

Intellectual Property and Sustainable Development Series



The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries



Enforcing Intellectual Property Rights: an Economic Perspective

By Carsten Fink,
Group d'Economie Mondiale, Sciences Po Paris

The Push for Stronger Enforcement Rules: Implications for Developing Countries

By Carlos M. Correa,
Centre for Interdisciplinary Studies on Industrial Property and Economics, University of Buenos Aires



International Centre for Trade
and Sustainable Development

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LIST OF ACRONYMS AND ABBREVIATIONS

ACE	WIPO Advisory Committee on the Enforcement of Intellectual Property Rights
ACP	African, Caribbean, and Pacific states
ACTA	Anti-Counterfeiting Trade Agreement
API	Active Pharmaceutical Ingredient
BASCAP	Business Coalition to Stop Counterfeiting and Piracy
BSA	Business Software Alliance
CBP	US Customs and Border Protection
CNCP	National Anti-Piracy Council
DA	WIPO Development Agenda
EPAs	Economic Partnership Agreements
EU	European Union
FAO	Food and Agricultural Organization
FDI	Foreign Direct Investment
FTAs	Free Trade Agreements
FTC	Federal Trade Commission
G8	Group of Eight
GAO	US General Accounting Office
GATT	General Agreement on Tariffs and Trade
GIs	Geographical Indications
GSP	Generalized System of Preferences
HCV	Hepatitis C Virus
ICC	International Chamber of Commerce
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
INCB	International Narcotics Control Board
INTA	International Trademark Association
INTERPOL	International Criminal Police Organization
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITA	US Department of Commerce's International Trade Administration
LR/ACT	Lyon-Roma Anti-Crime and Terrorism Group
NIPLECC	National Intellectual Property Law Enforcement Coordination Council
NGO	Non Governmental Organization
OECD	Organization for Economic Co-operation and Development
OIPR	Office of Intellectual Property Rights
PRSP	Poverty Reduction Strategy Papers
SECURE	Provisional Standards Employed by Customs for Uniform Rights Enforcement
SMEs	Small and Medium Enterprises
STOP!	Strategy Targeting Organized Piracy
TRIPS	Agreement on Trade Related Aspects of Intellectual Property
UNCTAD	United Nations Conference on Trade and Development
US	United States
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative

WCO	World Customs Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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FOREWORD

Enforcement has once more emerged as a pressing issue on the global trade and intellectual property (IP) agenda. Although the achievement of a more effective enforcement of intellectual property rights (IPRs) was already one of the main driving forces behind the conclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), it increasingly appears that TRIPS - while being an important milestone - did not, for some, represent a conclusive and satisfactory response to what is perceived as a significant rise in levels of counterfeiting and piracy. In this context, recent years have witnessed an unprecedented proliferation of initiatives relating to IPRs enforcement. These range from enforcement provisions in regional and bilateral free trade agreements (FTAs), to deliberations in plurilateral fora such as the G8, to multilateral fora such as the TRIPS Council of the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the World Customs Organization (WCO), the World Health Organization (WHO), to litigation under the WTO dispute settlement system, and finally, to ongoing negotiations of new international agreements such as the Anti-Counterfeiting Trade Agreement (ACTA).

The global IP landscape, in which the push for stronger enforcement standards is taking place, differs significantly from the one in which the TRIPS Agreement was concluded in 1994. Today, our understanding of IP norms and their impact on development policy has significantly improved. The limits of a «one-size-fits-all» approach to international IP norm setting are increasingly recognized. Open collaboration and alternative innovation models are acquiring greater importance in generating wealth.

In addition, developing countries and civil society have become more active in international processes and discussions dealing with IP matters. The WIPO Development Agenda (DA) has crystallized many of these changes. In this regard, the 45 WIPO DA recommendations adopted in September 2007 represent a landmark development in efforts to achieve a more balanced and development oriented IP system. The last of these recommendations deals precisely with IPRs enforcement as it underlines the need to "approach intellectual property enforcement in the context of broader societal interests and especially development oriented concerns" in accordance with Article 7 of the TRIPS Agreement.

Significantly, there is an increasing realization that tinkering with rules on IPRs enforcement can have profound effects on the regulation of knowledge goods and flows in our knowledge-based economies. Issues of competitiveness, innovation, access to knowledge, technological development, and thus ultimately, *sustainable development*, are at stake.

Against this background, it is relatively easy to understand why the current global debate on IPRs enforcement is marred with controversy and the subject of polarized perspectives. This polarization is amplified by the limited number of in-depth analytical studies and evidence-based empirical analysis that could contribute to foster a more informed and constructive discussion.

To contribute toward addressing this gap, ICTSD's Programme on Intellectual Property Rights and Sustainable Development commissioned two studies that have been brought together in this issue paper on *The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries*. As both studies put it upfront, the debate is not - and should not be - about whether IPRs should be enforced or not. Enforcement is an integral part of any effective IP regime. However, IPRs are private rights and upholding them is, first and foremost, the responsibility of private rights holders. Given that governments play an important role in ensuring the enforcement of these private rights, the debate is rather about how to achieve an appropriate balance between private rights and

public interest in setting and implementing IPRs enforcement standards and in allocating resources for IPRs enforcement in the face of other competing, and more immediate, public policy priorities, particularly in developing countries.

In this regard, the first study by Carsten Fink, (Group d'Economie Mondiale, Sciences Po Paris), seeks to provide a much needed economic perspective on IPRs enforcement. The study evaluates the welfare effects of different forms of IPRs infringements and reviews available empirical evidence on the economic impact of piracy and counterfeiting. Its findings suggest that governments should particularly focus their enforcement efforts on cases of deceptive trademark infringements, especially those that create health and safety risks.

The study seeks also to identify a number of key considerations in the formulation of a strategy towards IPRs enforcement, particularly in developing countries, where many public goods are underprovided, enforcement challenges exist in many areas of law and governments typically face other priorities for public spending.

In this regard, the author estimates that while appropriate funding of competent government agencies in developing countries is necessary, it is not sufficient prerequisite for effective IPRs enforcement. Only as countries reach a certain threshold level of income and domestic IPRs ownership becomes more widespread, will the domestic incentive for stepping-up the fight against counterfeiting and piracy grow.

He underlines, that while implementing 'TRIPS-plus' enforcement obligations often contained in FTAs will likely require additional resources, there is little evidence available that could guide policymakers on the precise resource implications of implementing such obligations. The study highlights this gap and points to the importance future of better quantifying the budgetary costs of different types of enforcement activities in the future.

The author also raises the question of whether stepped-up IPRs enforcement in less developed countries should not be financed by developed country governments. He argues that since developed country firms derive a direct benefit from stronger IPRs enforcement, it may indeed be

in the interest of their governments to subsidize IP enforcement activities in developing countries. Another approach, he suggests would be to have enforcement costs borne directly by private rights holders as they are the most direct beneficiary of better enforcement and they can therefore be expected to make a substantial contribution to the financing of underlying costs

Finally, the study indicates that if weak IPRs enforcement in developing countries reflects fundamental institutional deficiencies, it is not clear how far obligations in trade agreements or technical assistance activities can at all remedy such deficiencies. He argues that in many cases sustained reductions in IPRs violations may invariably have to wait for broader institutional development.

In the second study in this issue paper, Professor Carlos M. Correa (University of Buenos Aires) examines the recent drive for TRIPS-plus enforcement standards, which go beyond the requirements of the TRIPS Agreement and risk undermining the balanced contained therein. The study cautions against an expansive use of the terms 'counterfeiting' and 'piracy' as these terms are confined by the TRIPS Agreement to very specific infringing acts (i.e. "counterfeit trademark good" and "pirated copyright goods"). The author further indicates, for instance, that while article 61 of the TRIPS Agreement requires criminal sanctions only in cases of willful trademark counterfeiting or copyright piracy on a

commercial scale, the TRIPS-plus agenda aims at criminalizing other infringing acts, including patent infringement. However, in the United States and other developed countries, patent infringement is only dealt with under civil remedies.

Similarly, the study points to efforts the Agreement to strengthen provisional measures, as well as border measures, beyond what is required by the TRIPS Agreements and even by the national jurisprudences of many developed countries. Another recurrent issue is the demand that developing countries establish special units/task forces in national administrations or special judicial courts to deal with IPRs infringements.

Finally, the study addresses a major issue in the enforcement debate, notably the fight against counterfeit medicines. The author contends that arguments and proposals made in relation to this subject often confuse IP and public health considerations. Indeed, he argues, the application of an IP approach to what is essentially a public health issue may lead to the adoption of an inadequate set of measures. The study emphasizes the appropriate design and implementation of drug regulations as the most critical element in combating counterfeiting in medicines.

Together, we hope that these two studies bring greater clarity and intelligibility to the discussions on IPRs enforcement by improving the understanding of the issues at hand and their implications.

Beyond these studies, it is important to recognize that IPRs enforcement cannot be approached as a stand alone issue. The global debate about IPRs enforcement should be part of wider discussions about the balance on which the current IP architecture stands and the challenges it faces in ensuring that the benefits of IP regimes outweigh their costs, particularly for developing countries, which have undertaken significant efforts in past years to modernize and overhaul their IP systems.

Addressing these wider questions has been a central objective of ICTSD's Programme on Intellectual Property Rights and Sustainable Development since its launch in July 2000. It has sought to achieve a better understanding of IP in the context of sustainable development with a view to ensure proper balance between the different interests at stake in designing appropriate IP regimes compliant with international commitments. Another central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries - including decision makers and negotiators, but also actors in the private sector and civil society - able to define their own sustainable human development objectives in the field of IP and effectively advance them at the national and international levels.

The premise of ICTSD's work is based on the understanding that IPRs have never been more economically and politically important - or controversial - than they are today. Patents, copyrights, trademarks, and geographical indications are frequently mentioned in discussions on such diverse topics as public health, climate change, food security, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet, and creative industries. In a knowledge-based economy, a better understanding of IP is indispensable to informed policy making in all areas of development.

Empirical evidence on the role of intellectual property protection in promoting innovation and growth remains inconclusive. Diverging views also persist on the impacts of intellectual property rights on development prospects. It continues to be urgent, therefore, to ask how developing countries can use IP tools to advance their development strategy. How is IP directly relevant to sustainable development and to the achievement of agreed international development goals? How we can facilitate technological flows among all countries? Do they have the capacity, especially the least developed among them, to formulate their negotiating positions and become well informed negotiating partners? How can

we foster an enabling international environment that would be conducive to greater respect for IPRs in a sustainable and balanced manner? These are essential questions that policymakers need to address in order to design IP laws and policies that best meet the needs of their societies and that enable effective negotiations in future agreements. These are also questions that should be taken into consideration in the current discussions on IPRs enforcement.

In this context, we hope that you will find this issue paper a useful contribution to discussions on IP and sustainable development and a valuable response to the need for a better understanding of the global IPRs enforcement debate and its implications for developing countries.

A handwritten signature in black ink, appearing to read 'R-M-O', with a horizontal line underneath.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

PART 1

Enforcing Intellectual Property Rights: an Economic Perspective

Carsten Fink, Group d'Economie Mondiale, Sciences Po Paris

EXECUTIVE SUMMARY

The enforcement of intellectual property rights (IPRs) is receiving increasing attention as counterfeiting and piracy are perceived to have reached unprecedented levels. Initiatives pushing for stronger IPRs enforcement have proliferated in recent years. Examples include G8 calls for stepped-up enforcement of IPRs, the initiation of a WTO dispute on China's IPRs enforcement regime, and the launch of inter-governmental negotiations towards an Anti-Counterfeiting Trade Agreement (ACTA). In addition, intellectual property (IP) chapters of free trade agreements (FTAs) negotiated over the past few years have introduced obligations on IPRs enforcement that go beyond multilateral standards inscribed in the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

In this context, an economic perspective on policies towards IPRs enforcement is much needed. Drawing on key insights from the economic literature, it should contribute towards identifying priorities for the allocation of scarce law enforcement resources.

It is important to note that there is little empirical evidence that would shed light on the economic impact of piracy and counterfeiting as the production and sale of counterfeit and pirated goods largely escapes official statistical recording systems. The OECD (2007) estimated the value of international trade in IPRs-infringing goods at 200 USD billion, or slightly more than 2 per cent of global merchandise trade in 2005. Nevertheless, close inspection of the methodology applied to arrive at this figure reveals that it is more an "educated guess" than a true estimate. Industry associations also regularly publish estimates of lost revenues due to piracy. However, such estimates often rely on questionable assumptions about market demand.

Economic analysis shows that the welfare effects of different types of IP infringement impact differently on consumers, producers, and the economy at large. Welfare considerations suggest that governments should focus their enforcement efforts on cases of deceptive trademark infringements, especially those that create health and safety risks. In addition, a case can be made for pursuing producers rather than small-scale distributors of illicit goods, especially where the former are linked to organized crime syndicates. Governments are well-advised to take these differences into account when developing an IPRs enforcement strategy.

Although IPRs are private rights, governments play an important role in enforcing these private rights, and exert considerable control over the level of IPRs enforcement in their jurisdictions. In developing an IPRs enforcement strategy, governments need to make choices about how many resources to spend on combating piracy, as opposed to enforcing other areas of law, building roads and bridges and providing other public goods.

In this regard, deciding on appropriate allocation of resources for IPRs enforcement is especially difficult in developing countries, where many public goods are underprovided and enforcement challenges exist in many areas of law.

In addition, most IPRs holders in developing countries tend to be of foreign origin, suggesting that the short-run domestic welfare gains of stepped-up IPRs enforcement are likely to be limited—except where domestic consumers may be harmed (such as in the case of counterfeit pharmaceuticals). Only as countries reach a certain threshold level of income, and domestic IPRs ownership becomes more widespread, will the domestic incentive for fighting counterfeiting and piracy grow.

Yet precisely because most IPRs holders are foreigners, usually from OECD countries, developing countries will invariably face trade and foreign policy pressures to rein in IPRs violations.

FTAs will likely require developing countries to implement ‘TRIPS-plus’ enforcement obligations which will entail the allocation of additional resources towards fighting IPRs violation. There is little evidence available that could guide policymakers on the precise resource implications of different kinds of treaty obligations. This knowledge gap arguably represents an important area for future research. In particular, it would be important to quantify the budgetary costs of different kinds of enforcement activities. Case studies of countries that strengthened their enforcement regime would be especially helpful.

While appropriate funding of competent government agencies in developing countries is necessary, it is not sufficient prerequisite for effective IPRs enforcement. In some countries, such agencies may be ineffective. Institutional deficiencies often prevail at the level of states and municipalities. It is difficult to give general recommendations on how to overcome such governance deficiencies as they are often country-specific and may be rooted in broader governance deficiencies.

Since developed country firms derive a direct benefit from stronger IPRs enforcement, it may be in the interest of their governments to subsidize IPRs enforcement activities in developing countries. Thus, the question of whether stepped-up IPRs enforcement in less developed countries should not be financed by developed country governments is a matter for reflection.

Another approach would be to have enforcement costs borne directly by private rights holders. Arguably, at least some consumers benefit from stronger enforcement action and should therefore share the costs of the public good represented by law enforcement activities. However, private rights holders are the most direct beneficiary of better enforcement and they can therefore be expected to make a substantial contribution to the financing of underlying costs.

In the case of trademarks and patents, governments could charge a special levy upon registration and renewal of IP titles. The size of the levy could depend on the market capitalization or sales revenues of firms in a given country, so that levies do not discriminate against small enterprises that face comparatively fewer infringements of their IP. In poorer countries where the most ‘valuable’ IP assets are held by foreigners, this approach would imply substantial foreign financing of domestic enforcement costs. At the same time, as domestic firms grow and develop their own IP portfolios, the domestic financing share would rise.

In the case of copyright, the levy approach may not be feasible because in most jurisdictions copyright protection does not necessitate the registration of copyrighted works. That said, copyright piracy is concentrated in a relatively small number of industries and it should be possible to impose “lump-sum” enforcement taxes on companies benefiting from stronger law enforcement actions.

Finally, if weak IPRs enforcement in developing countries reflects fundamental institutional deficiencies, it is not clear how far obligations in trade agreements or technical assistance activities can at all remedy such deficiencies. Outside incentives—whether positive or negative—may well make a difference in containing counterfeiting and piracy activities and their international proliferation. However, in many cases, sustained reductions in IPRs violations may invariably have to wait for broader institutional development

1. INTRODUCTION

Upholding the protection of intellectual property rights (IPRs) has emerged as a prominent policy issue. The year 2007 alone saw a G-8 summit calling for stepped-up enforcement of IPRs, the initiation of a WTO dispute on China's IPRs enforcement regime, and the launch of inter-governmental negotiations towards an Anti-Counterfeiting Trade Agreement (ACTA).¹ In addition, intellectual property (IP) chapters of free trade agreements (FTAs) negotiated over the past few years have introduced obligations on IPRs enforcement that go beyond multilateral standards inscribed in the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Several developed countries, in turn, have called for renewed discussions on enforcement in the TRIPS Council.

Concerns about trademark counterfeiting, copyright piracy, and other forms of IPRs violations are not new. Already back in 1985, *Business Week* characterized counterfeiting as "perhaps the world's fastest growing and most profitable business."² Indeed, the desire to stem trade in counterfeit goods was at the origin of the GATT negotiations, which eventually led to the conclusion of the TRIPS Agreement. However, two developments have sharpened the policy discourse on IPRs violations in recent years.

First, rapid global economic integration and the fast growth of middle income countries—led by China and India—have raised the stakes for IP-owning companies. They see counterfeiting and piracy as a constraint on their ability to expand their sales in rapidly growing markets. More fundamentally, they also view IPRs infringements as a direct competitive threat, as firms in labour-abundant countries copy the latest technologies and undermine what is perceived to be their remaining competitive edge. In the US, politicians have linked lax IPRs enforcement abroad to the country's persistent trade deficit, especially with China. While such a link has little economic basis—the trade balance primarily reflects the difference between domestic savings and investment—it carries political weight and is shaping US trade and foreign policy.

Second, counterfeiting and piracy are perceived to have reached unprecedented levels. In part, the growth of counterfeiting has been spurred by technological developments that have facilitated the copying of original products. For example, the emergence of easy-to-copy digital storage mediums has enabled the cheap reproduction of audiovisual and software products without any loss of quality. The spread of online patent databases has permitted easy access to new technologies.³

Due to their illegal nature, there are no reliable figures on the sales of IP infringing products. The Organisation for Economic Co-operation and Development (OECD, 2007) estimates that international trade in counterfeit and pirated goods in 2005 may have amounted to as much as USD 200 billion, or slightly more than 2 per cent of global merchandise trade. This figure understates global commerce in IPRs-infringing goods, as it excludes domestic sales and digital products distributed via the Internet. Even though there are no hard numbers on the growth of IPRs violations, anecdotal evidence suggests that their scale and scope is expanding. For example, newspaper articles and government surveys in recent years indicate that counterfeiting activity has expanded from luxury to common consumer goods, affecting products as diverse as automotive replacement parts, electrical appliances, and toys. In addition, IP violations are increasingly linked to organized crime.⁴

At one level, one might ask: why worry about IPRs enforcement as a matter of public policy? Governments set standards of IP protection through national laws and ensuring that firms and individuals obey these laws seems only natural. To be sure, some observers have argued that the exclusive rights granted by IP laws have become overly strong (Jaffee and Lerner, 2004 and Maskus and Reichman, 2004). However, no one would seriously argue for correcting this suspected overshooting of IPRs laws by promoting illegal behavior. If laws do not serve the public interest, they ought to be changed rather than disregarded.

Yet there is one important reason for regarding IPRs piracy as an issue of public policy: resources needed for enforcing IPRs are invariably scarce. Counterfeiting and product piracy exist even in the richest countries that have the best staffed and most equipped law enforcement agencies. For example, the Business Software Alliance (BSA) estimates that, in 2006, 45 per cent of software was pirated in France, 28 per cent in Germany, 25 per cent in Japan, and 21 per cent in the US.⁵ Governments need to make choices about how many resources to spend on combating piracy, as opposed to enforcing other areas of law, building roads and bridges, protecting national security, and providing other public goods. Such choices are usually not stated in explicit terms, but they underlie every budgetary decision by federal and local governments. For example, greater spending on counter-terrorism in the US after September 11, 2001 has left fewer resources for fighting crime, reportedly causing rates of crime to go up in many US cities.⁶ Deciding on appropriate spending for IPRs enforcement is especially difficult in developing countries, where many public goods are underprovided and enforcement challenges exist in many areas of law—fighting violence, guaranteeing real property rights, upholding contracts, stopping illegal logging of endangered forests, regulating traffic, and so on.

This study seeks to offer an economic perspective on policies towards IPRs enforcement. It draws on key insights from the economic literature to

identify priorities for the allocation of scarce law enforcement resources. Two major themes emerge from this literature. First, different types of IP infringements have different welfare effects, depending on underlying market failures and market characteristics. Past studies that have attempted to quantify the “losses” due to IPRs piracy have sometimes ignored these differences. Second, in designing an IPRs enforcement strategy, policymakers need to account for the incentives of producers and consumers to break the law. Understanding these incentives offers important insights about the limits of government policy and the effectiveness of different types of enforcement activities.

The paper is structured as follows. The next section will briefly review the main economic rationales for protecting different types of IPRs, by pointing to the different market failures giving rise to government intervention. This discussion will set the scene for an evaluation of the welfare effects of different forms of IPRs infringements—an exercise performed in Section 3. Then available empirical evidence on the economic impact of counterfeiting will be reviewed (Section 4) and set out a broad framework for developing a national strategy towards IPRs enforcement (Section 5). The final section will conclude by briefly discussing what this study’s economic perspective suggests for policymakers in developing and developed countries.

2. IPRS AND MARKET FAILURES

Intellectual property rights describe a set of legal instruments that, loosely speaking, guard firms' intangible assets. From an economic perspective, it is useful to place these instruments into two categories: IPRs that protect firms' reputation (trademarks and geographical indications) and IPRs that stimulate inventive and creative activities (patents, utility models, industrial designs, copyright, plant breeders' rights, and layout designs for integrated circuits). While IPRs in both categories seek to address the failure of private markets to provide an efficient allocation of resources, the underlying market failures differ.

In the case of trademarks and geographical indications (GIs), exclusive rights reduce inefficiencies that result from a mismatch of information between buyers and sellers on certain attributes of goods and services. Nobel prize-winning economist George Akerlof first pointed out that markets may fail when consumers have less information about the quality of goods than producers.⁷ Trademarks identify a product with its producer and his reputation for quality, generated through repeat purchases and word of mouth. They create an incentive for firms to invest in maintaining and improving the quality of their products. Similarly, GIs identify a product as originating from a particular region, signaling that it possesses a certain quality associated with that region.

For certain classes of goods, trademarks and GIs fulfill an additional function. Consumers sometimes attach status value to products bearing a well-known brand-name. For example, buyers of designer handbags or high-end watches not only care about the functional and physical characteristics of their purchases, but also about the name of the product or producer itself. In such cases, trademarks not only protect a company's reputation for objectively measured quality, but also its "prestige" built-up through marketing campaigns often stretching over years and decades. As it shall be seen in the next section, the presence of status value has an important

bearing on the welfare implications of product counterfeiting.

Intellectual property rights belonging to the second category resolve inefficiencies in markets for information and knowledge. Another Nobel prize-winning economist, Kenneth Arrow, long ago pointed out that information and knowledge can be easily reproduced once introduced in the market.⁸ In economic jargon, they possess characteristics of public goods. As their name suggests, public goods are usually not provided by private markets. If firms cannot prevent third parties from copying the fruits of their inventive and creative activities, they have little incentive to invest financial resources into such activities. Arguably, inventive and creative activities would not grind to a halt without government intervention: artists may be motivated by prestige or inherent self-interest in pursuing their profession and firms may have other means of profiting from new technologies, such as benefiting from a first-mover advantage. Nonetheless, governments have historically opted to supplement these "natural" incentives with exclusive rights to IP.

In their essence, IPRs in this second category seek to prevent free-riding behavior. They allow private agents to generate a profit from their intellectual assets with which they can recover the initial investment cost of creating these assets. However, exclusive rights also come with a cost. They confer market power to their owners, allowing them to price their intellectual goods above their costs of reproduction, to the detriment of consumers. Governments thus face a trade-off in formulating IP policies: stronger exclusive rights increase incentives for information and knowledge-producing investments, but they also increase the economic efficiency loss due to market structure deviating from its competitive ideal.

In actual policy-making, this trade-off is reflected in the fact that exclusive rights are time-bound (in contrast to trademarks and GIs, which can last forever). In addition, various forms of exclusive

rights have emerged to account for the diverse characteristics of different economic sectors: chiefly, patents (for industrial technology), copyright (for literary and artistic expressions as well as computer software), and industrial designs (for ornamental features of goods). Technological change has led to a continuous

adaptation of these instruments. Equally, different segments of society continuously challenge the appropriateness of various standards of exclusive rights and exceptions to them, with some groups even advocating alternative government policies to promote innovation—a debate that is beyond the scope of this paper.

3. EVALUATING THE WELFARE EFFECTS OF DIFFERENT FORMS OF IPRS INFRINGEMENTS

What happens if the exclusive rights conferred by IPRs are violated? This question has received some attention by economists, mostly in law, economics and trade literature. Most academic studies are of a theoretical nature: that is, they develop models of supply and demand to ascertain how unauthorized uses of IP affect different agents in the economy. In particular, studies in this area have adopted so-called partial equilibrium models, whereby economic welfare is measured by the sum of consumer and producer surplus (see Box 1). By nature, these models cannot capture the sophisticated complexities of how markets for IPRs-protected goods function in the real world. At the same time, their strength is to distill key aspects of consumer and producer behavior and evaluate their welfare consequences. Indeed, any statement about the economic effects of

IPRs infringement will invariably carry some assumptions about how markets function. The advantage of economic models is making those assumptions explicit and assessing their effects in a rigorous way.

In what follows, we review key insights from the economic literature for the different types of IP, starting first with trademark violations and then moving on to infringements of copyright, patents, and related IPRs. After summarizing the different welfare effects predicted by the literature, several additional effects that typically fall outside the scope of academic studies will be considered. Throughout this section, we will, for now, leave aside the direct costs of enforcing IPRs, which will be the focus of the discussion in Section 5.

Box 1. *Partial Equilibrium Models and Economic Welfare*

The economic studies described in this section typically model the effects of counterfeiting and piracy in a partial equilibrium, meaning they only focus on the market for one good (or one class of goods) and do not take into account linkages of that market with the overall economy. For example, economy-wide wages and the prices of goods sold in other markets are assumed to be constant.

Economic welfare in partial equilibrium models is typically measured by the sum of consumer and producer surplus. In a nutshell, consumer surplus is the difference between the maximum price a consumer is willing to pay for a good and the actual market price. Intuitively, the lower the market price, the bigger the saving to consumers from not paying what they would be prepared to pay. Producer surplus, in turn, measures the difference between the market price and the minimum price at which producers would be willing to sell the good. Intuitively, the higher the market price, the bigger the benefit to producers from selling a good for more than what it would take to cover costs.

Partial equilibrium models introduce certain assumptions about consumer preferences, the cost structure of producers and their competitive behavior. The degree of IP enforcement impacts on one or more of these variables and, ultimately, market prices, from which changes in consumer and producer surplus can be derived.

Trademark Counterfeiting

A crucial consideration for evaluating the welfare implications of trademark counterfeiting is whether consumers are misled by the falsified brand name attached to their purchases. For example, most buyers of a 10-dollar watch bearing

the Rolex label know perfectly well that they acquire a fake product. Simple inspection can often reveal if a product is fake or genuine and, even if not, most consumers know that genuine Rolex watches do not sell for 10 dollars. By

contrast, simple inspection may not easily reveal whether a pharmaceutical product is counterfeit and the purchase price alone is unlikely to offer additional information on the product's origin.

We will first analyze product counterfeiting assuming that buyers really do not know that they purchase a counterfeit product. We will then turn to the case where buyers know that they are purchasing a fake. As will become clear, the welfare consequences from counterfeiting in these two cases differ markedly.

Case 1: Consumers are misled

If consumers cannot by themselves distinguish fakes from originals, the presence of counterfeit goods undermines the signaling function of trademarks, as described in the previous section. Consumers will invariably be worse off. Purchasers of counterfeit products will, at best, derive a value from the product that is lower than the price they paid for it and, at worst, be exposed to physical harm if counterfeit products create health or safety risks. The consumption of misbranded products may also adversely affect other individuals—for example, when the intake of drugs with no or insufficient levels of active ingredients increases the risk of disease transmission or when defect vehicle replacement parts provoke traffic accidents.⁹ In the parlance of economists, the consumption of counterfeit goods may impose “negative externalities.”

In the long-run, if consumers know that trademarks are imperfectly enforced, markets for certain high-quality goods may not exist to begin with. Consumers would not be willing to pay the full price of a high quality original, since they fear that their purchase may be a fake. At lower prices, in turn, producers of original products would not be willing to sell. In other words, the market failure of asymmetric information strikes exactly as George Akerlof predicted more than thirty years ago.

The only beneficiaries of counterfeiting are the producers of counterfeits. However, the benefits accruing to those producers are bound

to be lower than the losses to consumers and original producers, such that economy-wide welfare is generally lower in the presence of counterfeiting.¹⁰

This result holds for closed economies and for the world economy at large. What if counterfeit producers are located in certain countries and export the overwhelming share of production, with domestic sales constituting a negligible share of output? For example, 90 per cent of IPRs-infringing activities seized at the European border in 2006 originated in only eight countries, with China alone accounting for 79 per cent of all seizures.¹¹ Even though producers in these countries invariably profit from counterfeiting activities, it is not clear how far the economies hosting such producers gain as a whole. Welfare effects will depend on patterns of comparative advantage and, in particular, how production factors in those economies would be used if counterfeiting were not feasible. Nonetheless, stronger trademark enforcement may well lead to substantial short-run employment losses in the concerned countries—an issue to which we will return below.

Case 2: Consumers are not misled

If consumers are perfectly aware that their purchases are fakes, a natural question to ask is: why do they prefer a product bearing a falsified label to a “generic” product of identical quality? The only plausible explanation is that they derive prestige or status value from the display of a particular brand name. Prestige value may be partly imaginary, such as when a consumer derives pleasure from carrying the same handbag as a Hollywood actress. More often, consumers derive status value by belonging to an exclusive club of consumers who share the same preferences and are able to afford high-end products. Individual consumers' taste for status thus needs to be included in social welfare calculations. Such an exercise may at first seem tenuous. However, a taste for status is quite real. Why else would a consumer be ready to pay several thousand dollars for a brand-name watch, when a reliable generic timekeeper can

be purchased for far less? Indeed, the very presence of counterfeit status goods indicates that status matters.

What can we say about the welfare consequences of counterfeiting in these circumstances? To begin with, consumers who knowingly purchase fake products are likely to be better off from counterfeiting activity. They always have the option of buying either the original or a generic product of comparable quality. If they choose the fake product and are not misled, their choice reflects a rational trade-off between price, status value, and quality.¹²

For consumers of original products, a crucial question is whether and how their welfare is affected by the presence of fake goods. Suppose first that such consumers can perfectly observe whether other buyers acquire fake or original products. If so, their welfare is unaffected, as the composition of the exclusive club of original purchasers remains the same. Their welfare may even increase, as the presence of fakes may raise the status value derived from owning the “real thing.”

However, in most cases, it is more likely that consumers of originals cannot tell whether other consumers own counterfeit or original products. For many fashion products and accessories, the difference between a fake and an original can only be ascertained by close inspection or by the fanciness of the store in which the product is bought. To the casual observer, fakes and originals are often indistinguishable. Indeed, consumers of fakes would unlikely derive much status value from counterfeit products if they could not successfully pretend that they own the genuine product.

Grossman and Shapiro (1988b) develop a simple model in which the prestige value a consumer derives from a given brand is negatively related to the number of consumers who own products displaying the same brand name—regardless of whether those products are fake or genuine. The presence of fake goods thus undermines the prestige of owning the genuine product,

leaving buyers of those genuine products worse-off from counterfeiting. However, Grossman and Shapiro show that the economy-wide welfare consequences from stronger trademark enforcement are ambiguous: depending on demand structures, the loss suffered by consumers of counterfeits may exceed the gain to consumers of originals.¹³

Trademark owners will experience an increase in profits from stronger trademark enforcement, as some consumers switch from fakes to originals. In the long term, greater profitability in the market for genuine products will induce entry of additional firms. The arrival of additional brands brings about a dual benefit to consumers of originals: each brand is purchased by fewer consumers, thus raising the prestige value associated with each brand, and greater competition between brands leads to a fall in the price of those products.¹⁴ Notwithstanding these additional benefits from market entry, the welfare consequences of stronger trademark enforcement remain ambiguous, as the loss to consumers of counterfeits may still outweigh any gain to consumers of originals.

Two additional considerations further complicate an already complex assessment of the welfare effects from counterfeiting. First, the presence of status goods may lead those consumers who cannot afford originals to be envious of those who can. Since the presence of counterfeit products may reduce this form of jealousy, there may be additional welfare losses from stronger trademark enforcement.¹⁵ Second, since consumers able to afford original products are likely to have higher incomes than those unable to do so, stronger trademark enforcement may have distributional implications. A government seeking a more equal distribution of real incomes may assign a stronger weight to low income consumers in its social welfare calculations. On balance, the inclusion of distributional concerns along these lines makes it more likely that stepped-up trademark enforcement will lower economy-wide welfare—though, in the end, it remains an empirical question.

Infringements of Copyright, Patents, and related IPRs

In general, violations of copyright, patents, and related IPRs affect the policy trade-off outlined previously: they weaken incentives for investments in inventive and creative activities but benefit users of these rights by offering them access to IPRs-protected goods at competitive prices.¹⁶ If governments maintain socially optimal standards of protection, IPRs violations, by definition, will lead to a welfare loss. However, this is a big “if.” Actual patent and copyright regimes are often the outcome of history, rules of thumb, and the influence of vested interests. Economic optimization hardly plays a role—not least because the social benefits of inventive and creative activities are unknown *ex-ante*. If the degree of protection as inscribed in laws is too strong, some levels of IPRs violations will increase welfare. If the degree of protection is too weak, any IPRs violation will invariably lower welfare.

An interesting question is how consumers of original products will fare upon stepped-up IPRs enforcement. Reduced competition from IPRs-infringing goods may increase the market power of the IPRs-holder, leading to higher prices for originals. However, the price effect will also depend on the price sensitivity of demand exhibited by the group of consumers that purchase originals. If their price sensitivity is lower than the average price sensitivity among all consumers in the economy, producers of originals may respond to stronger enforcement by lowering their prices. Such an outcome is consistent with consumers of originals being relatively well-off compared to consumers of illegitimate products. Indeed, original copyrighted works (e.g., audiovisual recordings) are sometimes more expensive in developing countries with higher piracy rates, as copyright holders set prices mostly reflecting demand from high-income consumers.¹⁷ However, possible price effects on stronger IPRs enforcement may well be small if the distribution of income is such that only few consumers will be able to switch from IPRs-infringing to legitimate goods.

As in the case of trademarks, stronger enforcement of copyright, patents, and related IPRs is likely

to have distributional consequences, which governments may want to consider in their social welfare calculations. The effect on the distribution of real incomes will, in part, depend on the average incomes of consumers of illegitimate products relative to the average incomes of workers engaged in creative and inventive activities. In a developing country context, where most IP is owned by foreign residents, governments seeking to promote a more equal distribution of real incomes may attach more weight to the welfare losses suffered by low income consumers of IPRs-infringing goods relative to the strengthened incentive for investments in creative and inventive activities. Yet again, the national and global welfare effects of stronger IPRs enforcement remain ultimately an empirical question.

Notwithstanding these general considerations, there is one important market characteristic that affects the welfare calculus associated with certain types of IPRs violations: the presence of demand linkages.

Demand linkages

In certain cases, consumers’ valuations of products increase with the number of other consumers who own the same product. Economists call such positive interdependencies among consumer valuations “network externalities” (or demand-side economies of scale).¹⁸ An example would be packaged computer software protected by copyright. The value of one person’s purchase of a word processing application is enhanced if that person’s colleagues and friends use the same application, such that electronic documents can be easily exchanged. Network externalities may also exist for certain patented technologies that evolve into an industry standard.

What happens if goods possessing network externalities—say a popular software product—are illegally copied? As in the more general case, consumers of pirated versions of the product will likely be better off, as they gain royalty-free

access to the software. For example, Microsoft's Office Suite, selling for several hundred dollars in the US, can be purchased illegally for just a few dollars in many developing countries. However, consumers of the genuine software product will also benefit from the presence of pirated copies, as they expand the size of the product's user network.

In addition, Takeyama (1994) formally shows that even the original producer of the software may benefit from unauthorized copying activity. The intuition behind this result is that the higher valuation of consumers of genuine copies may allow the producer to charge a higher price supporting larger profits. In theory, the software producers could reap the same higher profits by simply giving away legitimate copies of the software to those consumers who otherwise would purchase pirated copies. However, in practice, this strategy would not be possible, because those consumers willing to buy the full price for the original copy would nonetheless line up to obtain a free one. In other words, illegal copying activity in the presence of network externalities can allow the software producer to segment the market and to price-discriminate, reaping higher profits compared to a scenario where there is no illegal copying.¹⁹

This result raises the possibility that IPRs infringement may be Pareto improving—meaning that some economic agents are better off without any other agent being worse off. However, gains to IPRs-owning producers are, by no means, guaranteed. At extremely high rates of infringement activity, these producers are bound to lose. In the end, the direction of the welfare effect is again an empirical question that will depend *inter alia* on the strength of the network externality at hand and the dispersion of consumer incomes.

Some observers have also pointed to network externalities in the case of copyrighted material, when the consumption of such material necessitates ownership of hardware. For example, higher piracy rates of musical recording might increase ownership of CD-

players, which in turn may stimulate the demand for legitimate CDs.²⁰ However, the increasing role of the Internet in distributing copyrighted material may well have diminished the importance of such externalities.

Another effect may be at work in the case of certain audiovisual works. Buyer decisions for such works are often influenced by the purchasing decisions of their peers. This may be either because the decisions of the latter may provide the former information about new product offerings or the former simply wants to conform to social trends.²¹ While these types of demand linkages are different from the network effects outlined above, their implications are similar: the spread of pirated products may further stimulate demand, part of which may fall onto legitimate copies. In addition, depending on demand structures, it is theoretically possible that copyright holders profit from some levels of piracy.

Summary

Table 1 summarizes the welfare effects from stronger trademark enforcement associated with different types of IPRs, as discussed in this section. The table also suggests examples of products falling into the different categories of IPRs violations. This classification is somewhat crude and one product may well fall into several categories. Similarly, the direction of welfare effects should be considered as indicative only. In some cases, they depend on certain assumptions about market demand and supply.

In addition, where economy-wide welfare effects are ambiguous, the inclusion of distributional objectives would affect the direction of the final outcome. These caveats notwithstanding, the table reveals quite clearly that different types of IP infringement impact differently on consumers, producers, and the economy at large. Governments are well-advised to take these differences into account when developing an IPRs enforcement strategy and deciding about the allocation of scarce enforcement resources.

Table 1. *Overview of Welfare Effects from Stronger IPRS Enforcement*

Intellectual Property Right	Market Characteristic	Examples of Products	Welfare Effects From Stronger IPRs Enforcement
Trademarks	Consumers are misled	Pharmaceuticals, chemicals, pesticides, vehicle replacement parts, food and drink products, tobacco, electrical components, toys	<u>Consumers</u> : positive (especially where negative externalities are present) <u>Producers</u> : positive <u>Economy</u> : positive
	Consumers are not misled	Fashion apparel, footwear, handbags, personal accessories (sunglasses, handbags, leather articles, watches), cosmetics	<u>Consumers of counterfeit goods</u> : negative <u>Consumers of genuine goods</u> : positive <u>Producers</u> : positive <u>Economy</u> : ambiguous
Copyright, patents and related IPRs	No demand linkages present	Designs (cars, tools, toys), industrial technology, literary works	<u>Consumers of infringing goods</u> : negative <u>Consumers of original goods</u> : ambiguous <u>Producers</u> : positive <u>Economy</u> : positive, assuming standards of protection are socially optimal; ambiguous otherwise
	Demand linkages present	Certain types of computer software, patented technology that evolves into an industrial standard, audiovisual recordings, DVDs, PC and video games	<u>Consumers of infringing goods</u> : negative <u>Consumers of original goods</u> : negative <u>Producers</u> : ambiguous <u>Economy</u> : ambiguous

Other Effects

In addition to the core welfare implications outlined above, there are three additional channels through which IPRs violations may affect economic performance and other aspects of societal well-being. In particular, stronger IPRs enforcement may have a bearing on tax revenues, employment, and organized criminal activity.²² In the remainder of this

section, we will briefly discuss possible short and long-run effects in these three areas and point to difficulties in assessing such effects. As will become clear in the discussion, a common problem in this context is the establishment of appropriate counterfactual scenarios to compare different enforcement regimes.

Tax revenue

There is little doubt that stronger IPRs enforcement will impact government tax revenue. Given the illegal nature of the transaction, consumers do not pay sales, value added, or excise taxes on purchases of counterfeit or pirated goods. To the extent that stronger IPRs enforcement will lead some consumers to switch from illicit to legitimate products, governments will likely collect more revenue from these types of taxes.²³ Larger profits of IPRs-owning producers may, in turn, increase revenue from corporate income taxes. Finally, where governments maintain positive import tariffs and strengthened border enforcement leads to an increase in imports of legitimate goods, revenue may receive an additional boost.

While larger tax revenues are likely to be welcomed by governments in the short-run, the critical question is: what will governments do with the additional funds? In principle, enhanced tax revenues should not affect society's preferences for public spending in the long-run. Governments may thus either use additional revenues to lower tax rates or pay down the national debt. The new fiscal policy has the potential to increase economic efficiency, but such an outcome is not guaranteed. It depends on the specific tax measures employed and larger considerations relating to public debt management. Equally, the distributive consequences of reduced tax evasion are unclear *ex ante*. The final outcome will depend on the type of taxes affected by stronger IPRs enforcement and the real incomes of persons paying less or more taxes.

Employment

Economists like to think that in the long-run economies will converge towards full employment (leaving aside frictional unemployment). Thus, those workers who lose their jobs as a result of stronger IPRs enforcement will invariably find different employment. By definition, enforcement policies will, in the long-run, not affect the national unemployment rate.

However, this view is incomplete for two reasons. First, there may well be substantial unemployment

in the short-run. In many developing countries, the distribution of counterfeit and pirated goods often offers an important source of employment for low-skilled workers. Typically, there is no social safety net offering short-term relief for workers losing their jobs in the informal sector. Such workers and their dependents may thus experience hardship and, in the absence of legitimate alternatives, may well return to the IPRs-infringing business. As will be discussed in Section 5, sustained reductions in rates of piracy and counterfeiting will likely require the creation of legitimate employment opportunities for low-skilled workers who earn their living from selling counterfeit and pirated goods.

Second, stepped-up IPRs enforcement may affect the economy-wide composition of jobs. The OECD (2007) indicates that working conditions in the informal IPRs-infringing sector are poor, with low levels of pay and exposure to health and safety risks. By contrast, jobs created by IPRs-holders tend to be better paid and offer workers greater benefits and job security. Such a comparison seems too simplistic, however. Working conditions in the informal sector may be appalling, but the mere fact that workers are willing to accept such conditions suggests that they have no better alternative. In addition, the number of jobs lost due to strengthened IPRs enforcement is unlikely to match the number of jobs gained and, in any case, the identity of affected workers—and possibly the country they live in—will be different. That said, compositional effects due to stronger IPRs enforcement are difficult to evaluate, as they depend on economy-wide labor market dynamics.

Organized crime

That IPRs violations may stimulate organized crime follows tautologically from the fact that commercial-scale counterfeiting and piracy are criminal activities and require non-trivial organizational efforts. However, the concern is usually broader. Evidence reported by the OECD (2007) suggests that groups and individuals establishing and profiting from IPRs-infringing operations may also be involved in other

criminal activities, such as heroin trafficking, prostitution, extortion, and alien smuggling. There may, indeed, be “economies of scope” from engaging in different criminal activities.²⁴ If so, counterfeiting and piracy activities may stimulate other forms of crime and, reversely, increased IPRs enforcement—in the form of pursuing the criminal syndicates behind large-scale IPRs-violations—may lead to a reduction of other crimes. In economics jargon, there may be a “positive externality” from enhanced IPRs enforcement. Yet, it is not clear whether scarce law enforcement resources should be devoted to pursuing IPRs violations rather than other criminal activity to the extent that such a distinction is meaningful.

The OECD (2007) also points to evidence of links between counterfeiting and piracy activity and

the financing of extremist or paramilitary groups, notably in Northern Ireland, Kosovo, and through South American free-trade zones. Again, stepped-up IPRs enforcement may serve to reduce the harm that such groups inflict on societies, though one needs to consider that they may respond by switching to other—including legitimate—financing sources.

As a final caveat, available evidence on the links between IPRs infringements, organized crime, and the financing of extremist groups is anecdotal in nature. While credible, it would be important to have more systematic evidence of potential positive externalities from stronger enforcement action. Otherwise, loose references to links to organized crime or even “terrorism” risk being abused by vested interests that stand to benefit from strengthened enforcement of their exclusive rights.

4. EMPIRICAL EVIDENCE

The discussion of the preceding section suggested that the economic effects of IPRs violations depend critically on the types of IPRs involved and underlying market characteristics. In developing an IPRs enforcement strategy, policymakers would thus benefit from empirical guidance on how producer, consumer, and economy-wide welfare will cope under alternative enforcement policies. Several questions appear paramount. What share of output in a given sector and in the economy at large is associated with IPRs violations? What is the relative importance of the different categories shown in Table 1? How many consumers would switch to legitimate products if IPRs-infringing goods are removed from the market? How will lower rates of counterfeiting and piracy affect price-setting by IPRs-holders?

As pointed out in the introductory section, the production and sale of counterfeit and pirated goods largely escapes official statistical recording systems. Accordingly, there is little empirical evidence that would shed light on these questions. Nonetheless, some studies exist. The purpose of this section is to briefly review these studies and their methodologies.

As mentioned in the introductory section, the OECD (2007) estimated the value of international trade in IPRs-infringing goods at 200 USD billion, or slightly more than 2 per cent of global merchandise trade in 2005. Close inspection of the methodology applied to arrive at this figure reveals that it is more an “educated guess” than a true estimate. Essentially, OECD staff made use of seizure rates across different product categories and exporting nations to extrapolate what a given share of IPRs-infringing trade in one individual product category means for the overall share of trade in counterfeit and pirated goods. However, the share in the relevant “fix-point” product categories—wearing apparel, leather articles and tobacco products—underlying the 200 USD billion estimate is not based on any hard data, but rather reflects the best guess of OECD staff.

This should not be seen as a criticism of the OECD’s analysis—though one should be concerned about the use of the 200 USD billion figure as a statement of fact in the popular press.²⁵ In fact, the OECD study offers insightful evidence of the relative importance of IPRs violations across different product categories. Two findings are particularly noteworthy. First, trade in IPRs-infringing goods appears to be concentrated in a small number of “sensitive” product categories: the top five product groups account for more than three-quarters of all customs seizures.²⁶ Even if shares of trade in counterfeit and pirated goods in these categories were substantially larger than assumed by the OECD study, the corresponding share in overall trade would likely remain small.²⁷ Second, the four most-affected product categories—accounting for 65 per cent of all seizures—pertain to fashion apparel and related items on the one hand, and audiovisual recordings and software on the other.²⁸ This pattern suggests that for a substantial proportion of IPRs-infringing goods consumers know that they are purchasing counterfeit and pirated goods, and they likely derive some benefit from doing so. In fact, this notion is confirmed by consumer surveys that reveal that lower prices are a critical motivation for purchasing counterfeit or pirated products.²⁹

Industry associations representing copyright-holders regularly publish estimates of lost revenues due to piracy.³⁰ However, such estimates often rely on questionable assumptions about market demand. For example, BSA (2007) simply assumes that, in the absence of piracy, all consumers of pirated software would switch to legitimate copies at their current prices. This outcome is unrealistic—especially in developing countries where low incomes would likely imply that many consumers would not demand any legitimate software at all. Accordingly, estimated revenue losses by software producers are bound to be overestimated.³¹

Hui and Png (2003) estimate the effects of piracy on the legitimate demand for recorded music in an econometric setting. One notable feature

of their underlying model is that it accounts for the demand linkages outlined in the previous section—sales of pirated products stimulating demand for legitimate ones. Testing their model in a panel covering twenty-eight countries during the 1994-1998 period, they find that the net effect of piracy on the demand for legitimate music is negative. However, their estimate of forgone sales by copyright holders is 58 per cent lower than the music industry's estimate. The latter assumes that every sale of a pirated unit reduces legitimate sales by exactly one unit. The difference between Hui and Png's estimate and that of the music industry is not only due to

the presence of demand linkages, but also the possibility that stronger IPRs enforcement will drive some price-sensitive consumers out of the market.³²

The study by Hui and Png is the only econometric study that has employed a structural model of the demand and supply for IPRs-protected goods.³³ More such studies could usefully inform policymakers. Even if they fall short of gauging the long-term economy-wide welfare effects, they are helpful in offering a realistic estimate of the short-term impact of stepped-up IPRs enforcement on consumers and firms' profits.

5. TOWARDS AN IPRS ENFORCEMENT STRATEGY

Intellectual property rights are private rights and upholding such rights is, first and foremost, the responsibility of rights holders. Nonetheless, governments play an important role in enforcing private rights. For companies to pursue and receive compensations for IPRs infringement acts, they need the assistance of courts. In addition, certain forms of IPRs violations—such as commercial-scale copyright piracy—are considered criminal activities and the prosecution of such violations is the direct responsibility of governments. Even when IPRs infringements fall under civil law, many governments allow for so-called *ex officio* actions—competent law enforcement authorities pursuing infringements without a right holder's complaint. For example, *ex officio* actions are commonly applied to intercept shipments of IPRs-infringing goods when they pass through customs.

In principle, governments thus exert considerable control over the level of IPRs enforcement in their jurisdictions. At the same time, enforcement actions take real resources. Courts, police forces, customs offices, and other competent authorities need to be adequately staffed and equipped to respond to complaints by right holders and to act on their own. In addition, governments face the costs of maintaining prisons and, possibly, destroying seized pirated and counterfeit products that cannot be auctioned off as generic goods. In analyzing the welfare consequences of piracy and counterfeiting, Section 3 left aside the real resource costs associated with IPRs enforcement. In this section, we will explore government strategies towards IPRs enforcement, explicitly taking these costs into account.

Violations of IPRs do not arise out of intrinsic disregard for the law. Individuals break the law largely because it “pays” to do so. Starting with the seminal study by Becker (1968), economists have long analyzed the incentives for illegal behavior and their implications for the design of law enforcement policy.³⁴ Even though this branch of the literature has not specifically explored violations of IPRs, its general approach and several broadly applicable insights are

helpful in framing government policy towards IPRs enforcement.

The point of departure in economic analysis is the existence of a market for offenses. The supply side of this market is made up by individuals, who consider entering an illegal activity. Let's take the production of counterfeit goods as an example. Each individual's decision to break the law depends on the expected pay off (the profit from selling counterfeit goods), the costs of escaping punishment, the wage rate in an alternative legitimate activity, the probability of apprehension and conviction, the prospective penalty if convicted, and the individual's (dis-)taste for breaking the law (consisting of a combination of moral values and preference for risk).

The demand for offenses stems directly from consumers' demands for products at different levels of quality. If consumers purchase fake products unknowingly, the demand for offenses will equal regular market demand. If they purchase such products knowingly, the demand for offenses will fall short of regular demand; only at a price sufficiently below the price of original products are consumers willing to take on the risk of getting caught and punished or, at the least, to set aside moral concerns about supporting an illegitimate business.

Before turning to enforcement actions by governments, the simple model of a market for offences already offers an important insight about the extent of IPRs violations. Levels of economic development will invariably affect the equilibrium level of offences. Theoretically, this effect is ambiguous. On the supply side, richer countries are likely to offer higher wages in alternative legitimate activities, thus increasing the opportunity cost of breaking the law. At the same time, richer markets may also offer potential offenders a higher expected pay off from violating IPRs. On the demand side, average incomes of consumers in rich countries are higher, rendering them less budget-

constrained when deciding about their purchases and therefore less likely to turn to counterfeit or pirated products. Empirically, the first supply and demand-side effects appear to dominate: IPRs violations usually correlate negatively with per capita income. For example, the correlation coefficient between rates of software piracy and per capita GDP in 2004 takes on a value of -0.89.³⁵ Notwithstanding the importance of policy, such a strong correlation suggests that substantial reductions of piracy levels in less developed countries will, to a large extent, emanate from sustained economic growth.

Turning to policy, it is optimal for governments to devote a level of public spending on law enforcement, such that the marginal benefit of fighting IPRs violations equals the marginal cost of enforcement activity. The marginal benefit includes the welfare effects outlined in Section 3. The marginal cost includes the opportunity cost of not using scarce fiscal resources to provide other public goods. Public spending on law enforcement will affect the probability of apprehension and the penalties faced by suppliers, distributors and (knowing) consumers of IPRs-infringing goods, leading to adjustments in the market for offenses until equilibrium is reached.

Even though theoretical in nature, the economic approach to illegal behavior offers three important insights applicable to violations of IPRs law. First, optimal government spending on enforcement is consistent with positive “equilibrium” levels of counterfeiting and piracy. Given other demands on public expenditure and diminishing returns to enforcement actions, society “tolerates” to some extent violations of laws (Ehrlich, 1996). Of course, this prediction is perfectly consistent with observed practice: sales of counterfeit and pirated goods take place in every economy. In addition, “tolerable” levels of IPRs-infringements may well differ from country to country, depending, *inter alia*, on societies’ preferences for different public goods. As mentioned in the introductory section, developing countries are likely to have different public spending priorities. Even within the law enforcement domain, the optimal share of budgetary resources devoted

to IPRs enforcement will be lower in countries with higher levels of violence or less secure real property rights. Indeed, the enforcement part of the TRIPS Agreement sensibly recognizes that governments face competing demands for scarce law enforcement resources. In particular, Article 41.5 of the TRIPS Agreement reads:

It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

Second, should IPRs enforcement activities target the producers of fake and pirated goods, their distributors, or consumers who knowingly buy illegal goods? To answer this question, it is important to differentiate between the effects of enforcement actions at the level of individuals and the effects at the level of markets. In particular, an increase in the number of raids of pirated goods sellers will lead some distributors to exit the market, either because they are deterred by the raids or they are caught and temporarily incarcerated. However, if production and demand of illicit goods remain undeterred, other distributors will expand their sales and make up for those who exited the market. The overall piracy rate would remain unaffected. A case can therefore be made for focusing enforcement efforts on producers of IPRs-infringing goods, which are bound to be smaller in number. Such a focus may also create positive externalities, if producers are linked to organized crime syndicates (as discussed in Section 3).

Third, in addition to negative incentives posed by penalties, governments can affect the equilibrium level of offenses through positive incentives, notably by adopting measures that

create legitimate employment opportunities. Such measures will likely lead to a more durable reduction in IPRs infringement rates, as it fundamentally alters the net pay-off from illegitimate activities. Short-term incarceration of offenders, by contrast, may have little impact on individual incentives. Offenders discount the risk of apprehension when they decide to break the law and they are therefore bound to return to their illegal activity upon termination of the prison sentence. Although long-term job creation will mainly result from sustained economic growth, targeted employment measures could well make a difference in the short-term.

Another way of containing the supply and demand for offences is for governments (and IPRs holders) to sensitize the public to the illegal nature of counterfeiting and piracy, and their potentially adverse social implications. As noted above, moral values enter the pay-off function of individuals considering the production of illicit goods and consumers contemplating their purchase. Indeed, there are many “educational”

campaigns operating at the national and international levels, though there is no empirical evidence on how successful they are in limiting IPRs violations.

As a final caveat, it is worth acknowledging that appropriate funding of competent government agencies is a necessary, but not sufficient prerequisite for effective IPRs enforcement. In some countries, such agencies may be ineffective, or public entities may themselves be engaged in counterfeiting or piracy (or using IPRs-infringing products). For example, military bases in Russia have been alleged to host optical disk plants that manufacture and distribute pirated audiovisual products.³⁶ Institutional deficiencies often prevail at the level of states and municipalities, over which federal governments may have little control. It is difficult to give general recommendations on how to overcome such institutional deficiencies. They are often country-specific and may be rooted in broader government failures, to the extent that poor IPRs enforcement may be the “fifth wheel of the coach.”

6. CONCLUSIONS AND RECOMMENDATIONS

What are the practical policy implications of the approach outlined in the previous section? Admittedly, policymakers may be forgiven in finding the advice of “equating marginal benefits associated with enforcement activities to their marginal costs” unhelpful. Welfare considerations suggest that governments should focus their enforcement efforts on cases of deceptive trademark infringements (the first row in Table 1), especially those that create health and safety risks. In addition, a case can be made for pursuing producers rather than small-scale distributors of illicit goods, especially where the former are linked to organized crime syndicates. To some extent, policy choices will also need to rely on the judgments of local law enforcement authorities, who are often best placed to assess what types of enforcement actions are most effective.

What do the economic considerations outlined in this paper imply for IPRs enforcement policy in developing countries? To begin with, the domestic incentive to devote substantial resources to fighting counterfeiting and piracy is bound to be smaller in developing countries. Governments in such countries typically face other priorities for public spending. In addition, most IPRs-holders tend to be of foreign origin, suggesting that the short-run benefits of stepped-up IPRs enforcement are likely to be limited—except where domestic consumers are harmed (such as in the case of counterfeit pharmaceuticals).³⁷ Only as countries reach a certain threshold level of income and domestic IPRs ownership becomes more widespread will the domestic incentive for fighting counterfeiting and piracy grow.³⁸

Yet precisely because most IPRs holders are foreigners, usually from OECD countries, developing countries will invariably face trade and foreign policy pressures to rein in IPRs violations. The TRIPS Agreement introduced minimum standards for the enforcement of IPRs, including certain civil and administrative remedies, provisional measures, border measures, and criminal procedures that WTO members must have in place. It is unclear to what

extent these standards have caused significant changes in developing countries’ enforcement policies. Many countries probably complied with the TRIPS enforcement requirements before the Agreement came into force and there are important flexibilities in the implementation of these requirements—such as the ‘distribution of resources’ caveat, quoted in Section 5.³⁹

Enforcement obligations in recent bilateral and regional FTAs are more stringent. For example, US FTAs go beyond TRIPS requirements in several areas: they expand the scope of border measures, lower the threshold of forms of IPRs violations that constitute a criminal activity, and do not provide for a ‘distribution of resources’ caveat along the lines of the TRIPS Agreement (see Fink and Reichenmiller, 2005). Similarly, the envisaged Anti-Counterfeiting Trade Agreement (ACTA) specifically seeks to establish “new international norms, helping to create a new global gold standard on IPR enforcement.”⁴⁰ Recent initiatives in other forums—such as WIPO, the TRIPS Council, the World Customs Organization, INTERPOL, and the World Health Organization—aim in the same direction.⁴¹

Implementing ‘TRIPS-plus’ enforcement obligations will likely require governments to devote additional resources towards fighting IPRs violation. There is little evidence available that could guide policymakers on the precise resource implications of different kinds of treaty obligations. This knowledge gap arguably represents an important area for future research. In particular, it would be important to quantify the budgetary costs of different kinds of enforcement activities. Case studies of countries that strengthened their enforcement regime would be especially helpful.⁴²

If resource shifts associated with the implementation of international treaties do not reflect domestic priorities, public spending in affected countries would be distorted. This concern raises the question of whether stepped-up IPRs enforcement in less developed

countries should not be financed by rich country governments. Since developed country firms derive a direct benefit from stronger IPRs enforcement, it may indeed be in the interest of their governments to subsidize IPRs enforcement activities in developing countries. The case for subsidies seems especially strong when law enforcement activities target international crime syndicates and thereby limit the flow of counterfeit and pirated goods into rich country markets. In addition, rich country financing may be coupled with technical cooperation between national law enforcement authorities, which may lead to the transfer of valuable know-how to IPRs enforcement agencies in developing countries (to the extent that such know-how is applicable in a developing country context).

From the viewpoint of developing countries, one concern with rich country financing is that it may crowd out development aid in areas where the purely domestic pay-offs to such aid may be higher—say, investments in health and education. Indeed, questions of IP protection do not feature prominently in countries' Poverty Reduction Strategy Papers (PRSPs), which are supposed to provide the basis for the allocation of international development assistance.⁴³ Of course, the allocation of development aid is ultimately a decision of the donor country and it may be driven by altruism as well as self-interest.

Another approach would be to have enforcement costs borne by private rights holders. Arguably, fully privately funded law enforcement would be economically second-best, because at least some consumers benefit from stronger enforcement action (see Table 1) and should therefore share the costs of the public good represented by law enforcement activities. However, private rights holders are the most direct beneficiary of better enforcement and they can therefore be expected to make a substantial contribution

to the financing of underlying costs. In the case of trademarks and patents, governments could charge a special levy upon registration and renewal of IP titles.⁴⁴ The size of the levy could depend on the market capitalization or sales revenues of firms in a given country, so that levies do not discriminate against small enterprises that face comparatively fewer infringements of their IP. In poorer countries where the most 'valuable' IP assets are held by foreigners, this approach would imply substantial foreign financing of domestic enforcement costs. At the same time, as domestic firms grow and develop their own IP portfolios, the domestic financing share would rise. In the case of copyright, the levy approach may not be feasible because in most jurisdictions copyright protection does not necessitate the registration of copyrighted works. That said, copyright piracy is concentrated in a relatively small number of industries and it should be possible to impose "lump-sum" enforcement taxes on companies benefiting from stronger law enforcement actions.⁴⁵

As a final remark, if weak IPRs enforcement in developing countries reflects fundamental institutional deficiencies, it is not clear how far obligations in trade agreements or technical assistance activities can at all remedy such deficiencies. The record of aid agencies in changing institutions in developing countries is, at best, mixed. Historical evidence and contemporary research suggests that institutional change occurs only gradually and is more frequently brought about by bottom-up evolution rather than top-down planning (see Easterly, 2008). Outside incentives—whether positive or negative—may well make a difference in containing counterfeiting and piracy activities and their international proliferation. However, in many cases, sustained reductions in IPRs violations may invariably have to wait for broader institutional development.

ENDNOTES

- 1 See the G-8 summit declaration “Growth and Responsibility in the World Economy,” (June 7, 2007, available at www.g-8.de), WTO Dispute DS362 “China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights” (http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds362_e.htm), and the press release “European Commission Seeks Mandate to Negotiate Major New International Anti-Counterfeiting Pact” by the European Commission (available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1573>).
- 2 See “The Counterfeit Trade: Illegal Copies Threaten Most Industries,” *Business Week*, December 1985, pp. 64-72.
- 3 Admittedly, taking advantage of freely available information on technologies embedded in patents requires absorptive capacity, which differs markedly from country to country. At the same time, anecdotal evidence suggests that firms in developed countries increasingly refrain from filing patents, fearing misappropriation of their technologies in foreign countries. See “Firmen verzichten auf Patente,” *Financial Times Deutschland*, January 2, 2008.
- 4 See OECD (1997).
- 5 See <http://w3.bsa.org/globalstudy//upload/2007-Losses-EMEA.pdf> and <http://w3.bsa.org/globalstudy//upload/2007-Losses-Global.pdf>.
- 6 See “US Switches Resources to Fight Terror,” *Financial Times*, October 10, 2007.
- 7 See Akerlof (1970).
- 8 See Arrow (1962).
- 9 Similarly, substandard counterfeit products can harm the environment. In the chemical industry, counterfeit fertilizers have reportedly caused the destruction of harvests in China, Italy, Russia, and Ukraine (OECD, 2008).
- 10 Grossman and Shapiro (1988a) confirm the welfare-reducing effect of counterfeiting when there is free entry into markets for original products. Surprisingly, they also find that welfare effects are more ambiguous if the number of original producers in a particular market is fixed. This counter-intuitive result is due to information asymmetries leading market outcomes to be second-best even in the absence of counterfeiting. The existence of counterfeiting, in turn, may alter the rivalry among original producers in a way that they supply products at higher quality, leading to consumer welfare gains. However, the policy implications of this special result are not clear, as governments would find it difficult to fine-tune trademark enforcement such as to maximize overall welfare.
- 11 See European Commission (2006).
- 12 The OECD (2007) reckons that even if consumers knowingly purchase fake products, they may still suffer a utility loss, because of unexpected lower quality of such products. However, this prediction appears overly pessimistic. For many counterfeit goods, such as fashion apparel, or handbags, there is little uncertainty about quality at the time of purchase. Even where such

uncertainty exists, it is not clear why rational consumers would systematically overestimate the quality of fake goods.

- 13 In addition, stronger trademark enforcement will lead some consumers of counterfeits to switch to originals. If market entry is restricted, this effect will impact positively on welfare, as it leads oligopolistic producers of originals to expand output. However, the overall welfare effect remains ambiguous.
- 14 Technically, prices of branded products only fall if underlying demand curves are convex.
- 15 The inclusion of jealousy effects in consumer utility may again be seen as tenuous. However, studies in the field of behavioral economics have confirmed these effects in a variety of settings. See Zizzo (2007) for a recent review of the literature.
- 16 Johnson (1985) shows that additional welfare losses occur if the production of a copy uses more resources than the production of an original product. However, digitization has arguably reduced the costs of copying, such that original producers are unlikely to have a substantial production cost advantage. Besen and Kirby (1989), in turn, show that original producers might even benefit from copying if the marginal cost of producing copies is increasing in the number of copies. Yet again, with modern copying technology, this assumption is unlikely to hold. Finally, Bakos et al. (1999) show that the sharing of copyrighted material among small social communities (e.g., family or friends) can increase or decrease copyright holders' profits, depending on the structure of consumer preferences. However, their analysis does not apply to large-scale commercial piracy—the main focus of this study.
- 17 Price-setting in any given country may also be influenced by parallel import policies in foreign countries. Rights holders may not be willing to offer a lower price domestically for fear that products are parallel exported to rich country markets and undermine higher prices in those markets. See Fink (2005).
- 18 In fact, goods possessing network externalities can be seen as the opposite to status goods, for which consumer valuations decline with the number of other consumers (see the discussion above).
- 19 Software piracy could also prove beneficial to original producers in an inter-temporal setting. In the presence of network externalities and high costs of switching to a competing software product, consumers of a pirated product may be more likely to purchase newer versions of the original product, once copyright protection is more stringently enforced in the future.
- 20 For empirical evidence of such demand complementarities for CD players and music CDs, see Gandal et al. (2000). Karaca-Mandic (2003) offers similar evidence for DVD players and digital video disks.
- 21 See Burnkrant and Cousineau (1975) for a formal exposition of these effects.
- 22 An additional consideration may be the waste entailed in the destruction of seized counterfeit or pirated goods. However, as shown in Grossman and Shapiro (1988b), producers of IPRs-infringing goods will pass on the loss associated with seized shipments to consumers through higher prices for the goods that make it to the market—an effect already taken into account in the analysis outlined above. If governments cannot auction off seized goods as “generic”

products, they face the additional cost of destroying those goods. This cost can be seen as part of the law enforcement cost addressed in Section 5.

- 23 Theoretically, it is also possible that tax revenue falls if stronger IPRs enforcement will lead to a sufficiently large fall in prices for genuine products, as outlined in the discussion above.
- 24 For example, the OECD (2007) reports that Chinese crime syndicates force people they smuggle into Europe to pay off their transport costs by working as distributors of pirated goods.
- 25 See, for example, “World ‘losing’ war against fakes and piracy”, *Financial Times*, December 4, 2007.
- 26 Product groups are defined as 2-digit chapters of the Harmonized System. There are 96 such chapters. As the OECD report acknowledges, seizure rates may be a biased indicator of the relative distribution of IPRs-infringing goods, as interceptions by customs authorities may be more frequent in product categories known to be sensitive to trade in counterfeit or pirated goods.
- 27 The share of the top-five product categories in world trade is 18.5 percent. However, in the largest 2-digit category (HS85), one sub-category (HS 8524) accounts for 85 percent of all seizures but only 2 percent of world trade. Taking this bias into account, the share of the most-affected product categories in world trade drops far below 10 percent.
- 28 To be precise, the four categories are articles of apparel and clothing accessories (HS61, HS62); records, tapes, and other recorded sound media including software (HS8524); articles of leather, saddlery and harness, travel goods, handbags, articles of gut (HS42); and footwear, gaiters, and the like (HS64).
- 29 For example, see the report *Fake Nation?*, available at <http://www.allianceagainstiptheft.co.uk/downloads/pdf/Fake-Nation.pdf>.
- 30 See, for example, BSA (2007) and IFPI (2006). For a critique, see “BSA or Just BS?”, *The Economist*, May 19th, 2005.
- 31 IFPI (2007) offers a more nuanced approach for the music recording industry, by simply publishing an estimate of the value of pirated goods (presumably valued at pirated goods prices). However, the methodology for arriving at this value estimate is not explained.
- 32 One limiting feature of Hui and Png’s model is that copyright holders are assumed to not adjust their prices in response to lower piracy. If the presence of pirated copies in the market leads copyright holders to lower prices, they will incur additional losses, which are not captured by Hui and Png’s estimate of forgone sales.
- 33 In the area of trademarks, the International Trademark Association (INTA, 1998) estimated that apparel and footwear producers lost an average of 22 percent of their sales in 1995 as a result of trademark counterfeiting. This estimate was obtained from an econometric model relying on sales data of selected firms and their perception of the quality of trademark protection in 40 countries. However, the study’s econometric set-up seems questionable. In particular, the trademark variable is interacted with countries’ population size. The rationale for doing

so is not further explained. Given the much larger variation in population sizes, it may well be that the interaction term mainly picks up a population rather than a trademark effect. Unfortunately, the study does not report results using the trademark variable only.

- 34 Ehrlich (1996) offers a review of the literature up to the mid-1990s.
- 35 Software piracy rates were taken from BSA (2007) and data on GDP per capita (measured on a purchasing power parity basis) come from the World Bank's World Development Indicators. In analyzing seizure rates from different countries, the OECD (2007) finds an inverted U-relationship between a country's propensity to export counterfeit and pirated goods and its GDP per capita. This finding is not necessarily inconsistent with the strong negative correlation for rates of software piracy, as the BSA data mainly covers middle and high income countries. That said, the export propensity measure constructed by the OECD captures the production (and distribution) of IPRs-infringing goods, whereas software piracy rates relate to the consumption of such goods.
- 36 See the "2006 Special 301 Report" submission on Russia by the International Intellectual Property Alliance (available at <http://www.iipa.com/rbc/2006/2006SPEC301RUSSIA.pdf>).
- 37 Baroncelli et al. (2005) document that foreign residents account for 46 percent of trademark registrations in middle income countries and 81 percent in low income countries. However, the propensity of trademark violations is arguably higher for better known foreign trademarks.
- 38 More generally, Maskus (2000) has documented a U-shaped relationship between the strength of IPRs protection and the level of economic development. At the lowest levels of development, rising incomes lead countries to weaken IPRs protection, as they develop imitative capacity. This trend is reversed once domestic firms create IPRs themselves and demand their protection.
- 39 See UNCTAD-ICTSD (2005) for a detailed legal review of the TRIPS enforcement provisions.
- 40 See the press release by the European Commission available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1573>.
- 41 See Biadgleng and Munoz Tellez (2008) for a review of these initiatives. It is worth noting that there is a certain asymmetry in international enforcement obligations. Existing international agreements and current initiatives seek to strengthen the enforcement of private rights. By contrast, there are no international obligations to enforce laws against the abuse of these rights—for example, in the form of erroneous patent awards for subject matter already in the public domain or anti-competitive business practices associated with intellectual property ownership.
- 42 Such case studies have been conducted for other treaty negotiations. For example, the World Bank has established a technical assistance facility to assist developing countries assess the cost implications of a new agreement on trade facilitation in the WTO. See <http://go.worldbank.org/VKY547AFU0>.
- 43 An electronic search of more than 50 national PRSP documents published between 2000 and 2007 revealed that the terms "intellectual property", "copyright", and "trademark" are not at all mentioned in these documents. (See <http://www.imf.org/external/np/prsp/prsp.asp>).

- 44 Maskus (2006) makes a similar proposal.
- 45 Lump-sum taxes—such as the proposed levy on the registration and maintenance of trademarks and patents—should have no direct bearing on consumer prices. By contrast, if taxes were to take the form of sales levies, companies would pass at least part of the tax onto consumers through higher product prices.

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PART 2

The Push for Stronger Enforcement Rules: Implications for Developing Countries

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EXECUTIVE SUMMARY

Since the adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), a wide range of initiatives have been launched by developed countries and business organizations to enhance different measures that would aid in the enforcement of intellectual property rights (IPRs). Although many of such initiatives refer to counterfeiting and piracy, their scope is much broader and generally involves any type of infringement of IPRs.

One of the principal arguments for the new offensive on enforcement is the level of economic losses caused by acts of counterfeiting and piracy. Estimates, however, are based on a broad definition of such acts and on questionable methodologies. It is also often argued that counterfeiting and piracy are associated with criminal activities and terrorism. The enforcement offensive assumes, without supporting evidence, that the current levels of enforcement are inadequate or insufficient. In addition, it overlooks that the economic and social impacts of IPRs violations and enforcement actions may significantly differ between developed and developing countries and that cultural perceptions about such acts also vary significantly.

A diverse set of actions aiming at enhancing enforcement of IPRs domestically and internationally is undertaken by various United States (US) agencies, including the US Trade Representative (USTR), the State Department, the Department of Commerce, the US Customs and Border Protection (CBP), and the US Patent and Trademark Office (USPTO). A coordination mechanism (National Intellectual Property Law Enforcement Coordination Council- NIPLECC) has also been established. The agenda of these entities is strongly influenced by private sector organizations.

A similar IP enforcement activism can be found in the European context both for the internal market and internationally. This is exemplified by the adoption of the Enforcement Directive 2004/48/EC and by the 'Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries', which aims at enhancing IPRs enforcement outside the European Union (EU).

In addition to unilateral actions, developed countries have promoted a number of initiatives regarding enforcement in international fora and organizations. For instance, the OECD, the Group of Eight (G8), and the World Intellectual Property Organization (WIPO) have initiated activities in this area. Submissions on the matter have also been made by developed countries to the Council for TRIPS and a number of countries have also started negotiations of a new international treaty (Anti-Counterfeiting Trade Agreement, or ACTA).

The enforcement offensive is focused on several critical issues. Although Article 61 of the TRIPS Agreement requires criminal sanctions only in cases of willful trademark counterfeiting or copyright piracy on a commercial scale, the current offensive aims at criminalizing other infringing acts, thereby ignoring the differences between various types of infringers and shifting the burden of enforcing private IPRs to states. This drive includes patent infringement, despite the fact that in the US and other developed countries patent infringement is only dealt with under civil remedies. The European Parliament recently refused its criminalization as well.

There are also efforts to strengthen provisional measures beyond what is required under Article 50 of the TRIPS Agreement. A summary review of the implementation of such measures in developed countries shows, however, that they are applied by courts cautiously, particularly in the case of alleged patent infringement. There is also evidence about abuses of provisional measures by right holders.

The treatment of permanent injunctions in the US suggests the extent to which developed countries' demands to developing countries may exceed the standards actually applied in the developed countries themselves. Thus, based on 'equity' grounds, US courts have denied permanent injunctions in a series of cases of patent infringement where purely commercial interests are at stake.

Border measures constitute an outstanding item in the current enforcement offensive. Developed countries' governments and industry are actively seeking to induce changes in the regulation of such measures in developing countries, beyond what is required under the TRIPS Agreement. They aim, *inter alia*, at broadening their scope of application (limited to the importation of counterfeit trademark or pirated copyright goods under the Agreement) and at reducing the requirements imposed on right holders to obtain such measures. As it is extremely difficult or impossible for custom authorities to make a *prima facie* determination of infringement, the expansion of border measures may have deleterious effects on trade, particularly in the case of patent protected goods. The expansion of border measures has been proposed, in particular, in the framework of the World Customs Organization (WCO).

Another recurrent issue is the demand for developing countries to establish special units/task forces in national administrations or special judicial courts to deal with IPRs infringement. Although the activities of such bodies would primarily benefit right holders, they would have to be funded by developing countries' public budgets.

Finally, a major issue in the enforcement offensive relates to the fight against counterfeit medicines and other products that may create health or environmental risks. The arguments and proposals made in relation to this subject often confuse IP and public health considerations. The application of an IP approach to what is essentially a public health issue may lead to the adoption of an inadequate set of measures. In the case of counterfeit medicines, the appropriate design and implementation of drug regulations is the most critical element in combating counterfeiting in medicines.

TRIPS-plus enforcement measures have also become a common element in free trade agreements (FTAs) between the US and developing countries, in the Economic Partnership Agreements (EPAs) negotiated by the European Union (EU) with African, Caribbean, and Pacific (ACP) states, and in the process of accession to the World Trade Organization (WTO)

Considering the reach of the enforcement offensive and the repercussions that the adoption of the proposed measures may have in developing countries, a number of actions can be taken in order to adapt enforcement rules to the conditions and needs of each country in a way consistent with the requirements of the TRIPS Agreement.

1. INTRODUCTION

The activism deployed by some business groups and developed country governments to enhance the enforcement of intellectual property rights (IPRs) raises growing concerns in developing countries. While the main argument for such action is the fight against counterfeiting and piracy, developed countries aim to expand enforcement rules well beyond what is necessary to combat such acts. That expansion, if successful, may alter the balance between the rights of title-holders, competitors, consumers, and the public at large.

In examining this issue, it is important to bear in mind that the economic and social impacts of IPRs violations and enforcement actions may significantly differ between developed and developing countries. While in the former, IPRs enforcement costs may be off-set by economic and other benefits, including higher tax revenues. On the other hand, for developing countries, increasing enforcement activities might entail the use of already scarce resources to protect what are substantially commercial interests of foreign companies.¹ Moreover, enforcement rules that do not adequately take public interests into account may deprive significant portions of developing country populations from access to IPRs-protected products necessary to address public health, educational, and other needs.²

One of the main justifications for the current enforcement offensive is the high income loss that counterfeiting and piracy would cause to right holders. However, the empirical basis of this claim is weak and the dimension of the loss often exaggerated. For instance, the Business Coalition to Stop Counterfeiting and Piracy (BASCAP) estimated 600 USD billion per year is lost globally due to counterfeiting and piracy.³ A study by the Organisation for Economic Co-operation and Development (OECD) on the economic impact of counterfeiting and piracy estimated that the volume of internationally traded counterfeit or pirated products amounted to USD 200 billion in 2005.⁴ At the same time, the study recognized that 'to date, no rigorous quantitative analysis has been carried out to measure the overall

magnitude of counterfeiting and piracy... The overall degree to which products are being counterfeited and pirated is unknown, and there do not appear to be any methodologies that could be employed to develop an acceptable overall estimate.'⁵

Available estimates are generally provided by interested business groups based on arbitrary hypotheses and flawed methodologies. In some cases, their claims about lost sales due to infringement are 'almost as great as the total legitimate trade itself.'⁶ If, as argued by Business Software Alliance (BSA)⁷, Chinese software piracy rate were 90 per cent (data for 2005), it would amount to nearly ten times the number of original copies. If all the copies used were original, the market turnover of the software industry in China would be close to 4,000 billion yuan or nearly 25 per cent of China's GDP in 2005.⁸ Instead, a 'more authoritative Survey on the Chinese Software Piracy Rate commissioned by the Chinese State Intellectual Property Office shows, on the basis of the newly installed software market in 2006, that the piracy rate in China was 20 per cent (down from 25 per cent in 2005) by converting the market value of pirated software.'⁹

The claimed losses are generally calculated taking the retail price of 'original' products into account¹⁰ 'since copies are priced below originals, many consumers of illegitimate copies would not likely consume originals even if copies were not available.'¹¹

Not only do accurate methodologies to measure counterfeiting and piracy not exist, but also there was no evaluation of the effectiveness of current enforcement rules before it was concluded that the adoption of new rules is urgent and indispensable. Indeed, often what is required are not new rules but more resources to effectively implement existing ones. Although the drive for enhanced enforcement puts the main burden on states, as discussed below, it systematically eludes the question of resources needed to enforce such rules.

Considerable efforts are being made by developed country governments and industry, including business associations and coalitions, to get developing countries' acceptance of the idea that broader and tougher enforcement rules are in the latter's best interest. It is argued that the fight against counterfeiting and piracy would protect 'local and regional industries, foreign investment and investor confidence, price levels, jobs, international trade relations, tax and customs income, public health and safety, and the prevention of corruption and organized crime.'¹² However, these arguments should be subjected to careful scrutiny. For instance, the OECD has observed that counterfeiting and piracy 'serve only a limited role in explaining FDI behavior.'¹³ The key question that remains unanswered is whether the current level of counterfeiting and copyright infringement significantly erodes innovation or creation, and whether such erosion is socially inefficient. It has been noted in this regard that:

[T]here are several possible ways in which infringement might be socially efficient..., and might even have a positive effect upon the amount of secondary creation that takes place. First, of course, we have the fact that, since private infringement takes place at prices below the legitimate market price, it allows consumption by individuals that have a willingness to pay below the market pricing allowed by copyright. In this way, infringement reduces the consumption deadweight loss, and if infringement were only engaged in, say, by those with values below market pricing, society as a whole would gain....¹⁴

In addition, arguments in favour of enhanced enforcement mechanisms generally overlook the conception that IPRs, as enshrined in the TRIPS Agreement, are not embraced in the same way by societies with different social organizations, cultural attitudes, and legal traditions.¹⁵ For instance, in Asia, under the influence of Confucianism, the unauthorized reproduction

of a work has been seen as useful for its broad diffusion rather than as an illicit or immoral act. Even in the West many people are also 'prepared to knowingly purchase or obtain pirated works without considering themselves as 'thieves', as evidenced by the growing downloading of music and video from Internet and the copying of software.'¹⁶ Moreover, the dominant paradigm of knowledge appropriation based on IPRs is increasingly under question. What is termed the 'access to knowledge movement', actively promoted by a large group of scholars, civil society organizations, and developing countries, aims at an information society where the appropriation of knowledge is minimized so as to make it openly accessible to the benefit of all.¹⁷

While legal action against counterfeiting and piracy is important, the main defense of right holders would probably be reasonable pricing of 'original' products. For instance, the 'recording industry underestimates the elasticity of its demand curve and would likely benefit from lower prices.'¹⁸ A study on copyright piracy sponsored by the Indian government concluded that:

[T]hough social factors like illiteracy, unemployment etc. influence piracy, the phenomenon occurs more because of economic reasons than anything else. For pirates it is an easy way of making quick bucks. For the end users it is a gainful arrangement for buying/using a variety of info-entertainment products which otherwise remain unaffordable at least to a vast majority. Basically, this 'win-win' situation for pirates and end users keeps the piracy alive and active in the society. Other socio-economic variables like poverty and high prices etc. only add to the degree of the problem.¹⁹

Finally, it is to be noted that the current initiatives by developed countries to enhance enforcement rules and mechanisms are often associated with expansive concepts of 'counterfeiting' and 'piracy'. Correctly interpreted, these concepts are limited to very specific types of infringing

acts, as defined in footnote 14 to article 51 of the TRIPS Agreement:

- (a) “counterfeit trademark goods” shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;
- (b) “pirated copyright goods” shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

In contrast, the OECD study, *The Economic Impact of Counterfeiting and Piracy*, illustrates the broad concept used in many studies and initiatives arguing for increased enforcement standards. In accordance to this study those terms:

are used to describe a range of illicit activities linked to intellectual property rights (IPR) infringement. The work that the OECD is conducting focuses on the infringement of IPRs described in the WTO Agreement on Trade-Related Aspects of

Intellectual Property Rights (TRIPS); it includes trademarks, copyrights, patents, design rights, as well as a number of related rights.²⁰

As a result of this expansive approach, counterfeiting and piracy, which are often associated to the operation of criminal networks, are confused with other infringements of IPRs where no criminal behavior exists, such as in cases of the non-attributed quotation of a copyrighted work, the downloading of a piece of music from an Internet site, or the infringement of a patent by a competitor. Such an approach improperly equates any IP infringement with crime and elevates IP enforcement to the category of a vital tool against crime and even terrorism.²¹

This paper describes, first, some of the initiatives by the US and the EU aimed at enhancing enforcement rules domestically and internationally. Second, it discusses the main components of the enforcement offensive, notably the criminalization of commercial scale IP violations, the strengthening and expansion of provisional and border measures, and the demands for the establishment of special administrative units or courts to deal with IP enforcement. Third, it considers the myths and realities surrounding the debate on IP enforcement and health risks. Fourth, it briefly discusses the TRIPS-plus standards on enforcement incorporated into free trade agreements (FTAs) and Economic Partnership Agreements (EPAs), as well as those resulting from accession processes in WTO. Finally, a number of conclusions are drawn and some recommendations are made.

2. DEVELOPED COUNTRIES' ENFORCEMENT OFFENSIVE

The TRIPS Agreement is the first international treaty on IPRs²² that has included specific norms on the *enforcement* of IPRs.²³ The detailed enforcement standards incorporated therein were essentially based on the submissions by the European Commission and the US government during the Uruguay Round. Unlike other sections of the Agreement, developing countries did not seek significant changes to the European and US draft texts during the negotiations, as they were primarily concerned with and focused on the substantive standards contained in Part II of the Agreement.²⁴

The TRIPS Agreement's provisions became mandatory for developed countries in 1996. For developing countries and the economies in transition provisions were obligatory only in January 2000 at the end of the general transitional period provided for in Article 65.2 of the Agreement. However, initiatives for the strengthening of enforcement rules domestically and in third countries proliferated soon after the adoption of the Agreement in the US and the European Union.²⁵ Some of these initiatives are briefly reviewed below.

Various agencies in the US have undertaken a wide range of actions in the area of IP enforcement. In 1999, the Treasury/Postal Appropriations Act (Pub. L. 106-58) created the 'National Intellectual Property Law Enforcement Coordination Council' (NIPLECC) with the mission of coordinating 'domestic and international intellectual property law enforcement among federal and foreign entities.'²⁶ In addition to a number of initiatives at the national level,²⁷ several activities were addressed to foreign countries, such as training provided to government officials,²⁸ lobbying and interventions in support of US businesses, coordination of US IP right holders, technical assistance, and advocacy.

The US Department of Commerce's International Trade Administration (ITA) established the Office of Intellectual Property Rights (OIPR) that, among other tasks, leads the US Administration 'Strategy

Targeting Organized Piracy' ('STOP!') Initiative. Announced in October 2004, this initiative 'brings together all Federal Government agencies to take comprehensive action in cracking down on piracy and counterfeiting. The initiative has enhanced coordination among all relevant US Government agencies, as well as with our trading partners to tackle this global problem.'²⁹ Under the STOP! initiative, the US Administration has worked to 'empower US companies to protect their IPRs, to stop trade in fake products at US borders, to keep such products out of the global supply chain, and to ensure that US companies receive the benefits of the trade agreements signed by the United States.'³⁰ A key goal of STOP! is 'to aggressively engage US trading partners to join our efforts against counterfeiting and piracy.'³¹

The US State Department has taken an active role in IP enforcement through unilateral actions as well as bilateral and multilateral mechanisms. It has developed 'focused technical assistance pilot plans for developing countries' jointly with other US Government agencies and WIPO, such as a 'technical assistance pilot plan to combat trade in counterfeit and pirated goods and to strengthen IP enforcement in Indonesia.'³² The Department's activities include '...strengthening customs and law enforcement; ensuring legal production of safe and effective medicines, foods, and consumer products; and improving critical government IP functions' as well as 'using State Department resources abroad to encourage foreign government officials and local populations to take steps to reduce piracy and counterfeiting.'³³ In accordance with the NIPLECC Report,

State Department officials at our Embassies and Missions regularly engage with foreign government officials to encourage them to improve IP protection and enforcement and to collaborate with private sector rights holders. Department personnel also are involved in implementing U.S. IP trade policy, IP related trade capacity building, and other major IP efforts on

the ground in host countries. Embassy and Mission officials serve as the front line of US Government outreach in monitoring IP enforcement, legislation and regulation abroad, and advocating US IP priorities to foreign government officials. Embassy and Mission officials monitor and promote implementation of IP-related provisions in Free Trade Agreements, Trade and Investment Framework Agreements, and WTO accession commitments.

In order to better promote the rule of law and the protection of IP worldwide, the State Department is in its fifth year of formally funding IP criminal enforcement training and technical assistance programs in developing countries... The Department's criminal enforcement training focus is designed specifically to complement private sector training initiatives by focusing on government-to-government.

The State Department launched its IP Public Diplomacy Initiative in early FY2007 to provide resources, information, and expertise to our embassies and consulates around the world for their use in promoting the importance of IP to foreign consumers. The initiative utilizes open editorials, media tours, digital video conferences (DVCs), and information fact sheets that provide information by region and topic...³⁴

IP enforcement is also one of the 'Priority Trade Issues' in the Trade Enforcement program of the US Customs and Border Protection (CBP), particularly in the context of "STOP!"³⁵

The USTR is a key agent in pushing forward the US IP agenda. It does so in various ways, including:

- Investigations under and application of the Special Section 301;
- Negotiation of FTAs and other agreements³⁶ involving IP substantive or enforcement issues;
- Review of Generalized System of Preferences (GSP) and other preference programs that

afford developing countries with duty-free access to the U.S. market for certain products;

- Review of country practice regarding the protection of intellectual property upon petitions submitted by US right holders³⁷;
- WTO accession negotiations under which TRIPS-plus substantive and enforcement obligations are imposed;
- Dispute settlement under bilateral and multilateral mechanisms.³⁸

These actions taken by US State agencies complement or are coordinated with activities undertaken by business groups. For instance, ITAC-15, the USTR advisory Board in the area of IP (jointly administered by the Department of Commerce) is exclusively composed of representatives from the private sector³⁹ despite objections from the US General Accounting Office (GAO).⁴⁰ ITAC-15, in particular, provided advice during FTA negotiations with various developing countries, identified business concerns regarding IP in countries that are eligible beneficiaries under the Generalized System of Preferences (GSP) programme, counseled US trade negotiators on WTO Members' implementation of and compliance with the WTO TRIPS Agreement, and provided advice on WTO dispute settlement cases.⁴¹ ITAC-15 also plays an essential role in channeling private sector recommendations into the annual Special 301 Review.⁴²

In some developing countries, the US government and private sector have been able to engage local business groups and associations in their pro-enforcement actions. For instance, the US embassy involved the Confederation of Indian Industry in their drive for higher IPRs protection and enforcement standards.⁴³ The reasons for these collaborations are unclear given that the main beneficiaries of such a drive are likely to be foreign right holders, though this coordination may be explained by the participation and influence of foreign companies in local business associations.

IP enforcement activism can also be found in the European context. The Enforcement Directive

2004/48/EC of the European Parliament and of the Council of 29 April 2004, addressed ‘the disparities between the systems of the Member States as regards the means of enforcing intellectual property rights’ which ‘are prejudicial to the proper functioning of the Internal Market and make it impossible to ensure that intellectual property rights enjoy an equivalent level of protection throughout the Community. This situation does not promote free movement within the Internal Market or create an environment conducive to healthy competition’ (preamble, para. 8). The objective of the Directive is ‘to approximate legislative systems so as to ensure a high, equivalent and homogeneous level of protection in the Internal Market’ (preamble, para. 10).⁴⁴

In addition, the Customs Regulation (Council Regulation (EC) No 1383/2003 of 22 July 2003)⁴⁵ strengthened the measures available at the border. In particular, it broadly empowered custom authorities to suspend the release or detain goods whether imported, exported, or in transit ‘suspected of infringing an intellectual property right’ (article 9.1).

The EU enforcement activity has not been confined, however, to the internal market. In a communication setting the ‘Strategy for the Enforcement of Intellectual Property Rights (IPRs) in Third Countries’⁴⁶ the European Commission proposed a set of actions to:

- Provide a long-term line of action for the Commission with the goal of achieving a significant reduction of the level of IPR violations in third countries;
- Describe, prioritise and co-ordinate the mechanisms available to the Commission services for achieving their goal;
- Inform right-holders and other entities concerned of the means and actions already available and to be implemented, and raise their awareness for the importance of their participation;
- Enhance co-operation with right-holders and other private entities concerned, by seeking their input on the identification of priorities

and establishing public-private partnerships in fields like technical assistance, information to the public, etc.

The basic rationale for this Strategy is that:

[T]he Community, being a market that traditionally invests heavily in IP-protected goods and services and receives considerable added-value for this effort, is particularly affected by poor enforcement of IP, even when it takes place in third countries, and even if the pirated / counterfeit goods or services are not destined for the Community market.’⁴⁷

The Strategy specifically states that it does *not* intend to:

- Impose unilateral solutions to the problem – It is clear that, ultimately, any proposed solutions will only be effective if they are prioritised and considered to be important by the recipient country. The Commission is ready to assist in the creation of such conditions.
- Propose a one-size-fits-all approach to promoting IPR enforcement – It will be necessary to have a flexible approach that takes into account different needs, level of development, membership or not of the World Trade Organization (WTO), and main problems in terms of IPR (country of production, transit or consumption of infringing goods) of the countries in question.
- Copy other models of IPR enforcement or create alliances against certain countries. The Commission is ready and willing to improve co-operation and to create synergies with countries sharing its concerns and facing similar problems. It is, however, important that this strategy remains primarily focused on positive and constructive efforts.

However, the Commission’s determination to go beyond the TRIPS Agreement and to transplant the EU enforcement policies into other countries is explicitly stated. One the ‘specific actions’ proposed at the bilateral/multilateral level is to:

Revisit the approach to the IPR chapter of bilateral agreements, including the clarification and strengthening of the enforcement clauses. Although in designing the rules for each specific negotiation it is important to take into account the situation and the capacity of our partners, instruments such as the new EU Directive harmonizing the enforcement of IPR within the Community, as well as the new customs' Regulation on counterfeit and pirated goods may constitute an important source of inspiration and a useful benchmark.⁴⁸

Consistent with this approach, a prominent feature of the free trade agreements (FTAs) proposed by the EU to developing countries is a significant expansion of the IP enforcement obligations as compared to the TRIPS requirements.⁴⁹

In addition, in its resolution of 7 September 2006 on counterfeiting of medicinal products,⁵⁰ the European Parliament indicated that the European Community 'should equip itself as a matter of urgency with the means to combat effectively illicit practices in the area of piracy and the counterfeiting of medicines.' It called on the creation of an international convention to fight counterfeiting of medicines and urged the EU 'to play a key role in promoting an international convention to create a specific criminal offence of counterfeiting or the receiving and distribution of counterfeit medicines in the legislation of every country.'

The European Neighborhood Policy also includes an IP component and enforcement obligations. In accordance with the European Neighbourhood Policy Strategy Paper, 'increased levels of effective protection of intellectual and industrial property rights as well as effective enforcement of such rights ... are likely to have significant effects on economic development and on investment levels'.⁵¹ The 'action plans' established with developing countries in the context of this policy include obligations, defined in general terms, on enforcement of IPR. For instance, the Action Plan of Egypt includes strengthening enforcement 'of IPR legislation within TRIPS requirements'

and reinforcing 'the fight against piracy and counterfeiting and promote cooperation.'⁵² The Action Plan of Lebanon requires the strengthening of the 'administrative capacity for enforcement of legislation and implementation of sanctions.'⁵³ In the case of Morocco, it committed itself to 'increase resources dedicated to enforcement, in particular for the customs authorities and the judicial system.'⁵⁴ Lastly, the Action Plan for Tunisia requires *inter alia* the enforcement of the IPRs rules 'particularly as regards fines, to ensure effective protection for right-holders', and stepping-up 'action on counterfeit/pirated goods in specifically targeted sectors.'⁵⁵

Developed countries have also deployed a vast set of actions at the multilateral level in order to tighten enforcement standards and their implementation. The WIPO Advisory Committee on the Enforcement of Intellectual Property Rights (ACE), established in 2002, has provided a forum for developed countries and a number of associations representing right holders' interests, for the promotion of an agenda focused on the concerns of right owners without adequate consideration of the social aspects of enforcement.⁵⁶

In October 2005, the European Communities and their member states proposed that the TRIPS Council review enforcement of obligations under TRIPS to establish ways to help fight problems of piracy and counterfeiting.⁵⁷ While several developed countries such as the US and Japan showed general support for this proposal, many developing countries voiced strong opposition.⁵⁸ Later, in a Joint Communication of the European Communities, Japan, Switzerland, and the US on 'Enforcement of intellectual property rights', these countries recalled 'the importance of effective IPR enforcement for developing and developed country economies, in particular in terms of innovation and investment' and acknowledged that members are free to determine the appropriate method of implementing enforcement provisions while ensuring effective IP enforcement. Ultimately, however, such implementation must ensure adequate achievement of the objectives of the TRIPS Agreement.⁵⁹

Developed countries have intensified their cooperation in the area of enforcement during the last ten years. Thus, in addition to the US-EU Intellectual Property Working Group mentioned above, the European Commission and Japan agreed at the EU-Japan Summit of 2003 to launch an “EU - Japan Joint Initiative for IPR Enforcement in Asia” focusing on elements like the close follow-up of the progress of Asian countries in the field; coordinating technical assistance programmes and responsibilities; enhancing EU-Japan efforts to raise awareness in the fight against piracy and counterfeiting and to promote the strengthening of IPRs enforcement; and exploring the possibility to cooperate in other areas of IPRs.

This activism has also reflected itself in other developed countries’ fora such as the OECD⁶⁰ and the Group of Eight (G8). One of the priorities of the agenda of the G8, as expressed at its summits in the last three years, is to strengthen the international legal framework on the enforcement of IPRs. At the 2006, G8 Leaders Summit in St. Petersburg, a comprehensive IPRs enforcement strategy was announced inline with the strategy adopted in 2005. The G8 issued a Statement on “Combating IPR Piracy and Counterfeiting” where it calls on G8 governments to:

- a. Keep the spotlight on trade in counterfeit and pirated goods and secure agreement on projects that promote greater cooperation among national law enforcement and customs officials
- b. Link victims of intellectual property rights infringement to national enforcement authorities
- c. Build capacity in developing countries to combat trade in counterfeit and pirated goods
- d. Further research the economic impact of piracy and counterfeiting on national economies, brands, rights holders and public health/safety

e. Task relevant law enforcement work (including online piracy) to the Lyon-Roma Anti-Crime and Terrorism Group (LR/ACT).

A year later, in June 2007, specific initiatives were endorsed by the G8 aimed at improving and deepening cooperation among G8 members and delivering real enforcement results.⁶¹

In October 2007, the USTR announced that the United States, Canada, the European Union, Japan, Korea, Mexico, New Zealand, and Switzerland had agreed to negotiate a new ‘Anti-Counterfeiting Trade Agreement’ (ACTA). The ACTA would complement the Administration’s work to encourage other countries to meet the enforcement standards of the TRIPS Agreement and to comply with other international IPR agreements. It would not involve any changes to the TRIPS Agreement. Rather, the goal is to set a new, higher benchmark for enforcement that countries can join on a voluntary basis.

The negotiations represent a cooperative effort by the governments involved and are dissociated with any international organization.⁶² Of course, the risk is that after a text has been agreed upon by a small number of countries and locked up for amendments, other developing countries may be pressured to sign up to it in exchange for, or in order to, preserve certain trade advantages. The possible effects of ACTA on competition have also raised concerns in some industries in developed countries.⁶³

The envisioned ACTA ‘would include commitments in three areas: (1) strengthening international cooperation; (2) improving enforcement practices; and (3) providing a strong legal framework for IP enforcement.’⁶⁴ A text of the draft ACTA is not yet publicly available; discussions held in Geneva in June 2008⁶⁵ apparently focused on border measures.⁶⁶

3. NEW TARGETS IN ENFORCEMENT POLICY

The main objective of this enforcement offensive is to introduce changes into the legislation and the practices of developing countries' administrations and courts dealing with IPRs. As noted, the changes sought for are not limited to acts relating to trademark counterfeiting and copyright piracy, which only represent a vehicle that might permit deeper reforms in enforcement rules applicable to patent and other categories of infringement. This is illustrated, for

instance, by the outcomes of several sessions of the 'Global Congress on Combating Counterfeiting and Piracy' jointly organized by WIPO, the World Customs Organization (WCO), INTERPOL, the International Trademark Association (INTA), and the International Chamber of Commerce (through the 'Business Action to Stop Counterfeiting and Piracy'-BASCAP⁶⁷). Some relevant sections of the Outcomes Statement of the Third Global Congress are reproduced in Box 1.

Box 1. *Third Global Congress on Combating Counterfeiting and Piracy. Shared Challenges, Common Goals, Geneva, 30-31 January 2007*

- Consider providing for criminal sanctions for commercial scale IP violations, which fully reflect the current dimension of counterfeiting and piracy and to underline that they are serious economic crimes.
- Encourage the review of sanction structures to ensure that they are strong enough to serve as effective deterrents, and encourage courts and competent administrative authorities to use criminal sanctions.
- Examine whether, and under which circumstances, consumers should also be penalized for purchasing and/or possession of counterfeit and pirated products in countries that don't already have such measures.
- Encourage countries to strengthen civil remedies and procedures, such as effective provisional measures, and provide more adequate compensation for rights holders through appropriate methods for the calculation of damages.
- Analyze and, as appropriate, eliminate jurisdictional inconsistencies concerning judicial interpretation of law, for example in the context of the release of goods and the issue of parallel importation.
- Encourage governments to further develop and clarify legal standards for the availability of civil remedies, including damages and their calculation, and procedural law.
- Reduce litigation costs for the use of the civil system to enforce IP rights.
- Take appropriate measures to ensure Free Trade Zones provisions are not unfairly and illegally manipulated by counterfeiters.
- Elaborate rules for Free Trade Zones to facilitate seizures of counterfeit and pirated goods and to prevent the trade in counterfeit and pirated goods, most particularly by eliminating the practice of disguising the origin of products.
- Establish legislative standards on prohibiting the movement of counterfeit and pirated goods that are in transit or in the transshipment process.
- Explore the proposal by the Government of Japan to develop an international treaty on the manufacturing and distribution of counterfeit and pirated goods, as well as consumer education.
- Explore options for improvement in international legal framework systems for sanctions against IP crimes, either separately or in connection with another international instrument, e.g., on organized crime in general
- Formulate and/or finalize guidelines for global protection of IP rights, such as the WCO Framework of Standards, and promote and support their wide adoption by governments to further strengthen national customs administrations in their efforts to combat counterfeiting and piracy.

Source: <http://www.ccapcongress.net/archives/Geneva/Geneva.htm>.

Although a review of these proposals is outside the scope of this study, it should be noted that there is set of recommendations that emphasize the criminalization of infringement acts, improving the availability of provisional measures

and permanent injunctions, and expanding and strengthening border measures. These issues are examined in more detailed below. The demands for the establishment for special IP units or courts⁶⁸ are also briefly discussed.

4. CRIMINALIZATION OF COMMERCIAL SCALE IP VIOLATIONS

Article 61 of the TRIPS Agreement TRIPS requires (see Box 2). the criminalization of certain violations of IPRs

Box 2. *Criminal Procedures and Penalties in Trips*

Article 61

Criminal procedures

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

The scope of this obligation is determined by a reading of this provision in conjunction with the above mentioned footnote 14 to Article 51 of the TRIPS Agreement, which defines the concepts of ‘counterfeit trademark goods’ and ‘pirated copyright goods’. In the light of this footnote, the obligation to impose criminal sanctions is limited to:

- a) The use without authorization of a trademark that is identical or that cannot be distinguished in its essential aspects from a trademark registered in respect of certain goods. This means that the utilization of a merely confusing trademark on the same or similar goods need not be penalized. Likewise, criminalization does not apply in cases where a mark is used without authorization in relation to goods that are similar to the goods in respect of which the trademark is registered, even if there exists a likelihood of deception or confusion;
- b) The violation of trademarks that are ‘validly registered’, thereby excluding the penalization in cases of well-known or other unregistered trademarks;
- c) Situations in which an infringement of the trademark owner’s rights occur under the law of the country of importation;

d) Cases of *wilful* counterfeiting;

e) Acts of counterfeiting made on a commercial scale;

d) The counterfeit of *goods* marks, since the referred to footnote to article 51 of the TRIPS Agreement does not allude to service marks.⁶⁹

In the case of copyright piracy, the obligation to penalize is limited to *copies* made without the consent of the copyright holder or person duly authorized by the right holder in the country of production. Whether an infringement or not exists is judged in accordance with the law of the country of importation. As in the case of trademark counterfeiting, piracy must be wilful and on a commercial scale to be penalized in accordance with Article 61 of the TRIPS Agreement. In addition, it is limited to copyright protection and does not include related rights, which constitute a different category of rights.⁷⁰

Like in the case of trademark counterfeiting, copyright piracy must be penalized only when undertaken ‘on a commercial scale’. Given that these terms are not defined in the TRIPS Agreement, there is considerable room for WTO Members to define what their meaning is in the context of trademark and copyright law. Members may provide

their own definitions on the matter, subject only to the interpretive rules of the Vienna Convention on the Law of the Treaties (articles 31 and 32).

For instance, the revised draft European Directive on 'Criminal measures aimed at ensuring the enforcement of IPRs defines 'infringements on a commercial scale' as 'any infringement of an intellectual property right committed to obtain a commercial advantage; this excludes acts carried out by private users for personal and not-for-profit purposes.'⁷¹ However, members may adopt a narrower interpretation as this definition seems to focus on the adjective 'commercial' and overlook the meaning of 'scale', which may have multiple connotations. The latter suggests the relative dimension of an object. In economic and business terminology, for example, 'economies of scale' exist when savings are obtained by using large quantities.⁷² Hence, it would seem legitimate that a country limits penalization in situations where a large number of counterfeit or pirated products are distributed with a for-profit intent.

The US filed a complaint against China at the WTO where several issues relating to enforcement will be considered.⁷³ Essentially, the complaint is based on the allegation that there are cases of willful trademark counterfeiting and copyright piracy on a commercial scale for which China has not provided for criminal procedures and penalties. As is alleged, this is inconsistent with Articles 41.1 and 61 of the TRIPS Agreement. The basis of this complaint is that under the Chinese Criminal Code, the penalization of trademark counterfeiting and copyright piracy depends on certain thresholds: that is, 'serious/especially serious circumstances', 'large/huge amount of sales', 'large/huge amount of illegal gains'. The code does not establish procedures and penalties for infringements by natural persons.

According to the US communication, the criminal law does not contain definitions for the thresholds 'serious,' 'especially serious,' 'relatively large,' and 'huge' as used in the above-referenced articles. However, judicial interpretations do contain such definitions. Here, thresholds are stated as minimum 'illegal business volumes' (stated in

terms of minimum values of products produced, stored, transported. or sold), minimum illegal gains', or minimum numbers of 'illegal copies.' On 30 December 2006, the Supreme People's Court adopted the "Explanation on Several Issues on the Application of Law in Adjudicating Civil Unfair Competition Cases." The Court lowered the threshold to prosecute people who manufacture or sell counterfeit products: anyone who manufactures 500 or more counterfeit copies (discs) of computer software, music, movies, TV series, and other audio-video products faces a prison term of up to three years and anyone who produces more than 2,500 counterfeit copies can be jailed for up to seven years. Fines can range from one to fifteen times the illegal gains, or from 50 to 200 per cent of the business turnover. The new regulations also tighten the rules on granting probation. In addition, the Court instructed IPR criminal courts to accept cases filed by individual complainants, in addition to those filed by procurators.⁷⁴

The US has also complained about the rules applicable to custom's disposal of confiscated goods that infringe IP rights. According to the US, these statutes violate Articles 46 and 59 of the TRIPS Agreement. In accordance with Chinese Custom Regulations infringing goods must be destroyed only if infringing features cannot be removed. Otherwise, they can be released into the channels of commerce.

The US-China case requires the interpretation of several TRIPS provisions that have not yet been interpreted by the WTO panels or Appellate Body, such as the meaning of the term 'deterrent' in Articles 41.1 and 61, or the definition of 'commercial scale' in Article 61.1.⁷⁵ This case will also test the policy space provided for WTO Members to implement TRIPS obligations in accordance with 'their own legal system and practice' (article 1 of the TRIPS Agreement). Such space is particularly broad in Part III of the TRIPS Agreement. Here, the provisions determine what the outcomes of the adopted measures should be rather than specifically prescribing how to enforce covered IPRs. In fact, because the TRIPS Agreement has established minimum thresholds for IPRs enforcement but has not harmonized rules,⁷⁶ there is enormous diversity in the way WTO Members implement IPRs.

Despite the clearly circumscribed scope of Article 61 and the room for maneuver it leaves for interpretation at the national level, the current enforcement offensive aims at extending the application of criminal sanctions to any commercial infringing act and to infringements that do not fall under the well-defined categories of trademark counterfeiting and copyright piracy.

Criminalization is regarded by its proponents as a stronger deterrent than civil remedies. For right holders there are some significant advantages: actions can or must be initiated *ex officio* and the cost of procedures is fully borne by the states. However, it is clear that IPRs are private rights⁷⁷ and that states' only obligation under the TRIPS Agreement is to ensure that enforcement procedures are *available*, and not to enforce IPRs themselves on its own cost and responsibility.⁷⁸

It has been noted, however, that criminalization may entail some disadvantages for right holders as 'the rights owner has no control over the case, has to submit to the slow pace of criminal cases, and does not as a rule receive any compensation.'⁷⁹ But this is not always the case, as in many instances the right holder can participate in criminal procedures, which may be faster than civil litigation, and judges are also authorized to determine damages. Instead, the main hurdle for right holders may be the need to produce clear and convincing evidence about the infringement, while a preponderance of evidence may suffice in civil litigation.

While developing countries are rushed to broadly criminalize IPRs violations, high *civil* statutory damages (up to 1 USD million per type of good) are deemed a sufficient deterrent against counterfeit trademark and infringement in the US. The US Department of Justice justifies criminal sanctions only in order 'to punish and deter the most egregious violators: repeat and large-scale offenders, organized crime groups, and those whose criminal conduct threatens public health and safety.'⁸⁰ As noted by Harms, 'criminal enforcement is not the preferred method of enforcing IPRs in developed countries. In contrast, criminal enforcement is now the main tool of enforcement in developing countries.'⁸¹

Judge Jumpol Pinyosinway of the Central Intellectual Property and International Trade Court of Thailand has summarized some of the concerns of developing countries in this area. In his opinion:

- IPR enforcement, in principle, should be civil. This is the preferred method of protecting IPRs in developed countries.
- IPR criminalization, with severe penalties, has grown rapidly in developing countries. This coincides with the broadening of IPRs under pressure of developed countries.
- "All expected and unexpected infringements" are now criminalized even if the particular act is not perceived to be morally reprehensible within a particular community or is criminalized to the same extent in developed countries.
- Although there is scope for criminalization, the new crimes ignore the differences between the different types of infringers.⁸²

Notably, in the US, Canada, and other developed countries, patent infringement is only dealt with under civil remedies. Likewise, the European Parliament refused to criminalize such infringement in considering a revised text of the draft 'Directive (2005/0127(COD) on criminal measures aimed at ensuring the enforcement of intellectual property rights' adopted on 25 April 2007.⁸³ However, in developing countries (e.g., Argentina, Brazil, Thailand) that followed the approach of some European countries (such as France) during the nineteenth century, patent infringement is subject to criminal sanctions.

The criminalization of patent infringement is a particularly delicate matter. Several reasons militate against criminalization of such infringement:

- The interpretation of patent claims requires special skills that are generally lacking in criminal courts.
- Patent infringement under most jurisdictions may be literal or by equivalence.
- There is a considerable discretion in courts' judgment to establish when an infringement by equivalence has taken place.
- Often patents are found invalid or revoked when scrutinized by courts, due to the lack

of patentability requirements, insufficient disclosure, or other reasons.⁸⁴

- Criminal accusations may be prone to abuse by patent holders as they would intimidate competitors and force them out of the market even if infringement did not exist.
- The cost of defense in criminal courts may be prohibitive for alleged infringers, particularly SMEs.
- It is virtually impossible for law enforcement officers and border officials to determine *prima facie* whether⁸⁵ any particular product is an infringing product.
- There is no conclusive evidence about the effectiveness of criminalization of IP infringements.⁸⁶

In the light of these considerations, it seems advisable for developing countries to cautiously calibrate the extent to which criminal sanctions are used to enforce IPRs. In particular, patent infringements should be addressed through civil measures only. In this context, it also seems that the recommendation of the 'Geneva Conference'

(see Box 1 above) to 'examine whether, and under which circumstances, consumers should also be penalized for purchasing and/or possession of counterfeit and pirated products in countries that don't already have such measures' is excessive. Consumers should not bear the cost of the right holders' inaction against the producers of counterfeit and piracy goods, nor of the shortcomings in state interventions where mandated by law. It is unfair to encumber consumers with liabilities that would limit their freedom to choose along with the burden of identifying what is or is not a legitimate product.

Finally, in developing countries that suffer from high levels of street crime and other forms of criminality that put at risk the life, integrity, or freedom of persons on a daily basis, it seems reasonable that fighting such crimes should receive higher priority than IP-related crimes where protected interests are essentially of a commercial nature (except when associated with adulteration of health and other risky products⁸⁷).

5. PROVISIONAL MEASURES

Article 50 of the TRIPS Agreement mandates WTO Members to authorize judicial authorities to grant provisional measures that prevent the infringement of any intellectual property right from occurring, and to preserve relevant evidence with regard to the alleged infringement.

While provisional measures should be available to ensure the protection of right holders' legitimate interests, they should be granted in a prudent manner so as to protect the equally legitimate right of third parties not to be unduly prevented from non-infringing activities.

There is evidence of abuse of interlocutory injunctions that are strategically used to block competition. In the US, for instance, multiple 'automatic stays'⁸⁸ for thirty months each could be obtained in cases where a generic company attempted to receive marketing approval of a drug where a patent had been granted. This allowed patent holders to delay the entry of generic competition for additional four to forty months.⁸⁹ A US FTC study found that for nearly 75 per cent of drugs covered by the study, brand-name companies initiated patent infringement litigation against the first generic applicant.⁹⁰ A court decision had been made (at the time of conclusion of the study) for 53 out of 75 drug products.⁹¹ A court decision resolved the patent infringement claims for thirty drug products. Generic applicants prevailed 73 percent of the time. In eighteen instances, a court held that the brand-name company's patents were either invalid or not infringed.⁹²

There is also evidence of abuse of interlocutory injunctions in some developing countries, where judges have little knowledge of patent issues and are often inclined to support complaints of alleged infringement on the basis of a superficial assessment.⁹³

In implementing provisional measures, three important issues need to be considered. First, while in some jurisdictions patents are presumed to be valid, the limitations in the examination process (where it is made)⁹⁴ suggest that such a presumption is inappropriate or should be taken

with extreme caution. In the US, the patent holder seeking preliminary relief bears the burden of production and persuasion of likelihood of success regarding validity, but the party opposing the injunction must produce sufficient evidence to raise a substantial question regarding validity. In this case, the burden of production and persuasion shifts back to the patent holder to prove likelihood of validity by demonstrating that the substantial question 'lack[s] substantial merit' without resort to the clear and convincing evidence of persuasion imposed by the presumption of validity.⁹⁵

As noted by the FTC, the shortcomings of the procedures for assessing patent applications 'suggest that an overly strong presumption of a patent's validity is inappropriate. Rather, courts should require only a "preponderance of the evidence" and not clear and convincing evidence to rebut the presumption of validity.'⁹⁶ A bill under consideration by the US Congress proposes, among other changes to the patent statute, a relaxation of the presumption of validity of patents by requiring only a 'preponderance of the evidence' to rebut it.⁹⁷

In other countries, national laws exclude a presumption of validity of patents. In the United Kingdom, for instance, as 'a foolproof search is basically impossible' to establish that the patentability requirements are met, 'the validity of granted patents cannot be guaranteed'.⁹⁸ In India, section 13(4) of the Indian Patent Act, 1970 states that:

The examination and investigation required under section 12 and this section shall not be deemed in any way to warrant the validity of the patent, and no liability shall be incurred by the Central Government or any other officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

Based on this provision, the Delhi High Court recently decided two appeals against *ex parte* provisional measures in patent infringement suits

filed by Bilcare Limited (*Bilcare v. Amritdhara*, pending before the High Court of Delhi) and *Bilcare vs. Associated Capsules & Supreme Industries* (pending before the Delhi District Court). Both cases, filed by the same plaintiff (Bilcare) substantially refer to the same facts.⁹⁹ One of the main issues addressed in both cases was whether there was a presumption in favour of the validity of the patent for the grant of a temporary injunction in favour of the patentee. In both decisions, the judges decided that there was no presumption of validity of a patent. Justice JM Malik quoted from *National Research Development Corporation v. Delhi Cloth and General Mills*, AIR 1980 Delhi 132:

It is also a rule of practice that if a patent is a new one, a mere challenge at the bar would be quite sufficient for a refusal of a temporary injunction but if the patent is sufficiently old and has been worked the court would for the purpose of temporary injunction, presume the patent to be valid one. If the patent is more than 6 years old and there has been actual user it would be safe for the court to proceed upon this presumption.¹⁰⁰

A second important issue is when an interlocutory injunction should be granted *inaudita altera parte*. Although judges should be empowered to grant an interlocutory injunction¹⁰¹ given the contentious nature of the issues at stake (for instance, when patent infringement depends on establishing the ‘equivalence’ of the allegedly infringing object), such a measure should be exceptional. This is generally the case in the US, India, and other countries¹⁰² where interlocutory relief is ‘an exceptional remedy ... for which exceptional cause [is] to be shown’.¹⁰³ *Inaudita parte* measures deprive the judges from the possibility of assessing factual or legal arguments that may be crucial for a fair decision, and may prejudice the public when a competitor is unjustifiably barred from the market.

Thirdly, in many jurisdictions an ‘irreparable harm’ must be shown in order to grant a provisional measure, but interpretations vary regarding when such harm exists. In some countries, the likely violation of an IPR is deemed to provide sufficient basis for an allegation of irreparable harm even

when damages would be an adequate remedy should the claim succeed. However, this is not an advisable approach as the alleged infringer may be able to pay the determined damages if an infringement were actually found. In India, for instance, irreparable harm is not deemed to exist in such cases.¹⁰⁴ In Canada, like in the US, irreparable harm generally means that the harm ‘either cannot be quantified in monetary terms or that cannot be cured by payment of damages such as permanent loss of market share or damage to one’s business reputation.’¹⁰⁵ However, ‘the loss of goodwill cannot be *inferred*, it must be established by “clear evidence.”’¹⁰⁶

Fourth, courts should consider the public interest implications of granting a provisional measure, particularly where public health is at stake. This is illustrated, for instance, in a decision by the High Court of Delhi in a case from March 2008 (*F. HOFFMANN-LA ROCHE LTD., and ANR. V. CIPLA LIMITED*).¹⁰⁷ In this case, the plaintiff sought a provisional injunction to restrain the defendant from manufacturing, offering for sale, selling, and exporting the drug *Erlotinib* for which the plaintiff held a patent.

Among other considerations, the court considered ‘the two competing public interests, that is, the public interest in granting an 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.’ In noting that, ‘for good reason, the courts have refused to permanently enjoin activities that would injure the public health’, it ruled that the balance has to be tilted in favour of the alleged infringer:

...the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are uncompensatable [sic]....

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 [sic], it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted'.¹⁰⁸

Interlocutory injunctions in patent litigation are very difficult to obtain in developed countries, given the burden imposed on the applicant of an interlocutory injunction in patent litigation. This is particularly true in the case of alleged infringement of chemical patents¹⁰⁹ where the need for expert advice is almost inexcusable. In France, for instance, interlocutory injunctions were granted in only 19 out of 6,000 patent lawsuits between 1984 and 2004.¹¹⁰ In Germany, only a few courts have granted preliminary injunctions without oral hearings with both parties' participation.¹¹¹ Similarly, in the US, the bar to obtain such injunctions is very high. Here,

the judge needs to consider the following factors:

- Reasonable likelihood of prevailing if the validity of the patent were challenged;
- Irreparable harm (it is not irreparable if an economic compensation may be obtained) ;
- Proportionality (harm caused to right holder higher than harm caused to alleged infringer if measure were wrongly granted);
- Reasonable likelihood that infringement exists;
- Impact on the public interest.¹¹²

In sum, provisional measures that may have a direct and immediate effect on competition should only be granted exceptionally and after both parties have been heard, particularly in the case of alleged patent infringement. As the experience of developed countries demonstrates, courts have been extremely cautious in this matter. Developing countries should follow the same approach and take with reservation demands for strengthening provisional measures beyond what is necessary to keep a fair balance between the parties and protect the public interest. Allegations about mistrust in the judicial systems and weak structures in developing countries do not justify stricter rules than those applicable in developed countries themselves.

6. PERMANENT INJUNCTIONS

Paragraph 1 of Article 44 (injunctions) of the TRIPS Agreement states that ‘[T]he judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods...’

This provision reflects the long standing national practice of preventing the use of a subject matter after determination that an infringement has occurred. This rule is a corollary of the exclusive rights conferred on the title holder. Paradoxically, in the US - a champion for the adoption of stringent enforcement rules worldwide- this rule has been substantially mitigated by courts.

In a landmark decision by the US Supreme Court (*eBAY INC. et al v. MERCEXCHANGE*),¹¹³ a permanent injunction in a case of patent infringement was denied, thereby changing the judicial practice of automatically granting such an injunction once a *prima facie* case of infringement was established. The court stated that ‘the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts.’ This decision effectively opened the possibility for the courts to allow the continuous use, on ‘equity’ grounds, of infringed patents against payment of a compensation.

The eBay doctrine has immediately influenced subsequent lower level court decisions. A US District Court jury in Boston in October 2007 found that three patents on Amgen’s anemia drugs were valid and infringed by ‘Mircera’ commercialized by Roche Holding AG. But the US District Judge William Young declined to issue a permanent injunction and instead opted for imposing a compulsory license allowing Roche to launch its drug. The argument was essentially that it would not be in the public interest to ban ‘Mircera’ sales. Roche agreed to benefit from such compulsory

license against payment of a royalty to Amgen.

There is yet another case that shows how this court-made policy may favor large companies vis-à-vis small inventors. Carlos Armando Amado from Guatemala obtained US Patent 5,293,615 covering a ‘point and shoot interface for linking database records to spreadsheets whereby data of a record is automatically reformatted and loaded upon issuance of a recalculation command.’

Amado sued Microsoft, successfully arguing patent infringement. He asked for a license of 2 USD for every copy of Microsoft Office. Microsoft, however, asked a federal court in California to grant a compulsory license on the patent, at a much lower royalty rate. The judge gave Microsoft a compulsory license with a royalty of 0.12 USD per copy of MS Office. On 26 February 2008, the US Court of Appeals for the Federal Circuit agreed the compulsory license was appropriate and asked the district court to reconsider the royalty amount.

Yet in another case in January 2008, the Court of Appeals of the Federal Circuit decided to grant a compulsory license for Innogenetics’s patents for the hepatitis C virus (HCV) in favour of the US pharmaceutical company Abbott, which was found to infringe those patents.¹¹⁴

As these cases indicate, US courts are flexible in dealing with patent infringement consequences. Based on their own judgment about equity, US courts may grant compulsory licenses with regard to any patent, including in cases (as illustrated by *Amado v. Microsoft*) where purely commercial interests are at stake and no considerations about public interests or exceptional circumstances may be alleged. This policy amounts, in practice, to a judicially- administered liability regime that allows the third parties’ use of innovations against a remuneration.¹¹⁵ Paradoxically, developing countries are consistently required to apply stricter standards.¹¹⁶

7. BORDER MEASURES

Much of the current debates surrounding IP enforcement refer to border measures: that is, measures that may be adopted by customs authorities or courts to control the movement of infringing goods through one country's territory borders. Over the last ten years, developed

country governments and industries have strongly advocated for broad border measures as essential to prevent IP infringement. However, the obligation imposed on WTO Members by Article 51 of the TRIPS Agreement (see Box 3) is subject to various important limitations.¹¹⁷

Box 3. *Border Measures under the TRIPS Agreement*

Article 51

Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures¹³ to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods¹⁴ may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

Footnote 13:

It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

Footnote 14: For the purposes of this Agreement:

(a) «counterfeit trademark goods» shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

(b) «pirated copyright goods» shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

First, the intervention of customs authorities is required regarding the *importation* of goods only. Members *may* also provide for corresponding procedures for infringing goods destined for exportation, as well as for products in transit.¹¹⁸ However, these would be TRIPS-plus requirements that are not obligatory for WTO members.

Second, Article 51 applies to only two particular types of IPRs infringements:

1. Counterfeit trademark: that is, cases where a mark used without authorization of its owner is identical or substantially indistinguishable from a genuine mark. As

noted above, it does not include cases of trademarks that may be found confusing with other protected trademarks.¹¹⁹

2. Pirated copyright goods, as defined in footnote 14(b) of Article 51, which refers to infringing *copies* of a work.¹²⁰ This expression does not cover cases of plagiarism where, for instance, verbal passages of a work are copied without acknowledgement.¹²¹

Third, while under Article 51 the provisional suspension of the release of goods may be decided by customs authorities, WTO members can require the intervention of a judicial authority.

Fourth, there is no obligation under Article 51 that requires or empowers custom authorities to adopt provisional measures *ex officio*. National laws may establish that an order by a judge is needed for the custom authority to detain suspected goods.

Fifth, the commented TRIPS provision does not apply to other types of IPRs, such as patents. This differentiation is crucial. Whereas trademark counterfeiting and copyright piracy may be easily established through visual inspection, it is extremely difficult to determine whether an infringement of a product or process patent, even if literal,¹²² has taken place without appropriate testing or producing other evidence, and without technical and legal expertise. For instance, without proper research or experimentation custom authorities cannot possibly establish whether an imported pharmaceutical active ingredient infringes a patent covering a particular process for manufacturing it, or whether a patent covering a gene construct used in plants is violated by the importation of grains or a derivative product from such plants.

In sum, Article 51 of the TRIPS Agreement leaves considerable room for WTO Members to determine how they control IP infringements at the border. This is confirmed by the diversity of existing regulations on the matter.¹²³ Given the burden that the application of broad border measures would put on customs and other competent authorities, many WTO Members limit them to the situations delineated by Article 51 of the TRIPS Agreement. However, many developed countries do extend such measures beyond the TRIPS' requirements.

In some jurisdictions, border measures are applied to patents and other IPRs. In the US, for instance, the International Trade Commission commonly issues broad injunctions or import restrictions that prohibit unlicensed entry of products that infringe certain patents.¹²⁴ Likewise, in accordance with the European Council Regulation (EC) No. 1383/2003 of 22 July 2003 'concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights' (Customs Regulation), the customs authorities may provisionally

suspend the release of the goods or detain them even before an application has been lodged by a right holder, if such authorities have 'sufficient grounds for suspecting that goods infringe an intellectual property right' (Article 4). In addition to trademark counterfeiting and copyright piracy, this rule applies to the infringement of patents¹²⁵ and supplementary protection certificates¹²⁶, national plant variety rights, designations of origin, and geographical indications and designations.

Developed country governments and industry (notably the pharmaceutical industry) are actively seeking to induce changes in border measures in developing countries beyond what is required under the TRIPS Agreement. For instance, the European Commission has suggested an enhancement of the TRIPS rules in this regard.¹²⁷ The Commission has entered into a number of 'customs cooperation agreements' with countries like India and China that include training and sharing of the European 'experience and methods', which build on the existing TRIPS requirements and extend the control of imports to exports and goods in transit.¹²⁸

Further, in the referred Joint Communication to the Council for TRIPS, the European Communities, Japan, Switzerland, and the US invited other WTO Members to engage 'in a constructive discussion of how to implement the enforcement provisions of TRIPS in a more effective manner' and 'in a constructive discussion of accompanying measures which could enhance the effectiveness of national implementing legislation and enforcement efforts, such as for example promoting interagency co-operation, fostering a higher public awareness, and reinforcing institutional frameworks.'¹²⁹

The push for an expansive application of border measures has now advanced to the World Customs Organisation (WCO), which, going beyond the organization's mandate, is recommending far-reaching IPRs standards. WCO has promoted the adoption of Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE), which include a number of TRIPS-plus standards on the matter (see Table 1).

Table 1. Comparison of SECURE and TRIPS Provisions

SECURE	Issue	TRIPS Agreement	Comments
Standard 1	Scope	Article 51	Extends the scope from import to ‘export, transit, warehouses, transshipment, free zones, duty free shops, etc.’
Standard 2	Definitions	Article 51	Extends the protection from trademark and copyright to all other types of intellectual property rights
Standard 3	Procedures	Article 51	Extends the procedure from ‘suspension of the release of goods’ to other types of procedures
Standard 4	Application and right of Information	Articles 52, 57	It is unclear what defines ‘costs to right holders’ and there is no justification for why the costs to right holders should be reduced; Removes the obligations of right holders to provide adequate evidence to satisfy the competent authorities that there is <i>prima facie</i> an infringement to initiate the procedure.
Standard 5	Central Office	Article 41	A single contact point governing applications should be designated by Customs authority, which imposes an additional burden. Under Article 41 (5) of the TRIPS Agreements, however, WTO Members are not obliged with respect to the distribution of limited resources as between enforcement of IPR and the enforcement of law in general.
Standard 6	<i>de minimis</i> import	Article 60	Establishes a principle that the quantities of exempted goods should be ‘as low as possible.’
Standard 7	Ex Officio	Article 58	Expands the right of customs authority to take action upon their own initiatives, but it removes the obligations from remedial measures when they did not act in good faith; Specifies the right of right holders to make requests, but the importers’ minimum right of prompt and properly notification is shrunk
Standard 8	Application	Article 52, 58	Reversed the burden to provide evidence from the right holder to customs administration. Under TRIPS, it is the obligation of the right holder to provide evidence and satisfy the customs authority to make determination. To satisfy, two evidences should be provided, (a) a <i>prima facie</i> infringement of an IPR under the laws of the country of importation; and (b) a sufficiently detailed description of the goods to enable customs authorities to identify the goods in question.
Standard 9	Notification	Article 54	Under TRIPS, the importer and the applicant shall be promptly notified of the suspension of the release of goods; Under SECURE, no safeguard is available for importers regarding the right of notification of suspension and detention.

Standard 10	Remedies	Article 59	Under TRIPS, (a) It is the authority of the judicial body, rather than customs administration to dispose or destroy the infringing goods; (b) It is the decision of the competent body to determine either destruction or disposal of infringing goods; (c) It establishes the procedure that any order to destroy or dispose of the goods is subject to a right of review by the importer or other defendant and without prejudice to the right-holders' rights of action. Under Standard 10, it (a) expands the authority of customs administration; and (b) it regulates that all infringing goods should be destructed.
Standard 11	Disposal	Article 51	Under SECURE, the customs administration has authority to detail, move, or seize IPR infringing goods while specifying that the burdens of fee should not be unreasonable on rights holders, no security on other stakeholders.
Standard 12	Criminal procedure	Article 61	Under TRIPS, Members shall provide for criminal procedurals and penalties for trademark counterfeiting and copyright piracy on a commercial scale; Under SECURE, custom administration has legal authority to impose deterrent penalties against entities knowingly involved in the importation/exportation of goods under custom's control that violate any IPR laws.

Source: Xuan Li (2008), *SECURE: A Critical Analysis and Call for Action*, SOUTH BULLETIN. Reflections and Foresights, 16 May 2008, Issue 15. Available at <http://www.southcentre.org>

A number of custom authorities from developing countries¹³⁰ expressed their intention to implement the WCO SECURE IPR Program standards proposed by SECURE before its formal approval.¹³¹ While some of those countries have already accepted TRIPS-plus standards on border measures in the context of FTAs,¹³² others have opposed TRIPS-plus standards and resisted the attempts by developed countries to introduce the issue of enforcement for debate at the Council for TRIPS. This is another example of the lack of internal coordination within developing countries that leads to substantial inconsistencies in negotiations regarding IPRs.¹³³

WCO has also elaborated 'Model provisions for national legislation to implement fair and effective border measures consistent with the agreement on trade-related aspects of intellectual property rights.'¹³⁴ The purpose of these 'model provisions' is:

[T]o provide national authorities in charge of the preparation and modernisation of customs and/or intellectual property legislation worldwide with recommendations

for the implementation of border measures for the protection of intellectual property rights. This guide is intended both for authorities that are introducing border measures for the enforcement of intellectual property rights (IPR) for the first time as well as for those that are conducting or considering legislative reviews or reforms.

The WCO model provisions are deliberately aimed at surpassing the TRIPS standards. WCO argues that:

The experience of customs administrations in numerous countries has indicated, however, that only by granting certain powers and measures that go beyond the minimum requirements set forth in the TRIPs Agreement, Governments can provide an effective and efficient level of IPR protection and enforcement at their borders.¹³⁵

One of the premises of the 'model provisions' is that:

[T]he holders of intellectual property rights have the primary responsibility to take measures

to protect their rights...However, Governments have recognised that it is in the public interest that customs authorities have the power, in appropriate cases, to assume an active role and take action on their own initiative in cases involving counterfeiting and piracy.

On the basis of this premise, the ‘model provisions’ promote the adoption of border measures *ex-officio*, which are not required by the TRIPS Agreement. In accordance with the proposed Article 9:

Customs shall, on its own initiative, suspend the clearance of goods in respect of which it has acquired prima facie evidence that an intellectual property right has been infringed or is about to be infringed or that the goods are protection-defeating devices. Customs may, on its own initiative, also suspend the clearance of goods whenever there are reasonable grounds to suspect that the goods are infringing goods or protection-defeating devices.

The increased adoption of *ex-officio* measures is one of the main elements in the current move towards higher levels of enforcement promoted by developed countries. *Ex-officio* interventions, however, shift the responsibility for damages to the state and should be limited to very exceptional situations in which there is a justification to provisionally substitute the right holder in defence of his private rights.

In addition, the WCO discourages the intervention of courts in the adoption of border measures and suggests empowering custom authorities to take direct action:

[I]n some countries applications for border seizures are dealt with by the courts. However, practical experience has shown that authorising customs to deal with this task ensures that the applications are processed in a fair and effective manner without unnecessary burdening the courts. Naturally the decisions by the customs should be subject to a judicial review by administrative or civil courts.¹³⁶

Another premise of the WCO proposal is that border measures should apply to goods infringing IPRs whether they are imported, destined for exportation or re-exportation, or in transit. As noted, the TRIPS Agreement only obliges the application of such measures to imported goods.

The ‘model provisions’ are also clearly TRIPS-plus with regard to the coverage of border measures. While, as mentioned, Article 51 of the TRIPS Agreement only applies to trademark counterfeiting and copyright piracy, such provisions would apply in relation to *any* kind of IPRs ‘as defined in the national law.’¹³⁷ In accordance with the definition proposed by the WCO:

Goods Infringing Intellectual Property Rights shall mean:

Any goods which are made, reproduced, put into circulation or otherwise used in breach of the intellectual property laws and without the consent of the right holder or a person duly authorized to do so by the right holder. If such making, reproduction, use or putting into circulation of the goods took place outside [the country] the goods are deemed to be infringing if the acts would have constituted an infringement in [the country] had they been undertaken in the country.

For the purposes of this law goods protected with copyright or related rights with respect to which the rights management information they may incorporate has been removed, altered, or added without the right holders. authorisation shall be deemed to be goods infringing the said intellectual property rights.¹³⁸

The WCO model provision not only significantly expands the scope of border measures but may prevent a legitimate acquirer to parallel import goods, as it seems to preclude the applicability of the principle of international exhaustion.¹³⁹ In effect, the proposed model provision would deem the goods to be infringing ‘if the acts would have constituted an infringement’ in the importing country, had they been undertaken in that country,

as is the case when parallel imports occur.¹⁴⁰ Parallel imported products are genuine and display a genuine trademark used with the permission of the trademark owner. The only difference with the non-parallel trade is that products have been imported outside the trademark holder's authorized distribution channel.

Moreover, the WCO model provision incorporates the removal or alteration of 'rights management information' as a modality of infringement of copyright and related rights. Again, this is not a TRIPS requirement.¹⁴¹ Similarly, copyright protection-defeating devices are subject to *ex*

officio detainment irrespective of the legitimacy or their intended use.¹⁴²

One basic rule in the TRIPS Agreement is that enforcement procedures should be applied 'in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse' (Article 41.1) and should 'be fair and equitable' (Article 41.2). The balance and protection of public interest must, therefore, guide the elaboration and application of such procedures. As a strong bias in favour of right holders is apparent, the WCO model provisions do not seem to comply with these standards.

8. SPECIAL UNITS AND COURTS

A permanent demand of right holders associations and developed country governments is that developing countries establish special units/ task forces in national administrations or special judicial courts to deal with IPRs infringement. Although the activities of such bodies would primarily benefit right holders, they would have to be funded by developing countries' public monies. The sophistication and cost of the means necessary to deter IPRs infringement are significant and may well exceed the tax income eventually generated by legitimate activities that would have been otherwise displaced.¹⁴³ Demands for higher investment in IPRs enforcement tend to put IPRs violations at the same level of other crimes that cause tremendous economic and social disruptions in some developing countries.¹⁴⁴ In fact, for many developing countries, the protection and enforcement of IPRs 'is not, nor should it be, a national priority. Financial resources are better invested in public infrastructure projects, such as water purification and power generation'.¹⁴⁵

Upon insistence from developing countries during the Uruguay Round negotiations, the adopted Article 41.5 of the TRIPS Agreement states that:

It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

However, many developing countries have set up administrative or judicial bodies to deal with this subject. For instance, Brazil established the National Anti-Piracy Council (CNCP) under the coordination of the Federal Ministry of Justice, with public and private sector representatives. In China, the No 3 Civil Tribunal Supreme People's Court of the People Republic of China was formed and special divisions in high courts were introduced to deal with IP matters.¹⁴⁶ Dedicated IP enforcement courts have also been created in several developing countries, such as Chile, Malaysia, and the Philippines.¹⁴⁷

While the establishment of specialized IP courts may have advantages in terms of the capacity to address complex IP matters, there are also some risks. The creation in the US of the Court of Appeals for the Federal Circuit specialized in IP, for instance, is broadly seen as one of the main factors behind the proliferation of low quality patents in that country.¹⁴⁸ Although the recent decision by the US Supreme Court in *KSR International Co. v. Teleflex, Inc*¹⁴⁹ may require the USPTO and lower courts to tighten-up the assessment of the non-obviousness requirement, the extent to which this case may revert the lax assessment of patentability standards that has characterized the Court of Appeals' decisions¹⁵⁰ is still uncertain. Improvements in the implementation of existing enforcement rules may be achieved, without the creation of special IP courts, through appropriate training of judges in IP matters still operating within the general judicial system. Such training, however, should be done in accordance with the national laws and account for domestic interests and conditions. Training offered by developed country governments and the private sector may unduly bias future judicial decisions in favour of rights holders.¹⁵¹

9. COUNTERFEITING AND HEALTH RISKS

The case of counterfeit medicines and other products that may create risks to the public health or the environment is worth particular consideration. Demands for broader and more effective IP enforcement measures have often been made by some governments and industries on grounds related to health and safety concerns. For instance, PhRMA's President and CEO stated in responding to the USTR 2007 Special 301 Report:

I am especially pleased that the USTR highlighted the importance of battling dangerous and potentially lethal counterfeit medicines throughout the world, especially in China, India, and Russia. Patients around the world deserve confidence that the medicines they purchase are safe and effective and not dangerous counterfeit medicines sold by shady businesses and individuals. These countries need to take concrete steps to address this problem and strengthen IP regimes. Addressing the lack of regulation of active pharmaceutical ingredient (API) in China is critical to these efforts.¹⁵²

In the same vein, the European Community, Japan, Switzerland, and the United States argued in the referred to Joint Communication to the Council for TRIPS that:

It is clear that global counterfeiting and piracy activity is expanding rapidly. This activity is increasingly sophisticated, in part due to the development and wider availability of new technologies...This activity has harmful effects on society as a whole: it puts at risk public health and safety, threatens legitimate commerce, and entails loss of jobs and government tax revenues. This activity is also often linked to organized crime and other types of crimes.¹⁵³

In accordance with these statements, the problem of counterfeiting is directly linked to the implementation of IP regimes. However, the terms 'counterfeiting', 'piracy' and 'product falsification' are often misused. The World

Health Organization (WHO) defines a "counterfeit medicine" as one 'which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.'¹⁵⁴ Thus, counterfeiting may exist without infringement of IPRs, for instance, when a medicine is sold under an International Non-proprietary Name (INN) without improper use of a trademark or trade name.

Counterfeiting in medicines may take place 'regardless of whether the product bears a counterfeit trademark or is substandard in any respect.'¹⁵⁵ In most cases, counterfeit medicines lack the required active ingredients or are otherwise of inferior quality¹⁵⁶ and may pose a significant health risk to patients.

Counterfeiting in medicines, as well as in other products, takes place both in developed and developing countries.¹⁵⁷ The fight against such counterfeiting has been actively undertaken in many developing countries. For instance, the Philippines has been praised by PhRMA and its member companies because of 'improvements in anti-counterfeiting activities. The Philippine Government has conducted a number of high-profile activities, including partnering with the industry to raise awareness of the dangers associated with counterfeit drugs; increased law enforcement raids of counterfeit drug sites; and, the successful prosecution of a drug counterfeiter resulting in a substantial prison sentence.'¹⁵⁸

The debates about counterfeiting in medicines are often obscured by the inappropriate use of the concept of 'counterfeiting' or 'piracy' to describe situations in which legitimate generic versions of medicines are introduced without the consent of the originator of the drug. For instance, in many countries where, consistent with the TRIPS Agreement, governments do not

grant 'data exclusivity' (i.e. exclusive rights for the originators of test data), pharmaceutical companies have argued that the generic versions of their products are 'pirated.' The same confusion has been common in countries that did not grant patent protection for pharmaceuticals before they were obliged to do so under the TRIPS Agreement.¹⁵⁹ Even when a drug is manufactured and sold by a company without the consent of the patent holder, if it contains the required

quantity and quality of ingredients, there might be a case of patent infringement but it is not a 'counterfeit' or 'fake' drug.

Based on reports received by WHO between January 1999 and October 2000 from twenty developing and developed countries, the 'copies' of an original product only accounted for 1 per cent of the counterfeit products (see Table 2).

Table 2. Counterfeiting of Medicines reported to WHO between January 1999 and October 2000 from twenty countries

Type of counterfeit	Percentage
Products without active ingredients	32.1
Products with incorrect quantities of active ingredients	20.2
Products with wrong ingredients	21.4
Products with correct quantities of active ingredients but with fake packaging	15.6
Copies of an original product	1
Products with high levels of impurities and contaminants	8.5

Source: <http://www.who.int/medicines/services/counterfeit/overview/en/>

As shown in Table 2, in the overwhelming majority of cases of drug counterfeiting, there is no 'copy' of an original product. The main IPRs affected by counterfeiting are trademarks and trade names. Patents protecting particular active ingredients or formulations are in most cases not violated, since the counterfeit products only exceptionally reproduce the original products.

Hence, the most important challenge posed by counterfeit medicines is not IP infringement, but the health risks created for patients by adulterated products. The main concern in combating drug counterfeiting should not be, as suggested in the statements quoted above, to protect private IPRs but the right of the public not to be deceived about the characteristics or source of a product.

Moreover, increasing IP protection and enforcement would not solve the serious problems deriving from the alteration in the

content of products. The actions needed essentially belong to the general category of criminal prosecution and depend on the strict application of drug regulations. For instance, the WHO recommends the following actions to fight drug counterfeiting:¹⁶⁰

- Enacting new drug laws or updating existing drug laws for prohibiting counterfeit medicines;
- Establishing institutions for the regulation of medicines and clearly setting out in the drug laws, the power, duties and responsibilities of the institution(s);
- Training of personnel, including enforcement officers, for national drug control;
- Making available necessary financial and other resources;
- Ensuring that the drug laws are enforced; and
- Fostering international cooperation in the control of pharmaceuticals and entering into bilateral and multilateral agreements with

other governments and with international organizations such as WHO, Interpol and the World Customs Organization (WCO).¹⁶¹

None of these measures specifically refer to IP enforcement. In fact, what is crucial for combating counterfeiting in medicines is the

appropriate design and implementation of drug regulations: that is, the set of rules that govern the marketing approval (subject to compliance with quality, safety, and efficacy standards) and commercialization of medicines, as suggested also by the Third Global Congress on Combating Counterfeiting and Piracy (see Box 4).

Box 4. Counterfeit Medicines: Recommendations of the Third Global Congress on Combating Counterfeiting and Piracy. Shared Challenges, Common Goals, Geneva, 30-31 January 2007

- Encourage governments to establish well-equipped and competent national drug regulatory authorities that will ensure control and regular inspection of entities involved in the manufacture, trade and distribution of pharmaceuticals.
- Encourage governments to establish legislation that the manufacture and distribution of counterfeit drugs are punishable as serious, potentially life-threatening crimes.
- Better coordinate, at the national, regional and international levels, preventive and investigative efforts by involving drug regulatory authorities, law enforcement agencies, manufacturers of pharmaceuticals, professional associations of medical practitioners and pharmacists, as well as consumer protection groups, to strengthen concerted action against the manufacturing and distribution of counterfeit pharmaceuticals.
- Establish strict regulations for licensing wholesalers to ensure maximum control of legitimate supply chains of pharmaceuticals, car parts and other sensitive merchandises.
- Monitor the Internet and take action whenever possible and appropriate to discourage the distribution of fake pharmaceuticals, as well as the illegal supply of narcotic drugs.
- Support international authorities such as the International Narcotics Control Board (INCB) in developing guidelines for governments to counteract the spread of illegally operating Internet pharmacies.
- Liaise with enforcement agencies working against fake narcotic drugs to explore synergies and disclose links between the manufacturing and distribution of counterfeit pharmaceuticals on the one hand, and that of fake narcotic drugs on the other.
- Raise awareness among consumers on the dramatic level of health and safety risks resulting from the use of counterfeit drugs, fake car parts or electric or electronic devices.
- Encourage companies to improve the packaging of pharmaceuticals to make counterfeiting more difficult.
- Further strengthen cooperation between all stakeholders involved in the fight against counterfeit drugs, including supporting the work of the WHO International Medical Products Anti- Counterfeiting Taskforce (IMPACT).
- Support the further collection and updating of data to continue to assess the full extent of health and safety risks for consumers from counterfeiting and then assist in communicating this information to policy-makers, law enforcement agencies, and the public.
- Intensify training of law enforcement authorities, especially customs administrations, that focus on counterfeit products posing health and safety risks.

Source: <http://www.ccapcongress.net/archives/Geneva/Geneva.htm>.

A process of harmonization of drug regulations has been carried out by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

However, the core members are the research-based industry and developed country regulators. The applicability and relevance of each and every ICH standard to the needs of the developing world is questionable.¹⁶²

10. TRIPS-PLUS ENFORCEMENT IN FTAS AND WTO ACCESSION

While at the multilateral level the enforcement offensive by developed countries has yet to deliver concrete outcomes in terms of international rules,¹⁶³ the US and the EU are obtaining tangible results at the bilateral level.

A salient feature of the FTAs signed by the USA since year 2000¹⁶⁴ is the inclusion, as part of extensive IP chapters, of a set of detailed TRIPS-plus requirements in the area of enforcement: the volume of the new regulations introduced under the FTAs is such that they may force state partners to reallocate resources in order to enforce intellectual property rights. In fact, 'FTAs themselves declare that the choices that countries make in distributing resources shall not be an excuse for failure to comply with IPRs chapters.'¹⁶⁵

The TRIPS-plus standards include, *inter alia*, limitations to the liability of service providers, the obligation to consider as infringing even acts made in good faith, a series of legal presumptions, border and provisional measures (including *ex-officio*) broader than those available under the TRIPS Agreement, expanded criminal procedures, new modalities for calculating damages (on the basis of the retail price of the infringed product), destruction of infringing goods, and the partner state's obligations to make available enforcement statistics and to publicize efforts to enforce IPRs.¹⁶⁶

The EU has also started to harvest some fruits from its enforcement policy for third countries. The Economic Partnership Agreement (EPA) concluded between the EU and the CARIFORUM States (excluding Haiti) in December 2007 and signed in October 2008, includes a variety of TRIPS-plus enforcement obligations namely regarding entitled applicants, evidence, measures for preserving evidence, right of information, provisional and precautionary measures, corrective measures, injunctions, alternative measures, damages, legal costs, publication of judicial decisions, and border measures.¹⁶⁷

While the European Commission seems to apply the same IPRs template to negotiate other agreements with developing countries, at least in the case of the Andean Community, the EU's proposal also includes the obligation to criminalize intentional infringements of any kind of IPR on a commercial scale. Paradoxically, the European Commission is demanding from these countries a higher standard than that domestically deemed acceptable in the EU context.¹⁶⁸ As mentioned above, criminalization was rejected by the European Parliament for patents and other modalities of IPRs.¹⁶⁹

The FTAs signed by EFTA with developing countries also contains commitments relating to IPRs enforcement, but formulated in general terms. For instance, the FTAs signed with Chile, Egypt, Jordan, and Mexico, states that '[T]he Parties shall provide for enforcement provisions under their national laws of the same level as that provided in the TRIPS Agreement, in particular Articles 41 to 61.'¹⁷⁰

The TRIPS-plus enforcement standards add to the substantive standards that the US FTAs and the EPAs contain. Even in cases where no TRIPS-plus substantive standards are incorporated, such as in the case of patents in the EU-CARIFORUM EPA,¹⁷¹ the enhanced enforcement rules increase the right holders' power to exercise their rights. They may, in particular, use that power to exclude competitors from the market through provisional measures until a final decision is made.¹⁷²

Finally, WTO accession processes have also allowed developed countries to introduce TRIPS-plus enforcement standards among the commitments made by the acceding countries. They have included, notably, the extension of criminal sanctions for IPRs other than trademarks and copyright and the expansion of the scope of border measures,¹⁷³ thereby confirming the strategic importance attributed to these measures by developed countries.

11. CONCLUSIONS AND RECOMMENDATIONS

The strengthening and expansion of IP enforcement rules enhance the power that right holders may exercise against third parties. If such rules do not contain the adequate check and balances, competition may be distorted both in technology markets and in the markets for goods and services. Moreover, the type and level of IPRs enforcement should be in correspondence to the levels of development of the countries where such rights are exercised.

Part III of the TRIPS Agreement established a detailed set of enforcement provisions, under the concept that the availability of IP protection must be accompanied with measures to make effective the granted rights. The Agreement did not require the harmonization of enforcement rules. It left considerable space for the national laws to determine how to achieve the objectives set forth in the various provisions of the Agreement. The current offensive to expand, both domestically and internationally, the rules applicable to the enforcement of IPRs, aims at drastically limiting such a policy space.

One of the main arguments for the demand of TRIPS-plus enforcement rules is the need to combat acts of counterfeiting and piracy. Although the merits of curbing counterfeiting and piracy are clear—and many developing countries have taken important steps to curb such activity—a significant confusion has been created around the types of acts to be condemned. Although *trademark* counterfeiting and *copyright* piracy are very specific types of infringement, there seems to be an attempt to extend the rules applicable to them (particularly, criminal sanctions and *ex-officio* intervention) to other forms of IPRs infringements. This ignores the nature of various IPRs and the modalities that infringement may assume, and it generates the risk of over protection and abuses, notably in the case of patents (the validity of which may not be automatically presumed).

Another important argument articulated to sustain the demand for higher enforcement standards is that they will benefit all countries, including developing countries, *inter alia*, via increased tax income, jobs, and foreign direct investment. There is no evidence, however, to support these assumptions. While it may benefit a selected group of individuals or innovative domestic companies, tightened measures against IPRs

violations are in the primary interest of right holders in developed countries, who control the vast majority of IP-protected intellectual assets worldwide. Enforcement rules generate costs for developing countries that may not be compensated by the alleged benefits. In fact, costs may off-set benefits, especially when the states are required to substitute right holders in the defence of their private rights and assume liabilities that correspond to the latter.

In addition, developing countries' economies will be disadvantaged by the application of standards that discourage potential competitors from undertaking legitimate activities when there is a risk of facing long and costly litigation and substantial damages. Tight enforcement rules favour actions (often of a strategic nature) by undertakings with sufficient resources to engage in legal proceedings. Indeed, they may exclude from the market those who cannot bear the costs and uncertainty of such proceedings, as is generally the case with small and medium enterprises in developing countries. For instance, a small innovative company may be extremely reluctant to develop and commercialize a new product if there is the risk of lawsuits by patent holders that may argue, albeit without justification, that their rights are infringed. An unintended effect of higher enforcement standards may be, however, an inducement for local governments and companies to adopt open source technologies whenever available.

Therefore, applying TRIPS-plus standards in developing countries, like those imposed through FTAs and EPAs, may reduce the chances for local innovation and for the emergence of local competition. The outcome may be higher concentration, less jobs and value added, and less innovation.

Confusion also often exists about the role that IP enforcement may play in combating counterfeit medicines and preventing the health risks that the latter may create. A counterfeit drug is one which does not contain active ingredients, or which contains an insufficient quantity of or an entirely incorrect active ingredient. Infringement of IPRs may or may not occur when counterfeit drugs are commercialized. The enforcement of such rights, therefore, is not the principal means that states should apply to fight that illicit activity. In addition,

it is inappropriate to associate the concept of counterfeit medicines to generic versions sold in developing countries where pharmaceutical product patents or data exclusivity are not recognized.

Combating counterfeiting in medicines is an important responsibility of governments. They would be grossly misled, however, if they were induced to focus their actions in the area of IP enforcement. The implementation of drug regulations is of primary importance. IP enforcement, particularly against trademark infringement, may complement, but cannot substitute, actions that need to be taken in non-IP fields. Thus, international cooperation may be enhanced in order to address safety in the international trade of medicines (as well as in foodstuffs and chemical products) through the joint action of the WTO, WHO, and FAO.

In the light of the previous analysis, the following recommendations can be made in relation to the design and implementation of enforcement standards in developing countries:

- Enforcement rules should be adapted to the conditions and needs of the country, consistent with the requirements of the TRIPS Agreement;
- Such rules should not constitute, in particular, a threat to local competitors nor deter local innovative initiatives;
- Criminal sanctions should be provided, as required by the TRIPS Agreement, against trademark counterfeiting and copyright piracy, but excluded for other types of infringement that may be addressed through civil remedies;
- Courts and administrative bodies (including customs authorities) should not substitute right holders in the exercise and defence of their IPRs; actions should be taken, when appropriate, upon request of the right holder;
- Provisional measures should be applied with caution, particularly in cases of alleged patent infringement, only when a likelihood of infringement and an irreparable harm (when damages would not be an adequate remedy) are shown;
- Only exceptionally provisional measures should be granted *inaudita altera parte*;
- Border measures should be limited to the importation of goods in cases of trademark counterfeiting and copyright piracy, as required by the TRIPS Agreement;
- Border measures should be preferably ordered by a judicial authority expeditiously but upon *prima facie* confirmation of counterfeiting or piracy of imported goods;
- IPRs enforcement need not be given priority over other law enforcement functions;
- Enforcement costs should be borne by their direct beneficiaries; in particular, the level of registration fees should take into account enforcement-related costs;
- The fight against counterfeit medicines should be addressed through drug regulations and other appropriate mechanisms; IP enforcement may play a complementary role but should not be seen as the primary instrument or as a substitute for actions needed in other fields;
- TRIPS-plus enforcement standards should be avoided in the negotiation of FTAs and EPAs, as compliance with the TRIPS Agreement already provides a strong framework for the exercise and defence of IPRs;
- New cooperation modalities among international agencies, such as the WTO, WHO, and FAO, should be explored in order to address safety issues in international trade;
- When technical assistance on enforcement is provided by WIPO, it should be supplied in accordance with recommendation 45 of the WIPO Development Agenda; a similar approach should be applied by other providers of technical assistance to developing countries;
- Developing countries should collect information about domestic enforcement of IPRs, identify possible abuses, and develop a framework to inform other WTO members, when required in accordance with the procedures of the Council for TRIPS, about the measures they have adopted in compliance with the TRIPS standards;
- Coordination between different areas of government, including customs authorities, should be improved in order to consistently deal with enforcement issues in different international fora; and
- Custom and competition authorities, the private sector, and the judiciary should be made aware of the implications of abuses of enforcement rules and of TRIPS-plus standards.

ENDNOTES

- 1 Large companies in the pharmaceutical and in the software, film, and music industries, are the principal actors behind the present IPRs enforcement offensive in developing countries. See, with regard to the music industry, S. Liebowitz and R. Watt (2007), How to best ensure remuneration for creators in the market for music? Copyright and its alternatives, in M. McAleer and L. Oxley (2007), *Economic and legal issues in intellectual property*, Blackwell, p. 31-63.
- 2 In order to counter third countries' perceptions about who actually benefits from enhanced enforcement mechanisms, the European Commission has suggested to 'get across the message that effective enforcement of IP rights (even if these belong to third parties) is an essential tool to attract foreign investment and the transfer of technology and know how, as well as to protect local right-holders in developing and least-developed countries who are already suffering the misappropriation of their intellectual property...In the mid-to-long term, it will also encourage domestic authors, inventors and investors and contribute to the development of these countries' (European Commission Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries, available at http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_129/c_12920050526en00030016.pdf, p. 3, last visited, 10 March 2008).
- 3 See <http://www.uscib.org/index.asp?DocumentID=3492> (accessed 24 June 2008). BASCAP is an initiative of the International Chamber of Commerce.
- 4 OECD (2007), *The Economic Impact of Counterfeiting and Piracy*, DSTI/IND(2007)9/PART4/REV1, Paris, available at <http://www.oecd.org/dataoecd/11/38/38704571.pdf>, p. 3 (accessed 10 March 2008).
- 5 Idem, p. 3 and 13. See also Carsten Fink (forthcoming), *Enforcing intellectual property rights: an economic perspective*, ICTSD, Geneva.
- 6 S. Liebowitz and R. Watt (2007), op. cit., p. 37 (referring to the outcries of the record industry in the *IFPI Report on Piracy*, 2003).
- 7 Business Software Alliance Reports (2004, 2005, 2006) available at <http://w3.bsa.org/globalstudy> (accessed 10 March 2008).
- 8 Xuan Li (2008), Ten Common Misunderstandings about the Enforcement of Intellectual Property Rights, *South Bulletin Reflections and Foresights*, Issue 9, South Centre, p. 7.
- 9 Ibidem, based on *2006 Survey on Chinese Software Piracy Rate* commissioned by Chinese State Intellectual Property Office, available at <http://hot.techcn.com.cn/070514copy/bg.pdf> (accessed 10 March 2008).
- 10 See, e.g, John Dryden "Counting the Cost: The Economic Impacts of Counterfeiting and Piracy", Third Global Congress on Combating Counterfeiting and Piracy. (www.ccapcongress.net)
- 11 S. Liebowitz and R. Watt (2007), op. cit., p. 37.
- 12 Louis Harms (2007), *The enforcement of intellectual property rights by means of criminal sanctions: an assessment*, prepared for the WIPO Advisory Committee on Enforcement, WIPO/ACE/4/3, September 7, para. 16.

- 13 OECD, 2007, op. cit., p. 15. The argument relating to health and safety is examined in more detail below.
- 14 S. Liebowitz and R. Watt (2007), op. cit. p. 36. These authors further note that for the particular case of the market for music, ‘...the most likely scenario is that the groups of artists that are hardest hit (both in absolute and relative terms) by copyright infringement are those with super-star status and incomes. However, these individuals are likely to be earning large economic rents so the effect of lost dollars to these artists might have little impact on their creative works’ (Idem, p. 37).
- 15 See, e.g., Ronald Bettig, *Copyrighting Culture. The Political Economy of Intellectual Property*, Boulder: Westview Press, p. 13.
- 16 Harms, 2007, para. 21.
- 17 See, e.g., CPTech, ‘Access to knowledge’, available at <http://www.cptech.org/a2k/>. See also the the ‘Adelphi Charter on creativity, innovation and intellectual property’, available at www.adelphicharter.org.
- 18 S. Liebowitz and R. Watt (2007), op. cit., p. 36.
- 19 See <http://copyright.gov.in/maincpract9.asp>, quoted in Harms, 2007, op. cit. para. 23 (accessed 12 March 2008).
- 20 OECD (2007), op. cit. p. 6 .
- 21 The linkage with terrorism is highlighted, for instance, in the following statements: ‘The link between organized crime groups and counterfeit goods is well established. But INTERPOL is sounding the alarm that intellectual property crime is becoming the preferred method of funding for a number of terrorist groups’ (statement by INTERPOL Secretary General Ronald K. Noble, in ‘INTERPOL warns of link between counterfeiting and terrorism. Cites evidence that terrorists fund operations from proceeds’, available at <http://www.interpol.int/Public/ICPO/PressReleases/PR2003/PR200319.asp> (accessed 12 March 2008); ‘[A] growing concern in recent years is the increased involvement of criminal organisations and sometimes even of terrorist groups in major international trafficking of counterfeit and pirated goods’, European Commission, ‘Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries, Available at http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_129/c_12920050526en00030016.pdf. (accessed 10 March 2008).
- 22 There was an attempt at the GATT Tokyo Round by the US—supported by the European Communities—to establish a set of rules against counterfeiting, but it did not find support from other Contracting Parties. See, e.g., Bernard M. Hoekman and Michel M. Kostecki (2001), *The Political Economy of the World Trading System: The WTO and Beyond* (second edition), Oxford: Oxford University Press, p. 282.
- 23 There were a few precedents of enforcement provisions in pre-TRIPS treaties. For instance, Article 9 (1) of the Paris Convention established that all goods unlawfully bearing a trademark or trade name shall be seized on importation into those countries of the Union where such mark or trade name is entitled to legal protection. The same applies, in accordance to Article 10 (1)

of the Convention to cases of direct or indirect use of a false indication of the source of the goods or the identity of the producer, manufacturer, or merchant.

- 24 See, e.g, UNCTAD-ICTSD (2005), *Resource Book on TRIPS and Development*, New York: Cambridge University Press, p. 578.
- 25 The US and the European Union set up a coordination mechanism (US-EU Intellectual Property Working Group) to promote the protection of IPRs internationally. See The National Intellectual Property Law Enforcement Coordination Council (NIPLECC)(2008), *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, available at http://www.commerce.gov/opa/press/Secretary_Gutierrez/2006_Releases/September/2006%20IP%20report.pdf, p. 28 (accessed 15 March 2008).
- 26 The Council is composed of the following officials: the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office; the Assistant Attorney General, Criminal Division; the Under Secretary of State for Economic, Business, and Agricultural Affairs; a Deputy United States Trade Representative; the Commissioner of Customs; the Under Secretary of Commerce for International Trade; and in a consulting capacity, the Register of Copyrights. See <http://www.iipa.com/niplecc.html> (accessed 10 March 2008).
- 27 For instance, the Stop Counterfeiting in Manufactured Goods Act (March 2006) criminalized shipping of falsified labels or packaging that counterfeiters could attach to fake products. It also strengthened penalties for counterfeiters and gave prosecutors new tools. The US Attorney General transmitted to Congress in May 2007 the Intellectual Property Protection Act of 2007 (H.R. 2391), which includes a bundle of pending intellectual property bills. This Act would provide tougher sentences for counterfeiting crimes that threaten the public health and safety (up to 20 years imprisonment in some cases); strengthen the repeat-offender penalties against copyright criminals; implement stronger forfeiture and restitution provisions for certain IP crimes; criminalize the attempt to commit copyright infringement; clarify that registration of copyright is not a prerequisite to criminal prosecution; and ensure that the exportation and trans-shipment of pirated (copyright-infringing) goods violates criminal law. See NIPLECC (2008), op. cit., p. 78.
- 28 E.g., the US Patent and Trademark Office USPTO ‘intends to vastly expand its long distance training capabilities via the Internet and digital video conferencing. Through this new expanded training and technology, the office will be able to reach even more government officials and train them without bringing them to USPTO or conducting training within the country or region’, NIPLECC, (2008), op. cit., Appendices, p. 21.
- 29 NIPLECC (2008), op. cit., p. 24-25.
- 30 See http://trade.gov/press/publications/newsletters/ita_0406/stop_0406.asp (accessed 18 March 2008).
- 31 Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes, 23 October 2007, available at http://www.ustr.gov/Document_Library/Press_Releases/2007/October/Ambassador_Schwab_Announces_US_Will_Seek_New_Trade_Agreement_to_Fight_Fakes.html (accessed 18 March 2008).

- 32 NIPLECC (2008), op. cit., Appendices, p. 41.
- 33 Ibidem.
- 34 Idem, Appendices, p. 42 and 45.
- 35 Idem, Appendices, p. 81.
- 36 While Trade and Investment Framework Agreements (TIFAs) typically do not contain detailed IP provisions, ‘the TIFA discussions are a productive forum to discuss intellectual property. For instance, our TIFA dialogue helped persuade Taiwan to pass legislation to make peer-to-peer file sharing services illegal. Through our TIFA dialogue, we have also encouraged Taiwan to clamp down on counterfeit pharmaceuticals, leading to police shutting down 40 drug counterfeiting operations; pass legislation to create specialized IP courts; and create a task force to combat copyright infringement on university campuses’ (NIPLECC, 2008, op. cit. Appendices, p. 49).
- 37 Idem, Appendices, p. 51.
- 38 The vast majority of TRIPS related complaints submitted under the WTO Dispute Settlement Understanding has been initiated by the US, which is the most litigious Member under WTO agreements. See below the complaint against China relating to enforcement provisions in the TRIPS Agreement.
- 39 They include: International Intellectual Property Alliance, the Gorlin Group, Cisco Systems, Inc., the U.S.-China Business Council, Global Health Council, Anheuser-Busch Companies, Inc. , Merck & Co., Inc. , Biotechnology Industry Organization , Entertainment Software Association, CropLife America, Zippo Manufacturing Company, Recording Industry Association of America, IBM Corporation, Intellectual Property Owners Association, Motion Picture Association of America, Association of American Publishers, Inc., General Motors Corporation, Automotive Aftermarket Industry Association, National Paint & Coatings Association, Abbott Laboratories, Inc., Distilled Spirits Council of the United States, Inc., the Engineered Wood Association Public Policy , Software and Information Industry Association, Princeton Healthcare, Inc., and the Warnaco Group, Inc. Some of the members represent other ITACs. See http://www.ustr.gov/assets/Who_We_Are/Advisory_Committee_Lists/asset_upload_file786_5754.pdf.
- 40 In 2002, a GAO’s ‘report on the role, structure and operations of the trade advisory committee system (prepared at the request of the US Senate Committee on Finance) noted that at that time only two of USTR’s industry advisory committees ‘included non-business interests—in both instances as a result of legal challenges...While USTR took steps earlier this year [2004] to revise its Committee Structures in response to many of the GAO’s findings, the issue of greater non-business participation was left aside...[t]he Department of Commerce (DOC) maintains that the US Trade Act, as amended, allows the US President to ‘establish functional committees comprised solely of industry representatives’. The DOC argues that in the context of industry advisory committees, FACA [Federal Advisory Committee Act] ‘fair balance’ requirements call for a balance among industry points of view’ (Isabelle Scherer, 2004, USTR’s Advisory Committee on Intellectual Property Rights: Public Interest Groups Still Calling for a Voice, *Intellectual Property Watch*, available at <http://www.ip-watch.org/weblog/index.php?p=5>).
- 41 NIPLECC (2008), op. cit., Appendices, p.51.

- 42 Ibidem.
- 43 See Latha Jishnu (2008), *'Is the US style of examination right for India? Patently absurd*, New Delhi April 30, available at <http://commonslaw.freeflux.net/blog/archive/2008/04/> (accessed 20 June, 2008).
- 44 See http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/L_195/L_19520040602en00160025.pdf (accessed 18 March 2008).
- 45 Available at http://europa.eu.int/comm/taxation_customs/customs/counterfeit_piracy/files/counterfeit_en.pdf.
- 46 Available at. http://trade.ec.europa.eu/doclib/docs/2005/april/tradoc_122636.pdf (accessed 20 March 2008).
- 47 European Commission, *Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries*, op. cit., p. 15.
- 48 European Commission, *Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries*, available at http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_129/c_12920050526en00030016.pdf, p. 6 (last visited, 20 March 2008).
- 49 See some examples below.
- 50 Available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+MOTION+P6-RC-2006-0467+0+DOC+XML+V0//EN>.
- 51 Commission of the European Communities, *European Neighbourhood Policy Strategy Paper*, Brussels, 12.5.2004, COM(2004) 373 final, available at http://ec.europa.eu/world/enp/pdf/strategy/strategy_paper_en.pdf (accessed 20 June 2008).
- 52 See http://ec.europa.eu/world/enp/pdf/action_plans/egypt_enp_ap_final_en.pdf (accessed 20 June 2008).
- 53 See http://ec.europa.eu/world/enp/pdf/lebanon_enp_ap_final_en.pdf (accessed 20 June 2008).
- 54 See http://ec.europa.eu/world/enp/pdf/action_plans/morocco_enp_ap_final_en.pdf (accessed 20 June 2008).
- 55 See http://ec.europa.eu/world/enp/pdf/action_plans/tunisia_enp_ap_final_en.pdf (accessed 20 June 2008).
- 56 Such as the relationships between enforcement and privacy (in the case of copyright), enforcement and control of anticompetitive practices, enforcement and development, and between affordability and infringement. Consumer Project on Technology (CPTech) (2004), *Social Aspects of Enforcement of Intellectual Property Rights*, available at <http://lists.essential.org/pipermail/random-bits/2004-June/001201.html> (accessed 20 June 2008).
- 57 One of the main reasons why developed countries possibly brought to the TRIPS Council the

enforcement issue was developing countries' resistance against developing TRIPS-plus standards at WIPO's Advisory Committee on Enforcement. This Committee was created on the condition that norm setting would be excluded from its mandate.

- 58 See Intellectual Property Watch, 2005, 'TRIPS Council Issues Still Alive for WTO Ministerial', *Intellectual Property Watch*, 28 October, available at <http://www.ip-watch.org/weblog/index.php?p=123> (accessed 2 March 2008).
- 59 IP/C/W/485, November 2006.
- 60 See OECD (2007), *op. cit.*
- 61 See *Summit Declaration, Growth and Responsibility in the World Economy*, 7 June 2007, G8 Summit Heiligendamm. Summit documents are available at <http://www.g-8.de>. See also Ermias Biadgleng and Viviana Muñoz Tellez (2007), *The Changing Structure and Governance of Intellectual Property Enforcement, Research Paper No. 15*, South Centre, Geneva.
- 62 *Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes*, 23 October 2007, available at http://www.ustr.gov/Document_Library/Press_Releases/2007/October/Ambassador_Schwab_Announces_US_Will_Seek_New_Trade_Agreement_to_Fight_Fakes.html (accessed 20 March 2008).
- 63 See *EGA Statement on Counterfeiting and Patent Infringement in the Context of the Anti-Counterfeiting Trade Agreement (ACTA)*. Position paper, June 2008, available at www.egagenerics.com/pol-positions.htm (accessed 30 June 2008).
- 64 NIPLECC, *op. cit.*, Appendices, p. 48.
- 65 With the participation of Australia, Canada, the European Union, Japan, Jordan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland, the United Arab Emirates, and the United States.
- 66 See http://trade.ec.europa.eu/doclib/docs/2008/june/tradoc_139086.pdf (accessed 30 June 2008).
- 67 See <http://www.iccwbo.org/bascap/id1127/index.html> (accessed 20 March 2008).
- 68 The Second Global Congress on Combating Counterfeiting and Piracy, Lyon, France, 14-15 November 2005, recommended '[C]onvincing governments of the advantages of dedicating more specialized judges and prosecutors to intellectual property (IP) matters'. See <http://www.ccapcongress.net/archives/Lyon/files/OutcomesStatement20051115.pdf> (accessed 20 March 2008).
- 69 See, e.g., Harms, 2007, para. 51.
- 70 See article 14 of the TRIPS Agreement.
- 71 COD/2005/0127 Criminal measures aimed at ensuring the enforcement of intellectual property rights, available at <http://www.europarl.europa.eu/oeil/file.jsp?id=5263692> (accessed 21 March 2008).
- 72 See *The Concise Oxford Dictionary*, p. 934.

- 73 See WT/DS362/5 China - Measures affecting the protection and enforcement of intellectual property rights. Japan, Mexico, the European Communities, Argentina, and Chinese Taipei reserved their third-party rights in the dispute. Another related complaint (WT/DS363/5 China- Measures affecting trading rights and distribution services for certain publications and audiovisual entertainment products) was filed by the US. It alleges denial of copyright and related rights protection and enforcement for works that have not been authorized for publication or distribution within China. The US argues that there are different pre-authorization review processes for domestic authors and foreign authors, more favorable protection and enforcement of related rights for domestic performers' and producers of sound recordings.
- 74 See http://english.peopledaily.com.cn/200704/06/eng20070406_364218.html (accessed 2 April 2008), quoted in Harms, 2007, para. 25.
- 75 See Fernando Piérola, Commentary on the WTO dispute China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights (complaint by the United States) (DS362), presentation at the South Centre Seminar 'Examining IP Enforcement from a Development Perspective', Geneva, 9 October 2007.
- 76 See, e.g., Christopher Heat (2005), 'Comparative overview and the TRIPS enforcement provisions' en Christopher Heat y Laurence Petit (Eds), *Patent Enforcement Worldwide. A survey of 15 countries*, the Max Planck Institute and CEIPI, Hart Publishing, Portland.
- 77 See the Preamble of the TRIPS Agreement ('Recognizing that intellectual property rights are private rights').
- 78 In the US, for instance, it has been held that the authorization to the Justice Department to file civil actions against copyright infringers proposed by pending legislation S. 2237 'The Protecting Intellectual Rights Against Theft and Expropriation (PIRATE) Act', would amount to 'an inappropriate use of federal funds to enforce private rights of action' (Public Knowledge, at <http://www.publicknowledge.org/issues/hr2391>, (accessed 2 April 2008).
- 79 Harms, 2007, op. cit. para. 18.
- 80 United States Department of Justice, *The Computer Crime & Intellectual Property Section, Intellectual Property—An Introduction*, available at www.justice.gov/criminal/cybercrime/ipmanual/01ipma.html.
- 81 Harms, 2007, op. cit. para. 28.
- 82 'Criminal Enforcement of IPR: The Problem of "Over-Criminalization,"' which appeared in the Sixth Anniversary Special Issue 2003 of the Intellectual Property and International Forum, Thailand, quoted in Harms, 2007, para. 19.
- 83 On the obstacles faced by the harmonization proposed by this Directive, see Marius Schneider and Olivier Vrins (2006), The EU offensive against IP offences: should right holders be offended?, *Journal of Intellectual Property Law & Practice* 2006 1(3):173-176.
- 84 In the US, for instance, patent owner's likelihood of success in patent validity challenges is only 51 per cent if the trial is heard before a judge alone. If the trial is heard before a judge

and jury: 68 per cent. Overall chances of success for the patent owner if the trial is held in Massachusetts and Northern California, respectively: 30 per cent, 68 per cent. (Pearl Patent Enforcement and Royalties Ltd, at www.pearlltd.com, accessed 3 April 2008).

- 85 The same applies to trademark and copyright infringements.
- 86 See, e.g. in Harms, 2007, para. 27 (quoting the ‘Intellectual Property Report-FY 2006’ of the US Department of Justice, available at http://www.usdoj.gov/ag/annualreports/pr2006/Appd/appd_f.pdf, accessed 3 April 2008).
- 87 See an analysis of these issues below.
- 88 Such stays automatically suspend the procedures for the marketing approval of a drug when infringement of a patent is claimed.
- 89 See *FDA Fact Sheet. FDA Acts to Lower Drug Prices By Implementing New Regulation to Improve Generic Drug Competition*, available at http://www.fda.gov/oc/initiatives/generics/fs_rule.html (accessed 15 March 2008). In 2003 the Food and Drug Administration (FDA) rules were changed in order to allow for only one automatic stay for one drug.
- 90 The brand-name company generally sued all generic applicants if the drug product had annual sales larger than 500 USD million in the year the first generic applicant filed its marketing approval (Federal Trade Commission (2002), *Generic Drug Entry Prior to Patent Expiration*, available at <http://www.ftc.gov> (accessed on March 15 2008), p. 18.
- 91 *Ibidem.*
- 92 *Idem*, p. 16-17.
- 93 See, e.g., Carlos Correa, “Medidas cautelares en materia de patentes de invención”, *Lexis Nexis Jurisprudencia Argentina*, (2002) JA-2002-IV, No. 8, 21-28; Jorge Kors (editor) (2005), *Patentes de invención. Diez años de jurisprudencia-Comentarios y fallos La Ley-Colección CEIDIE*, Buenos Aires; Gustavo Silva Tamayo (2007), ‘Medidas precautorias y patentes de invención’, *La Ley* Año LXXI, No. 237 (commentary on the decision by the Cámara Nacional de Apelaciones en lo Civil y Comercial Federal, sala I (CNFedCivyCom)(Sala I) Bristol Myers Squibb Company).
- 94 In many countries (e.g. South Africa, Netherlands, Luxembourg) patents are granted without prior substantive examination or based only on a search report on the state of the art. In the US, examination was abolished and a registration system was established between 1793 and 1836. see Dominique Guellec (2007), ‘Historical insights’, in Dominique Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System. IP Policy for Innovation and Competition*, Oxford: Oxford University Press, p. 22.
- 95 Joshua D. Sarnoff (2008), Preliminary Relief, and Obviousness in Patent Law, *Cardozo Arts & Entertainment Law Journal*, Vol. 25:3, available at <http://www.cardozoelj.net/issues/08/Sarnoff.pdf> (accessed 18 April 2008).
- 96 FTC (2003). *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*. Federal Trade Commission. (available online at: <http://www.ftc.gov/os/2003/10/>

- innovationrpt.pdf. (accessed 2 April 2008)), p. 8. See also Samuelson, P. (2004). "Legally Speaking: Why Reform the U.S. Patent System?" *Communications of the ACM* 47(6), available at <http://www.sims.berkeley.edu/~pam/papers/cacm%20patent%20reform.pdf> (accessed 2 April 2008).
- 97 See Leahy-Hatch/Berman Smith, *The patent reform Act of 2007*, available at <http://leahy.senate.gov/press/200704/041807a.html> (accessed 2 April 2008).
- 98 W. Caengem (2007), *Intellectual Property Law and Innovation*, Cambridge: Cambridge University Press, p. 82.
- 99 See Mrinalini Kochupillai, The Bilcare decisions by the Delhi High Court: Preliminary injunctions and the presumption of validity of a 'new' patent (12 May 2007), available at <http://spicyipindia.blogspot.com/search/label/Injunction>.
- 100 The court quoted another earlier case holding that 'the grant and sealing of the patent or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent.... It is pertinent to note that this position ... is now expressly provided in Section 13(4) of the Patents Act, 1970. In the light of this principle, [counsel's] argument that there is a presumption in favour of the validity of the patent cannot be accepted' (Bishwanath Prasad Radhey Shyam v. H.M. Indus., AIR 1989 SC 1444, para. 33).
- 101 See article 50 of the TRIPS Agreement.
- 102 In Spain, for instance, judges have been very reluctant to grant provisional measures *inaudita altera parte* in IP litigation. See, e.g., Antonio Castán Pérez-Gómez (2005), Las medidas cautelares "inaudita altera parte" en propiedad industrial e intelectual, in *Estudios sobre propiedad industrial e intelectual y derecho de la competencia: colección de trabajos en homenaje a Alberto Bercovitz Rodríguez-Cano*, Grupo Español de la AIPPI, Madrid, p. 232.
- 103 See *Bilcare*, No. FAO 70/2007, para. 23.
- 104 See *Bilcare*, No. FAO 70/2007, para. 25.
- 105 G. Alexander Macklin (2003), Interlocutory injunction: strategies, *Canadian Intellectual Property Review*, vol. 19, No. 1, p. 31.
- 106 Ibidem (emphasis in the original).
- 107 See (<http://www.supremecourtus.gov/opinions/05pdf/05-130.pdf> (accessed 20 June 2008)).
- 108 The High Court of Delhi also noted that the public health implications of a provisional injunction regarding a drug had been taken into account in the US as well. In *Cordis Corporation v. Boston Scientific Corporation* (2004 US App. LEXIS 11557), the US Court of Appeals for Federal Circuit compared the public interest in protection of the patentee's right with the broader public interest in availability of a drug-eluting stent and affirmed the refusal of such injunction on the ground that it would inhibit a broad choice of availability of such stents.
- 109 See Gert Würtenberger (1992), Interlocutory injunctions as a remedy against patent infringement

- in Germany, *Patent World*, April, p. 30; Joseph Strauss (2000), “Reversal of the burden of proof, the principle of ‘fair and equitable procedures’ and preliminary injunctions under the TRIPS Agreement, *The Journal of World Intellectual Property*, vol. 3. No. 6.
- 110 Institut National de Propriété Industrielle (2006), *Litiges de contrefaçon de brevets. Une étude comparative des systèmes juridiques*, La Documentation Française, Paris, p. 63.
- 111 Würtenberger (1992), p. 30.
- 112 See, e.g., J. Reichman and M. Zinnani (2002). ‘Las medidas precautorias en el derecho estadounidense: el justo balance entre las partes’, *Lexis Nexis Jurisprudencia Argentina* 2002-IV, N°8.
- 113 No. 05-130; 401 F. 3d 1323, available at <http://www.supremecourtus.gov/opinions/05pdf/05-130.pdf> (accessed 19 July 2008).
- 114 See United States Court of Appeals for the Federal Circuit 2007-1145, -1161 INNOGENETICS, N.V., Plaintiff-Cross Appellant v. ABBOTT LABORATORIES, Defendant-Appellant.
- 115 On the characteristics and possible implications of a liability regime, see Jerome Reichman, (2000) Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation. *Vanderbilt Law Review*, 53 . pp. 1743-1798 (available at <http://eprints.law.duke.edu/456/>, accessed 20 June 2008).
- 116 For instance, in a letter dated 20 July 2007 to the Thai Prime Minister criticizing the use of compulsory licenses on essential medicines, the US ambassador stated that such WTO flexibilities should only be used to ‘address urgent situations’ and that ‘decisions should not be made lightly and only as last resort’. Similarly, in a letter dated 10 July 2007 to the Thai Minister of Commerce, the then EU Commissioner Peter Mandelson argued that compulsory licenses constituted ‘exceptional measures’ and called upon the Thai government to review its policy regarding compulsory licenses on essential medicines. In the same year, the Italian Competition Authority (ICA) granted a compulsory license to produce an active ingredient (ceimipenem/cilastatina-IC) needed for the production of an antibiotic (carbapenems) used in the treatment of infectious diseases (Decision A364 Merck—*Principi Attivi in Boll.* November 2007 available online at: www.agcm.it, (accessed 20 April 2008)). See, e.g., Carlos Correa (2007), *Intellectual property and competition law: exploring some issues of relevance to developing countries*, ICTSD, Geneva.
- 117 See generally Carlos Correa (2007), *Trade Related Aspects of Intellectual Property Rights (Volume VI of Commentaries on the GATT/WTO Agreements)*, Oxford: Oxford University Press.
- 118 The Paris Convention establishes in Article 9(2) that seizure of goods unlawfully bearing a trademark shall be effected in the country of importation or ‘where the unlawful affixation occurred’, whereas Article 9 (4) provides that the authorities ‘shall not be bound to effect seizure of goods in transit’.
- 119 See, e.g., the definition contained in Article 2(1)(a) of the Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing

certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!clexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2003&nu_doc=1383 (accessed 22 April 2008).

- 120 See, e.g. the definition contained in article 2(1)(b) of the Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [Official Journal L 196 of 2.8.2003].
- 121 See Richard Posner, *The Little Book of Plagiarism*, New York, Toronto: Pantheon Books, p. 19.
- 122 In most countries infringement can also occur 'by equivalence', when it is found that certain patent claims have not been literally violated but the alternative product or process is equivalent, structurally and functionally, to the patented invention. The 'theory of equivalence' applied in various jurisdictions considerably differ as there is no international standard on the matter. See, e.g., Mario Franzosi (1996), "La teoría degli equivalenti", en *Il brevetto: quale tutela?*, Ed. Giuffrè, Milán.
- 123 See *Border Control of Intellectual Property Rights* (2002) Hampshire: Sweet & Maxwell; O. Vrins and M. Schneider (editors) (2006), *Enforcement of IPRs through Border Measures. Law and Practice in the EU*, Oxford: Oxford University Press.
- 124 However, US customs has no authority to make patent infringement determinations, according to US Customs and Section 337 Investigations. See, Li, op. cit.
- 125 For instance, on the basis of European patents EP0218571 and EP 546090 that protect the RR gene construct that generates tolerance to glyphosate in soy plants, Monsanto requested the custom authorities of several European countries (The Netherlands, Denmark, United Kingdom, Spain, Italy, France, Belgium) to detain the importation of soymeal from Argentina (where the RR technology was not patented) into the European Community. Such authorities (with the exception of Italy) suspended the release or detained such soymeal on the basis of the European Regulation 1383/2003. However, two national courts (Juzgado Mercantil No. 6, 27, Madrid in *Monsanto Technology LLC v. Sesostris SAE*, July 2007; UK High Court of Justice, Chancery Division, Patents Court, 10 October 2007, in *Monsanto Technology LLC v. Cargill International and SA Cargill PLC*) ruled that infringement of Monsanto's patents did not exist. See, e.g., Carlos Correa (2007), *The Monsanto vs. Argentina Dispute on GM Soybean*, *Resurgence*, Number 203-204, pp. 13-16.
- 126 Granted pursuant to Council Regulation (EEC) No 1768/ 92 or Regulation (EC) No 1610/96 of the European Parliament and of the Council.
- 127 European Commission, 'Customs response to latest trends in counterfeiting and piracy', available at <http://europa.eu/scadplus/leg/en/lvb/l11016.htm>.
- 128 See European Commission's Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries', op. cit., p. 9.
- 129 Joint Communication from the European Communities, Japan, Switzerland and the United States, *Enforcement of intellectual property rights*, IP/C/W/485, 2 November 2006, para. 7.

- 130 See http://www.wcoomd.org/files/1.%20Public%20files/PDFandDocuments/Enforcement/WCO%20TABLE%20Intention%20to%20implement%20the%20SECURE-%20EN-FR_April08.pdf (accessed 30 June 2008).
- 131 Such approval is still pending. In June 2008 the standards were sent back to the SECURE Working Group for further discussion.
- 132 See below the section on FTAs and WTO accession.
- 133 For an analysis of this subject, see Ahmed Abdel Latif (2005), *Developing Country Coordination in International Intellectual Property Standard-setting*, T.R.A.D.E. Working Papers 24, Geneva.
- 134 While developed countries are hoping that the model provisions will be approved in June 2008, Brazil has raised developing countries' concerns about the proposal. See William New (2008), World Customs Organization Recommends Far-Reaching New Rules On IP, *Intellectual Property Watch*, 28 February, available at <http://www.ip-watch.org/weblog/index.php?p=939> (accessed 2 May 2008).
- 135 See <http://www.wcoipr.org/wcoipr/gfx/ModelLawfinal.doc> (accessed 20 June 2008).
- 136 Note on article 1.
- 137 Part I, 'Definitions and interpretations'.
- 138 Ibidem.
- 139 It is to be noted that the European Parliament elaborated the following definition to exclude 'gray goods' from the application of the draft Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights: 'parallel importation of original goods, which have been marketed with the agreement of the right-holder in a third country'.
- 140 In accordance with the 'Note on Definitions and Interpretations', WCO Member States 'are encouraged to amend their substantive intellectual property laws, where necessary, so as to define as infringing, goods that are in transit and that have been manufactured or put into circulation without the right holders permission'. If this recommendation were followed, products legitimately commercialized under a compulsory license should be deemed as infringing.
- 141 The concept of 'rights management information' has been introduced internationally by the 1996 WIPO Copyright Treaty (Article 12).
- 142 See article 9 of the 'Model Provisions'. This requirement is not only beyond TRIPS but also the 1996 WIPO Copyright Treaty.
- 143 See, e.g., Leesti, M. & Pengelly, T. (2002), *Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement*, Study Paper 9, Commission on Intellectual Property Rights, London, available at <http://unpan1.un.org/intradoc/groups/public/documents/APCITY/UNPAN017421.pdf>, p. 38 (accessed 20 April 2008).
- 144 For instance, the NIPLECC Report states that the Criminal Division of the Department of Justice

'has worked closely with the State Department to engage the government of South Africa in identifying and addressing limitations in its ability to enforce IP laws. These difficulties include a limited understanding of IP rights enforcement by its police, prosecutors, and customs officers; a lack of cooperation and communication between the agencies responsible for IP enforcement; and the perception that IP violations are victimless or minor crimes, especially when compared with the number of violent crimes occurring in South Africa' (NIPLECC, 2008, op. cit. p. 76).

- 145 Frederick M. Abbott, Carlos M. Correa (2007), *World Trade Organization Accession Agreements: Intellectual Property Issues*, QUNO, Geneva, available at Frederick M. Abbott, Carlos M. Correa, p. 31.
- 146 Harms, 2007, op. cit., para. 25. Currently, more than fifty courts deal solely with intellectual property issues in China (The Economist, 12 April 2008, p. 70).
- 147 In other countries, some courts have special competence in IP due to jurisdictional reasons (for instance, federal courts in Argentina) or to the nature of the issues subject to litigation. For instance, in Egypt special courts have been created to deal with economic matters including IP.
- 148 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, p. 10; Landes W., and Posner, R. (2003), *The Economic Structure of Intellectual Property Law*, Cambridge: The Belknap Press of Harvard University Press.
- 149 127 S. Ct. 1727 (2007). See, e.g., Joshua Sarnoff (2008), *Bilcare, KSR*, presumptions of validity, preliminary relief, and obviousness in patent law, *Cardozo Arts & Entertainment*, vol. 25:3.
- 150 See, e.g., Jaffe and Lerner, Josh (2004) op. cit.,.
- 151 For instance, in Argentina, the US embassy and the American Chamber of Commerce announced in May 2008 a programme to train federal judges in charge of IP issues in the USA. Training of at least one judge of the Delhi High Court by the US Patent and Trademark Office has also been reported (see infobae.com/contenidos/378706-100799-0-Jueces-federales-estudiar%E1n-c%F3mo-combatir-la-pirater%EDa, accessed 30 June 2008). The US and India signed a memorandum of understanding to further cooperation on IP rights, with a focus on the training of personnel with the goal of 'strengthening the working of the IP systems in the two countries'. See Latha Jishnu (2008), op. cit.
- 152 PhRMA Response to 2007 Special 301 Report, http://www.phrma.org/news_room/press_releases/phrma_response_to_2007_special_301_report/ (accessed 15 April 2008).
- 153 Joint Communication from the European Communities, Japan, Switzerland and the United States, *Enforcement of intellectual property rights*, IP/C/W/485, 2 November 2006, para. 2.
- 154 See <http://www.who.int/medicines/services/counterfeit/faqs/05/en/index.html>. WHO established in 2006 the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in order to contribute to the fight against counterfeiting of medicines. See www.who.int/impact (accessed 15 June 2008).
- 155 See Pharmaceutical Research and Manufacturers of America (PhRMA) Special 301 submission 2007, available at international.phrma.org/content/download/916/5369/file/PhRMA%20

Special%20301%20Submission%202007.pdf (accessed 15 April 2008).

- 156 However, lower quality does not characterize all counterfeit products. While estimating a ‘1000 per cent increase in counterfeiting and piracy between 1998 and 2004’, particularly of household goods, the European Commission also noted that the ‘quality of these counterfeits is now so good that it is becoming difficult to distinguish the real article from the fake’ (European Commission, ‘Customs response to latest trends in counterfeiting and piracy’, available at <http://europa.eu/scadplus/leg/en/lvb/l11016.htm>, accessed 15 April, 2008).
- 157 ‘All economies are facing the problems caused by counterfeiting and piracy, as well as the challenges of measuring these problems’ (Joint Communication from the European Communities, Japan, Switzerland and the United States, *Enforcement of intellectual property rights*, IP/C/W/485, 2 November 2006, para. 2); in accordance with PhRMA, ‘[A]lthough the prevalence of counterfeit medicines appears to be greatest in developing and least-developed markets, the counterfeit supply chain has no geographic boundaries, threatening every drug distribution channel in the world, including that of the United States’ (PhRMA, Special 301 submission 2007, op. cit).
- 158 PhRMA, National Trade Estimate Report On Foreign Trade Barriers (NTE) 2007 Philippines, available at international.phrma.org/content/download/1028/5826/file/Philippines%202007%20NTE%20Final.pdf (accessed 15 April, 2008).
- 159 See, e.g., Pharmaceutical Research and Manufacturers of America (PhRMA), *Intellectual property (IP) damages calculation for the PhRMA Special 301 submission 2007*, available at international.phrma.org/content/download/916/5369/file/PhRMA%20Special%20301%20Submission%202007.pdf (accessed 15 April 2008).
- 160 The ‘Principles and Elements for National Legislation against Counterfeit Medical Products, Text endorsed by IMPACT General Meeting Lisbon, 12 December 2007’ state that ‘Counterfeit medical products need to be addressed through different bodies of legislation: on intellectual property protection and enforcement, on pharmaceutical and medical devices regulation and control, and criminal law. All these bodies of legislation should be in place’. However, no specific recommendations regarding enforcement of IPRs are suggested. See www.who.int/impact/events/FinalPrinciplesforLegislation.pdf (accessed 20 June 2008).
- 161 See <http://www.who.int/medicines/services/counterfeit/overview/en/index2.html> (accessed 18 April, 2008). The WHO set up in 2006 a coalition of stakeholders called IMPACT (International Medical Products Anti-Counterfeiting Taskforce) to promote international collaboration against counterfeiting in drugs. The WHO has developed and published the *Guidelines for the development of measures to combat counterfeit medicines*, which provide advice on measures that should be taken by the various stakeholders and interested parties to combat counterfeiting of medicines (available at <http://www.who.int/medicines/publications/counterfeitguidelines/en/index.html>).
- 162 See, e.g., Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) (2006), *Public Health, Innovation and Intellectual Property Rights*, World Health Organization, available at www.who.int (accessed 15 April 2008), p. 155. It is to be noted that, unlike the TRIPS Agreement, which sets out *minimum* standards of protection, the relevant WTO agreement in the area of drug regulation -the Agreement on Technical Barriers to Trade (TBT)- aims at establishing *upper limits* to the establishment and enforcement of technical standards for the commercialization of goods. One of the main objectives of TBT is to avoid that technical

regulations have ‘the effect of creating unnecessary obstacles to international trade’ (Article 2.2 of TBT) through discrimination against imported products. Therefore, the TBT would be of little help in dealing with drug counterfeiting.

- 163 For instance, developing countries have refused to accept enforcement as an agenda item for discussions at the Council for TRIPS. See below IP enforcement in WTO accession processes.
- 164 They include agreements already in force with Jordan Chile, Singapore, Australia, Morocco, CAFTA-DR (El Salvador, Nicaragua, Honduras, Guatemala and the Dominican Republic) and Bahrain. FTAs with Colombia, Panama and Republic of Korea are pending congressional approval and with Peru and Oman pending implementation. See http://www.ustr.gov/Trade_Agreements/Bilateral/Section_Index.html (last visited 15 April, 2008)..
- 165 Biadgleng and Muñoz Tellez (2007), op. cit. p. 31.
- 166 Idem, p. 31-35. The US FTAs also incorporate what is termed the ‘linkage’ between drug registration and patents, which amounts in its more extreme version to an automatic enforcement of patents against applicants of drug registration.
- 167 See Sisule Musungu (2007), *An Analysis of the EC Non-Paper on the Objectives and Possible Elements of an IP Section in the EC-Pacific EPA*, ICTSD-CAFOD, available at <http://www.iprsonline.org/resources/FTAs.htm> (accessed 15 April 2008).
- 168 The same imbalance is present in US demands in FTAs. See Frederick M. Abbott (2006) *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*, Issue Paper No. 12, Geneva.
- 169 The European parliament excluded from criminal sanctions infringements to utility models and plant variety rights, as well as parallel imports of original goods from a third country which have been allowed by the right holder. See article 1 of the draft Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights, available at <http://www.europarl.europa.eu/oeil/file.jsp?id=5263692> (accessed 25 April 2008).
- 170 See http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/CL/CL_RUAP/annexes/CL_FTA_Annex_XII.pdf (accessed 2 March 2008).
- 171 Article 147.2 - Patents and public health- provides that ‘[T]he EC Party and the Signatory CARIFORUM States recognise the importance of the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO and the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and agree to take the necessary steps to accept the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005’. There are no specific TRIPS-plus substantive standards in the agreement.
- 172 For some examples of abuse of enforcement rules, see Carlos Correa (2007), *Intellectual Property and Competition*, op. cit. (accessed 25 April 2008), p. 13-20.
- 173 Frederick M. Abbott, Carlos M. Correa (2007), op. cit. (accessed 25 April 2008), p. 58.

- 174 Recommendation 45: ‘To approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view 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 conducive to social and economic welfare, and to a balance of rights and obligations”, in accordance with Article 7 of the TRIPS Agreement’ (available at http://www.wipo.int/ip-development/en/agenda/cdip_recommendations.html, accessed 20 June, 2008).

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