## RESEARCH PAPERS

**15** 

# THE CHANGING STRUCTURE AND GOVERNANCE OF INTELLECTUAL PROPERTY ENFORCEMENT

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**SOUTH CENTRE** 

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## TABLE OF CONTENTS

EXE	CUTIVE SUMMARY	vii
I.	INTRODUCTION	1
II.	THE CURRENT MULTILATERAL STRUCTURE FOR INTELLECTUAL PROPERTY ENFORCEMENT	3
	II.1 The TRIPS Agreement	4
	II.1.1 Main Elements of Intellectual Property Enforcement in the TRIPS Agreement II.1.2 The Relationship between the TRIPS Agreement and the WTO Dispute Settlement Mechanism	
	Ді <i>ѕрше зешетеш меспаті</i> зт	/
	II.2 Intellectual Property Enforcement in WIPO	10
III.	RECENT LEGAL AND POLICY TRENDS IN INTELLECTUAL PROPERTY ENFORCEMENT	11
	III.1 Recent Trends in the United States	11
	III.2 Recent Trends in the European Union	14
	III.3 United States and European Union Foreign Policy	17
	III.3.1. Bilateral Technical Assistance	
	III.4 The Role of Industry in Shaping the Structure of Intellectual Property Enforcement	19
	III.5 Recent Trends in Developing Countries	21
IV.	THE CHANGING STRUCTURE AND GOVERNANCE OF INTELLECTUAL PROPERTY ENFORCEMENT	23
	IV.1 The Agenda of the G8, the Heiligendamm Process, the OECD and the Emerging Interest in a New International Framework on Enforcement	23
	IV.2 The TRIPS Council and Accession Protocols	25
	IV.3 The WIPO Advisory Committee on Enforcement	26
	IV.4 Intellectual Property Technical Assistance	26
	IV.5 The World Customs Organization and Interpol	27
	IV 6. The World Health Organization	28

	IV.7 Free Trade Agreements and Economic Partnership Agreements  IV.7.1 Main TRIPS-plus Features in FTAs  IV.7.2 Expanded Scope of Enforcement Standards under FTAs  IV.7.3 Intellectual Property Rights as an Investment.	30 31
V.	CONCLUSION: THE CHANGING STRUCTURE OF INTELLECTUAL PROPERTY ENFORCEMENT AND THE POLICY OPTIONS FOR DEVELOPING COUNTRIES	36
Bibli	OGRAPHY	39
Anne	X: SELECTED PROVISIONS OF THE AGREEMENT ON TRADE-RELATED  ASPECTS OF INTELLECTUAL PROPERTY RIGHTS	46

#### **EXECUTIVE SUMMARY**

Twelve years ago the TRIPS Agreement introduced global minimum standards of intellectual property protection and enforcement. To the extent that the substantive obligations under the Agreement have now been widely implemented in national legislation, developing countries are facing increased pressure to bolster intellectual property enforcement.

The European Union, Japan and the United States are undertaking new efforts to strengthen and harmonize at the international level the various means by which countries seek to enforce intellectual property rights. To boost the agenda they have jointly announced plans to negotiate a new international anti-counterfeit treaty independently of WIPO and have made intellectual property enforcement a priority issue for the G8.

This research paper provides a broad overview and analysis of the changing multilateral framework for intellectual property enforcement and the challenges that it presents for developing countries. It examines current multilateral obligations and traces developments in the field of intellectual property enforcement in various multilateral fora, including the WCO, WHO, WIPO, WTO and Interpol. Finally, it analyses the approach of the United States and European Union to strengthening intellectual property enforcement in third countries through regional, bilateral and unilateral mechanisms such as regional and bilateral agreements.

The main findings of the paper are the following:

- Greater coordination and dialogue involving the private sector, government and civil society stakeholders are necessary to find appropriate solutions to both supply and demand problems related to the trade in international counterfeit trademark and pirated copyright goods. The initiatives and activities being undertaken to enforce intellectual property rights by different multilateral fora and agencies can benefit from greater coherence.
- Developing countries are increasingly redirecting resources to strengthen the enforcement of intellectual property rights at a time when global investment in areas of poverty, hunger, health, and education is less than half of what is needed to reach the Millennium Development Goals.
- Countries that adopt TRIPS-plus enforcement obligations may be renouncing sovereign authority to adopt innovation and intellectual property policies suited to their level of development. They may also forego important flexibilities afforded under the TRIPS Agreement that accommodate differences among national legal systems and levels of development. In the case where such obligations are acquired through FTAs, they may also suffer trade and other economic sanctions due to their potential inability to comply with new obligations that may be excessively intrusive and restrictive.
- There is a lack of reliable information and objective data as well as of harmonized definitions
  that would allow proper quantification of the magnitude and impact of international trade in
  counterfeit and pirated goods and an adequate definition of the problems it poses.
- The continued exchange of national information, experience and practice aimed at tackling counterfeiting and piracy is positive and desirable as a means of acquiring a better understanding of the problems and building common agendas. Current sharing of experience should be broadened to include the use of enforcement measures to ensure the exercise of limitations on and exceptions to intellectual property rights and to prevent abuse of intellectual property rights; the use of competition law; and analysis of related national case law.

The main recommendations suggested for developing countries are the following:

- Enforcement measures must be equitable and fair and must balance the intellectual property rights of their holders and the rights of third parties, and the limitations and exceptions provided in the intellectual property system.
- Do not adopt stronger measures and procedures for the enforcement of intellectual property rights beyond those found in the TRIPS Agreement, unless prior assessment is made to determine that TRIPS-plus enforcement standards would bring domestic benefits. TRIPS-plus enforcement standards in regional and/or bilateral FTAs and EPAs should be avoided.
- Resist developed country pressure in the WTO TRIPS Council, the WIPO and other fora to
  establish soft law norms, including best practices and declarations that may require
  strengthening domestic enforcement of intellectual property rights beyond TRIPS standards and
  may lead to harmonization of enforcement standards.
- Maintain flexibilities available in the TRIPS Agreement as they apply to the enforcement of intellectual property rights, including: 1) flexibility as to the method of implementing enforcement measures and procedures in national legal systems; 2) flexibility to balance resources for general law enforcement with those that may be mobilized for the specific enforcement of intellectual property rights; 3) flexibility confine the availability of procedures for border measures and criminal sanctions to cover counterfeit trademark or pirated copyright goods as defined in Article 51, footnote 14; 4) flexibility as to the granting of injunctions; 4) flexibility as to determining what amounts to 'adequate compensation' in awarding damage.
- Adopt clear definitions of counterfeiting and piracy to avoid legal uncertainty and potential abuse of enforcement measures. Definitions can be found in the TRIPS Agreement's Article 51, footnote 14. The common elements of the agreed definition in TRIPS should be applied: (1) identical or close similarity to intellectual property protected locally, (2) unauthorized use, (3) infringement in a country of importation, (4) traded internationally. Ensure that TRIPS-compliant parallel importation of goods is excluded from the definition of counterfeit or piracy. Do not extend definition to include patent infringement.
- Avoid making use of criminal law to deal with intellectual property infringement. At the least, limit the application of criminal law to cases of intellectual property infringement that are wilful and occur on a commercial scale, and thoroughly define the elements that would constitute a "crime".
- Avoid commitments to act directly against infringement of intellectual property rights. While
  government ought to provide intellectual property right holders with the legal means to enforce
  their private rights, responsibility for intellectual property rights enforcement must be vested in
  right holders. Right holders must initiate any legal actions and bear their full costs.
- Strengthen checks against abuse and misuse of intellectual property rights and enforcement
  measures. The means to do so include more rigorous vetting of patent applications, stronger
  enforcement of competition law, ensuring that measures for intellectual property rights
  enforcement are equitable and fair, and providing stronger protection of limitations on and
  exceptions to intellectual property rights, such as "fair use" for access to information,
  educational and research purposes.

#### I. Introduction

Intellectual property law refers to the general area of law that encompasses copyright and related rights, patents, design rights, marks and trade secrets. A common characteristic of the various forms of intellectual property is that they establish property rights over intangible subject matter such as inventions capable of industrial application, the form in which an idea or information is expressed, and signs distinguishing goods and services. The term intellectual property rights refers to the specific legal rights which authors, inventors and other right holders may hold and exercise in relation to intellectual property subject matter. Intellectual property rights are granted by governments and operate within the territory where they are granted. Countries have undertaken bilateral and multilateral agreements to allow national intellectual property rights holders to gain protection in other jurisdictions. Most intellectual property-related agreements adhere to the principle of "national treatment" as a rule of non-discrimination. That is, each member state must offer protection to the nationals of other member states that is not less favourable than that which it gives to its own nationals. However, it is important to note that while national treatment is a mechanism of international protection, it does not amount to harmonization. As noted by Bentley and Sherman "the beauty of the principle of national treatment is that it allows countries the autonomy to develop and enforce their own laws, while meeting the demands for international protection".\(^1\)

The autonomy of countries to develop and enforce their own intellectual property law while complying with their international obligations is essential to the effective functioning of a national intellectual property system. Whether an intellectual property system can function as an instrument promoting economic and social policy objectives is directly linked to how the system is designed to fit the particular needs, conditions and context of each country.

Historically, national intellectual property systems have developed progressively with the evolving economic and social context. It was only in the nineteenth century that countries which were net exporters of intellectual property began to seek international agreements for the protection of intellectual property. Initial agreements included mainly European countries and excluded others such as the United States, a country that later became a leading intellectual property exporter. In the 1980s, concerns about eroding national competitiveness led the United States along with other industrialized countries to seek to expand the protection of intellectual property globally in the pursuit of their economic interests.

The flexibility in the design of national intellectual property systems has been rapidly eroding since the 1960s when the World Intellectual Property Organization (WIPO) was established, the peak being the conclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which in 1995 entered into force among member states of the World Trade Organization (WTO). The TRIPS Agreement created a new multilateral framework for global minimum standards on the protection of intellectual property at the national level. The substantive obligations cover various intellectual property subject matters, including the availability and scope of patents, copyright, industrial designs, topographic circuits, trademarks and undisclosed information. The TRIPS Agreement also established for the first time obligations in respect of national measures and procedures for the enforcement of intellectual property rights. Nonetheless, TRIPS did not harmonize standards of protection among intellectual property systems. These still may vary substantially from jurisdiction to jurisdiction. Recognizing the differences in member states' legal systems and practices, the TRIPS Agreement left room for countries to exercise various flexibilities and did not cover all aspects of intellectual property law. One of the most significant flexibilities provided by the TRIPS Agreement is the freedom for member states to determine the method of implementing the provisions of the Agreement, including both the substantive obligations and the procedures for the enforcement of intellectual property rights.

<sup>&</sup>lt;sup>1</sup> Bently and Sherman (2004), p.5.

One of the main reasons why developing countries agreed to the TRIPS Agreement during the Uruguay Round was the expectation that once it was concluded that the United States would ease off negotiating intellectual property standards bilaterally.<sup>2</sup> Another reason is that they expected the TRIPS Agreement to exclude unilateral retaliatory actions by developed countries. Both assumptions, however, proved to be incorrect. The United States and other developed countries continue to push for TRIPS-plus standards at both the multilateral and the bilateral level. Higher standards of intellectual property protection are being set multilaterally at WIPO and at the bilateral level through the inclusion of intellectual property provisions in free trade agreements (FTAs). Recent trends are marked by the increase in number of multilateral institutions participating in the policy and norm setting on intellectual property enforcement.

This research paper provides a broad overview and analysis of the changing structure and governance of intellectual property enforcement and the challenges that it presents for developing countries. It examines current multilateral obligations and traces developments in the field of intellectual property enforcement in various multilateral fora, including the World Customs Organization (WCO), WIPO, the World Health Organization (WHO), WTO and Interpol. It analyses the United States and European Union approach to strengthening intellectual property enforcement in third countries through regional, bilateral and unilateral mechanisms such as regional and bilateral agreements. Finally, it synthesizes the nature of the changing structure, the main governance issues, and the policy options for developing countries.

<sup>2</sup> Drahos (2002), p. 16.

## II. THE CURRENT MULTILATERAL STRUCTURE FOR INTELLECTUAL PROPERTY **ENFORCEMENT**

The effectiveness of procedures for enforcement of intellectual property is more than ensuring that intellectual property rights are respected. To guarantee a proper balance in the intellectual property rights system, the policy of intellectual property enforcement should be supported by (1) substantive laws safeguarding the legitimate interest of third parties and the public at large, providing adequate limitations on and exceptions to rights conferred by intellectual property, and regulating anti-competitive practices; and (2) procedural rules that are equitable and fair to all parties.

Intellectual-property based industries have pushed developed countries to aggressively promote at the multilateral level a narrow approach for the enforcement of intellectual property rights focusing on the interest of right-holders. This approach can be partly evidenced in the TRIPS Agreement, which dedicates a whole section (Section III) to the enforcement of intellectual property rights, while including some elements to balance the obligations. However, since the conclusion of the TRIPS Agreement there are ongoing efforts by developed countries to strengthen the TRIPS enforcement obligations via new multilateral and bilateral mechanisms. As a result, intellectual property enforcement is one of the major emerging challenges for developing countries to maintain balance in their national intellectual property systems.

As national legal systems vary widely among countries, so do the procedures and measures available for enforcement of intellectual property rights under the different national systems. National governments, in safeguarding the balance between the interest of the right holders and the public interest, should have the policy space to determine the kind of administrative structures and legal procedures necessary for both right holders and third parties. Addressing intellectual property rights infringement relies primarily on the right holder. Intellectual property rights are, in fact, rights conferred on individuals by law and rely on the private right holder for their enforcement.<sup>3</sup> The state may assist a right holder in enforcing such rights, yet it is the foremost responsibility of the affected party to take action. It is up to the right holder to assume the initiative and costs of enforcing their private rights.<sup>4</sup>

The substantive obligations under the TRIPS Agreement are now being widely implemented in national legislations and so have become common denominators among member states of the WTO. Most countries make available various procedures and remedies for intellectual property enforcement. However, intellectual property right holders, especially bigger companies, constantly demand further government-led efforts for strengthening intellectual property right protection. Thus, developing countries are facing increased pressure from developed countries to bolster their efforts on the enforcement of intellectual property rights. These efforts are largely beyond international obligations as set out in the TRIPS Agreement.

In most developed countries, intellectual property right holders use civil processes to deal with cases of infringement of their private rights. The types of remedy, in particular the injunction (interlocutory and permanent) and damages are also more useful for the right holders than criminal punishment. Criminal law usually plays a limited role in dealing with intellectual property infringements, and criminal judgements are very seldom passed in such cases, particularly in patent law. Generally where criminal law is applied it is for intellectual infringement that is wilful and on a commercial scale, or because of other major threats to the state or its citizens. In addition, unless the scale and damage of the infringement merits it, and given the lengthy and expensive nature of litigation processes, the complainant would generally rather not take any action at all against the infringer or would rather settle the dispute out of court. Increasingly, developed

<sup>&</sup>lt;sup>3</sup> The Preamble of the TRIPS Agreement expressively recognizes intellectual property rights as private

<sup>&</sup>lt;sup>4</sup> Commission on Intellectual Property (2002a), p. 165.

countries have sought to make use of criminal law as a deterrent to infringement, but such use may work against the intellectual property system itself by creating public resentment.

Police raids and the use of criminal law enforcement mechanisms can be effective deterrents but they may also be highly dangerous. Moreover, these require extensive use of public funds and in developing countries may entail pulling resources away from other law enforcement efforts when there are other means, particularly via civil law, that may be strengthened to allow private parties to enforce their rights and which do not require extensive use of public funds. Furthermore, even when a country's legal enforcement agencies aim at combating infringements, they may be unable to do so, especially if the right holder does not take the lead in establishing whether harm has in fact been done or in determining the scale of damages and the appropriate remedies. In short, a central question in defining what type of measures and procedures should be made available and utilized under national legislation relates to determining at what point the state should be involved in the enforcement of intellectual property rights and whether it has the capacity to do so.

Developing countries require ample policy space to address this key policy question. Today, this same exercise of judgment and discretion for the enforcement of private intellectual property rights that has historically persisted, including under the TRIPS Agreement, is being eroded through bilateral FTAs and other bilateral pressures. The erosion of policy space necessary to determine the appropriate enforcement policies and procedures based on the public interest and the capacity of government institutions is the new emerging challenge for developing countries. This new emerging challenge involves the increased pressure to use the state machinery to reduce the cost of private enforcement for multinational companies based in the developed world.

#### **II.1 The TRIPS Agreement**

The TRIPS Agreement constituted a paradigm shift in intellectual property rights enforcement. While prior to the TRIPS Agreement international treaties for the protection of intellectual property rights included a few obligations regarding enforcement,<sup>5</sup> none had explicitly dealt with intellectual property enforcement; nor did these instruments provide for any mechanism for settling disputes that could arise between States over intellectual property-related obligations, including those concerning enforcement. Precisely because of this, industrialized countries sought to define common standards for the enforcement of intellectual property rights in the TRIPS Agreement sanctioned by recourse to the WTO dispute settlement mechanism.

Under the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention), the adoption in domestic law of norms that embodied an international minimum standard was sufficient to fulfil the obligation of members. The benchmark for the standards of enforcement was that members should strictly observed national treatment in the application of such law. Under the TRIPS Agreement, in contrast, adopting legislation that complies with international minimum standards is only the starting point. Domestic laws must be adequately enforced in compliance with the provisions concerning enforcement of intellectual property rights. However, the TRIPS Agreement clearly recognizes the existence of widely varying standards in the protection and enforcement of intellectual property rights among countries. It only attempts to establish general standards to be implemented according to the mechanism determined by each Member. For example, The Agreement in Article 1.1 on the nature and scope of the obligations establishes that Members are free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. In this regard, the Agreement does not attempt to harmonize procedural rules for enforcement of intellectual property rights.

<sup>7</sup> UNCTAD-ICTSD (2005), p. 575.

<sup>&</sup>lt;sup>5</sup> These include Art. 25 of the Paris Convention 1883, Art. 36 of the Berne Convention 1886, and Art. 26 of the Rome Convention 1961.

<sup>&</sup>lt;sup>6</sup> Reichmann (1997), p. 2.

The general principles of the TRIPS Agreement established in Article 8, including the explicit recognition that Members may need to take measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, also apply to Section III of the Agreement on the Enforcement of Intellectual Property Rights.

#### II.1.1 Main Elements of Intellectual Property Enforcement in the TRIPS Agreement

The enforcement provisions of the TRIPS Agreement "are truly minimum standards, unlike the substantive standards set out by the TRIPS Agreement, as attempted by the loose and open-ended language in which they are cast." Creating an international standard on enforcement procedures for private rights was practically impossible owing to the large differences in countries' legislations. As a result, the provisions of the TRIPS Agreement essentially define the objective to be attained rather than the specific details of the procedures that may be brought into play. Following this approach, the language is minimal, and openended in setting the obligations.<sup>9</sup>

Part III of the TRIPS Agreement includes general obligations, rules on civil and administrative procedures and remedies to fulfil the general obligations, provisional measures, special requirements related to border measures, and criminal procedures.

Article 41 sets out the main principles regarding enforcement, as follows:

- procedures must be available under domestic laws to permit effective action against infringement of intellectual property rights, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements;
- enforcement procedures must be applied in such a manner as to safeguard against abuse and to avoid the creation of barriers to legitimate trade;
- procedures must be fair and equitable and not unnecessarily complicated or likely to cause unwarranted delays;<sup>10</sup>
- courts and administrators must base their decisions only on evidence available to all parties, and these should preferably be written and reasoned;
- there must be some form of review for decisions handed down by first instance administrative or judicial agencies;
- Members are under no 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. Members do not acquire any obligations as to the distribution of resources between the enforcement of intellectual property rights and the enforcement of law in general.

The TRIPS Agreement includes both compulsory and optional provisions on intellectual property rights enforcement. Most of the provisions do not establish straightforward obligations, but require Members to empower judicial or other competent authorities to order certain acts. The relevant national

<sup>&</sup>lt;sup>8</sup> Reichmann (1997), p. 5

<sup>&</sup>lt;sup>9</sup> As noted in UNCTAD-ICTSD (2005), p. 580, in assessing whether a Member's enforcement procedures actually permit "effective action", the effectiveness of measures may be differently assessed in different legal systems. There cannot be one single standard of what constitutes effectiveness, which is confirmed in the TRIPS Preamble by the statement that the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights needs to take into account "differences in national legal systems."

<sup>&</sup>lt;sup>10</sup> This corresponds to the principle of fairness and equity that "applies to all parties concerned in enforcement procedures, and not only to right holders." See UNCTAD-ICTSD (2005), p. 582.

authorities may order certain procedural remedies, but they are not obliged to do so, and can exercise discretion in applying the mandated rules.<sup>11</sup>

Some procedures are compulsory only with regard to certain types of intellectual property rights. For example, the availability of the procedures for border measures and criminal sanctions under Articles 51 to 61 apply only to "counterfeit trademark or pirated copyright goods" as clearly defined in footnote 14 to Article 51. The definition provides four elements of what constitute "counterfeit trademark goods" and "copyright piracy". First, counterfeit goods shall mean goods bearing a trademark identical to, or that cannot be distinguished in its essential aspects from, the validly registered trademark. Pirated goods shall mean copies of the copyrighted material or copies made directly or indirectly from an article. Secondly, the goods are to be considered counterfeit or pirated only where the use of the trademark was without authorization and the reproduction of the copyright material was without the consent of the right holder or person duly authorized by the right holder in the country of production. Third, the definitions clearly provide that the existence of infringement is to be determined by the law of the country of importation.

Since the TRIPS Agreement does not harmonize the substantive laws on copyright and trademark, the infringement of the rights conferred by copyright and trademark can only be determined in each jurisdiction. The emphasis on the laws of the country of importation under the definitions indicates that the definitions are supposed to guide only the procedures for the application of border measures rather than to other forms of infringement for which Member States are required to make available civil procedures and remedies. As a result, the fourth element of the definitions pertains to their applicability to goods traded internationally. Among other things these specifications mean that infringement of a trademark or copyright, i.e. unauthorized use, is a necessary but insufficient condition for counterfeit and piracy.

Under the provisions on border measures, members are required to provide the legal procedures for right holders to lodge an application in writing with competent authorities to suspend the release of imported goods into free circulation when the right holders have valid grounds for suspecting the goods are "counterfeit trademark or pirated copyright goods". The provisions spell out the basic procedures for lodging applications, rights of inspection and information, the required security and assurance, remedies for wrongful suspension of the release of goods, conditions for *ex officio* action and remedies. Finally, according to Article 61, States must provide criminal procedures and penalties, at least, for cases of "wilful trademark counterfeiting or copyright piracy on a commercial scale".

The intellectual property rights enforcement provisions also allow for certain exceptions. According to Article 44.2, where the remedies against infringements stipulated under the TRIPS Agreement are inconsistent with a Member's law, the remedies shall be limited to declaratory judgments and payment of adequate compensation. Members also have significant leeway in determining what amount of compensation is 'adequate.' Similarly, under Article 44.1, Members are not required to grant injunctions in respect of intellectual property rights acquired by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

Finally, the TRIPS Agreement provides a "checks and balances approach" to the application of procedures for intellectual property enforcement that safeguard the interests of third parties and of the public. Article 48.1 empowers judicial authorities to order a plaintiff who has abused enforcement procedures to provide to the defendant adequate compensation for the injury suffered. Articles 50.3 and 53.1 also empower judicial authorities to request the applicant to provide security or other assurances sufficient to protect the defendant and to prevent abuse of proceedings for provisional measures. Judicial authorities must have the authority to impose certain requirements on the applicant of a provisional measure "in order to satisfy themselves that the applicant is the right holder and that the applicant's right is being infringed or that infringement is imminent." Other main standards to be applied include the proportionality of the measure with respect to the seriousness of the infringement, and the protection of confidential information. According to Article 46 of the TRIPS Agreement, the authorities should consider

<sup>&</sup>lt;sup>11</sup> UNCTAD-ICTSD (2005), p.593

<sup>&</sup>lt;sup>12</sup> WTO (1994), the TRIPS Agreement, Article 50 (3).

the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties. In addition, Article 42 requires fair and equitable procedures under civil and administrative proceedings. Article 41.4 exempts member states from obligation to provide an opportunity for review of acquittals in criminal cases. A clear safeguard exists in Article 41.5 that attenuates the obligations on intellectual property rights enforcement. 13 Members are not obliged to establish court divisions specialised on the enforcement of intellectual property rights and to allocate resources separately for intellectual property rights enforcement. The provision relieves Members from any duty to beef up their overall judicial and administrative structures to emphasize and/or prioritize the enforcement of intellectual property rights over the enforcement of law and order in general.<sup>14</sup>

#### II.1.2 The Relationship between the TRIPS Agreement and the WTO Dispute Settlement Mechanism

Disputes among WTO Members regarding the violation of any of the provisions embodied in the TRIPS Agreement are subject to the dispute settlement mechanism. As a result, failure of a member state to meet its obligations regarding intellectual property rights enforcement can jeopardize its market access rights and other benefits at the multilateral level. Nevertheless, many complexities arise in applying the WTO dispute settlement mechanism to the TRIPS Agreement and, in particular, to its enforcement provisions.

The language of the provisions on procedures for enforcement of intellectual property rights allows wide interpretation that could have a specific meaning largely when the domestic legislation determines the exact procedure to be followed in the legal system and, most importantly, when the competent authorities or the judiciary apply the rules to specific cases.<sup>15</sup>

The TRIPS Agreement omits various details, such as time-bound limitations on the right to institute claims or appeal a ruling. However, there are cases where the general availability of the minimum standards is interpreted under dispute settlements with wider application. In Canada - Patent Term, the Panel in its finding referred to the application of Article 41.2 to acquisition procedures of patents under Article 62.4 and stated that:

In our view, requiring applicants to resort to delays such as abandonment, reinstatement, nonpayment of fees and non-response to a patent examiner's report would be inconsistent with the general principle that procedures not be unnecessarily complicated as expressed in Article 41.2 and applied to acquisition procedures by Article 62.4. By their very nature, the delays, which are not tied to any valid reason related to the examination and grant process, would be inconsistent with the general principle that procedures not entail 'unwarranted delays' as expressed in Article 41.2 and applied to acquisition procedures by Article 62.4.

.... We find potential requirements that an applicant commence proceedings [in a court of law] for a writ of mandamus and pay additional fees to be in breach of the general principle that procedures not be 'unnecessarily complicated or costly' as expressed in Article 41.2 and applied to acquisition procedures by Article 62.4. 16

The findings of the Panel were not subsequently reviewed by the Appellate Body (AB). It is possible for the AB to confirm the findings of the Panel, in so far as it relates to legislative matters that are not in compliance with Article 41. However, the AB may need to consider the difficulty of applying the

<sup>&</sup>lt;sup>13</sup> This article was not suggested in the original US and EC proposals but was introduced by India during negotiations on the adoption of the TRIPS Agreement in its proposal, MTN.GNG/GN11/W/40, at 3, No.4 (e). See also UNCTAD-ICTSD (2005), p.585.

<sup>&</sup>lt;sup>14</sup> Reichmann (1997), p.5.

<sup>&</sup>lt;sup>15</sup> The nature of the inconsistency that the Dispute Settlement Body (DSB) should examine could be evidence of a failure to provide effective enforcement procedures that shows a systemic problem. See UNCTAD-ICTSD

<sup>&</sup>lt;sup>16</sup> WTO (2000) Panel Report on Canada- Patent Terms, WT/DS170/R, para. 6.117 and 6.118.

general standard of procedures not to be unnecessarily complicated or costly, when the TRIPS Agreement clearly imposes the obligation to safeguard the same procedures from abuse, and most importantly, when generalization is not possible in procedural rules that may take a different form of application depending on the cases.

The compliance with the provisions that require members to make available civil procedures and provide for criminal procedures and penalties would be evaluated based on the general availability of rules and procedures domestically. In the *US* - *Section 211 Appropriations Act* both the Panel and the Appellate Body relied on the ordinary meaning of to 'make available' under Article 42 of the TRIPS Agreement that provides for fair and equitable standards of enforcement procedures. Accordingly, the phrase suggests that "right holders" are entitled under Article 42 to have access to civil judicial procedures that are effective in bringing about the enforcement of their rights covered by the Agreement. Furthermore, the AB stated that:

Article 42, first sentence, does not define what the term "civil judicial procedures" in that sentence encompasses. The TRIPS Agreement thus reserves, subject to the procedural minimum standards set out in that Agreement, a degree of discretion to Members on this, taking into account "differences in national legal systems". Indeed, *no Member's national system of civil judicial procedures will be identical to that of another Member*.<sup>17</sup>

The above findings of the AB should be the basis for interpretation of Part III of the TRIPS Agreement. The Panel found that the wording of Section 211(a)(2), which provides that "[no] U.S. court shall recognize, enforce or otherwise validate any assertion of rights" in certain circumstances, effectively prevents the right holder from substantiating a claim. However, the AB went further and vacated the decision of the Panel, stating that Article 42 is basically a procedural obligation and it does not prevent members from legislating whether courts should consider each and every requirement of substantive law at issue before making a ruling. Accordingly, the AB determined that the legislation does not deny the procedural rights guaranteed by Article 42.<sup>18</sup>

In so far as the application of the fair and equitable procedures to domestic judicial proceedings is concerned, Article 42 cannot be interpreted as requiring WTO panels to review or exercises appellate jurisdiction over domestic administration of justice. The TRIPS Agreement establishes minimum standards that should be in place, and it is quite unnecessary for WTO panels to act as an appeal forum over dissatisfaction with the procedures and final rulings of an administrative or judicial body of member states. Investment arbitration tribunals in the case of *Loewen v US* (2003) have rejected any interpretive approach to fair and equitable treatment as requiring the tribunal to function as an appellate or reviewing panel with respect to how national courts administer justice.

A number of the provisions of the TRIPS Agreement on enforcement of intellectual property require only the availability of judicial discretionary power to order procedural relief. The enforcement provisions of the TRIPS Agreement have not adequately developed through case law or practices of dispute settlement panels. But panel and appellate body rulings have provided important observations on the interpretation of the provisions. The Panel in *India - Patents (EC)* confirmed that the function of the words 'shall have the authority' is to address the issue of judicial discretion, not that of general availability. Accordingly, countries can comply with their obligation by providing under their legislation the relevant judicial discretionary power. Some of the 'shall have the authority' provisions prescribe conditions on the exercise of the discretionary power. For example, under Article 45 member states should provide the judicial power to award damage. In exerting their power, judicial authorities may or may not order damage. If they do, Article 45 requires that the award must be adequate to compensate for the injury to the right holder. It is an important flexibility under the enforcement section of the TRIPS Agreement that national authorities maintain significant leeway to determine what amounts to 'adequate compensation' in awarding damage.

<sup>19</sup> WTO (1998), Panel Report on *India - Patents (EC)*, WT/DS79/R, para. 7.66.

<sup>&</sup>lt;sup>17</sup> WTO (2002) Report of the Appellate Body in *US - Section 211 Appropriations Act*, WT/DS176/AB/R, para. 216 (emphasis added).

<sup>&</sup>lt;sup>18</sup> *Ibid.*, para. 227.

The requirement to provide for criminal procedures and penalties under Article 61 should be interpreted on the basis of the ordinary meaning of words and phrases. Article 16 of the TRIPS Agreement establishes that the rights conferred by a trademark consist of the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. Use of a trademark in the course of trade may infringe the rights conferred by a validly registered trademark in accordance with Article 16. Article 61 applies only to counterfeiting or copyright piracy on a commercial scale as opposed to all other infringing activities in the course of trade. What amounts to 'counterfeiting and copyright on a commercial scale' must be different from infringing use of trademark in the course of trade. Otherwise, Article 61 would have simply referred to use of trademark in the course of trade. From this, one could adduce that 'commercial scale' must imply a far greater infringement than use of trademark in the course of trade infringing the right conferred by a registered trademark. The use of the phrase 'commercial scale', for example, in industrial production does not convey the sense of usage limited to value of goods traded but of the operation of industrial production, marketing channels and sufficient supply of goods in such quantities, value and persistence that establish commercial viability for the producer. The interpretation of Article 61 should be limited to determining the general availability of the specific criminal procedures and remedies.

The provisions of the TRIPS Agreement on enforcement of intellectual property rights could also be interpreted in conjunction with the provisions of the General Agreement on Tariffs and Trade (GATT). According to Article 41 of the TRIPS Agreement, the procedures for enforcement of intellectual property rights shall be applied in a manner to avoid the creation of barriers to legitimate trade. A GATT Panel in United States- Section 337 found that the fact that legislations are applied as a means of the enforcement of intellectual property at the border does not provide an escape from the applicability of Article III (4) of the GATT.20 The approach remains valid, although the TRIPS Agreement has adopted a mandatory requirement to maintain the means for right holders to lodge an application for suspension of the release of goods. Similarly, Article XX of the GATT and Article XVI of the General Agreement on Trade in Services (GATS) could be applied to provisions of the TRIPS Agreement on enforcement of intellectual property rights to avoid barriers to international trade.

One of the current processes taking place at the WTO is the recent dispute settlement consultations initiated by the United States with the People's Republic of China on intellectual property rights protection and enforcement.<sup>21</sup> If the consultations fail a WTO dispute panel will be convened to settle the dispute.

An unsettled issue with regards to the enforcement of the TRIPS Agreement, and to the rest of the TRIPS provisions for that matter, is whether non-violation complaints would apply to intellectual property rights enforcement provisions.<sup>22</sup> Many developing countries have clearly and repeatedly indicated in the TRIPS Council that non-violation complaints should not be applicable to intellectual property rights as it raises fundamental and systemic concerns.<sup>23</sup> The Hong Kong Ministerial Declaration has extended further the moratorium on non-violation and situation complaints until the adoption of modalities that should be reported to the next ministerial conference.

<sup>&</sup>lt;sup>20</sup> GATT (1989), Panel Report on United States - Section 337 of the Tariff Act of 1930, L/6439, BISD 36S/345, 385-386, para. 5.10.

<sup>&</sup>lt;sup>21</sup> See USTR Press Release (2007), United States Files WTO Cases Against China Over Deficiencies in China's Intellectual Property Rights Laws and Market Access Barriers to Copyright-Based Industries, 4 September 2007. <sup>22</sup> Under Article XXIII of the GATT 1994, WTO Members can challenge one another not only for actions contrary to their obligations under the WTO agreements, but also for actions that, though consistent with those agreements, otherwise nullify or impair a benefit arising from them. See South Centre-CIEL (2004), p.2.  $^{23}$  Ibid.

#### **II.2 Intellectual Property Enforcement in WIPO**

There is no in-built dispute settlement mechanism in WIPO similar to that of the WTO which can be used to compel the observance of provisions on enforcement under WIPO-administered treaties.<sup>24</sup> While members of WIPO-administered treaties are obliged to adopt measures to ensure the implementation of the treaties they ratify, some of the treaties provide special provisions with regard to enforcement.

Two of the most recent treaties negotiated in WIPO, namely the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) (jointly called "Internet Treaties"), signed in 1996, include specific intellectual property rights enforcement provisions. The provisions require Members to provide, on the one hand, adequate legal protection and, on the other, effective legal remedies against the circumvention of effective technological measures (such as encryption) used by right holders to protect their rights and against the deliberate alteration or deletion of electronic 'rights management information.' These are two very new areas concerning the grant of intellectual property rights that create specific enforcement obligations. It should be noted that developing countries are the main subscribers to these treaties.

The International Convention for the Protection of New Varieties of Plants (UPOV) of 1991 defines the scope of the rights of plant breeders with respect to plant varieties. The Convention do not provide for detailed procedures on the enforcement of plant breeders' rights. Article 30 of the Convention requires courtiers to adopt all measures necessary for the implementation of the Convention. Such measures should at least;

- a) provide for appropriate legal remedies for the effective enforcement of breeders' rights
- b) maintain an authority entrusted with the task of granting breeders' rights
- c) ensure that the public is informed through the regular publication of information concerning applications for and grants of breeders' rights, and proposed and approved denominations

The nature and scope of the legal remedies for the effective enforcement of breeders' rights would be determined by each country. However, countries have the obligation to ensure that the public will be notified through a regular publication of information concerning the application and grant of rights.

In addition to enforcement provisions in recent WIPO treaties, WIPO has established a permanent committee for members to discuss and share national experiences on intellectual property enforcement. The WIPO Advisory Committee on Enforcement (ACE) was established in 2002, which structured the discussion on enforcement of copyrights and industrial property rights. The establishment of the ACE merged the Advisory Committee on Enforcement of Industrial Property Rights and the Advisory Committee on Management and Enforcement of Copyright and Related Rights in Global Information Networks into a single forum. When the ACE was established, it was agreed that its mandate would be limited to discussions on technical assistance and coordination. It was specifically agreed that the mandate would not include norm-setting in the field of enforcement. Several members are of the view that the issue of enforcement should be seen in the broader context of the public interest and the obligations of right holders, and not just in the context of combating infringement of protected intellectual property rights. However, to date the focus of the ACE has been on strengthening the enforcement of intellectual property rights and the problems right holders face in enforcing their intellectual property rights in third countries.

<sup>27</sup> WIPO (2003), WIPO/ACE/1/7 Rev., para. 7.

<sup>&</sup>lt;sup>24</sup> Other than the obligations of certain WIPO treaties (Paris Convention and Berne Convention) that were incorporated into the TRIPS Agreement.

<sup>&</sup>lt;sup>25</sup> WIPO (1996), Performances and Phonograms Treaty, Article 19.

<sup>&</sup>lt;sup>26</sup> WIPO (2002), WO/GA/28/7.

## III. RECENT LEGAL AND POLICY TRENDS ON INTELLECTUAL PROPERTY **ENFORCEMENT**

The European Union and the United States have defined intellectual property rights enforcement as one of their core areas of transatlantic cooperation.<sup>28</sup> The growing pressures for increased intellectual property protection reflect the shift in the capital structure of industries as well as changes in the developed countries' trade policies aimed at reinforcing the international competitiveness of their industries.<sup>21</sup>

The recent policy trends in developed countries show a marked shift from the minimum standard to the highest achievable, and considerable emphasis is placed on the enforcement of intellectual property rights. Unilateral measures and FTAs are employed as effective tools to demand an increased level of enforcement of intellectual property rights. On the promise of reciprocal concessions, more developing countries are undertaking FTAs, in particular with the United States, whereby they assume "TRIPS-plus" obligations with respect to intellectual property rights to which they are effectively bound under the dispute settlement mechanism of the agreement.

The United States, in particular, is pursuing its aggressive intellectual property protection strategy by combining higher standards and harmonization of intellectual property rules at the multilateral and bilateral level together with increased enforcement of the standards by way of FTAs. So far, the United States' strategy has proved highly effective for the interests of multinationals, and the European Union has moved in the same direction. In the process, developing countries are bound by intellectual property enforcement standards beyond the multilateral commitment.. Developing countries continue to engage in a highly complex multilateral and bilateral web of intellectual property rights standards.<sup>30</sup>

#### **III.1 Recent Trends in the United States**

In the United States the enforcement of intellectual property rights is strengthen by measures implemented throughout government agencies. Intellectual property rights enforcement involves the Office of the United States Trade Representative, the Department of Commerce, the Patent and Trademark Office, the International Trade Administration, the Department of Homeland Security, which includes Customs and Border Protection and Immigration and Customs Enforcement, and the Department of Justice and the State Department. The effort of these organs is coordinated by the National Intellectual Property Law Enforcement Coordination Council established in 1999.<sup>31</sup>

United States launched the Strategy Targeting Organized Piracy (STOP!) initiative in October 2004. The strategy aims at aggressively engaging trading partners in increasing efforts to seize counterfeit goods at United States borders, pursuing criminal enterprises involved in piracy and counterfeiting.<sup>32</sup> The

<sup>&</sup>lt;sup>28</sup> European Union (2006), EU - US Summit Declaration

<sup>&</sup>lt;sup>29</sup> In this regard, Joseph Papovich, former United States Assistant Trade Representative on Services, Investment and Intellectual Property, in discussing how the US programme for promoting intellectual property in other countries came about, noted: "In the 1980s the United States began facing chronic trade deficits, so our government undertook a rather intensive examination about how we should address these deficits. One of the things that became apparent was that we needed to emphasize exports of products for which we had a comparative advantage. The area of intellectual property... is one in which the United States has a strong comparative advantage. It became apparent to US policy-makers that potential US exports were not being exported because people in other countries were copying, were counterfeiting these US products." Papovich and Claude (1998).

<sup>&</sup>lt;sup>30</sup> Drahos (2004), p.14.

<sup>&</sup>lt;sup>31</sup> United States National Intellectual Property Law Enforcement Coordination Council (2006).

<sup>&</sup>lt;sup>32</sup> *Ibid.*, p. 10.

Department of Justice of the United States has developed what it calls 'a comprehensive, multi-dimensional strategy to fight intellectual property crime'. The strategy includes the following principles:

- 1. laws protecting intellectual property rights must be enforced;
- 2. government and intellectual property rights owners have *a collective responsibility* to take action against violations of intellectual property rights laws;
- 3. the Department should take a leading role in the prosecution of the most serious violations of the laws protecting copyrights, marks, and trade secrets;
- 4. government should punish the misappropriation of innovative technologies rather than innovation itself:
- 5. intellectual property rights enforcement must include the coordinated and cooperative efforts of foreign governments through informal assistance and formal cooperation, such as treaties and international agreements.<sup>33</sup>

These principles are meant to addresses the many different aspects of intellectual property rights enforcement, including criminal enforcement and prevention and civil and antitrust enforcement. Recent trends in intellectual property rights enforcement in the United States are also marked by an increase in the involvement of the Supreme Court of the United States since the creation of the United States Court of Appeal for the Federal Circuit.<sup>34</sup> It is also notable that while the United States Supreme Court has been active only occasionally in reviewing patent cases, it is currently increasing its reviews of decisions of the appellate court.

In *MedImmune, Inc. v. Genentech, Inc.* (2007), with respect to declaratory Judgement, the Supreme Court ruled that subject matter jurisdiction stands, even though the licensee did not refuse to make royalty payment under the license agreement.<sup>35</sup> This decision follows *Illinois Tool Work, Inc. v. Independent Ink, Inc.* (2006), where the Supreme Court ruled that a patent does not necessarily confer market power upon the patentee, and in all cases involving a tying arrangement the plaintiff must prove that the defendant (patentee) has market power in the tying product.<sup>36</sup>

In *Metro-Goldwyn-Mayer Studios Inc. v. Grokster*, (2005) the Supreme Court established the jurisprudence for secondary liability. It state that:

one who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, going beyond mere distribution with knowledge of third-party action, is liable for the resulting acts of infringement by third parties using the device, regardless of the device's lawful uses.<sup>37</sup>

In *McFarling v. Monsanto* (2005) the Supreme Court denied petition to appeal in a case concerning the refusal to permit the saving and replanting of second generation genetically-modified agricultural seeds. The court agreed to the argument under amicus brief and the ruling of the appellate court that it is well settled that a patent does not engage in patent misuse when it merely invokes its core right to refuse to license its patented invention.

Although the trends in the Supreme Court of the United States reinforce the right of intellectual property owners to exercise their rights, there is one particular decision that could be singled out as promoting equity in enforcement proceedings. In *eBay Inc V. MercExchange, L.L.C.*, the Supreme Court

<sup>35</sup> United States Supreme Court (2007), *MedImmune, Inc. v. Genentech, Inc, et. al.*, Certiorari to the United States Court of Appeal for the Federal Circuit, (No. 05-608) 427 F. 3d 958 (2007).

<sup>&</sup>lt;sup>33</sup> United States Department of Justice (2006), pp. 15-16.

<sup>&</sup>lt;sup>34</sup> Arthur and Cogswel III (2005), 821-23.

<sup>&</sup>lt;sup>36</sup> Arthur and Cogswel III (2005), 821.

<sup>&</sup>lt;sup>37</sup> United States Supreme Court (2005), *Metro-Goldwyn-Mayer Studios Inc. v. Grokster*, Certiorari to the United States Court of Appeals for the Ninth Circuit, (04-480) 545 U.S. 913 (2005)

swept away a well established practice of the Federal Circuit in issuing injunction relief automatically when there is infringement of valid patents. The Court holds that traditional equitable principles apply in enforcement proceedings. By applying traditional equitable considerations for injunction, the Supreme Court narrowed down the long-standing jurisprudence in the United States that emphasised that a patent is the inventor's 'absolute property' when it stressed that 'the creation of a right is distinct from the provision of remedies of that right.'39 In seeking injunction the Supreme Court emphasized the four tests of equity: namely, that (1) the patentee has suffered an irreparable injury; (2) remedies available in law, such as monetary damages, are inadequate to compensate for that injury; (3) considering the balance of hardship between the plaintiff and defendants, a remedy in equity is warranted; and (4) the public interest would not be disserved by a permanent injunction. However, the court also stated that the mere fact of non-working of patent does not establish that the patentee will not suffer irreparable damage.

The trends in the United States reflect the focus on enforcement of intellectual property rights, at the same time narrowing down the applicability of antitrust law and regulations of misuse of intellectual property rights. In April 2007, the United States Department of Justice and the Federal Trade Commission jointly issued a report on antitrust enforcement and intellectual property rights.<sup>40</sup> The conclusion of the two agencies is important to understand the policy orientation in the United States, as their analysis is based on the legal, judicial and policy developments of the country. The agencies stated that licensing practices, tying arrangements and incorporation of intellectual property rights in standards do not create anti-trust liability or require a case by case analysis. However, the agencies concluded that conditional refusal to license that causes competitive harm is subject to antitrust liability. They also concluded that a tying arrangement would likely be susceptible to challenge if (1) the seller has market power in the relevant market in the tying product, (2) the arrangement has an adverse effect on competition in the relevant market for the tied product, and (3) efficiency justifications for the arrangement do not outweigh the anticompetitive effects. 41 On many of the instances that lead to competition concerns, the agencies framed their conclusion in favour of the rights conferred by intellectual property rights.

These developments should be assessed in the light of other legislative developments that have implications that go beyond the understanding of the relevant government agencies in the United States. The United States continues to update its legislation on intellectual property rights enforcement, and in 2007 the Department of Justice submitted an Intellectual Property Protection Act for approval by the Congress. The Act would provide:

- 1. authority to prosecute criminal copyright offences before the registration of claims of copyright has been made;
- 2. a new federal offence of attempting to commit criminal copyright infringement;
- 3. ex parte order for seizure in civil copyright cases of records related to infringement of copyright, and forfeiture in criminal copyright cases of any copies manufactured, reproduced, distributed, sold, or otherwise used, intended for use, or possessed with intent to use, and any property that constituted or was derived from any proceeds obtained directly or indirectly as a result of copyright infringement offences. The same applies to any property used or intended to be used in any manner or part to commit or facilitate the commission of a copyright infringement offence;
- 4. that the export of infringing copies should be treated as an infringing distribution and may form the basis for a criminal copyright prosecution in certain cases;
- 5. application of the repeated-offender penalties when the copyright infringing committed any two copyright felonies, regardless of the particular type of offence - including attempt offences;

<sup>40</sup> United States Department of Justice and Federal Trade Commission (2007).

<sup>&</sup>lt;sup>38</sup> Otherwise known as the "continental Paper bag" after Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405 (1908).

<sup>&</sup>lt;sup>39</sup> Tang (2006), p. 241.

<sup>&</sup>lt;sup>41</sup> *Ibid*. See the introduction section for the summary of all conclusions of the agencies.

6. voice intercept (wiretap) authority for offences that are equivalent, if not greater, in impact to other predicate offences that already give rise to such authority.<sup>42</sup>

Criminal persecution for enforcement of intellectual property rights is increasing and forming a part of bigger offences such as financing terrorism and organized crime, including organized online piracy. These efforts have led to enforcement procedures involving highly sophisticated intelligence, and the worldwide arrest of suspects targeting various acts that include peer-to-peer file sharing, satellite signal theft, counterfeiting of luxury goods, pharmaceuticals and cosmetics, theft of trade secretes, and selling of counterfeit goods such as software.<sup>43</sup>

In summary the legal and policy trends in the United States demonstrate the strict enforcement of intellectual property rights as the main public policy objective. The rights conferred by intellectual property reduce the role of competition/antitrust rules.

#### **III.2** Recent Trends in the European Union

The European Union has been actively pursuing measures to harmonize standards and institutional mechanisms for intellectual property rights enforcement. In 2003 a new common regulation 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, entered into force. The regulation extends the scope of intellectual property rights subject to action by customs authorities. In addition to trademark counterfeit goods and copyright piracy goods as defined in the TRIPS Agreement, the scope of infringement of intellectual property rights are extended to include, among others, goods infringing a patent, a supplementary certificate (plant protection or medicinal product) and geographical indications.

The regulation also extends the scope of possible actions by customs authorities on border measures. The possible actions will include suspension of the release of goods in the European market, detention of the goods for three days or destruction of the goods without awaiting the outcome of final legal proceedings with the agreement of the holder of the goods or the declarant. The regulation provides for certain safeguards against the potential abuse of the border measures and provides rights for the declarant, importer or consignee of the goods. For example, under Article 4 of Council Regulation 1383/2003, customs authorities act only at the right-holder's request. The customs authority may also ask the right holder to provide information in the application for customs action before taking any action on the suspected infringing good. The importer, holder or consignee of the goods can obtain release of the goods if proceedings for a substantive decision are not taken within 10 days.

However, there are reasonable grounds to be concerned about the potential impact of extending broad powers to customs officials on border measures. The potential danger is exemplified in the strategic use by the United States' multinational Monsanto Co. of the European Union's legislation on customs action in suspected cases of intellectual property infringements. Monsanto filed patent infringement lawsuits against soymeal importers in Denmark, the Netherlands, the United Kingdom and Spain. Monsanto Co. aimed at collecting royalties on imports of Argentine soymeal based on a European patent on the company's "Roundup Ready" soybeans. Monsanto Co. argued that these were illegal imports given

<sup>&</sup>lt;sup>42</sup> United States Department of Justice, Office of Legislative Affairs (2007).

<sup>&</sup>lt;sup>43</sup> Department of Justice, *Progress Report of the Department of Justice's Task Force on Intellectual Property*, 2006, pp. 25-29.

<sup>&</sup>lt;sup>44</sup> European Union, Council Regulation (EC) No 1383/2003 of 22 July 2003. See also Commission Regulation (EC) No 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003.

<sup>&</sup>lt;sup>45</sup> WTO (1994), TRIPS Agreement Article 51, footnote 14.

<sup>&</sup>lt;sup>46</sup> European Union, Council Regulation (EC) No 1383/2003 of 22 July 2003, Article 4.

<sup>&</sup>lt;sup>47</sup> El-Amin , Ahmed, 2006, "Soy imports delayed as Argentina fights Monsanto over GM", *GRAIN*, available at http://www.grain.org/research/contamination.cfm?id=368

that the soymeal was made from soybeans that Argentine farmers use without paying royalties. The European Commission gave its expert opinion that soybean by-products are not covered under European patents held by Monsanto Co. Monsanto Co. requested customs officials in various ports of European Union countries to seize incoming soymeal shipments from Argentina. Given that the common regulation on customs actions concerning intellectual property infringements No 1383/2003 extends coverage to include patent and plant variety infringements, Monsanto Co. was able temporarily to block the shipments from entering European territory, from which both Argentine exporters and European importers of soymeal suffered extensive losses, including legal expenses and costs of storing the merchandise delayed at the ports. Recently, the Spanish court<sup>48</sup> and United Kingdom High court<sup>49</sup> ruled against Monsanto's claims.

The regulations on border measures and their impact as to whether they may constitute barriers to legitimate trade might constitute non-compliance with Article 41 of the TRIPS Agreement and the relevant provisions of GATT. The European Commission has established that an annual report should be produced to evaluate the regulation and that, where necessary, it should include recommendations for its amendment.

A second important development in the European Union is the adoption of Directive 2004/48/EC on enforcement of intellectual property rights in April 2004. The stated aim of the Directive was to 'approximate legislative systems so as to ensure a high, equivalent and homogenous level of protection in the Internal Market.'50 The Directive applies to any infringement of intellectual property rights that have been harmonized among the European Union, including those not covered under the TRIPS Agreement such as utility model rights and the sui generis right of a database maker, and establishes penalties and remedies that must be available under civil law. Some of the "TRIPS plus" elements of the Directive include: (1) the power for the authorities to seize documentary evidence relating to the suspected infringement and the suspected goods themselves, (2) an obligation for courts to provide information on the source of infringing goods, (3) interlocutory (preliminary) injunctions that may be provided in advance of a decision on the merits of a case, (4) the seizure of offenders' bank accounts and other assets and profits to ensure payment of due damages, (5) the recall of infringing goods at the offender's own expense, and (6) the choice for the right holder of either lump sum damages (up to double normal royalties or license fees) or compensation for lost profits.

The Directive underlines that it should not be used to restrict competition unduly in a manner contrary to the Treaty establishing the European Community.<sup>51</sup> The European Commission undertook several measures to ensure the implementation of the Directive, including signing cooperation agreements with major trade representatives such as airlines, shipping companies and express carriers with a view to improving information exchange on traffic in fakes.<sup>52</sup>

Recent efforts in the field of intellectual property rights enforcement in the European Union are focusing on the Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights.<sup>53</sup> However, the move to harmonize and implement higher criminal sanctions under intellectual property rights enforcement faces difficult challenges considering the divergence in the legal systems and policies of European countries.

<sup>&</sup>lt;sup>48</sup> Ruling of the Madrid Trade Tribunal, Monsanto vs. Sesostris, 6 September 2007.

<sup>&</sup>lt;sup>49</sup> United Kingdom England and Wales High Court (Patents Court) Decisions (2007), Monsanto Technology LLC vs. Cargill International S.A. & Anor [2007] EWHC 2257 (Pat), 10 October 2007, available at http://www.bailii.org/ew/cases/EWHC/Patents/2007/2257.html.

<sup>&</sup>lt;sup>50</sup> European Union, Directive 2004/48/EC of the European Parliament and the Council of 29 April 2004 on the enforcement of intellectual property rights, 30.4.2004 Official Journal of the European Union L157/47, preamble, para. 10.

Ibid., preamble, para. 12.

<sup>&</sup>lt;sup>52</sup> United Kingdom Central Government (2005), p. 25.

<sup>&</sup>lt;sup>53</sup> European countries are also continuing to explore the possibility of establishing an optional European Patent Litigation Agreement. The proposed agreement would establish a European Patent Judiciary and its organ, the European Patent Court.

After much debate, the more stringent initial proposal of the Directive that included applying criminal sanctions and penalties to patent infringements was required to be revised. The European Parliament legislative resolution on the recent draft of the Directive on criminal measures amended and clarified various provisions of the Directive. For example, the resolution clarifies that the Directive does not apply to any infringement of an intellectual property right related to patents, utility models and supplementary protection certificates or to parallel imports of original goods which have been marketed with the agreement of a right holder in the third country. Member States are also required to ensure that the rights of defendants are duly protected and guaranteed. The resolution also requires Member States to prohibit and sanction the misuse of threats of criminal sanctions, and requires that Member States prohibit procedural misuse, especially where criminal measures are employed for the enforcement of the requirements of civil law. The justification provided for this amendment is as follows:

"the potential for a right-holder to deter potential infringers (i.e., competitors) increases considerably if he can threaten them with criminal penalties. Both international and European law require the prevention of misuse of intellectual property rights. Misuse disrupts free competition". 56

The development in jurisprudence with respect to intellectual property rights enforcement in the European Union is fragmented. However, a landmark decision in Finland in a criminal case involving the distribution of a computer programme for circumventing effective technological protection measures (TPM) in DVDs may set a precedent if it is upheld by appellate bodies. The Court ruled that the specific TPM affected by the computer programme distributed by the defendants is not an 'effective' protection measure for protection purposes since it has been circumvented before and the conduct in challenge cannot be considered to have caused any slight gap in the protection compared to the circumstances already existing.<sup>57</sup> In another cases a Belgian court has ruled that internet service providers (ISP) should install the filtering mechanism to prevent the illegal sharing of copyrighted materials in peer-to-peer file sharing platforms.<sup>58</sup>

The growing consideration in Europe on the interaction between competition law and intellectual property law may in future impact the current framework for enforcement of intellectual property rights. The European Commission has recently issued various landmark decisions related to competition and intellectual property rights. The *IMS Health* case concerns the refusal to license to use a database in which copyright subsists despite an offer to pay valuable considerations for the license. The European Court of Justice stated that in order for the refusal to license to be abusive it is sufficient that three cumulative conditions be satisfied, namely, (1) the refusal prevented the emergence of a new product for which there was a potential consumer demand; (2) the refusal to license by the copyright owner was not justified by objective considerations; and (3) the refusal was such as to exclude any competition on a secondary market.<sup>59</sup>

In a case against Microsoft, the European Commission rejected Microsoft's argument that its rights in intellectual property rights products should justify maintaining absolute discretion with respect to the licensing of its product, regardless of antitrust law. The Commission reasoned that lack of interoperability would lock in consumers to a specific product, that if Microsoft's strategy is successful new products will be confined to niche existence or not be viable at all, that there will be little scope for innovation, and that these reasons outweigh the mere protection of the proprietary interest if Microsoft's anti-competitive

<sup>&</sup>lt;sup>54</sup> European Parliament (2007a), P6\_TA(2007)0145.

<sup>&</sup>lt;sup>55</sup> European Parliament (2007b), A6-0073/200.

<sup>&</sup>lt;sup>56</sup> *Ibid.*, Amendment 12, Article 2.

<sup>&</sup>lt;sup>57</sup> Helsinki District Court (2007), 07/4535, Public Prosecutor v. Rauhala and X, (Misdemeanor of violating a technological measure), 5 February 2007.

<sup>&</sup>lt;sup>58</sup> Intellectual Property Watch (2007).

<sup>&</sup>lt;sup>59</sup> Stockholm Network (2006), p.12.

behaviour remains unfettered. 60 The European Court sustained the decision of the Commission. Microsoft declared that it would comply with the ruling.

Recently the European Commission began an enquiry into the pharmaceutical sector in Europe to the whether companies have undertaken anti-competitive practices including deliberate abuse of patent rights and patent-dispute settlements between companies to ward of competition.<sup>61</sup> The enquiry so far has included a number of raids of the offices of European-based pharmaceutical companies such as Pfizer and GlaxoSmithKline. One of the concerns that prompted the enquiry is the declining number of new pharmaceuticals coming to market alongside the growing number of patents being granted.

In brief, the European Union is aggressively pushing to harmonize the legal mechanisms and facilitate the enforcement of intellectual property rights under a community rule. The effort of the European Union with regard to the enforcement of intellectual property rights is accompanied by the active role of the European Parliament in attempting to ensure that the European Commission regulations respect due process, balance interests and provide safeguard mechanisms. Moreover, Europe is emerging as the world's top regulator of competition, at least in cases involving Microsoft.

#### **III.3** United States and European Union Foreign Policy

There are several initiatives in the developed countries targeting the developing countries and transition economies on intellectual property rights enforcement. The enforcement of intellectual property rights in third countries is the main foreign policy objective and driving force for trilateral cooperation between the European Union, Japan and the United States on intellectual property rights. The most recent initiative of the triad is to negotiate a new international treaty on "anti-counterfeiting" - known as the Anti-Counterfeiting Trade Agreement (ACTA) - with major trading partners. 62 The stated purpose of the agreement is to "contribute to fighting counterfeit by building international cooperation leading to harmonized standards and better communication between authorities, establishing common enforcement practices to promote strong intellectual property protection, and creating a strong modern framework which reflects the changing nature of intellectual property theft in the global economy."63

The United States position on intellectual property rights enforcement is clear: the 'goal is to control piracy through strong laws and effective enforcement worldwide, and to ensure that protection remains effective as technology develops in the future.

Likewise, the European Union's policy shows that it considers it to be legitimate to utilize asymmetrical powerful positions in the world economy to carry out international intellectual property rights policy. 65 The European Commission adopted a strategy for the enforcement of intellectual property rights in third countries in 2005. 66 The strategy provides for several action areas that include:

- 1. periodically conducting surveys in order to develop a list of priority countries for the implementation of the strategy;
- the possibility of launching an initiative in the TRIPS Council highlighting the fact that the implementation of the TRIPS Agreement requirements in national laws has proved to be insufficient to combat piracy and counterfeiting, and of considering possible amendments to the TRIPS Agreement so that countries apply border measures not only on imports but also on exports and transit trade.

<sup>63</sup> European Union press release (2007).

<sup>&</sup>lt;sup>60</sup> Commission Decision of 24.03.2004 relating to a proceeding under Article 82 of the EC Treaty (Case Comp/C-3/37.792 Microsoft), Apr. 21, 2004, paras. 694, 700 and 724.

European Union press release IP/08/49, Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections, Brussels, 16 January 2008.

<sup>&</sup>lt;sup>62</sup> USPTO (2007) press release.

<sup>&</sup>lt;sup>64</sup> United States Trade Representative, Work on Intellectual Property webpage, visited on December 2007.

<sup>&</sup>lt;sup>65</sup> Braithwaite and Drahos (2000), p. 27-33.

<sup>&</sup>lt;sup>66</sup> European Commission Directorate General for Trade (2004).

- 3. full implementation and strengthening of bilateral customs-cooperation agreements with China, the United States, Japan and other trading partners;
- 4. turning technical assistance from 'demand-driven' to 'dialogue driven' and, in the case of 'production' countries, shifting the focus in any cooperation programmes from assistance in drafting legislation to a more enforcement-oriented strategy, including training programmes for judges, police and customs. The strategy also aims at improving dialogue with international organizations to ensure that their technical assistance is compatible with the strategy for enforcement of intellectual property rights;
- 5. considering trade dispute settlement and sanctions within the WTO.

As part of STOP!, both the United States Trade Representative (USTR) and the State Department are actively promoting the adoption of best practices, sharing information, streamlining procedures and strengthening technical assistance efforts for enforcement internationally. These efforts include new initiatives in multilateral fora to improve global intellectual property rights environment, such as the G8, the United States–European Union Summit, the Organization for Economic Cooperation and Development (OECD), the Asia-Pacific Economic Cooperation (APEC) forum and the Security and Prosperity Partnership (Canada and Mexico).

#### III.3.1 Bilateral Technical Assistance

The United States and European Union are utilizing technical assistance as a means of strengthening intellectual property rights enforcement in third countries. Under Article 67 of the TRIPS Agreement, developed countries are obliged to provide technical assistance in favour of developing countries and least developed countries (LDCs). The examination of the submissions of developed countries to the TRIPS Council demonstrates that most of the technical assistance provided is now aimed at strengthening the capacity of developing countries to enforce the protection of intellectual property rights. <sup>67</sup>

The United States government has undertaken extensive training in China and the rest of Asia, Latin America and the Caribbean, Africa and the Middle East, and other countries. The training involved interagency arrangements and discussions, academic training and seminars, and even an intellectual property rights enforcement program for Supreme Court and Appellate Court judges from 23 countries. There were joint operations and international enforcement coordination with other countries. The first joint operation with China led to the arrest and prosecution of United States' citizens in China for trade in counterfeited DVDs. Moreover, the United States has increased the number of its official representatives abroad dedicated exclusively to intellectual property rights enforcement.

#### III.3.2 Unilateral Trade-Related Mechanism

Important foreign policy tools of the developed countries include the combined use of unilateral trade review mechanisms and the WTO dispute settlement mechanism. The challenges in intellectual property enforcement for developing countries are aggravated by the fact that their efforts in this field are not measured only by their compliance with enforcement obligations under the TRIPS Agreement but by the *results* achieved. To Key activities include Special 301 reviews of United States' trading partners, the special provincial review of China, and continued engagement with Russia through both bilateral and multilateral

<sup>&</sup>lt;sup>67</sup> D. Matthews and V. Munoz-Tellez (2006), p. 629-653.

<sup>&</sup>lt;sup>68</sup> United States National Intellectual Property Law Enforcement Coordination Council (2005), pp. 48-60.

<sup>&</sup>lt;sup>69</sup> United States Department of Justice (2006), p. 27.

<sup>&</sup>lt;sup>70</sup>As the former United States Trade Representative Robert Zoellick noted in a speech at the Electronics Industries Alliance 2004 Government – Industry Dinner, May 25, 2004, the U.S. strategy is "not focused on process, but on producing real results that create opportunities for American workers and American companies."

avenues. The United States maintains a review mechanism for protection and enforcement of intellectual property rights in other countries called 'Special Section 301.'71 The European Union Trade Barrier Review (TBR) mechanisms also function as key tools to influence countries to increase the enforcement of intellectual property rights. While it is a basic obligation of all WTO Members to channel any controversy relating to intellectual property rights through the multilateral procedure under Article 23 of the Dispute Settlement Understanding, the United States has continued to use the threat of sanctions relying on unilateral determinations made under its Section 301 Review. <sup>72</sup> In the case of the United States, in order for developing countries to achieve beneficiary status for preferential trade programmes, they must provide adequate and effective protection of intellectual property rights. However, the interpretation of what constitutes enforcement is subject to the discretionary power of the United States.

While the unilateral mechanisms and United States and European Union cooperation create the necessary pressure, FTAs and the WTO dispute settlement mechanism secure compliance. The most active negotiations on intellectual property rights are currently occurring at the bilateral level, mainly through FTAs. The FTAs and the subsequent changes in intellectual property enforcement standards are analysed in the next section. An integral part of the United States' strategy with regards to FTAs is to provide for higher standards of intellectual property rights protection and enforcement. For the powerful United States domestic corporations, the negotiation of each FTA is a new opportunity to lobby the government for new and higher standards, which serve as precedents for future intellectual property rights policy.<sup>73</sup> Moreover, the coming into force of the 2002 Trade Act, which was valid until July 2007, solidified the relationship between the United States' intellectual property rights policy-making officials and the industry groups.<sup>74</sup>

#### III. 4 The Role of Industry in Shaping the Structure of Intellectual Property Enforcement

The adoption of the TRIPS Agreement under the WTO was the direct result of the demands of the information technology, biotech, pharmaceutical, entertainment and semiconductor industries in the advanced countries.<sup>75</sup> These industries continue to play an important role in the subsequent implementation of the agreement, upgrading the standards of protection and intellectual property rights enforcement. The current national and international discourse led by the industries in the developed countries is important for an understanding of the policy developments and approaches of governments.

From the industry perspective, international discourse is an important element in the strategy aimed at establishing harmonized standards of intellectual property protection and enforcement modelled on the normative framework of the United States, European Union and Japan, and which surpass the obligations of the TRIPS Agreement. Industrial groups and developed countries are aggressively promoting a narrow approach for intellectual property rights enforcement, which is unduly limited to defending only the interests of right holders. <sup>76</sup> The objective is to achieve an international framework that acts as a deterrent to

<sup>74</sup> Section 2104 (e) of the Trade Act of 2002 requires that separate advisory committees provide the President and the U.S. Trade Representative and Congress with a detailed report, which must include an advisory opinion as to whether and to what extent the agreement promotes the economic interests of the U.S..

75 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was adopted upon the conclusion of the Uruguay Round of multilateral trade negotiations in 1994 as part of the 'single undertaking'.

<sup>&</sup>lt;sup>71</sup> Section 301 of the United States. Trade Act of 1974, as amended.

<sup>&</sup>lt;sup>72</sup> During negotiations on the Dispute Settlement Understanding (DSU) in the Uruguay Round, other Quad countries (European Union, Japan and Canada) and main players from the developing world had agreed on Article 23 to put an end to the United States' unilateralism and to scrutinize actions through the multilateral system. However, the basic consistency of Section 301 was unsuccessfully challenged by the EC in 2000. See WTO (2000), Panel Report, United States — Sections 301-310 of the Trade Act of 1974, WT/DS152/R, adopted 27 January 2000, DSR 2000:II, 815.

<sup>&</sup>lt;sup>73</sup> ITAC (2004a), p.4.

<sup>&</sup>lt;sup>76</sup> WIPO's webpage on Intellectual Property Enforcement Issues and Strategies defines intellectual property enforcement as "the guarantee that the private rights the intellectual property right holder has obtained through the intellectual property system are respected" (last visited in August 2006).

infringements of state-conferred intellectual property rights and to assist right holders to obtain quick and efficient remedies when infringements take place. The aim is to make intellectual property rights enforcement cheaper, easier and more secure and to put industries in a better position to earn profits from the export of their intellectual property rights-based products. As a result, the industry approach to enforcement, in sharp contrast to a public policy approach that takes into consideration issues broader than industry interests in formulating policy, is one of the major emerging challenges for national intellectual property rights systems, particularly for developing countries.

The current industry discourse, which is also reflected in the official stance of the United States and the European Union, has taken a particular new form: a massive global campaign against 'piracy and counterfeit' based on claims of losses by industries. It is important to note the specific language and linkages in the discourse. For example, while not making any distinction as to the types, areas and scope of the infringement, generally the arguments seek to connect intellectual property rights "piracy and counterfeiting" to theft, criminal activities and organized crime, even to terrorism. While there might be instances where this in fact occurs, it distorts the perspective of what intellectual property rights infringement is and what intellectual property rights enforcement is about.

While the terms 'counterfeiting' and 'piracy' do not follow a single agreed definition and are used in various ways, international business associations, developed country governments and WIPO refer to these terms as relating to the infringement of trademarks, in the case of 'counterfeit', whereas 'piracy' is associated with infringements of copyright or related rights. However, more recently the term is being redefined to include patent infringement, which is not included in the definition of counterfeit and piracy in the TRIPS Agreement. In relation to copyrighted works, piracy is said to occur mainly with respect to digital media, e.g., DVDs and CDs, as well as in the digital distribution of films, music and software on internet. In relation to trademarks, it is argued that counterfeiting takes place mainly in clothing, footwear, electronic devices, and pharmaceutical products.

The powerful corporations holding strong economic interests lobby their governments to set up complex legal frameworks in developing countries. It is important to note that many of the piracy and counterfeit activities were until recently legitimate activities in most countries, including in developed countries (e.g., circumvention of DVD encryption systems). It is only recently that such acts have been deemed illegitimate, and thus considered serious infringements and criminal acts. While it is clear that serious intellectual property rights infringement should be tackled, expanded claims of infringement based on loss of profit and a loose interpretation of enforcement rules without balanced and pro-competitive mechanisms are emerging as a challenge for developing countries.<sup>77</sup> According to the proposed intellectual property enforcement Act of the United States, an attempt to infringe intellectual property rights could also entail criminal responsibility. A similar approach was pursued, but defeated, in the second European intellectual property Directive.

Another problematic area is the accounting of and data on the extent and effect of international counterfeiting and piracy. While it is necessary that claims on intellectual property rights infringement be based on substantial evidence, the United States and the European Union are evaluating intellectual property enforcement in developing countries against levels of counterfeiting and piracy that are mainly based on estimated losses that their industries claim to exist according to their own surveys. The industry surveys are often subjective, based on uncertain methodologies and special pleading.<sup>78</sup> The estimates of the levels of counterfeit and piracy are imperfect and tend to exhibit an upward bias. The difficulty in estimating levels of actual counterfeiting and piracy is exacerbated by the lack of common use of the definition of the terms in the TRIPS Agreement. The problem in accounting the levels of counterfeiting and piracy and the upward bias in most industry-based figures were confirmed in recent expert reports leading up to the 2007 OECD report on counterfeiting and piracy.<sup>79</sup>

<sup>&</sup>lt;sup>77</sup> Commission on Intellectual Property (2002a), p. 167

<sup>&</sup>lt;sup>78</sup> Business Software Alliance (BSA) and International Data Corporation (IDC) (2004), IIPA (2004b) and Appendix B, for the methodologies used. See also Drahos (2004), p.14.

<sup>&</sup>lt;sup>79</sup> Karsten Olsen (2005), and OECD Report (2007).

Most estimates assume, for example, that counterfeit and pirated sales displace legitimate sales, regardless of how the price and purchasing behaviour may be affected by stronger copyright and trademark protection. Likewise, the methodology used in the surveys to calculate levels of intellectual property rights infringement in foreign countries is largely based on the industry's subjective opinion. This disregards the conduct of trade and business organizations in price fixing or in arbitrary inflation of price and remains the continued challenge for developing countries.

The emerging trends in the promotion of intellectual property rights enforcement, based on narrow interest-group politics, increase the need for human and financial resources, undermine the development of a balanced public policy and disregard the conduct and practices of companies. The challenge emerging from the current discourse is enormous, as it is pursued at the coordinated European Union/United States level for the exercise of power and influence through unilateral trade review mechanisms, through the multilateral process (including the TRIPS Council and WIPO) and through FTAs.

#### III. 5 Recent Trends in Developing Countries

Many developing countries started to implement the TRIPS Agreement in 2000 upon the expiry of the transition period provided under it. The least developed countries are not required to implement the provisions of the TRIPS Agreement until 2013, except for the obligation to provide national treatment and most-favoured-nation treatment.

The most notable trend in intellectual property enforcement in developing countries is the increase in awareness campaigns, the coordination of government agencies for enforcement of intellectual property rights, the establishment of specialized benches with jurisdiction over intellectual properly rights, the undertaking of various administrative measures, police raids, and an extensive review of laws.

The establishment of a national mechanism for coordination of government agencies for the enforcement of intellectual property rights has been the major trend since 2000. In Brazil the National Council against Piracy was established on 1 October 2004, The Council is composed of seven ministeriallevel agencies, other federal agencies, and six private associations: the audiovisual industry (ADEPI), phonograms (ABPD), software (BSA), publishing (ABDR), tobacco, alcohol and fuel (industrial sector – ETCO) and the Brazilian Intellectual Property Association (ABPI).<sup>81</sup> In India an Inter-ministerial Coordination Committee was established consisting of 10 ministries and departments.

Some developing countries are also establishing divisions in courts of law with jurisdiction exclusively over intellectual property rights. Malaysia introduced court divisions dedicated to their enforcement in July 2007. Thailand has had intellectual property courts since 1997. 82

Campaigns, police raids and sudden crackdowns have become the most reported government-led efforts in the enforcement of intellectual property rights. In China arrests related to intellectual property enforcement crimes increased by 36% and prosecutions by 75% from 2000 to 2004. During that period 5,305 criminal intellectual property infringement cases were brought to court.<sup>83</sup> Administrative remedies are also used extensively to address infringements of intellectual property rights.<sup>84</sup>

<sup>80</sup> See for example, WIPO/ACE/3/16 (China) WIPO/ACE/3/5 (Sri Lanka) and WIPO/ACE/3/8 Rev. (South

<sup>&</sup>lt;sup>81</sup> WIPO (2006), Public Policy for Combating Piracy in Brazil, WIPO/ACE/3/14, May 2006.

<sup>&</sup>lt;sup>82</sup> Ariyanuntaka (1998), Vichai TRIPS and the Specialized Intellectual Property Court in Thailand, available at http://asialaw.tripod.com/articles/trips-vichai.html.

<sup>&</sup>lt;sup>3</sup> Hunter (2007), 545.

<sup>&</sup>lt;sup>84</sup> *Ibid*. 528.

Furthermore, several countries continue to introduce intellectual property enforcement legislation. Since its accession to the WTO, China has adopted legislation and judicial interpretations of existing legislation on enforcement of intellectual property rights that includes:

- 1. Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues of Concrete Application of Laws in Handling Criminal Cases of Infringing Intellectual Property (2004 and 2007). The interpretation lowered the economic value of the infringement for the initiation of criminal proceedings, expanded the definition of an intellectual property infringement accomplice, and increased the punishment. However, this interpretation of the Supreme Court has become the basis for the United Sates to initiate a WTO dispute settlement case against China.<sup>85</sup>
- 2. Regulation of People's Republic of China on Customs Protection of Intellectual Property Rights, Order of the State Council of the People's Republic of China, No. 395, Adopted by the State Council on 26 November 2003, enacted from 1 March 2004. These regulations have also become the basis for the United States to request a panel on measures affecting the enforcement of intellectual property rights in China.
- 3. Interpretations of the Supreme People's Court of Several Issues Concerning the Application of the Law to the Trial of Civil Dispute Cases Involving Trademarks, promulgated on 12 October 2002 and effective from 16 October 2002
- 4. Measures for Administrative Enforcement of Patent, promulgated on 17 December 2001 by the State Intellectual Property Office
- 5. Several Provisions of the Supreme People's Court for the Application of Law to Stopping Infringement of Patent Right Before Instituting Legal Proceedings, adopted on 5 June 2001 at the 1179th Meeting of the Adjudication Committee of the Supreme People's Court. 86

The developments show the major challenges of developing countries in building their intellectual property system and meeting the demands of developed countries. Enforcement of intellectual property rights appears to have been taken mainly as the responsibility of government involving the use of law enforcement agencies.

<sup>85</sup> WTO (2007), WT/DS362/7.

<sup>&</sup>lt;sup>86</sup> All laws available at <a href="http://www.chinaiprlaw.com/english/default.htm">http://www.chinaiprlaw.com/english/default.htm</a>

## IV. THE CHANGING STRUCTURE AND GOVERNANCE OF INTELLECTUAL PROPERTY **ENFORCEMENT**

Developed countries are making a concerted and coordinated effort to increase enforcement of intellectual property rights globally through a combination of efforts at the multilateral, regional and bilateral level. These include:

- 1. setting enforcement of intellectual property rights as a priority in the common agenda of the G8 countries and proposing negotiations on a new international treaty on anti-counterfeiting;
- 2. demanding that the WTO make enforcement part of the permanent agenda of the TRIPS Council;
- 3. exerting pressure at WIPO to strengthen the mandate of the ACE to include soft law normsetting, such as developing best practices and guidelines on enforcement
- 4. increasing the role of the WCO and Interpol in intellectual property enforcement, particularly through border measure controls and the use of criminal law;
- 5. introducing detailed TRIPS-plus obligations in the enforcement of intellectual property rights in bilateral FTAs and EPAs (economic partnership agreements) negotiated by the United States and European Union with developing countries.

#### IV.1 The Agenda of the G8, the Heiligendamm Process, the OECD and the Emerging Interest in a **New International Framework on Enforcement**

At the 2006 G8 Leaders Summit in St. Petersburg, a comprehensive intellectual property rights enforcement strategy was announced that delivered upon the strategy adopted in 2005. The G8 Statement on "Combating International Property Rights Piracy and Counterfeiting" has several key objectives, namely:

- a. to 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. to link victims of intellectual property rights infringement to national enforcement authorities;
- c. to build capacity in developing countries to combat trade in counterfeit and pirated goods;
- d. to conduct further research into the economic impact of piracy and counterfeiting on national economies, brands, rights holders and public health/safety;
- e. to refer relevant law enforcement work (including online piracy) to the Lyon-Roma Anti-Crime and Terrorism Group (LR/ACT);

A year later, specific initiatives were endorsed by the G8 in June 2007 aimed at improving and deepening cooperation among G8 members and deliver real enforcement results<sup>87</sup>. These include:

- a. guidelines for customs and border enforcement cooperation, designed to strengthen cooperation and coordination among G8 nation customs and law enforcement administrations;
- b. guidelines for technical assistance on intellectual property rights protection to developing countries, and a mechanism to better coordinate and leverage existing G8 assistance to such

<sup>87</sup> 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.

- countries to build capacity to combat trade in counterfeited and pirated goods and to strengthen intellectual property enforcement.
- c. recommendations aimed at improving G8 countries' cooperative actions to combat serious and organized intellectual property rights, and further work on this basis to facilitate structured international cooperation in the investigation and prosecution of those crimes.

Progress of the pilot plans will be reviewed by the G8 in 2008.

The G8 also established an "IPR Taskforce" focusing on "anti-counterfeiting and piracy" to look together at how best to improve international intellectual property rights protection and enforcement and to produce recommendations for action. The G8 intends to place the recommendations emerging from the IPR Taskforce for discussion as part of the Heiligendamm process. The G8 also expects that while "fully respecting the mandate, function and role of the component multilateral organizations, in particular WTO and WIPO, participants in the Heiligendamm dialogue may also discuss initiatives aimed at the strengthening of intellectual property rights protection which should then be addressed in the appropriate fora."

The Heiligendamm process is a new two-year high-level dialogue between the G8 countries and emerging countries, mainly Brazil, China, India, Mexico and South Africa. The platform for the dialogue will be the Organization for Economic Cooperation and Development (OECD), which is dominated by developed countries. But, while the initiative is a significant step towards increasing collaboration among the G8 and the larger developing country economies on issues of global importance, the desire for participation in the "club-of-the-rich" should not come at any price.<sup>88</sup>

Intellectual property rights protection and enforcement is not an integral part of the issues that make up the Heiligendamm dialogue. The joint statement of the G8 and the Heads of State and/or Government of Brazil, China, India, Mexico and South Africa in Heigendamm on 8 June 2007 clearly specifies the issues on which there is to be dialogue<sup>89</sup>, namely:

- promoting cross border investment to their mutual benefit;
- promoting research and innovation;
- fighting climate change;
- energy
- development, particularly in Africa

The commitment to cooperate in "promoting research and innovation" includes "a positive exchange of views on international experiences" related to intellectual property protection and implementation of agreed international intellectual property rights' protection standards. It does not envisage strengthening intellectual property rights protection and enforcement, or discussing recommendations from the G8 "IPR Taskforce on anti-counterfeiting and piracy". Instead, the Joint Statement of Heiligendamm provides a more balanced approach to the expected dialogue, highlighting that in the exchange of views on international experience of intellectual property rights protection there is a "need to consider the protection of intellectual property rights in conjunction with the common good of human kind for the purposes of protecting the environment and supporting health. In this regard, we recall the Doha Declaration on the TRIPS Agreement and Public Health".

The continued push by the G8 to impose new intellectual property standards of protection and enforcement on developing countries risks tarnishing the new cooperation envisaged by the Heigendamm process in the area of promoting research and innovation, even before dialogue has commenced.

...

<sup>88</sup> Katharina Gnath (2007).

<sup>&</sup>lt;sup>89</sup> See Joint Statement by the German G8 Presidency and the Heads of State and/or Government of Brazil, China, India, Mexico and South Africa on the occasion of the G8 Summit in Heiligendamm, June 8, 2007.

On 23 October 2007, the Ministry of Foreign Affairs of Japan, the European Commission and the Office of the United States' Trade Representative (USTR) separately announced their intention to bring about "a new international legal framework to strengthen the enforcement of intellectual property rights." The USTR pointed out that the agreement would not involve changes to the TRIPS Agreement; rather, the goal was to set a new, higher benchmark for enforcement that countries could join "on a voluntary basis" and negotiations would not be conducted as part of any international organization.

According to the United States Patent and Trademark office (USPTO), the reasoning for the new treaty is that "worldwide proliferation of counterfeit and pirated products poses an ever-increasing threat not only to sustainable economic development but also to consumers' health and safety. Moreover, new issues have also been emerging rapidly on a global scale, such as the violation of intellectual property rights through the trading of counterfeit goods over the Internet."91 This statement disregards many important facts and omits important information. First, there is no conclusive evidence as to the extent or effects of international trade in "counterfeiting and pirated products". Second, it is unclear from the use of the terms "counterfeit" and "piracy" what the new treaty would actually cover. Third, the statement omits the fact that many countries have not taken up international obligations and granted rights incorporated under the WIPO Copyright and the WIPO Performances and Phonograms Treaties. Whether there is "violation of intellectual property rights through the trading of counterfeit goods over the Internet" depends on whether such intellectual property rights are protected or not in the respective jurisdiction.

Other misleading statements such as that "developing countries are among the biggest victims [of counterfeiting and piracy], as counterfeiters passing off shoddy and unsafe goods undermine emerging local economies",92 also need dissecting.

The effects of trade in trademark counterfeit, copyright piracy and other forms of intellectual property infringement cannot be judged as a whole. To address the real problems there is a need to provide clear facts and information, avoiding dogma and rhetoric. The trade in substandard or "counterfeit" pharmaceutical drugs provides a case example. Counterfeit drugs can be understood as those that mimic authentic drugs, that is, substandard drugs produced with little or no attention to good manufacturing practices. 93 A problem of concern for both developed and developing countries on which collaboration may be meaningful is that of organized illegal circuits dealing in the trade of substandard drugs. However, such collaboration should ensure that the legal trade in generic drugs in accordance with the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health and the related Decision of 6 December 2005 is not in any way affected. It should not be an opportunity for pharmaceutical multinationals to cut back trade by potential competitors from developing countries manufacturing generic drugs. Generic drugs are chemically identical to their branded counterparts, yet they are sold at substantially lower prices. Problems related to the existence of substandard "counterfeit" drugs, mainly in developing country markets, should be clearly distinguished and separated from the broader debate and differing interests in the strengthening of global enforcement of intellectual property rights.

#### **IV.2** The TRIPS Council and Accession Protocols

The TRIPS Council continuously reviews the implementation of the TRIPS Agreement and commitments by developing countries under the accession protocols.<sup>94</sup> Developed countries, particularly the United States, the European Union, Switzerland and Japan, are actively seeking that the TRIPS Council increase

<sup>90</sup> See), Ministry of Foreign Affairs of Japan (2007), press release.

<sup>&</sup>lt;sup>91</sup> See USPTO (2007) press release.

<sup>93</sup> Definition of "counterfeit drugs" as found in Pécoul, Chirac, Trouiller and Pinel (MSF), Access to essential drugs in poor countries: a lost battle?, JAMA, 27 January, 1999. 94 WTO (2005), IP/C/38.

its vigilance role in respect of member states' compliance with their obligations under the TRIPS Agreement. In particular, they seek that enforcement be a standing agenda item of the TRIPS Council and that the TRIPS Council follow up and discuss members' compliance and share experiences in implementing enforcement measures. They argue that the TRIPS Agreement has given the TRIPS Council the role of overseeing members' commitments.

Moreover, in the negotiations of accession to the WTO, acceding countries were required to review their laws, and sometimes enter into a commitment to adopt intellectual property enforcement procedures beyond those required under the TRIPS Agreement. The full extent of the TRIPS-plus impact of accession procedures is difficult to measure for each acceding countries. The obligations of members of the WTO in respect of intellectual property now cannot be explained only by the provisions of the TRIPS Agreement; they also include the commitments they made during accession to the WTO.

Finally, there are increased initiatives by developed countries to challenge developing country intellectual property enforcement efforts under WTO dispute settlement. The United States recently submitted a formal request under the WTO Dispute Settlement Understanding (DSU) to establish a panel regarding China's compliance with the obligations under the TRIPS Agreement.

#### IV.3 The WIPO Advisory Committee on Enforcement

The exclusion of norm-setting from the mandate of the ACE has not stopped the push from developed countries in this committee to work towards standard-setting in the form of soft law. At the past WIPO Assemblies in September 2007, Italy proposed that the ACE be entrusted with a broader mandate to include the establishment of guidelines and best practices on enforcement of intellectual property rights. This approach of seeking soft-law norm-setting would increase pressure on developing countries to establish TRIPS-plus enforcement standards and serve to legitimize such standards that are being developed through bilateral trade agreements. At the past ACE meeting in November 2007 the issue of the mandate of the committee was not raised.

The discussions in the ACE should continue to focus on sharing national experiences. In the unlikely event that mandate of the ACE be revised to include any form of norm-setting, it is unlikely that developing countries would be in a position to participate fully in its development. The participation of developing countries in the ACE remains limited.

The participation of multiple stakeholders in the ACE is important in seeking that enforcement is discussed in a more holistic manner, not restricted to intellectual property rights enforcement. Part of the implementation of the Development Agenda recently approved by the General Assembly in September 2007 requires the ACE to examine the development dimension of intellectual property enforcement and technical assistance and consider such issues as competition and transfer of technology in relation to enforcement.

#### **IV.4 Intellectual Property Technical Assistance**

WIPO is the main intellectual property rights-related technical assistance provider to developing countries. WIPO and the WTO have an agreement for the provision of intellectual property-related technical assistance, in which WIPO provides technical assistance, including assistance in the implementation of the TRIPS Agreement, to member states of WIPO and the WTO. As enforcement becomes a key priority of

<sup>&</sup>lt;sup>95</sup> The Committee itself is heavily influenced by industry-based trade groups such as the Anti-Counterfeiting Group, AIPPI, and the International Anti Counterfeit Coalition. Only recently have NGOs representing wider public interests begun to join the Committee.

industries in the developed countries and greater influence is exerted by WIPO committees, technical assistance focuses increasingly on strengthening the enforcement of intellectual property rights enforcement in developing countries. Programmes provided through WIPO for intellectual property rights enforcement have been increasing rapidly, though technical assistance in principle should be provided solely on a demand-driven basis.<sup>96</sup>

The development of the principles and guidelines for technical assistance under the WIPO Development Agenda provides an important opportunity for developing countries and WIPO to redirect technical assistance to a more development-oriented and demand-driven system.<sup>97</sup> The WIPO Development Agenda requires the approach on intellectual property to be framed in the context of broader societal interests, and especially development oriented concerns, with the objective 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. 98

### IV.5 The World Customs Organization and Interpol

WIPO is increasingly coordinating its enforcement activities with other intergovernmental organizations such as the World Customs Organization (WCO) and the International Criminal Police Organization (Interpol). Recent developments in the WCO and Interpol also show the growing interest of developed countries in increasing intellectual property enforcement by means of greater border measure controls and the criminalization of intellectual property infringement.

The WCO has developed model legislation related to border measures and customs legislation to deal with intellectual property enforcement. One of the dangers of the increased focus on border control measures is the possibility that the powers given to customs authorities over intellectual property enforcement may be too broad if they have not been adequately trained to pass judgement on whether goods are actually counterfeit or pirated. The risk is even greater for patent infringements, where the criteria determining infringement may vary significantly from one jurisdiction to another. There is also the possibility that the granting of excessively broad powers to customs officials to control the flow of imports and exports of goods that they suspect to be infringing intellectual property rights may create barriers to trade.

Interpol has established a new unit on "intellectual property crime" to deal specifically with intellectual property infringements that may be connected to terrorist and other criminal activities. Interpol characterizes trademark counterfeiting and copyright piracy as "serious intellectual property crimes" but does not provide a clear definition of the terms to clarify what are the necessary elements that must be present to constitute counterfeiting and piracy. This is a serious concern for developing countries and consumers, given that the potential scope of the definition of counterfeit and piracy may be so wide as to include legitimate uses of works and cases where an individual may infringe an intellectual property right without knowing it. There has so far been no harmonization of the scope or definitions of counterfeiting, piracy or crimes related to intellectual property infringements, but the definitions given by the TRIPS Agreement are sufficiently explicit and should be used for reference purposes by the various organizations dealing with counterfeiting and piracy.

<sup>&</sup>lt;sup>96</sup> WIPO (2004), Intellectual Property Enforcement Issues and Strategy webpage, Report of Activities.

<sup>&</sup>lt;sup>97</sup> WIPO, (2005), IMM/1/4.

<sup>98</sup> WIPO (2007), A/43/13 REV, Annex, para. 45.

<sup>&</sup>lt;sup>99</sup> See INTERPOL webpage on Intellectual Property Crime.

#### IV.6 The World Health Organization

The G8 stressed in its declaration that trade in pirated and counterfeit goods threatens health, safety and consumers worldwide, particularly in poorer countries, and added that "in this regard we welcome the work on the WHO initiative to implement the International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT)".

While it may be a worthy initiative, public health groups have expressed concern that the G8 is prioritizing counterfeit medicines over other pressing issues. The international non-governmental organization *Médecins sans frontières* (MSF) on the G8 Declaration on "Promoting Innovation – Protecting Innovation" affirmed that "counterfeit medicines are a danger to people's health that received particular attention by the G8. Similar attention should have been paid to the need for affordable, quality generic medicines upon which poor countries can rely." The Millennium Development Goals were also not high on the priority of the G8 agenda. Moreover, other important processes related to innovation and intellectual property rights taking place in the WHO were absent from the G8 high level declaration. <sup>101</sup>

The WHO International Medicinal Products Anti-Counterfeit Taskforce (IMPACT) was created in 2006 as a global coalition of stakeholders to "build coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines around the globe." The participation of government representatives is voluntary. The taskforce is composed of representatives of the WHO, Interpol, Organization for Economic Co-operation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, International Federation of Pharmaceutical and Manufacturers' Associations, International Generic Pharmaceuticals Alliance, World Self-medication Industry, *Asociación Latinoamericana de Industrias Farmacéuticas*, World Bank, European Commission, Council of Europe, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, and *Pharmaciens sans frontières*. 102

While, on the one hand, the United States has strongly opposed the idea that the WHO should play a greater role in issues related to intellectual property rights and public health, in the context of the Intergovernmental Working Group on Intellectual Property Rights, Innovation and Public Health, by limiting its scope and mandate, the United States and other G8 countries are strongly backing the pharmaceutical industry-led initiative linked to the WHO on counterfeit medicines. Counterfeit medicines are described in a WHO fact sheet as constituting a "global public health crisis", 103 though there is a lack of comprehensive data or studies on the matter other than estimates of industry losses. While manufacturing and trade in suboptimal counterfeit medicines pose a health risk for patients and a hindrance to the development of the nascent domestic pharmaceutical industry in developing countries, the IMPACT taskforce focuses narrowly on "mobilizing awareness and action against fake drugs". The five areas of focus are:

1. **Legislative and regulatory infrastructure**, focusing on developing stronger legislation to empower the police, customs officials and the judiciary. The taskforce is to look at existing laws in countries and present effective models that countries can replicate and adapt to meet their own needs, and will focus on developing principles for the establishment of appropriate legislation and penal sanctions, including a clear legal definition of counterfeit medicines.

<sup>100</sup> MSF press release, "G8 declaration on innovation and intellectual property will directly harm access to medicines across the developing world", 7 June 2007.

International Medicinal Products Anti-Counterfeit Taskforce (IMPACT): <a href="http://www.who.int/impact/impact\_q-a/en/index.html">http://www.who.int/impact/impact\_q-a/en/index.html</a>

A WHO intergovernmental working group is currently developing a Global Strategy and Plan of Action for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries. See <a href="http://www.who.int/phi/en/">http://www.who.int/phi/en/</a>.

World Health Organization, Fact Sheet No.275, "Counterfeit Medicines", Revised 14 November 2006.

- 2. Regulatory implementation, to identify means by which regulators may take action and implement legislative measures taken on counterfeit medicines, including revised approaches to ensure the standards for quality, safety and efficacy are implemented and distribution chains effectively controlled.
- 3. Enforcement, to help identify and coordinate actions between customs, police and the judiciary of different countries to monitor borders, track counterfeit goods and apprehend counterfeiters.
- 4. **Technology,** to help facilitate the transfer of technology across both developed and developing countries, by utilizing the broad partnership from health agencies to pharmaceutical manufacturers and distributors.
- 5. Risk communication, to identify and create coordinated and effective mechanisms to respond and alert key audiences, stakeholders and the general public about counterfeits in communities and across countries. 104

The broad scope of the IMPACT programme calls for close examination and monitoring. It is of concern that while emphasizing enforcement and regulatory reform to include criminal measures to deal with the production of and trade in counterfeit medicines, the potential problems that this may entail for access to medicines are disregarded. For example, as noted by MSF: "Counterfeiting and piracy are different from patent infringement. The TRIPS Agreement does not require that patent infringement be made a criminal offence—it only requires that the patent holder be able to take legal action against the infringement. Where people cannot afford the patented version of a life-saving medicine they may try to import or use a less expensive generic version; the patent holder may then choose to sue to cut off the supply of generic medicines. Legal provisions that criminalize patent infringement... could result in sending doctors and patients to prison for trying to get access to affordable medicines. Such provisions are harsh, extreme, and certainly not required by TRIPS."105

Similarly, the question of the pricing of medicines as an underlying problem related to trade in counterfeit medicines will not fall within the purview of the WHO IMPACT initiative. Moreover, there is no emphasis on the need to stimulate and improve local production capabilities in developing countries to ensure quality and safety. The means through which IMPACT would provide an incentive for the transfer of technology to developing countries to improve local production through IMPACT is unclear. There is a risk that, without proper monitoring, the legislative and regulatory reforms promoted by the IMPACT taskforce may put at risk the legitimate production of and trade in generic drugs, thereby further hindering access to medicines.

#### **IV.7** Free Trade Agreements and Economic Partnership Agreements

The most active negotiations on intellectual property rights are currently occurring at the bilateral level, mainly through FTAs. Developing countries may seek to engage in FTAs with the aim of, among other reasons, strengthening political ties and, in particular, gaining preferential market access. The explanations for the bilateralism of developed countries compared to that of developing countries are fairly straight-forward. FTAs allow the United States and the European Union to tailor concessions from developing countries. Through FTAs, the European Union and the United States are also able to by-pass the dead-end debates at the TRIPS Council and to consolidate key elements of multilateral intellectual

<sup>105</sup> MSF report, "DOHA derailed: Extra burdens - IP provisions not required by TRIPS", 10.09.2003.

<sup>&</sup>lt;sup>104</sup> Ibid, at 100.

<sup>106</sup> In the case of the United States-Chile FTA, for example, Chilean authorities, clearly aware of the asymmetries, perceived the signing of the agreement as a major economic and political success. The consolidation of the United States preferential trade system (GSP) granted to Chile and subject to periodical renewal and negotiations was considered an important achievement deriving from the agreement. See Roffe (2004), p.4.

Both the United States and the European Union have so far pursued a multilateral approach in parallel with bilateral mechanisms. The form and extent to which the United States and the European Union's FTAs are changing the intellectual property rights enforcement structure differ in some important aspects. The treatment of intellectual property rights in the European Union agreements is not as extensive as the provisions of the United States' FTAs. There is a clear scaling up of provisions with each FTA that is negotiated, with few 'reversals' from the higher standards obtained in previous FTAs by the United States. The strategic goals of the industry are being fully achieved, and this is further demonstrated in issues that are still under negotiation at the multilateral level, such as those relating to technical enforcement and updates of precedents as best practices. The European Union agreements require an adequate and effective protection of intellectual property rights in accordance with the 'highest international standards,' including 'effective means to enforce such rights.' The highest international standards function as a platform for the European Union to demand the standards as developed at the multilateral and FTA level, including WIPO treaties, which are in force at the time the obligation is accepted. The European Union is following the United States in seeking to include 'TRIPS-plus' intellectual property rights enforcement provisions under the ongoing negotiation with African, Caribbean and Pacific (ACP) countries.

The intellectual property rights provisions of both the United States and the European Unions' agreements are reinforced by providing recourse to the dispute settlement mechanism established in the agreements. These mechanisms can be triggered under the European Union agreements in cases of noncompliance with the required "highest" standards of intellectual property rights protection. In the case of the European Union–Mexico FTA, an independent Consultation Mechanism for Intellectual Property Matters is provided 'with a view to reaching mutually satisfactory solutions to difficulties arising in the protection of intellectual property. The FTA defined 'protection' as including the maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights. The dispute settlement chapters in selected United States FTAs explicitly establish the application of non-violation and situation complaints that are suspended under the TRIPS Agreement.

### IV.7.1 Main TRIPS-plus Features in FTAs

The TRIPS Agreement established the minimum standards on which countries could later build if they wished to do so. Since the rights and obligations under the TRIPS Agreement do not derogate from or cease to apply in FTAs, the intellectual property rights chapters build on the set of minimum standards in selected areas and addresses new issues considered key to the industries in the developed world. Both the

<sup>&</sup>lt;sup>107</sup> Morin (2003).

<sup>&</sup>lt;sup>108</sup> See Art 168, European Union-Chile FTA (2002).

<sup>109</sup> See e.g. Art 182 European Union–Chile FTA.

See Art 40(1), Decision 2/2000 of the EU-Mexico Joint Council of 23 March 2000.

<sup>&</sup>lt;sup>111</sup> *Ibid*, Art 40(2).

See Annex 22.2 of the United States. – Chile FTA, Annex 20.2 of the United States – CAFTA FTA. A safeguard on non-violation complaints that both Agreements contain is that the benefits expected under the intellectual property chapter cannot be invoked with respect to measures taken under the general exception provisions, under Article XX of GATT 1994.

European Union and the United States' FTAs can become TRIPS-plus in varying degrees by incorporating one or more of the following:

- provisions that extend coverage of intellectual property rights to new areas not addressed by the TRIPS Agreement, and the requirement for accession to, or the ratification of, WIPOadministered treaties and the UPOV Convention 1991. These treaties include the WIPO Copyright Treaty (WCT), the WIPO Performances and Phonograms Treaty (WPPT), the Patent Law Treaty (PLT), the Trademark Law Treaty (TLT) and the Budapest Treaty;
- provisions that change the optional provisions of the TRIPS Agreement on intellectual property rights enforcement to mandatory obligations and that extend the patent term for delays caused by regulatory approval processes;
- provisions that extend the scope of enforcement and require wider use of the criminal justice system to tackle intellectual property rights violations as a deterrent to possible future infringements:
- provisions in the dispute settlement chapters of FTAs that explicitly establish non-violation and situation complaints:
- Definitions of 'investment' in the "Investment" chapters of FTAs that include intellectual property rights as investment assets.

#### IV.7.2 Expanded Scope of Enforcement Standards under FTAs

The general provisions of the intellectual property rights chapters in the United States' FTAs expand existing obligations under the TRIPS Agreement and omit important flexibilities that take into account the differences in national legal systems. The FTAs underscore that the procedures and enforcement of intellectual property rights are established in accordance with the foundations of the respective legal systems of the countries. In particular, the FTAs establish, as does the TRIPS Agreement, that the enforcement provisions do 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; or with respect to the distribution of resources for the enforcement of intellectual property rights and the enforcement of law in general. 113 However, the volume of new regulations and new principles introduced under the FTAs call into question whether United States' partners have any choice to safeguard their legal system and not 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 intellectual property rights chapters. 114 In other words, the enforcement provisions do not necessary call for the increased allocation of resources as a matter of principle; however, the implementation of the agreements would, in any case, require doing so.

FTAs require the accession to WIPO-administered treaties and the UPOV Convention 1991. Under the WTO system the rights and obligations of member states arising from treaties other than those incorporated in the TRIPS Agreement would not be enforced through the dispute settlement mechanisms. However, the first important implication of the FTAs is to subject claims of violation of the obligations and the enforcement of the rights under the WIPO treaties and the UPOV Convention to FTAs dispute settlement mechanisms.

Similarly, although potentially advantageous, FTAs establish for the United States partners the principles of limitation of liabilities of service providers that are involved in the hosting and transmission of infringing material through their facilities. These provisions establish the basic functional equivalent of the concepts and provisions embodied in Section 512 of the United States' Digital Millennium Copyright Act of 1998 (DMCA). Under FTAs, if the general norms and principles for the limitation of liabilities of an FTA partner do not confirm a limitation in favour of ISPs, each FTA partner will have to introduce similar

<sup>&</sup>lt;sup>113</sup> See Article 15 (11) (1) and (2) of CAFTA- DR.

legal or statutory limitations. The TRIPS Agreement was never meant to address the limitation of liabilities and other related issues, except in cases of remedies related to use by governments or by third parties authorized by a government, without the authorization of the right holder.

The general obligations in the intellectual property rights enforcement section of the intellectual property rights chapters of the United States' FTAs expand existing TRIPS obligations in Article 41 and rephrase the language of the provisions of the TRIPS Agreement so as to reduce the scope of different interpretations. The general principle of fairness and equitability, which rules of enforcement are required to meet under the TRIPS Agreement, is absent in the FTAs. The same is true of those provisions on the protection against abuses by right holders and on the proportionality of the measure *vis-à-vis* the seriousness of the infringement.<sup>115</sup>

Instead of the more general principle of fairness and equitability, which is applicable and evaluated on a case by cases basis and depending on the circumstances of each case, FTAs adopt more precise and detailed provisions on enforcement. However, they tighten the scope of flexibility for the implementing countries and redefine the standard when countries could be considered as failing to comply with the provisions. The resort to detailed and more precise enforcement standards overcomes the limitations of the TRIPS Agreement and allows the United States to challenge, under dispute settlement proceedings, the implementation of the enforcement provisions of the agreement and to upgrade intellectual property rights norms by harmonizing procedural laws — something that would have been difficult to achieve under public international law.

FTAs further impose the obligation to make available enforcement statistics with regard to transparency obligations on the publication of information on enforcement. FTAs also create the obligation to publicize efforts to enforce intellectual property rights, i.e. media dissemination, arguably for awareness raising. This would shift the focus of the public relation activities of governments from questioning the balance of interests in intellectual property rights to enforcing rights.

The TRIPS Agreement requires decisions to be made preferably in writing and reasoned, as well as to be made available to the parties, whereas FTAs require that they be in writing, reasoned, that they state the relevant facts and that they be published or made publicly available.<sup>117</sup>

Border enforcement measures in FTAs are also more stringent than those under the TRIPS Agreement. For example, parties must provide for enforcement at the border without any formal complaint filing requirements, and the competent authorities must have the power to initiate actions *ex officio* relating to suspect shipments being imported, exported or in transit. The provisions of FTAs on provisional measures are short and the emphasis is on summary proceedings — known as provisional measures *inaudita altera parte*. Even in situations when no irreparable harm has been done to the right holder and there is no evidence that may be destroyed, judicial authorities should issue an injunction if requested. A proceeding for provisional measures would not enable defendants to argue against the claims of a right holder. As a result, judicial authorities in ordinary provisional measure proceedings and in provisional measures *inaudita altera parte* have little or no authority to question or allow arguments against the plaintiff on claims of entitlement and validity. Instead, they are required to act on the plaintiff's request and to execute such request. The provisional measures in the plaintiff's request and to execute such request.

<sup>&</sup>lt;sup>115</sup> As in Arts 41.1, 48.1, 50.3 and 53.1 in TRIPS

<sup>&</sup>lt;sup>116</sup> USTR (2005), United States- CAFTA, Article 15.11 (4).

<sup>&</sup>lt;sup>117</sup> *Ibid.*, 15.11 (1)and (3).

<sup>&</sup>lt;sup>118</sup> *Ibid.*, 15.11 (17)-(19).

#### Table 1: Border Measures under FTAs

Border enforcement measures in FTAs are more stringent than those under the TRIPS Agreement. Based on the reading of Article 15. 11 (20-25) of the United States, Central America and Dominican Republic Free Trade Agreement (CAFTA), the following are the notable changes to enforcement standards required under the TRIPS Agreement:

- Procedures for suspension of the release of goods by customs authorities apply to 'counterfeit or confusingly similar trademark goods, or pirated copyright goods' following the standard set on the protection of trademarks under the FTAs;
- Parties must provide the competent authorities the power to initiate actions ex officio relating to suspect shipments, including goods in transit, and to the country's own exports without any formal complaint filing requirements;
- Right holders supply only sufficient information that may reasonably be expected to be within his/her knowledge to make the suspected goods reasonably recognizable by the competent authorities. In contrast to the TRIPS Agreement, the information submitted by the right holder should only help to "reasonably" recognize the goods by the competent authorities as opposed to "readily" recognize them;
- The requirement for reasonable security or equivalent assurances can take the form of any of instruments issued by a financial service provider;
- Where storage fees are assessed in connection with border measures, the fee shall not be set at an amount that unreasonably deters recourse to border measures;
- The competent authorities are required to destroy the infringed goods in all cases, unless the right f) holder consents to alternative disposal. In cases of counterfeit and pirated goods the only alternative avenue for authorities is to donate the goods for charity, provided that the removal of the trademark effectively eliminates the infringing characteristics of the goods;
- The provisions are silent about (1) the authority to order the indemnification of the importer and of the owner of the goods subject to border measures for any injury caused to them through the wrongful detention of goods; (2) procedures with respect to the release of goods upon deposit of a security by the importers in the absence of provisional measures or in cases of delayed border proceedings with respect to goods involving industrial designs, patents, layout designs or undisclosed information; (3) duration of suspension, and (4) exceptions for de minimis imports and exceptions for border trade where an FTA partner has dismantled substantially all controls over the movement of goods across its border in the context of customs union or trade arrangements with neighbouring countries.

The provisions of FTAs on provisional measures are short and the emphasis is on summary proceedings – known as provisional measures inaudita altera parte. Even in situations when no irreparable harm has been done to the right holder and there is no evidence that may be destroyed, judicial authorities should issue an injunction if requested. A proceeding for provisional measures would not enable defendants to argue against the claims of a right holder. As a result, judicial authorities in ordinary provisional measure proceedings and in provisional measures inaudita altera parte have little or no authority to question or allow arguments against the plaintiff on claims of entitlement and validity. Instead, they are required to act on the plaintiff's request and to execute such request. 119

FTAs are silent or ambiguous on several procedures that are intended to protect abuse of enforcement procedures. These, however, are not derogations from the obligations under the TRIPS Agreement. The FTAs reaffirm the existing obligations and rights of parties under the TRIPS Agreement. The omissions include: procedures requiring the plaintiff to institute regular proceedings on the claim of an

<sup>&</sup>lt;sup>119</sup> *Ibid.*, 15.11 (17)-(19).

infringement that is the subject of a provisional measure proceeding within a reasonable period; procedures for revocation of the provisional measure; the exception provided under Article 44.1 concerning injunctions in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right; exceptions provided under Article 44.2 authorizing declaratory judgements and payment of adequate compensation where remedies recommended under the agreement are inconsistent with the laws of member states.

FTAs have expanded the criminal procedures and remedies available for the protection of intellectual property rights.

#### **Table 2: Criminal Procedures and Penalties under FTAs**

The following are the major TRIPS-plus elements of FTAs on criminal procedures and remedies based on Article 15. 11 (18 and 26) of CAFTA.

- a) The criminal procedures and penalties under FTAs include wilful piracy of related rights in addition to copyright piracy and trademark counterfeiting, on a commercial scale and receiving and further distributing wilfully a programme-carrying signal that originated as an encrypted satellite signal, knowing that it has been decoded without the authorization of the lawful distributor of the signal. Furthermore, in addition to intellectual property rights, the manufacture, assembly, modification, import, export, sale, lease, or otherwise distribution of a tangible or intangible device or system, primarily of assistance in decoding an encrypted programme-carrying satellite signal without the authorization of the lawful distributor of such signal are considered as criminal offences.
- b) The standard to measure the infringement giving rise to criminal liability is relaxed and includes wilful infringements that have no direct or indirect motivation of financial gain, provided that there is more than a *de minimis* financial harm. The application of criminal procedures should also include the wilful importation or exportation of counterfeit or pirated goods.
- c) Parties should establish policies or guidelines that encourage penalties to be imposed by judicial authorities at levels sufficient to provide deterrence to future infringements. This requirement overemphasises one purpose of criminal punishment (deterrence) as opposed to the reformative objectives of the justice system.
- d) The procedure for requesting discovery and seizure of evidence and infringing goods is relaxed by stating that such request should neither describe in detail nor individually identify the evidence and goods.
- e) The judicial authority is expanded to order the forfeiture of any asset traceable to the infringing activity, the forfeiture and destruction of all counterfeit or pirated goods without compensation of any kind and, with respect to wilful copyright or related rights piracy, the forfeiture and destruction of materials and implements that have been used in the creation of the infringing goods. The standards reflect the intention of establishing 'deterrence' as the main purpose of criminal penalty. The forfeiture of any asset traceable to the illegal activity might also end up affecting third parties that do not know or have reason to know that their assets leased to, or in any other way employed by, the defendant are being used for an alleged criminal activity'
- f) Finally, criminal law enforcement in cases of counterfeiting or copyright piracy are required under FTAs to be instituted *ex officio*, without the need for a formal complaint by a private party or right holder, at least for the purpose of preserving evidence or preventing the continuation of the infringing activity.

FTAs also provide that damages should be payable in all cases of infringement. In determining the amount of damage, the judicial authorities are required to consider, *inter alia*, the value of the infringed good or

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<sup>&</sup>lt;sup>120</sup> *Ibid.* Article 15.11 (15) –that omits the exception for good faith use.

service, based on the suggested retail price or other legitimate measure of value that the right holder presents. Under the FTAs, in all cases lost profits are to be calculated as part of the damages.<sup>121</sup> In the United States-Chile FTA and the CAFTA, the court of law is provided the authority to order the destruction of infringing goods 'at its discretion', whereas the Morocco FTA requires such orders 'at the right holder's request'.12

In respect of copyright piracy, the United States FTAs differentiate between the civil remedies available for TPMs and DRMs and those for other intellectual property rights infringements. While generally requiring the civil remedies to be available to TPMS and DRMs, FTAs in particular require:

- a) provisional measures, including the seizure of devices and products suspected of being involved in the prohibited activity;
- b) actual damages plus any profits attributable to the prohibited activity not taken into account in computing the actual damages or pre-established damages;
- c) payment to the prevailing right holder as opposed to the prevailing party at the conclusion of civil judicial proceedings, of court costs and fees and reasonable attorney's fees by the party engaged in the prohibited conduct; and
- d) destruction of devices and products found to be involved in the prohibited activity, at the discretion of the judicial authorities.

FTAs relieve libraries, archives, educational institutions or public broadcasting entities from payment of awards if they are non-profit organizations and if they can prove that they are not aware and have no reason to believe that their acts constitute a prohibited activity. FTAs do not provide a similar level of difference or limitation of liabilities with respect to government agencies and their officials. <sup>123</sup>

### IV.7.3 Intellectual Property Rights as an Investment

The United States FTAs further facilitate the effectiveness of intellectual property rights enforcement by providing an expanded definition of 'investment', which explicitly includes intellectual property rights as an investment asset protected. 124 FTAs may potentially allow an investor to bring a violation and/or nonviolation claim by seeking diplomatic protection of the home state before the state-to-state dispute settlement mechanism, or choose to bring a claim directly under an investor-State dispute settlement procedure, bypassing domestic legal processes and 'giving ascendancy to the investor, who is the principal beneficiary of rights under investment agreements'. 125 In these cases, by asserting a violation or "nonviolation" of the broad substantive rights provided to investors, investors can demand compensation for the impact of governmental actions (including enacted laws and regulations and government 'inaction') on the investment interests. Some of the enforcement procedures in fact have direct relevance to subsidiaries and intellectual property rights asset management service providers.

<sup>&</sup>lt;sup>121</sup> *Ibid*. Article 15.11 (6), (7) & (8).

<sup>&</sup>lt;sup>122</sup> USTR (2004), United States - Morocco FTAs Article 15.11 (10).

<sup>&</sup>lt;sup>123</sup> *Ibid.*, Article 15.11 (14)

<sup>&</sup>lt;sup>124</sup> See Art 10.28, United States. – CAFTA FTA.

<sup>&</sup>lt;sup>125</sup> UNCTAD (2003) as quoted in Correa (2004).

# V. CONCLUSION: THE CHANGING STRUCTURE OF INTELLECTUAL PROPERTY ENFORCEMENT AND THE POLICY OPTIONS FOR DEVELOPING COUNTRIES

As enforcement of intellectual property rights gains greater preponderance on the international agenda, developing countries must develop appropriate policy responses. Our research indicates that the concerns regarding international trade in counterfeiting and piracy on a global scale require greater coordination and dialogue involving the private sector, government and civil society stakeholders in order to find appropriate solutions to both supply and demand problems. There is also need for greater coherence among the initiatives and activities being undertaken on enforcement of intellectual property rights by different multilateral fora and agencies.

The continued exchange of national information, experiences and practices to tackle counterfeiting and piracy is positive and desirable in order to foster a better understanding of the problems and build common agendas. Current sharing of experiences should be broadened to include the use of enforcement measures to ensure the exercise of limitations and exceptions to intellectual property rights and prevent abuse of intellectual property rights the use of competition law, and analysis of related national case law.

In order to work towards a common definition of the problems and identification of solutions, there is a dire need for reliable information and objective data, as well as harmonized definitions that would allow proper quantification of the magnitude and impact of international trade in counterfeit and pirated goods and to define the problems adequately.

Developing countries are facing increased pressure to bolster intellectual property enforcement. In response, developing countries are increasingly redirecting resources to strengthen the enforcement of intellectual property rights and involving public agencies in the efforts. While government ought to provide intellectual property right holders with the legal means to enforce their private rights, the responsibility for intellectual property rights enforcement must be vested in right holders.

An increasing number of developing countries are adopting TRIPS-plus enforcement obligations and renouncing sovereign authority in order to adopt innovation and intellectual property policies suited to their level of development. They may also be foregoing important flexibilities afforded under the TRIPS Agreement that accommodate differences among national legal systems and levels of development. In the case where such obligations are acquired through FTAs, they may in future also suffer trade and other economic sanctions owing to their possible inability to comply with new obligations that may be unduly intrusive and restrictive.

Enforcement of intellectual property rights is costly in financial terms. There are high costs linked to institutional reform and the training of judges *inter alia*, which in the short term make compliance with the enforcement obligations in FTAs highly questionable. This is evidenced by the fact that many developing countries are still struggling to implement the substantial provisions in the TRIPS Agreement. Under the FTAs, the substantive issues in intellectual property rights will prove ever more difficult to implement. Clearly, there will continue to be an "*unwillingness to absorb the costly administrative expenses associated with enforcement and an inability to manage many of the technical and judicial issues associated with the use and infringement of intellectual property rights.*" <sup>126</sup>

Tailored national solutions are the best means to meet practical intellectual property rights enforcement concerns and the actual needs of each country. Thus, countries should maintain the ability to protect intellectual property rights from illegal violations in the manner that best suits their circumstances. Likewise, as members from parliaments of WTO member countries recently proposed, different and less

<sup>&</sup>lt;sup>126</sup> Maskus Keith (1997:10)

expensive mechanisms for addressing the problems of counterfeit and piracy should be promoted, including competition regulations,. 127

As in the case of the WIPO Development Agenda, the framing of the issue of intellectual property enforcement by developing countries should focus on two critical elements: (1) the interests of other stakeholders beyond those of right holders, and (2) the limited role that governments should play in the enforcement of private rights.

In particular, the main recommendations suggested for developing countries are the following:

- Enforcement measures must be equitable and fair and must balance the intellectual property rights of their holders and the rights of third parties, and the limitations and exceptions provided in the intellectual property system.
- Do not adopt stronger measures and procedures for the enforcement of intellectual property rights beyond those found in the TRIPS Agreement, unless prior assessment is made to determine that TRIPS-plus enforcement standards would bring domestic benefits. TRIPSplus enforcement standards in regional and/or bilateral FTAs and EPAs should be avoided.
- Resist developed country pressure in the WTO TRIPS Council, the WIPO and other fora to establish soft law norms, including best practices and declarations that may require strengthening domestic enforcement of intellectual property rights beyond TRIPS standards and may lead to harmonization of enforcement standards.
- Maintain flexibilities available in the TRIPS Agreement as they apply to the enforcement of intellectual property rights, including: 1) flexibility as to the method of implementing enforcement measures and procedures in national legal systems; 2) flexibility to balance resources for general law enforcement with those that may be mobilized for the specific enforcement of intellectual property rights; 3) flexibility confine the availability of procedures for border measures and criminal sanctions to cover counterfeit trademark or pirated copyright goods as defined in Article 51, footnote 14; 4) flexibility as to the granting of injunctions; 4) flexibility as to determining what amounts to 'adequate compensation' in awarding damage.
- Adopt clear definitions of counterfeiting and piracy to avoid legal uncertainty and potential abuse of enforcement measures. Definitions can be found in the TRIPS Agreement's Article 51, footnote 14. The common elements of the agreed definition in TRIPS should be applied: (1) identical or close similarity to intellectual property protected locally, (2) unauthorized use, (3) infringement in a country of importation, (4) traded internationally. Ensure that TRIPS-compliant parallel importation of goods is excluded from the definition of counterfeit or piracy. Do not extend definition to include patent infringement.
- Avoid making use of criminal law to deal with intellectual property infringement. At the least, limit the application of criminal law to cases of intellectual property infringement that are wilful and occur on a commercial scale, and thoroughly define the elements that would constitute a "crime".
- Avoid commitments to act directly against infringement of intellectual property rights. While government ought to provide intellectual property right holders with the legal means to

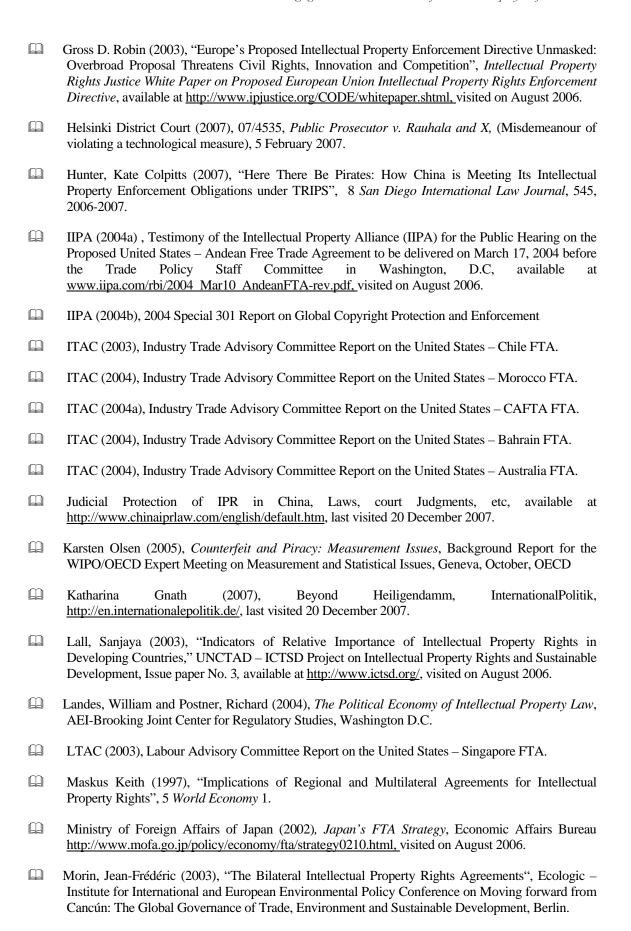
<sup>127 &</sup>quot;We stress the need to continue making progress in the area of trade-related aspects of intellectual property rights (TRIPS) and taking action against counterfeiting and piracy by promoting fair forms of competition." Declaration of the Brussels Session of the Parliamentary Conference on the WTO adopted on 26 November 2004

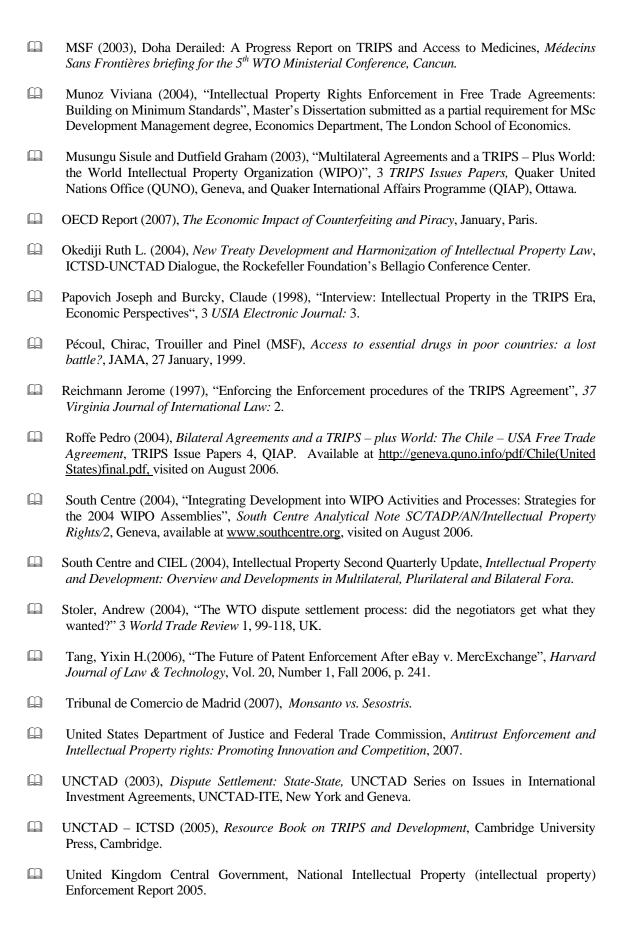
- enforce their private rights, responsibility for intellectual property rights enforcement must be vested in right holders. Right holders must initiate any legal actions and bear their full costs.
- Strengthen checks against abuse and misuse of intellectual property rights and enforcement measures. The means to do so include more rigorous vetting of patent applications, stronger enforcement of competition law, ensuring that measures for intellectual property rights enforcement are equitable and fair, and providing stronger protection of limitations on and exceptions to intellectual property rights, such as "fair use" for access to information, educational and research purposes.

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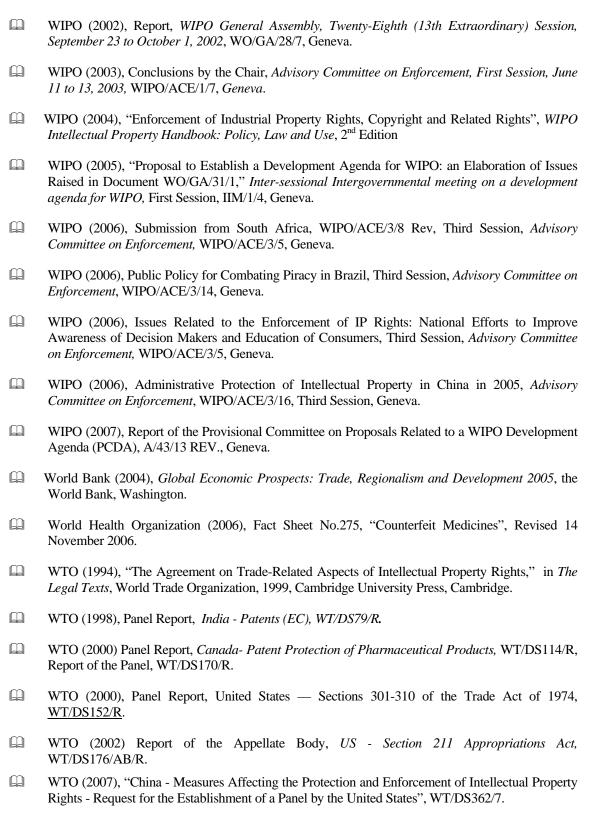
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#### ANNEX

# SELECTED PROVISIONS OF THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

(Preamble, Part I, III, IV and V)

Members.

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

*Recognizing*, to this end, the need for new rules and disciplines concerning:

- (a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;
- (b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;
- (d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and
- (e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

*Recognizing* the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

*Recognizing* the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

*Recognizing* also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

*Emphasizing* the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

*Hereby agree* as follows:

PART I

GENERAL PROVISIONS AND BASIC PRINCIPLES

#### Article 1

#### Nature and Scope of Obligations

- Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged 1. to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.
- For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.
- 3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members. 128 In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions. 129 Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

### Article 2 Intellectual Property Conventions

- In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).
- Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

#### Article 3 National Treatment

Each Member shall accord to the nationals of other Members treatment no less favourable than that it 1. accords to its own nationals with regard to the protection <sup>130</sup> of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the

<sup>128</sup> When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

<sup>129</sup> In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

<sup>130</sup> For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

# Article 4 Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

- (a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;
- (b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;
- (c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;
- (d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

# Article 5 Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

# Article 6 Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

# Article 7 Objectives

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.

### Article 8 **Principles**

- Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement.
- Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

#### PART III

#### ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: GENERAL OBLIGATIONS

#### Article 41

- Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.
- Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.
- Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.
- Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.
- 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.

#### SECTION 2: CIVIL AND ADMINISTRATIVE PROCEDURES AND REMEDIES

#### Article 42 Fair and Equitable Procedures

Members shall make available to right holders<sup>131</sup> civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice

<sup>131</sup> For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

#### Article 43 Evidence

- 1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.
- 2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly impedes a procedure relating to an enforcement action, a Member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.

# Article 44 Injunctions

- 1. The 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. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.
- 2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

### Article 45 Damages

- 1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.
- 2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

### Article 46 Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

### Article 47 Right of Information

Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.

### Article 48 Indemnification of the Defendant

- The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.
- In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of that law.

### Article 49 Administrative Procedures

To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

#### **SECTION 3: PROVISIONAL MEASURES**

#### Article 50

- 1. The judicial authorities shall have the authority to order prompt and effective provisional measures:
  - (a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;

- (b) to preserve relevant evidence in regard to the alleged infringement.
- 2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.
- 3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.
- 4. Where provisional measures have been adopted *inaudita altera parte*, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed.
- 5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.
- 6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.
- 7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.
- 8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

# SECTION 4: SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES<sup>132</sup>

# Article 51 Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures<sup>133</sup> to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods<sup>134</sup> may take place, to lodge an application in writing with competent authorities, administrative or judicial,

<sup>&</sup>lt;sup>132</sup> Where a Member has dismantled substantially all controls over movement of goods across its border with another Member with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border.

<sup>&</sup>lt;sup>133</sup> 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.

<sup>134</sup> For the purposes of this Agreement:

<sup>(</sup>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;

<sup>(</sup>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

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.

### Article 52 **Application**

Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is prima facie an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

### Article 53 Security or Equivalent Assurance

- The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.
- Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in Article 55 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.

## Article 54 Notice of Suspension

The importer and the applicant shall be promptly notified of the suspension of the release of goods according to Article 51.

### Article 55 **Duration of Suspension**

If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified,

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.

revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.

# Article 56 Indemnification of the Importer and of the Owner of the Goods

Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to Article 55.

# Article 57 Right of Inspection and Information

Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.

### Article 58 Ex Officio Action

Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired *prima facie* evidence that an intellectual property right is being infringed:

- (a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;
- (b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, *mutatis mutandis*, set out at Article 55;
- (c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

### Article 59 Remedies

Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46. In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

#### Article 60 De Minimis Imports

Members may exclude from the application of the above provisions small quantities of goods of a noncommercial nature contained in travellers' personal luggage or sent in small consignments.

#### SECTION 5: CRIMINAL PROCEDURES

#### Article 61

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.

#### PART IV

#### ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED INTER-PARTES PROCEDURES

#### Article 62

- Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.
- Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.
- 3. Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.
- Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and inter partes procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.
- Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

#### DISPUTE PREVENTION AND SETTLEMENT

#### Article 63 Transparency

- 1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.
- 2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6ter of the Paris Convention (1967).
- 3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.
- 4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

# Article 64 Dispute Settlement

- 1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.
- 2. Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.
- 3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.