid.
7. World Health Organization, 1988, The World Drug Situation, WHO, Geneva.
8. World Intellectual Property Organization, 1996, Provisions on the Protection against Unfair Competition WIPO Model, WIPO, Geneva.

Endnotes

1. If the product is not new but new clinical research data is submitted, an exclusivity period of three years is granted.
2. This is the approach adopted by Argentina's Law No. 24.766.
3. Canada's Federal Appeals Court sustained that the national authority may, in virtue of Canadian laws and the NAFTA standards, use the confidential information which is available to it (*Bayer Inc, the Attorney General and the Minister of Health and Apotex Inc. and Novopharm Ltd*., May 19 1999).
4. For a more detailed analysis of the interpretation of Article 39.3, see Carlos Correa, Protection of Data Submitted for the Registration of Pharmaceuticals. Implementing the Standards of the TRIPS Agreement, South Centre/WHO, Geneva, 2002.
5. Concise Oxford Dictionary, seventh edition, Oxford University Press, Oxford 1989.
6. See Rothman, K, Michels, K, and Baum, M, "Declaration of Helsinki should be strengthened", British Medical Journal, August 12, 2000.

paper 12

IPR provisions in FTAs: Implications for access to medicines

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Many developing countries are in the process of implementing the TRIPS Agreement. This involves finding a balance between competing national interests and international obligations. Incorporation of TRIPS flexibilities in the domestic patent law is a key part of establishing this delicate balance. However, in many developing countries there are institutional and policy bottlenecks in the implementation of TRIPS flexibilities. In addition, policy makers in developing countries should be aware that certain developments are taking place that could undermine the effectiveness of the TRIPS flexibilities. Developed countries are seeking to conclude agreements with developing countries that entail TRIPS-plus obligations—obligations which go beyond the TRIPS Agreement—with regard to intellectual property rights. There are several reasons why developing countries may undertake TRIPS-plus obligations, such as bilateral pressure, obligations in bilateral investment treaties or in bilateral or regional free trade agreements with developed countries, concessions made during the WTO accession process, and through accession to treaties establishing a regional patent office. This paper reviews different TRIPS-plus provisions that are frequently found in free trade agreements, and analyzes their implications with regard to access to medicines.

Free trade agreements: an introduction

International trade is regulated through a set of multilateral agreements. One of the most important pillars of the international trade regime is the Final Act embodying the results of the Uruguay Round of multilateral trade negotiations, which established the World Trade Organization (WTO). Non-discrimination is one of the fundamental principles of the multilateral trade regime. This principle of non-discrimination is implemented through the most favoured nation (MFN) clause and the national treatment clause. Under

the MFN principle, any privilege extended to any member country of the multilateral system would get automatically extended to all other member countries. The national treatment clause means that member countries should not discriminate between nationals and foreigners. However, there is an exception under the General Agreement on Tariff and Trade (GATT), which is part of the Final Act. GATT provides an exception to the MFN principle in the case of regional trade agreements. Under this exception, preferential treatment between two or more countries that are party to a regional trade agreement need not be extended to all other members of the multilateral trade regime.

Of late, there has been an increase in the number of free trade agreements (FTAs) that WTO Member States have entered into. However, most FTAs that have recently been signed between developed and developing countries go beyond the traditional subject matter of FTAs (i.e. trade in goods), and cover trade in services, intellectual property rights (IPR), investment etc.

Generally speaking, the advantage of such FTAs is that they improve access to the developed country's market for (agricultural) export products. But there are disadvantages too. Firstly, FTAs with developed countries undermine the right of "*special and differential treatment*" explicitly recognized under the WTO framework. Under the right of special and differential treatment, developing countries do not have to make the same concessions as developed countries, or are given a longer period before they have to comply with the obligation—but under FTAs usually there is no such differential treatment and both parties have the same obligations. Secondly, preferences obtained through FTAs from developed countries tend to lose their value relatively quickly, as those developed countries conclude new FTAs with other developing countries, including developing countries that compete in the same product range. Thirdly, many FTAs with developed countries contain provisions related to investment, intellectual property, competition policy, government procurement, and services, and require legislative and policy changes in developing countries. Such changes often reduce the policy space available to developing countries in these critical areas. Lastly, in FTA negotiations, developing countries usually are the weaker party and lack the collective bargaining power that they have in multilateral negotiations; thus, they may have to agree to terms that are not favorable. Moreover, once sufficient FTAs are in place, the new regime can more easily be generalized in multilateral forums like the WTO.

Currently, the European Free Trade Association (EFTA), the European Union (EU), Japan and the United States are actively pursuing TRIPS-plus standards through FTAs. Often, FTA provisions on intellectual property rights include an MFN clause (without exceptions). As a result, any advantage, favour, privilege or immunity granted to a third party would be automatically

extended to the FTA partner. As a result, if a country signs an FTA with TRIPS-plus provisions, these TRIPS-plus provisions will be extended to all other countries with which it has signed FTAs containing an MFN clause.

TRIPS-plus provisions in an FTA may include: accession to other international treaties on IPR, specific provisions to expand the scope of patent protection, limitations on procedural safeguards, patent term extension and linkage, restrictions on public interest safeguards, strong IP enforcement, harmonization of patent laws, linking IPR with investment, and new forms of IP protection. However, there is no fixed set of TRIPS-plus provisions; the requirements vary depending on the country concerned. Some typical TRIPS-plus provisions that are likely to affect access to medicines are discussed below.

Accession to intellectual property treaties

Under the TRIPS Agreement, WTO member countries have to comply with several provisions of certain other international intellectual property treaties, notably the Paris and Berne Conventions. However, TRIPS is silent on the accession to many other IP treaties, which harmonize IP procedures among countries. FTAs may also propose accession to a number of international agreements on intellectual property rights, such as the Patent Cooperation Treaty (PCT), the Patent Law Treaty (PLT), the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the Madrid Protocol and the Singapore Treaty.

The PCT is designed to enable people to apply for a patent in multiple countries more easily. It standardizes the application procedures. Applications can then be designated to multiple countries simultaneously through a single application (basically by "ticking a box"). The PCT is more beneficial for countries with relatively large numbers of inventors who wish to apply for patents in other countries. In most developing countries, the majority of patents are granted to foreign applicants. For example, in Malaysia, 98% of patents granted are to foreigners, and this has been constant for the last five years according to Malaysian Government statistics.[1] Similarly, only 1.1% of patents granted in Indonesia from 1993-2006 were to Indonesians.[2] From 1998-2005, 0.6-1.4% of patents in the Philippines were granted to Filipinos.[3] In sub-Saharan Africa, 0.01% of patent applications filed in 1997 were by residents.[4] Even in Australia, approximately 90% of patents granted each year are to foreigners.[5] As the PCT makes it easier to apply for patents in other countries by lowering the procedural hurdles, a developing country can expect to receive more patent applications after joining the PCT. This has been the experience of all countries joining the PCT except one according to WIPO data. For example, China's patent applications increased fivefold, Iceland's increased twelvefold and Vietnam's increased fifteenfold.[6] With

a significant increase in the number of patent applications, patent offices may fall behind in examinations—and more medicines may be under patent. However, it is possible for countries to unilaterally withdraw from the PCT,[7] without penalty, if joining the PCT has not been locked in by an FTA.

Similarly, accession to the Madrid Protocol increases the risk that a country will be flooded with trademark applications. Under the protocol, a trademark that has been granted by the international bureau of WIPO comes in force in Member States automatically in the absence of any objection or opposition. Under the Singapore Treaty, member countries have to extend trademark protection to non-traditional trademarks including sound marks, smell marks, taste marks etc. Non-traditional trademarks have direct implications for access to medicines, because the medicine market is highly brand driven. Physicians often prescribe by brand name, leaving consumers little choice. Moreover, consumers may be reluctant to switch to a product with a different taste or smell. Meanwhile, due to the monopoly that results from patent protection, the originator company has ample time to build brand awareness. The pharmaceutical industry may try to use a taste mark or smell mark to block generic competition. This could delay generic competition, and result in prices of medicines remaining high even in the absence of a patent monopoly.

Elimination of pre-grant opposition

Patent offices may make mistakes in their examination of a patent application, which could result in the granting of frivolous or unjustified patents. Further, most patent offices in developing countries suffer from infrastructural and human resource constraints. However, certain procedural safeguards can be instituted to reduce the risk that patents are granted without sufficient scrutiny. A pre-grant opposition mechanism is one such procedural safeguard. It allows third parties to oppose a patent application before the grant of the patent. The TRIPS Agreement leaves it to countries to decide whether to provide for a pre-grant opposition mechanism or not.

Pre-grant opposition is usually cheaper, simpler and faster than opposing a patent after it has been granted, so it can be an effective means to help ensure that only high-quality patents are granted, for medicines that are really new, inventive and industrially applicable.

TRIPS-plus provisions in FTAs—mainly US FTAs—may prevent (or restrict) pre-grant opposition. This means patents can only be opposed after they have been issued, typically via the courts. This is more expensive and slower – and in the meantime the patent usually remains in force and generic versions of the medicine are not available in the country.

Expansion of the scope of patent protection

Patents on known substances can be used for the purpose of "evergreening", i.e. for extending patent protection over the same compound beyond the original patent term. For instance, some medicines are in fact new uses of an existing medicine. For example, zidovudine (AZT) was first patented for treating cancer, but subsequently it was found to be effective against HIV/AIDS.[8] If patents for new uses are allowed, in such cases medicines could enjoy a monopoly for up to 40 years; 20 years for the original substance, plus another 20 years for the new use of that substance. Some FTAs require countries to allow patents on new uses of existing medicines and diagnostic, therapeutic and surgical methods (as well as on plants and animals). This would reduce access to more affordable (generic) versions of these medicines. For instance, US FTAs may make it mandatory for countries to grant patents on new uses of a known substance. Similarly, Japanese FTAs may require countries to extend patent protection to naturally occurring microorganisms. Such expansion of the scope of patent protection undermines the TRIPS flexibilities. Further, they restrict the policy space related to access to medicines.

Extension of the duration of patent protection

According to the TRIPS Agreement, WTO member countries should provide a minimum of 20 years of patent protection (from the date of filing).[9] Through FTAs, developed countries seek to extend the duration of a patent beyond this 20-year period. The usual argument is that this is necessary to "compensate" for any "unreasonable" delay in the patent office, or for "unreasonable" time required by the national drug regulatory authority (DRA) to provide marketing authorization. Such extensions would allow patent holders to enjoy a monopoly beyond the 20-year period, and further delay generic competition.

A related risk that is an issue for public health is that, if a DRA feels pressured to quickly approve medicines (out of concern that that delay will mean the monopoly period will be extended), it may hurry the examination of the data and inadvertently approve unsafe medicines. Also, if a patent office feels it has to quickly issue patents (or risk that the monopoly period will be extended), it may not have time to check all the existing inventions in other countries (whether in written or oral records) which could result in patents being granted for products that are not really new or inventive and that do not merit a patent.

Linkage of patents with drug registration

DRAs do not normally deal with patents or the patent status of a medicine. However, the United States has concluded FTAs with developing countries that require that the DRA "shall not grant marketing approval to any third party prior to the expiration of the patent term unless by consent of the patent owner".[10] This is not required by TRIPS.

These provisions significantly alter the role of DRAs by making them, in effect, a kind of "patent police". They require the DRA, on receiving a registration application for a generic version of a drug, to inquire:

(1) whether there is a patent in the country for that particular product;

(2) whether that patent is actually in force (i.e. whether the fees have been paid on time); and

(3) whether the patent actually covers the generic version of the medicine (generic manufacturers usually try to ensure that their version does not infringe any valid patents).

Ascertaining this can take the courts several years, and may require expert witnesses as well as substantial documentation. It also tends to be expensive. These are therefore not easy questions for a DRA—which usually does not have specific expertise on patents—to answer.

Historically, the duty of the DRA has been to ensure that a medicine is safe, effective and of sufficient quality before it registers the medicine. It is the patent office's task to ensure that patents meet the criteria of patentability, while the patent holder is responsible for enforcing the patent. Finally, the courts are the only authority that can determine whether a patent is valid and whether or not it has been infringed by a generic product.

Elimination of or restrictions on parallel imports

Parallel importation is one of the key methods of keeping medicines affordable. It involves legitimately importing the patented product from another country where it is sold more cheaply (for example because of price controls in that other country). TRIPS allows parallel importation, and it is an important safeguard for developing countries.

Some FTAs—especially US FTAs—have effectively undermined parallel importation by requiring countries to prevent it if the patent holder has not consented to it. Since in practice it is unlikely that patent holders will consent, parallel importation will be made virtually impossible.

However, the US Congress has refused to support the inclusion, in any new FTAs, of provisions restricting parallel importation such as those that

are found in some existing US FTAs.[11] This decision by Congress should make it easier for developing countries to reject any proposed restrictions on parallel importation in FTA negotiations with the United States.

Restrictions on compulsory licensing

TRIPS allows countries to issue compulsory licences (to companies or government agencies, in order to produce or import generic versions of a medicine that is under patent) and does not restrict the situations in which compulsory licenses can be used. The Doha Declaration on TRIPS and Public Health confirms that countries have "the freedom to determine the grounds upon which such licences are granted." However, there are FTAs that seek to limit the circumstances under which compulsory licences on medicines may be issued. For example, the US–Singapore FTA allows compulsory licences only for remedying anti-competitive practices by the patent holder; for public non-commercial use; and in the case of national emergency or circumstances of extreme urgency. Such limitations lessen the policy space available to governments to issue compulsory licences. The effectiveness of compulsory licences can also be limited by data exclusivity (see paper 10.1 and 10.2) and linkage (see above).

Some Japanese FTAs may restrict the use of compulsory licensing through investment provisions. In these FTAs, the definition of investment includes "intellectual property rights as recognised by the laws and regulations of the party in whose area the investment is made".[12] Further, the investment chapter of the FTA puts restrictions on expropriation of investments. The concerned clause states that neither party shall take any measure equivalent to expropriation or nationalisation except for a public purpose. Hence compulsory licensing for commercial reasons could potentially be hampered.

Enforcement of IPR

Enforcement standards contained in the TRIPS Agreement provide a certain amount of freedom to frame appropriate standards in the domestic law. One of the principal TRIPS norms related to enforcement is that measures taken to enforce IPRs should not act as a barrier to legitimate trade. Under the TRIPS Agreement, criminal remedies are only required in case of copyright piracy and trademark counterfeiting on a commercial scale. Border measures are also mandatory only in case of trademark counterfeiting and copyright piracy. Furthermore, border measures are mandatory only in case of imports, and ex officio border measures are optional. However, several Japanese FTAs impose criminal remedies against patent infringement. Similarly EU and EFTA FTAs expand border measures to all IP-related infringements, including patent infringements, as well as to goods in transit. Recently, generic medicines

transiting through several European ports to various developing countries in Africa and Latin America were seized on the basis of the EU IP enforcement directive; this blocked or delayed access to medicines in several developing countries.

The TRIPS Agreement furthermore does not make it mandatory for courts to be allowed to award pecuniary damages or issue injunctions against intermediaries whose services are used by a third party to infringe IPR. But some FTAs concluded by the EU and EFTA do make it mandatory for developing countries to allow their courts to grant pecuniary damages, to expand the scope of injunctions against intermediaries whose services are used by a third party to infringe an IPR and to provide for interlocutory injunctions.[13]

These "TRIPS-plus" provisions are bound to create a chilling effect on generic market entry and competition.

Conclusion

Over the past decade, there has been a significant change in the scope of FTAs signed between developed and developing countries, which encompass various issues not directly linked to traditional trade in goods—such as IPR, investment, competition law etc. IP provisions in FTAs often go beyond the TRIPS requirements. Such TRIPS-plus obligations have several disadvantages. First, they reduce the scope of public interest safeguards and tilt the balance towards the IP owner. Second, TRIPS-plus provisions reduce the policy space for protecting the public interest. Third, they strengthen or expand the duration of the patent and thus delay competition. Cumulatively, they result in a significant reduction of developing countries' policy space to safeguard access to medicines. Hence, IP provisions in FTAs interfere with states' ability to deliver on a key international human rights obligation, namely the right to health.

References and further reading

1. Carlos Correa, Implications of bilateral free trade agreements on access to medicines, available at http://www.who.int/entity/bulletin/volumes/84/5/399.pdf
2. Carlos Correa, Bilateral Investment Agreements: Agents of new global standards for the protection of intellectual property rights? Available at http://ictsd.net/i/ip/18366/
3. Carlos Correa, Negotiation of a Free Trade Agreement European Union-India: Will India Accepts TRIPS Plus Protection? Available at http://www.oxfam.de/download/correa_eu_india_fta.pdf

4. Maximiliano Santa Cruz S, Intellectual Property Provisions in European Union Trade Agreements: Implications for Developing Countries. Available at http://www.iprsonline.org/
5. Xavier Seuba, The Protection of Health in the New Association Agreement between the CAN and the EU in the light of Intellectual Property Rights. January 2009. Available at http://www.haiweb.org/23032009/18%20Mar%202009%20Policy%20Paper%20EU-CAN%20Association%20Agreement%20FINAL.pdf
6. Sanya Reid Smith, "Intellectual Property Rights in Free Trade Agreements", Third World Network 2008.

Endnotes

1. http://www.mipc.gov.my/index.php?option=com_content&task=view&id=3&Itemid=10
2. http://www.dgip.go.id/ebscript/publicportal.cgi?.ucid=2715
3. http://www.ipophil.gov.ph/statreport/statistics.htm
4. World Bank, World Development Indicators 2000
5. Australian Government statistics from www.ipaustralia.gov.au
6. The other countries registering significant increases in patent applications were Canada, Croatia, Israel, Mexico, New Zealand, Serbia and Montenegro and Turkey. Of the countries with sufficient data to analyse, only Algeria did not register a significant increase in patent applications when it joined the PCT.
7. Art 66.
8. See for example http://aidshistory.nih.gov/transcripts/bios/Samuel_Broder.html
9. LDC WTO Members have a transition period, see above.
10. United States-Singapore Free Trade Agreement (2003), Article 16.8, paragraph 4(c).
11. s631, Science, State, Justice, Commerce, and Related Agencies Appropriations Act, 2006 (Public Law No: 109-108, H.R.2862).
12. See for example the Agreement between Japan and the Kingdom of Thailand for an Economic Partnership (2007), Art. 91(j)(ii)(BB).
13. An interlocutory injunction (or preliminary injunction) is a provisional remedy granted (by a court) to restrain activity on a temporary basis until the court has made its final decision.

paper 13

A few questions on health and human rights*

Q.1 What are human rights?

Human rights are legally guaranteed by human rights law, protecting individuals and groups against actions that interfere with fundamental freedoms and human dignity. They encompass what are known as civil, cultural, economic, political and social rights. Human rights are principally concerned with the relationship between the individual and the state. Governmental obligations with regard to human rights broadly fall under the principles of *respect, protect and fulfil*.

Q.2 How are human rights enshrined in international law?

In the aftermath of World War II, the international community adopted the Universal Declaration of Human Rights (UDHR, 1948). However, by the time that States were prepared to turn the provisions of the Declaration into binding law, the Cold War had overshadowed and polarised human rights into two separate categories. The West argued that civil and political rights had priority and that economic and social rights were mere aspirations. The Eastern bloc argued to the contrary that rights to food, health and education were paramount and civil and political rights secondary. Hence two separate treaties were created in 1966 – the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the International Covenant on Civil and Political Rights (ICCPR). Since then, numerous treaties, declarations and other legal instruments have been adopted, and it is these instruments that encapsulate human rights.

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* This paper is excerpted from: 25 *Questions & Answers on Health and Human Rights*, Geneva: World Health Organization, 2002. NB: footnotes and references have been omitted in this shortened version. The full document is available at: http://www.who.int/hhr/NEW37871OMSOK.pdf

Q.3 What is the link between health and human rights?

There are complex linkages between health and human rights:

- Violations or lack of attention to human rights can have serious health consequences;
- Health policies and programmes can promote or violate human rights in the ways they are designed or implemented;
- Vulnerability and the impact of ill health can be reduced by taking steps to respect, protect and fulfil human rights.

The normative content of each right is fully articulated in human rights instruments. In relation to the right to health and freedom from discrimination, the normative content is outlined in Questions 4 and 5, respectively. Examples of the language used in human rights instruments to articulate the normative content of some of the other key human rights relevant to health follow:

- ***Torture*:** "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."
- ***Violence against children*:** "All appropriate legislative, administrative, social and educational measures to protect the child from all forms of physical or mental violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation, including sexual abuse..." shall be taken.
- ***Harmful traditional practices*:** "Effective and appropriate measures with a view to abolishing traditional practices prejudicial to the health of children" shall be taken.
- ***Participation*:** The right to "…active, free and meaningful participation".
- ***Information*:** "Freedom to seek, receive and impart information and ideas of all kinds".
- ***Privacy*:** "No one shall be subjected to arbitrary or unlawful interference with his privacy".
- ***Scientific progress:*** The right of everyone "to enjoy the benefits of scientific progress and its applications".
- ***Education:*** The right to education, including access to education in support of "basic knowledge of child health and nutrition, the advantages of breast-feeding, hygiene and environmental sanitation and the prevention of accidents".
- ***Food and nutrition*:** "The right of everyone to adequate food and the fundamental right of everyone to be free from hunger".

- ***Standard of living*:** Everyone has the right to an adequate standard of living, including adequate food, clothing, housing, and medical care and necessary social services.
- ***Right to social security*:** "The right of everyone to social security, including social insurance".

Q.4 What is meant by "the right to health"?

The right to the highest attainable standard of health (referred to as "the right to health") was first reflected in the WHO Constitution (1946) and reiterated in the 1978 Declaration of Alma-Ata and in the World Health Declaration adopted by the World Health Assembly in 1998. It has been firmly endorsed in a wide range of international and regional human rights instruments.

In international human rights law, the right to the highest attainable standard of health is a claim to a set of social arrangements–norms, institutions, laws, an enabling environment–that can best secure the enjoyment of this right. The most authoritative interpretation of the right to health is outlined in Article 12 of the ICESCR, which has been ratified by 145 countries (as of May 2002). In May 2000, the Committee on Economic, Social and Cultural Rights, which monitors the Covenant, adopted a General Comment on the right to health. General Comments serve to clarify the nature and content of individual rights and States Parties' (those states that have ratified) obligations. The General Comment recognized that the right to health is closely related to and dependent upon the realization of other human rights, including the right to food, housing, work, education, participation, the enjoyment of the benefits of scientific progress and its applications, life, non-discrimination, equality, the prohibition against torture, privacy, access to information and the freedoms of association, assembly and movement.

> "The right to health does not mean the right to be healthy, nor does it mean that poor governments must put in place expensive health services for which they have no resources. But it does require governments and public authorities to put in place policies and action plans which will lead to available and accessible health care for all in the shortest possible time. To ensure that this happens is the challenge facing both the human rights community and public health professionals."
>
> UN High Commissioner for Human Rights,
> Mary Robinson

Further, the Committee interpreted the right to health as an inclusive right extending not only to timely and appropriate health care but also to

the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions and access to health-related education and information, including on sexual and reproductive health.

The General Comment sets out four criteria by which to evaluate the right to health:

(1) *Availability*. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity.

(2) *Accessibility*. Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions:

- Non-discrimination;
- Physical accessibility;
- Economic accessibility (affordability);
- Information accessibility.

(3) *Acceptability*. All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, sensitive to gender and life-cycle requirements, as well as designed to respect confidentiality and improve the health status of those concerned.

(4) *Quality*. Health facilities, goods and services must be scientifically and medically appropriate and of good quality.

Q.5 How does the principle of freedom from discrimination relate to health?

Vulnerable and marginalized groups in societies tend to bear an undue proportion of health problems. Overt or implicit discrimination violates a fundamental human rights principle and often lies at the root of poor health status. In practice, discrimination can manifest itself in inadequately targeted health programmes and restricted access to health services.

The prohibition of discrimination does not mean that differences should not be acknowledged, only that different treatment–and the failure to treat equal cases equally–must be based on objective and reasonable criteria intended to rectify imbalances within a society.

In relation to health and health care the grounds for non-discrimination have evolved and can now be summarized as proscribing "any discrimination in access to health care and the underlying determinants of health, as well as to means and entitlements for their procurement, on the grounds of race,

colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, health status (including HIV/AIDS), sexual orientation, civil, political, social or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right to health".[1]

Q6: What international human rights instruments set out governmental commitments?

Governments decide freely whether or not to become parties to a human rights treaty. Once this decision is made, however, there is a commitment to act in accordance with the provisions of the treaty concerned. The key international human rights treaties, the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966) and the International Covenant on Civil and Political Rights (ICCPR, 1966), further elaborate the content of the rights set out in the Universal Declaration of Human Rights (UDHR, 1948) and contain legally binding obligations for the governments that become parties to them. Together these documents are often called the "International Bill of Human Rights".

Building upon these core documents, other international human rights treaties have focused on either specific groups or categories of populations, such as racial minorities, women and children, or on specific issues, such as torture. In considering a normative framework of human rights applicable to health, human rights provisions must be considered in their totality.

The Declarations and Programmes of Action from United Nations world conferences such as the World Conference on Human Rights (Vienna, 1993), the International Conference on Population and Development (Cairo, 1994), the World Summit for Social Development (Copenhagen, 1995), the Fourth World Conference on Women (Beijing, 1995) and the World Conference Against Racism, Racial Discrimination, Xenophobia and Related Intolerance (Durban, 2001) provide guidance on some of the policy implications of meeting governments' human rights obligations.

Q.7 What international monitoring mechanisms exist for human rights?

The implementation of the core human rights treaties is monitored by committees of independent experts known as treaty monitoring bodies, created under the auspices of and serviced by the United Nations. Each of the six major human rights treaties has its own monitoring body which meets regularly to review State Party reports and to engage in a "constructive dialogue" with governments on how to live up to their human rights obligations. Based on the principle of transparency, States are required to submit their progress reports to the treaty bodies and to make them widely

available to their own populations. Thus, reports can play an important catalytic role, contributing to the promotion of national debate on human rights issues, encouraging the engagement and participation of civil society and generally fostering a process of public scrutiny of governmental policies. At the end of the session, the treaty body makes concluding observations which include recommendations on how the government can improve its human rights record. Specialized agencies such as WHO can play an important role in providing relevant health information to facilitate the dialogue between the State Party and the treaty monitoring body.

Other mechanisms for monitoring human rights in the United Nations system include the Commission on Human Rights and the Sub-Commission on the Promotion and Protection of Human Rights. These bodies appoint special rapporteurs, other independent experts and working groups to monitor and report on thematic human rights issues (such as violence against women, sale of children, harmful traditional practices and torture) or on specific countries. In addition, the post of High Commissioner for Human Rights was created in 1994 to head the United Nations human rights system. The High Commissioner's mandate extends to every aspect of the United Nations human rights activities: monitoring, promotion, protection and coordination.

Regional arrangements have been established within existing regional intergovernmental organizations. The African regional human rights instrument is the African Charter on Human and Peoples' Rights, which is located within the Organization of African Unity. The regional human rights mechanism for the Americas is located within the Organization of American States and is based upon the American Convention of Human Rights. In Europe, a human rights system forms a part of the Council of Europe. Key human rights instruments are the European Convention on the Protection of Human Rights and Fundamental Freedoms and the European Social Charter. The European Union has detailed rules concerning human rights issues and has integrated human rights into its common foreign policy. In addition, the Organization for Security and Cooperation in Europe (OSCE), a 55 Member State organization, has separate mechanisms and agreements. In the Asia-Pacific region, extensive consultations among governments are underway concerning the possible establishment of regional human rights arrangements.

Q.8 How can poor countries with resource limitations be held to the same human rights standards as rich countries?

Steps towards the full realization of rights must be deliberate, concrete and targeted as clearly as possible towards meeting a government's human rights obligations. All appropriate means, including the adoption of legislative measures and the provision of judicial remedies, as well as administrative, financial, educational and social measures, must be used in this regard. This

neither requires nor precludes any particular form of government or economic system being used as the vehicle for the steps in question.

The principle of *progressive realization* of human rights imposes an obligation to move as expeditiously and effectively as possible towards that goal. It is therefore relevant to both poorer and wealthier countries, as it acknowledges the constraints due to the limits of available resources but requires all countries to show constant progress in moving towards full realization of rights. Any deliberately retrogressive measures require the most careful consideration and need to be fully justified by reference to the totality of the rights provided for in the human rights treaty concerned and in the context of the full use of the maximum available resources. In this context, it is important to distinguish the *inability* from the *unwillingness* of a State Party to comply with its obligations. During the reporting process the State Party and the Committee identify indicators and national benchmarks to provide realistic targets to be achieved during the next reporting period.

Q.9 Is there, under human rights law, an obligation of international cooperation?

Malaria, HIV/AIDS and tuberculosis are examples of diseases that disproportionately affect the world's poorest populations, placing a tremendous burden on the economies of developing countries. Although the human rights paradigm concerns obligations of States with respect to individuals and groups within their own jurisdiction, references to "State's resources" within human rights instruments include international assistance and cooperation.

In accordance with Articles 55 and 56 of the Charter of the United Nations, international cooperation for development and the realization of human rights is an obligation of all States. Similarly, the Declaration on the Right to Development emphasizes an active programme of international assistance and cooperation based on sovereign equality, interdependence and mutual interest.

In addition, the ICESCR requires each State party to the Covenant to "take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized [herein]".

In this spirit, "the framework of international cooperation" is referred to, which acknowledges, for instance, that the needs of developing countries should be taken into consideration in the area of health. The role of specialized agencies is recognized in human rights treaties in this context. For example, the ICESCR stresses that "international action for the achievement of the

rights ... includes such methods as ... furnishing of technical assistance and the holding of regional meetings and technical meetings for the purpose of consultation and study organized in conjunction with the Governments concerned".

Q.10 What are governmental human rights obligations in relation to other actors in society?

As government roles and responsibilities include increased reliance on non-state actors (such as health insurance companies), governmental health systems must ensure the existence of social safety nets and other mechanisms to ensure that vulnerable population groups have access to the services and structures they need.

The obligation of the State to *protect* human rights means that governments are responsible for ensuring that non-state actors act in conformity with human rights law within their jurisdiction. Governments are obliged to ensure that third parties conform with human rights standards by adopting legislation, policies and other measures to assure adequate access to health care, quality information, etc., and an accessible means of redress if individuals are denied access to these goods and services. An example is the obligation of governments to regulate the tobacco industry in order to protect its population against infringements of the right to health, the right to information and other relevant human rights provisions.

In the corporate and NGO contexts, there is a proliferation of voluntary codes which reflect international human rights norms and standards. Increasing attention to the human rights implications of work in the private sector has resulted in human rights being placed higher on the business agenda, with several businesses beginning to incorporate concern for human rights into their daily operations.

Endnotes

1. General Comment 14.

paper 14

Excerpts from the report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*

Anand Grover

Introduction

In this report, the Special Rapporteur explores the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and "TRIPS plus" standards on access to medicines within the broader framework of the right to health. The Special Rapporteur commends the work done by the former Special Rapporteur on the right to health and the Office of the United Nations High Commissioner for Human Rights (OHCHR) on trade and intellectual property issues relevant to the right to health.[1] He found these reports highlighted the need for TRIPS flexibilities to be implemented and noted the adverse impacts of free trade agreements (FTAs) on access to medicines. The full use of TRIPS flexibilities can help countries meet their obligations to protect, promote and fulfil the right to health by improving access to affordable medicines. The Special Rapporteur notes, however, that use of TRIPS flexibilities has been variable and that there are growing instances of developing countries and least developed countries (LDCs) adopting TRIPS-plus standards that may have an adverse affect on the right to health. He therefore highlights the need to revisit trade-related agreements in light of their impact on the right to health and in particular on access to medicines.

* The full report is available at: http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf. These excerpts are reproduced with the permission of the UN High Commission for Human Rights.

The right to the highest attainable standard of health

The right to health, enshrined in numerous international and regional human rights treaties and in many national constitutions,[2] is an inclusive right, extending not only to timely and appropriate health care, but also to the underlying determinants of health, such as access to clean water and sanitation, adequate housing and nutrition as well as social determinants such as gender, racial and ethnic discrimination and disparities.

In recent years, the Committee on Economic, Social and Cultural Rights, WHO and many others have developed an analysis of the right to health to make it easier to understand and apply to health-related laws, policies, programmes and practices.[3] Key elements of the analytical framework relevant to this report include the propositions that:

(a) All health services, goods and facilities shall be available, accessible, acceptable and of good quality. In the context of access to medicines this requires States to ensure that medicines are available, accessible, culturally acceptable, and of good quality;

(b) States have a duty to respect, protect and fulfil the right to health.

Furthermore, the Committee's general comment No. 14 (2000) on the right to the highest attainable standard of health reaffirms the framework as it adopts the aforesaid key elements of the right to health. In this regard, medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central features of the right to health. These features depend upon access to medicines. Therefore, access to medicines forms an indispensable part of the right to health.[4]

States have an obligation under the right to health to ensure that medicines are available, financially affordable, and physically accessible on a basis of non-discrimination to everyone within their jurisdiction. Developed States also have a responsibility to take steps towards the full realization of the right to health through international assistance and cooperation.[5] Moreover, all States parties to the International Covenant on Economic, Social and Cultural Rights have a legal obligation not to interfere with the rights conferred under the Universal Declaration of Human Rights and the Covenant, including the right to health.[6]

State of health and access to medicines

The state of health correlates significantly with poverty. Public health spending in both high and low income countries benefits the rich more than the poor. People with the most means and often with less need consume the most care, while those with the least means and most need consume the least

care.[7] Over 100 million people fall into poverty annually because they have to pay for health care.[8] In developing countries, patients themselves pay for 50-90 per cent of essential medicines.[9] A report from WHO and Health Action International on the results of surveys undertaken in 36 countries reported that in the public sector only one third of essential medicines needed were available and in the private sector only two thirds of such medicines were available.[10]

Nearly 2 billion people lack access to essential medicines.[11] Improving access to medicines could save 10 million lives a year, 4 million in Africa and South East Asia.[12] The inability of populations to access medicines is partly due to high costs.[13] In the context of HIV, as of 2007, only 31 per cent of people living with HIV who needed treatment received it.[14] Furthermore, it is estimated that people living with HIV will become resistant to their first-line medicine regimens and will need second-line treatment which can currently cost between 9 and 19 times as much as first-line medicines.

Accessibility of medicines has different dimensions.[15] This report specifically considers the dimension of financial affordability. In this regard intellectual property (IP) laws as they impact on the affordability of medicines can have a significant bearing on access to medicines.[16]

Current health inequalities regarding access to medicines demonstrate the need for States to respect their obligations under international law to protect the right to health. This includes ensuring that their laws and practices, including those related to IP, take into consideration the right to health and the need to ensure access to affordable medicines to all. This report highlights some measures that States can take to ensure that their national IP regimes protect the right to health.

Intellectual property laws and access to medicines

Patents confer legal rights on inventors, more importantly negative rights over process or product inventions. Patentees can, therefore, prevent persons not authorized by them from making, using, offering for sale, selling or importing the patented invention. Patents create monopolies, limit competition and allow patentees to establish high prices. While product patents confer absolute monopolies, process patents lead to relative monopolies.[17]

In regard to medicines, a product patent enables a patentee to set high prices. Higher standards of patent protection, which can reduce the number of easily granted patents, can facilitate competition and lower the prices of medicines. Lower standards of patent protection, however, which can increase the number of easily granted patents, can lead to higher prices. Generic competition in the field of pharmaceuticals has the potential to significantly lower prices and increase access.

However, the continued supply of generic medicines is now in doubt. For developing countries, including those that manufacture and supply generic medicines, the deadline for TRIPS compliance and the introduction of product patents came in 2005. There is concern that the ability of companies to patent new pharmaceutical products on a near-global scale could inhibit further competition and prevent the price reductions needed to make antiretroviral therapy more widely available.[18] For instance, several developing countries and LDCs expressed concerns to WHO that future, generic ARVs would not be available from India after 2005.[19] This issue is valid for medicines for other diseases as well. Even where some countries are able to continue to manufacture generic medicines, TRIPS implementation in other countries may make it difficult to import these medicines.

With growing concern over TRIPS implementation and its impact on access to medicines, several initiatives have been launched in recent years by countries, the private sector, charitable foundations and nongovernmental organizations to increase access to existing medicines. However, these initiatives have not been sufficient to surmount the challenge of ensuring access to medicines.[20] Developing countries and LDCs should be enabled to take steps to modulate the implementation of TRIPS on access to medicines including by encouraging competition and being able to access affordable generic versions of patented medicines. The next section of the report discusses TRIPS and more particularly the flexibilities that can enable developing countries and LDCs in this regard.

Agreement on trade-related aspects of intellectual property rights (TRIPS)

Background

TRIPS came into force along with the establishment of the World Trade Organization (WTO) in 1995. It was one of the most controversial agreements, as developed countries pushed for extensive IP protection and the harmonization of IP norms.[21] Developing countries argued that extensive IP standards would hinder their development prospects as they were not well-equipped to reap the benefits of such standards. Developing countries eventually gave way, under the pressure of developed countries, as they were ultimately dependent on them for trade. It has to be noted, however, that TRIPS was a compromise. The ultimate goal of developed countries was and is the universal harmonization of IP laws according to their standards. Therefore, post-TRIPS, they have continued to push for standards of IP protection through various free trade and multilateral trade agreements, which conform to standards in their countries.

TRIPS establishes minimum global standards for all major IP rights and sets rules for their enforcement.[22] […] TRIPS is binding on all WTO Member States and is legally enforceable through the Dispute Settlement Body, backed by sanctions. For most developing countries and LDCs, TRIPS implementation requires them to update their IP standards, which in turn involves a complex set of reforms to redraft and update existing laws.[23] It also requires considerable increase in the financial and human resources allocated to IP issues.[24]

TRIPS flexibilities and their implementation

TRIPS provides flexibilities that WTO Member States can use. Article 1 establishes the core principle that Member States can determine the appropriate method for implementing TRIPS within their own legal system and practice. Furthermore, the objectives and principles of TRIPS emphasize the balance of rights and obligations and provide the basis for countries to utilize the flexibilities and adopt IP protection at the national level to meet their social and developmental needs. Article 8 specifically provides that Member States may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health. The Declaration on the TRIPS Agreement and public health (Doha Declaration) adopted by the WTO Ministerial Conference in 2001 recognized concerns over the effect of IP on medicine prices and reaffirmed the right of Member States to use TRIPS flexibilities to achieve public health needs and promote access to medicines for all.

From a right to health perspective, developing countries and LDCs should be enabled to use TRIPS flexibilities. More particularly, their national laws should incorporate the flexibility to:

(a) Make full use of the transition periods;

(b) Define the criteria of patentability;

(c) Issue compulsory licences and provide for government use;

(d) Adopt the international exhaustion principle, to facilitate parallel importation;

(e) Create limited exceptions to patent rights;

(f) Allow for opposition and revocation procedures.

In addition, countries need to have strong pro-competitive measures to limit abuse of the patent system.

Concerns regarding the implementation of TRIPS flexibilities

Developing countries, while attempting to implement TRIPS flexibilities in order to address public health concerns, have experienced pressures from

developed countries and multinational pharmaceutical corporations. In this respect, the cases of South Africa, Thailand and India are particularly illustrative.

In 1996, South Africa adopted a new National Drugs Policy with the goal of "ensuring an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa".[25] Following the principles of the policy, the South African Government amended its existing Medicines Act to improve access to medicines.[26] In response, South Africa was placed on the United States Special 301 Watch List[27] and 39 pharmaceutical companies filed a suit, challenging the amendments, contending that they would destroy patent protections by giving the Health Minister overly broad powers to produce or import cheaper versions of drugs still under patent.[28] Worldwide public outrage eventually led to a change in the US position[29] and to the withdrawal of the lawsuit by the pharmaceutical companies in 2001.

Thailand also faced pressure following its attempts to lower prices of medicines through compulsory licensing. Between 2006 and 2007, Thailand issued compulsory licences for HIV and heart disease medicines in order to meet its obligations to provide universal access to medicines.[30] In 2007, Thailand was placed on the Special 301 Priority Watch List.[31] The position of the European Commission was also unwelcoming of the measures taken by Thailand.[32] One of the affected companies withdrew seven pending applications for registration of new medicines in Thailand, thus effectively withholding them from the Thai market.[33]

In 2008, noting the burden of cancer and the necessity for the government health programme to provide access to cancer medicines, Thailand issued compulsory licences for three anti-cancer medicines.[34] A global campaign to support the Thai compulsory licences led to several statements of support for the use of this TRIPS flexibility;[35] however, Thailand continues to face growing pressure in response to its use of compulsory licensing.[36]

Similarly, India faced pressure for its attempt to use safeguards. India, in 2005 included strict patentability criteria in its patent law to address the evergreening of patents.[37] This provision was challenged by a pharmaceutical company in the Madras High Court alleging it was a violation of TRIPS and of the constitutional equality provision. The amendment was upheld, among other grounds as a fulfilment of the right to health obligations of the Government.[38] The Indian case also garnered significant global international support for the use of public health safeguards by developing countries in their patent laws.[39]

The experiences of South Africa, Thailand, and India provide examples of difficulties countries have had to overcome to implement TRIPS flexibilities.

Although they were successful in their attempts, there is fear that pressure from developed countries and pharmaceutical companies will thwart future actions.[40]

Furthermore, different aspects of the capacity of governments of developing countries and LDCs also contribute to variations in the use of TRIPS flexibilities. This includes the degree of technical expertise, of technological capacity and of engagement amongst national law and policy-makers and the public in the implementation of TRIPS flexibilities.

Many developing countries and LDCs inherited IP laws from former colonizers. As a result, when TRIPS came into force, many countries did not necessarily have the technical expertise to effectively implement the Agreement or take advantage of the flexibilities. In some cases, limited institutional capacity led to dependence on developed countries and independent bodies for technical assistance in drafting laws.[41] It should be noted that there have been concerns regarding the qualitative nature of assistance that is typically provided in relation to TRIPS,[42] and in some cases LDCs seeking external assistance have adopted TRIPS-plus standards in their national laws.[43]

The capacity of countries is also influenced by the degree of participation by individuals, communities and their representatives. Experiences from Argentina, Brazil, India, Mexico, the Philippines, and South Africa indicate that public interest groups can help promote efforts to pass laws that facilitate access to medicines.[44] Furthermore, rights impact assessments can help highlight the impact of TRIPS and TRIPS-plus standards on the right to health.[45] Examples and models to assess the impact of these provisions on access to medicines including in relation to affordability have also emerged.[46] Such initiatives should be encouraged to assist developing countries and LDCs in making decisions about the implementation of TRIPS flexibilities.

Few LDCs have local manufacturing capacities or any technological base to fully take advantage of TRIPS or TRIPS flexibilities.[47] In this regard, concrete steps towards the specific obligation under Article 66, paragraph 2, of TRIPS of developed countries to provide incentives to promote and encourage technology transfer to LDCs in order to enable them to create a sound and viable technological base should be encouraged.

The lack of capacity and external pressures imposed by developed countries significantly contribute to difficulties faced by developing countries, especially LDCs, in the use of TRIPS flexibilities. Therefore there is a real need for developing countries and LDCs to seek appropriate means to build up their capacity, and for developed countries to refrain from hampering the use of TRIPS flexibilities.

Free trade agreements, the right to health and access to medicines

This section examines the effect of standards imposed beyond TRIPS (TRIPS-plus) by FTAs on access to medicines and the right to health. Due to space constraints, not all issues arising out of existing or proposed international trade agreements that affect access to medicines will be discussed.

Background

Many countries have signed or are currently engaged in negotiations on extensive trade agreements, including bilateral investment treaties (BITs), FTAs, economic partnership agreements (EPAs) etc. Such agreements have extensive implications for pharmaceutical patent protection, which can directly impact access to medicines. Some developed countries, for example, have negotiated FTAs which reflect their standard of IP protection.[48]

These agreements are usually negotiated with little transparency or participation from the public, and often establish TRIPS-plus provisions. These provisions undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPS.[49] Studies indicate that TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition.[50] It should also be noted that TRIPS-plus measures could also arise in other contexts such as terms for WTO accession.[51]

The need for public health to be taken into consideration in negotiating these agreements has been highlighted not only in developing countries and LDCs but also in developed countries. The European Parliament for example, in 2007, specifically asked the European Commission to take into consideration the need to protect public health in support of the Doha Declaration and refrain from negotiating TRIPS-plus provisions. Nevertheless, countries continue to negotiate and introduce agreements with TRIPS-plus standards.[52] TRIPS and the Doha Declaration specifically allow for countries to protect the right to health. As FTAs can directly affect access to medicines, there is a need for countries to assess multilateral and bilateral trade agreements for potential health violations and that all stages of negotiation remain open and transparent.

Restricting TRIPS flexibilities

Several FTAs and BITs seek to restrict countries from implementing TRIPS flexibilities. An illustrative example is the attempt to broaden the scope of patentability.

As discussed, TRIPS flexibilities allow Member States to define patentability criteria. However, a number of FTAs signed or currently being negotiated

have restricted or even eliminated this flexibility by requiring that parties provide patent protections for second uses,[53] thereby allowing patentees to evergreen existing patents.

In addition, Article 27 (3) (b) of TRIPS also allows members to exclude plants and animals from patentability as long as some sui generis system of protection for plant varieties is put in place. Some FTAs, however, look to enhance patent protection for plants and animals, which can have an impact on access to medicine.[54]

Some FTAs also restrict procedural flexibilities, such as prohibiting pre-grant opposition procedures. Still others seek to limit the grounds on which compulsory licences can be issued.[55]

TRIPS-plus standards in the area of patent law in free trade agreements (FTAs)

TRIPS-plus provisions in FTAs differ from agreement to agreement, but their purposes are by and large to:

- Extend the patent term
- Introduce data exclusivity
- Introduce patent linkage with drug registration and approval
- Create new enforcement mechanisms for IPRs

(1) Patent term extensions

TRIPS provides for a 20-year patent protection term, starting from the date of filing the patent application. It should be noted that prior to TRIPS, developing countries only allowed 5-10 year patent protection while developed countries allowed 15-17 years.[56]

Several FTAs require an extension of the patent term for pharmaceutical products under certain circumstances.[57] The extension of patent life in developing countries and LDCs can significantly impact the ability of patients to access medicines, and may pose a burden for national health budgets. For instance, it has been estimated that the three-year patent extension provision in the United States–South Korea FTA would cost US$ 504.5 billion and a four-year extension would cost US$ 722.5 billion, consequently putting a strain on the national health insurance system in South Korea.[58]

(2) Data exclusivity

Before a pharmaceutical company introduces a new medicine onto the market, it has to submit clinical test data to national drug regulatory authorities (DRA) to prove the medicine's safety and efficacy. In many countries, a subsequent generic manufacturer who seeks approval to market the generic equivalent is

not required to submit fresh clinical test data but can show that its medicine is bioequivalent to the medicine of the originator company. Relying on the clinical test data of the originator, the DRA can grant marketing approval to the subsequent version. This allows generic medicines to enter the market quickly. Data exclusivity prevents such reliance on the original clinical test data by the DRA for a number of years and requires generic producers to submit their own clinical test data. Such a replication requires generic producers to allocate time and money to prove what is "already known" and also raises ethical concerns of replicating trials on human populations. Data exclusivity deters and considerably delays the entry of generic medicines and can lead to the maintenance of high prices of medicines.[59]

The requirement to impose data exclusivity features in several FTAs. For instance, the US–Morocco FTA provides for data exclusivity. In fact, it does not limit data exclusivity to a "new chemical entity", which is known internationally, but mandates the protection of test data of any "new product", defined as one previously unapproved in that territory.[60]

In some cases, the period of data exclusivity may run during the life of the patent. However, there are a number of circumstances in which exclusive rights over test data can restrict the availability of medicines. Data exclusivity, being independent from patent protection, can allow pharmaceutical companies to secure monopoly rights for off-patent or non-patentable medicines. Evidence from Jordan indicates that pharmaceutical companies are choosing to rely on data exclusivity to enforce their monopoly instead of filing for patents.[61] In the context of developed countries, as evidence from Australia and Canada suggests, data exclusivity leads to higher costs of prescription medicines.

(3) Patent linkage

Patent linkage is another TRIPS-plus obligation imposed through FTAs. It makes the marketing approval of a medicine dependent on its patent status. Thus if the medicine is patented, no marketing approval would be given to its generic version.

The laws of a number of countries permit national DRAs to grant marketing approval to a medicine, irrespective of its patent status.[62] Some countries, however establish a link between the patent system and drug marketing approval procedures.[63] For many developing countries and LDCs, patent linkages are introduced through FTAs that require the national DRA either to refuse to grant marketing approval for the generic version or to disclose to the patentee the identity of a third party seeking approval.

While some argue that patent linkage merely prevents governments from issuing patents while simultaneously permitting their infringement,

it should be noted that patent linkage is at odds with the conception of patents as private rights.[64] It imposes an obligation on a country's DRA to prevent possible infringement of the private rights of patent holders either by denying registration or informing a patentee.

Further, it should be noted that the European Union (EU) does not have a system of patent linkages[65] and in the United States, the Food and Drug Administration has stated that it does not have the expertise or resources to review patents.[66]

This is of particular concern as patent linkage would affect the entry into the market of generic medicines in the case of the patents being invalidated. By delaying the process of granting marketing approval, patent linkage provides patent holders with additional opportunities to prolong their monopoly rights and delays the entry of generic medicines into the market. In fact, a United States Federal Trade Commission study showed that the United States linkage system is subject to substantial abuse by patent holders.[67] The Canadian Federal Government and Supreme Court have also recognized that companies had been using the Canadian linkage system to evergreen their patents.[68]

(4) Intellectual property (IP) enforcement mechanisms

The enforcement of IP claims should refrain from creating any undue barriers to access to medicines. In this respect, FTAs that impose TRIPS-plus IP enforcement measures are a cause for concern. For instance, proposals in the EU-CAN FTA under negotiation remarkably expand the scope of information that can be requested in IP infringement proceedings.[69]

The most important provisions of the EU-CAN (Andean Community of Nations) proposal remain those establishing criminal sanctions for IP infringement. Whereas TRIPS mandates "criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale", the proposal encompasses intentional infringement of all IP rights, including patents, with sanctions ranging from imprisonment, monetary fines, confiscation of equipment and products, destruction of goods to permanent closure of involved establishments. Criminalizing patent infringement is particularly worrisome given that patents challenged in court by alleged infringers are often found to be invalid.[70] Such overreaching provisions, with a low evidentiary standard, may have a chilling impact on producers of generic medicines who could be threatened with sanctions before the validity of the patent is even determined.

Furthermore, TRIPS-plus IP enforcement can adversely impact access to medicines. In this regard, the Special Rapporteur is concerned with reports of IP enforcement measures that have resulted in multiple seizures at some

ports of shipments of generic medicines heading to developing countries and LDCs.[71] Customs regulations of some countries allow the seizures of goods suspected of IP infringement even if they are only in transit.[72] Such regulations impose a far higher standard of IPR enforcement than that required by TRIPS, which requires that IP enforcement measures should not create barriers to legitimate trade.[73] In effect, such actions can bring to naught TRIPS flexibilities exercised by developing countries and LDCs, and de facto impose IP protection on LDCs that are not yet required to comply with TRIPS as generic medicines they need do not reach them. In particular the use of compulsory licensing or the 30 August decision to export and import medicines is effectively negated.

The Special Rapporteur also notes possible concerns that recent developments in national legislation[74] and international negotiations on an anti-counterfeiting trade agreement (ACTA) may impose a TRIPS-plus enforcement regime.[75] The lack of transparency and the secrecy surrounding the negotiations is of particular concern.

Conclusions and recommendations

The framework of the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health.

Similarly, lack of capacity coupled with external pressures from developed countries has made it difficult for developing countries and LDCs to use TRIPS flexibilities to promote access to medicines.

Flexibilities were included in TRIPS to allow States to take into consideration their economic and development needs. States need to take steps to facilitate the use of TRIPS flexibilities.

The Special Rapporteur therefore recommends that developing countries and LDCs should review their laws and policies and consider whether they have made full use of TRIPS flexibilities or included TRIPS-plus measures, and if necessary consider amending their laws and policies to make full use of the flexibilities.

LDCs should make full use of the transition period and in relation to medicines revoke or suspend their patent laws, if necessary, for the balance of the period. LDCs should also consider asking for a further extension of the transition period.

LDCs should use the transition period to seek the most effective technical and other assistance from countries and institutions to develop technical capacity and also explore options to establish local manufacturing capabilities.

Developing countries and LDCs should establish high patentability standards and provide for exclusions from patentability, such as new forms and new or second uses, and combinations, in order to address evergreening and facilitate generic entry of medicines.

Developing countries and LDCs should adopt the principle of international exhaustion and provide for parallel importation with simplified procedures in their national laws.

Developing countries and LDCs need to incorporate in their national patent laws all possible grounds upon which compulsory licences, including government use, may be issued. Such laws provide straightforward, transparent procedures for rapid issue of compulsory licences. There is also a need to revisit the 30 August decision and provide for a simpler mechanism.

Developing countries and LDCs should specifically adopt and apply pro-competition measures to prevent the abuse of the patent system, particularly in regard to access to medicines.

Developing countries and LDCs should incorporate a Bolar (early working) exception, as well as research, experimental and educational exceptions in their patent laws and explore how additional limited exceptions could further promote access to medicines.

Developing countries and LDCs should establish liberal pre-grant, post-grant opposition and revocation procedures, which can be taken advantage of by all concerned stakeholders, including patients' groups.

Developing countries and LDCs should seek international assistance in building capacity to implement TRIPS flexibilities to promote the right to health. WHO and other United Nations bodies could provide such assistance.

LDCs and developing countries should actively promote the participation of individuals and communities in decision-making processes relating to TRIPS and TRIPS flexibilities and conduct impact assessments of the same.

Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions that may infringe upon the right to health.

All technical assistance and cooperation by developed countries, WHO and the World Intellectual Property Organization (WIPO) to developing countries and LDCs should be based on the obligation to respect, protect and fulfil the right to health.

Endnotes

1. E/CN.4/2004/49/Add.1, E/CN.4/Sub.2/2001/13.
2. The right to health was first addressed in the 1948 Universal Declaration of Human Rights. It is established under Article 12 of the International Covenant on Economic, Social and Cultural Rights and is also well recognized in the Convention on the Elimination of All Forms of Discrimination against Women and the Convention on the Rights of the Child.
3. See for instance, World Health Organization, *Human Rights, Health and Poverty Reduction Strategies*, (Geneva, 2005); Physicians for Human Rights, *Deadly Delays: Maternal Mortality in Peru*, (Boston, 2007).
4. A/61/338, para. 40.
5. E/CN.4/2004/49/Add.1, para. 28.
6. Article 30 of the Universal Declaration of Human Rights, Article 5 of the International Covenant on Economic, Social and Cultural Rights.
7. WHO, World Health Report, *Primary Health Care Now More than Ever* (Geneva, 2008), p. xiv, box 1.
8. Ibid.
9. A/61/338, para 75.
10. A. Cameron et al., "Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis", *Lancet*, vol. 373, issue 9659, (January 2009), p. 240.
11. WHO, "WHO Medicines Strategy: Countries at the Core, 2004-2007", (2004).
12. A/61/338, para. 37.
13. E. t'Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, Diemen, AMB, 2009.
14. WHO, *Towards Universal Access - Scaling up priority HIV/AIDS interventions in the health sector, Progress Report 2008*, p. 7.
15. Accessibility has four dimensions; first, medicines must be accessible in all parts of the country; second, medicines must be affordable to all, including those living in poverty; third, medicines must be accessible without discrimination on any of the prohibited grounds; fourth, reliable information about medicines must be accessible to patients and health professionals for them to take well-informed decisions (A/61/338, para. 49).
16. Intellectual property laws can also affect medical research and this can bear upon access to medicines. The Commission on Intellectual Property, Innovation and Public Health (CIPIH) has noted that, "There is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II, and particularly Type III diseases. Insufficient market incentives are the decisive factor." See footnote 9 above, p. 85.

17. Product patents can create absolute monopolies as they can restrict use of a product. Process patents only restrict the use of the patented process and therefore a generic version of the product could be made using an alternative process.
18. WHO/UNAIDS, *Progress on Global Access to HIV Antiretroviral Therapy: a Report on "3 by 5" and Beyond* (March, 2006), p. 60.
19. Letter from WHO HIV/AIDS Director to Indian Health Minister, 17 December 2004. See also E. Kameni, "Implications of Indian intellectual property law on sub-Saharan African countries", *The Botswana Review of Ethics, Law & HIV/AIDS*, vol. 2, No. 1 (2008), p. 57.
20. World Health Assembly resolution WHA61.21, annex, para. 3 (Global strategy on public health, innovation and intellectual property).
21. See generally, J. Watal, *Intellectual Property Rights in the WTO and Developing Countries*, (Oxford University Press, 2001).
22. C. Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, (Oxford University Press, 2008).
23. Ibid., p. 11.
24. Ibid.
25. National Drug Policy for South Africa, 1996, p. 3.
26. Medicines and Related Substances Control Amendment Act No. 90 of 1997.
27. See Special 301 Report 1999. This list is maintained under the United States Trade Act, 1974, in respect of each country. It is a precursor to trade sanctions that the United States may impose on any country unilaterally.
28. Essential Drugs in Brief, issue No. 04, April 2001, Department of Essential Drugs and Medicines Policy, WHO.
29. See Executive Order 13155, "Access to HIV/AIDS Pharmaceuticals and Medical Technologies" (10 May 2000).
30. Compulsory licences were issued for clopidogrel for heart disease, and lopinavir/ritonavir and Efavirenz for HIV.
31. Office of the United States Trade Representative (USTR), Special 301 Report, 2007.
32. See F. M. Abbott and J. H. Reichman, "The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions", *Journal of International Economic Law,* vol. 10, No. 4, (2007), p. 921. In a letter dated 10 July 2007 to the Minister of Commerce of Thailand, the EU Trade Commissioner claimed that, "neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licenses wherever medicines exceed certain prices".
33. WHO Access to Medicines, Briefing Note - Country Experiences in Implementing TRIPS Safeguards, February 2008.
34. A fourth drug, imatinib, for treating leukaemia and other cancers was also to have been subjected to a compulsory licence, but the licence was not implemented after it was given for free to a Thai public health programme.
35. Asia Pacific Network of People Living with HIV/AIDS (APN+), Our Health, Our Rights, (2008), p. 73.
36. 2008 PhRMA Submission to USTR for the Special 301 Report, excerpt on Thailand.

37. The Patents (Amendment) Act 2005, Section 3 (d).
38. *Novartis AG v. Union of India*, (2007) 4 MLJ 1153.
39. See footnote 35 above, p. 30.
40. Despite the 2001 Doha Declaration and other commitments, countries issuing compulsory licences as part of national drug programmes aimed at providing universal access to HIV/AIDS and other treatments continue to be placed on the United States Special 301 Watch List.
41. *Integrating Intellectual Property Rights and Development Policy*, Commission on Intellectual Property Rights (CIPR), (London 2002), p. 138.
42. Ibid., see also United Nations Conference on Trade and Development (UNCTAD), The Least Developed Countries Report, 2007.
43. For example, the Bangui Agreement contains TRIPS-plus standards. Furthermore, the 12 LDC members of the African Intellectual Property Organization (OAPI) brought most of their IP laws in line with TRIPS in 2002.
44. See footnote 22 above, p. 208.
45. E/CN.4/2004/49/Add.1.
46. See for example, "Impact Assessment of TRIPS-plus provisions on health expenditure and access to medicines" report of a workshop organized by the Ministry of Public Health, Thailand and WHO, Bangkok 22-24 Nov. 2006; Miguel Ernesto Cortes Gamba, "Intellectual property in the FTA: impacts on pharmaceutical spending and access to medicines in Colombia", Mision Salud and Fundacion IFARMA, Bogota, 2006.
47. See footnote 41 above, p. 137 .
48. US Trade Promotion Authority Act (2002), 116 STAT. 933, s. 2102 (b) 4 (A) (II).
49. Several authors have written on this subject. See, e.g., C. Correa, "Implications of bilateral free trade agreements on access to medicines", *Bulletin of the World Health Organization*, vol. 84, No. 5 (May 2006), p. 399; F. Abbott, "The Doha Declaration on the TRIPS Agreement and public health and the contradictory trend in bilateral and regional free trade agreements", occasional paper 14, Quaker United Nations Office (April 2004); Study of the Commission on Intellectual Property Rights, Innovation and Public Health (2005), executive summary.
50. "All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines", Oxfam Briefing Paper (March 2007). See also, UNDP-ICTSD conference: Monitoring the Impact of IP Protection on Public Health: Reviewing Progress, 2008.
51. E/CN.4/2004/49/Add.1.
52. European Parliament, Resolution on the TRIPS Agreement and access to medicines (12 July 2007). The Resolution specifically mentions prevention of use of data exclusivity and patent extension.
53. See for example, Article 17.9 (1), United States-Australia FTA, Article 15.9 (2), United States-Morocco FTA and Article 14.8 (2), United States-Bahrain FTA.
54. Article 15.9 (2) United States-Morocco FTA.
55. United States–Singapore FTA, and draft United States-Thailand FTA.
56. See footnote 21 above, p. 114.
57. The United States–Jordan FTA, which requires a term extension for delays in marketing approval but not for patent grant procedures, is an exception. However, most United States negotiated FTAs require extension to "compensate

the patent holder for unreasonable curtailment of the effective patent term" due to delays in the marketing approval of the medicines and the examination of the patent.

58. The Hankyoreh, "U.S. FTA may cost drug industry $1.2 billion" (18 Oct 06).
59. See WHO, *Public Health Innovation and Intellectual Property Rights, A Report of the Commissionon Intellectual Property Rights, Innovation and Public Health* (Geneva, 2006) p. 125
60. US-Morocco FTA, Section 15.10.
61. A country analysis of public health and patent law in Jordan has shown that of 103 medicines registered and launched since 2001 that currently have no patent protection in Jordan, at least 79 per cent have no competition from a generic equivalent as a consequence of data exclusivity. See footnote 50 above, p. 9.
62. Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals*: *Implementing the Standards of the TRIPS Agreement* (Geneva, South Centre, 2002).
63. Drug Price Competition and Patent Term Restoration Act (The Hatch-Waxman Act), United States 1984.
64. See TRIPS Agreement, preamble.
65. "Patent linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No. 2001/83." See EU Directorate-General for Competition, *Pharmaceutical SectorInquiry - Preliminary Report*, 28 November 2008.
66. "FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."59 Fed. Reg. 50338, 50343 (Oct. 3, 1994). See "Generic drug entry prior to patent expiration: an FTC study", Federal Trade Commission, July 2002, p. 44.
67. Ibid.
68. T.A. Faunce and J. Lexchin, "Linkage in pharmaceutical evergreening in Canada and Australia", *Australia and New Zealand Health Policy*, vol. 4, (2007), p. 8, referring to the two following sources: Government of Canada. Canada Gazette Part II Regulations amending the patented medicines (notice of compliance) regulations 2006, 140 (21): 1503-1525; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49.
69. In addition to the requirement mandated by the TRIPS Agreement that the infringing party provide the information, the EU proposal would also require any other person who was found in possession of, using, or providing the infringing goods or services on a commercial scale to provide the information.
70. See "Generic drug entry prior to patent expiration: an FTC study", Federal Trade Commission, July 2002, and K.A. Moore, "Judges, juries and patent cases - an empirical peek inside the black box", *Michigan Law Review*, vol. 99, No. 2 (November 2000) p. 365.
71. See Statement by Brazil at TRIPS Council: Public Health dimension of TRIPS Agreement, 3 March 2009 and UNITAID, statement on Dutch confiscation of medicines shipment, 4 March 2009.
72. EU Council Regulation (EC) No. 1383/2003.
73. Article 41, TRIPS Agreement.
74. Kenya Anti-Counterfeit Act and Uganda anti-counterfeit bill.
75. EU Parliament resolution, INI/2008/2133 of September 2008.

paper 15

Protection of traditional medicine: lessons from India

Dr. N.S. Gopalakrishnan

Developments in biotechnology and information technology that took place towards the end of the last century led to a demand for the protection of traditional knowledge. The momentum picked up when the interest in traditional knowledge associated with genetic resources that have medicinal value increased. Attempts made by large pharmaceutical industries to conduct bio-prospecting in developing countries rich with genetic resources, with the objective of identifying active ingredients that potentially could be developed into new drugs made the traditional knowledge-holders conscious of the value of their knowledge system. The use of modern intellectual property laws, particularly patent law, to acquire private property rights on the isolated parts of genetic resources led to the demand for the development of legal norms to effectively protect traditional knowledge.

Efforts to document and digitize undocumented traditional knowledge, particularly that belonging to the tribal and local communities, on the pretext of defensive protection, made the position more complex, because this resulted in the disclosure and dissemination of knowledge hitherto confined to the members of the community. Thus, this "protective" strategy actually made the knowledge potentially available to scientists and industries for commercial exploitation without the knowledge or consent of the original knowledge-holders. Furthermore, the modern intellectual property system could not offer effective protection to this body of knowledge, which it considers to be in the public domain. This problem, and the absence of a specific legal framework to protect traditional knowledge, facilitated its commercial exploitation without adequate compensation for the holders of the knowledge. This paper briefly outlines efforts to develop different approaches for the protection of traditional knowledge in India.

Context

India is rich in genetic resources and biodiversity, as well as possessing well-established systems of traditional medicine such as ayurveda, unani and sidha. The knowledge associated with these systems is well documented and successfully practiced in India. In addition, there are innumerable health practices that are transmitted orally and are undocumented. A majority of the people living in the villages of India still maintain their health based on these practices. Because of the culture and tradition followed by the practitioners of these systems, the need for a formal legal framework to protect and monitor this rich traditional system was never felt. However, the demand for protection emerged in the context of biopiracy and patenting of new products based on traditional knowledge using biotechnology and information technology.

It was the finalization of the Convention on Biological Diversity (CBD) that ignited the demand for legislative protection of traditional knowledge in many countries rich in genetic resources. The CBD for the first time recognized the sovereign right of nations over their natural resources.[1] The nature of ownership over these resources and the manner in which they are to be managed is left to the discretion of the nations. This was necessary because of the complex nature of the issue and the diverse manner in which these resources have been managed in various countries. But the convention does mandate the recognition of the rights of the holders of the knowledge associated with genetic resources in case of the use of their knowledge. The obligations include (1) to respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities; (2) to promote its wider application with *the approval and involvement* of the holders of such knowledge, innovation and practices (emphasis added); and (3) to encourage equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.[2] The requirement of the involvement and approval of the holders of knowledge before the use of their knowledge and the obligation to share the benefits makes it clear that the convention recognizes, albeit not explicitly, the ownership of such knowledge by its holders. The convention leaves it to individual nations to develop mechanisms through which to satisfy this obligation.[3] The Indian effort in the last decade to protect traditional knowledge has been based on the above obligations.[4]

The Biological Diversity Act

The Biological Diversity Act, 2002[5] is the basic law in India regulating access to genetic materials and the knowledge associated therewith. The mechanism followed in this act to protect traditional knowledge is to ensure benefit-sharing to the holders of knowledge in case of its use. One of the

important provisions is to take prior informed consent (PIC) before using genetic resources and associated traditional knowledge. But this is obligatory only in the case of access by foreigners.[6] The power to give PIC and to set the terms and conditions of use, including benefit-sharing, is vested with the National Biodiversity Authority (NBA), presently located in Chennai.[7] Prior approval from the National Biodiversity Authority is also mandatory for all persons (nationals and foreigners) applying for any intellectual property right for inventions based on genetic resources and associated traditional knowledge of India.[8] The latter obligation does not extend to new plant varieties, since specific provisions are included in an act governing protection of new plant varieties (see below).

The obligation of the NBA at the time of granting access or permission to file an IPR application includes giving directions relating to benefit-sharing fees, royalties or both, or the NBA may impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.[9] It is expressly mentioned in the act that the benefit-sharing may include: joint ownership of intellectual property; transfer of technology; location of research and development (R&D) facilities or production units in such areas (which may improve the living standards of the holders of such knowledge);[10] association of Indian scientists and local people with R&D activities, bio-surveys and bio-utilization initiatives; provision of venture capital for the benefit of knowledge-holders; and payment of compensation. However, even though the act envisaged decentralized management of genetic resources and associated traditional knowledge by creating a State Biodiversity Board and Biodiversity Management Committees (BMC) at the local level, the law failed to recognize their right to manage these resources. An apparent gap left by the law is the absence of express provisions recognizing the power of benefit claimers, the BMC[11] and the State Biodiversity Board[12] to enter into agreements with persons seeking access or filing patent applications. There is no provision under the act enabling the BMC, constituted as part of the local bodies (the Panchayat), to enter into an agreement with the person seeking access. There is also no provision in the act obligating the BMC to enter into such agreements *only* with the prior informed consent and participation of the holders of knowledge—particularly tribal and local communities—in cases where the knowledge belongs to them. The only obligation of the NBA is to ensure that the benefit-sharing agreement is equitable and in accordance with the mutually agreed terms and conditions between the persons applying for approval and the local bodies and benefit claimers.[13] Moreover, though the NBA is bound to consult the BMC before taking decisions relating the use of biological resources,[14] it does not have to follow the suggestions or decisions of the BMC; the obligation is only to "consult".

It is also interesting to note that the act is silent about the constitution of the BMC, which is supposed to ensure the management and sustainable use of genetic resources. According to Article 22 of the Biodiversity Rules 2004, the Biodiversity Management Committee shall be constituted by the local body and shall consist of a chairperson and not more than six persons nominated by the local body, of whom not less than one third should be women and not less than 18% should belong to the Scheduled Castes/Scheduled Tribes. It appears that the local body is left to decide the members to be included in the committee. Thus, while it may be possible to include holders of traditional knowledge in the committee, their representation is not made mandatory in the act or rules. The act is also silent about the ownership and control of genetic resources and associated traditional knowledge by the tribal and local communities, even when clearly associated with them. In fact, there is no mention of local or tribal communities in the act. Section 2 of the act defines "benefit claimers" as follows: "the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application".

Thus, the act followed a centralized approach for granting PIC, and appears to have given the NBA the power to transfer traditional knowledge without the active involvement and consent of the holders of that knowledge.

It is interesting to note that the act permits Indian citizens and Indian industries to use the biological resources and associated knowledge—for all purposes—without permission from anyone, and without any obligation to share the benefits. The only obligation is to give prior notice to the State Biodiversity Board (SBB) of the intention to obtain any biological resources for commercial utilization, bio-survey and bio- utilization.[15] The local people and communities in the area, including *vaids* and *hakims,*[16] who have been practicing indigenous medicine are excluded from the obligation to give notice to the SBB. It is important to note that the definition of biological resources[17] excludes value-added products. Similarly, the definition of commercial utilization of biological resources excludes traditional use.[18] It appears that these exclusions would in many cases exempt Indian industries and other citizens who are manufacturers of traditional medicines from the obligation of informing the SBB regarding use of biological resources. There is also no obligation to share the benefits derived from the commercial utilization of the resources.

Thus, the legislation seems to allow the exploitation of the biological resources and associated knowledge of local communities, without enforcing prior informed consent and the sharing of benefits. This appears to be against the premise of conservation and sustainable use of genetic resources through the protection of the interests of local communities responsible for

their conservation. It would appear that the act requires restructuring if it is to protect traditional knowledge associated with biological resources belonging to the tribal and local communities. Though the act came into force and the NBA has been functioning for five years, there has yet to be any dispute based on the act. One may have to observe the functioning of the bodies created under the act to assess its real impact on the protection of traditional knowledge associated with genetic resources. It is also important to note that this law can not protect all elements of traditional medicines, because coverage is confined to genetic resources and associated traditional knowledge.

The Protection of Plant Varieties and Farmers' Right Act

Another law that may have–limited–application with regard to the protection of traditional medicine is the Protection of Plant Varieties and Farmers' Right Act, 2001. This act, though primarily intended to protect new plant varieties, contains provisions for the registration of existing varieties and payment of compensation to and benefit-sharing with the community.[19] But the act is useful for the protection of traditional medicine only if medicinal plant varieties are involved. The main beneficiaries of this act are farming communities. To protect the traditional knowledge of farming communities, the act facilitates the registration of extant varieties and farmers' varieties. Though there is some overlap between the definition of extant varieties[20] and farmers' varieties,[21] the object seems to be to cover existing varieties that have traditionally been cultivated by the farmers in their fields, or wild relatives or landraces of a variety about which farmers possess knowledge. In addition, the act also contains a separate chapter, entitled Farmers' Rights, to protect the interests of the farming community while providing protection for new plant varieties.[22] The special provisions included in the act are for the recognition of the rights of farmers, benefit-sharing, payment of compensation to communities for their contributions, immunity from prosecution in case of innocent infringement, payment of an annual fee by breeders, and the creation of a Gene Fund. But interestingly, just as in the case of the Biodiversity Act, there is no provision to recognize the community's ownership of traditional knowledge. The approach is to provide a share of the benefits to the community through a complex set of procedures—not to give them control over the resources. This legislation may cover medicinal plant varieties, provided there are medicinal plants that have the potential to be developed into new varieties.

The Patents Amendment Act

The Patents Amendment Act, 2002[23] introduced some provisions to prevent the patenting of traditional knowledge and to elicit information on whether

a new invention claimed is based on traditional knowledge. It expressly states that "an invention which in effect is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components" is not patentable.[24] This provision gives the impression that what is prohibited is the patenting of traditional knowledge per se, not the patenting of new inventions based on traditional knowledge.[25] The absence of a definition of traditional knowledge in the Patents Act, and the use of the expression "an invention which in effect is traditional knowledge" in Section 3, may permit the filing of patent applications by persons who are adding value to the traditional knowledge, or are producing improved products and processes based on traditional knowledge. If the applicant can show that there is an inventive step that improved a product or process based on traditional knowledge, it may be possible to obtain a patent on those improved products, even though they are based on traditional knowledge.

The Act mandates the disclosure of the source and geographical origin of the biological material in the patent specification when the invention claimed is based on biological materials.[26] Moreover, it is possible to oppose a patent application or revoke a patent if this disclosure is not made, or if it has wrongly mentioned the source or geographical origin of biological materials upon which the invention is based.

It has furthermore become clear that a patent application can be opposed if the invention claimed in the application is anticipated (i.e., it is not new) because the knowledge is available, orally, or otherwise, within any local or indigenous community in any country.[27] Similarly, it is possible to revoke a patent on these grounds.[28]

But unfortunately there is no requirement that the patent applicant disclose either the nature of the traditional knowledge used or the community or the knowledge holder from which it originates. Nor is there a requirement in the Patents Act related to prior informed consent of, or benefit sharing with, the community or the knowledge holder.

Thus, the provisions specifically included to prevent the patenting of existing knowledge of local and tribal communities may in fact facilitate the patenting of new products and processes based on traditional knowledge. Given the differences between traditional medicine systems based on inherited knowledge and "modern" medicine based on western scientific research, the norms for patenting (particularly the requirement of inventive step) are likely to favour modern pharmaceuticals and give protection to new products based on traditional knowledge.[29] The act, as framed, does not protect the traditional knowledge of communities from being used in patented products and processes without their prior informed consent and on mutually agreed terms and conditions, including sharing of economic benefits. Indeed, the

Patents Act in fact treats traditional knowledge as being in the public domain, and fails to recognize the customary ownership and rights of the holders of this knowledge.

The Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act

Another important piece of legislation that has a bearing on the traditional knowledge of certain communities is the Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 (Forest Right Act, 2006). This legislation is primarily intended to recognize and protect the customary rights in forest and forest produce of forest dwellers. It is interesting to note that Section 3 of the act includes the "right to access to biodiversity and community right to intellectual property and traditional knowledge related to biodiversity and cultural diversity".[30] Section 4 of the act makes it clear that these rights are vested in scheduled tribes or traditional forest dwellers notwithstanding any provisions in any other law in force.[31] This is the first legislation in India to expressly recognize ownership rights over traditional knowledge of the people who are the holders of traditional knowledge. It protects not only traditional knowledge associated with biodiversity but also cultural diversity. It is the "community right to intellectual property and traditional knowledge" that is recognized, rather than individual rights. The act envisages a decentralized mechanism for vesting of forest rights as well as their management. One of the limitations of this legislation is the failure to evolve a collective management structure of the knowledge that is vested in the communities. It is important to note that this legislation takes away the power of the NBA under the Biodiversity Act to give PIC and enter into benefit-sharing arrangements with regard to traditional knowledge associated with biodiversity.

Traditional Knowledge Digital Library

The Government of India also took steps to document traditional medicinal knowledge using digital technology, in order to prevent patenting of it.[32] The Traditional Knowledge Digital Library (TKDL) is a project sponsored by the Government of India[33] to create a database on Indian traditional medicinal practices, using the tools of digital technology. Its objective is to prevent bio-piracy and the granting of questionable patents. The fact that patents have been granted, in the United States and the EU, based on traditional knowledge from India prompted the government to start this project. It was argued that one of the reasons for this was the non-availability of adequate databases on traditional medicine systems, which patent offices can search for prior art before granting patents.[34] It was also realized that traditional knowledge lacks a proper classification under the International Patent

Classification System to enable the patent examiners to conduct proper prior art searches. The language in which the traditional knowledge is available also is an impediment in this regard. It was believed that if traditional knowledge that is in the public domain would be properly organized and made available using digital technology, it could to a large extent prevent the grant of patents on existing traditional knowledge.[35] Though the Indian system of medicine includes Ayurveda, Yoga, Naturopathy, Sidda and Uniani, the first phase of the project was the creation of database on Ayurveda.[36]

Ayurveda is a documented knowledge system; information on about 36 000 compositions of medicines that have been used for centuries is available, scattered in 14 Sanskrit texts. Ayurveda originated about 5000 years ago and has been practiced and transferred from generation to generation. Codification and re-codification took place at different periods of time, and it remains an evolving system in the hands of the practitioners. There are about 430 263 registered practitioners in India.[37] This is in addition to the large number of unregistered traditional medicine practitioners in villages.

In the last century, organized industrial activity in the field of Ayurveda developed.[38] The present industries not only manufacture and sell drugs based on the recognized texts, but also produce new combination drugs that are not described in those texts. There is also research activity in this area.[39] Practitioners of Ayurveda can be broadly classified into individuals who practice it based on the recognized texts plus their own experience, and industrial manufacturers of drugs based on the texts as well as of new combinations they have developed using the knowledge contained in the texts.

The TKDL project sifted and collated existing information and put it in digitized form in Hindi and in five international languages (English, German, French, Spanish and Japanese) using the Traditional Knowledge Resource Classification (TKRC). The TKRC is an innovative classification system developed to facilitate the systematic arrangement, dissemination and retrieval of this information under 5000 subgroups within AK61K35/78—the single international patent classification for medicinal plants. The TKDL is the result of the creative effort of an interdisciplinary team consisting of 25 Ayurveda experts, one patent examiner, three scientists, five IT professionals and four technical officers over one and a half years.[40]

The unique feature of the TKDL is the innovative classification system that facilitates the interaction of modern scientific medicinal knowledge with Ayurveda. This is expected to enhance research in Ayurveda using modern scientific techniques in order to invent new products. Another interesting feature is the use of software to facilitate the understanding of the complex Sanskrit *Slokas* by a layman. This is achieved through interpretations of these

Slokas by Ayurveda experts, so that they can be read and understood by those without knowledge of Sanskrit. A web version of the TKDL providing access to this information, including full text search and retrieval, was originally envisaged but has yet to be launched.[41]

Modern scientific names are provided, in addition to the traditional names of plants, diseases and preparations, in order to establish a relationship between the traditional knowledge and modern science. This is expected to help patent examiners to find relevant prior art and reject patent applications that are based on existing Ayurvedic products or processes. It will also make it easier to distinguish new products and processes from existing ones. The database can be searched using the name of the formulation, the ingredients used in the formulation, the method of preparation, the method of administration of the medicine, the name of the disease and the name of the therapeutic action. A link is established between the TKRC and the IPC classification by using both the traditional names and their equivalents in English.[42] A glossary of traditional terms explained in simple language[43] is included to facilitate the user's understanding of the terminology used in the *Slokas.* Moreover, the Sanskrit text is explained using Roman script, with English definitions, to make the information more user-friendly and to avoid ambiguity in the translation and interpretation.[44] There are also pictures of the plants and other ingredients to facilitate their identification. The search is very user-friendly.

The TKDL is a very useful tool to enable people who have no knowledge of Ayurveda to find relevant information. It will surely help in preventing grant of "turmeric-type" patents[45] in future. But one has to wait and see whether the TKDL will actually prevent or facilitate biopiracy. The TKDL, once made available, will be a powerful digital tool for research in the area of Ayurveda. By making it much easier to learn about existing Ayurvedic drugs and their ingredients, it will also make it easier to use them in research aimed at developing new combinations and modern drugs. These new products will most likely be patentable. At present, however, the database has not yet been put on the Internet. The policy on access to this database is not clear. It seems that the database has been given to European Patent Office and the US Patent and Trademark Office free of cost. Thus, valuable information that remained scattered and inaccessible to modern drug developers has now been consolidated and is going to be made available for the development of new products that will be private property of the developers, not the holders of traditional knowledge; furthermore, such new products are not going to be available to the traditional practitioners of Ayurveda. Thus information regarding Ayurveda, once only available to traditional practitioners, is going to be transformed into new products with intellectual property protection that will be controlled by corporations for commercial use.

It therefore appears that the TKDL initiative will benefit modern researchers and corporations rather than the traditional practitioners of Ayurveda. It is needless to add that digital technology plays a pivotal role in this transformation and new wealth generation. It is not clear whether the provisions of the Biodiversity Act regarding access and benefit-sharing are going to be applied when access is provided through the TKDL. The Government of India is now in the process of creating similar databases for other Indian traditional medicinal systems.

Finally, it should be noted that there are also other efforts to document undocumented medicinal knowledge, for example through the development of Peoples Biodiversity Registers with the participation of local people. Another effort worth mentioning is the work of the Foundation for Revitalization of Local Health Tradition (FRLHT). The FRLHT has introduced different activities to protect and promote local health traditions.[46] It is expected that these collective efforts will enable the protection and preservation of traditional medicinal practices in India.

Conclusion

The complex nature of traditional knowledge and the lack of clarity regarding the manner of its management have resulted in the inclusion of different provisions in various laws. These provisions recognize the right to share in the benefits derived from the use of this knowledge. However, the absence of an expressed provision recognizing the community's ownership of this knowledge is a major drawback. Even the Forest Rights Act, which recognizes the rights of forest dwellers over "intellectual property and traditional knowledge related to biodiversity", does not put in place a system for sustained management of those rights. There is also a lack of clarity on the nature of traditional knowledge.

While some knowledge still is confined to the members of a community, a substantial part of the knowledge that originated with the community is now widely practiced by outsiders. If the objective is to protect the whole range of traditional knowledge spread over the length and breadth of India, there is a need to develop a decentralized collective management mechanism. It is the absence of such a mechanism that resulted in the present state of affairs. Increasing the dissemination of knowledge, while leaving the ownership of that knowledge ambiguous, makes it more easily exploitable. Thus, the efforts undertaken thus far may turn out to be counterproductive unless comprehensive legislation is developed to prevent the unauthorized use of traditional knowledge.[46] To be sustainable, any such legislation should aim, furthermore to ensure the social, economic and cultural development of traditional communities and the preservation and promotion of their culture and specific traditional practices, including medicinal practices.

Endnotes

1. Article 15 reads: "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation".
2. Article 8(j) reads: "Subject to its national legislation, respect, preserve and maintain knowledge, innovation and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".
3. For an analysis of the provisions of the CBD see N.S. Gopalakrishnan, "Diversity Related Intellectual Property Rights- GATT Final Act, The Convention on Biological Diversity and the Challenges", XVIII *Academy Law Review*, 281 (1994).
4. For an elaborate analysis of various laws in India see N.S. Gopalakrishnan, "Protection of Traditional Knowledge: Need for a *Sui Generis* Law in India", *The Journal of World Intellectual Property*, September 2002, Vol.5 No.5 pp.725-742. The following discuss is adopted based on this paper.
5. The Act was passed based on the modification suggested by Parliamentary Standing Committee on Science and Technology, Environment and Forest and placed before the Rajya Sabha on 4th December, 2001. For details see "Ninety-Fifth Report on The Biological Diversity Bill, 2000", Rajya Sabha Secretariat, New Delhi, December, 2001 (Here in after referred as Report).
6. See Section 3.
7. See Section 19.
8. See Section 19(2).
9. See Sections 19(3) & 21(2).
10. Section 2(a) reads: "benefit claimers means the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application".
11. Chapter X of the Act envisage creation of Biodiversity Management Committee in every local administration body such us Panchayat for the purpose of promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals etc. with the participation of people.
12. Chapter VI of the Act envisage creation of State Biodiversity Board for the purpose of management of biodiversity in the State.
13. See Section 21(1). Section 2 of the act defines "benefit claimers" as follows: "the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application".
14. See Section 41(2).
15. Section 7 reads: "No person who is a citizen or a body corporate, association or organization which is registered in India shall obtain any biological resources for commercial utilisation or bio-survey and bio-utilisation except after giving

prior intimation to the State Biodiversity Board concerned. Provided that the provision of this section shall not apply to the local people and communities of the area, including vaids and hakims, who have been practicing indigenous medicine".

16. These are traditional medicinal practitioners practicing indigenous medicine.
17. Section 2(c) reads: "means plants, animals and micro-organisms or parts thereof, their generic material and byproducts *excluding value added products*, with actual or potential use or value, but does not include human genetic material. Value added products means products, which may contain portions/extracts of plants and animals in unrecognizable and physically inseparable form (emphasis mine).
18. Section 2(f) reads: "Commercial Utilization means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through breeding or genetic intervention and *shall not include traditional practices in use in any agriculture, horticulture, poultry, dairy farming or animal husbandry and bee keeping*" (emphasis mine).
19. The Bill was referred to the Joint Committee of Parliament and many of the provisions regarding the farmers' protection were introduced by the committee. For details see Lok Sabha, *Report of the Joint Committee on the Protecting of Plant Varieties and Farmers' Rights Bill, 1999,* Lok Sabha Secretariate, New Delhi, August, 2000 (herein after Joint Committee Report).
20. See Section 2(j).
21. See Section 2(l).
22. See Chapter VI Sections 39-46.
23. For a critical comment on the Bill see N.S. Gopalakrishnan, "The Patents (Second Amendment) Bill, 1999 – An Analysis", (2001)1 SCC (Jour) 14.
24. See Section 3(p) as introduced by the Joint Committee. The Joint Committee submitted the report on the Bill by including an express provision to exclude patenting of traditional knowledge. See Report of the Joint Committee on Parliament, Rajaya Sabha Secreteriate, 2001.
25. This is evident from the explanation to this section in the Patent Manual 2008 which reads: "Traditional Knowledge, being knowledge already existing, is not patentable. An example is the anti septic property of turmeric for wound healing. Another example is the pesticidal and insecticidal properties of *neem"*
26. See Section 10(d)(ii)(D).
27. See Section 25(j) &(k).
28. See Section 64(p) & (q).
29. For an elaborate analysis see N.S. Gopalakrishnan, "TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System", *European Intellectual Property Review* (Sweet & Maxwell, London, (January), 11-18 (2005).
30. See Section 3(1)(k) of the Forest Rights Act, 2006 reads: "For the purpose of this Act, the following rights, which secure individual or community tenure or both, shall be the forest rights of the forest dwelling Scheduled Tribes and other traditional forest dwellers on all forest land, namely... (k) right of access

to biodiversity and community right to intellectual property and traditional knowledge related to biodiversity and cultural diversity".

31. See Section 4(1).
32. For a detailed analysis of use of digital technology see N.S. Gopalakrishnan, "Traditional Knowledge, Information Technology and Development – The Challenges", *Cochin University Law Review*, 132-147 (2005). The following pages are reproduced with modifications from this paper.
33. TKDL is developed by the Science Communication and Information Resources (NISCAIR) with the support of Ministry of Science and Technology, Office of the Controller General of Patent, Design and Trademark, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, Central Council for Research in Ayurveda & Siddha and Department of Indian System of Medicine and Homoeopathy. See Traditional Knowledge Digital Library: User manual, NISCAIR, New Delhi, p. 1.
34. See, NISCAIR, "Bio-piracy of Traditional Knowledge", *TKDL 1 – Ayurveda,* NISCAIR, New Delhi.
35. *Ibid.*
36. Ayurveda is the oldest surviving complete medicinal system in the world originating form India. The name is derived from two Sanskrit words "Ayur (life) and ved (knowledge) meaning knowledge of life. For details see http://www.allayurveda.com/discover.htm
37. For details see http://indianmedicine.nic.in/html/ayurveda/asmain.htm
38. *Ibid.* manufacturers.
39. http://www.ccras.org/research.htm
40. See, "TKDL Concepts and Over View", *TKDL 1 – Ayurveda,* NISCAIR, New Delhi.
41. See, "Features of TKDL", *Ibid.*
42. See, "Content, Identifiers and TKDL details", *Ibid.*
43. See, "Glossary", *Ibid.*
44. See, "Help on Diacritical", *Ibid.*
45. A 1995 US patent (later revoked) claimed the use of turmeric to promote the healing of wounds. The Council of Scientific and Industrial Research of India successfully challenged the patent based on the fact that the wound-healing properties of turmeric had been known in India for centuries, citing both an ancient text and a 1953 scientific paper.
46. For details see www.frlht.org.

paper 16

Using competition law and policy to increase access to a sustainable supply of affordable medicines*

Tenu Avafia, Jonathan Berger,
Trudi Hartzenberg

Introduction

This paper focuses on the potential role of competition law and policy in advancing public health by increasing access to a sustainable supply of affordable essential medicines. It does so by briefly considering the broader framework provided by the WTO's TRIPS Agreement before looking at the appropriateness of using competition policy within a developing country context. In countries where legal change is slow, where court processes are unduly time-consuming and not particularly user-friendly, and where laws often exist only on paper, the introduction and successful implementation of a complex and comprehensive competition policy framework will require a significant degree of political will and technical support, which may not always be forthcoming. Why then even consider competition law and policy?

There are four key reasons why developing countries should—if at all possible—use the regulatory tools available in terms of competition law and policy to ensure access to a sustainable supply of affordable essential medicines. In so doing, however, they should also seek to make full use of the public health safeguards and flexibilities elaborated upon by the Doha Declaration.[1] That agreement, adopted at the WTO's ministerial meeting in Doha, Qatar, in November 2001, sets out what can and cannot be done to ensure access to medicines insofar as patent law and policy are concerned.

* This paper is excerpted from Avafia T, Berger J, Hartzenberg T. The ability of selected sub-Saharan African countries to utilize TRIPS Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries. ICTSD, UNCTAD and TRALAC, 2006.

First, TRIPS accords Member States considerable flexibility in dealing with anticompetitive practices. Importantly, it also recognizes the particularly egregious nature of anti-competitive conduct.[2] The broader international trade law framework provided by TRIPS is relevant largely because it provides some degree of guidance for determining in what circumstances it may be appropriate to invoke competition policy to increase access to essential medicines.[3]

Second, unlike the degree of consensus reflected in the Doha Declaration, which clearly sets the boundaries of what is permissible in terms of patent law and policy, there is sufficient disagreement between and within developed countries on the relationship between competition policy and intellectual property to provide significant space within which to manoeuvre. This is not to imply that developing countries should take their lead from the industrialized world if and when it reaches consensus on the relevant issues. Instead, it is simply to draw attention to the window of opportunity that such a lack of consensus provides.

Third, competition law and policy is well suited to implementation by an independent competition authority vested with strong investigative powers. Unlike patent law, the effective use of competition law is ordinarily not reliant on the conduct of certain parties that may be reluctant to act. In particular, it may facilitate action by a range of interested parties other than the state and generic pharmaceutical manufacturers, providing a mechanism for action that does not necessarily require such parties to invest significant resources in risky litigation that may drag on for years. Instead, the regulatory authority may pursue the matter in the public interest simply on the basis of a third party complaint. Fourth, the rich (albeit limited) experience of South Africa in using competition law to increase access to medicines for the treatment of HIV infection and AIDS-related illnesses provides helpful insights into the potential benefits of exploiting competition law and policy in a developing country context. While South Africa may differ in many respects from its African neighbours and other developing countries, the lessons learnt in two abuse-of-dominance matters (both of which focused on allegations of excessive pricing) are of broader application. The two South African case studies are considered in more detail below. The other three reasons advanced in support of using competition law and policy are explored in greater detail elsewhere.[4] When taken together, they provide a particularly strong basis for the creative and expansive use of anti-competitive regulatory tools to ensure access to a sustainable supply of affordable medicines.[5] But in and of themselves, such policy instruments are insufficient. As already mentioned, developing countries should also seek to make full use of the public health safeguards and flexibilities identified in and clarified by the Doha Declaration. For competition policy tools to be used efficiently and effectively, they need

to be viewed as complementary to the regulatory instruments identified in the Doha Declaration.[6]

Using South Africa's Competition Act 89 of 1998

South Africa's new competition law framework has been in force for almost six years.[7] While it is possible—and indeed constitutionally mandated – to interpret the Competition Act in a manner that takes full advantage of the regulatory flexibility permitted by TRIPS,[8] this has largely not been achieved outside of academic, activist and advocacy circles. In particular, the jurisprudence developed by the specialist bodies,[9] primarily charged with adjudicating competition disputes has not begun to consider the interface between competition law principles and exclusive rights in patents. While a plain reading of the Competition Act shows that the exercise of exclusive rights in patents is not ordinarily exempt from the reach of competition law[10] the nature and extent of the reach of the law in this arena remains in significant doubt.

Interestingly, however, the competition authorities have already considered a wide range of health-related matters.[11] Recently, the Competition Tribunal refused to sanction a merger between two health care groups in the "capitated managed care" market, which seeks to provide low-income earners with access to private health care services. In its decision, the Tribunal gave an indication of the approach that it is likely to adopt in interpreting the provisions of the Competition Act, relevant for increasing access to a sustainable supply of affordable medicines. In setting out its approach to Section 12A, which sets out the considerations relevant to the approval of mergers, the Tribunal held as follows:

> Section 12A(2)(e) of the Act provides that when determining whether or not a merger is likely to substantially prevent or lessen competition we should take account of "the dynamic characteristics of the market, including growth, innovation and product differentiation." … Pertinent to our consideration [of the proposed merger] are the general state of healthcare provisioning in South Africa, the policy objectives of the South African Government in the realm of healthcare provision, the mechanisms whereby government intends achieving those objectives, and the place and role of the private sector.[12]

On 31 January 2006, the Competition Appeal Court overturned the ruling of the Competition Tribunal and approved the merger unconditionally. To date, it has yet to issue reasons for its decision.

There are potentially a number of sections in the Competition Act that could provide a basis for challenging anticompetitive practices in the health

sector broadly and in the pharmaceutical sector in particular. These are set out in Chapter 2, which deals with "prohibited practices" in two parts: "Restrictive Practice" in Part A and "Abuse of a Dominant Position" in Part B. In Part A, the Competition Act prohibits certain "restrictive horizontal practices",[13] such as price fixing between competitors,[14] as well as certain "restrictive vertical practices",[15] such as agreements between a supplier and a customer relating to minimum resale prices.[16] Part B deals with four main categories of prohibited abuse of dominance.[17] Section 8, the primary provision dealing with the abuse of dominance which is of significant importance and relevance to essential medicines, provides as follows:

> It is prohibited for a dominant *firm* to –
>
> (a) charge an *excessive price* to the detriment of consumers;
>
> (b) refuse to give a competitor access to an *essential facility* when it is economically feasible to do so;
>
> (c) engage in an *exclusionary act*, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain; or
>
> (d) engage in any of the following *exclusionary acts*, unless the *firm* concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act –
>
> (i) requiring or inducing a supplier or customer to not deal with a competitor;
>
> (ii) refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;
>
> (iii) selling *goods or services* on condition that the buyer purchases separate *goods or services* unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
>
> (iv) selling goods or services below their marginal or average variable cost; or
>
> (v) buying-up a scarce supply of intermediate goods or resources required by a competitor.

Three terms, which are defined in Section 1 of the Competition Act, merit further attention:

> *essential facility* means an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide *goods or services* to their customers;
>
> *excessive price* means a price for a good or service which –

(aa) bears no reasonable relation to the economic value of that good or service; and

(bb) is higher than the value referred to in subparagraph (aa);

exclusionary act means an act that impedes or prevents a *firm* entering into, or expanding within, a market.

Collectively, when considered in the context of a legal system based on the authority of a Constitution that expressly recognizes that all people have a right of access to health care services[18]—and which places corresponding positive obligations on the state regarding the progressive realization of the right[19]—they potentially provide a range of tools to challenge various anticompetitive practices such as unjustifiable refusals to license intellectual property and price gouging. To date, Section 8 of the Competition Act has been used successfully to challenge both, even though the matter that resulted in the grant of "non-voluntary" licences was in fact framed as an excessive pricing claim.

This section now considers the two excessive pricing matters that have managed to use competition law effectively in order to increase access to a sustainable supply of affordable essential medicines. The first, *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, dealt with antiretroviral (ARV) medicines for the treatment of HIV infection. The second, *Treatment Action Campaign v Bristol-Myers Squibb*, considered an antifungal medicine used to treat cryptococcal meningitis, an AIDS related opportunistic infection. In both matters, the stakes could not be higher—literally matters of life and death. Unsurprisingly, neither matter proceeded to adjudication. Both were settled.

Hazel Tau takes on GlaxoSmithKline and Boehringer Ingelheim

As part of a national campaign to increase access to treatment for HIV/AIDS, which includes taking steps to ensure access to a sustainable supply of affordable HIV-related medicines, a group of concerned individuals and organisations lodged a complaint against the GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) groups of companies with South Africa's Competition Commission in September 2002. Acting in terms of Section 49B(2)(b) of the Competition Act, which permits "any person" to "submit a complaint against an alleged prohibited practice", the complainants argued that the two companies were acting in violation of competition law by charging excessive prices for certain of their ARV medicines to the detriment of consumers.[20]

In essence, the complainants alleged that the prices charged by GSK and BI for their essential medicines were directly responsible for the premature,

predictable and avoidable loss of life".[21] Deliberately adopting a conservative approach to the issue of prohibited excessive pricing, they argued that even when full allowance was made for the costs of research and development, the incentive to develop new drugs, higher profits and licensing fees,[22] the prices of these patented medicines remained excessive and unjustifiable.[23] Whilst argued in terms of the Competition Act, the complainants located their arguments firmly within the broader context provided by the public health emergency of HIV/AIDS in South Africa, as well as the constitutional guarantee of access to health care services.[24]

At the time that the complaint was lodged, the South African Government had yet to commit itself to the development and implementation of a public sector ARV treatment programme.[25] This meant that access to appropriate treatment in the public sector was not an option. In a country where the vast majority of people are reliant on the public sector for the provision of health care services, this meant no access to ARV treatment for most of those in need. But access for some was still possible, albeit limited. In essence, there were only three options available to people in South Africa for accessing this life-saving treatment: out-of-pocket purchase from private pharmacies; medical scheme (health "insurance") cover; and employer-funded workplace treatment programmes for uninsured workers. By challenging the high prices of drugs, the complaint sought "to ensure that people living with HIV/AIDS who are working can afford to buy medicines to save their lives; that medical … [insurers] treat people living with HIV/AIDS without going bankrupt; and that employers are able to pay for the treatment of workers on a sustainable basis".[26]

Given the paucity of jurisprudence on the use of competition law to increase access to patented medicines, the lack of clarity in the Competition Act regarding the patent law and competition policy interface, and the inherent risks of litigation, the complainants decided to tread cautiously. Their goal was to make best use of the available legal framework to ensure access to a sustainable supply of affordable ARV medicines and to break the paralysis resulting from state inaction. After much internal debate, a decision was taken to focus on allegations of excessive pricing in respect of three medicines sold in the private sector. If successful, the case would go some way towards achieving the goal of the broader treatment access campaign. But in and of itself, it was never intended to be—nor was it executed as—the "magic bullet". In fact, the very nature of litigation precludes such an approach.

Even though other provisions of the Competition Act were identified as providing alternative courses of action,[27] the singular focus on excessive pricing was deliberate. On its own, the excessive pricing case brought enough legal obstacles to clear, such as market definition and the impact of patent protection on market definition and the determination of dominance

within the relevant market. In addition, the complainants recognized that broadening the scope of the enquiry had the potential to shift the focus away from the compelling facts to a technical and largely legal sideshow (the patent/competition policy interface) concerned with, amongst other things, the circumstances within which an exclusive rights holder can legitimately refuse to license a potential competitor. Any course of action that brought additional hurdles was considered as too risky to contemplate.

However, the deliberate focus on excessive pricing was not adopted simply to avoid addressing difficult (and potentially complicating) legal issues, such as whether intellectual property constitutes an essential facility or a refusal to license—in certain circumstances—falls within the concept of an exclusionary act. Rather, the complainants believed that the manner in which they framed their case was most likely to get the respondent drug companies to take the matter seriously, because answering an excessive pricing claim would very likely result in the forced public disclosure of costing models. This, the complainants believed, was something that GSK and BI would seek to avoid at all costs. Further, it was the one ground—if properly approached—that was most likely to elicit broad public support, because it could avoid challenging the patent system head-on whilst still focusing on the abuse of exclusive rights in patents with which any person who has ever needed medical care could identify.

The complaint was not only pursued through the formal means provided by the Competition Act. Instead, the legal case provided the basis for a larger public campaign that included the production of popular materials, including the glossy booklet entitled *The Price of Life—Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim: a report on the excessive pricing complaint to South Africa's Competition Commission*[28] and numerous press releases, fact sheets and advertisements.[29] Other actions aimed at supporting the complaint included a series of legal literacy workshops held across the country for staff members, provincial office bearers and volunteers of the TAC, in which the intricacies of the complaint were explained and debated, as well as the use of high profile events such as the first South African AIDS Conference in August 2003 to popularize the case.[30]

Settlement negotiations with GSK began on 11 September 2003, almost a year after the complaint had been lodged. At that point, BI did not seem to be interested in entering into a settlement. But two events shortly thereafter appeared to shift the balance. On 26 September 2003, two not-for-profit organisations formally requested non-exclusive voluntary licences from BI "to import into South Africa, and to use, offer to dispose of and dispose of in South Africa, and to export from South Africa, nevirapine".[31] That case—which was based on Section 56 of the Patents Act, which allows for an interested person to be awarded a compulsory licence if it is able to

be shown that the exclusive rights in a patent are being abused—sought to develop the jurisprudence consistent with the constitutional guarantee of access to health care services. In the alternative, it sought to declare Section 56 unconstitutional in the event of its being understood as not allowing the granting of licences in the circumstances. But instead of proceeding to litigation, which brought with it the risk of South Africa's first compulsory licence, the request resulted in the grant of nonexclusive royalty-free voluntary licences largely for the importation of generic nevirapine products.[32]

And just three weeks after the request by the not-for-profit organizations for nonexclusive voluntary licences, the Competition Commission decided to refer the *Hazel Tau* matter to the Competition Tribunal for adjudication. As a result of its year-long investigation, the Competition Commission had found sufficient evidence to support the referral to the Competition Tribunal on the basis of prohibited excessive pricing as well as two additional grounds, both of which deal with the failure of GSK and BI to license generic manufacturers in certain circumstances. BI may have been late in coming to the negotiating table, but when it came, it was prepared to reach a comprehensive agreement in a reasonably short period.

Simply put, the Commission found that GSK and BI were using their exclusive rights in the patents to deny appropriate licences to other manufacturers, whilst simultaneously keeping their own prices high. By early December 2003, within two months of the Commission's referral announcement, GSK and BI had entered into separate settlement agreements with the complainants and the Commission respectively.[33] In essence, the two groups of companies agreed to open up the market for these drugs to generic competitors.[34] For the first time in South Africa, generic versions of on-patent drugs were to become commercially available.

Hazel Tau shows that competition policy instruments can indeed be used to great effect, particularly in a context where other key role-players—such as developing country governments and generic pharmaceutical manufacturers—are either unwilling or unable to act. In this case, civil society was able to take the lead in advancing a public health agenda, not being constrained by the failure of others to take appropriate action.[35] Faced with the adverse findings of an independent investigation, a protracted public hearing into its pricing practices and the potential for the strengthening of the legal framework through unfavourable jurisprudence, all of which were strong possibilities, GSK and BI acted as any rational corporation would do and decided to settle.

For their part, the complainants chose to abandon a particularly strong case in favour of a relatively speedy resolution of the matter, despite the historical complaint and the complex legal and regulatory issues that remain

unresolved. Knowing that the public sector ARV treatment plan was in the process of being finalized, that not only price but also sustainability of supply would become increasingly relevant, and that thousands of deaths could be averted if the matter were resolved, the complainants had no reasonable alternative but to settle the matter. Even when viewed in hindsight, the decision to settle appears to remain appropriate.

Bristol-Myers Squibb sidesteps an attack

On 15 February 2005, acting on behalf of the TAC and the Southern African HIV Clinicians' Society, the AIDS Law Project (ALP) threatened to lodge an excessive pricing complaint against Bristol-Myers Squibb (BMS) regarding amphotericin B (AmB), referred to in the letter of demand as "the antifungal agent of choice to treat cryptococcal meningitis, a common cause of death amongst people living with HIV/AIDS in Africa having a mortality rate of between 25 and 40 per cent".[36] Unlike Hazel Tau, the medicine at the centre of this dispute was no longer on patent. Nevertheless, BMS still enjoyed a de facto monopoly for its version of AmB marketed as Fungizone® (as generic AmB was not (and is still not) available for sale in South Africa), for which it used to charge excessive prices.

According to the letter of demand, generic AmB was sold in Brazil for a fraction of the South African price. Fungizone® itself was alleged to be priced in the British National Formulary at less than 30% of the public sector price in South Africa. Various other comparisons supported a strong case that the South African price of the essential medicine could not be justified. On this basis, and with a complaint in terms of Section 8(a) of the Competition Act clearly in mind, BMS was put on terms "to reduce the public and private sector prices of Fungizone to no more than that charged for AmB in a comparable country such as Brazil".

Despite an initial response that seemed to indicate a willingness on the part of BMS to fight,[37] the matter was resolved within a relatively short time through a series of letters that were faxed between the ALP and BMS's legal representative. On 28 April 2005, a little over ten weeks after sending the letter of demand, the ALP informed BMS's legal representative that in the light of his client's "decision to lower the price of Fungizone in South Africa to R22.60, effective 1 July 2005 and applicable in both the public and private sectors, we have advised our clients not to pursue this matter by way of legal action against your client". In effect, the new price represented a reduction of more than 80% and 85% of the public and private sector prices of Fungizone® respectively.[38]

In many ways, the particular facts and timing of the Fungizone® matter represented the perfect case. Coming hot on the heels of the *Hazel Tau*

case, where GSK and BI had been forced to settle in a case that presented a greater legal challenge to the complainants, BMS was on the back foot from the start. In addition, its product was already off-patent, meaning that the "incentives to innovate" argument often trotted out in defence of high medicine prices was unavailable. Moreover, the substantially lower price for the same medicine in Great Britain appeared to provide clear evidence of price gouging in South Africa. The facts spoke for themselves and BMS acted rationally. Understandably, it persisted in the argument that it had "no legal obligation" to reduce the price of the medicine.

Amending South Africa's Competition Act

South Africa's Competition Act clearly has the potential to deliver in the public interest. Indeed, as the two case studies presented here show, it has already done so. However, if it is to deliver on its promise, certain structural and legal changes are inevitable. Consider, for example, one of the central reasons that limited the scope of the *Hazel Tau* complaint to a single ground—the complex set of hurdles that had to be overcome before the substance of the matter could be addressed. In short, the complainants had to deal with complex issues (such as market definition and the establishment of dominance) in the absence of limited statutory (and no regulatory) guidance and without being able to rely on the financial and institutional resources that were within the grasp of their corporate counterparts. With each hurdle, the odds of a successful challenge for the exposure of unjustifiable pricing practices were lowered.

There are numerous ways in which such barriers could be addressed. First, the statute could be fine-tuned to ensure that form does not stand in the way of substance by providing clearer guidance on the extent to—and the manner in—which it applies to various forms of intellectual property. Second, the Competition Commission could make use of its powers in Section 79(1) of the Competition Act to "prepare guidelines to indicate … [its] policy approach" to the patent law/competition policy interface. Such guidelines, which must be published in the *Government Gazette* and are not binding on anyone, would nevertheless provide much-needed direction for all role-players, including both holders of exclusive rights in patents as well as consumers.[39] Third, the Commission should be empowered to make resources available to complainants, such as access to certain information held by industry that is ordinarily inaccessible.

Most crucial in the field of access to medicines, however, is an amendment that expressly recognizes the grant of a compulsory licence as appropriate relief for certain forms of prohibited conduct. In terms of the provisions of Section 58(1) of the Competition Act, the Competition Tribunal may "make an

appropriate order" upon a finding of an abuse of dominance as contemplated by Section 8 of the Act, including—

(a) An order that the prohibited practice stop;[40]

(b) An order that goods be supplied "on terms reasonably required to end a prohibited practice", that is, at non-excessive prices;[41]

(c) A declaration that the conduct be regarded as a prohibited practice for purposes of a damages claim;[42] and

(d) The imposition of an administrative penalty.[43]

Clearly, Section 58(1) does not expressly mention compulsory licensing. Whether or not its provisions permit the issuing of a compulsory licence will depend largely on how, when and to what extent the Competition Tribunal and the Competition Appeal Court interpret the concepts of an "essential facility" and an "exclusionary act". In addition, whether or not Section 58(1) is interpreted as empowering the Tribunal to grant a compulsory licence following a finding of prohibited excessive pricing of a patented product will depend on whether the Tribunal and the Appeal Court view the subsection as a closed list of permitted orders, and how, when and to what extent they interpret what is meant by an "appropriate order".

While there are strong arguments in favour of interpreting the provisions on relief as permitting the granting of compulsory licences to prevent and control prohibited practices, such as excessive pricing, the lack of express recognition remains problematic. There is sufficient uncertainty to discourage the active use of the Competition Act for the purpose of seeking the early market entry of generic competition, as well as weaken the deterrent effect of the law insofar as the conduct of patentees and other exclusive rights holders is concerned. Further, one cannot disregard the possibility that competition law jurisprudence may develop which excludes such a form of relief.

To provide sufficient clarity and avoid unnecessary litigation, an appropriate amendment of Section 58 would require the following minimum components:

(a) An express recognition that the Competition Tribunal has the power to order the grant of a non-exclusive compulsory licence to any firm that is able to satisfy a published list of objective criteria;

(b) Detailed provisions relating to the amount of the royalty to be paid, such as 4% or 5%, for example;

(c) An express mechanism to adjust the royalty rate—either upwards or downwards—in exceptional circumstances, taking into consideration a range of factors, including: The actual research and development (R&D) undertaken by the patentee in respect of the patented product concerned; The extent of publicly-funded R&D in respect

of the product concerned, whether in South Africa or elsewhere; and The public interest in varying the royalty rate;

(d) In accordance with Article 31(k) of the TRIPS Agreement,[44] express provisions permitting exports of all products produced pursuant to the grant of the licence to all countries where such products are either not patented or in respect of which compulsory or voluntary licences are—or have been—issued.

Both the *Hazel Tau* and the Fungizone® matters have focused attention on the need to draw together the separate statutes dealing with competition policy, patents and the regulation of medicines in a cohesive and rational way. A TRIPS-plus patent law has ensured limited action on the part of generic pharmaceutical manufacturers and "forced" civil society (in the *Hazel Tau* case) to make creative use of a competition law framework that does not yet fully understand its implications for products protected by patents and other forms of intellectual property. A lack of competition authority jurisdiction was asserted in the Fungizone® matter in the wake of the confusion generated by the uncertain relationship between competition and medicines regulation law. But the type of comprehensive and co-ordinated legal framework required is dependant on political will that has yet to surface in South Africa. For as long as the regulatory framework remains unchanged or undeveloped, either through a lack of jurisprudence or legislative reform, the Competition Commission would be advised to invoke its powers to issue guidelines.

The potential impact in SADC: lessons from South Africa

Despite the significant regulatory flexibility regarding competition policy accorded to all WTO members under the TRIPS Agreement, some SADC members may have found that they have neither the level of expertise nor the institutional capacity to take full advantage, particularly insofar as enforcement is concerned. With this in mind, such countries may have decided against investing resources in giving effect to competition policy unless and until required to do so. Instead, they may have chosen to focus attention on the public health safeguards and flexibilities under patent law, particularly given the requirement under TRIPS to provide a minimum level of patent protection.[45] It lies beyond the scope of this paper to consider why such an approach may prove to be an unfortunate and short-sighted way of advancing public health. This is done in some detail elsewhere.[46]

Instead, this paper has focused on the effective use of competition law and policy in South Africa, against the backdrop of the failure of that country to take advantage of the Doha Declaration in the four years since its adoption by the WTO.[47] In short, three separate but complementary approaches have been identified and implemented. First, competition law has been used to

great effect by civil society organizations to ensure access to a sustainable supply of certain ARV medicines at affordable prices. Second, a third party application for a compulsory licence sought to develop the jurisprudence in a manner more consistent with a constitutional guarantee of access to health care services, as well as to give added boost to a separate competition law matter regarding the same medicine. Third, activists have started to step up their demands on government to take the requisite executive action by issuing licences for the local production and/or importation of certain generic ARV medicines.[48] This is an integral part of their demands for the state to develop the comprehensive and coordinated legal framework discussed above.

References and endnotes

1. *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, 20 November 2001, at paragraphs 1 and 4.
2. There are five key provisions in TRIPS that directly or indirectly provide the framework within which competition policy can operate. These range from broad principles regarding the need to deal with the potentially negative consequences of IP protection and concerns relating to issues, such as public health and socio-economic development, to specific provisions dealing with competition policy. While differing in focus, each of the five provisions underscore the proposition that TRIPS provides significant scope within which competition policy may be employed to advance a public health agenda that may be compromised if IP protection is left unchecked. For more detail on these provisions, see Berger, above note 1 at 3.
3. While TRIPS is not alone in regulating the use of competition law and policy in this regard (see, for example, UNCTAD. 2000. *The United Nations Set of Principles and Rules on Competition: The Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices*, (Geneva: UNCTAD), originally adopted by the General Assembly at its 35th session in resolution 35/63 of 5 December 1980 and reaffirmed as valid by the Fourth Conference to Review All Aspects of the Set in resolution TD/RBP/CONF/10. Rev.2 of 4 October 2000), it is the only international law framework that legally binds all WTO members at the moment. Some limitations already exist (and others may very well arise at a later stage) in regional and/or bilateral trade agreements that seek to impose TRIPS-plus standards of IP protection (see, for example, Carlos Correa, Chapter 22: Formulating effective pro-development national intellectual property policies in Bellmann, Christophe et al. (eds.). 2003. *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (London and Sterling, VA, USA: Earth scan Publications Ltd, pp. 211–212; and ICTSD/UNCTAD.2003. *Policy Discussion Paper – Intellectual Property Rights: Implications for Development.* Geneva, Switzerland: ICTSD and UNCTAD. Available at: http://www.ictsd.org/iprsonline at 56.
4. See Berger, above footnote 1, at note 56.
5. It is generally understood that the simple exercise of exclusive rights in patents cannot in and of itself provide a basis for using competition policy to advance public health. In such circumstances, which Patent law ordinarily does not regard as abusive, states are nevertheless permitted by TRIPS to take a range of regulatory measures to increase access to essential medicines and other patented

technologies necessary for safeguarding public health. (See, in particular, Articles 7, 8, 27.2, 30 and 31 of the TRIPS Agreement, as well as the Doha Declaration.) But, as is discussed in greater detail elsewhere (see Berger, above note 1), there are various ways in which competition policy may appropriately be used to advance the public interest even where the conduct of the exclusive rights holder is not necessarily abusive nor have any direct anti-competitive effect. The various regulatory options available under competition policy can be divided into three broad but interrelated categories: remedies, preventative measures and measures that serve the public interest by promoting competition, whether directly or indirectly. Thus the simple existence of measures to remedy anticompetitive practices, for example, may act as a sufficient disincentive for exclusive rights holders to engage in abusive or otherwise problematic conduct. In such cases, there may be no need to deal proactively with the problematic conduct. This may be important for those countries without significant institutional capacity to regulate proactively. In contrast, those countries with capacity may rather choose to frame such measures in the language of prevention, such as by subjecting licensing agreements to prior approval processes of the sort ordinarily associated with merger regulation.

6. This is particularly important given that not all types of problematic conduct on the part of patentees or other exclusive rights holders in patents can or should be seen as anti-competitive. In addition, not all states are unwilling to act against exclusive rights holders. Where they are, patent law provisions may be easier and more powerful to use.
7. While a few provisions of the Competition Act came into force on 30 November 1998, the Act—as a whole—has been in force since 1 September 1999.
8. Section 39(2) of the Constitution provides—in relevant part—as follows: "When interpreting any legislation, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights." In Section 27, the Bill of Rights expressly recognises a right to have access to health care services. Section 27(2) mandates the state to take "reasonable legislative and other measures, within its available resources, to achieve the progressive realisation" of this right. In addition, the Competition Act itself states in Section 1(2) that it must be interpreted "in a manner that is consistent with the Constitution" and "in compliance with the international law obligations of the Republic [of South Africa]".
9. These bodies are the Competition Tribunal and the Competition Appeal Court, set up in terms of Sections 26 and 36 of the Competition Act respectively. While other bodies (the Supreme Court of Appeal and the Constitutional Court) also have jurisdiction to adjudicate on competition matters, the nature of their limited appellate jurisdiction means that these specialist bodies will develop the vast bulk of competition jurisprudence.
10. See, for example, the provisions in Section 10(4) dealing with exemptions from the application of the chapter on prohibited practices to any "agreement or practice, or category of agreements or practices that relates to the exercise of intellectual property rights".
11. See, for example, *National Association of Pharmaceutical Wholesalers and Others v Glaxo Wellcome (Pty) Ltd and Others* (Competition Appeal Court, case no: 29/CAC/JUL03, 18 February 2005, available at http://www.comptrib.co.za/CAC/Pharmaceutical%20vs%20Glaxo1.pdf) dealing with interim relief in a matter

considering vertical agreements between pharmaceutical manufacturers and exclusive distributors.

12. *Medicross Healthcare Group (Pty) Ltd and Prime Cure Holdings (Pty) Ltd* (Competition Tribunal, case no: 11/LM/Mar05, 13 October 2005. Berger, Jonathan. 2004. Advancing public health by other means: using competition policy to increase access to essential medicines. *Bellagio Series on Development and Intellectual Property Policy: Policy Options for Assuring Affordable Access to Essential Medicines, ICTSD,* 2004. [Online]. Available: http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004/bell3_documents.htm http://www.comptrib.co.za/decidedcases/doc/11LMMar05.doc) at paragraph 55.
13. Section 4.
14. Subsection (1)(b)(i).
15. Section 5.
16. Subsection (2).
17. Sections 8 and 9.
18. Section 27(1) of the Constitution.
19. Section 27(2) of the Constitution.
20. In addition to the Treatment Action Campaign (TAC), South Africa's largest and most effective organisation advocating for the rights of people living with HIV/AIDS (PLWHAs), the complaint was lodged by the AIDS Law Project on behalf of a number of PLWHAs who are open about their status, health care workers treating PLWHAs, the AIDS Consortium and a number of trade unions. In June 2003, before the matter was resolved, one of the complainants died of AIDS-related complications.
21. See the Statement of Complaint at paragraph 107. [Online]. Available: www.tac.org.za/Documents/DrugCompaniesCC/HazelTau AndOthersVGlaxoSmith KlineAndOthersStatementOf Complaint.doc
22. Where applicable, as is the case with the ARV medicine lamivudine, marketed by GSK in South Africa as 3TC® (and in many other places as Epivir®).
23. See Beresford, Belinda. 2003. *The Price of Life: Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim* [Online]. Available: http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=222 at 41.
24. In terms of Section 39(2) of the Constitution, "every court, tribunal or forum", when "interpreting any legislation … must promote the spirit, purport and objects of the Bill of Rights".
25. The *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* was adopted on 19 November 2003, some 20 days before the complainants entered into settlement agreements with both GSK and BI.
26. Beresford, above note 24 at page 5.
27. See, for example, "Media Release 30: Competition Commission finds pharmaceutical firms in contravention of the Competition Act", identifying three separate legal bases for referring the matter to the Competition Tribunal for adjudication. [Online]. Available: http://www.compcom.co.za/resources/media2003.asp?level=1&child=2).
28. See above note 24.

29. See, for example, TAC News Service, 'WE WILL SAVE LIVES AND END DRUG COMPANY PROFITEERING: TAC STATEMENT ON EXCESSIVE PRICING COMPLAINT TO COMPETITION COMMISSION' (19 September 2002). [Online]. Available: http://www.tac.org.za/Documents/DrugCompaniesCC/statement.txt. See also the TAC advertisement captioned "Support Legal Action against GlaxoSmithKline and Boehringer Ingelheim!" that appeared in the largest financial daily newspaper in South Africa (*Business Day*) in October/November 2002. A copy of the advertisement is available online at http://www.tac.org.za/Documents/Pamphlets/TACBUSDAYAD.jpeg.
30. A presentation as part of the main conference programme (entitled "Using the law to increase access to treatment: *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*") was used to raise awareness as well as to launch the publication "The Price of Life".
31. See TAC Electronic Newsletter (29 September 2003), "Generic Antiretroviral Procurement Project (GARPP) and TAC Treatment Project Request Permission to Import Generic Nevirapine". [Online]. Available: http://www.tac.org.za/newsletter/2003/ns28_09_2003.htm.
32. The agreement which sets out the terms and conditions of the settlement, is available online: http://www.tac.org.za/Documents/DrugCompaniesCC/GARPP-BI-Settlement-20031209.pdf.
33. The settlement agreements with the complainants are available online: http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=225.
34. At the time that the complaint was lodged, both GSK and BI had granted licences (on unacceptable terms and conditions) to South Africa's Aspen Pharmacare. In the case of GSK, for example, sales were permitted only to the South African public sector, subject to a 30% royalty rate. That licence was amended in accordance with the settlement agreement to extend sales to the private sector, also allowing for exports to all sub-Saharan African countries and a royalty rate of not more than 5%. By the end of 2004, GSK and BI had licensed five and three generic manufacturers respectively, although GSK's licensees included two companies that do not appear to be able to make use of the licences in the short- to medium-term. A third GSK licensee (one of BI's three licensees) – the joint venture of South Africa's Adcock Ingram and India's Ranbaxy Laboratories named Thembalami Pharmaceuticals – is no longer trading. Aspen and Cipla-Medpro, both licensed by GSK and BI, have placed their ARV products on the market, resulting in significantly lower prices and ensuring sustainability of supply. To date, it appears as if neither Adcock Ingram nor Ranbaxy has managed to secure licences from GSK and BI.
35. One generic company (Cipla-Medpro) had unsuccessfully attempted to use the Competition Act, arguing that because it was both willing and able to provide certain ARV medicines at significantly lower prices than the exclusive rights holder was doing, the latter was charging excessive prices to the detriment of consumers.
36. The letter of demand also hinted at other forms of legal action, which are not relevant to this discussion. The correspondence between the ALP and BMS is available online: http://www.tac.org.za.
37. BMS's initial substantive response (15 March 2005) raised concerns about the relevant market and whether BMS was dominant in that market, and that given the uncertainty regarding the medicine pricing regulations issued in terms of

the Medicines and Related Substances Act, 101 of 1965, it was "premature, if not inappropriate, to seek to resolve … [the] concerns under Section 8(a) of the Competition Act … rather than under the process set forth in the Pricing Regulation". The ALP responded that its clients were "not prepared to engage in a debate on the applicability of South African competition law or the medicine pricing regulations" as this was "better suited to an appropriate legal forum, if and when the matter proceeds to litigation". Instead, it expressly demanded that BMS "justify the price at which Fungizone is sold in South Africa".

38. Subsequent to the price reductions BMS failed to anticipate the extent of increased demand for the drug and it ran out of stocks earlier this year in South Africa. According to BMS the problem has since been resolved.
39. In publishing guidelines, the Commission would not be doing anything particularly groundbreaking. See, for example, US Department of Justice and Federal Trade Commission. 1994. *Antitrust Guidelines for Licensing of Intellectual Property* (6 April 1994). [Online]. Available: http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.
40. Section 58(1)(a)(i).
41. Section 58(1)(a)(ii).
42. Section 58(1)(a)(v).
43. Section 58(1)(a)(iii).
44. Article 31(k) exempts members from legislating certain conditions attached to the grant of compulsory licences, such as the restrictions on exports, where such licences are issued "to remedy a practice determined after judicial or administrative process to be anti-competitive".
45. Other than LDCs that have until 1 January 2016 to provide patent protection for pharmaceutical products, all developing countries were required as of 1 January 2005 to provide minimum levels of IP protection, including patent protection for all technologies.
46. See Berger, above note 1 at 15.
47. Furthermore, a powerful TRIPS-compliant government-use provision in Section 4 of the South African Patents Act that allows "a Minister of State … [to] use an invention for public purposes" remains unused, despite repeated calls by civil society groups for either the Minister of Health or her Trade and Industry counterpart to use it. To date, the South African Government has failed to issue—or even threaten to issue—compulsory licences for the importation or local production of affordable generic ARV medicines.
48. See TAC. 2005. *Electronic Newsletter,* 19 May 2005. [Online]. Available. http://www.tac.org.za/newsletter/2005/ns19 05 2005.htm, demanding that the Minister of Health issue licences for the local production and/or importation of generic efavirenz products.

paper 17

Is Bayh-Dole good for developing countries? Lessons from the US experience*

Anthony D. So et al.

Recently, countries from China and Brazil to Malaysia and South Africa have passed laws promoting the patenting of publicly funded research [1,2], and a similar proposal is under legislative consideration in India [3]. These initiatives are modeled in part on the United States Bayh-Dole Act of 1980 [4]. Bayh-Dole (BD) encouraged American universities to acquire patents on inventions resulting from government-funded research and to issue exclusive licenses to private firms [5,6], on the assumption that exclusive licensing creates incentives to commercialize these inventions. A broader hope of BD, and the initiatives emulating it, was that patenting and licensing of public sector research would spur science-based economic growth as well as national competitiveness [6,7]. And while it was not an explicit goal of BD, some of the emulation initiatives also aim to generate revenues for public sector research institutions [8].

We believe government-supported research should be managed in the public interest. We also believe that some of the claims favoring BD-type initiatives overstate the Act's contributions to growth in US innovation. Important concerns and safeguards—learned from nearly 30 years of experience in the US—have been largely overlooked. Furthermore, both patent law and science have changed considerably since BD was adopted in 1980 [9,10]. Other countries seeking to emulate that legislation need to consider this new context.

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Overstating claims

On a positive note, the BD Act required different agencies that funded US research and development to adopt more consistent policies about ownership of patents arising from federal funding [5]. One of BD's intended virtues involved transferring default patent ownership from government to parties with stronger incentives to license inventions. BD assigned ownership to institutions, such as universities, nonprofits, and small businesses, although it could just as easily have opted for individual grant and contract recipients.

Nevertheless, many advocates of adopting similar initiatives in other countries overstate the impact of BD in the US. Proponents note *The Economist's* 2002 claim that the Act was "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century" [11]. They also cite data (originally used by US proponents of the Act) on the low licensing rates for the 28 000 patents owned by the US Government before BD to imply that the pre-BD legal regime was not conducive to commercialization [12]. But as Eisenberg [5] has argued, that figure is misleading because the sample largely comprised patents (funded by the Department of Defense) to which firms had already declined the option of acquiring exclusive title. Moreover, these figures are of questionable relevance to debates about public sector research institutions, because most of the patents in question were based on government-funded research conducted by firms, not universities or government labs [13]. Finally, and most importantly, the narrow focus on licensing of patented inventions ignores the fact that most of the economic contributions of public sector research institutions have historically occurred without patents—through dissemination of knowledge, discoveries, and technologies by means of journal publications, presentations at conferences, and training of students [6,14,15].

Throughout the 20th century, American universities were the nation's most powerful vehicles for the diffusion of basic and applied research results [16], which were generally made available in the public domain, where industry and other public sector researchers could use them. These activities were central to the rise of American technological success broadly and to the growth of knowledge-based industries, such as biotechnology and information technology, in particular.

Public sector research institutions also relied on generous public funding for academic research—from a highly diverse group of federal funding agencies—which grew dramatically after the Second World War, and on the availability of venture capital to foster the development of early-stage ideas [6]. These and other unique features of the US research and development system explain much more about innovation in the US after BD than the rules about patenting that BD addressed.

In the pre-BD era, discoveries emanating from public research were often commercialized without patents, although academic institutions occasionally patented and licensed some of their publicly funded inventions well before BD, and these practices became increasingly common in the 1970s [17]. Since the passage of the Act in 1980, US academic patenting, licensing, and associated revenues have steadily increased. BD accelerated this growth by clarifying ownership rules, by making these activities bureaucratically easier to administer, and by changing norms toward patenting and licensing at universities [6]. As a result, researchers vested with key patents sometimes took advantage of exclusive licenses to start spin-off biotechnology companies. These trends, together with anecdotal accounts of "successful" commercialization, constitute the primary evidence used to support emulating BD in other countries. However, it is a mistake to interpret evidence that patents and licenses have increased as evidence that technology transfer or commercialization of university technology has increased because of BD.

Although universities can and do patent much more in the post-BD era than they did previously, neither overall trends in post-BD patenting and licensing nor individual case studies of commercialized technologies show that BD facilitated technology transfer and commercialization. Empirical research suggests that among the few academic patents and licenses that resulted in commercial products, a significant share (including some of the most prominent revenue generators) could have been effectively transferred by being placed in the public domain or licensed nonexclusively [6,18].

Another motivation for BD-type legislation is to generate licensing revenues for public sector research institutions. In the US, patents are indeed a source of revenues for some universities, but aggregate revenues are small. In 2006, US universities, hospitals, and research institutions derived US$ 1.85 billion from technology licensing compared to US$ 43.58 billion from federal, state, and industry funders that same year [19], which accounts for less than 5% of total academic research dollars. Moreover, revenues were highly concentrated at a few successful universities that patented "blockbuster" inventions [20].

A recent econometric analysis using data on academic licensing revenues from 1998 to 2002 suggests that, after subtracting the costs of patent management, net revenues earned by US universities from patent licensing were "on average, quite modest" nearly three decades after BD took effect. This study concludes that "universities should form a more realistic perspective of the possible economic returns from patenting and licensing activities" [21].

Similarly, the head of the technology licensing office at MIT (and former President of the Association of University Technology Managers) notes that

"the direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that royalties could compensate for declining federal support of research)… [M]ost university licensing offices barely break even" [22].

It is thus misleading to use data about the growth of academic patents, licenses, and licensing revenues as evidence that BD facilitated commercialization in the US. And it is little more than a leap of faith to conclude that similar legislation would automatically promote commercialization and technology transfer in other, very different, socioeconomic contexts.

Sources of concern

What have we learned from the US experience with BD? Because the Act gives recipients of government research funds almost complete discretion to choose what research to patent, universities can patent not only those inventions that firms would fail to commercialize or use without exclusive rights, but also upstream research tools and platforms that do not need patent protection and exclusive licensing to be adopted by industry [6,9,10].

For example, while the patented technologies underlying recombinant DNA were fundamentally important for biotechnology and generated ample revenues for Stanford, the University of California, Columbia University, and City of Hope Medical Center [6], the patenting and licensing of these research platforms and technologies were not necessary for commercialization. Both the Cohen-Boyer patents for recombinant DNA and the Axel patents on cotransformation were rapidly adopted by industry even though neither invention came with the BD "carrot" of an exclusive right. The Cohen-Boyer patents reportedly contributed to 2442 new products and US$ 35 billion in sales. Its licensing revenues to Stanford University and the University of California San Francisco were US$ 255 million [23]. With 34 firms licensing the technology, the Axel patents earned US$ 790 million in royalties for Columbia University over the patent period (Colaianni and Cook-Deegan, unpublished data). While the patenting and licensing of these inventions clearly enriched the universities involved, there is no reason to believe that nonexclusive licensing (as opposed to simple dedication to the public domain) deterred commercialization of the invention(s). In fact, Columbia University justified efforts to extend the life of its Axel patents not because such extension would improve commercialization, but rather because it protected royalty income that would be channeled back into its educational and research mission.

While BD gave those conducting publicly funded research the discretion to patent fundamental technologies, changes in US patent law since 1980 provided the means, by expanding eligibility standards to include

basic research and research tools. These trends have been notable in the biotechnology and information technology sectors [24,25]. A widely watched, recent consequence of this shift involves the suite of University of Wisconsin patents on embryonic stem cell lines [26–28]. Biotechnology firms eager to do research on stem cells have complained about the excessive licensing fees that Wisconsin charges (as well as about "reach through" provisions that call for royalties on any product developed from research on embryonic stem cells, and impose restrictions on use) [29]. Rather than promote commercialization, these patents on basic research platforms constitute a veritable tax on commercialization [30]. Nor were these efforts to tax future innovation unprecedented, as the example of recombinant DNA shows. The Wisconsin Alumni Research Foundation's extension of licensing terms to academic research institutions [31] and its imposition of restrictions on use became especially controversial because these measures went beyond the Cohen-Boyer precedent. The manager of recombinant DNA licensing at Stanford quipped, "[W]hether we licensed it or not, commercialization of recombinant DNA was going forward…a nonexclusive licensing program, at its heart, is really a tax…But it's always nice to say 'technology transfer'" [32].

The broad discretion given to publicly funded research institutions to patent upstream research raises concern about patent thickets, where numerous patents on a product lead to bargaining breakdowns and can blunt incentives for downstream research and development (R&D) [33,34]. Barriers to bundling intellectual property necessary for R&D become higher in frontier interdisciplinary research areas, such as synthetic biology, microarrays, and nanobiotechnology, because they draw upon multiple fields, some of which may be likelier than others to form thickets over time [9,10,32,35]. Although there is some evidence that biotechnology and pharmaceutical firms may be able to avoid thickets through secret infringement or by "off-shoring" research to countries with fewer patent restrictions [36], secret infringement and the transfer of R&D to other countries are hardly tactics that government policy should encourage.

The problems that BD has raised for the biopharmaceutical industry are dwarfed by the problems it has raised for information technology. Universities may too often take a "one size fits all" approach to patenting research results, notwithstanding the evidence that patents and exclusive licensing play a much more limited role in the development of information technology than they do in the pharmaceutical sector [37]. In testimony to the US Congress, a prominent information technology firm complained that aggressive university patenting impeded both product development and university–industry collaboration, which encouraged companies to find other university partners, often outside the United States [38]. Expressing similar

concerns in a proposal to explore alternatives to the BD model, officials from the Ewing Marion Kauffman Foundation (the leading US foundation supporting entrepreneurship research) recently argued that "Technology Transfer Offices (TTOs) were envisioned as gateways to facilitate the flow of innovation but have instead become gatekeepers that in many cases constrain the flow of inventions and frustrate faculty, entrepreneurs, and industry" [39].

These problems have not escaped the attention of funding agencies, most notably the US National Institutes of Health (NIH), which has issued guidelines stating that patents should be sought, and exclusive licenses should be restricted, only when they are necessary for purposes of commercialization [40,41]. Beyond such hortatory guidelines, however, US funding agencies retain very limited authority to guide the patenting and licensing practices of publicly funded research institutions. Under BD, agencies can declare particular areas off-limits to patenting only when they find "exceptional circumstances." Moreover, they must present this decision to the Department of Commerce, the primary administrator of BD. The "exceptional circumstances" authority has only rarely been used [30]. However, when exclusive licensing demonstrably impeded commercialization, the funding agencies did not intervene by exercising their authority to mandate additional licensing. Their reluctance to take such action stems in part from the realization that, under the BD regime as enacted, any mandate could immediately be challenged (and its effect stayed) pending the outcome of protracted litigation [30].

Some of the top US universities have themselves begun to recognize the difficulties that overly aggressive proprietary behavior can engender, as demonstrated by their March 2007 declaration highlighting "Nine Points to Consider in Licensing University Technology" [42]. How this declaration will affect university behavior is difficult to predict. Moreover, the "Nine Points" declaration focuses almost entirely on licensing and fails to address how universities should determine whether patents are necessary for commercialization in the first instance.

BD has also led to downstream concerns. The BD framework makes minimal reciprocal demands from licensees of government-funded technologies, and neither universities nor government agencies have sought to include requirements that products derived from these inventions be sold to consumers on reasonable terms [43]. Nor do funders require either disclosure of follow-on investments, so that prices might reflect the private contribution to development or the avoidance of abusive or anticompetitive marketing practices [43–47].

Some have raised concerns that the Act contributed to a change in academic norms regarding open, swift, and disinterested scientific exchange

[48,49]. For example, in a survey to which 210 life science companies responded, a third of the companies reported disputes with their academic collaborators over intellectual property, and 30% noted that conflicts of interest had emerged when university researchers became involved with another company [50]. Nearly 60% of agreements between academic institutions and life science companies required that university investigators keep information confidential for more than six months—considerably longer than the 30 to 60 days that NIH considered reasonable—for the purpose of filing a patent [50]. Similarly, in a survey of life science faculties at universities receiving the most NIH funding, nearly a third of the respondents receiving a research-related gift (e.g., biomaterials, discretionary funds, research equipment, trips to meetings, or support for students) reported that the corporate donor wanted prepublication review of any research articles generated from the gift; and 19% reported that the companies expected ownership of all patentable results from the funded research [51].

Although the surveys discussed above were conducted in the mid to early 1990s, their findings appear robust over time. In a more recent survey of university geneticists and life scientists, one in four reported the need to honor the requirements of an industrial sponsor as one of the reasons for denying requests for post-publication information, data, or materials [52]. This finding is also corroborated by a survey of US medical school faculty. In these settings, researchers most likely to report being denied research results or biomaterials by others were "those who have withheld research results from others" or who had patented or licensed their own inventions [53]. So the practices of patenting and licensing clearly encumber the openness of scientific exchange in universities.

Box 1: Safeguards serving the public interest

Governments adopting laws styled after the US BD Act should be vigilant to ensure that the public's interests are served. In commercializing publicly funded research, a number of safeguards on patenting and licensing practices should be built into any law or its regulatory implementation.

No exclusive licensing unless necessary for commercialization

Any BD-style legislation should be founded on the principle that publicly funded research should not be exclusively licensed unless it is clear that doing so is necessary to promote the commercialization of that research. Public sector institutions should not, for example, exclusively license research tools that were developed with public funding if those tools can instead be used off the shelf by others. Where exclusive licenses are not required for commercialization, one may ask whether universities and public sector labs should be patenting research at all. Will encouragement

of patenting and nonexclusive licensing, as in the Cohen-Boyer model discussed above, help or hurt researchers, firms, and the public in developing countries? Even nonexclusive licenses will tax downstream users, although presumably with lower rents and transaction costs and more procompetitive effects. As suggested above, revenues from licensing academic inventions are likely to be minuscule for most institutions, and aggressive university patenting can have other deleterious effects. A robust research exemption can ward off some of the problems potentially associated with restrictive licensing of upstream inventions [62].

Transparency

The legislation should ensure transparency in the patenting and licensing of publicly funded research. Public accountability should follow public funding. Institutions that engage in patenting and licensing should be required to report or make public all information that is necessary to determine whether they are reasonably serving the public interest. Such information may include the number of patents and licenses obtained, the funds expended on patenting and licensing activities, licensing revenues, and the key terms (e.g., exclusive or nonexclusive, humanitarian access, research exemption, definition of market segmentation or field of use, performance milestones, and march-in rights) of licenses. The lack of a transparency mandate is a key flaw of the BD Act that should not be replicated.

Government authority to issue additional licenses

Where licensing arrangements for publicly funded research do not achieve public interest objectives, governmental authorities must have power to override such licenses and to grant licenses to additional or alternative parties [9,10,43]. In the US, this authority is formally embodied in the government's "march-in" rights under BD, but this power has never been exercised. Petitions to invoke it have been made a few times [46,47,63,64], but they have never been granted, and because of the administrative disincentives built into BD, this power is unlikely ever to be used [30]. To avoid this result, legislatures must develop standards to ensure that march-in rights or comparable authority will be exercised when public interest objectives are not otherwise attained.

In evaluating licensing options, those receiving government research funding could also be required to consider the option of licensing patented inventions to a "technology trust," that is, a commons that would ensure designated inventions remained available to all interested parties on predetermined terms. Such a commons could enable the pooling of socially useful bundles of technology, particularly research tools and health technologies for neglected or rare diseases. Governments might also consider reducing or waiving patent application and maintenance fees for such inventions when they are made broadly available for research

and humanitarian application, without royalty, for a specific geographical area or field of use.

Government use rights

The government should retain an automatic right to use any invention arising from its funding. Under BD, the US Government has an automatic "nonexclusive, nontransferable, irrevocable, paid-up license" [65] to use any invention developed with government funds. Typically, however, it does not invoke such a license and often pays monopoly prices for products that it funded. The US experience shows the importance both of establishing that the government should be provided with an automatic license in products resulting from its funding and of elaborating standards to ensure such licenses are actually exercised in appropriate circumstances.

From a broader perspective, governments retain the right to use any invention, whether or not it arises from public funding, under international law [66]. Governments may choose to use patented inventions to promote public health [67], national security [66], or comparable objectives, while public-interest compulsory licenses may sometimes be granted to avoid abusive licensing practices or to ensure access to patented research products on reasonable terms and conditions [43,66]. Where publicly funded grantees fail to commercialize a technology appropriately or to foster its availability, the trigger for government use—under any enabling provision adopted in domestic law—must work better than the march-in right has under BD.

Access to end products

Besides promoting commercialization, the government must ensure consumer access to end products. The public is entitled to expect that the inventions it paid for will be priced fairly. The US experience shows that a BD system that lacks mandatory rules concerning the affordability of end products will not deliver on this reasonable expectation [43–47]. As a condition of receiving a license to a government-funded invention, parties should be required to ensure that end products are made available to the public on reasonable terms and conditions. What constitutes "reasonable" will vary by national context, but it is important to ensure that the term is defined with enough precision to be enforceable.

Licenses to government-funded inventions should presumptively include access-oriented licensing provisions that address humanitarian needs in other countries [68]. One such provision is an open license for production and sale of end products in (or to) developing countries in exchange for a fair royalty [69]. At the very least, when inventions have foreseeable applications in resource-poor regions, a plan for access in those regions should be explicitly incorporated into technology licensing.

Instituting safeguards

Countries seeking to enhance the contributions of universities and public sector laboratories to social and economic development have numerous policy options. Many of these policies do not involve intellectual property rights at all, but rather look to provide funds for basic and applied research, subsidize scientific and engineering education, strengthen firms' ability to assimilate university research, and invest in extension, experimentation, and diffusion activities [39,54,55]. But even policies focused on intellectual property management need not presume that patenting and exclusive licensing are the best options. For example, they may instead focus on placing by default or by strategy government-funded inventions into the public domain, creating a scientific commons, enabling collective management of intellectual property, or fostering open-source innovation [56–60]. Where greater commercial incentives seem necessary, the benefits of nonexclusive licensing should always be weighed against the social cost of exclusive licenses.

The appropriate array of policies will vary from country to country: there is no "one size fits all" solution. Based on our review above, we believe it is doubtful that the benefits of legislation closely modeled on BD would outweigh their costs in developing counties. For those countries that nonetheless decide to implement similar laws, the US experience suggests the crucial importance, at a minimum, of considering a variety of safeguards (see Box 1).

Conclusion

While policies supporting technological innovation and diffusion contribute to economic growth and development, the appropriate sets of policies to harness public sector R&D are highly context-specific. Much depends on factors such as the level of publicly funded research, the focus of such research on basic versus applied science, the capabilities of industry partners, and the nature of university–industry linkages [54,55].

Recognizing these difficulties, reasonable minds may disagree about the likely impact of BD-type legislation elsewhere. Nevertheless, the present impetus for BD-type legislation in developing countries is fueled by overstated and misleading claims about the economic impact of the Act in the US, which may lead developing countries to expect far more than they are likely to receive. Moreover, political capital expended on rules of patent ownership may detract from more important policies to support science and technology, especially the need for public funding of research. Given the low level of public funding for research in many developing countries, for example, the focus on royalty returns at the expense of public goods may be misplaced [61]. Furthermore, it is unclear whether any of the positive impacts of BD

in the US would arise in developing countries following similar legislation, absent the multiagency federal pluralism, the practically oriented universities, and other features of the US research system discussed above.

In any event, both the patent laws and patterns of scientific collaboration have changed substantially since BD was passed in 1980. To the extent that legislation governing the patenting and licensing of public sector research is needed in developing countries at all, it should reflect this new context rather than blindly importing a US model that is 30 years old.

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References

1. Graff GD (2007) Echoes of Bayh-Dole? A survey of IP and technology transfer policies in emerging and developing economies. In: Krattiger A, Mahoney RT, Nelsen L, Thompson JA, Bennett AB, et al., editors. Intellectual property management in health and agricultural innovation: A handbook of best practices. Oxford (UK): MIHR, and Davis(CA): PIPRA. pp. 169-195.
2. Republic of South Africa (2008) Intellectual Property Rights from Publicly Financed Research and Development Bill [B46B-2008]. Available: http://www.pmg.org.za/bill/20080815-intellectual-property-rightspublicly-financed-research-and-developmen-0. Accessed 16 September 2008.
3. Jishnu L (2008) Does India need a Bayh-Dole Act? Patently absurd. Business Standard. Available: http://www.business-standard.com/india/storypage.php?autono=328187. Accessed 16 September 2008.
4. United States Code (1980) The Patent and Trademark Act of 1980. Public Law 96-517. §6(a), 94 Stat. 3015, 3019-3028.
5. Eisenberg RS (1996) Public research and private development: Patents and technology transfer in government-sponsored research. Va Law Rev 82: 1663-1727.
6. Mowery DC, Nelson RR, Sampat BN, Ziedonis AA (2004) Ivory tower and industrial innovation: University-industry technologytransfer before and after Bayh-Dole. Stanford (CA): Stanford University Press. 241 p.
7. Mowery DC, Sampat BN (2005) The Bayh-Dole Act of 1980 and university-industry technology transfer: A model for other OECD governments? J Technol Transf 30: 115-127.
8. Pathak K (2008) Varsities may soon own patent rights. Business Standard. Available: http://www.business-standard.com/india/storypage.php?autono=317122. Accessed 16 September 2008.

9. Reichman JH, Giordano Coltart J (2008) A holistic approach to patents affecting frontier science: Lessons from the seminal genomic technology studies. Paper presented to the European Patent Forum 2008; 6-7 May 2008; Ljubljana, Slovenia.
10. Mackey TM (2008) Nanobiotechnology, synthetic biology, and RNAi: Patent portfolios for maximal near-term commercialization and commons for maximal long-term medical gain. Marquette Intellect Prop Law Rev: In press.
11. [No authors listed] (2002) Innovation's golden goose. The Economist 365: 3.
12. Pitroda S (2007) Letter to Indian Prime Minister from The National Knowledge Commission. Available: http://knowledgecommission.gov.in/downloads/recommendations/LegislationPM.pdf. Accessed 16 September 2008.
13. Sampat BN (2006) Patenting and US academic research in the 20th century: The world before and after Bayh-Dole. Res Pol 35: 772-789.
14. Cohen WM, Nelson RR, Walsh JP (2002) Links and impacts: The influence of public research on industrial R&D. Manage Sci 48: 1-23.
15. Agrawal A, Henderson R (2002) Putting patents in context: Exploring knowledge transfer from MIT. Manage Sci 48: 44-60.
16. Nelson RR (2004) The market economy, and the scientific commons. Res Pol 33: 455-471.
17. Mowery DC, Sampat BN (2001) University patents and patent policy debates in the USA, 1925-1980. Ind Corp Change 10: 781-814.
18. Colyvas J, Crow M, Gelijns A, Mazzoleni R, Nelson RR, et al (2002) How do university inventions get into practice? Manage Sci 48: 61-72.
19. Association of University Technology Managers (2007) AUTM U.S. licensing activity survey: FY2006 survey summary, Data Appendix. Available: http://www.autm.net/events/file/AUTM_06_US%20LSS_FNL.pdf. Accessed 16 September 2008.
20. Mowery DC, Nelson RR, Sampat BN, Ziedonis AA (2001) The growth of patenting and licensing by U.S. universities: An assessment of the effects of the Bayh-Dole Act of 1980. Res Pol 30: 99-119.
21. Bulut H, Moschini G (2006) U.S. universities' net returns from patenting and licensing: A quantile regression analysis. Center for Agricultural and Rural Development at Iowa State University Working Paper 06-WP 432. Available: http://www.card.iastate.edu/publications/DBS/PDFFiles/06wp432.pdf. Accessed 16 September 2008.
22. Nelsen L (1998) The rise of intellectual property protection in the American university. Science 279: 1460-1461.
23. Feldman MP, Colaianni A, Liu CK (2007) Lessons from the commercialization of the Cohen-Boyer patents: The Stanford University licensing program. In: Krattiger A, Mahoney RT, Nelsen L, Thompson JA, Bennett AB, et al., editors. Intellectual property management in health and agricultural innovation: A handbook of best practices. Oxford (UK): MIHR, and Davis(CA): PIPRA. pp. 1797-1807.
24. United States Supreme Court (1972) Gottschalk v. Benson. 409 U.S. 63, No. 71-485. Available: http://www.altlaw.org/v1/cases/398051. Accessed 16 September 2008.
25. Reichman JH, Cooper Dreyfuss R (2007) Harmonization without consensus: Critical reflections on drafting a substantive patent law treaty. Duke Law J 57: 85-130.

26. Thomson JA, inventor; Wisconsin Alumni Research Foundation, assignee (1998) Primate embryonic stem cells. US Patent 5,843,780. Available: http://www.patentstorm.us/patents/5843780.html. Accessed 16 September 2008.
27. Thomson JA, inventor; Wisconsin Alumni Research Foundation, assignee (2001) Primate embryonic stem cells. US Patent 6,200,806. Available: http://www.patentstorm.us/patents/6200806.html. Accessed 16 September 2008.
28. Thomson JA, inventor; Wisconsin Alumni Research Foundation, assignee (2006) Primate embryonic stem cells. US Patent 7,029,913. Available: http://www.patentstorm.us/patents/7029913.html. Accessed 16 September 2008.
29. Holden C (2007) U.S. Patent office casts doubt on Wisconsin stem cell patents. Science 316: 812.
30. Rai AK, Eisenberg RS (2003) Bayh-Dole reform and the progress of biomedicine. Law Contemp Probl 66: 289-314.
31. Abrams I (2006) Human embryonic stem cells: A review of the intellectual property landscape. J Assoc Univ Technol Manag 8: 1-14.
32. Reimers N (1998) Stanford's Office of Technology Licensing and the Cohen/Boyer cloning patents: An oral history conducted in 1997 by Sally Smith Hughes, Ph.D. Regional Oral History Office, The Bancroft Library, University of California, Berkeley. Available: http://tinyurl.com/53olgt. Accessed 16 September 2008.
33. Heller MA, Eisenberg RS (1998) Can patents deter innovation? The anticommons in biomedical research. Science 280: 698-701.
34. Lemley MA (2008) Are universities patent trolls? Fordham Intellect Prop Media Entertain Law J 18: 611-631.
35. Kumar S, Rai A (2007) Synthetic biology: The intellectual property puzzle. Tex Law Rev 85: 1745-1768.
36. Walsh JP, Arora A, Cohen WM (2003) Working through the patent problem. Science 299: 1021.
37. Rai AK (2007) The role of federally-funded university research in the patent system. Hearing before the United States Senate Committee on the Judiciary, 110th Congress. Available: http://www.law.duke.edu/news/pdf/rai_testimony.pdf. Accessed 16 September 2008.
38. Johnson W (2007) Bayh-Dole: The next 25 years. Hearing before the Subcommittee on Technology and Innovation of the United States House of Representatives Committee on Science & Technology. Available: http://science.house.gov/publications/Testimony.aspx?TID=7129. Accessed 16 September 2008.
39. Litan RE, Mitchell L, Reedy EJ (2007) Commercializing university innovations: A better way. National Bureau of Economic Research working paper. Available: http://www.brookings.edu/papers/2007/05_innovations_litan.aspx?rssid=education. Accessed 16 September 2008.
40. Department of Health and Human Services, National Institutes of Health (1999) Principles and guidelines for recipients of NIH research grants and contracts on obtaining and disseminating biomedical research resources: Final notice. Fed Regist 64: 72090-72096. Available: http://ott.od.nih.gov/policy/rt_guide_final.html. Accessed 16 September 2008.

41. Department of Health and Human Services, National Institutes of Health (2005) Best practices for the licensing of genomic inventions: Final notice. Fed Regist 70: 18413-18415. Available: http://ott.od.nih.gov/policy/genomic_invention.html. Accessed 16 September 2008.
42. Stanford News Service (2007) In public interest: Nine points to consider in licensing university technology. Available: http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf. Accessed 16 September 2008.
43. Reichman JH (2004) Testimony before the NIH Public Hearing on March-In Rights under the Bayh-Dole Act, National Institutes of Health. Available: http://www.ott.nih.gov/policy/meeting/Jerome-Reichman-Duke-Univ.pdf. Accessed 16 September 2008.
44. US Office of Technology Assessment (1992) Federal and private roles in the development and provision of alglucerase therapy for Gaucher disease. Publication OTA-.BP-H-104. Available: http://www.princeton.edu/~ota/disk1/1992/9214/9214.PDF. Accessed 16 September 2008.
45. United States General Accounting Office (2003) Technology transfer: NIH-Private sector partnership in the development of Taxol. Report to the Honorable Ron Wyden, GAO-03-829. Available: http://www.gao.gov/new.items/d03829.pdf. Accessed 16 September 2008.
46. Love J, Flynn S (2004) Petition to use authority under Bah-Dole Act to promote access to Latanoprost. Letter to Thomas Thompson, Secretary of United States Department of Health and Human Services. Available: http://www.essentialinventions.org/legal/xalatan/xalatan-29jan04petition.pdf. Accessed 16 September 2008.
47. Love J, Flynn S (2004) Petition to use authority under Bah-Dole Act to promote access to Norvir. Letter to Thomas Thompson, Secretary of United States Department of Health and Human Services. Available: http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf. Accessed 16 September 2008.
48. Washburn J (2005) University Inc.: The corporate corruption of higher education. New York: Basic Books. 352 p.
49. Greenberg DS (2007) Science for sale: The perils, rewards, and delusions of campus capitalism. Chicago: University of Chicago Press. 288 p.
50. Blumenthal D, Causino N, Campbell E, Louis KS (1996) Relationships between academic institutions and industry in the life sciences: An industry survey. New Engl J Med 334: 368-374.
51. Campbell EG, Louis KS, Blumenthal D (1998) Looking a gift horse in the mouth: Corporate gifts supporting life sciences research. JAMA 279: 995-999.
52. Campbell EG, Clarridge BR, Gokhale M, Birenbaum L, Hilgartner S, et al. (2002) Data withholding in academic genetics: Evidence from a national survey. JAMA 287: 473-480.
53. Campbell EG, Weissman JS, Causino N, Blumenthal D (2000) Data withholding in academic medicine: Characteristics of faculty denied access to research results and biomaterials. Res Pol 29: 303-312.
54. Mazzoleni R, Nelson RR (2007) Public research institutions and economic catch-up. Res Pol 36: 1512-1528.

55. Mowery DC, Sampat BN (2005) Universities in national innovation systems. In: Fagerberg J, Mowery DC, Nelson RR, editors. The Oxford handbook on innovation. New York: Oxford University Press. pp. 209-239.
56. Marshall E (2001) Bermuda Rules: Community spirit, with teeth. Science 291: 1192.
57. International AIDS Vaccine Initiative (2007) An interview with Dennis Burton. IAVI Report 11. Available: http://www.iavireport.org/Issues/Issue11-1/Burton.asp. Accessed 16 September 2008.
58. Atkinson RC, Beachy RN, Conway G, Cordova FA, Fox MA, et al. (2003) Public sector collaboration for agriculture IP management. Science 301: 174-175.
59. von Hippel E, von Krogh G, editors (2003) Open source software development. Res Pol 32: 1149-1291. doi:10.1016/S0048-7333(03)00054-4
60. Reichman J, Uhlir P (2003) A contractually reconstructed research commons for scientific data in a highly protectionist intellectual property environment. Law Contemp Probl 66: 315-462.
61. Maskus KE, Reichman JH (2003) The globalization of private knowledge goods and the privatization of global public goods. In: Maskus KE, Reichman JH, editors. International public goods and transfer of technology under a globalized intellectual property regime. Cambridge: Cambridge University Press. pp. 3-45.
62. Dreyfuss R (2004) Protecting the public domain of science: Has the time for experimental use defense arrived? Arizona Law Rev 458: 457-472.
63. Bar-Shalom A, Cook-Deegan R (2002) Patents and innovation in cancer therapeutics: Lessons from CellPro. Milbank Q 80: 637-76.
64. McGarey BM, Levey AC (1999) Patents, products, and public health analysis of the CellPro march-in petition. Berkeley Technol Law J 14: 1095-1116.
65. United States Patent and Trademark Office (1980) March-in rights. US Code title 35, part II, chapter 18, §203. Available: http://uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_203.htm#usu35s20.3. Accessed 16 September 2008.
66. Reichman JH, Hasenzahl C (2002) Nonvoluntary licensing of patented inventions: Historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA. UNCTAD-ICTSD Project on IPRs and Sustainable Development Series. Available: http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf. Accessed 25 September 2008.
67. Abbott FM, Reichman JH (2007) The Doha Round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. J Int Econ Law 10: 921-987.
68. Outterson K (2006) Patent buy-outs for global disease innovations for low-and middle-income countries. Am J Law Med 32: 159-161.
69. Kapczynski A, Chaifetz S, Katz Z, Benkler Y (2005) Addressing global health inequities: An open licensing approach for university innovations. Berkeley Technol Law J 20: 1031.

This volume contains a selection of papers used in the course "Towards an Intellectual Property Regime that Protects Public Health". They explore the principal issues in intellectual property as it relates to public health. They are comprehensive, though not exhaustive, as the field is a constantly evolving one.

This publication is intended to facilitate the conducting of further courses on the implications of intellectual property rights on access to medicines. However, it can also be used as a reference for readers who, having already acquired an understanding of the basic concepts in this field, would like to gain a deeper understanding of the issues.

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