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Welfare Implications of Intellectual Property Enforcement Measures

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WELFARE IMPLICATIONS OF INTELLECTUAL PROPERTY ENFORCEMENT MEASURES

Xavier Seuba, Joan Rovira, Sophie Bloemen¹

ABSTRACT

The enforcement of intellectual property rights is often presented as a neutral legal phenomenon aimed at ensuring compliance, or giving effect or force to a law. Enforcement of intellectual property rights has gained increasing international attention and legal strength. More and more, existing international substantive standards are being supplemented with secondary norms, which in principle deal with the fulfillment of the former. However, the value placed on these secondary norms and intellectual property enforcement initiatives contrasts with little knowledge or understanding of their implications for resources and overall welfare. Moreover, the aforementioned neutrality recedes when it becomes apparent that some of the enforcement provisions contained in treaties, in fact, constitute a substantive expansion of rights instead of merely adding secondary norms of adjudication. This trend requires a much better understanding of what enforcement signifies and what the costs of implementing international intellectual property commitments may be, taking account of its effect on the economy and on society as a whole. This understanding may be particularly important when a lack of ownership of the agreements setting up new enforcement obligations exists, namely, when some of the parties are pursuing goals distinct from those mentioned in the text of the agreement.

A useful analytic tool with regard to the definition of enforcement can be found in the distinction between primary and secondary norms, with enforcement norms falling into the category of secondary norms of adjudication. Additionally, when considering the resource implications of enforcement, it is important to distinguish between the costs of enforcement and the welfare effects of enforcement. The costs of

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enforcement represent the investment a country makes in order to adequately comply with the commitments it has made, whilst the welfare effects denote the impact of new enforcement measures, assessed using variables that stem from the initial economic variables affected (i.e. production, exports, imports, investment). These changes in turn affect consumption and access to public goods, expenditure and welfare.

This conceptual framework leads first to seek to identify the costs of adequately complying with a treaty, and second to devise a methodology that allows, in a case-specific manner, to identify the impact or effects of enforcement measures on the economy and on society as a whole.

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I. INTRODUCTION

At the beginning of the twenty-first century, at a time when almost all of the transitional periods built into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)² had expired and numerous national regulations had been modified to fulfill the TRIPS requirements, a new trend in global intellectual property (IP) standards-setting emerged. This new period was characterized by a strong emphasis on the enforcement of intellectual property rights.³

The markers of this new phase went initially unnoticed. Enforcement sections of new free trade agreements (FTAs), the use of the Section 301 of the United States (US) Trade Act of 1974⁴ and the European Union (EU) *Strategy for the enforcement of intellectual property rights in third countries*⁵ were considered of minor importance in comparison with the difficulties faced in granting compulsory licenses or adhering to the international exhaustion of rights doctrine. Nevertheless, in a short period of time, countries, in particular developing countries, faced a cascade of new norms and new policies on IP enforcement.

Since then, the scope and reach of the IP enforcement movement has expanded considerably. New EU free trade agreements, the draft Anti-Counterfeiting Trade Agreement (ACTA) and discussions taking place in diverse forums, such as the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and even the World Health Organization (WHO), are evidence of this. Some of these forums were foreseeable; others were not.⁶ The commonly-invoked argument to support the numerous IP enforcement efforts, namely that if countries have agreed on certain intellectual property standards, they should be honoured, can sound entirely rational at face value. However, the complexities and unknown consequences warrant a more nuanced

² Agreement on Trade Related Aspects of Intellectual Property, Apr. 15, 1994, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].

³ Although there is no specific date to identify when the enforcement of IPR acquired its present strength, the EU 2004 *Strategy for the enforcement of intellectual property rights in third countries* was a turning point. The *Strategy* was adopted at a time when most developing countries that did not offer patent protection to some areas of technology before the conclusion of the TRIPS had to adjust to the entire Agreement. The rest of the obligations were already obligatory. At present, only the least developed countries are exempted from applying most of the provisions of the TRIPS in the specific domain of pharmaceutical patents.

⁴ Trade Act of 1974, 19 U.S.C.A. § 2411 (2010).

⁵ STRATEGY FOR THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS IN THIRD COUNTRIES (European Commission Directorate General for Trade, ed. Apr. 2005) available at http://trade.ec.europa.eu/doclib/docs/2005/april/tradoc_122636.pdf.

⁶ The WHO has pushed the controversial IMPACT initiative, which mixes public health concepts and IP rights-holders aspirations ostensibly to attain public health goals.

approach and a more proportionate stance toward IP enforcement measures.

There is good reason to recommend slowing the progress of some enforcement initiatives. New compromises on enforcement are still being made despite the fact that some countries have not yet been able to honour all the obligations enshrined in the TRIPS, and there are unknown and potentially significant costs involved for state bodies. This is happening even though IPRs are private rights, whose protection is first and foremost the responsibility of the right-holder. Furthermore, new enforcement obligations further diminish the policy space that countries need in order to determine the most appropriate method of implementing the provisions of these diverse agreements within their own legal system and practice.⁷ Some of the new legal enforcement frameworks also complicate the implementation of TRIPS and other agreements that affirm that they create no obligations to shift resources away from general law enforcement towards the enforcement of intellectual property rights.⁸ However, it is difficult for countries to make use of this freedom whilst, at the same time, fulfilling the new IP enforcement obligations. In fact, it has been argued that some new enforcement provisions not only make it difficult to use flexibilities recognized in the TRIPS, but are also in conflict with the TRIPS Agreement.⁹ In the most classical sense, this could be identified as a conflict of treaties.¹⁰ Perhaps most importantly, some of these ‘enforcement’ provisions, in actuality, constitute an expansion of the exclusivity rights for rights-holders. This certainly warrants analysis and delimitation of the concept of enforcement. Although impact studies have become usual in the field of intellectual property, none have attempted to capture the overall economic costs and effects on welfare from IP enforcement measures.

⁷ See, e.g. TRIPS Agreement, *supra* note 2, art. 1.1; and Economic Partnership Agreement between the CARIFORUM States and the European Community, art. 139(2), CARIFORUM-EC, Oct. 15, 2008, 2008 O.J. (L 289/I/3) (EC).

⁸ See TRIPS Agreement, *supra* note 2, art. 41.5; and Anti-Counterfeiting Trade Agreement Informal Predecisional/Deliberative Draft: Aug 25, 2010, art. 1.2, PIJIP IP Enforcement Database, <http://sites.google.com/site/iipenforcement/acta> (follow “Full Leaked Text Dated August 25, 2010” hyperlink).

⁹ See Henning Große Ruse-Khan & T. Jaeger, *Policing Patents Worldwide? EC Border Measures against Transiting Generic Drugs under the EC - and WTO Intellectual Property Regimes*, 40 Int’l Rev. Intell. Prop. and Competition Law 502, 2009.

¹⁰ A constrained notion of a conflict of treaties sustains that this exists only when two provisions of two different treaties cannot be fulfilled altogether. Nevertheless, this notion excludes other conflictive interactions, for instance when a norm grants a power and another norm establishes an obligation: if the power is not exercised, the conflict will never arise. More contemporary interpretations of treaty conflicts hold that this exists when the fulfillment of a norm affects another norm contained in another treaty.

II. OBJECT OF STUDY

The issue at the heart of enforcement discussions, including the debate about costs and effects, is the definition of enforcement, which has both systemic and politico-legal consequences. It is worth noting that the meaning of enforcement is not often questioned because it is assumed that a general consensus exists. However, when analyzed in greater detail, the certainty of the assumption vanishes. Numerous treaties, treaty sections and provisions “on enforcement” do not deal exclusively with enforcement. On the contrary, norms that create new rights for title holders and expand the power to exclude third parties from acts deriving from rights conferred by each intellectual property category are also included under the enforcement ‘label’. These issues need to be unpacked to illustrate how some of the enforcement measures not only “externalize the cost of enforcement” (making a private right a public concern) but are, in fact, expansions of substantive rights.

Given the importance bestowed on enforcement initiatives, a better understanding of the costs of enforcement including their impact on welfare is necessary. Previous studies have gathered data on the sums of money that international organizations have granted to developing countries in order to implement their obligations pursuant the TRIPS Agreement. However, the global welfare implications of enforcement are not captured in those studies, mainly because they deal with a single funding source and generally examine only one cost effect of enforcement (*i.e.* capacity building, creation of a new institution, etc.). There have been studies on the impact and effects of enforcement on the economy and on society; however, these have looked only at the positive effects of IP enforcement, such as the number of jobs created, taxes paid or the positive linkage between IP enforcement and the protection of public health. To date, there have been no assessments of the potentially negative effects on welfare from new IP enforcement standards.

Therefore, there is a need to identify two things: to identify first the resources needed to implement (additional) enforcement provisions; and secondly to answer a more elusive question about the economic and social impact, or effects caused by IP enforcement measures. The objective of the second question is on one hand, to highlight the absence of data and analysis on this matter and, on the other, to develop a methodology, or at least the foundation of a methodology to identify the costs of enforcement and the effects of such enforcement on the economy and on society as a whole.

III. DEFINING ENFORCEMENT

To “enforce” means “to compel or ensure compliance with something, to give effect or force to a law or command.”¹¹ The “command” can adopt many formal figures, for instance a writ, a mandate or a sentence. Hence, IP enforcement provisions are designed to establish the mechanisms and the legal framework that will compel compliance with the rights conferred by each of the intellectual property categories. “Enforce” is a broad-ranging term that includes: provisions to identify an infringement; norms that establish the mechanisms to take action when an infringement has occurred; and other rules that permit action even before an infringement has taken place, which are, thus, preventive in nature. In addition, “enforcement” requires the existence of institutions to oversee the aforementioned actions. These are enforcement-related bodies, such as courts, police or customs authorities.

There is an inherent link between procedural and institutional enforcement provisions on the one hand, and norms that enshrine the rights and obligations of intellectual property rights holders, on the other. The TRIPS Agreement acknowledges this relationship. TRIPS Article 41 states that enforcement procedures shall “permit effective action against any act of infringement of intellectual property rights.”¹² Therefore, norms on intellectual property enforcement can be conceived as tools at the disposal of rights holders. Taking TRIPS as the reference, the point of departure lies in the articles that set out the rights granted to holders for each IP category. This is the case for Articles 11 and 14 for copyright, Article 16 for trademarks, Article 22 for geographical indications, Article 26 for industrial designs, Article 28 for patents, and Article 36 for layout designs of integrated circuits. It is only with reference to the conferred rights that the enforcement provisions make sense. That is, the legal framework for enforcement enshrined in TRIPS Part III only functions with reference to the granted rights.

The conventional view offered in the previous paragraph could be expanded, so that the rights of consumers were also taken into account in the enforcement debates. That is, a more comprehensive stance regarding enforcement could be adopted, in which the enforcement of pro-competition tools is considered equal to the enforcement of the restrictive IP holders rights. This would lead to “enforcement” with the same strength that is currently promoted for provisions favourable to IP holders, with further provisions aimed at guaranteeing some equilibrium between broader social interests and private interests. Although this might seem obvious, within the current enforcement debate there is

¹¹ Black’s Law Dictionary 549 (7th ed. 1999).

¹² See TRIPS Agreement, *supra* note 2, art. 41.

almost no reference made to enforcing provisions designed to avoid market dominance or fraudulent IP practices, such as evergreening or strategic litigation.

Enforcement provisions are not expected to grant new substantive rights or obligations, but rather to refer to other norms. Enforcement provisions fulfill a characteristic that H. L. A. Hart conferred to “secondary norms”: they allude to other norms.¹³ More precisely, enforcement provisions pertain to those norms that H. L. A. Hart called *rules of adjudication*. In this group, Hart gathered norms enshrining the procedure to be used in judging infringements and identifying who is to judge. That is, these are norms that regulate the establishment and identification of the corresponding sanctions if the violation of a primary norm occurs. In fact, it is due to these secondary norms that respect for the rights conferred by an intellectual property category does not only depend on social pressure to honour them. *Rules of adjudication* and the coercion attached to legal norms mark the distinction between legal rules and social norms.

The concept of infringement is the most visible aspect of enforcement, constituting the reaction to the violation of IP rights. In this sense, enforcement provisions establish the mechanisms to identify, prevent or react to intellectual property infringements. They revolve around the rights granted by each intellectual property category. An “infringement” takes place when acts under the exclusive control of the title holder and not subject to admissible exceptions, are performed by third parties without the consent of the title holder.¹⁴ This sustains the argument that there must be a direct link between the rights granted and the enforcement provision.

Several cases have been identified where, under the term “enforcement,” new provisions enabling title holders to exclude third parties from acts that are not already excluded by the corresponding intellectual property category. That is, the substantive rights granted to title holders are extended by expanding the scope of exclusions. Granting title holders the possibility of blocking the transit of products that are protected by IP solely in the jurisdiction of the transit area represents one such example of these substantive extensions. Consequently, the balance of rights and obligations is changed and with it the very nature of the intellectual property category in question. Though these provisions may be grouped under the enforcement section or chapter of a specific treaty, these types of provisions should not actually be considered enforcement provisions by States and international organizations. Another example of a substantive extension

¹³ See H.L.A. Hart, *THE CONCEPT OF LAW* (2d ed. 1997).

¹⁴ *RESOURCE BOOK ON TRIPS AND DEVELOPMENT*, 575 (UNCTAD-ICTSD, eds. 2005) available at <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>.

of IP holders' rights can be found in the scope for damages and increase in the damage award for IP infringements. This will limit the gray area in which competitors potentially infringe IPRs and take some risk.¹⁵ In the same vein, provisions on acquisition and maintenance of IP rights should also not be featured in the enforcement section. Norms on acquisition and maintenance are a prerequisite for the existence of rights. Once these rights have been granted, and if they are duly maintained, then their infringement can activate the enforcement norms.

Enforcement should be perceived as a continuum ranging from no enforcement to full enforcement. There are likely to be different interpretations from the various signatories of an agreement on what precisely constitutes adequate enforcement of the provisions.¹⁶ The same applies to the different stakeholders, and local laws and regulations that implement international commitments on enforcement. These interpretations will be influenced by the consistency of legal argument, which explains why defining enforcement provisions should be done on a case-by-case basis.

Finally, the specific and tangible interests of each country and stakeholder in respecting certain levels of IPR will also play a role in discussions about what the required level of enforcement is. The sense of ownership over the agreement that contains the enforcement obligations (that is whether the agreement was adopted with conviction or not) will also have a substantial influence. Signaling this phenomenon, the concept paper that Pakistan presented in November 2009 to the WIPO Advisory Committee stated that "invariably, in bilateral free trade agreements, higher standards of IPR protection are demanded in return for trade and market access. This reinforces the view that IPRs are an external imposition, rather than a domestic need."¹⁷

IV. RESOURCE EFFECTS OF ENFORCEMENT

The resource effects of enforcement can be classified in two broad categories:

¹⁵ See James Love, *Comments on ACTA Provisions on Injunctions and Damages*, Knowledge Ecology International, April 6, 2010, <http://keionline.org/node/826>.

¹⁶ This is not new. Despite the almost automatic assumption of the 20 years of exclusivity standard for pharmaceutical patents, the fact is that there is neither consensus nor empirical knowledge supporting the adequacy of that standard. See H. Grabowski, *Follow-on biologics: data exclusivity and the balance between innovation and competition*, 7 *Nature Rev. Drug Discovery* 479 (2008).

¹⁷ CONCEPT PAPER BY PAKISTAN: CREATING AN ENABLING ENVIRONMENT TO BUILD RESPECT FOR IP, in WIPO Advisory Committee on Enforcement: Fifth Session, WIPO/ACE/5/11 Annex I, 2 (2009). The reference made to "high IP standards" usually has nothing to do with the quality of the rights granted. On the contrary, it relates to the level of protection afforded to the right-holder.

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1. The cost of enforcement, which equals the value of additional resources required to implement new obligations.
2. The impact or effects of enforcement on the economy and on society, defining impact as effects on public goods, prices, consumption, production, innovation, etc., and ultimately on welfare.

This distinction resembles the one already in use in the economic evaluation of health programs, which distinguishes between direct and indirect costs. Direct costs include, for instance, money to pay for hospitalization or the amount spent on pharmaceutical products. Indirect costs signify those such as the economic impact of lost work days or losses due to the unexpected or premature death of somebody.

A. *Cost of Enforcement*

Enforcing IPR is costly and most new IP obligations will require assigning additional resources for the institutions that deal with IPR.¹⁸ New enforcement obligations will require the modification of the IP regulatory and management framework. This will require raising additional resources to create new organisations and agencies, to hire additional staff, to train existing human resources, to buy additional equipment, to build new installations, to amend laws, etc. To fulfill new compromises in the enforcement field, States must guarantee that judges, police forces, customs officers and other competent authorities are adequately staffed and equipped. Only then will they be able to respond to complaints by rights holders and to act of their own accord. These constitute the proper opportunity costs of enforcement as it implies using resources that may have been used for other purposes, like the provision of public goods. This raises the question of how much of its resources a government should dedicate to protecting private economic rights when they are not related to health or public safety concerns.

There will be considerable variations from country to country in the degree and the nature of the reforms that will be necessary to adjust national regulations to the new enforcement framework. The necessary reforms and investment will depend on what is already in place in the country. For example, in a trade agreement between a OECD and a developing country, many of the enforcement provisions will cost the OECD countries very little as it will require only small changes to existing laws, whilst for developing countries the costs can be

¹⁸ Ronald Brohm, ADDRESSING COSTS AND BALANCING RIGHTS *in* WIPO Advisory Committee on Enforcement: Fifth Session, WIPO/ACE/5/7, 1 (2009).

significant. Developing countries will usually lack the institutional framework to meet the standards demanded, and implementation certainly requires an infrastructure and the institutions that facilitate the execution of the new laws.

The costs of previous reforms and implementation of IP provisions contained in the TRIPS Agreement can be studied to get a general perspective of the present costs of implementing an IP treaty. During the Uruguay Round, developing countries took on unprecedented obligations to implement significant reforms in many areas of economic activity, including IP law. The TRIPS Agreement included new commitments on enforcement that incurred significant costs for developing countries. In the majority of cases the investment made to fulfill those obligations has not been recorded or is not accessible.¹⁹ This is why attention should be paid to international assistance projects for IP enforcement that were conducted after the TRIPS. These projects offer information regarding both the areas of investigation and their respective budgets. Although there are additional questions surrounding the budgets,²⁰ they remain one of the clearest available sources to offer a general perspective of the costs of implementing an IP treaty.

There have been various donor-funded reform projects that can give an idea of the modifications and associated costs to accommodate trade commitments. Agencies like the World Bank have run trade facilitation programs to assist developing countries with implementing the commitments made in trade negotiations. This is also the case for international organizations such as the WIPO, the World Customs Organization and the European Union. Countries such as the United States and Japan also run IP enforcement programs abroad. Taking as a reference the budgets that these projects devoted to issues such as technical assistance, drafting new laws, modernization of the IP office, personnel training, refurbishment of buildings, equipment for IP-related agencies, computerization, customs modernization, institution building, curriculum development and implementation of new procedures, among others, Finger and Schuler estimated that the costs of implementing the Uruguay Round trade obligations for some countries amounted to more

¹⁹ Something similar presently happens with free trade agreements. Monitoring the implementation of free trade agreements in developing countries could provide good data to impact calculation. Nevertheless, many countries are not doing it consistently.

²⁰ These projects raise many questions with regards to their necessity, the amounts spent and the parallel obligations imposed. For instance, they usually require the beneficiary State to invest considerable sums on IP enforcement; they establish questionable priorities and methodologies, such as the hiring of international consultants and payment of questionable honoraria.

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than a year's development budget. IPR regulation and custom reforms formed a substantial part of these costs.²¹

*World Bank Projects*²²

Country	Project Description	Cost
Brazil, 1997-2002	To train staff involved in intellectual property administration – component of a science and technology reform project.	\$4,000,000
Indonesia, 1997-2003	To enhance the intellectual property regulatory framework – component of a larger information infrastructure development project.	\$14,700,000
Mexico, 1992-1996	To establish an agency to implement industrial property laws – component of a science and technology development project	\$32,100,000

*UNCTAD cost estimates for reforming and strengthening IP regimes*²³

Country	Reforms	Cost
Bangladesh	To draft new laws; to improve enforcement	\$250,000 initially and \$1,100,000 annually
Chile	To draft new laws; to train staff involved in intellectual property administration	\$718,000 initially and \$837,000 annually
Egypt	To train staff involved in intellectual property administration	\$1,800,000
India	To modernize the patent office	\$5,900,000
Tanzania	To draft new laws; to build capacity for enforcement	\$1,000,000 – \$1,500,000

While it is difficult to specify all the costs of additional enforcement obligations, as governmental data are lacking and new investments will depend on the current level of implementation per country and on already existing infrastructure, there are some conclusions to be drawn from the empirical data contained in international assistance projects. The main conclusion relates to the freedom not to deviate resources away from the implementation of law in general towards IP enforcement, granted in the TRIPS Agreement and in many IP chapters contained in free trade agreements. The conciseness of the new

²¹ See J. Michael Finger & Philip Schuler, *Implementation of the Uruguay Round Commitments: The Development Challenge*, (World Bank Development Research Group, Policy Research, Working Paper 2215, Oct. 1999).

²² *Id.* at 9.

²³ *Id.* at 25.

obligations, together with the budget restrictions of many developing countries, imply that if no new resources are expressly generated, countries will have to channel resources away from other law enforcement activities.²⁴

B. Effects of Enforcement on Welfare

The latter type of resource implications from enforcement provisions refer to the changes they cause to economic activities. In this context, the impact of IP provisions contained in a treaty can be defined as the changes it causes to a set of variables/outcomes in relation to a reference scenario, where all things except the changes caused by the treaty remain the same. The effects can affect the various parties involved differently and can be both positive and negative in character. On the positive side, for instance, enforcement provisions tend to strengthen government tax collection and are a way to protect some countries' national industries. Most of the existing literature on the effects of IP enforcement has focused on these types of consequence from enforcement, and issues such as labour (jobs created rather than destroyed); public health protection or tax collection have received almost all the attention. Nevertheless, up till now, the welfare effects of IP enforcement have not been considered.

Given the tremendous importance gained by IP enforcement, and the emphasis placed not only on customary approaches but also on developing new standards, it is important to take into account the potential impacts on welfare. For instance, in the field of health, introducing and increasing certain enforcement standards is likely to have negative effects for consumers, health systems and domestic manufacturers in developing countries. The reason is that new enforcement standards could increase costs of medicines and reduce access, weakening the marketing opportunities for domestic manufacturers and parallel imports.

New enforcement standards are likely to reinforce the position of rights holders, mainly multinational companies, by extending their market dominance, while the position of other actors such as national industries and consumers is weakened. This is the case not only when IP rights are infringed, but also in the run up to the determination (or not) of the existence of an IP violation. Examples of this last aspect are the strengthening of precautionary measures and the lifting of the title holders' obligation to provide security when they ask for the border detention of goods. These are new rights granted to title holders which, even without any proven infringement, can impede competition.

²⁴ Or channel resources away from other public budget items, such as health, education or infrastructure.

The area of patents granted to pharmaceutical products is a good example. Consumption of medicines in a country depends either on the type and volume of production available in the country, or on what can be imported. The institutional framework, including IPR rules and standards if products are patented, is also a factor that has an impact on medicine consumption. A higher level of enforcement implies a change in the institutional framework and is therefore likely to have an impact on production, investment (including R&D), imports, exports and other related variables. As long as enforcement measures reinforce the position of the IP rights holder, it is likely to reduce national production, to increase imports and to reduce exports. It is also likely to reduce investment by national companies. The effect on foreign companies is more uncertain: some claim that a higher level of protection of IP rights will provide incentives for foreign investors, but others maintain that originator companies will face less competition from domestic industry and hence may find it more profitable to concentrate production in central sites.

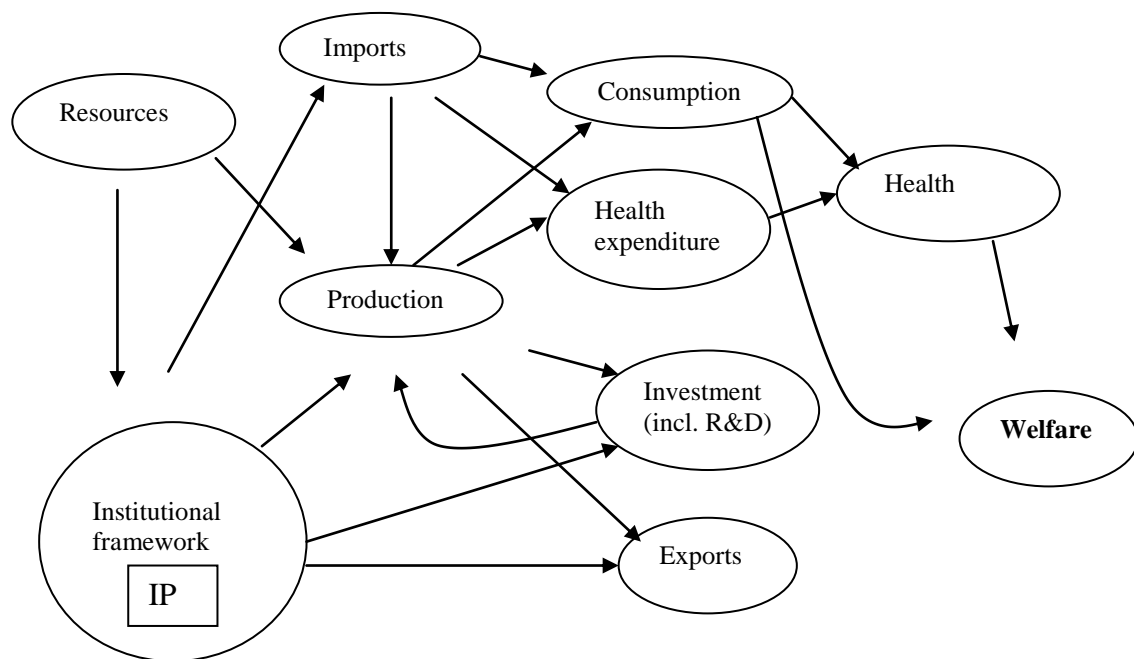


Figure 1: Resource implications of enforcement measures.

In terms of welfare, the impact of new enforcement measures can be assessed using variables that depend on the first set of affected economic variables (i.e. production, exports, imports, investment, etc). In the field of pharmaceutical products for instance, changes in the latter will in turn affect consumption and access to medicines, health expenditure and health status. If the attention is focused on enforcement measures that reinforce the position of IP rights holders (originators) it might be

expected that prices of medicines will rise, thus increasing health expenditure and/or reducing affordability (access) and consumption. Higher medicines prices mean that either consumers or health insurers have to spend more in order to buy the same amount of medicines, or they have to reduce their consumption of medicines. In the first case, welfare will come down as a reduction of general consumption or as a likely reduction in health conditions following the reduction in medicine consumption.

V. METHODOLOGIES TO MEASURE/QUANTIFY THE IMPACT OF ENFORCEMENT

A. *Tentative categories of provisions according to their impact on welfare*

Not all enforcement provisions can be assessed in the same way because the effects of each may be distinct. Leaving aside the questions concerning their legality, and without intending to establish a *numerus clausus* list, at least three different categories of enforcement provisions can be identified according to their impact on welfare:

1. Provisions that clearly may impact on the accessibility of goods
2. Provisions with clear but almost impossible to quantify consequences
3. Provisions of little relevance in terms of impact on costs and availability of goods

Numerous enforcement provisions fall into the first group, such as constraints in exceptions to the use of injunctions, the widening of entitled applicants and the enlargement of border measures to embrace all categories of IP and all customs situations. This last is a clear case. On the one hand, new border measures imply the already mentioned costs of implementation.²⁵ On the other hand, the new regime for border measures will also have other types of resource implications, such as the associated changes in economic activities and, in consequence, to social priorities such as health, culture or food supply. That is, new border measures would impact welfare. As the *Medicines detentions case* proves, some border measures restrain the import of generic drugs

²⁵ States adopting the EU-style border measures regime are obliged to control more IP categories and more border situations, and will require more resources for IP administration. For instance, the new regime obliges States to display more personnel at the border, to build new facilities to stockpile suspected goods, to set up laboratories to conduct rapid chemical analysis, and to build facilities to destroy infringing goods and goods that have not been claimed by the owners.

because of the constraints imposed by transit countries, and may oblige manufacturers to change routes of transport. Both consequences have an impact on medicines prices and availability, therefore affecting consumption, and access.²⁶

A second category of enforcement provisions, according to their impact on welfare, is made up of provisions with clear but very difficult to quantify consequences. This would be a category composed of *chilling effect* provisions. Some types of enforcement measures have the effect of deterring legal activities. The threat or risks of sanctions or of high litigation costs may be too high for some stakeholders to undertake even some legal activities. For instance, it has been noted that:

Innovation is also chilled by the statutory damages permitted in copyright infringement cases. Under 17 U.S.C. § 504, a plaintiff can obtain up to \$30,000 in damages for each work infringed, regardless of the actual injury it suffered. In cases involving willful infringement, the statutory damages can rise to \$150,000 per work infringed. Because cases involving digital technologies often implicate hundreds, if not thousands, of works, providers of information technology products and services face truly astronomic damages liability. The threat of enormous damages encourages rights holders to assert aggressive theories in the hope of coercing quick settlements. The threat of enormous damages also causes technology companies to withhold new products and services from the market.²⁷

One way to measure the effects of these provisions could be looking into the industrial organization and business decision making of affected companies. Nevertheless, companies tend to protect this information due to its commercial and industrial value.

Lastly, it is also envisaged that there is a category of enforcement provisions that will be of little relevance in terms of impact on costs and availability of goods. This could be the case for new obligations to provide information on the origin and network distribution of the goods or services that infringe an intellectual property right.

²⁶ Xavier Seuba, *FREE TRADE OF PHARMACEUTICAL PRODUCTS. THE LIMITS OF INTELLECTUAL PROPERTY ENFORCEMENT AT THE BORDER 1* (ICTSD, ed. 2010).

²⁷ Response of Netcoalition and the Computer & Communications Industry Association to the Intellectual Property Enforcement Coordinator's Request for Comments on the Joint Strategic Plan 14 (Netcoalition-CCIA, eds. 2010) *available at* <http://www.docstoc.com/docs/31483004/IPEC-Comments-FINAL-w-Attachments>.

In reality, provisions will rarely be ascribed only to one group. In many cases, a single provision will have several categories of effect. For instance, the same provision can, at the same time, be both chilling and limitative of the availability of goods. Nevertheless, on most occasions one characteristic will be clearer than others.

B. The IPRIA Model

As far as the impact assessment of new enforcement provisions, this can be done either retrospectively (e.g. x years after a country implemented enforcement) or prospectively (before doing it). In the first case, assessing the impact implies comparing what actually happened with the hypothetical situation/scenario of not having implemented it. In the second case, the comparison involves two future, hypothetical scenarios. In the two cases, the exercise requires some form of modelling or estimation, as it would be practically impossible to design a natural experiment of these issues.

Some types of impacts can be assessed with the help of mathematical and simulation models such as the IPRIA, which is of use in the public health field. The IPRIA focuses on the share of the drug market which is under exclusivity and on the consequent effects on prices, expenditure and consumption, by comparing the estimated scenario of a given IP change with a reference scenario, normally the present situation. The applications of the IPRIA have usually assumed full compliance of the country with the provisions agreed, but this is not necessarily so. In fact, the IPRIA has been applied in Costa Rica and Dominican Republic with the aim of assessing alternative implementation options of an already signed free trade agreement.²⁸ Other countries and non-governmental organizations have also applied the IPRIA in the context of free trade agreement negotiations.

The causality chain implicit in the IPRIA starts with changes to the proportion of medicines that enter the market with some form of exclusivity (patent protection and test data protection) and on the duration of that exclusivity. Exclusivity leads to higher prices of the medicines, which finally causes either an increase of expenditure or a reduction in consumption or a combination of the two effects.

Some forms of enforcement, such as increasing monitoring activities, criminalising IP violations or changing the roles of stakeholders, will also be likely to affect production, trade, prices and access. The causal chain might, however, be much harder to conceptualise and to quantify in a credible way, than changes in the

²⁸ See generally, Greivin Hernández-González & Max Valverde, *EVALUACIÓN DEL IMPACTO DE LAS DISPOSICIONES DE ADPIC+ EN EL MERCADO INSTITUCIONAL DE MEDICAMENTOS DE COSTA RICA* (ICTSD, ed. 2009) available at http://ictsd.org/downloads/2010/01/costa-rica_web_final.pdf.

duration of exclusivity. It may not be feasible to develop formal models with empirical bases and so assessments might, at best, rest on subjective expert opinion.

As the baseline, this study uses the scenario that derives from the obligations of the TRIPS and compares it with four alternative scenarios derived from the free trade agreement concluded between the United States, Central American countries and the Dominican Republic (CAFTA-DR). The four scenarios represent different implementation possibilities of the CAFTA-DR. The features of the four different scenarios are mostly related to enforcement.

1. Scenario CAFTA-DR – (very favorable)

It assumes pro-competition implementation. It optimistically assumes that the patent office will appropriately increase its capacity to process patent claims. The increased capacity will almost completely remove delays in the granting process (i.e. it would never extend further the 18 months agreed in the CAFTA-DR). As a consequence, there would be no need to grant the patent extensions the CAFTA-DR mandates in case of backlogs. This scenario also assumes that private players would not use strategic litigation in order to delay the market entry of generic medicines.

In this case, the costs of enforcement (strengthening the IP office) will arguably have a positive effect on welfare, because it will reduce the chances of having to extend patents. It seems obvious, however, that enforcement provisions should not be evaluated in isolation, but always in relation to substantive provisions forming part of the same agreement, since both categories of norms contribute to the final impact. In this case, if the 18 months period had never been agreed, strengthening the IP office budget would not have been considered a tool for achieving the abovementioned positive effect.

2. Scenario CAFTA-DR – (intermediate)

This scenario also assumes no patent extensions due to delays in the processing of applications. However, it assumes a two year delay in generic entry after the expiration of the originator's patent due to strategic litigation by patent holders.

This scenario also assumes a relaxation of the industrial applicability of an invention as a criterion for granting a patent. As a result the number of patented new drugs is assumed to increase by 50%.

3. Scenario CAFTA-DR + (negative)

It incorporates higher commitments on IPR and a less optimistic view of the institutional capacity of the government in relation to IP management and enforcement. More specifically, it introduces patent extensions due to process delays and assumes an increase in patentability, namely that all new medicines would enter the market patent-protected.

4. Scenario CAFTA-DR ++ (very negative)

This last scenario assumes the former factors plus additional changes in the behavior of some market players. For instance, it assumes that originators will take advantage of its market dominance to increase the prices of new, patented medicines in relation to the previous scenarios. Generic market entry is assumed to rise to 4 years.

The increase in medicines' expenditure over the baseline scenario varies across the four alternative scenarios between 17% and 31%.

VI. FINAL REMARKS

If IP enforcement is limited to compelling or ensuring obedience to IP rights and obligations, it is clear that not all the provisions contained in enforcement chapters are strictly provisions on enforcement. This has several potential explanations and consequences. One explanation refers to the technical quality of some FTA and IP treaties. A second explanation, compatible with the former, may be found in the alleged 'extra legitimacy' attached to enforcement obligations. That is, enforcement provisions seem to be less controversial than substantive provisions: if a right was already accorded, it is generally considered fair to respect it.

The identification of substantive provisions located under the enforcement sections of IP treaties confirms that there is a substantive rights-based aspect to the so-called *enforcement offensive*. On the other hand, including in enforcement treaty chapters provisions of a distinct nature may give rise to systemic problems with practical consequences. In this last regard, the potential consequences of TRIPS footnote #3 should be analyzed. This footnote deals with the scope of the non-discrimination principle (that is, the most favoured nation treatment and the national treatment). It establishes that the non-discrimination principle applies to "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 the TRIPS.”²⁹ If it was proven that treaty sections dealing with “enforcement” contain provisions that do not address enforcement, there would be space to argue that new substantive rights and obligations would not benefit from the national treatment or the most favoured nation treatment.

As far as the costs of enforcement and its impact on welfare are concerned, it is necessary to conduct more analysis and research. States routinely execute economic impact studies before adopting new international economic obligations. This practice has been common as far as trade liberalization agreements are concerned, and it started to emerge with respect to IP treaties at the end of the nineties. However, and despite the significance of new enforcement obligations, these studies have not been able to capture the costs of enforcement or its effects on welfare. The distinction drawn here is not only helpful for explanatory purposes, but it also reflects the distinct nature of the resource effects from enforcement norms. That is, on the one hand, new obligations on enforcement compel States to invest in areas such as personnel, infrastructure and institutions. On the other hand, enforcement provisions impact on economic activities and, in the end, on welfare. In this last regard, it is possible to identify provisions that clearly impact the availability of goods, obligations with clear but almost impossible to quantify consequences, and provisions of little relevance in terms of impact on costs and availability of goods.

Regarding the costs of enforcement, it is sometimes stated that since developed countries or international institutions tend to finance the activities that trigger those costs, there is no need to be concerned. Nevertheless, even if the required reforms are financed by developed countries through technical assistance programs or projects of multilateral organizations, this might supersede development aid to other areas.³⁰ Additionally, some claim that for developing countries the benefits of the new enforcement obligations are related to health and safety concerns for consumers. The examples justifying this thesis are usually extracted from the areas of willful commercial trademark counterfeiting. Nevertheless, whether IP is the proper channel to address health and safety concerns is a highly disputed question. What it is indeed true is that in the case of developing countries most IP rights holders tend to be non-nationals. This is why short run benefits of increased IPR enforcement are unlikely for national industries and national development.

²⁹ TRIPS Agreement, *supra* note 2, footnote 3.

³⁰ See Carsten Fink, *Enforcing Intellectual Property Rights: An Economic Perspective*, in *THE GLOBAL DEBATE ON THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS AND DEVELOPING COUNTRIES* 1, 19 (ICTSD, ed. 2009).

The TRIPS Agreement states that enforcement obligations must be fair, equitable and not unnecessarily complicated, costly or time consuming, and that TRIPS creates no obligation to shift resources away from general law enforcement towards the enforcement of IPR. However, higher standards of enforcement seen in trade agreements do not allow for this balance of enforcement with public interests. The resource shifts associated with the implementation of international and bilateral treaties on enforcement could distort public spending in affected countries.

Enforcement of an agreement on IPR should not necessarily mean reinforcing only the position of the right holders. It can also refer to improving the rights of other stakeholders. For instance, enforcement might refer to the right of society (competitors, consumers, third party payers) to have full access to the innovation once the exclusivity rights have expired and to have the right to produce and have the product available at lower prices. The right to issue compulsory licenses or to deny protection to spurious innovation should also be seen as potential objectives of enforcement measures. This last point shows that there is also space for a proactive -not merely reactive- stance as far as enforcement issues are concerned.