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Global Governance in Intellectual Property Protection: Does the Decision-making Forum Matter?

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☞ Intellectual property; International law; Norms; TRIPS

The question whether the TRIPS would bring economic benefit not only to the developed but also developing countries has been debated ever since the nascence of this legal instrument. This has been widely assessed through the so-called balance of rights and obligations established in the TRIPS Agreement. With the advent of parallel bilateral and plurilateral IP rule-making fora, this question has acquired even more nuances requiring examination of specific legal language at all these different levels. Against this background and by examining the balance language of the relevant treaties, this paper examines how the negotiation fora producing IP rules impact on the achievement of a balance between the rights and obligations of the stakeholders involved. Global, plurilateral and bilateral IP norm-making avenues are assessed with a view to understanding whether there is any discrepancy in their capacity to reflect a balance of rights and obligations. We are mainly interested in comparing multilateral fora, bilateral and plurilateral fora and how they differ in terms of outcomes. We find that this balance is better secured under the WTO TRIPS Agreement and other multilateral fora in particular WIPO. This is why we propose greater judicial openness towards the developments in this organisation at the WTO—a mechanism which should partially compensate for the Doha negotiations stalemate.

I. Introduction

The adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the presumed hard-line enforcement of the minimum intellectual property (IP) standards enshrined therein have attracted much attention. Ever since the advent of the agreement, it has raised multiple questions with regard to its economic benefit, mostly whether the benefits accruing to developed, developing and least-developed countries are comparable and sufficiently balanced. In the aftermath of the completion of the Uruguay Round negotiations, a considerable amount of scholarly work has emerged on this topic. Interest has been further enhanced by the spread of bilateral free trade agreements and plurilateral agreements which incorporate more expansive and stronger IP obligations than those adhered to under the TRIPS Agreement. While TRIPS has received a significant amount of criticism for favouring privatization of knowledge, entrenching economic privileges centred in the developed world and neglecting the “social function of IP laws”,¹ the question that arises is how one should characterize the bilateral and

¹ Sub-Commission on Human Rights Resolution 2000/7, *Intellectual Property Rights and Human Rights*, August 17, 2000, E/CN.4/Sub.2/RES/2000/7.

plurilateral IP-related agreements from this point of view. Against this background, we examine how the negotiation fora producing IP rules impact on the achievement of a balance between the rights and obligations of the stakeholders involved.

The balance of rights and obligations also relates to vertical allocations of power between international and domestic fora. The minimal standards set out in the TRIPS Agreement have been criticized for being too rigid and for not sufficiently taking into account different levels of social and economic development. Power, in other words, has been unduly centralized in the World Trade Organization (WTO), and a more flexible mode emphasizing domestic legislation should be sought. Moreover, the TRIPS Agreement does not constrain Members from imposing even higher standards. It does not establish ceilings, but remains open-ended. Members are free to adopt higher levels of protection, and checks based upon competition law have remained purely national or regional.

Against this background, it is important to examine the role and experience of different fora and layers of governance in shaping and applying IP rules. Global, regional, bilateral and sectoral avenues need to be assessed as to how they relate to each other and to the domestic fora of legislation in nation states. We are interested in assessing substance-structure pairings, that is, how substantive rules relate to the procedures and fora which bring them about and which apply them.² In this article, we compare multilateral fora, with bilateral and regional fora to explore how they differ in terms of outcomes. Insights from past experience may assist in predicting appropriate allocations of power which may also be relevant to other regulatory fields still unchartered or less developed than IP protection.

Section II sets out IP protection as a paradigm of both international legislation and multilayered governance. It briefly covers the foundations based upon which horizontal and vertical relations in regulating intellectual property rights (IPRs) are assessed.

Section III examines the horizontal international IP governance. Given the complexity of the international IP regime and the number of actors involved in the regulation process, we look at the multilateral IP rule-making and bilateral (and plurilateral) treaties. This examination takes account of the decision-making processes at the WTO and the World Intellectual Property Organization (WIPO)—the most important multilateral IP norm-creation fora—as well as plurilateral and bilateral settings. Then we analyse the IP obligations entrenched therein with regard to their capacity to achieve a balance of rights and obligations. Showing that the balance is better preserved in a multilateral setting, we suggest that rule-making in these fora is encouraged while taking proper account of the current political constraints under which they operate.

Section IV examines the interrelationship of different international fora in the international IP governance system. The issue responds to the quest to design an efficient regime or forum management which would contrast with the present deliberate regime proliferation in the regime-shifting game which actors play on the global IP chessboard.³ The proper way of managing these relationships is seen through the WTO's collaboration with WIPO. We argue that this institutional networking should, among other things, work towards overcoming fragmentation and current deficiencies and that the two organizations should act as guardians in the process of global IP governance.

Section V offers a number of conclusions emphasizing the need to return to multilateral fora and how they should be reformed in order to respond to the needs of future global IP governance.

² See T. Cottier, "Constitutional Trade Regulation in National and International Law: Structure-Substance Pairings" in M. Hilf and E.-U. Petersmann (eds), *National Constitutions and International Economic Law* (The Hague: Kluwer Law International, 1993), Vol.8, pp.409, 411; T. Cottier, "Preparing for Structural Reform in the WTO" (2007) 10 *Journal of International Economic Law* 497.

³ See also C. Oguamanam, "IP in Global Governance: A Venture in Critical Reflection" (2011) 2(2) *WIPO Journal* 196, 215, who has suggested better IP regime management as one of the elements to be considered in designing the new IP order. For a more in-depth analysis see his recent book, C. Oguamanam, *Intellectual Property in Global Governance: A Development Question* (London: Routledge, 2011).

II. IP as a paradigm of international legislation and multilayered governance

IP protection in international law is perhaps the area of law which is most advanced in terms of international standards and norms prescribing the conduct of governments—and often indirectly, of private actors. It is a paradigm of international legislation. There is hardly any other field in international economic law where rules on substantive and procedural standards offer a more comprehensive and common set.⁴ Interest in securing foreign trade and investment and in protecting domestic markets from counterfeiting and piracy induced strong pressures from industry to address IP in diplomacy and international and regional law. The multilateral Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property were adopted in 1886 and 1883 respectively, long before the multilateral rules of the General Agreement on Tariffs and Trade (GATT) were drawn up in 1947. While the GATT rules focused on rules setting limits for members in terms of tariff and non-tariff measures, IP from its very inception was designed in terms of positive integration: members of these conventions are obliged to actively provide protection at least to the levels provided for in these conventions. The 1995 TRIPS Agreement built on that tradition. None of the other WTO Agreements are prescriptive to the same extent. Many felt it was too prescriptive and uniform in the light of the diverging needs and stages of development of members. None of the other agreements has been as controversial as the TRIPS Agreement with its positive minimal standards.

A number of international institutions are involved in setting and operating minimal standards and procedural requirements, ranging from the WTO, WIPO, the International Union for the Protection of New Varieties of Plants (UPOV), the World Health Organization (WHO), the United Nations Food and Agriculture Organization (FAO), the United Nations Conference on Trade and Development (UNCTAD), and the United Nations Educational, Scientific and Cultural Organization (UNESCO) to regional bodies, in particular the European Union, the European Patent Organization and others such as the African Intellectual Property Organization (OAPI). Moreover, IP rules are not limited to specific IP conventions, but can also be found in sectoral agreements, such as the Convention on Biological Diversity (CBD) and related instruments and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). They also appear in the UNESCO Convention on Cultural Diversity. A number of functional institutions are involved in regulating IPRs, and horizontal coordination is an important task in this area.

The field of IP protection is strongly anchored and is mainly operational in domestic law from which it expanded to regional and international law. Conversely, parts of the protection formed harmonization or minimal standards. Thus, multilateral or regional systems to obtain protection, developed in international law, feed back into the realm of domestic law. The interaction between and complementarity of rules located on different layers of governance offer a complex web of vertical allocations of power. This constellation promises interesting insights into the doctrine of multilayered or multilevel governance.

Building upon the precepts of federalism, this doctrine expounds the relationship between different layers of governance and how they interact.⁵ It designs a system of vertical separation and allocation of power, all with a view to installing mutual and vertical checks and balances between different layers. It no longer makes a fundamental differentiation between domestic, regional and global law, but perceives them all as forming part of a single and coherent system of mutual interactions in producing global public goods and promoting welfare. The different layers are all informed by shared principles and the rule of law. They mutually complement, control, limit and stabilize each other.

⁴ See generally F.M. Abbott, T. Cottier and F. Gurry, *International Intellectual Property in an Integrated World Economy*, 2nd edn (Austin: Aspen Publishers, 2011).

⁵ See T. Cottier, "Multilayered Governance, Pluralism, and Moral Conflict" (2009) 16(2) *Indiana Journal of Global Legal Studies* 647.

The doctrine of multilayered governance essentially emanates from the idea of constitutionalizing international law and looks at overall governance in a comprehensive manner.⁶ There is no single school of thought or agreed set of terms.⁷ Research efforts range from explaining the functions of international economic and trade law in terms of embedded liberalism to explanations based upon the precepts and functions of administrative law partly assumed by international levels.⁸ The underlying theory used in the present context is that of a five-storey house—a metaphor used to depict different layers of government at the local, provincial, national, regional, and global levels.⁹ While these levels are subject to an ordering hierarchy essentially based upon *pacta sunt servanda*, this does not exclude the possibility of subsequent layers predominating in the pursuit of protection for fundamental values and human rights. All layers share common values and principles, entailing the preservation of peaceful relations, fundamental principles of law, the rule of law, democracy and human rights protection. Yet, these principles operate with divergent priorities. While democracy is key at the local, provincial and national levels, maintaining peaceful relations and the rule of law dominate at the international level, without excluding other and shared principles.

Applying this metaphor is essentially a matter of properly allocating power and functions with a view to producing appropriate public goods—local, provincial, national, regional and global. The main focus is on vertical allocations. The task, however, equally entails horizontal allocations among different functions of governance. The topic is of particular relevance at the global level. There is a lack of centralizing governance structures, and international organizations are functionally defined. Fragmentation is the norm. Allocation of power and cooperation with a view to achieving greater coherence is a major goal of the doctrine of multilayered governance not only vertically, but also horizontally.

So far, the horizontal aspect has not been paid as much attention as vertical relations. Yet, checks and balances within a particular layer of governance are of equal importance and, of course, lie at the heart of constitutional law. The same holds true for the level of international governance, albeit hardly discussed in constitutional terms. The interaction of different organizations and treaties is of equal importance in shaping a new IP order and deserves fuller attention in the quest to find coherence and appropriate structures of governance in a particular regulatory field. The emergence of the G-20 following the financial crisis renewed the debate on the legitimacy and architecture of global governance and the need to enhance awareness.

There is hardly any other field of law and policy offering such a complex and advanced example of the interplay of different regulatory levels as IP protection. There is hardly any other field allowing the pros and cons of vertical distribution and allocations to be discussed in an equally comprehensive manner, adding in a specific area insights into the doctrine of multilevel governance. And there is hardly any other field more suitable to further learning from the doctrine of multilayered governance in finding and filling existing lacunas and regulatory deficiencies. Importantly, it offers particular insights into horizontal allocations of power as IP is addressed and administered by a number of international organizations and bodies, both global and regional, and is strongly influenced by bilateral and preferential agreements.

⁶ See T. Cottier and M. Hertig, “The Prospects of 21st Century Constitutionalism” (2003) 7 *Max Planck Yearbook of International Law* 261; T. Cottier, “The Constitutionalism of International Economic Law” in K.M. Meessen (ed.), *Economic Law as an Economic Good* (Munich: Sellier European Law Publishers, 2009); J.H. Jackson, *Sovereignty, the WTO and Changing Fundamentals of International Law* (Cambridge: Cambridge University Press, 2006); A. Peters, “Compensatory Constitutionalism: The Function and Potential of Fundamental International Norms and Structures” (2006) 19 *Leiden Journal of International Law* 579; A. Peters, “The Merits of Global Constitutionalism” (2009) 16 *Indiana Journal of Global Legal Studies* 397; J. Klabbers, A. Peters and G. Ulfstein, *The Constitutionalization of International Law* (Oxford: Oxford University Press, 2009).

⁷ K. Milewicz, “Emerging Patterns of Global Constitutionalization: Towards a Conceptual Framework” (2009) 16 *Indiana Journal of Global Legal Studies* 413.

⁸ See C. Joerges and E.-U. Petersmann (eds), *Constitutionalism, Multilevel Trade Governance and Social Regulation*, 2nd edn (Oxford: Hart Publishing, 2011). Many scholars remain critical of the process of constitutionalization of international law: e.g. S. Besson, “Whose Constitution(s)? International Law, Constitutionalism and Democracy” in J. Dunoff and J. Trachtman (eds), *Ruling the World? Constitutionalism, International Law and Global Governance* (Cambridge: Cambridge University Press, 2009); D. Cass, *The Constitutionalization of the World Trade Organization* (Oxford: Oxford University Press, 2005); R. Howse and K. Nicolaidis, “Legitimacy through ‘Higher Law’? Why Constitutionalizing the WTO Is a Step Too Far” in T. Cottier and P.C. Mavroidis (eds), *The Role of the Judge in International Trade Regulation* (Ann Arbor: Michigan University Press, 2003).

⁹ T. Cottier, “Towards a Five Storey House” in Joerges and Petersmann (eds), *Constitutionalism, Multilevel Trade Governance and Social Regulation*, 2nd edn (2011).

Finally, IP protection reflects the impact of modern technology more than in other fields.¹⁰ It allows a discussion on the impact of technology on governance structures. It is very dear to the hearts of competing nation states and local exporting and importing industries. Key industries, ranging from chemicals and pharmaceuticals to genetic engineering, from mechanics and avionics to computers, from print and film to digital products and programming, are all subject to IP protection. In the information society, the lead and thus the power of economies is largely defined by knowledge and information in terms of goods and services subject to IP protection. Rights and obligations define the realms of private and public spheres. They define the control of information and use of knowledge and determine how much of this knowledge may be appropriated and how much it ought to be shared with the public at large. Marketing and commerce largely depend on trademarks and related forms, and these are a key prerequisite of commerce, both domestic and international. It is a domain close to the heart of national sovereignty, and countries seek to preserve appropriate policy space. The pursuit of economic interests abroad encourages, at the same time, international disciplines and restrictions of national sovereignty in a sensitive area of regulation. The battle for key industries in goods and services makes it a pivotal point and domain of law on all layers alike. The paradigms of international law and of multilayered governance are therefore at the heart of the battle for international competitiveness, which in return should inform suitable structures of governance.

III. The horizontal level of international IP law

The exploration of the horizontal level of global IP governance is the focus of this study, which is concerned with the institutions and norms emerging on the international plane. We look into the relationship of different treaty systems and organizations and how they relate to bilateral and plurilateral avenues of protecting IP. We submit that the IP forum matters in terms of results and that multilateral instruments offer a more appropriate balance of rights and obligations than bilateral and plurilateral instruments.

The alleged superiority of multilateral regimes over the bilateral and plurilateral ones lies in their ability to reflect and achieve a finer balance among the interests at stake. Thus, despite its limitations, the TRIPS Agreement has a claim in serving as a suitable benchmark, allowing judgement as to whether other free trade agreements provide—at least on the face of it—any flexibilities comparable to those enunciated in the Agreement. Peter Yu has described this feature of the TRIPS Agreement as a “seed” which should direct the development of new IP norms.¹¹

Against this background, Subsection A below examines the extent to which the balance between rights and obligations and the respect for wider public interests are entrenched in the TRIPS Agreement and other IP norm-setting arrangements. In particular, we look at whether they provide policy scope reflecting various interests. Subsection B focuses on the institutions with greatest relevance to today’s global IP governance—that is, the WTO and WIPO—addressing the question of what should be their proper interface in managing and strengthening multilateral IP norm generation.

Taking at its word, the TRIPS Agreement seems to offer both a utilitarian means of promoting public welfare and a means of fitting together diverse rights and interests to produce, in the words of Taubman, a “positive-sum accommodation”.¹² IP protection should thus yield a “balance” of rights and obligations, to the mutual advantage of different interest groups and overall social and economic welfare.

The interests to be weighed depend on the issues and forms of IP concerned in a specific case and may appear in diverse forms. Examples include public or collective interests against private interests, the interests of developing countries against those of developed countries, consumers against producers,

¹⁰ See F.M. Abbott and D. Gerber (eds), *Public Policy and Global Technological Integration* (The Hague: Kluwer Law International, 1997).

¹¹ P.K. Yu, “The Objectives and Principles of the TRIPS Agreement” (2009) 46 *Houston Law Review* 979, 1042.

¹² The term has been used by A.S., Taubman, “TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic” in C. Lenk, N. Hoppe and R. Andorno (eds), *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology* (London: Ashgate, 2007). In decision theory, this describes a “win-win” situation where no one wins at someone else’s expense, and the sum of winnings (positives) and losses (negatives) is positive.

rent-seeking or sectional interests against the defence of the public domain or free trade; access to technology against innovation; exclusivity of property rights against entitlements to equitable or adequate remuneration; and individual innovation against the collective innovation of an indigenous community.¹³ Although the list is long, it should not create the illusion that these interests can be neatly delineated. It is equally difficult to assess the extent to which the balance being pursued would tolerate having to lean “a little more” or “a little less” to one side or the other. As Dinwoodie has correctly acknowledged, even in the domestic context, the term balance is difficult to define, let alone in the multilateral context,¹⁴ where the interests at stake become more diverse given the differing levels of economic development of the interested parties. Moreover, specific terms can be employed only when discussing the balance in the context of a specific form of IP protection. For example, in any patent system, with a view to contributing to the promotion of technological innovation and to the transfer and dissemination of technology, finding the right balance between producers and users of technological knowledge is considered fundamental.¹⁵

The interests at stake in protecting the various forms of IP and across countries at various levels of development can generally be subsumed under two categories: (1) public or collective interests against private interests; and (2) exclusive rights as a means of promoting or rewarding the production of knowledge goods against limitations and exclusions to such rights as a means of diffusing and accessing such goods. Thus, good IP policy balances these interests, while bad policy would be tilted to favour one interest over another. The continued search for this balance is evidenced in various policies covering a vast array of IP forms. For example, the debate over biopiracy concerns both limiting the patenting of material in the public domain and affirming rights to exclude unauthorized third party use of traditional knowledge and genetic resources, even when users assume this material to be in the “public domain”.¹⁶ In the copyright context, for example, laws generally only protect a concrete expression of an idea, whereas ideas as such are for free use in the public domain.¹⁷ Thus, these laws will protect, for example, scientific articles, but not the ideas or scientific concepts expressed therein. As in the case of other forms of IP, and flowing from the TRIPS Agreement, they may further provide for exceptions which allow the (non-commercial) educational use of such articles to a certain extent.¹⁸

A. The TRIPS Agreement

In response to the realization of the value of IPRs after the 1980s, different strategies have been developed by governments in order to reap the benefits conferred by these rights. These strategies started to take shape with the emergence of the TRIPS Agreement imposing minimum IP standards upon WTO Members.¹⁹ Within the Uruguay Round negotiations, the TRIPS Agreement mainly pursued the interests and concerns of developed countries competing in the globalizing economy.²⁰ These interests were overall balanced with those of developing countries in negotiations on textiles and agriculture. The criticism of the TRIPS Agreement as neglecting the social function of IP law, along with the traditional fears related thereto, stems from the genesis and negotiation dynamics of the Agreement, its initiation having been characterized

¹³ On the last example see A.S. Taubman, “Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge” in K.E. Maskus and J.H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005).

¹⁴ G.B. Dinwoodie, “The WIPO Copyright Treaty: A Transition to the Future of International Copyright Lawmaking?” (2007) 57(4) *Case Western Reserve Law Review* 751.

¹⁵ WIPO Standing Committee on the Law of Patents, “Transfer of Technology”, December 11, 2009, SCP/14/4, para.119.

¹⁶ Taubman, “TRIPS Jurisprudence in the Balance” in Lenk, Hoppe and Andorno, *Ethics and Law of Intellectual Property* (2007), p.9.

¹⁷ See TRIPS art.9.2.

¹⁸ See art.5.3 of the EC Copyright in the Information Society Directive 2001.

¹⁹ See generally T. Cottier, *Trade and Intellectual Property Protection in the WTO: Collected Essays* (London: Cameron May, 2005); D.J. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 3rd edn (London: Sweet & Maxwell, 2008).

²⁰ F.M. Abbott, “Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT” (1989) 22 *Vanderbilt Journal of Transnational Law* 689.

as a form of regulatory capture by the interests of specific producers.²¹ Since the TRIPS deal concerns various stakeholders, including individuals, corporations, nations and society—all having different goals and expectations from IP²²—the critics have viewed the TRIPS Agreement as a symbol of imbalance.²³

But not everyone shares these perceptions. The criticism in itself had the effect of contributing to a better understanding of how to differentiate “the political and axiological penumbra of the TRIPS Agreement from its core legal effect, and its positive role in setting bounds to and alleviating trade disputes on IP issues between WTO Members”.²⁴ A striking feature of the TRIPS Agreement is that it is beginning to serve as a broadly accepted benchmark for an overall balance of interests (notwithstanding certain strongly contested elements). It also testified to the fact that it is taken as a *de facto* benchmark in the critical analysis of other IP norm-setting processes, like those emerging in the context of free trade agreements with their so-called “TRIPS-plus” obligations.

The evolution in the perceptions of the TRIPS Agreement, from being regarded as promoting specific industry interests to its broader acceptance as mediating diverse objectives and public interests as enunciated in TRIPS arts 7 (entitled “Objectives”) and 8 (entitled “Principles”) is evidenced through a number of examples. First, this changing perception emerges from the explicit language of these provisions, which guide the general interpretation of the TRIPS Agreement and serve as the basis for justification of policy choices not explicitly addressed by the Agreement. An interpretation based on the TRIPS Agreement, balancing objectives and public interest principles, confirms a horizontal flexibility which affects the understanding of all individual TRIPS obligations. This is particularly true for broad and open terms with more than one defensible meaning. An interpretation compatible with TRIPS objectives and principles would allow WTO Members to reconcile IP protection and public interests, such as access to medicines, in their domestic IP laws.

Further room for manoeuvre is accorded to domestic policies allowing remedies against anti-competitive practices, including licensing, which constrain transfer of technology (art.40), provisions introduced to incentivize the transfer of technology to least developed countries as a matter of obligation (art.66.2), and the requirement that enforcement provisions must be *fair* and *balanced* (art.41.2). Secondly, as alluded to above, the evolution of these perceptions is confirmed by a renewed concentration of the attention of the international community on the systemic benefits of multilateral norm-setting and judicial regimes, as reflected in the debate over the implications of new IP standards and dispute settlement procedures in bilateral and regional mechanisms. Thirdly, the frequency with which the TRIPS Agreement is referred to in international norm-setting denotes its transformation into a sort of benchmark for international standard-setting in the IP field.²⁵

Additionally, the Doha Declaration and the decisions taken thereafter provide further evidence of the detachment of the TRIPS Agreement from its partisan perceptions. The Declaration initiated the “paragraph 6” process to amend the TRIPS Agreement to enable countries with insufficient or no manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing under art.31. Many considered this outcome a tautology, or an assertion of existing law so as to validate the flexibilities arising

²¹ P. Drahos and J. Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy* (London: Earthscan, 2002).

²² O. Granstrand, *The Economics and Management of Intellectual Property: Towards Intellectual Capitalism* (Cheltenham: Edward Elgar, 2000), p.9.

²³ See e.g. M.A. Hamilton, “The TRIPs Agreement: Imperialistic, Outdated and Overprotective” (1996) *Vanderbilt Journal of Transnational Law* 613.

²⁴ Taubman, “TRIPS Jurisprudence in the Balance” in Lenk, Hoppe and Andorno, *Ethics and Law of Intellectual Property* (2007), p.26.

²⁵ But the polarities over TRIPS are not all settled by these arguments. As Taubman noted, those polarities in most need of resolution are (1) where the TRIPS Agreement serves as a source of law for international dispute settlement, with which states comply either by virtue of the *pacta sunt servanda* principle or for fear of adverse effects under the DSU; and (2) where the TRIPS Agreement constitutes an essential element of a model law with the purported goal of promoting the social and economic welfare benefits of IP protection. See Taubman, “TRIPS Jurisprudence in the Balance” in Lenk, Hoppe and Andorno, *Ethics and Law of Intellectual Property* (2007), p.29.

out of the TRIPS Agreement. The balance was already entrenched in the language of the TRIPS Agreement, but it needed restatement, which was what the Declaration did, since the WTO Members were not entirely clear as to how they could benefit from these provisions.

However, the evolutions in the perceptions of the TRIPS Agreement did not manifest only at the political level. After 15 years of operation, both the hopes and fears traditionally linked to the TRIPS Agreement and its enforcement under the WTO were and continue to be largely exaggerated. In this context, the TRIPS Agreement has been labelled as the “dog that barked but did not bite”.²⁶ On the “fear” side, many developing countries and NGOs expected, in line with the above perceptions, merciless enforcement of the negotiated IP standards with no room for manoeuvre within the national policy space.²⁷

Indeed, there was some convergence between proponents and critics of the TRIPS Agreement on the expectation that there would be a high rate of litigation under the TRIPS Agreement, especially between developed and developing countries, the latter being targeted by the former over non-compliance with the TRIPS minimum standards. This flood of IP disputes with the advent of the TRIPS Agreement, however, did not materialize.²⁸ The onslaught of IP enforcement against developing countries did not materialize either. Most of the case law relates to disputes among industrialized countries, reflecting the technological and commercial interests at stake.²⁹

A glance at the relevant IP disputes reflects how the WTO adjudicator perceives the two allegedly opposing poles: one stating that IP should promote innovation and the other concerned with balancing this with the rights of other stakeholders concerned. Although few substantive IP disputes have been settled by the WTO dispute settlement mechanism, these few settlements do allow some inferences to be drawn concerning the interpretation of the TRIPS general exceptions as pertaining to copyright (art.13), trademarks (art.17) and patents (art.30). The interpretation of these provisions is one of the most important contributions to the refinement of IP law to date. The cases concerned are *Canada—Patent Protection of Pharmaceutical Products*, which dealt with art.30 exceptions, and *United States—Section 110(5) of the US Copyright Act*, which tackled the copyright exception in art.13. The outcome of these interpretations has been characterized as nuanced and not consistently biased in favour of IP protection.³⁰ In both cases, the panel accepted at least one of the two limitations as meeting the relevant TRIPS exception (namely, the “regulatory review provision” and the “homestyle exemption”). Although the outcome of these disputes attracted broad support among the IP commentators, some criticism was also raised, and there is certainly scope for improvement in the panels’ endeavour to strike this balance.³¹

²⁶ See e.g. J. Pauwelyn, “The Dog that Barked but Didn’t Bite: 15 Years of Intellectual Property Disputes at the WTO” (2010) 1 *Journal of International Dispute Settlement* 389.

²⁷ Jayashree Watal, for example, notes “a strong and widespread perception that the TRIPS agreement is against the interests of developing countries” and argues that “[t]he focus for the demandeurs in the immediate future is likely to be on implementation of and dispute settlement under TRIPS rather than on further development”. See e.g. J. Watal, *Intellectual Property Rights in the WTO and Developing Countries* (The Hague: Kluwer Law International, 2001), p.363.

²⁸ Four TRIPS cases in the last nine years (2001–2010) would hardly strike anyone as constituting a flood of IP cases or major IP activity in the WTO dispute settlement system.

²⁹ Only 9 of the 27 TRIPS disputes (and 4 of the 9 TRIPS panels) were North-South cases. Rather than developing countries, the EC has been by far the most chosen target of TRIPS complaints (10 out of 27 complaints). Another striking feature of this review of the TRIPS disputes is the low number of disputes that are centred on traditional IP questions and that could not have been decided without the TRIPS Agreement and the overwhelming systemic (as opposed to immediate commercial) nature of the cases filed. See Pauwelyn, “The Dog that Barked but Didn’t Bite” (2010) 1 *Journal of International Dispute Settlement* 389.

³⁰ Pauwelyn, “The Dog that Barked but Didn’t Bite” (2010) 1 *Journal of International Dispute Settlement* 389. A similar outcome seems to have been registered in the case of *EC—Trademarks and GIs*. See “European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs”, Report of the Panel, March 15, 2005, WT/DS174/R, paras 7.625-7.682.

³¹ Pauwelyn, “The Dog that Barked but Didn’t Bite” (2010) 1 *Journal of International Dispute Settlement* 389, praised the outcome of the disputes and did not see a problem with the adjudicator’s balancing test since the litigants did not invoke specific third party or social interests in any of these cases. But there was considerable critique on the outcome of the *US—Copyright* panel, which was criticized for having been too lenient with the interpretation of the art.13 three-step test. See e.g. D.J. Brennan, “The Three-Step Test Frenzy—Why the TRIPS Panel Decision Might be Considered *Per Incuriam*” (2002) 2 *Intellectual Property Quarterly* 212. It has been argued that both litigants in the *Canada—Pharmaceuticals* case focused exclusively on the interests of the right holders and the generic producers and that in the *US—Copyright* case, no broader social concerns were invoked: “[I]t did not implicate for example any of free speech or scholarship interests that underlie many copyright exceptions”. See J.C. Ginsburg, “Toward Supranational Copyright Law? The WTO Panel Decision and the ‘Three-Step Test’ for Copyright Exceptions” (2001) 187 *Revue Internationale de Droit d’Auteur* 3, 9. For other examples of criticism of the interpretation of the TRIPS exceptions see Section IV.B(i).

While these disputes do not break any new ground on the issue of the reconciliation of different interests affected by the TRIPS obligations, which will have to await new disputes, the argumentation of the three panels in the above-mentioned disputes shows, however, that:

“TRIPS exceptions do refer to countervailing ‘legitimate interests’ of ‘third parties’ which Panels have found to include non-economic interests as well as consumer interests and interests of competing right holders. Moreover, even where ‘third party’ interests are not explicitly included in the terms of the TRIPS exception as such (as in TRIPS Article 13), the other qualifiers in these exceptions—i.e. ‘legitimate’ interests of right holders, ‘normal’ exploitation and ‘unreasonably’ conflict or prejudice—are broad enough to allow for a balancing of the interests of IP right holders and other interests including broader social or public interests.”³²

Thus, the three prongs of the TRIPS exceptions allow for interpretations to accommodate broader social interests. While one might think that the second and third prongs would be more suitable for this purpose, the first, too, has been used to this effect. In the *United States—Section 110(5)* case, for example, the panel under the first prong of art.13 drew “inferences about the reach of the business and homestyle exemptions from the stated policy purposes underlying these exemptions”.³³

But the TRIPS exceptions (along with arts 7 and 8, discussed above) are not the only provisions in the TRIPS Agreement that permit the interpreter to reconcile countervailing interests. An array of other provisions can be cited for this purpose, including exceptions which allow the preclusion of any IP rights granted. This includes TRIPS art.27.2 referring to “inventions, the prevention ... of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment” and TRIPS art.27.3 with respect to “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”, certain “plants and animals” and certain “biological processes”.³⁴ The list can be completed with the provisions allowing for compulsory licensing without the authorization of the right holder, like TRIPS art.31 (and art.5 of the Paris Convention), which has been consolidated through an amendment ensuing from the Doha Declaration on the TRIPS Agreement and Public Health, resulting in a waiver of para.(f).³⁵ The existence of compulsory licensing or even the mere threat of using it can be utilized by an interested member to bring down the price of the patented product and hence increase its availability. While this mechanism is seldom used in practice, the threat of and possibility to use the system remains an important tool that governments can use to address public interests and facilitate access to a particular patented technology.³⁶

Another important flexibility arising from the Doha Declaration relates to the fact that

³² Pauwelyn, “The Dog that Barked but Didn’t Bite” (2010) 1 *Journal of International Dispute Settlement* 389; see also Ginsburg, “Toward Supranational Copyright Law? The WTO Panel Decision and the ‘Three-Step Test’ for Copyright Exceptions” (2001) 187 *Revue Internationale de Droit d’Auteur* 3, 15, arguing that if there was “a non economic motivation for the exception ... it would be appropriate to develop the neglected normative dimension of ‘normal’ exploitation” and, at 16, “the third step may reduce to a balancing of the legitimacy of the interests of the rights holders and of the beneficiaries of the exception ... the reasonableness (if not also the legitimacy) criterion of step three by its own terms requires some weighing of conflicting interests”.

³³ “United States—Section 110(5) of the US Copyright Act”, Report of the Panel, June 15, 2000, WT/DS/160/R, para.6.113. The reading that an exception must be justified by some “clear reason of public policy or some other exceptional circumstance” is confirmed by the leading authority on the Berne Convention, Sam Ricketson. See S. Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886–1986* (London: Sweet & Maxwell, 1987), para.9.6.

³⁴ This is true for other forms of IP protection. With respect to copyright, for example, arts 2bis, 10 and 10bis of the Berne Convention (incorporated into the TRIPS Agreement through art.9) permit limitations for certain speeches, lectures and addresses and certain free uses of work, and the Appendix to the Berne Convention contains special provisions for developing countries. For trademarks, there is, for example, art.6ter of the Paris Convention, incorporated into the TRIPS through art.2(1) in respect of state emblems.

³⁵ The Doha Declaration recognizes that each WTO Member “has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”. The TRIPS amendment will enter into force when two-thirds of all the WTO Members have ratified it.

³⁶ H. Grosse Ruse-Khan, “Protecting Intellectual Property under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?” (2011) Max Planck Institute for Intellectual Property and Competition Law, Research Paper No.11-02, p.8, available at <http://ssrn.com/abstract=1757724> [Accessed March 25, 2012].

“[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”

This allows WTO Members to depart from some of the conditions of compulsory licensing enshrined in TRIPS art.31 by exercising their discretion in determining what instances will be covered by the term “extreme urgency” and other circumstances. This further enlarges the policy space of the WTO Members within which to address public health crises and the access to medicines.

The question of exhaustion of rights is also an example where the WTO Members have been granted considerable discretion in that they are entitled to decide their own regimes. TRIPS art.6 explicitly states that the Agreement leaves the question of “exhaustion” of IP rights untouched, thereby allowing countries to engage in so-called “parallel importation”—that is, import of, for example, cheaper medicines licensed and sold by the patent holder in a foreign country at a lower price in order to increase access to these medicines. The Doha Declaration clarifies in this context that

“the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of IP rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN [most favoured nation] and national treatment provisions of Articles 3 and 4.”

These flexibilities allow developing countries considerable policy space within which to maximize the benefits and minimize the social costs of adopting the international minimum standards. Some of these flexibilities are missing in the bilateral trade agreements containing IP obligations. Moreover, they exert pressure adding to the burden of implementing the minimum TRIPS standards.³⁷

Overall, the TRIPS Agreement shows a balanced set of rights and obligations, taking into account the need for enhanced protection of IPRs in a globalizing economy. Today, the main challenges in the Agreement relate to the absence of international disciplines in anti-trust and competition law and policy within and outside the WTO. The refusal by developing countries to take this relationship up under the Singapore issues has retarded the introduction of efficient anti-trust rules in many countries around the world, creating imbalances which need to be addressed in the coming years. The question relates to the fundamental problem concerning the extent to which the TRIPS Agreement should entail not only minimum, but also maximum standards of protection in order to preserve an overall balance of rights and obligations.³⁸

The second problem to be addressed relates to graduation of rights and obligations. The minimal standards of the TRIPS Agreement do not sufficiently reflect levels of involvement of countries and industries in the world economy. Levels of protection, of rights and obligations, should be commensurate with levels of competitiveness. Ideally, the application of IP standards should be linked to a number of economic factors and indicators of competitiveness. They should only become mandatory as a matter of international law once certain levels of competitiveness and participation in the world economy have been achieved.³⁹

³⁷ See F.M. Abbott, “Intellectual Property Rights in a Global Trade Framework: IP Trends in Developing Countries” (2004) 98 *American Society of International Law Proceedings* 95, 97–98.

³⁸ See H. Grosse Ruse-Khan, “Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection” (2009) 1(1) *Trade, Law and Development* 56; A. Kur and H. Grosse Ruse-Khan, “Enough Is Enough—The Notion of Binding Ceilings in International Intellectual Property Protection” (2008) Max Planck Institute for Intellectual Property, Competition & Tax Law, Research Paper Series No.09-01, available at <http://ssrn.com/abstract=1326429> [Accessed March 25, 2012].

³⁹ See T. Cottier, “From Progressive Liberalization to Progressive Regulation in WTO Law” (2006) 9 *Journal of International Economic Law* 779.

B. The balance in other multilateral IP treaties

Many of the TRIPS references above are accompanied by references to IP provisions contained in the TRIPS-incorporated treaties, like the historical Paris and Berne Conventions. The effects of these treaties in addressing the balance of rights and interests, however, are less evident. Rather, the balance was implicitly struck by leaving key issues to the realm of domestic law and thus granting members substantial policy space as to the contours and evolution of IP protection within their own jurisdiction.

The historical copyright treaties, like the Berne Convention, made no explicit reference to substantive balance. This does not mean that these classical systems were pursuing an imbalance. Rather, this situation can be explained by the fact that the international copyright system “was trying to do more and to do less with respect to balance than the domestic copyright system”.⁴⁰ It was doing less in the sense that these rules did not provide positive copyright law; instead they established parameters that allowed the domestic authorities to create the substantive balance themselves—something which could fit to particular circumstances. On the other hand, the international copyright framework was doing more than the national one by seeking to reflect an additional balance, namely the one between national autonomy and universal standards.

Moreover, the negotiating context of the Berne Convention should be considered. This instrument emerged at a time of heightened concerns about rampant piracy and where protection for foreigners was not yet available. Thus, the Convention sought to address these issues primarily by prescribing some minimum standards to this effect.⁴¹ At the time, the international IP protection system was largely a codifying device. Therefore the need for balance was not disregarded in the treaty in a negative sense, but rather it was deferred to domestic authorities for regulation in their national laws.⁴² In fact, the national legislation of a number of countries already contained regulations on technological protection measures—a concept which emerged in the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT).⁴³

The 1968 Stockholm Revision Act of the Berne Convention sought to reflect this balance, recognizing more explicitly the concerns of developing and least-developed countries about access to copyrighted works.⁴⁴ The mission was not accomplished, however, until 1996, when two important treaties emerged under the auspices of WIPO related to copyright protection in the digital environment.⁴⁵ These were WCT and WPPT, the so-called “Internet Treaties”.⁴⁶ These instruments introduced new concepts into the

⁴⁰ Dinwoodie, “The WIPO Copyright Treaty” (2007) 57(4) *Case Western Reserve Law Review* 751, 755.

⁴¹ See G.B. Dinwoodie, “A New Copyright Order: Why National Courts Should Create Global Norms” (2000) 149 *University of Pennsylvania Law Review* 469, 491.

⁴² That the Berne Convention left great discretion to contracting parties is also confirmed in the *US—Copyright* case in the interpretation of minor exceptions doctrine. See M. Foltea, *International Organizations in WTO Dispute Settlement: How Much Institutional Sensitivity?* (Cambridge: Cambridge University Press, 2012) (forthcoming).

⁴³ WIPO Copyright Treaty 1996; WIPO Performances and Phonograms Treaty 1996.

⁴⁴ See e.g. R.L. Okediji, “Sustainable Access to Copyrighted Digital Information Works in Developing Countries” in K.E. Maskus and J.H. Reichman (eds), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005), pp.142, 148.

⁴⁵ A question that naturally arises in this context concerns how the WTO should position itself with regard to these new treaties. For an account see F. Abbott, “Distributed Governance at the WTO-WIPO: An Evolving Model for Open-Architecture Integrated Governance” (2000) 3(1) *Journal of International Economic Law* 72. See also N.W. Netanel, “The Next Round: The Impact of the WIPO Copyright Treaty on TRIPS Dispute Settlement” (1997) 37 *Virginia Journal of International Law* 441.

⁴⁶ Note that in the post-TRIPS era, WIPO engaged in other norm-creation activities like the development of soft-law recommendations on the protection of well-known marks and marks on the Internet. WIPO, *Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks*, September 1999, 833(E); WIPO, *Joint Recommendation Concerning Provisions on the Protection of Marks, and Other Industrial Property Rights in Signs, on the Internet*, October 2001, 845(E). Another example is the negotiation of the WIPO Treaty on the Protection of Broadcasting Organisations. See WIPO Standing Committee on Copyright and Related Rights, *The WIPO Treaty on the Protection of Broadcasting Organisations*, November 3, 2008, SCCR/17/INF/1. Nevertheless, the negotiations have faced significant opposition in both areas. See W. New, “WIPO Committee Advances Agenda on Copyright Exceptions, Broadcasting”, *Intellectual Property Watch*, November 9, 2008, available at <http://www.ip-watch.org/weblog/2008/11/09/wipo-committee-advances-agenda-on-exceptions-to-copyright-broadcasting> [Accessed March 25, 2012].

previously familiar architecture of WIPO's normative orientation.⁴⁷ Both instruments formally acknowledged the intense impact of information and communication technologies on the creation and use of literary and artistic works and on the production and use of performances and phonograms.

Thus, it was not until the 1996 Diplomatic Conference, and in the aftermath of adopting the TRIPS Agreement, that we began to see the widespread explicit discussion of the concept of "balance" being integrated into international IP rule-making.⁴⁸ The levels of economic globalization achieved called for greater harmonization of IP rights at the level of international law. Balance could no longer be left to implied deference to the same extent as prior to the advent of the TRIPS Agreement. The discussions at the 1996 Conference led to the incorporation of these concerns into the Preamble of the WCT, which refers to a "balance between the rights of authors and larger public interest, particularly education, research and access to information". The two treaties are notable, however, for another feature: whereas the Berne Convention countries were all developed nations with fairly similar economic conditions, the WCT contracting parties were mainly developing countries and least-developed countries (LDCs). Commentators argue that the implementation process of the WCT obligations reflects rather nuanced policy choices that calibrate a variety of the domestic interests at stake.⁴⁹

There has, however, been some controversy both domestically and globally over the impact of some of the obligations enshrined in the Internet Treaties, like the implementation of anti-circumvention and digital rights management by developed countries.⁵⁰ It has been argued that the benefit which may accrue to the developing countries and LDCs as a result of implementation of these treaties is impaired by a lack of infrastructure⁵¹ and the fact that only a small proportion of the populations of poor countries have access to the internet. The emergence of the two Internet Treaties has, however, been generally regarded as an outcome that recognized public-oriented considerations in the design of global copyright,⁵² and this should be counted among their merits. Moreover, what can be learned from this process is the level of transparency and openness of the rule-making process at WIPO, where space was given to a wide range of stakeholders during the multilateral discussions. This type of decision-making is more likely to garner the support of national lawmakers on the merits of the negotiated proposal and undoubtedly enhances the legitimacy of the multilateral norm-setting process.⁵³

C. The imbalance in IP-related preferential trade agreements

By subscribing to multilateral IP obligations, countries did not intend to foreclose the possibility of entering agreements which would seek to implement higher standards. This is the case not only for the TRIPS Agreement, but also for other IP treaties, like the Berne Convention.⁵⁴ Thus, ever since the foundation of international IP protection through international treaties, IP norm-setting has seen development in only

⁴⁷ The WIPO Internet Treaties opened for signature in 1996 and entered into force in 2002.

⁴⁸ Although the importance of copyright's attention to users has been evident since the first copyright law of modern history, the 1709 British Statute of Anne. That act offered a mechanism for curbing the overly aggressive exercise of new property rights.

⁴⁹ See U. Gasser, "Legal Frameworks and Technological Protection of Digital Content: Moving Forward towards a Best Practice Model" (2006) 17 *Fordham Intellectual Property, Media and Entertainment Law Journal* 39, 66–93.

⁵⁰ See e.g. J.M. Besek, "Anti-circumvention Laws and Copyright: A Report from the Kernochan Center for Law, Media and the Arts" (2004) 27 *Columbia Journal of Law and the Arts* 385, 467.

⁵¹ See R. Okediji, "The Regulation of Creativity under the WIPO Internet Treaties" (2009) 77 *Fordham Law Review* 2379, 2406. This author generally contends that "the WIPO Internet Treaties have fallen considerably short in what was to be their central mission, namely, to provide a relevant and credible source of norms to facilitate knowledge creation in the global digital context" (p.2380) and that "neither the WCT nor the WPPT reflect the complexity of creative endeavor in an online environment, nor, as increasingly dynamic uses of social networking sites show, do the agreements even portend the myriad of ways users interact with and within digital space" (p.2394).

⁵² See P. Samuelson, *The Copyright Grab, Wired*, January 1996, p.134; see also P. Samuelson, "The U.S. Digital Agenda at WIPO" (1997) 37(2) *Virginia Journal of International Law* 369, 370–371; D. Nimmer, "A Tale of Two Treaties: Dateline: Geneva-December 1996" (1997) 22 *Columbia-VLA Journal of Law and the Arts* 1.

⁵³ Dinwoodie, "The WIPO Copyright Treaty" (2007) 57(4) *Case Western Reserve Law Review* 751, 766.

⁵⁴ Article 20 of this Convention states: "The Governments of the countries of the Union reserve the right to enter into special agreements among themselves, in so far as such agreements grant to authors more extensive rights than those granted by the Convention, or contain other provisions not contrary to this Convention" Berne Convention for the Protection of Literary and Artistic Works 1886 (Paris Act 1971).

one direction, that is, towards continuously increasing protection.⁵⁵ This is explained by the fact that the international IP treaties set only minimum standards of protection; they create a “floor”⁵⁶ representing the minimum level of protection, and further extension is easily conceivable.

In light of the latest shifts in the post-TRIPS environment, however, one should explore the extent to which the exertion of this maximalist force over multilateral IP regulation contributes in practice to a balanced consideration of users. This would inevitably lead to a more general discussion, that is, to what extent the stronger IP rights are beneficial and whether these rights are still compatible with and consider the flexibilities currently read from deals struck at the multilateral level. Much scholarly debate has been dedicated to the effects of FTAs’ stronger IP rules on the exercise of national sovereignty in areas such as public health, food security, technological advancement, promotion of domestic industries and access to knowledge.⁵⁷ However, the positive effects of these rights have yet to be empirically proven. It has been claimed, for example, that strong IP rights would stimulate the transfer of technology to the south and encourage investment, domestic creativity and innovation and general development progress. None of these positive developments, however, have been confirmed in most developing countries and LDCs, and the relationship between IP and development is much more complex than suggested above. Claims that strengthening IP would create jobs all over the world in the many economic sectors that contribute to manufacturing, sales and services of the products concerned do not find support either from the existing empirical evidence or in the conclusions of leading economists.⁵⁸

The continual increase in the protection of IP in bilateral free trade agreements is an issue which has received significant scholarly attention. Rather than engaging in a general assessment of the IPR provided in these agreements,⁵⁹ consistent with the above inquiry, we focus on the extent to which these IP provisions allow policy space and flexibilities comparable to those flowing from the IP commitments undertaken multilaterally. The public health concerns will, thus, re-emerge as an example used in the context of these analyses.

One striking feature of the sheer amount of free trade agreements expanding IPRs⁶⁰ is that distinct from the effects of the FTAs concluded pursuant to GATT art.XXIV (and GATS art.V), any TRIPS-plus protection secured by one trading partner via an FTA is automatically and unconditionally available to right holders from all other WTO Members. These trends may thus result in effectively globalizing the increasing standards so that they become the internationally relevant standards.⁶¹ It has been found that

⁵⁵ There are only a few remarkable exceptions to this, that is the Revision of the Berne Convention 1971, where an Annex addresses the option for developing countries to grant compulsory licences mainly for translation purposes and the proposed amendment of the TRIPS Agreement in the course of the Doha process: see General Council, “Amendment of the TRIPS Agreement”, December 8, 2005, WT/L/641. Hardly any effort has been made to question or curtail incumbent rules; see Kur and Grosse Ruse-Khan, “Enough Is Enough” (2008) Max Planck Institute for Intellectual Property, Competition & Tax Law, Research Paper Series No.09-01.

⁵⁶ See A. Taubman, “Rethinking TRIPS: Adequate Remuneration for Non-Voluntary Patent Licensing” (2008) 11(4) *Journal of International Economic Law* 927, 944.

⁵⁷ See e.g. S. F. Musungu and G. Dutfield, *Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property Organisation (WIPO)* (Geneva: Quaker United Nations Office, 2003); see also K. Maskus and J.H. Reichman, “The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods” (2004) 7 *Journal of International Economic Law* 279; South Centre, “Intellectual Property in Investment Agreements: The TRIPS-plus Implications for Developing Countries”, May 2005, SC/TADP/AN/IP/5, available at http://www.southcentre.org/index.php?option=com_content&task=view&id=81 [Accessed March 25, 2012].

⁵⁸ See e.g. K.E. Maskus, *Intellectual Property Rights in the Global Economy* (Washington: Institute for International Economics, 2000); C. Carsten Fink and K.E. Maskus, *Intellectual Property and Development: Lessons from Recent Economic Research* (Washington: World Bank, 2004).

⁵⁹ Any comprehensive evaluation of TRIPS-plus standards in FTAs would by far exceed the space available here. For a comprehensive analysis of the IP provisions in FTAs, see P. Roffe, “Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation” (2007) Center for International Environmental Law, Intellectual Property, Bilateral Agreements and Sustainable Development Series, Paper No.1.

⁶⁰ An increasing level of IP protection is also found in bilateral investment treaties (BITs), where IP is enshrined as a protected investment. The model BITs of most countries address IP rights. See L. Liberti, “Intellectual Property Rights in International Investment Agreements: An Overview” (2009) 6(2) *Transnational Dispute Management* 5.

⁶¹ Grosse Ruse-Khan, “Protecting Intellectual Property under BITs, FTAs, and TRIPS” (2011) Max Planck Institute for Intellectual Property and Competition Law, Research Paper No.11-02, p.12.

not only do the IP provisions in the FTAs—as driven by the developed countries, the United States in particular—go beyond the TRIPS standards,⁶² but they sometimes constrain the public health related flexibilities discussed above.

Even though the detailed provisions differ from agreement to agreement, there are certainly common elements which can be analysed. To exemplify, while the TRIPS Agreement allows the use of compulsory licences without specifying the grounds for issuing them, four of the bilateral agreements (US-Vietnam, US-Jordan, US-Singapore and US-Australia) limit the use of compulsory licensing to emergency situations, anti-trust remedies, and cases of public non-commercial use. Secondly, there are agreements which prevent marketing approval of a generic drug during the patent term without the consent of the patent holder; an issue on which the TRIPS Agreement does not impose any obligation (US-Vietnam and US-Jordan). Thirdly, whereas the TRIPS Agreement requires protection of data only against “unfair commercial use” (art.39.3), many FTAs explicitly mandate test data exclusivity (e.g. US-Chile and US-Singapore). As a result, once a company has submitted original test data (e.g. for approval of a drug), a competing manufacturer is not allowed to rely on these data to request marketing approval for its own drug for a period of five years.⁶³ This may pose a second obstacle to governments making effective use of compulsory licensing, as the new compilation of comparable test data by competing manufacturers may take several years and may be prohibitively expensive.⁶⁴

Flexibilities have also been reduced with regard to the issue of parallel importation on which the TRIPS Agreement mandates discretion to the WTO Members; this has an impact on the access to medicines. Thus, the US agreements with Australia, Morocco and Singapore allow patent holders to prevent parallel importation through contractual means. As a final example, the Central American–Dominican Republic–United States Free Trade Agreement (CAFTA-DR)⁶⁵ encroaches less on the public health related flexibilities in the TRIPS Agreement. It does not prohibit parallel imports, nor does it limit the ability to grant compulsory licences. It does, however, constrain policy space under TRIPS art.27.3(b) to exclude biological material from patentable subject matter and sets out additional conditions for the revocation of patents.⁶⁶

Although there is no explicit conflict between the TRIPS language and these FTA provisions, the latter can still be seen as being at odds with the spirit of the TRIPS Agreement to the extent that they preclude the effective use of compulsory licensing systems by developing countries. The analysis of TRIPS-plus IP provisions suggests that certain obligations directly undermine these flexibilities. This is particularly true with regard to the US agreements which do not contain any specific clauses that safeguard or uphold the operation of the public health related flexibilities.⁶⁷ In this context one could question whether these TRIPS-plus provisions, although mandated under TRIPS art.1.1,⁶⁸ curtail TRIPS flexibilities and thus run afoul of the TRIPS Agreement.

⁶² For example, all FTAs include provisions regarding protection of patents and pharmaceutical test data. The patent protection term is frequently extended beyond the 20 years provided in the TRIPS Agreement when delays occur in the regulatory approval process (e.g. *EFTA-Chile*, *US-Singapore* and *US-Chile*). Extensions to the patent term are also granted under FTAs when there are delays in the examination of the patent application itself. Moreover, the patent scope is extended to cover patenting for new uses of unknown products (e.g. *US-Australia*, *US-Morocco* and *US-Bahrain*). It has been claimed that this provides patent holders with the opportunity to “evergreen” existing patents, adding another full term of protection for the already patented pharmaceutical product. Essentially, all bilateral agreements go beyond the TRIPS Agreement in enhancing patent protection for plants and animals. For an account see P. Roffe and C. Spennemann, “The Impact of FTAs on Public Health Policies and TRIPS Flexibilities” (2006) 1(1–2) *International Journal of Intellectual Property Management* 80.

⁶³ This has been found to create a new form of monopoly not required by the TRIPS Agreement. See F. Abbott, “The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements” (2004) Quaker United Nations Office, Occasional Paper No. 14.

⁶⁴ See C. Fink and P. Reichenmiller, “Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements” *World Bank Trade Note*, February 7, 2005, p. 2.

⁶⁵ The CAFTA-DR (signed in 2004) was the first free trade agreement between the United States and a group of smaller developing economies—five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua) and the Dominican Republic.

⁶⁶ A similar approach can be found in one of the most recent US FTAs—the one negotiated with South Korea.

⁶⁷ Another example is Japanese FTAs.

⁶⁸ TRIPS art.1.1, second sentence, makes the right of WTO Members to introduce more extensive protection subject to the condition that it does not “contravene” TRIPS provisions.

The issue of the consistent interpretation of TRIPS flexibilities also arises in the context of the IP provisions in the bilateral investment treaties (BITs). Although these treaties tend to contain the above-mentioned safeguard clauses,⁶⁹ which apparently offer investors predictability that the TRIPS standards will govern the question of (indirect) expropriation under investment protection, the issue is that the TRIPS consistency of these clauses is tested in arbitration proceedings *outside* the (state-to-state) WTO dispute settlement system.⁷⁰ There is risk to isolated analysis of consistency with certain TRIPS provisions, e.g. art.30 regarding exceptions to patent rights and interpretation of open terms therein such as unreasonableness or legitimacy. This process might not fully follow the imperative canons of Vienna Convention on the Law of Treaties (VCLT) rules of interpretation, in particular those requiring consideration to be given to the object and purpose of the treaty, and may disregard rules on legal standing and burden of proof.⁷¹ If analysis of consistency does not take into account the TRIPS object and purpose, the risk is that the resulting interpretation would prevent the operation of one of the main flexibilities for all WTO Members.⁷² As a result, the interpretative outcome in these bilateral settings may be quite different from that at the WTO where the conformity with the customary rules of interpretation is specifically prescribed by art.3.2 of the DSU. Another problem is that wherever (FTA-based) TRIPS-plus provisions apply in relations between the parties to a BIT, the latter provisions—rather than the TRIPS Agreement and its flexibilities—will form the consistency benchmark.

The above discussion reaffirms that the multilateral fora would be more appropriate to secure the flexibilities and policy space provided in the agreements drawn up multilaterally, such as the TRIPS Agreement, than the bilateral agreements which tend to erode them. As the WTO Doha Declaration has shown, these flexibilities are important for much of the global population in addressing their public health concerns. The TRIPS flexibilities are thus relevant in achieving the balance between the provision of incentives to innovate and access to the protected knowledge. The new bilateral and plurilateral layers of IP governance may well undermine the ability of countries to autonomously achieve a balance tailored to their domestic needs.

D. The imbalance in plurilateral agreements: The ACTA project

The ACTA⁷³ negotiations received significant attention not only due to the tenacious attempt of its promoters to strengthen the existent TRIPS rules for IP enforcement. This attention also owed to the lack of transparency in the ACTA negotiation process, which was conducted behind closed doors until a series of documents was leaked in 2010. Although the TRIPS Agreement offers the most comprehensive legal framework for dealing with IP enforcement, the initial reason why the developed countries pushed for this plurilateral agreement was the perceived lack of effective enforcement obligations, coupled with increasing trade in counterfeit goods.⁷⁴ The scope of the ACTA includes counterfeit goods, generic medicines and copyright infringement on the internet. It envisages the establishment of a new international legal framework that countries can join on a voluntary basis, and the arrangement would also create its own governing body outside existing international institutions such as the WTO, WIPO or the UN.

⁶⁹ Although this is not the case for all the investment chapters under FTAs negotiated by the United States.

⁷⁰ For a comprehensive account see Grosse Ruse-Khan, "Protecting Intellectual Property under BITs, FTAs, and TRIPS" (2011) Max Planck Institute for Intellectual Property and Competition Law, Research Paper No.11-02, pp.27-29.

⁷¹ See para.5 of the Doha Declaration, stating: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles".

⁷² According to Grosse Ruse-Khan, "[S]ince the questions of TRIPS consistency are incorporated into the BIT or FTA containing the safeguard clause, an arbitration panel may struggle to neglect context and objective of the BIT or FTA as guiding its interpretation of the consistency test". See Grosse Ruse-Khan, "Protecting Intellectual Property under BITs, FTAs, and TRIPS" (2011) Max Planck Institute for Intellectual Property and Competition Law, Research Paper No.11-02, p.27.

⁷³ See Anti-Counterfeiting Trade Agreement, December 3, 2010, final draft.

⁷⁴ C. Correa, *Trade Related Aspects of Intellectual Property Rights—A Commentary on the TRIPS Agreement* (Oxford: Oxford University Press, 2007), p.409, 575; see also ICTSD/UNCTAD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (Cambridge: Cambridge University Press, 2005).

The ACTA draft has been perceived to differ from the TRIPS Agreement in at least two important respects. First, it generally reduces the room for manoeuvre in matters which used to fall under the discretion of the nation states. Secondly, it expands the strength and scope of enforcement rules established under TRIPS Pt IV. For example, art.61 of the TRIPS Agreement requires that criminal sanctions be implemented by members only in “cases of wilful trademark counterfeiting or copyright piracy on a commercial scale”. These two conditions were assessed by commentators as according key flexibilities and leaving ample policy space for WTO Members.⁷⁵

The available ACTA consolidated draft of October 2010 allows analysis of criminal enforcement rules and a comparison with the corresponding standards contained in TRIPS art.61. As stated above, the general approach is to go beyond TRIPS art.61, adding mandatory criminal sanctions for goods infringing any of the IPRs covered by the TRIPS Agreement, except the exclusion of patents from border measures (which initially were part of the draft).⁷⁶ Among the various concerns expressed in relation to the ACTA is its potential impact on the free transit of goods and hence on international trade.⁷⁷ Removing patents from the border measures arsenal under the ACTA is an improvement on the earlier drafts but does not ensure that, for example, the highly disputed seizure of generic medicines in transit will not occur.⁷⁸

The inclusion of all forms of trademark is particularly problematic in this sense given the difficulty of assessing whether the signs or words used on the packages make them “confusingly similar trademark goods” which are similar or close to the trademarks of the original manufacturer.⁷⁹ The customs authorities are not well placed to carry out such an evaluation. This would require a comprehensive legal analysis which is less straightforward than identifying counterfeit goods, to be performed by courts or trademark offices. The situation is further aggravated by the fact that, unlike TRIPS art.53.2, which requires, for certain forms of alleged IP infringements, that the owner or importer of the goods must have the option for posting a security in order to have the goods released, the ACTA does not recognize such a right, and the defendant has to await a positive finding on the similarity of the trademark in order to gain possession of the goods at stake.⁸⁰

Finally, whereas TRIPS art.52 points to the laws of the country of importation against which the infringement of IP rights should be assessed,⁸¹ the ACTA requires the parties to apply “the laws of the Party providing the procedures”—meaning the domestic IP law of the authorities adopting the border measures. The broader public interests, such as the health implications of this provision, are complex given that this rule mandates the ACTA parties to apply their legislation not only with regard to imported goods, but also to those in transit through their territories. This means that even if the goods are not infringing any IPR in the country of exportation or importation they risk seizure in one of the ACTA parties. In fact this rule has been found to conflict with the TRIPS Agreement.⁸²

⁷⁵ C. Correa, “The Push for Stronger Enforcement Rules: Implications for Developing Countries” in ICTSD (ed.), *The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries* (Geneva: 2008), p.41; H. Xue, “An Anatomical Study of the United States versus China at the World Trade Organisation on Intellectual Property Enforcement” (2009) 6 *European Intellectual Property Review* 292, 295.

⁷⁶ ACTA Draft, December 3, 2010, arts 5 and 13, fn.6.

⁷⁷ For example, “Urgent ACTA Communiqué: International Experts Find that Pending Anti-Counterfeiting Trade Agreement Threatens Public Interests”, available at <http://www.wcl.american.edu/pjip/go/acta-communicue> [Accessed March 25, 2012]. This statement reflects the conclusions reached at a meeting of more than 90 academics, practitioners and public interest organizations from six continents gathered at the American University Washington College of Law on June 16–18, 2010.

⁷⁸ For a comprehensive account of the effect of ACTA on the transit of generic drugs see H. Grosse Ruse-Khan, “A Trade Agreement Creating Barriers to International Trade? ACTA Border Measures and Goods in Transit” (2011) 26 *American University International Law Review* 644.

⁷⁹ ACTA art.5.

⁸⁰ ACTA art.18, last sentence.

⁸¹ The first sentence of TRIPS art.52 obliges WTO Members to require from right holders applying for the seizure of goods “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”.

⁸² See Grosse Ruse-Khan, “A Trade Agreement Creating Barriers to International Trade?” (2011) 26 *American University International Law Review* 644.

In this context, the emergence of the ACTA has raised questions with regard to *public health* considerations and whether these rules would eventually imperil the pursuit of such goals in accordance with the TRIPS flexibilities and the Doha Declaration on the TRIPS Agreement and Public Health. While these concerns can be countered with the argument that these goals are covered by reference in the ACTA to TRIPS arts 7 and 8, this language still creates uncertainty and legal insecurity for all international trade in goods.⁸³ It remains to be seen whether the imbalances of the above-mentioned ACTA provisions would be interpreted away through reference to these provisions.

Apart from the specific differences between the above-mentioned ACTA border measure standards and those enshrined in the TRIPS Agreement, the concerns with the TRIPS Agreement go further in that the ACTA generally tends to extend the remedies for right holders, without providing for the necessary checks and balances to secure the rights of defendants. These concerns have been raised by developing countries in the TRIPS Council, in particular by India which argued that the ACTA was to be blamed for “lowering knowledge thresholds, limiting due process requirements (e.g. requirements to act within particular time frames), limiting evidentiary requirements, and by not specifying the type of authority empowered to make critical decisions”.⁸⁴ Despite the inclusion in the ACTA of a general proportionality rule⁸⁵ regarding the ultimate decisions on IP-infringing goods applicable to all ACTA enforcement procedures, concrete defences and other relevant safeguards for the rights of defendants are often absent from the ACTA. Thus, the asymmetry between concrete and concise remedies and general checks and balances is a systemic concern regarding the ACTA. Moreover, when the ACTA is committed to FTA deals by developing countries and small economies, the implementation of some of its provisions, like the applicable law, risks being challenged under the WTO dispute settlement system.

The ACTA, in conclusion, is likely to serve as a template for enhancing enforcement of IPRs vis-à-vis developing countries, although it stops short of having them involved in debating and negotiating these standards in the first place. It will be used to strengthen domestic procedures and to insert corresponding provisions into bilateral agreements. There is a serious risk that the approach, lobbied for by the industries affected and not sufficiently filtered by governments, will undermine the overall legitimacy of the international IP regime as fundamental precepts of participation and inclusiveness are not sufficiently complied with.

IV. Multilateral IP norm-setting institutions and their interface

The previous section illustrated and expanded upon a number of multilateral IP agreements with emphasis put on their ability to incorporate language which would strike a balance between rights and obligations—the interest of right holders on the one hand and the general public interests (or consumers) on the other. We noted that the WTO freeze of the IP law-making process is to some extent compensated by the evolutions taking place elsewhere, mostly under WIPO. IP regulation is evolving, and rightly so, beyond what the TRIPS minimal standards provide. It is also striving to respond to the new technological developments of the past 15 years. The TRIPS Agreement was negotiated in an era that pre-dated a number of new developments like the internet commerce in trademarked goods, the distribution of digitized copyrighted materials, and the informatics revolution within the patent industries.⁸⁶ This explains why the focus has even shifted back from the WTO to WIPO.

⁸³ ACTA art.2.3 provides: “The objectives and principles set forth in Part I of the TRIPS Agreement, in particular in Articles 7 and 8, shall apply, *mutatis mutandis*, to this Agreement”.

⁸⁴ Third World Network Info Service on Intellectual Property Issues, “Concerns Raised over ACTA at TRIPS Council”, November 1, 2010, SUNS#7030.

⁸⁵ ACTA art.6.3 reads: “In implementing the provisions of this Chapter, each Party shall take into account the need for proportionality between the seriousness of the infringement, the interests of third parties, and the applicable measures, remedies and penalties”.

⁸⁶ See e.g. K.J. Strandburg, “Evolving Innovation Paradigms and the Global Intellectual Property Regime” (2009) 41 *Connecticut Law Review* 861, discussing how the TRIPS Agreement institutionalized its approach before the explosion of open and collaborative innovation and thus is ill-equipped to deal with these new technologies and processes.

The analysis of the global IP governance, thus, cannot be detached and would remain incomplete if the negotiation environment of the new rules and the functioning of the relevant institutions are disregarded. This invites an inquiry into the IP norm-setting institutions. Given the existence of a number of these institutions which deal with IPRs and issues linking to IPRs,⁸⁷ one would naturally wonder what should be the way forward for the international IP governance. Peter Yu has called this the “IP regime complex” characterizing the larger conglomerate regime that includes not only the traditional area of IP laws and policies, but also the overlapping areas in related regimes or fora.⁸⁸ There would not be much of a problem with this conglomerate if one considered the advantages of regulatory competition alone, which, as already recognized, could enrich international innovation policy. But the downside, in the words of Dinwoodie and Dreyfuss, is that it leads “to a suboptimal global regime: thickets of rights, conflicting demands, disputes that perpetually cycle, and uncertainties created by institutional cacophony”.⁸⁹ Moreover, this structure of the international IP governance has been seen as enabling “regime games” which are more likely to place less-developed countries in a position of disadvantage in comparison with their developed counterparts.⁹⁰ This is true not only when it comes to rule-making, but also for dispute settlement. According to Drahos, developing countries would be worse off if they were to litigate under FTAs rather than the WTO. One of the major reasons for this is that under FTA litigation, developing countries would be deprived of the possibility to make coalitions and join litigation as third parties.⁹¹

Against this background, as part of our investigation of IP governance on the horizontal axis, this section addresses these complicated interactions and suggests some options for the future co-existence and proper functioning (interface) of the relevant international organizations.

A. The incorporation of IP agreements into the TRIPS Agreement

The first and most prominent example of IP law-making is seen in the WTO TRIPS Agreement which assimilated several pre-existing IP treaties—quite a novel feature in international treaty law.⁹² The incorporation technique produces the most substantive linkage between the TRIPS Agreement and various treaties or conventions administered by WIPO through what has been called “common object”.⁹³ Thus, a traditionally separate regime was taken into the body of WTO law through the TRIPS Agreement, which incorporates by reference most, though not all, obligations of several IPR treaties (i.e. the Paris Convention, the Berne Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits).⁹⁴ This combination of the IPR treaties with the TRIPS Agreement has been attributed high significance due to the merger of detailed technical rules with the effective dispute settlement resolution system under the

⁸⁷ To exemplify, the regulation of IPRs, plant genetic resources and their impact on a wide spectrum of issues are taken over by a number of international organizations (WTO, WIPO, UPOV, UNEP, FAO, UNESCO and CBD), often working in isolation and adopting divergent philosophies. We also distinguish interlinked, but not necessarily mutually supportive objectives in the fora regulating biodiversity and biotechnology: the regulation of international trade (WTO and UNCTAD); conservation of genetic resources (FAO and CBD); health (WHO); investment protection (UPOV); (agricultural) development (FAO and UNCTAD); access and benefit sharing (CBD); cultural and ethical values (UNESCO) and IPRs and innovation (WTO, WIPO and UPOV).

⁸⁸ See Yu, “The Objectives and Principles of the TRIPS Agreement” (2009) 46 *Houston Law Review* 979, 1040.

⁸⁹ G.B. Dinwoodie and R. Dreyfuss, “Designing a Global Intellectual Property System Responsive to Change: The WTO, WIPO and Beyond” (2009) 46 *Houston Law Review* 1187.

⁹⁰ Oguamanam, “IP in Global Governance: A Venture in Critical Reflection” (2011) 2(2) *WIPO Journal* 196, 215.

⁹¹ For a more detailed account see P. Drahos, “Weaving Webs of Influence: The United States, Free Trade Agreements and Dispute Resolution” (2007) 41(1) *Journal of World Trade* 191.

⁹² T. Cottier, “The Agreement on Trade-Related Aspects of Intellectual Property Rights” in P.F.J. Macrory, A.E. Appleton and M.G. Plummer (eds), *The World Trade Organisation: Legal and Political Analysis* (New York: Springer, 2005), Vol. 1, p.1063.

⁹³ D. Vivas-Eugui, “What Agenda for the Review of TRIPS?: A Sustainable Development Perspective”, Summer 2002, pp.2–3, available at http://www.ciel.org/Publications/AgendaTrips_Summer02.pdf [Accessed March 25, 2012]. The incorporation of these rules has been described as a “cannibalization of the WIPO conventions”. See S.A. Mort, “The WTO, the WIPO & the Internet: Confounding the Borders of Copyright and Neighbouring Rights” (1997) 8 *Fordham Intellectual Property, Media and Entertainment Law Journal* 184.

⁹⁴ See TRIPS art.1.3. The Rome Convention is also referenced in the TRIPS, but it has not been incorporated therein.

WTO.⁹⁵ Thus, with the advent of the TRIPS Agreement, the protection of various forms of IPRs became a mandatory part of the multilateral system, binding on all members alike and fully subject to WTO dispute settlement.⁹⁶

The selective incorporation of these treaties into the TRIPS Agreement has been referred to as “regime borrowing”,⁹⁷ whereas the transfer of this *corpus iuris* is known as “regime shifting”,⁹⁸ denoting the transfer of the IP regime from WIPO to the WTO. The main proponents of regime shifting were the United States and the European Community, which perceived a weakness of WIPO in its enforcement of IPRs.⁹⁹ Some commentators have also noted in this context the failure of WIPO to live up to the expectations of both industrialized and non-industrialized countries with respect to IP norm development.¹⁰⁰ As a result of the above process, there is substantial overlap between the TRIPS Agreement and the categories of IP covered by treaties administered by WIPO. Moreover, although much of the IP regime has shifted to the WTO, today WIPO administers almost two dozen other treaties, which are not incorporated into the TRIPS Agreement. Thus, as the administrator of the Madrid Arrangement and especially the Berne and Paris Conventions, WIPO has a special claim to a role in articulating international IP norms.¹⁰¹ As a consequence, the question arises as to what the interaction or linkage mechanism between the WTO and WIPO should be and what links there should be with other international institutions dealing with IP.

B. The WTO-WIPO cooperation

In this subsection we examine the interaction between the WTO and WIPO suggesting that the latter can serve as a vehicle for the much needed IP norm-creation process, patching up to some extent the stalemate in the IP law-making at the WTO. The two organizations can actually work hand-in-hand by combining their strengths—that is, the responsiveness to change of WIPO and the strong dispute settlement mechanism of the WTO. This is one of the exceptional cases where cooperation has been framed by an explicit agreement between international organizations.¹⁰² We discuss this cooperation in light of the WTO’s currently rather static situation in terms of treaty making and of its more dynamic efforts in terms of legal dispute settlement. Today we can observe a number of inter-institutional cooperation initiatives which are likely to produce positive results from the balance viewpoint.¹⁰³ These linkages should not be underestimated, and their ability to produce balanced results should be examined in more detail. Both situations—interaction in WTO dispute settlement and WTO cooperation with other international organizations (international

⁹⁵ Some even suggest employing this technique in order to bring into the WTO other trade-related rules, to the extent they are clear. This is perceived as something which would serve to tighten the relationship between the WTO and the relevant international organization, while the latter would continue to further develop the detail of the area concerned. See V. Hrbatá, “No International Organisation Is an Island ... The WTO’s Relationship with the WIPO: A Model of Governance of Trade Linkage Areas?” (2010) 44 *Journal of World Trade* 1, 35.

⁹⁶ T. Cottier and M. Oesch, *International Trade Regulation: Law and Policy in the WTO, the European Union and Switzerland* (London: Cameron May, 2005), p.916. For an overview of the TRIPS Agreement see also T. Cottier, “The Agreement on Trade-Related Aspects of Intellectual Property Rights” in Macrory, Appleton and Plummer (eds), *The World Trade Organization* (2005).

⁹⁷ D. W. Leeborn, “Linkages” (2002) 96 *American Journal of International Law* 5, 19–20.

⁹⁸ See J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000), pp.564–571, discussing the use of forum shifting; C. May, *The World Intellectual Property Organization: Resurgence and the Development Agenda* (Abingdon: Routledge, 2006), p.66, discussing forum proliferation; L.R. Helfer, “Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking” (2004) 29 *Yale Journal of International Law* 1, discussing the use of regime shifting.

⁹⁹ But see R.L. Okediji, “TRIPS Dispute Settlement and the Sources of (International) Copyright Law” (2002) 49 *Journal of the Copyright Society of the U.S.A.* 585, 594, noting that most commentators who criticize WIPO’s lack of enforcement power have ignored the possible role the International Court of Justice (ICJ) could have played with respect to compliance with WIPO treaties.

¹⁰⁰ See e.g. M.L. Cordray, “GATT v. WIPO” (1994) 76 *Journal of the Patent and Trademark Office Society* 122; M. Leaffer, *Understanding Copyright Law*, 2nd edn (New York: Matthew Bender, 1995), p.372.

¹⁰¹ But see R.L. Okediji, “WIPO-WTO Relations and the Future of Global Intellectual Property Norms” (2008) 39 *Netherlands Yearbook of International Law* 69, suggesting that the WTO is capable of setting more nuanced IP norms that take into account differences in cultural, economic and political factors which are more likely to be consistently produced by the WTO than WIPO.

¹⁰² Agreement Between the World Intellectual Property Organization and the World Trade Organization 1995.

¹⁰³ For example, the cooperation between the WTO, WIPO and WHO on access to medicines.

organizations)—are bound to affect the relationship and complementarity between the institutions. We focus mainly on WIPO in our discussion of these issues and the way in which the WTO judiciary has considered this actor in its decision-making process.

WIPO and its predecessor, the United International Bureaux for the Protection of Intellectual Property (BIRPI), were established to consolidate the international IP regime. Although the WTO's relationship with WIPO has been characterized as opaque,¹⁰⁴ art.68 of the TRIPS Agreement states specifically that the Council for TRIPS may consult with and seek information from any source it deems appropriate in carrying out its functions and shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with WIPO bodies. The Agreement Between the World Intellectual Property Organization and the World Trade Organization also calls for cooperation between the WTO and WIPO in the notification of, provision of access to, and translation of national legislation; the communication of national emblems and transmittal of objections pursuant to art.6ter of the Paris Convention; and legal-technical assistance and technical cooperation. Notably, by virtue of this Agreement, the TRIPS Council, at the request of its members might seek guidance from WIPO in the context of dispute settlement and might consult WIPO with regard to the evolution of multilateral rules on IPRs during the periodic review of the TRIPS Agreement. These actions represent a significant step towards establishing a cooperative and mutually supportive relationship between the WTO and WIPO.¹⁰⁵ However, despite the enunciation of WIPO's role in the TRIPS Agreement and the Cooperation Agreement, at best WIPO enjoys observer status at the TRIPS Council meetings. The Cooperation Agreement is somewhat limited as it is confined to legal and technical assistance, consisting in the provision of copies and translations of domestic legislation and assisting WTO Members in meeting their obligations.¹⁰⁶ The enunciation of the consultation prerogative of panels in WTO dispute settlement is important, but this has not been properly explored either, as noted above.¹⁰⁷ In order to enhance the legitimacy of WTO dispute settlement, the panels would need to show greater sensitivity towards the input of regimes possessing "epistemic superiority", *in casu* WIPO.¹⁰⁸

(i) WIPO in WTO dispute settlement

The WTO panels have turned to WIPO for advice on a few occasions. In the consideration of the TRIPS-related claims, WTO panels asked WIPO for advice in *United States—Section 211 Omnibus Appropriations Act of 1998*, *United States—Section 110(5)*, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, and *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*. This input was useful to the panels, but the case law analyses reveal that the information submitted was treated as factual rather than legal,¹⁰⁹ and was primarily used to elucidate the negotiation history of the TRIPS Agreement's incorporated treaties, rather than for elucidating context.¹¹⁰

¹⁰⁴ See e.g. F.-K. Beier and G. Schriker (eds), *GATT or WIPO: New Ways in the International Protection of Intellectual Property* (Munich: VCH, 1996), noting that on the eve of the conclusion of the TRIPS Agreement, scholars and policymakers seriously debated whether the new international IP system would develop in the WTO or WIPO.

¹⁰⁵ F. Abbott, T. Cottier and F. Gurry, *The International Intellectual Property System: Commentary and Materials* (The Hague: Kluwer Law International, 1999), pp.360–361; see also F. Abbott, "The Future of the Multilateral Trading System in the Context of TRIPS" (1997) 20 *Hastings International and Comparative Law Review* 661.

¹⁰⁶ Agreement Between the World Intellectual Property Organization and the World Trade Organization 1995, arts 2 and 4.

¹⁰⁷ See Foltea, *International Organizations in WTO Dispute Settlement* (2012).

¹⁰⁸ Foltea, *International Organizations in WTO Dispute Settlement* (2012).

¹⁰⁹ For a detailed account explaining the possible reasons behind this choice of the panels, see Foltea, *International Organizations in WTO Dispute Settlement* (2012).

¹¹⁰ See Dinwoodie and Dreyfuss, "Designing a Global Intellectual Property System Responsive to Change" (2009) 46 *Houston Law Review* 1187.

These analyses also reveal that the WTO panels will make efforts to interpret the TRIPS Agreement in a manner that preserves the flexibilities inherent in the pre-existing IP conventions, deferring to the IP origins of the disputes.¹¹¹ This has translated into leaving members with leeway to reconcile conflicting TRIPS obligations (e.g. the conflict between geographical indications and trademarks in *EC-Trademarks and Geographical Indications*) and to prevent rightholders from benefiting from exclusive terms in excess of those mandated by the TRIPS Agreement (e.g. to exploit the de facto exclusivity available to pharmaceutical companies by reason of the need for premarket clearance in *Canada—Pharmaceutical Products*).

At the same time, the TRIPS panels have been criticized for not having had a genuine incursion into a TRIPS obligation, ignoring the domestic rationales for the challenged legislation, refusing to provide a normative interpretation of terms like “normal”, “legitimate”, “prejudice” and “unreasonable”. This apparently resulted in the third parties’ interests not being looked after.¹¹² In this context, the panelers’ decisions have been contested for having looked to antecedent IP sources without understanding the greater complexity of these IP norms. They seem to have regarded the IPRs as commodities to be traded.¹¹³ Moreover, there has been overreliance by the panels on the negotiating history of the incorporated treaties without an appreciation of how radically the context in which these treaties emerged has evolved since the time when they were incorporated into the TRIPS Agreement.

This is not to say, however, that WIPO could not have been consulted on a wider range of issues than just historical documents. Should the panels have adopted a more open approach in these consultations, WIPO’s input could itself have signalled the ramifications of the transposition of certain rights (e.g. the reproduction right under the Berne Convention) into the TRIPS Agreement, stressing that the new context of these rights made them applicable to all user activities, all markets, and all principal IP regimes. Moreover, with WIPO’s technical input, the old rules could have been seen through the prism of a diverse technological reality.

(ii) WIPO’s strengths and weaknesses

WIPO has been criticized in the past for failing to achieve a balance between rights and obligations under the treaties it administers.¹¹⁴ Thus, recent developments have met with more success in meeting this challenge, as WIPO agreed that, as part of its mission, it would consider the impact of IP protection on the developing world.¹¹⁵ It recently renewed its commitment to a “Development Agenda” and has even discussed questions arising out of overprotection in developed countries.¹¹⁶ Commentators have argued that WIPO’s institutional structure—which requires members to enter into IP agreements without the possibility of side-payments in the form of concessions on unrelated matters, like in the WTO—has always forced it to strike a balance between access and proprietary interests.¹¹⁷

¹¹¹ See “United States—Section 110(5) of the US Copyright Act”, Report of the Panel, 2000, para.6.41.

¹¹² See Ginsburg, “Toward Supranational Copyright Law? The WTO Panel Decision and the ‘Three-Step Test’ for Copyright Exemptions” (2001) 187 *Revue Internationale Droit D’auteur* 3, 17; see also Dinwoodie and Dreyfuss, “Designing a Global Intellectual Property System Responsive to Change” (2009) 46 *Houston Law Review* 1187.

¹¹³ Dinwoodie and Dreyfuss, “Designing a Global Intellectual Property System Responsive to Change” (2009) 46 *Houston Law Review* 1187.

¹¹⁴ To exemplify, in one of its preparatory documents for the WCT in 1988, WIPO stressed: “The objective [of the proposals for the setting of norms in the field of intellectual property law] is to make the protection of intellectual property rights more effective throughout the world. ‘More effective’ means that the norms and standards of protection are raised, where necessary, to the required level, and that enforcement of intellectual property rights will be easier and the sanctions for infringement stricter. This objective may be achieved by creating new treaty obligations or by persuasion”. See M. Ficsor, *The Law of Copyright and the Internet* (Oxford: Oxford University Press, 2002), p.11.

¹¹⁵ D.J. Halbert, “The World Intellectual Property Organization: Past, Present and Future” (2007) 54 *Journal of the Copyright Society of the U.S.A.* 253, 263.

¹¹⁶ See generally N.W. Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford: Oxford University Press, 2009). See also *WIPO Provisional Committee on Proposals Related to a WIPO Development Agenda*, Fourth Session, June 11, 2007, available at http://www.wipo.int/ip-development/en/agenda/pca/pca07_session4.html.

¹¹⁷ See e.g. P. Samuelson, “The U.S. Digital Agenda at WIPO” (1997) 37 *Virginia Journal of International Law* 369.

This is exemplified by the pro-balance language which is reflected in the WCT Preamble.¹¹⁸ This trend has also been followed in a set of authoritative Agreed Statements on the WIPO Internet Treaties, which explicitly acknowledged limitations on the proprietary rights of copyright owners. These Statements recognize that states could exercise the necessary discretion to create additional limitations and exceptions at the domestic level, in order to maintain an appropriate balance between the interests of owners and users. It has been claimed that the interpretation of the TRIPS Agreement in the light of this policy shift at WIPO “may establish an evolving international norm of access that should surely, even if slowly, permeate the approach of TRIPS dispute panels with respect to how IP norms should be governed in a multilateral setting”.¹¹⁹

As the above analysis of the WCT negotiation illustrates, WIPO also has a decision-making structure which allows a more sensitive approach towards diverse negotiation input (including from non-governmental actors) than that of the WTO, coupled with greater flexibility in voting. This is epitomized not only by the evolution of treaty law, but also by the soft-law developments, which flow from a restructured norm-development process purporting to enable WIPO to respond expeditiously to the new regulatory issues.¹²⁰ WIPO furthermore has engaged in examining how flexible its instruments are by cataloguing national approaches to limitations and exceptions in various fields of IP.¹²¹ Thus, as noted by Dinwoodie and Dreyfuss, “the organization, along with the agreements it administers, bring to table an IP sensibility that is currently lacking in the WTO”.¹²²

Finally, it has been claimed that WIPO’s practice of appointing informal groups of experts to consider disputes under the treaties it administers provides, at least in theory, a mechanism for finding best rules.¹²³ Thus, WIPO emerges as a good example of an organization possessing superior legitimacy to that of the WTO on a specific subject matter, in particular given the claimed insufficiency of expertise at the WTO in this field. WIPO may also keep its norm-setting relevance due to the exemption of the new treaties from the MFN obligation set out in the TRIPS Agreement. This supposedly encourages participation in WIPO of the parties to the WTO Agreements.¹²⁴ Against this background, the importance of the cooperation between WIPO and the WTO is indisputable.¹²⁵

However, the nature of the law-making relationship between the two organizations has yet to be fully elucidated. It is not clear, for example, whether or how the WTO should be taking account of WIPO’s views on the incorporated treaties, or whether new developments at WIPO should affect WTO obligations. Moreover, it is quite unclear whether the dispute settlement mechanism offered by WIPO for private parties is to play any role in its interpretation of the TRIPS Agreement under the WTO. WIPO’s alternative dispute settlement resolution has evolved into a well-functioning system for commercial disputes related to IP. Thus, any person or entity whose interests have been affected may resort to the procedures of arbitration or expedited arbitration, mediation, and expert determination rendered by the WIPO Arbitration

¹¹⁸ See Section III.B.

¹¹⁹ Okediji, “TRIPS Dispute Settlement and the Sources of (International) Copyright Law” (2002) 49 *Journal of the Copyright Society of the U.S.A.* 46.

¹²⁰ See G.B. Dinwoodie, “The International Intellectual Property System: Treaties, Norms, National Courts and Private Ordering” in D. Gervais (ed.), *Intellectual Property, Trade and Development: Normative and Institutional Aspects* (Oxford: Oxford University Press, 2007), pp.80–84.

¹²¹ See WIPO Standing Committee on Copyright and Related Rights, *WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment*, April 5, 2003, SCCR/9/7, p.14, prepared by Sam Ricketson; *WIPO Standing Committee on the Law of Patents, Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*, February 4, 2009, SCP/13/3.

¹²² Dinwoodie and Dreyfuss, “Designing a Global Intellectual Property System Responsive to Change” (2009) 46 *Houston Law Review* 1187.

¹²³ R.C. Dreyfuss and A.F. Lowenfeld, “Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together” (1997) 37 *Virginia Journal of International Law* 293. But see E.-U. Petersmann, “Constitutionalism and International Organizations” (1997) 17 *Northwestern Journal of International Law & Business* 398, 467, noting that “the substantive standards, dispute settlement and enforcement mechanisms of the World Intellectual Property Organization have been criticized as inadequate by many countries. The proposals, made by the WIPO Secretariat after the conclusion of the Uruguay Round Agreements, to supplement the WTO dispute settlement system by a WIPO ‘Treaty on the Settlement of Disputes between States in the Field of Intellectual Property’ have so far been opposed, notably by the United States”.

¹²⁴ Leebron, “Linkages” (2002) 96 *American Journal of International Law* 5, 19, fn.47.

¹²⁵ See Dreyfuss and Lowenfeld, “Two Achievements of the Uruguay Round” (1997) 37 *Virginia Journal of International Law* 275, 293, noting how WIPO resonates well with the negotiating history of the TRIPS Agreement: the Uruguay Round would not have produced the TRIPS had the administrators of WIPO not participated in the identification of generally-accepted international norms.

and Mediation Centre. The Centre also takes, on its roll, disputes in the area of domain names relating to abusive registration and use of internet domain names (“cybersquatting”).¹²⁶ This system has been characterized as a quick and efficient one, which could be extended to other types of dispute resolution.¹²⁷

We argue in favour of substantive reliance of the WTO adjudicator on WIPO’s normative developments, expertise and judicial norm interpretation in the interpretation of the TRIPS obligations. This would not only satisfy the argument that more institutional sensitivity at the WTO is needed for its own legitimacy,¹²⁸ but we would go so far as to argue that the WTO cannot sustain a claim of legitimate interpretation of global IP norms without such deference. This would require pondering how the WTO adjudicator’s interpretative approach could reflect the fluidity of the current IP regime. How to implement this is a far trickier question since, for example, the VCLT rules of interpretation do not provide guidance on how the incorporated treaty law has to be dealt with. The WTO case law analysed above reflects the application of VCLT rules towards certain material ensuing from WIPO. We do not have any explicit reference so far to an authoritative interpretation of IP treaty provision or to rule interpretation in the process of WIPO commercial dispute settlement.

The proposition on greater sensitivity by WTO panels towards the judicial outcomes at WIPO is challengeable. With respect to WIPO’s inter-governmental dispute resolution, which may play a major role at the WTO, the well-functioning rule-setting process at WIPO is not coupled to a solid judicial mechanism. The latter could have been used to fill in the gaps through an effective judicial interpretation process at the WTO, but efforts towards creating such a mechanism were aborted in the 1980s.

As illustrated above, some have challenged the victory claimed for the Internet Treaties with the inclusion of explicit treaty language on balancing of interests between holders and users. The language can be vague and subscribing states may not know exactly what these flexibilities are about and in what precise legal form they may be reflected in national legislation. This situation reminds us of the post-TRIPS conditions which led to the approval of the Doha Declaration on the TRIPS Agreement and Public Health.¹²⁹

Thus, the major weakness of WIPO is that it hasn’t been equipped with a judicial mechanism which would fill gaps. In fact, it has been acknowledged that the organization does not have a well-functioning authoritative interpretation mechanism.¹³⁰ The treaty language is frequently purposely left vague so as to make agreement possible. Although this WIPO treaty-making strategy may not pose particular problems in fora supported by a well-functioning judicial system, like the one in the WTO, the treaty provisions which enunciate balance between holders and users may turn the victory into a lost battle. This is where the strengths of the WTO with its robust dispute settlement system come into play. As suggested above, the solution would lie in a proper interface and sensitivity of the WTO judicial bodies towards both the old treaties and the new legal developments at WIPO.

(iii) The consideration of WIPO’s IP law developments

Note should be taken that fn.2 to the TRIPS Agreement states that references to the IP conventions are to specific versions of these conventions; this does not mean, however, that these norms have stopped their evolution in WIPO. One of WIPO’s objectives is to ensure administrative cooperation among the unions

¹²⁶ WIPO, “The WIPO Arbitration and Mediation Center: Dispute Resolution for the 21st Century”, 779 (E), available at http://www.wipo.int/freepublications/en/arbitration/779/wipo_pub_779.pdf [Accessed March 25, 2012].

¹²⁷ See Hrbatá, “No International Organisation Is an Island ... The WTO’s Relationship with the WIPO: A Model of Governance of Trade Linkage Areas?” (2010) 44 *Journal of World Trade* 1, 15.

¹²⁸ See Foltea, *International Organizations in WTO Dispute Settlement* (2012).

¹²⁹ Although some authors note that the Doha Declaration took several years to negotiate and that its efficacy has yet to be demonstrated. See F.M. Abbott and J.H. Reichman, *European Parliament Committee on International Trade, Access to Essential Medicines: Lessons Learned since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union* (Brussels: European Parliament Committee on International Trade, 2007), p.13.

¹³⁰ See Foltea, *International Organizations in WTO Dispute Settlement* (2012), providing a comprehensive account on the issue; see also W.R. Cornish, “Genevan Bootstraps” (1997) 19 *European Intellectual Property Review* 336.

which formed around specific treaties. Accordingly, its functions include performing “the administrative tasks of the Paris Union, the Special Unions established in relation to that Union, and the Berne Union”.¹³¹ We suggest that with respect to these treaties WIPO remains an important source of *state practice* as provided by VCLT art.31.3(b), which would have to be taken into consideration by the WTO adjudicator. This practice can also be drawn from the outcomes of the dispute settlement mechanisms set out under WIPO.

But the development of new law carries the greatest weight in the interpretation of the TRIPS Agreement.¹³² Some WTO case law has already touched upon the issue. In *United States—Section 110(5)*, the panel noted that

“the wording of the WCT, and in particular of the Agreed Statements thereto, nonetheless supports, as far as Berne Convention is concerned, the Berne Union members are permitted to provide minor exception to the rights provided under Articles 11 and 11bis ...”¹³³

Following this line of argument, the panel considered the WCT as relevant to seek contextual guidance, as a treaty which was unanimously concluded at a diplomatic conference attended by 127 countries.¹³⁴ This is the right approach in trying to cope with the challenges posed by the new technological developments and the necessary normative adaptation.¹³⁵ Thus, the consideration of non-incorporated treaties would be possible under the VCLT art.31.3(b) as *subsequent practice*, given the emergence of this law in the post-TRIPS era (or as context, as illustrated by *United States—Section 110(5)*). This would also entail soft-law actions evolving from regimes in which IP issues are relevant to organizational mandates.¹³⁶

One important point is that the approach of the WTO panels which places the TRIPS Agreement in its historical perspective, taking into account post-TRIPS developments either as subsequent practice or context, will not be enough in and of itself. The future WTO interpretative endeavours would have to address a number of other important issues.¹³⁷ First, the objective of preserving the balance between the rights and obligations cannot be achieved solely by a mechanical transposition of the pre-existing IP treaties into the WTO context. This exercise would have to take into account the TRIPS Agreement’s own guidance, apart from its exception tests, which are the principles and objectives of the TRIPS Agreement as stated in arts 7 and 8.¹³⁸ The claim of superiority of the multilateral IP regulation over the bilateral and plurilateral ones would be feeble without a consistent attribution of a purposive gloss to the interpretative exercise.¹³⁹

¹³¹ See WIPO Convention art.4.

¹³² Netanel, “The Next Round” (1997) 37 *Virginia Journal of International Law* 441, 471–472.

¹³³ “United States—Section 110(5) of the US Copyright Act”, Report of the Panel, 2000, para.6.69.

¹³⁴ “United States—Section 110(5) of the US Copyright Act”, Report of the Panel, 2000, para.6.70.

¹³⁵ Elsewhere it has been suggested that one option for reflecting these new norms would be to amend the TRIPS Agreement through either the ordinary or *expedited* amendment procedure. The most difficult question with respect to the latter option, which requires a consensus vote of the TRIPS Council, is whether all Members of the WTO would accept a multilateral agreement negotiated under WIPO’s auspices. It would be unusual for all WTO Members to be parties to a WIPO agreement and they may not maintain the same perspective on desirable rules in each forum. Thus, additional treaties or protocols may be adopted in WIPO that are not contemporaneously approved or adopted in the WTO. These developments may lead to situations in which states may be in compliance with the TRIPS Agreement while in derogation of the rules of WIPO-administered treaties, and vice versa. See Abbott, Cottier and Gurry, *The International Intellectual Property System* (1999), p.362.

¹³⁶ An example can be found in the field of traditional knowledge and traditional cultural expressions where WIPO developed the so-called “draft provisions”.

¹³⁷ For an account see Dinwoodie and Dreyfuss, “Designing a Global Intellectual Property System Responsive to Change” (2009) 46 *Houston Law Review* 1187.

¹³⁸ See Section III.A.

¹³⁹ See, for example, the *Canada—Pharmaceuticals* panel which has been criticized for having essentially written off such considerations, rejecting the claim that they should be used to determine whether Canada’s policies in support of generic competition fall within the patents exception provision. While the panel agreed that the sentiments expressed in the Objectives and Principles had to be “borne in mind”, it also warned against using these provisions to alter the deal struck in the Uruguay Round. See “Canada—Patent Protection of Pharmaceutical Products”, Report of the Panel, March 17, 2000, WT/DS114/R, para.7.26; see also “India—Patent Protection for Pharmaceutical and Agricultural Chemical Products”, Report of the Appellate Body, December 19, 1997, WT/DS50/AB/R.

Secondly, the WTO panels should endeavour to be open to input from a larger variety of sources which would complete the development of the IP norms.¹⁴⁰ The VCLT rules of interpretation provide a number of methods which can be tried out in this context.¹⁴¹ This allows space for the consideration of the *state practice* under art.31.3(b) of the VCLT. This flexibility of the panels would ensure that the context in which international norms operate locally is fully taken into account. For example, the widespread adoption of rules like those German rules on the scope of gene patents might be interpreted as a response to upstream patenting rather than as an infringement of TRIPS clauses on non-discrimination.

The consideration of *subsequent WIPO material* under art.31.3(a) offers ample space to the WTO adjudicator to reconcile the TRIPS Agreement with the latest changes in the innovation landscape. Here, however, one should differentiate between the subsequent treaty law and other legal developments—for example, in the form of reports of the WIPO Standing Committees, Model Laws or advice provided by WIPO staff. The exploration of the consent required by this subsequent practice would have to be duly taken into account in order to assess the level of WTO judicial deference towards these instruments. Moreover, one would have to distinguish between post-TRIPS rules, which deal with TRIPS subject matter, and the new rights in new kinds of subject matter, such as databases, folklore, genetic endowment, traditional knowledge or agreements which mandate a level of protection below that offered under the TRIPS Agreement (such as potential findings of the WIPO Development Agenda).¹⁴² Finally, the idea has been put forward that WIPO's advice should continue to be sought in WTO dispute settlement, but that its role should be expanded beyond the provision of mere "factual information" on the pre-TRIPS practices. This would include the expert opinions of the WIPO Secretariat on implementation options and how to handle new issues. Thus, while a direct transposition of antecedent IP treaties into the TRIPS Agreement may mean greater deference to WIPO (but not necessarily a valid interpretative outcome), the consideration of post-TRIPS material is a feature which should consistently characterize the interpretation of any future WTOIP dispute.¹⁴³

C. Implications for inter-agency collaboration and beyond

Aside from the TRIPS Agreement, the WTO framework comprises many other agreements that rely explicitly on the expertise of non-WTO organizations by referring to standards set by international bodies with relevant expertise,¹⁴⁴ mandating consultations with various actors and international organizations (DSU art.13), or establishing joint oversight in areas where there are potential conflicts.¹⁴⁵ Although this subsection focuses on the WTO-WIPO interface, this analysis has a broader application in developing a paradigm which allows productive input from all the international institutions that have interests in IP norm development.

One essential point here is that whatever the form of the IP rules or expertise residing outside the WTO, the sensitivity of the WTO adjudicator thereto would largely depend on the decision-making process which lies behind the specific material, together with the reputation and credibility of the relevant international organizations.¹⁴⁶ This would take into account the extent to which state delegations participate in the decision-making, the voting procedures, the transparency and civil society participation in this process. A recent study which examined the functioning of the UPOV recommended addressing "some

¹⁴⁰ Dinwoodie and Dreyfuss, "Designing a Global Intellectual Property System Responsive to Change" (2009) 46 *Houston Law Review* 1187.

¹⁴¹ For a comprehensive account of how various VCLT interpretation rules can be used to enhance its sensitivity vis-à-vis other international organizations, see Foltea, *International Organizations in WTO Dispute Settlement* (2012).

¹⁴² Dinwoodie and Dreyfuss, "Designing a Global Intellectual Property System Responsive to Change" (2009) 46 *Houston Law Review* 1187.

¹⁴³ See Foltea, *International Organizations in WTO Dispute Settlement* (2012).

¹⁴⁴ For example, the three SPS sister organizations. For a comprehensive account of all of these linkages, see D.K. Tarullo, "The Relationship of WTO Obligations to Other International Arrangements" in M. Bronckers and R. Quick (eds), *New Directions in International Law: Essays in Honour of John H. Jackson* (The Hague: Kluwer Law International, 2000).

¹⁴⁵ See "Ministerial Decision on Trade and Environment", April 15, 1994, (1994) 33 I.L.M. 1125, which is part of the 1994 Final Act.

¹⁴⁶ See Foltea, *International Organizations in WTO Dispute Settlement* (2012).

issues such as insufficient participation of observers, lack of accessible information about the system and activities, and the lack of transparency".¹⁴⁷ These types of concern are not new, and they have permeated the agenda of various WTO committees, in particular those managing agreements which refer to the standards of other international organizations, like the Codex Alimentarius, the International Plant Protection Convention, and International Office of Epizootics.¹⁴⁸ These concerns also apply to the global governance of IP and the institutions involved in this process. The strength and legitimacy of multilateral rule-setting is entangled with these elements and therefore the institutions which do not operate on a transparent basis with the possibility of inclusion of a wide range of stakeholders would have to streamline their activities accordingly.

V. Conclusions

The decline of IPR structure pairings in multilateral, bilateral and plurilateral fora allow the conclusion to be drawn that the fora of negotiations truly matter in terms of achieving an appropriate balance of rights and obligations. The relationship between multilateral and preferential trade rules emerges as a key issue for horizontal multilevel governance. It involves both the relationship among various international organizations, and between bilateral and preferential agreements, seeking greater coherence among these instruments.

The WTO TRIPS Agreement emerged from a lack of responsiveness of developing countries to the further development of IPRs within the Paris and Berne Conventions within WIPO. It formed part of a package deal and brought about substantially enhanced levels of minimal protection on a global scale. A careful analysis of the agreement and of WTO jurisprudence shows that the multilateral negotiating process achieved a reasonably balanced result in terms of rights and obligations. The involvement of all pertinent interests in the negotiating process, both industrialized and developing countries, operating under consensus and within a package deal, in hindsight, produced a far-reaching result. The incorporation of the Paris and the Berne Conventions produced a comprehensive multilateral regime. The price to be paid for a package deal, however, has been that reform and further developments have been difficult. Improving access to essential drugs and the reform of the TRIPS art.31 has been the only, albeit major, development of the TRIPS Agreement since 1995.

In WIPO, it is interesting to observe an inverse trend: while the organization was largely blocked prior to the TRIPS negotiations, it benefited from the advent of the new IP disciplines in the WTO. The process of negotiations became more inclusive and opened up to civil society a process hitherto mainly controlled by governments and strongly influenced by professional organizations. WIPO has shown a host of interesting initiatives in treaty-making during the past 15 years, which have further developed IP protection in a globalised economy in a properly balanced manner. These efforts, however, are overshadowed by a persistently held perception by developing countries that the overall regime has remained the same and that additional instruments developed in WIPO run the risk of eventually being incorporated into WTO law.

We conclude that these concerns are ill-founded. Instead, incremental progress in treaty law developed in WIPO should eventually be adopted in WTO law and should be taken into account in interpreting rights and obligations of the TRIPS Agreement in WTO jurisprudence. The process of negotiations in WIPO today may also serve as a model of reform for the WTO; IP protection as a regulatory matter became more

¹⁴⁷ "Another concern is the lack of assessment of potential consequences on national policy objectives in key areas when countries become UPOV members. These consequences include economic development, food security and biological diversity". C. Saez, "Study: Change Needed at Plant Varieties Agency; WTO Talks Food Standards", Intellectual Property Watch, April 8, 2010, available at http://www.ip-watch.org/weblog/2011/04/08/study-change-needed-at-plant-varieties-agency-wto-talks-food-standards/?utm_source=weekly&utm_medium=email&utm_campaign=alerts [Accessed March 25, 2012].

¹⁴⁸ See e.g. T.P. Stewart and D.S. Johanson, "SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and International Office of Epizootics" (1998) 26 *Syracuse Journal of International Law and Commerce* 27.

suitable for an ongoing legislative process once the foundations had been laid in the broad package deal of the Uruguay Round. Impending challenges, in particular the problem of graduation and ceilings of obligations, can be dealt with more successfully within this type of ongoing process.

The perception of an imbalance of rights and obligations and stalemates in multilateral fora triggered a relocation of treaty-making to preferential trade agreements. The advent of enhanced standards, mainly applied to developing countries, in such agreements formed part of the broader migration towards preferential trade in response to the difficulties encountered in the Doha Development Agenda during the past decade. Partly, amendments to the TRIPS obligations are completing the multilateral rules, rendering them more operational, such as defining the periods of exclusivity of test data in the context of TRIPS art.39. To a large extent, however, preferential norms tend to upset the careful balance achieved in the multilateral system. IP norms in preferential trade agreements are generally subordinate, subject to broader interests, in removing trade barriers with a major partner and enhancing market access. Such norms, pressed for by interested industries, simply need to be taken into account. Developing countries therefore end up with a less balanced set of rights and obligations, which they need to apply practically on an MFN basis. Refusal to negotiate in multilateral fora also explains the advent of the ACTA which serves as a basis for the imposition by industrialized countries of unilateral disciplines on imports from developing countries. The process itself is unbalanced, as the countries concerned and most affected are not present at the negotiating table. Again, the balance of rights and obligations risks further deterioration.

In conclusion, the balance of rights and obligations in the IP field can best be achieved and developed through work done in multilateral fora. Both the WTO and WIPO offer appropriate foundations and should clearly be preferred to bilateral and plurilateral avenues. Efforts to reach agreement should primarily be made within these fora. Refusal to engage and to show constructive flexibility merely results in pressures elsewhere. Today's world and its economic structure depend upon a workable and reliable system of IP protection. It is simply a matter of how this can be best achieved in global and multilayered governance.

The interaction between the WTO and WIPO as a matter of horizontal multilateral governance requires further study. Much depends on the future of negotiating processes in the WTO as to whether reforms will lead to a more continuous development of a legislative process beyond administration of agreements and dispute settlement. Under the past and present philosophy of trade rounds, the WTO will be bound to address basic issues in an almost generational sequence, such as the introduction of patents for pharmaceuticals in the Uruguay Round, or the disciplines on enforcing IPRs. Major political decisions may be taken after a decade or so, with inertia reigning in the meantime. Thus, the WTO system is bound to remain static and not sufficiently responsive. The main contribution and focus is judicial dispute settlement, which includes the Berne and Paris Conventions administered by WIPO.

Work, in the meantime, essentially needs to take place within the more open processes of WIPO. Structural reform of the WTO may lead to a more dynamic and responsive approach to rule-making. Global governance and its regulatory challenges, of which IP is a key one, call for ongoing processes of legislation and what has been called a two-tier approach to decision-making.¹⁴⁹ To the extent that the WTO can develop a more continuous legislative process in the field, new forms of interaction and cooperation may emerge, perhaps even resulting in the merging of the two institutions, or their coordination under the umbrella of a future World Economic Organization. Countries will learn that balanced results in developing the law of IP protection are best achieved, in the long run, in constructively engaging in ongoing, well-informed legislative processes in global multilateral fora.

¹⁴⁹ T. Cottier, "A Two-Tier Approach to WTO Decision-Making" in D.P. Steger (ed.), *Redesigning the World Trade Organization for the Twenty-First Century* (Ottawa: Wilfried Laurier University Press, 2010); M. Elsig, "WTO Decision-Making: Can We Get a Little Help from the Secretariat and the Critical Mass?" in Steger (ed.), *Redesigning the World Trade Organization for the Twenty-First Century* (2010).

Weakening Multilateralism in Intellectual Property Lawmaking: A European Perspective on ACTA

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☞ Acquis communautaire; Copyright; Counterfeiting; Criminal law; EU law; Harmonisation; Intellectual property; International trade; Negotiations

*The Anti-Counterfeiting Trade Agreement (“ACTA”) is a plurilateral agreement aimed at combating the proliferation of counterfeiting within the global economy. It thus joins a vast panoply of measures already in place or in the course of implementation within the European Union to strengthen the enforcement of intellectual property rights. However, its provisions and its scope differ on a number of points from the *acquis communautaire* and from the international legal framework. This is particularly the case for the criminal enforcement provisions of the Agreement. In fact, criminal measures have not yet been harmonised within the European Union, and a proposed directive on this matter failed as a result of certain reservations expressed by the European Parliament. If adopted, ACTA would bind the European Union in its future efforts towards harmonisation on this subject and would very likely involve modifications to the criminal law of certain Member States. Moreover, while a large number of difficulties in the application of the Agreement related to a broad and sometimes vague wording might be resolved by means of interpretation, and in particular by using some of the general provisions aimed at ensuring balanced procedure, precise, transparent and above all binding interpretation guidelines should also be offered to the signatories. More generally, while effective enforcement of intellectual property rights at the global level is without doubt a legitimate objective, the main weakness of the Agreement lies in the way it was negotiated, i.e. in secret and outside the multilateral intellectual property framework, and without the emerging countries who are its main addressees. Such a method risks in the long term to considerably weaken multilateralism in the field of intellectual property lawmaking.*

Introduction

The Anti-Counterfeiting Trade Agreement (ACTA) is a plurilateral agreement aimed, according to its preamble, at providing effective and appropriate means for the enforcement of intellectual property rights (IPRs). The issue is obviously very important, since the attractiveness of IPRs risks being seriously

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undermined if they cannot be enforced in an appropriate manner. For this reason, the creation of an effective system to secure a proper enforcement of IPRs and to combat counterfeiting has been a constant preoccupation of the European Union over the last few years.

Serious efforts have been made, and the European Union and its Member States have undertaken numerous initiatives to improve the European legal framework in this regard. Following an evaluation report published on December 22, 2010,¹ the European Commission announced its intention to revise the reference text on the topic,² the Directive of April 29, 2004,³ which has now been implemented in all the Member States.⁴ Work has also started on an amendment of the Regulation of July 22, 2003⁵ concerning customs action against goods suspected of infringing certain IPRs.⁶ In 2009, the Commission set up a European Observatory on Counterfeiting and Piracy,⁷ one of whose principal objectives is to collect and transmit data on the economic and social consequences of counterfeiting, and whose powers were recently considerably increased.⁸ It is only in the sensitive field of criminal penalties for counterfeiting that harmonisation has not yet succeeded, mostly because of the considerable opposition that a proposed directive on this matter encountered within the European Parliament.⁹ This resistance ultimately led to the text being withdrawn by the European Commission on September 18, 2010.¹⁰

This withdrawal took place shortly before the publication of the consolidated draft of ACTA, a plurilateral agreement aimed at strengthening the enforcement of IPRs. Negotiated over a period of three years outside all multilateral bodies by the European Commission (for the European Union and its Member States) and 10 other countries,¹¹ the Agreement has led, and is continuing to lead, to the spilling of much ink.¹² The secrecy of the negotiation process has contributed considerably to the development of mistrust among the general public and has given rise to widespread speculation on the content and the objectives of the

¹ "Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2004/48 of the European Parliament and the Council of April 29, 2004 on the enforcement of intellectual property rights", December 22, 2010, COM(2010) 779 final. For a comment, see Ch. Geiger, J. Raynard and C. Rodà, "What Developments for the European Framework on Enforcement of Intellectual Property Rights? A Comment on the Evaluation Report of the European Commission Dated 22 December 2010" [2011] E.I.P.R. 543.

² See European Commission, "A Single Market for Intellectual Property Rights: Boosting Creativity and Innovation to Provide Economic Growth, High Quality Jobs and First Class Products and Services in Europe, Brussels", May 24, 2011, COM(2011) 287 final, p.20 et seq.

³ Directive 2004/48 of the European Parliament and of the Council of April 29, 2004 on the enforcement of intellectual property rights [2004] OJ L157, [2004] OJ L195/16.

⁴ For a comparative analysis, see C. Rodà, *Les conséquences civiles de la contrefaçon des droits de propriété industrielle: Droits français, belge, luxembourgeois, allemand, anglais* (Paris, Litec, CEIPI Series 2011)..

⁵ Council Regulation 1383/2003 of July 22, 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2003] OJ L196/7.

⁶ European Commission, "Proposal for a Regulation of the European Parliament and of the Council concerning customs enforcement of intellectual property rights", May 24, 2011, COM(2011) 285 final.

⁷ European Commission, "Enhancing the Enforcement of Intellectual Property Rights in the Internal Market", September 11, 2009, COM(2009) 467 final, p.5 et seq.

⁸ Regulation (EU) No 386/2012 of the European Parliament and of the Council of 19 April 2012 on entrusting the Office for Harmonization in the Internal Market (Trade Marks and Designs) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights, OJEU L 129 of 16 May 2012, p.1.

⁹ European Commission, "Amended Proposal for a Directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights", April 26, 2006, COM(2006) 168 final.

¹⁰ [2010] OJ C252/9.

¹¹ These countries are Australia, Canada, the Republic of Korea, the United States of America, Japan, the Kingdom of Morocco, the United States of Mexico, New Zealand, the Republic of Singapore and the Swiss Confederation.

¹² For a comment on this text, see for example, R. D'Erme, Ch. Geiger, H. Grosse Ruse-Khan, C. Heinze, T. Jaeger, R. Matulionyte and A. Metzger, "The Impact of the Anti-Counterfeiting Trade Agreement on the Legal Framework for IP Enforcement in the European Union" in Ch. Geiger (ed.), *Constructing European Intellectual Property: Achievements and New Perspectives* (Cheltenham: Edward Elgar, 2012); P. Arhel, "L'accord commercial anticontrefaçon: Version finale", *Propri. Industr.*, March 2011, p.13; J.-C. Galloux, *RTD com.*, January/March 2011, p.81. See also the study of the Institute for Globalisation and International Regulation (IGIR) of the University of Maastricht for the European Parliament: IGIR, *The Anti-Counterfeiting Trade Agreement (ACTA): An Assessment* (Maastricht: 2011), and the special edition of the *American University International Law Review*, "Intellectual Property Law Enforcement and the Anti-Counterfeiting Trade Agreement" (2011) 26(3) *Am. U. Int'l L. Rev.* 543-926; K. Weatherall, "Politics, Compromise, Text and the Failures of the Anti-Counterfeiting Trade Agreement" (2011) 33 *Sydney L. Rev.* 229; M. Stieper, "Das Anti-Counterfeiting Trade Agreement (ACTA)" [2011] *GRUR Int.* 124; Ch. Geiger, "Of ACTA, 'Pirates' and Organized Criminality: How 'Criminal' Should the Enforcement of Intellectual Property Be?" [2010] *IIC* 629; L.P. Devigne, P. Velasco-Martins and A. Iliopoulou, "Where Is ACTA Taking Us? Policies and Politics" in I.A. Stamatoudi (ed.), *Copyright Enforcement and the Internet* (Alphen aan den Rijn: Kluwer Law International, 2010), p.29.

Agreement.¹³ Many concerns, for example, have been expressed regarding an excessive tightening of penalties in the IP field, specifically in the context of the use of works on the internet by means of peer-to-peer networks or regarding excessive restrictions of certain fundamental rights.

It is for this reason that the European Parliament, echoing many of the worries expressed, adopted in March 2010 a resolution demanding full information about the progress of the negotiations on the proposed Agreement.¹⁴ As a result of this resolution, the Commission finally published the first version of the proposed Agreement on April 21, 2010,¹⁵ followed by a consolidated version on October 2, 2010¹⁶ and a final version on December 3, 2010 subsequent to the legal verification meeting in Sydney.¹⁷ For a long time only available in English,¹⁸ this last version of the Agreement was then published in a number of different languages on August 23, 2011.¹⁹

ACTA was signed on October 1, 2011 in Tokyo by the representatives of eight negotiating countries (Australia, Canada, Japan, the Republic of Korea, the Kingdom of Morocco, New Zealand, the Republic of Singapore and the United States of America) and on January 26, 2012 by the European Union and 22 of its Member States.²⁰ The Agreement has been submitted to the European Parliament for examination and will need to be adopted by the entirety of the Member States according to the requirements of their national constitutions, as the agreement constitutes a mixed agreement for which the European Union's competence is shared with that of the Member States.²¹ After heated discussions at the European Union and national levels, the European Parliament rejected ACTA on July 4, 2012 with an overwhelming majority. The future of the Agreement in the EU and in other negotiating countries is therefore uncertain.²²

In this article, we first briefly address the context of the Agreement, then evaluate its contents and assess the implications of its ultimate adoption for the European Union and, finally, draw some conclusions.

¹³ For a European perspective on the impact of the lack of transparency in the negotiations on the perception of the Agreement in public opinion, see for example A. Metzger, "A Primer on ACTA: What Europeans Should Fear about the Anti-Counterfeiting Trade Agreement" [2010] J.I.P.I.T.E.C. 109. For an international perspective, see P.K. Yu, "Six Secret (and Now Open) Fears of ACTA" (2011) 64(3) SMU L. Rev. 975; C.R. McManis, "The Proposed Anti-Counterfeiting Trade Agreement (ACTA): Two Tales of a Treaty" (2009) 46(4) Hous. L. Rev. 1235; M. Kaminski, "The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement (ACTA)" (2009) 24 Yale J. Int'l L. 247; M. Geist, "ACTA's State of the Play: Looking Beyond Transparency" (2011) 26(3) Am. U. Int'l L. Rev. 543; T. Hoeren, "ACTA ad acta? Überlegungen zum urheberrechtlichen Shitstorm" [2012] M.M.R. 137; D.S. Levine, "Transparency Soup: ACTA Negotiating Process and 'Black Box' Lawmaking" (2011) 26(3) Am. U. Int'l L. Rev. 813, according to whom "the lack of transparency placed leaked documents and hearsay at the center of public policy discussions, caused debates over both real and imagined issues, and brought about a general erosion of public knowledge and confidence in the ACTA process".

¹⁴ See European Parliament Resolution of March 10, 2010 on the transparency and state of play of the ACTA negotiations, P7_TA(2010)0058.

¹⁵ ACTA, consolidated text prepared for public release, April 2010, available at http://trade.ec.europa.eu/doclib/docs/2010/april/tradoc_146029.pdf [Accessed April 12, 2012].

¹⁶ Anti-Counterfeiting Trade Agreement, consolidated text, reflecting changes made during the September 2010 Tokyo Round, Informal Predecisional/Deliberative Draft, October 2, 2010; M. Blakeney, *Intellectual Property Enforcement A Commentary on the Anti-Counterfeiting Trade Agreement (ACTA)*, (Cheltenham: Edward Elgar, 2012).

¹⁷ Which, however, only had very little impact on the final text.

¹⁸ This might explain why most of the comments have been written in English so far.

¹⁹ Council of the European Union, August 23, 2011, 12196/11, Interinstitutional File, 2011/0166 (NLE).

²⁰ These countries are Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia, Spain, Sweden and the United Kingdom.

²¹ This results from the fact that a significant part of the Agreement is devoted to criminal enforcement (see below), for which the Union enjoys very limited competence (art.83(2) TFEU). For this reason, the competence of the European Union to adopt ACTA has been the subject of serious doubts: on this issue see in particular A. Ramalho, "The European Union and ACTA—Or Making Omelettes without Eggs (Again)" [2011] IIC 97; Ch. Geiger, "The Anti-Counterfeiting Trade Agreement and Criminal Enforcement of Intellectual Property: What Consequences for the European Union?" in J. Rosen (ed.), *IP Rights at the Crossroads of Trade* (Cheltenham: Edward Elgar, 2012).

²² European Parliament legislative resolution of July 4, 2012 on the draft Council decision on the conclusion of the Anti-Counterfeiting Trade Agreement between the European Union and its Member States, Australia, Canada, Japan, the Republic of Korea, the United Mexican States, the Kingdom of Morocco, New Zealand, the Republic of Singapore, the Swiss Confederation and the United States of America (12195/2011 – C7-0027/2012 – 2011/0167(NLE)), P7_TA-PROV(2012)0287).

The context of ACTA

The general context of ACTA is the proliferation of counterfeiting in third countries, notably in developing countries,²³ combined with a certain degree of weakness in international intellectual property (IP) law regarding enforcement mechanisms. The most developed countries therefore pushed for the adoption of stricter multilateral rules in the context of international organisations, such as the World Intellectual Property Organisation (WIPO) and the World Trade Organisation (WTO), but encountered some difficulties in imposing such changes on the international framework rapidly and without making concessions.

2.1 The EU premise for participation in the ACTA negotiations

Aware of the difficulty in enforcing IPRs effectively in certain regions of the world, the European Union adopted in 2005 a strategy aimed at ensuring the enforcement of IPRs in third countries.²⁴ Annex I of the text clearly identifies the nature of the problem:

“The TRIPs Agreement establishes for the first time a single, comprehensive, multilateral set of rules covering all kinds of IPR. It contains also a detailed chapter setting minimum standards of IPR enforcement to be adopted by all members of the WTO. However, despite the fact that, by now, most of the WTO members have adopted legislation implementing such minimum standards, the levels of piracy and counterfeiting continue to increase every year. These activities have, in recent years, assumed industrial proportions, because they offer considerable profit prospects with often a limited risk for the perpetrators. It has thus become clearly insufficient to limit the efforts of the EC to merely monitoring the creation of general legislative frameworks in WTO member countries. It is essential that the EC increasingly focuses on vigorous and effective implementation of the enforcement legislation.”²⁵

The European Union thus implicitly recognized that its efforts to improve the enforcement of IPRs outside the territory of the Union would be in vain and that it was therefore desirable for stricter rules to be adopted in countries where large scale infringements were occurring.

As a result, the European Union, along with a number of other countries with the same concerns, pushed for rapid action to tighten civil and criminal penalty provisions in international negotiations, but with little success due to the opposition from developing countries that did not necessarily share the EU’s interests and concerns.²⁶

2.2 The weakness of the international framework concerning the enforcement of IPRs

The minimum rules on enforcement in the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs)²⁷ were considered to be insufficient or ineffective at an early stage.²⁸ The “weakness”²⁹ of the international provisions for enforcing IPRs was illustrated by the WTO panel decision in a case brought

²³ See in particular the impressive figures quoted in the OECD study: OECD, *The Economic Impact of Counterfeiting and Piracy* (Paris: 2008). The study was updated in 2009: OECD, *Magnitude of Counterfeiting and Piracy of Tangible Products: An Update* (Paris: 2009), p.1.

²⁴ Strategy aimed at ensuring the enforcement of intellectual property rights in third countries [2005] OJ C129/3.

²⁵ [2005] OJ C129/12.

²⁶ Interestingly, some scholars have demonstrated that most of today’s developed countries went through a period of IP piracy or at least uncompensated uses of the IP of other more developed nations in order to foster their own innovation capacities. On this issue, see for example the interesting article by L.J. Gibbons, “Do as I Say (Not as I Did): Putative Intellectual Property Lessons for Emerging Economies from the Not So Long Past of the Developed Nations” (2011) 64(3) SMU L. Rev. 923.

²⁷ The TRIPs Agreement is reproduced as Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh on April 15, 1994.

²⁸ Certain scholars have thus not hesitated to argue that the provisions on enforcement provided in TRIPs can be seen as the “Achilles’ Heel” of the Agreement. P.K. Yu, “TRIPs and Its Achilles’ Heel” (2011) 18(2) J. Intell. Prop. L. 479.

²⁹ The word is in quotation marks, since the provision might be regarded as “weak” from the point of view of the richest countries as compared with their IP enforcement standards. In a more global context the flexibility of the international provision might be seen as an advantage allowing a compromise between the diverging interests of the parties to the Agreement.

by the United States against China.³⁰ The United States accused China of not providing for criminal penalties in its national legislation for the infringement of copyright on a commercial scale, thus failing to comply with art.61 of the TRIPs Agreement. Article 61 requires Member States to “provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale.” The WTO panel adopted a cautious interpretation of the concept of “commercial scale”, explaining that this referred “to counterfeiting or piracy carried on at the magnitude or extent of typical or usual commercial activity with respect to a given product in a given market.”³¹ Thus, the panel held that the notion should take account of the circumstances of the case and that its interpretation depended on the nature of the product, on the market in question as well as on the scale of the infringements.

The Panel’s caution is not surprising in the light of the negotiating record of the TRIPs Agreement, which clearly illustrates the difficulty in finding a compromise on the adoption of a common criterion for harmonising criminal penalties in the IP field. In fact, the parties were only able to reach agreement on a minimalist approach.³² While the flexible interpretation of the provisions of the TRIPs Agreement by the panel was welcomed by many commentators, permitting the adjustment of the obligations under the Agreement in terms of penalties to the specific circumstances and the needs of the country in question,³³ many developed countries saw it as confirmation of the inadequacies of the existing international provisions.

2.3 ACTA and forum shifting in international lawmaking

Given the difficulty in achieving satisfactory rules within the classical multilateral framework,³⁴ a number of likeminded countries engaged in what has been termed “forum shifting”³⁵ and opted to negotiate amongst themselves (and in secret) a stricter agreement, the ACTA.³⁶ The Preamble of the Agreement is clear on

³⁰“China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights”, Report of the Panel, January 26, 2009, WT/DS362/R. For comments see for example R. Creemers, “The Effects of World Trade Organization Case DS362 on Audiovisual Media in China” [2009] E.I.P.R. 568; H. Xue, “Enforcement for Development: Why Not an Agenda for the Developing World?”, in X. Li and C.M. Correa (eds), *Intellectual Property Enforcement, International Perspectives* (Cheltenham: Edward Elgar, 2009), p.133; H. Xue, “An Anatomical Study of the United States versus China at the World Trade Organization on Intellectual Property Enforcement” [2009] E.I.P.R. 292; D. Gervais, “China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights” (2009) 103 Am. J. Int’l L. 549; H. Grosse Ruse-Khan, “Criminal Enforcement and International Intellectual Property Law” in Ch. Geiger (ed.), *Criminal Enforcement of Intellectual Property: A Handbook of Contemporary Research* (Cheltenham: Edward Elgar, 2012), p.177; P.K. Yu, “Shaping Chinese Criminal Enforcement Norms through the TRIPs Agreement” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012), p.286; P.K. Yu, “The U.S.-China Dispute over TRIPs Enforcement” in Christoph Antons (ed.), *IP Enforcement and Awareness Raising in Asia* (Alphen aan den Rijn: Kluwer Law International, 2011), p.239; P.K. Yu, “The TRIPs Enforcement Dispute” (2011) 89(4) Neb. L. Rev. 1046; A. Adam, “What Is ‘Commercial Scale’? A Critical Analysis of the WTO Decision in WT/DS362/R” [2011] E.I.P.R. 342; M. Vivant and Ch. Geiger, “Comment of the Decision of the WTO Panel of 26 January 2009” (2010) 35 Propri. Intell. 747.

³¹“China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights”, Report of the Panel, 2009, para.7.577.

³² For a detailed analysis of the preparatory work for TRIPs in the field of criminal penalties see Adam, “What Is ‘Commercial Scale’? A Critical Analysis of the WTO Decision in WT/DS362/R” [2011] E.I.P.R. 346.

³³ See in particular Grosse Ruse-Khan, “Criminal Enforcement and International Intellectual Property Law” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012); Yu, “Shaping Chinese Criminal Enforcement Norms through the TRIPs Agreement” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012).

³⁴ This questioning of the multilateral system concerning the enforcement of IPRs was clearly expressed by the European Commission in 2009 as follows: “It is necessary to stress that attempts by the European Union and other supporters of an effective IPR system to constructively address enforcement problems in multilateral fora (World Trade Organisation, World Intellectual Property Organisation, World Customs Organisation) have been opposed by countries like Brazil and India, often supported by China, Argentina and others. This has prevented some of these institutions from addressing pressing IPR enforcement issues that could suitably be resolved multilaterally.” European Commission, “IPR Enforcement Report 2009”, October 9, 2009, SEC(2009) 1360, commission staff working document, p.4, available at http://trade.ec.europa.eu/doclib/docs/2009/october/tradoc_145204.pdf [Accessed April 17, 2012].

³⁵ Yu, “Six Secret (and Now Open) Fears of ACTA” (2011) 64(3) SMU L. Rev. 975, 1075; Weatherall, “Politics, Compromise, Text and the Failures of the Anti-Counterfeiting Trade Agreement” (2011) 33 Sydney L. Rev. 229; Kaminski, “The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement (ACTA)” (2009) 24 Yale J. Int’l L. 247. Very critically on this tendency in recent international IP law making, see S.K. Sell, “Everything Old Is New Again: The Development Agenda Then and Now” (2011) 3(1) WIPO J. 20, stating that “in the years since TRIPs, governments that are homes to intellectual property-based multinational corporations have continued to ratchet up standards of intellectual property protection outside of multilateral channels. US Free Trade Agreements, bilateral investment treaties, European Economic Partnership Agreements, and plurilateral efforts like the Anti-Counterfeiting Trade Agreement and the Trans-Pacific Partnership negotiations have all included stricter standards for protection and enforcement of intellectual property rights”. This strategy of “regime shifting” has also been used by developing countries, see L. Helfer, “Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking” (2004) 29(1) Yale J. Int’l L. 1.

³⁶ In a text entitled “10 Myths about ACTA (Anti-Counterfeiting Trade Agreement)” published on the DG Trade website, the European Commission explicitly concedes that it “would have preferred to address IPR enforcement problems in the WTO or in WIPO, and made many proposals to that effect. The point is that certain other members of these organisations opposed any enforcement debate there. ACTA sets international IPR standards,

this issue since it states that the new text aims at providing effective and appropriate means for enforcing IPRs *complementary* to the TRIPs Agreement. However, the majority of the states that negotiated the Agreement have in their national legislation legal provisions on IP enforcement that are often sufficiently developed and at times stronger than those provided for by TRIPS.

2.4 ACTA and non-signatory third countries

One of the arguments frequently advanced by the European Commission and the governments of the signatory parties to reassure the opponents of the Agreement is that the latter in no way modifies the legal provisions applicable in the field. Therefore, the Commission has on several occasions emphasised that ACTA is fully compatible with the *acquis communautaire*,³⁷ and the European Parliament also adopted a resolution in this sense on November 24, 2010.³⁸ Thus, it can be wondered why so much effort has been expended negotiating a text that, according to its main protagonists, will not change anything in the existing law.

The answer is that the Agreement seems to be mainly addressed at *non-signatory* emerging countries,³⁹ who will later be invited to “join the club”⁴⁰ by ratifying the text or by signing bilateral agreements.⁴¹ The preamble of the Agreement confirms that ACTA’s aim is “global”, that it concerns the “world economy and not merely the economies of the signatory countries”.⁴² Moreover, the establishment of a special body to implement the Agreement, the “ACTA Committee”,⁴³ whose functions are to examine “matters concerning the development of the Agreement”, to decide upon “the terms of accession to this Agreement of any member of the WTO” and to invite “those signatories not parties to this Agreement to participate in the Committee’s deliberations on those rules and procedures”,⁴⁴ likewise reinforces the view that the prime addressees are third countries.

However, it is not certain, contrary to what the European Commission has often claimed, that the Agreement will not have an impact on the legislation of the European Union and its Member States. The following section focuses on the content of ACTA in order to assess this possible impact.

The content of ACTA

The ACTA consists of five chapters, the most important within the context of the present article being without doubt the first and second ones. The first chapter contains the initial provisions, general definitions (concerning in particular the relationship with other agreements), the nature and the scope of the obligations,

and more countries are welcome to join this multilateral treaty”. European Commission, Directorate-General for Trade, “10 Myths about ACTA (Anti-Counterfeiting Trade Agreement)”, available at http://trade.ec.europa.eu/doclib/docs/2012/february/tradoc_149112.pdf [Accessed April 17, 2012].

³⁷ See in particular European Commission, “A Single Market for Intellectual Property Rights”, 2011, p.24.

³⁸ European Parliament Resolution of November 24, 2010 on the Anti-Counterfeiting Trade Agreement (ACTA), P7_TA(2010)0432.

³⁹ As an example, countries like China, Brazil, Russia and India were not invited to take part in the negotiations although they are regularly identified by certain signatory states as being the principal origin of counterfeit products: see in particular European Commission, “IPR Enforcement Report 2009”, 2009. According to Professor Galloux, the fact that the emerging countries were not involved or were not invited “constitutes beyond doubt one of the weaknesses of this project”. Galloux, RTD com., 2011, p.81. In this sense, see also A. Rens, “Collateral Damage: The Impact of ACTA and the Enforcement Agenda on the World’s Poorest People” (2010) American University Washington College of Law, PIJIP Research Paper No.5.

⁴⁰ To quote an expression used by Professor Gervais: “The approach is neither regional nor truly multilateral; it is a ‘club approach’ in which like-minded jurisdictions define enforcement ‘membership’ rules and then invite other countries to join, presumably via other trade agreements”. Gervais, “China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights” (2009) 103 Am. J. Int’l L. 549, 555; see also P.K. Yu, “ACTA and Its Complex Politics” (2011) 3(1) WIPO J. 3; IGIR, *The Anti-Counterfeiting Trade Agreement (ACTA)* (2011), p.11.

⁴¹ See also IGIR, *The Anti-Counterfeiting Trade Agreement (ACTA)* (2011), p.9. The European Commission explicitly denies this in a text entitled “10 Myths about ACTA (Anti-Counterfeiting Trade Agreement)”: “There is no intention to do so, and this has not been proposed in bilateral trade negotiations conducted by the EU”.

⁴² According to the Preamble, “the proliferation of counterfeit and pirated goods, as well as of services that distribute infringing material, undermines legitimate trade and sustainable development of the world economy, causes significant financial losses for right holders and for legitimate businesses, and, in some cases, provides a source of revenue for organized crime and otherwise poses risks to the public”; for this reason, the parties to the Agreement desire “to combat such proliferation through enhanced international cooperation and *more effective international enforcement*” (emphasis added).

⁴³ ACTA art.36.

⁴⁴ ACTA arts 36(2)(b), 36(2)(d) and 36(5).

the general principles relating to the Agreement. The second chapter lays down the legal framework for improving the enforcement of IPRs. That chapter also constitutes the core of the proposed regulation and contains in particular the provisions concerning civil enforcement, border measures, criminal enforcement and an additional section on the specific measures aimed at enforcing IPRs in the digital environment (the “digital chapter” of the Agreement).

The objective here is not to present an in-depth analysis of the proposed provisions, since this would go far beyond the framework of this article, but rather to make some observations and a general assessment of the differences between the text and current EU legislation. The complexity and technical nature of the Agreement, combined with the lack of transparency concerning the negotiation process, has given rise to numerous misunderstandings about its contents.

3.1 Abandonment of many of the most controversial provisions during the ACTA negotiations

First of all, it should be noted that in the final version of the Agreement, numerous controversial provisions envisaged during the negotiations, specifically regarding the implementation of “graduated response” systems for combating file sharing on the internet, have been dropped, or had their scope considerably narrowed.⁴⁵ In this regard, it is probable that the publication of the draft Agreement by the Commission under the pressure of the European Parliament contributed to the abandonment of some of these provisions, although it is known that they were envisaged by the negotiators. As a result, the “digital chapter” of the Agreement is less problematic, even if doubts persist as to the scope of certain provisions and how to safeguard uses covered by exceptions and limitations.⁴⁶ Anyhow, the criticism of ACTA is not unique in this regard. The same sort of difficulties had already arisen in the European Union following the adoption of the directive of May 22, 2001 on the harmonisation of certain aspects of copyright and related rights in the information society,⁴⁷ which has been criticised exactly for the same reason.⁴⁸

3.2 Introduction of safeguards into the general provisions of ACTA

Secondly, it should be noted that major efforts have been made to include, specifically in the general provisions of the Agreement, a number of rules aimed at guaranteeing balanced procedures. As an example, the Agreement refers to the principles and objectives of the TRIPs Agreement (arts 7 and 8) and states that they apply *mutatis mutandis* (art.2(3)). These articles can generally be regarded as having a “balancing” function, since they can be used as an interpretive guideline that allows the different interests involved to

⁴⁵ See also IGIR, *The Anti-Counterfeiting Trade Agreement (ACTA)* (2011), p.60; Hoeren, “ACTA ad acta? Überlegungen zum urheberrechtlichen Shitstorm” [2012] M.M.R. 137.

⁴⁶ On the topic, see in detail R. Matulionyte, “ACTA’s Digital Chapter: Remaining Concerns and What Can Be Done” (2011) 1(3) Q.M.J.I.P. 248; “Opinion of European Academics on Anti-Counterfeiting Trade Agreement” (2011) 2 J.I.P.I.T.E.C. 65, para.15 et seq. For an analysis of the ACTA provisions concerning internet service providers (art.27(4)) and the disclosure of data relating to their subscribers with regard to their compatibility with the *acquis communautaire*, see I.A. Stamatoudi, “ACTA, Internet Service Provider and the Acquis Communautaire” in Rosen (ed.), *IP Rights at the Crossroads of Trade* (2012).

⁴⁷ Directive 2001/29 of the European Parliament and of the Council of May 22, 2001 on the harmonisation of certain aspects of copyright and related rights in the information society [2001] OJ L167/10.

⁴⁸ See e.g. Ch. Geiger, “The Future of Copyright in Europe: Striking a Fair Balance between Protection and Access to Information: Report for the Committee on Culture, Science and Education—Parliamentary Assembly, Council of Europe, Strasbourg, July 2009” (extended version published in [2010] I.P.Q. 1).

be taken into account when defining the scope of the Agreement.⁴⁹ It should be noted, however, that these provisions in TRIPs have rarely been used by the WTO in its various reports.⁵⁰ Article 6(2) of the Agreement also states that

“procedures adopted, maintained or applied to implement the provisions of this Chapter shall be fair and equitable, and shall provide for the rights of all participants subject to such procedures to be appropriately protected. These procedures shall not be unnecessarily complicated or costly or entail unreasonable time limits or unwarranted delays”.

Paragraph 3 further provides that

“in implementing the provisions of this Chapter, each Party shall take into account the need for proportionality between the seriousness of the infringement, the interests of the parties, and the applicable measures, remedies and penalties.”

By emphasising that the procedures must be “fair” and “equitable”, and by referring to the principle of proportionality, the Agreement introduces several notions that could have a positive influence on its interpretation, specifically by guaranteeing a balanced understanding. Finally, art.27(2) further provides that the procedures for the enforcement of copyright in digital networks must preserve “fundamental principles such as freedom of expression, fair process, and privacy”.

3.3 *Uncertainties about the interpretation of ACTA*

These provisions are all the more important because the secret nature of the negotiations makes it more difficult to understand the text, since the negotiating record is neither known nor accessible, unlike the multilateral agreements adopted within the WTO or WIPO where the debates are documented.⁵¹ As noted above, the vague and uncertain nature of some provisions and the lack of clear limits may be the source of difficulties.⁵² The discretion left to Member States in the implementation of the Agreement may also allow “maximalist” readings of the provisions. Moreover, the Agreement still contains a number of controversial provisions that have for the most part been worded in a non-binding manner. Of course, this does not lead to a direct obligation to implement them, but can nevertheless reflect an intention to induce the parties to introduce those provisions into their national law.⁵³ For example, art.23(3) states that

“a Party may provide criminal procedures and penalties in appropriate cases for the unauthorised copying of cinematographic works from a performance in a motion picture exhibition facility generally open to the public.”

⁴⁹ Ch. Geiger, “Exploring the Flexibilities of the TRIPs Agreement Provisions on Limitations and Exceptions” in A. Kur and V. Mizaras (eds), *The Structure of Intellectual Property Law: Can One Size Fit All?* (Cheltenham: Edward Elgar, 2011) p.287; P.K. Yu, “The Objectives and Principles of the TRIPs Agreement” (2009) 46 Hous. L. Rev. 979.

⁵⁰ Grosse Ruse-Khan, “Criminal Enforcement and International Intellectual Property Law” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012). See also Grosse Ruse-Khan, “The (Non) Use of Treaty Object and Purpose in Intellectual Property Disputes in the WTO” (2011) Max Planck Institute for Intellectual Property & Competition Law, Research Paper No.11–15.

⁵¹ See IGIR, “*The Anti-Counterfeiting Trade Agreement (ACTA)* (2011)”, p.17. See also art.6 of the European Parliament Resolution of March 10, 2010 on the transparency and state of play of the ACTA negotiations, in which the Parliament “deplores the calculated choice of the parties not to negotiate through well-established international bodies, such as WIPO and WTO, which have established frameworks for public information and consultation”.

⁵² In this sense, see Hoeren, “ACTA ad acta? Überlegungen zum urheberrechtlichen Shitstorm” [2012] M.M.R. 137, 138, stating that the interpretation of the Agreement remains very unclear.

⁵³ See also “Opinion of European Academics on Anti-Counterfeiting Trade Agreement” (2011) 2 J.I.P.I.T.E.C. 65.

Leaving aside the fact that art.23(1) specifies that criminal penalties are in principle reserved to wilful counterfeiting “on a commercial scale” (and that this condition is not repeated in the context of para.3), under existing legislation it is not the copy itself that constitutes the problematic use,⁵⁴ but rather its dissemination such as by means of file sharing sites on the internet. Even if the text refers to the “unauthorised” copy, this is still ambiguous because it is not apparent who is entitled to give the authorisation: is it the right-holder (in which case, this would imply that the exceptions and limitations are to be left to the disposal of the right-holder) or is it the legislature—and if so, which legislator (as the private copy exceptions are not harmonised and the national laws vary considerably on this point)? This is a good illustration of the difficulties related to an unclear interpretation of the text.

3.4 Uncertainties about the consistency of ACTA with EU and international law

More generally, the Agreement contains a certain number of differences to provisions of European and international IP law, specifically regarding civil enforcement, border measures, criminal enforcement and the provisions concerning the enforcement of the IP rights in the digital environment. These differences were pointed out by a group of European academics in an Opinion, whose aim was to bring to the attention of the institutions of the European Union, the European Parliament in particular, that the ratification of the Agreement could lead to possible modifications of European law.⁵⁵ The objective of the Opinion was to provide the legal analysis required for an informed decision by the EU institutions (ACTA having been described a little too quickly by the European Commission and the European Parliament as being “entirely compatible with the *acquis communautaire*”). The Opinion led to an official reply on the part of the European Commission,⁵⁶ a fact that deserves to be mentioned because this is very rare for a text written by academics. Some of the explanations given in the reply are convincing and help specify the scope of certain ambiguous provisions. The problem is that the interpretations proposed by the Commission are not binding on the institutions of the European Union. Therefore, if the text were to be adopted, it would be highly desirable to publish some clear interpretative guidelines as an annex to complement the text of the Agreement. The precise understanding of the various ambiguous provisions could then be the subject of an open and transparent debate, helping thus to clarify the scope of the legal commitment that the adoption of ACTA would imply.

*3.5 The main inconsistency with the EU *acquis*: The criminal enforcement provisions of ACTA*

The Commission’s response to the Opinion was less convincing when it came to the criminal provisions in the Agreement.⁵⁷ Article 23(1) of ACTA provides that

“each Party shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright or related rights piracy on a commercial scale.”

⁵⁴ Indeed reproduction can be permitted by means of an exception, in particular the private copy exception, and can thus constitute a perfectly legitimate act. See “Opinion of European Academics on Anti-Counterfeiting Trade Agreement” (2011) 2 J.I.P.I.T.E.C. 65, para.9, according to which “ACTA prompts Contracting Parties to criminalize such an action (unauthorised copying of cinematographic works) without the commercial scale assessment and without any assessment of the intention of the defendant. Again, this disregards the exception in relation to fair use and copying for private and not-for-profit purposes repeatedly stressed by the EP.”

⁵⁵ “Opinion of European Academics on Anti-Counterfeiting Trade Agreement” (2011) 2 J.I.P.I.T.E.C. 65. A French translation of the Opinion was published in 2011(6) *Journal Auteurs et Médias*. The text was sent to the European Parliament and the European Commission in February 2011.

⁵⁶ “Comments on the ‘Opinion of European Academics on Anti-Counterfeiting Trade Agreement’, April 27, 2011, Commission services working paper, reproduced in (2011) 2 J.I.P.I.T.E.C. 171.

⁵⁷ On this question, see Geiger, “The Anti-Counterfeiting Trade Agreement and Criminal Enforcement of Intellectual Property?” in Rosen (ed.), *IP Rights at the Crossroads of Trade* (2012).

The term commercial scale is defined broadly as comprising at least acts carried out “as commercial activities for direct or indirect economic or commercial advantage”. The parties thus agree to introduce criminal penalties into their legislation. However, within the legislative framework of the European Union, there are currently no provisions concerning criminal penalties for the infringement of IPRs. On the contrary, a proposed directive on criminal enforcement was recently the subject of heated debate⁵⁸ and then ultimately rejected, largely due to an opposition from the European Parliament, which had sought significant amendments to guarantee a balanced implementation of the text.⁵⁹ As already noted, the proposed directive was withdrawn by the European Commission after several years of discussions just before the publication of the consolidated version of ACTA. It is difficult to see this as a coincidence given the Commission’s substantial efforts over many years to have a directive adopted and its emphasis on “enforcement” with regard to IP in its latest strategic documents.⁶⁰ The view among some scholars is that if ACTA should be adopted by the European Union, the Commission, strengthened by this new legitimacy, will propose a new directive on criminal enforcement of IPRs.⁶¹

The Commission rejects this argument by emphasizing the fact that the ACTA’s section on criminal enforcement was negotiated on behalf of the Member States.⁶² It is true that a very large majority of the Member States already provide for criminal penalties for infringement of IPRs in their national legislation and that these are often stricter than those provided for by the Agreement. Nevertheless, it remains the case that the criminal element of IP has not been significantly harmonised and that the approaches differ considerably across the Member States.⁶³ There is therefore an identified need for harmonisation that will have to be satisfied. It would be paradoxical for the Commission to claim the contrary today after having strongly insisted for many years on the necessity of having a directive on this subject. However, when a directive comes to be drafted in the future, ACTA will serve as a model, since the text will have to be compatible with the international commitments of the European Union. The problem is that the criminal component of the Agreement does not currently include the guarantees demanded by the European Parliament on the occasion of the discussions on the failed directive proposal.⁶⁴ Moreover, it might be necessary for the Member States to examine the precise impact of the Agreement on their national legislation, specifically on the criminal component of their IP law, in order to be able to commit themselves

⁵⁸ European Commission, “Amended Proposal for a Directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights”, April 26 2006, COM(2006) 168 final. Article 3 of the proposal for example provided: “Member States shall consider all intentional infringements of an intellectual property right on a *commercial scale* as a criminal offence. It also covers attempting, aiding or abetting and inciting such offences” (emphasis added), which had been the subject of strong criticism: see in particular R.M. Hilty, A. Kur and A. Peukert, “Statement of the Max-Planck Institute for Intellectual Property, Competition and Tax Law on the Proposal for a Directive of the European Parliament and the Council on Criminal Measures Aimed at Ensuring the Enforcement of Intellectual Property Rights” [2006] IIC 970, which considered in particular that the criterion of “commercial scale” was too vague to permit a sufficiently precise definition of the elements of the offence and proposed other, more restrictive criteria such as the need for an intention to earn profits.

⁵⁹ See in particular the amendments proposed in the European Parliament Legislative Resolution of April 25, 2007 on the “Amended Proposal for a directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights”. In particular the Parliament pointed out that “infringements on a commercial scale” means any infringement of an intellectual property right committed to obtain a commercial advantage; *this excludes acts carried out by private users for personal and not-for-profit purposes*. Moreover, the Member States should ensure “that the fair use of a protected work, including such use by reproduction in copies or audio or by any other means, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship or research, does not constitute a criminal offence” (emphasis added).”

⁶⁰ See in particular European Commission, “A Single Market for Intellectual Property Rights”, 2011”.

⁶¹ J. Gibson, “The Directive Proposal on Criminal Sanctions” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012), p.245; T. Mylly, “Criminal Enforcement and European Union Law” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012), p.213.

⁶² The Commission also insists that the TRIPs Agreement, which also provides for minimum criminal standards, did not require legislation by the EU: “Comments on the ‘Opinion of European Academics on Anti-Counterfeiting Trade Agreement’”, 2011, reproduced in (2011) 2 J.I.P.I.T.E.C. 171, 177. The Commission forgets that it had previously referred to the TRIPs Agreement to justify the European Union’s actions in the field of criminal enforcement. Indeed, the statement of the grounds for the proposal for the 2006 directive reads: “A start was made on harmonisation with the entry into force of the TRIPs agreement which lays down minimum provisions on means of enforcing trade-related intellectual property rights. These include the implementation of criminal procedures and criminal penalties, but there are still major disparities in the legal situation in the Community which do not allow the holders of intellectual property rights to benefit from an equivalent level of protection throughout the Community. As regards criminal penalties, there are considerable differences, particularly as regards the level of punishment laid down by national legislation”.

⁶³ On this point, see Gibson, “The Directive Proposal on Criminal Sanctions” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012).

⁶⁴ See “Opinion of European Academics on Anti-Counterfeiting Trade Agreement” (2011) 2 J.I.P.I.T.E.C. 65, para.6 et seq. See also Geiger, “The Anti-Counterfeiting Trade Agreement and Criminal Enforcement of Intellectual Property” in Rosen (ed.), *IP Rights at the Crossroads of Trade* (2012).

in full knowledge of the consequences.⁶⁵ It would therefore be preferable, before the adoption of ACTA, to undertake a broad comparative study on the provisions on criminal enforcement of IP rights in the national legislation of the European Union. IP criminal law is a sensitive subject and deserves to be examined in depth⁶⁶ to ensure that its future function will be dissuasive but also differentiated and balanced.⁶⁷ This reflection has, however, not been conducted sufficiently within the framework of ACTA.⁶⁸

Conclusion

ACTA aims to complete the international legal system concerning the enforcement of IPRs that resulted from the TRIPs Agreement. Sometimes weaker than the obligations laid down in EU law and national law of the negotiating parties in the field of civil and criminal enforcement, ACTA appears primarily addressed to non-signatory third countries which will be later invited to “join the club”, either by ratifying the Agreement *a posteriori* or by concluding bilateral agreements.

Some dark areas remain concerning the exact impact of the provisions of the Agreement on EU law. On February 22, 2012, the European Commission announced that ACTA will be referred to the European Court of Justice to verify its compatibility with primary EU legislation,⁶⁹ and specifically with fundamental rights,⁷⁰ which, with the entry into force of the Treaty of Lisbon, acquired “the same legal value as the Treaties”.⁷¹ Hopefully, the court will be able to provide useful guidance on this issue.⁷² But a clarification of the exact implications for the *acquis communautaire* and the law of the Member States would also have been helpful. Certainly, as the European Commission rightly asserts, ACTA as an international agreement is not required to comply with EU secondary legislation. Nevertheless, it is possible that it will have consequences on the latter by requiring (and/or strongly suggesting) changes or new legislative initiatives.

⁶⁵ The Commission incidentally concedes: “A very limited number of Member States may need to adapt their own legislation related to criminal enforcement to comply with the commitments they undertook (ACTA is a mixed EU/Member States’ competence Agreement). This has been confirmed in very clear terms by the two Opinions of the Legal Service of the European Parliament of 5 October 2011 and of 8 December 2011, answering respectively to questions by the INTA and JURI Committees.” European Commission, Directorate-General for Trade, “10 Myths about ACTA (Anti-Counterfeiting Trade Agreement)”, available at http://trade.ec.europa.eu/doclib/docs/2012/february/tradoc_149112.pdf [Accessed April 17, 2012].⁶⁶ For a comment relating to French law, see Galloux, RTD com., 2011, p.83, who emphasises that while the provisions of ACTA do not a priori lead to an amendment of the framework laid down by the Community directives, “this is not the case for French law”.

⁶⁶ For more detail on this subject, see Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012).

⁶⁷ The subject gets more complicated at the global level. Scholars have stated that, within the framework of such an approach, differentiation is also necessary by virtue of the level of development of the country in which criminal penalties are enforced. In this sense, see C.M. Correa, “The Push for Stronger Enforcement Rules: Implications for Developing Countries” in ICTSD (ed.), *The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries* (Geneva: 2009), p.60. See also Grosse Ruse-Khan, “Criminal Enforcement and International Intellectual Property Law” in Geiger (ed.), *Criminal Enforcement of Intellectual Property* (2012), according to whom “the question which conduct exactly deserves the sanction of criminal law should be left to the decision of national lawmakers—to be determined in line with the domestic social and economic environment”.

⁶⁸ See Ch. Geiger, “The Construction of Intellectual Property in the European Union: Searching for Coherence” in Geiger (ed.), *Constructing European Intellectual Property* (2012), where we emphasise the need for the European Union not to adopt laws under pressure. The future initiatives by the European legislature should instead rely more frequently on serious (and above all independent) economic data and on impact studies that allow the probable consequences of the legislative actions to be measured. In our opinion, the impact of ACTA on EU law and on national laws has not been sufficiently studied.

⁶⁹ See “Statement by Commissioner Karel De Gucht on ACTA (Anti-Counterfeiting Trade Agreement)”, February 22, 2012, MEMO/12/128, <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/12/128> [Accessed April 17, 2012].

⁷⁰ Expressing doubts in this respect is “Opinion of the European Economic and Social Committee on the “Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions—A Single Market for Intellectual Property Rights: Boosting Creativity and Innovation to Provide Economic Growth, High Quality Jobs and First Class Products and Services in Europe”, January 18, 2012, CESE 143/2012—INT/591. According to the Committee, ACTA’s exclusive focus “on increasing protection for right holders by means of customs, police and administrative cooperation measures continues to favour a certain view of rights ownership. Other doubtless more fundamental human rights, such as the right to information, health, sufficient food, the right of farmers to select seeds and the right to culture, are not taken sufficiently into consideration, and this will impact on future European legislation geared towards the harmonisation of Member States’ legislation” (para.3.13). See also D. Korff and I. Brown, “Opinion on the Compatibility of ACTA with the European Convention on Human Rights and EU Charter of Fundamental Rights”, October 2011, study prepared at the request of the Greens/European Free Alliance in the European Parliament, available at <http://rfc.act-on-acta.eu/fundamental-rights> [Accessed April 17, 2012].

⁷¹ TEU art.6(1).

⁷² Fundamental rights are now increasingly applied by the Court of Justice to interpret EU legislation in the IP field. As an example, the Court recently ruled on the balance of rights laid out in the EU Charter of Fundamental Rights in relation to IP enforcement measures, where it stated that national courts cannot order internet service providers or social networks to introduce monitoring or general filtering systems to identify potential infringers and prevent illegal file-sharing: see *Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (Sabam) v Netlog NV* (C-360/10) Unreported February 16, 2012.

Indeed, as we have emphasised, the scope of many provisions is vague, and there are currently uncertainties about the interpretation that will be given to the text.⁷³ It would therefore be desirable, if the Agreement is adopted, to complement it by means of binding interpretive guidelines that would give more clarity and be the subject of a transparent debate. Moreover, the adoption of ACTA by the European Union would mean that the latter would integrate the Union's legal system, with the consequence that any future directive or regulation would have to comply with it and be interpreted in its light. As a minimum, it is thus the interpretation of the *acquis communautaire* that will be affected. From this point of view, one might ask whether it is advisable for the European Union to adopt an additional instrument that could lead to complications, given that ACTA is not identical with EU law in terms of its provisions and scope.

Ultimately, it is perhaps not so much the content of the Agreement that is the most problematic but rather the method of adopting it. A secret negotiation of the future of IP law between a few like-minded countries, outside the competent international organisations, is clearly a bad method and by no means a guarantee of success.⁷⁴ On the contrary, it tends to undermine the credibility of multilateralism in the field of IP law and in the long term risks to considerably weaken the WTO and WIPO that are responsible for such legislation at the international level.⁷⁵ At a time when IP is more than ever a major aspect of the global economy, this is undoubtedly an undesirable signal. The struggle against counterfeiting and the effective enforcement of IPRs are perfectly legitimate objectives that can be effectively and probably successfully defended within the international bodies.⁷⁶ Equally, convincing the emerging countries that it is in their interests to have effective enforcement mechanisms does not seem an impossible task, particularly since several of these countries have gradually developed strategies for stronger protection of their IPRs. Obviously, such a multilateral approach will very likely require compromises and to take into account the equally legitimate demands of many developing countries, such as in the field of limitations and exceptions to copyright, and the protection of traditional knowledge or access to medicines. This will surely need

⁷³ Because of the vague and uncertain nature of some provisions of the Agreement, the European Parliament Rapporteur on ACTA, David Martin, recommended that the "European Parliament declines to give consent to ACTA". Draft Recommendation on the Draft Council Decision on the Conclusion of the Anti-Counterfeiting Trade Agreement Between the European Union and Its Member States, Australia, Canada, Japan, the Republic of Korea, the United Mexican States, the Kingdom of Morocco, New Zealand, the Republic of Singapore, the Swiss Confederation and the United States of America, April 12, 2012, 2011/0167(NLE).

⁷⁴ On this point, one might recall the failure of the Multilateral Agreement on Investment (MAI), which was negotiated in secret within the OECD between 1995 and 1997 with the intention of subsequently extending it to non-members, and which encountered huge opposition among the general public until it was finally abandoned in October 1998: on this question in particular, see D. Henderson, *L'accord multilatéral sur l'investissement, Leçons d'un échec* (Paris: GEM, 1999). While an international regulation of investments was certainly desirable, the method adopted blocked any progress on the topic for many years. It is not impossible for this scenario to be repeated with ACTA.

⁷⁵ See also Yu, "Six Secret (and Now Open) Fears of ACTA" (2011) 64(3) SMU L. Rev. 975, 1078: "By developing intellectual property protection outside the traditional fora, like WIPO and the WTO, the negotiation of ACTA undermined the stability of the international trading system and the preference for the multilateral process. It also alienated the trading partners of ACTA negotiating parties, making it more difficult to undertake future multilateral discussions". See also Yu, "ACTA and Its Complex Politics" (2011) 3(1) WIPO J. 1, 1: "This approach is likely to have serious ramifications for both the structural integrity and continued vitality of the existing international intellectual property regime". The WIPO Director General has also expressed his reservations about such a procedure, arguing that the approach adopted by the ACTA signatories risked damaging the multilateral intellectual property system: see the discussion reported by C. Saez, "ACTA a Sign of Weakness in Multilateral System, WIPO Head says", *Intellectual Property Watch*, June 30, 2010, available at <http://www.ip-watch.org/weblog/2010/06/30/acta-a-sign-of-weakness-in-multilateral-system-wipo-head-says/> [Accessed May 21, 2012]. According to Francis Gurry, "a number of countries feel (there is) an important area of public policy they are not able to address in the multilateral forum, and so have gone outside the multilateral framework to satisfy their desire for creating some form of 'international cooperation' ... That's the challenge for us. And whether it concerns enforcement, ACTA, or any other area, that, on the whole, is a bad development for a multilateral agency, that member states start to do things outside".

⁷⁶ Strengthening the enforcement mechanisms of IPRs is probably not the only solution to diminish piracy in developing countries. According to a recent study, the efficiency of these measures would even be quite uncertain. See J. Karaganis (ed.), *Media Piracy in Emerging Economies* (New York: Social Science Research Council, 2011), Executive Summary iii. The authors of the study concluded that "they have seen little evidence—and indeed few claims—that enforcement efforts to date have had any impact whatsoever on the overall supply of pirated goods. Our work suggests, rather, that piracy has grown dramatically by most measures in the past decade, driven by exogenous factors—high media prices, low local income, technological diffusion, and fast changing consumer and cultural practices". In this sense, but with regard to internet piracy, see also Stamatoudi, "ACTA, Internet Service Provider and the Acquis Communautaire" in Rosen (ed.), *IP Rights at the Crossroads of Trade* (2012), concluding that "internet piracy cannot be solved solely through the vehicle of law", but also by new business models and affordable prices.

efforts on both sides, but in the long term is likely to be much more effective than the iron fist which is currently being wielded by the rich countries and the equivalent defensive posture of developing countries as concerns the governance of IP.⁷⁷ In the meantime, it is the legitimacy of the entire system that is at risk.

⁷⁷ For a consideration of the future of the international intellectual property system, see A.A. Latif, "Change and Continuity in the International Intellectual Property System: A Turbulent Decade in Perspective" (2011) 3(1) WIPO J. 36.

Climate Change and the Debate around Green Technology Transfer and Patent Rules: History, Prospect and Unresolved Issues

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☞ Climate change; Environmental protection; International environmental law; Patents; Technology transfer

Since the 2009 Copenhagen Conference on climate change, developing countries (China and the G77) claim that international patent rules should be amended so as to facilitate the transfer of clean technologies and to address the climate change emergency. This could lead to the reopening up the WTO Agreement on Trade Related Aspect of Intellectual Property rights (TRIPS) which contains flexible provisions for all WTO Members. On the contrary, developed countries oppose any climate deal that would weaken the patent regime. The article first presents the history and the state of the international discussions on the controversial role of patent law with regard to the dissemination of clean technologies in the emerging and less developed countries. We conclude that it is unlikely that the ongoing discussions will result in some concrete outcome in the near future. As it is probably impossible to establish whether, on the whole, patents do promote or, on the contrary, do prevent the transfer of clean technologies, a more constructive approach requires to focus on the concrete obstacles that affect the international transfer of clean technologies.

Climate change is the greatest market failure the world has ever seen. ... The costs of stabilising the climate are significant but manageable; delay would be dangerous and much more costly. ... Action on climate change is required across all countries, and it need not cap the aspirations for growth of rich or poor countries. ... The development and deployment of a wide range of low-carbon technologies is essential in achieving the deep cuts in emissions that are needed. ... And there is some evidence that a more robust IPR [intellectual property rights] regime encourages such transfer.—Stern Review¹

Introduction

Today, as scientific literature continues to buttress existing evidence about “anthropogenic climate change”, highlighting the decisive role of human activity in the surge of carbon dioxide emissions, the broad diffusion and transition to environmentally sound technologies (ESTs) appears ever more likely to help the world break the climate stalemate.² By answering past human activity with equal ingenuity, it is possible

¹ N. Stern, *Stern Review on the Economics of Climate Change* (London: HM Treasury, 2006), available at http://webarchive.nationalarchives.gov.uk/+http://www.hm-treasury.gov.uk/sternreview_index.htm [Accessed March 25, 2012].

² UN Department of Economic and Social Affairs, “World Economic and Social Survey 2011: The Great Green Technological Transformation”, available at http://www.un.org/en/development/desa/policy/wess/wess_current/2011wess.pdf [Accessed March 25, 2012].

to envisage the world moving towards a low carbon economy. The development and the implementation of ESTs are heavily promoted through many schemes throughout the developed world. However, for a truly global issue such as climate change, the solutions should be deployed all over the world, not only in the Global North (North).

The transfer of ESTs to the Global South (South) is a major issue discussed within the framework of various international conventions, such as the United Nations Framework Convention on Climate Change (UNFCCC)³ and the Kyoto Protocol.⁴ Discussions centre on how “technology-importing countries” could benefit from such transfers in a sustainable way. After an introduction on ESTs, we will see how the discourse on the transfer of ESTs gained momentum, before reviewing the exchanges that have recently agitated the delegates in Durban on the occasion of the Seventeenth Conference of the Parties (COP) in December 2011.

The promotion of ESTs calls for adequate incentive mechanisms. Whilst financial incentives such as state aid and tax benefits will undoubtedly play a major role, patents can also act as strong incentives for companies to invest in certain technologies by allowing them to recoup their investments. The positive view on patents, as an enhancer of green technologies, posits that the patent system works as a platform around which “green transactions” can be brokered and completed. Accordingly, mechanisms allowing investors in ESTs to benefit from the revenue generated by the exploitation and licensing of patents appears necessary for the markets surrounding those technologies to flourish.

NGOs and civil society groups active in the environmental policy-making, however, share a rather sceptic view on patents, if not an anti-patents rhetoric. This echoes the debate on pharmaceutical patents that led to the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration),⁵ which aimed primarily at providing access to essential medicines in developing countries. These pressure groups contend that the patent system is a one-way street leading directly to the coffers of large corporations from the developed world while adversely impeding the economic development of the South.

The patent system is thus currently under scrutiny from various actors. The legal debate crystallizes around the “flexible provisions” of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) that allow the Member States to somewhat adapt their patent rules to the state of their economy and to their national public policies. The most popular of these flexibilities is the “compulsory license” mechanism provided for by art.31 of the TRIPS Agreement. In the third part, we will review the existing flexibilities and assess whether an additional mechanism is needed to support the promotion of ESTs and their deployment in the South. We will then conclude about what can be expected from COP 18 in Qatar and beyond.

The definition, types and origins of ESTs

The notion of EST.

While the issue of technology transfer (TT) agitates the delegates within the international climate change fora, the simple fact that there exists, in parallel, no agreed definition of what falls within the central notion of “green technology” illustrates the lack of understanding surrounding the debate.

³ United Nations Framework Convention on Climate Change 1992 (UNFCCC), entered into force on March 21, 1994.

⁴ Kyoto Protocol to the United Nations Framework Convention on Climate Change 1997 (Kyoto Protocol), entered into force on February 16, 2005.

⁵ World Trade Organization, “Declaration on the TRIPS Agreement and Public Health”, WT/MIN(01)/DEC/2, November 20, 2001, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [Accessed March 25, 2012].

The most commonly used definition of ESTs is based on Agenda 21, which arose from the UN Conference on Environment and Development, otherwise known as the Earth Summit, held in 1992. Since then, no unanimous improvements have been made to further develop the outlines of this concept showing the malaise that prevails among the climate change negotiators.

Box 1: Definition of ESTs

Chapter 34 of Agenda 21 defines ESTs as technologies which:

- protect the environment;
- are less polluting;
- use all resources in a more sustainable manner;
- recycle more of their wastes and products; and
- handle residual wastes in a more acceptable manner than the technologies for which they are substitutes.

ESTs are not just individual technologies. They can also be defined as total systems that include know-how, procedures, goods and services, and equipment, as well as organisational and managerial procedures for promoting environmental sustainability.

Based on these characteristics, the definition of ESTs:

- applies to the transition of all technologies in becoming more environmentally sound;
- captures the full life cycle flow of the material, energy and water in the production and consumption system;
- covers the full spectrum from basic technologies that are adjunct to the production and consumption system, to fully integrated technologies where the environmental technology is the production or consumption technology itself;
- includes closed system technologies (where the goal is zero waste and/or significant reductions in resource use), as well as environmental technologies that may result in emissions; and
- considers technology development within both the ecological and social context.⁶

Adaptation v mitigation technology.

While it has been widely recognized that the climate change challenge called for technological breakthroughs, a distinction needs to be made between at least two types of technologies each relevant in different but complementary areas.⁷

First, climate change mitigation technology (CCMT) refers to

“technological change and substitution that reduce energy resource inputs and emissions per unit of output. Although several social, economic and technological policies would also lead to an emissions reduction, for climate change mitigation encompasses implementing policies to reduce greenhouse gas (GHG) emissions and to enhance sinks.”

These technologies cover a vast range of sectors: energy supply, transport, buildings, industry, agriculture, forestry, and waste management.⁸

Secondly, adaptation technology concerns:

“Adjustment in natural or human systems in response to actual or expected climatic stimuli or their effects, which moderates harm or exploit beneficial opportunities. Various types of adaptation can be distinguished, including anticipatory and reactive adaptation, private and public adaptation, and autonomous and planned adaptation”.

⁶ Agenda 21, Ch.34 (“Transfer of Environmentally Sound Technology, Cooperation & Capacity-Building”), available at http://www.un.org/esa/dsd/agenda21/res_agenda21_34.shtml [Accessed March 25, 2012].

⁷ cf. the definitions given by the Intergovernmental Panel for Climate Change (IPCC), available at <http://www.ipcc.ch/pdf/glossary/ar4-wg3.pdf> [Accessed March 25, 2012].

⁸ For a list of key mitigation technologies already available and projected to be commercially available before 2030, see <http://www.greenfacts.org/en/climate-change-ar4/figtableboxes/40.htm> [Accessed March 25, 2012].

Again, these technologies are useful in many different sectors: agriculture, coastal zone, infrastructure, water resources and hydrology, tourism, finance, biodiversity and health. Moreover, in addition to “soft” technologies, such as crop rotation, “hard” technologies for adaptation include improved irrigation techniques to cope with drought, and new plant varieties which are resistant to drought or salt water.

Role of patents for mitigation and adaptation technologies.

There is evidence showing that the role of patents for adaptation technologies is very different from the role they play for CCMTs. With regard to the former, it seems that the privileged area for their implementation is the Least Developed Countries (LDCs) (i.e. sub-Saharan Africa, Asia and certain small island states) where the impact of patents in general is not likely to be significant, as a patent system is not generally in force or widely used in these countries. On the contrary, there is a large demand for CCMTs in the regions that have had the benefit, at one point of their history, from the industrialization process (European Union, United States, Japan, China, Brazil, India) and where the patent system is viewed as the cornerstone of the recent knowledge-based economy. For that reason, it is not surprising that the scientific community, in the intellectual property debate, is focusing on the impact of patents on the access, deployment and transfer of CCMTs at the expense of adaptation technologies that must be discussed in another forum.⁹ This assertion reflects the position taken by the European Patent Office (EPO) that recently launched a new classification scheme exclusively for CCMTs under the symbol YO2 aiming at hosting the many cross-sectoral green technologies in one single place.¹⁰ This initiative originates from the joint study launched in 2009 by the United Nations Environment Programme (UNEP) with the EPO and the International Centre for Trade and Sustainable Development (ICTSD) on the role of patents in the transfer of clean energy technologies (CETs).¹¹ The study expressively stated that “for the purposes of this study, CETs are energy generation technologies which have the potential for reducing greenhouse gas emissions”, i.e. CCMTs.

Green-novation: No more the appanage of the North?

While the European Union (followed by the United States and Japan¹²) has been, for the last three decades, a pioneer in the development and further patenting of green technologies,¹³ there is a clear trend that the emerging countries, with China at the head, are rapidly catching up. In fact, it is apparent from many studies done in the sector that patent protection is absent from most of the low-income countries for these technologies.¹⁴ By contrast, the patent protection of climate technologies is increasing exponentially in the emerging markets. In 2009, a study commissioned by the European Commission found that the growth rate of patent registration in emerging countries for the period 2004–2007, compared with 1998–2001, is five times higher than the worldwide growth rate for the same period.¹⁵ Most importantly, while the share

⁹ In this regards, it is worth noting that the Cook Islands, in their “letter of non-association to the UNFCCC”, decided not to endorse the Copenhagen Accord, on the ground that “[p]ast experience with the Expert Group on Technology Transfer has shown that mitigation technologies have received far more attention [than adaptation technologies]”. Baskut Tuncak, “Leading the Way towards Carbon Reduction”, Centre for International Environmental Law (CIEL) Blog—“Intellectual Property and Sustainable Development”, available at <http://ipsd.typepad.com/ipsd/green-innovation/> [Accessed March 25, 2012].

¹⁰ See EPO, “EPO Clean Energy”, available at <http://www.epo.org/news-issues/issues/classification/classification.html> [Accessed March 25, 2012].

¹¹ UNEP-EPO-ICTSD, “Patents and Clean Energy: Bridging the Gap between Evidence and Policy” (2010), p.8, available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/cc5da4b168363477c12577ad00547289/\\$FILE/patents_clean_energy_study_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/cc5da4b168363477c12577ad00547289/$FILE/patents_clean_energy_study_en.pdf) [Accessed March 25, 2012].

¹² cf. UNEP-EPO-ICTSD, “Patents and Clean Energy” (2010), p.31, fig.5.

¹³ E.g. “European Strategic Energy Technology Plan” (SET Plan), available at http://ec.europa.eu/energy/technology/set_plan/set_plan_en.htm [Accessed March 25, 2012]; “EU 2020 Strategy”, available at http://ec.europa.eu/europe2020/index_fr.htm [Accessed March 25, 2012].

¹⁴ John H. Barton, “Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis of Solar Photovoltaic, Biofuel and Wind Technologies” (2007) ICTSD Trade and Sustainable Energy Series, Issue Paper No.2, available at http://www.iprsonline.org/unctadicts/docs/BARTON_DEC_2007.pdf [Accessed March 25, 2012].

¹⁵ Copenhagen Economics and the IPR Company, *Are IPRs a Barrier to the Transfer of Climate Change Technology?* (Copenhagen: 2009), study prepared for the European Commission (DG Trade), p.16, available at <http://www.copenhageneconomics.com/Publications/IPR.aspx> [Accessed March 25, 2012].

of domestic ownership of patents in these countries was close to zero in the late 1990s, the study shows that almost one-third of all patents registered in emerging market economies are presently owned by residents of these countries.¹⁶ This means that local industries have, in theory, the capacity to substitute western technology for their own. In addition, the recent UNEP-EPO-ICTSD Joint Study concluded that

“the worldwide patenting activity is largely dominated by the OECD countries (80 percent of all patent applications), [but] a number of emerging economies are showing specialization in individual sectors, providing further competition in the field and potentially changing the future of the CET patent landscape.... For instance, such an analysis reveals that India features within the top five countries for solar [photovoltaic], while Brazil and Mexico share the top two positions in hydro/marine. [Moreover], in terms of patent filing trends between countries (structure of patent families), unsurprisingly, the majority of activity is currently taking place in the patent offices of the top six patenting countries. However, China is the next most important filing destination for actors in the top six countries.”¹⁷

Besides, those countries also reinforced their IP system through strategic collaboration with the EPO, the U.S. Patent and Trademark Office (USPTO) and the Japanese Patent Office (JPO).¹⁸ These partnerships recently took on new amplitude with the launch of the EPO new classification scheme (YO2) specifically designed to identify ESTs’ technical attributes within the “ESP@CENET” system.¹⁹ Because of the “technocratic trust” that prevails between the trilateral offices (USPTO, JPO and EPO) and the rest of the IP offices throughout the world,²⁰ this new classification will have effect in all of them and, consequently, will accelerate the diffusion and development of ESTs in those countries.²¹ As a matter of fact, the EPO rules of procedure and the “ESP@CENET” system serve as models for all other IP Offices which draw inspiration from them because of their world-known quality. For all these reasons, to the emerging countries which advocate the weakening of “northern” IP systems, the developed countries may thus reply that the world has changed dramatically.²²

¹⁶ “At the same time, it should be noted that this phenomenon is very much dominated by China: out of the 7400 climate change technology patents owned by residents of emerging market economies in 2008, 92% are owned in China by Chinese residents. None of the other emerging market economies has taken such a huge step forward in domestic ownership of IPR. It is somewhat surprising then to see China take the lead in the international debate on climate change technology transfers and advocate a more flexible IPR regime.” Copenhagen Economics and the IPR Company, *Are IPRs a Barrier to the Transfer of Climate Change Technology?* (2009), p.25.

¹⁷ UNEP-EPO-ICTSD, “Patents and Clean Energy” (2010), p.64.

¹⁸ In 2007, the European Commission and the Government of People’s Republic of China launched the EU-China Project on the Protection of Intellectual Property Rights (IPR2) aiming at improving the effectiveness of intellectual property rights enforcement in China, available at http://www.ipr2.org/index.php?option=com_content&view=article&id=44&Itemid=1 [Accessed March 25, 2012].

¹⁹ See EPO, “EPO Clean Energy”, available at <http://www.epo.org/news-issues/issues/classification/classification.html> [Accessed March 25, 2012]. See also the “IPC Green Inventory” scheme that is launched in September 2010 by WIPO and that is “hyperlinked to WIPO’s PATENTSCOPE service to automatically search and show all green international applications under the PCT”. WIPO, “WIPO Launches Tool to Facilitate Green Tech Patent Searches”, September 16, 2010, available at http://www.wipo.int/pressroom/en/articles/2010/article_0031.html [Accessed March 25, 2012].

²⁰ More specifically the so-called “Five IP Offices” regrouping the EPO, the Japanese Patent Office, the Korean Intellectual Property Office, the State Intellectual Property Office of the People’s Republic of China, and the United States Patent and Trademark Office: see <http://www.fiveipoffices.org> [Accessed March 25, 2012].

²¹ Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge: Cambridge University Press, 2010).

²² Rasmus Lema and Adrian Lema, “Whither Technology Transfer? The Rise of China and India in Green Technology Sectors” in Innovation and Development, Special Issue on Sustainability-Oriented Innovation Systems in China and India (forthcoming) (June 2011 draft version, cited with the express consent of the authors).

How TT became an important issue: From the Bali Plan of Action to the Copenhagen Conference

TT and development.

The North-South debate on the transfer of technology finds its roots in the call for development that arose from the newly independent states in the aftermath of the decolonisation process. It appeared to them that social and economic progress should work hand in hand with technological development. In the 1970s, harnessing this new awareness, developing countries pursued a series of initiatives aiming at rebalancing the gap that segregated the old colonies from their western counterpart—referred to as the “Old Development Agenda” by Peter Yu.²³ Among those initiatives, the international community focused on the establishment in 1977 of an “International Code of Conduct on the Transfer of Technology”²⁴ under the auspices of the United Nations Conference on Trade and Development (UNCTAD), which was in line with the *Declaration for the Establishment of a New International Economic Order*²⁵ adopted by the United Nations General Assembly in 1974. This Code was intended to apply to all international transactions involving TT in order to eliminate the numerous clauses in “transfer of technology contracts” (as well as other restrictive foreign investment practices), which were harmful to the economic development of developing countries (such as provisions on grant-back, exclusive dealing and price-fixing). Unfortunately, mostly because of the economic slump of the late 1970s and early 1980s, the support for the Code progressively disappeared, even within the developing country community, and the negotiation stopped in 1985.²⁶

This episode reminds us that the transfer of technology, while being widely promoted in the current climate talks, has already suffered in the past from a lack of understanding and goodwill on the part of the world leaders. A more constructive approach is needed for the transfer of ESTs. But the task is complex, as TT is a very comprehensive process. According to Rubens Ricupero and Carlos Correa:

“There are two relevant categories of knowledge that are essential for economic progress and competitiveness. The first consists of knowledge embodied in machines and equipment which makes it possible to control sophisticated processes for producing goods and services and marketing them at a profit. The other category, to some extent still elusive, consists of tacit knowledge, that is, knowledge embodied in the organizational routines and collective expertise or skills of specific production, management, research and development and marketing. It is the first type of knowledge that people generally have in mind when discussing today’s knowledge-intensive economy and the transfer and diffusion of technology. However, as knowledge becomes a more decisive factor, and a more critical commodity, its acquisition and diffusion will require that the two aspects of knowledge be considered as an integral part of knowledge transfer. This makes the process of technology transfer more than ever a continuous and uninterrupted learning process.”²⁷

²³ Peter K. Yu, “A Tale of Two Development Agendas” (2009) 35 Ohio N.U. L. Rev. 465.

²⁴ “International Code of Conduct on the Transfer of Technology”, December 17, 1985, A/RES/40/184, available at <http://www.un.org/documents/ga/res/40/a40r184.htm> [Accessed March 25, 2012].

²⁵ “Declaration on the Establishment of a New International Economic Order”, May 1, 1974, A/RES/S-6/3201, available at <http://www.un-documents.net/s6r3201.htm>. For a retrospective analysis of the effects of the Declaration, see UNCTAD, “Transfer of Technology” [2001] UNCTAD Series on International Investments Agreements, IIA Issues Paper Series, available at <http://www.unctad.org/en/docs/psiteiid28.en.pdf> [Accessed March 25, 2012].

²⁶ “The activist developing countries’ legislation, which had inspired numerous provisions in the draft code, was called into question by the countries’ own lawmakers and subsequently amended to reflect new economic realities. These trends, which became evident in the early eighties, led most developing countries to lose interest in the code effort.” Susan K. Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (Albany: State University of New York Press, 1998).

²⁷ Rubens Ricupero and Carlos Correa, “Preface” in Surendra J. Patel, Pedro Roffe and Abdulqawi A. Yusef (eds), *International Technology Transfer: The Origin and Aftermath of the United Nations Negotiations on a Draft Code of Conduct* (The Hague: Kluwer Law International, 2001). This broad definition of “technology transfer” draws inspiration from the IPCC vision on TT unanimously recognized by the international community: Technology Transfer is “a broad set of processes covering the flows of know-how, experience and equipment for mitigating and adapting to climate change amongst

TT is a treaty commitment.

While the overall issue of TT, as mentioned above, far outreaches the climate talks and has been the subject of endless discussion in the past, the particularities of the “green challenge” calls for a differentiated treatment of the transfer of ESTs. Indeed, the global commitments of the States (Annex I States)²⁸ to reduce their GHG emissions are enshrined in various multilateral environmental agreements such as the UNFCCC²⁹ (not legally-binding) and the Kyoto Protocol³⁰ (legally-binding). Both instruments emphasize the crucial role of technology-exporter countries in the mitigation of climate change. All in all, TT fell out of the humanitarian discussions to become a real treaty commitment.

In 2007, 15 years after the ratification of the Convention and one year after the entry into force of the Kyoto Protocol, the Expert Group on Technology Transfer (EGTT)³¹ wrote a report regarding the implementation of the Convention by the Member States in which it concluded that “discussions relating to technology transfer in the UNFCCC should evolve to a more practical, result-oriented actions in specific sectors and programs”.³² In other words, the expected results, announced by the international community, with regard to the transfer of ESTs, were far from being attained, and the EGTT, on this occasion, called the group of developed countries to reaffirm their commitments through practical and efficient initiatives.³³

The Bali Plan of Action and Beyond: The call for enhanced action on TT.

As a direct consequence of the 2007 report of the EGTT, the Member States and parties to the UNFCCC gathered in Bali for COP 13 under the Convention and, determined to take their responsibilities, established the renowned “Bali Plan of Action” (BPA). By doing so, they decided to

“launch a comprehensive process to enable the full, effective and sustained implementation of the Convention through long-term cooperative action, now, up to and beyond 2012, in order to reach an agreed outcome and adopt a decision at [COP 15]”.³⁴

The BPA put TT in the spotlight by insisting on the need to

“enhance action on technology development and transfer to support action on mitigation and adaptation” for the benefit of the developing countries. Paragraph 1(b)(ii) emphasized the importance that TT represented in the overall action on mitigation of climate change and stated that such action needed to be “Measurable, Reportable and Verifiable”.

different stakeholders such as governments, private sector entities, financial institutions, non-governmental organizations and research/education institutions”. IPCC *Special Report on Methodological and Technological Issues on Technology Transfer* (Geneva: 2000), available at <http://www.ipcc.ch/pdf/special-reports/spm/srmt-en.pdf> [Accessed March 25, 2012].

²⁸ The Convention divides countries into three main groups according to differing commitments: Annex I, Annex II and Non-Annex I. Annex I Parties include the industrialized countries that were members of the OECD (Organisation for Economic Co-operation and Development) in 1992, plus countries with economies in transition (the EIT Parties), including the Russian Federation, the Baltic States, and several Central and Eastern European States. More information is available at http://unfccc.int/parties_and_observers/items/2704.php [Accessed March 25, 2012].

²⁹ UNFCCC arts 4.1(c), 4.3, 4.5, 4.7, 4.8 and 4.9.

³⁰ Kyoto Protocol art.10.

³¹ The EGTT was established at COP 7, with the objective of enhancing the implementation of art.4, para.5 of the Convention, including by analysing and identifying ways to facilitate and advance technology transfer activities: see <http://unfccc.int/tclear/jsp/EGTT.jsp> [Accessed March 25, 2012].

³² UNFCCC, *Expert Group on Technology Transfer: Five Years of Work* (Bonn: 2007), p.12, available at http://unfccc.int/files/essential_background/background_publications_htmlpdf/application/pdf/egtt_en_070523.pdf [Accessed March 25, 2012].

³³ This assertion must be put into perspective as quite some work has been done by the Global Environmental Facility (GEF) instituted by the UNFCCC (art.11). The GEF “over its 17-years of history, has extensive experience in the transfer of climate change mitigation and adaptation technologies. A total of around 2.5 billion dollars has been allocated to support climate change projects in over 100 countries. These catalytic projects have addressed more than 30 technologies and leveraged 15 billion dollars in co-financing.” Global Environment Facility, *Transfer of Environmentally Sound Technologies: the GEF Experience* (Washington: 2008), available at http://www.thegef.org/gef/sites/thegef.org/files/publication/GEF_TTbrochure_final-lores.pdf [Accessed March 25, 2012].

³⁴ UNFCCC, “Report of the Conference of the Parties on its thirteenth session, held in Bali from 3 to 15 December 2007”, March 14, 2008, FCCC/CP/2007/6/Add.1, available at <http://unfccc.int/resource/docs/2007/cop13/eng/06a01.pdf> [Accessed March 25, 2012].

While para.1(d) called for the Member States to “further complement this by pushing for more effective and enhanced modalities for technology transfer to be agreed upon and implemented as part of the negotiated outcomes of the Bali Action Plan”.³⁵

The BPA raised the awareness of the international community about the need to create clear mechanisms facilitating the flow of green technologies needed in the South. Having this in mind, the Copenhagen Accord in 2009 provided for the establishment of a “Technology Mechanism” (TM) aimed at addressing all aspects of cooperation on technology research, development, diffusion and transfer in accordance with arts 4.1(c), 4.3, 4.5 and other relevant articles of the UNFCCC. Further, the Accord stated that the TM would consist of two components: the “Technology Executive Committee” (TEC) and the “Climate Technology Centre and Network” (CTC&N). The outline and specific functions of the TM were further developed in the text negotiated under the Ad Hoc Working Group on Long-Term Cooperative Action (AWG-LCA) in Copenhagen and during subsequent sessions throughout 2010. In Cancun, the parties agreed on a decision³⁶ consisting of operational provisions (i.e. the establishment of the TM, including the TEC mandate, composition and operationalisation) and process provisions (i.e. a work program for 2011 on unresolved issues). Paragraph 128 of the decision mandated the following COP in Durban, South Africa (held in 2011) to resolve the following: (a) the relationship between the TEC and the CTC&N and their reporting lines; (b) the governance structure and terms of reference for the CTC&N and how the CTC will relate to the Network, drawing upon the results of a workshop authorized by the Cancun decision; (c) the procedure for calls for proposals and the criteria to be used to evaluate and select the host of the CTC&N; (d) the potential links between the TM and the financial mechanism of the Convention; and (e) consideration of additional functions for the TEC and CTC&N. The scene is set but the effective outcome of the Durban conference on TT issues remains uncertain and will need further work in the future.³⁷

IP in a post-Kyoto perspective: The real challenge.

There exist three major factors that need to be tackled when dealing with IP in the context of climate change.

First, IP would not be on the agenda if the developed countries had not failed to fulfil their TT commitments under the UNFCCC and the Kyoto Protocol. Indeed, while developing countries were supposed to overcome (to some extent) the technological divide that separates them from the developed world before the end of the Kyoto Protocol in 2012, much still needs to be done. According to developed countries, patents act as a catalyst for the transfer of technologies and must be promoted internationally to facilitate trade among states. In their view, the TRIPS Agreement is a tool for development. In practice, though, developing countries fail to observe any improvement in the transfer of technologies following the implementation of the TRIPS Agreement and argue in favour of the weakening of the IP system worldwide.

Secondly, the transition period for LDCs under art.66.1 of the TRIPS Agreement is about to expire in 2013. This will bring the obligation for LDCs to come on board and to implement the controversial TRIPS provisions in their national legal order although they are often far from being able to cope with those requirements and even further away from deriving any benefit from those rules.

³⁵ The South Centre, “Accelerating Climate-Relevant Technology Innovation and Transfer to Developing Countries: Using TRIPS Flexibilities under the UNFCCC”, August 2009, SC/IAKP/AN/ENV/1, SC/GGDP/AN/ENV/8, available at http://www.southcentre.org/index.php?option=com_docman&task=doc_download&gid=1692&lang=en [Accessed March 25, 2012].

³⁶ Decision 1/CP.16, “The Cancun Agreements: Outcome of the work of the Ad Hoc Working Group on Long-term Cooperative Action under the Convention (Section IV.B.)”, March 15, 2011, FCCC/CP/2010/7/Add.1, available at <http://unfccc.int/resource/docs/2010/cop16/eng/07a01.pdf#page=2> [Accessed March 25, 2012].

³⁷ Climate Justice Now, “Movement of Technology Mechanism in Durban Outcome”, December 23, 2011, available at <http://www.climate-justice-now.org/movement-of-technology-mechanism-in-durban-outcome/> [Accessed March 25, 2012].

Last but not least, while the last decade witnessed the emergence of new economical powers in the South (China, India and Brazil ahead), the new climate deal that might be ratified by the parties in the coming years (in a post-Kyoto perspective) will, most certainly, include new stringent GHG commitments for Non-Annex I countries. The prospect of being subject to those GHG obligations lead many countries to request that they should at least have access to the most efficient technologies available for doing so. This eventually has prompted a call by the same countries for an in-depth reform of the TRIPS Agreement.

The progressive IP awareness: From Bali to Copenhagen.

The appearance of IP-related issues within the environmental discussions is relatively recent. Until now, there existed no specific references to IP in the various multilateral environmental agreements and, as a result, no clear consensus on how to deal with this matter in the environmental community.³⁸ An OECD study conducted by Keith Maskus in 2010 corroborates this finding by stating that

“to date there is little systematic evidence that patents and other IPRs restrict access to ESTs, which largely exist in sectors based on mature technologies in which there are numerous substitutes among global competitors. This situation may change as new technologies based on biotechnologies and synthetic fuels, which are likely to be more dependent on patent protection, become more prominent.³⁹ At present, however, there is little evidence to support significant limitations on the issuance and use of IPRs in this area. In particular, it is unlikely that an international agreement on a compulsory licensing regime could achieve significant ITT [international technology transfer] benefits, while it may raise considerable costs”.⁴⁰

In 2007, during COP 13 in Bali, a group of countries (China, Indonesia, Cuba, Tanzania and India) requested the parties to put this question on the Agenda in order to assess and further legislate on the role of IP in the overall access, deployment and transfer of ESTs.⁴¹ This claim was supported, at that time, by the European Parliament that passed a French MP’s motion calling for

“a study on possible amendments to the WTO Agreement on Trade Related Aspects of Intellectual Property Rights in order to allow for the compulsory licensing of environmentally necessary technologies”.⁴²

This sudden expression of interest gave rise to a series of negotiations within the AWG-LCA, in the hope of integrating an IP Compromise in the Climate Deal.⁴³ The Group of 77, supported by China, prompted the developed countries to revise the flexible provisions of the TRIPS Agreement on the occasion of the UNFCCC Climate Talks. As a result of this “snowball effect”, Ch.IV of the AWG-LCA negotiating text on “Enhanced Action on Development and Transfer of Technology” was remodelled countless times with the aim of proposing a balanced approach to the delegates for approbation. In Copenhagen, representatives

³⁸ The first reference to IP in a multilateral environmental agreement can be found in Ch.34 of Agenda 21 on “Transfer of Environmentally Sound Technology, Cooperation and Capacity-building”.

³⁹ On this matter, see Jerome Reichman, Arti K. Rai, Richard G. Newell and Jonathan B. Wiener, “Intellectual Property and Alternatives: Strategies for Green Innovation” (2008) Chatham House, Energy, Environment and Development Programme (EEDG), Paper No.08/03, available at http://www.chathamhouse.org/sites/default/files/public/Research/Energy%2C%20Environment%20and%20Development/1208eedp_duke.pdf [Accessed March 25, 2012].

⁴⁰ Keith Maskus, “Differentiated Intellectual Property Regimes for Environmental and Climate Technologies” (2010) OECD, Environment Working Papers No.17, available at <http://dx.doi.org/10.1787/5kmfjwvc83vk-en> [Accessed March 25, 2012].

⁴¹ Sangeeta Shashikant and Martin Khor, “Intellectual Property and Technology Transfer Issues in the Context of Climate Change” (2010) Third World Network, Intellectual Property Rights Series No.14, p.14, available at <http://www.twinside.org.sg/title2/IPR/pdf/ipr14.pdf> [Accessed March 25, 2012].

⁴² “European Parliament Resolution on Trade and Climate Change”, November 29, 2007, 2007/2003 (INI), available at <http://www.europarl.europa.eu/sides/getDoc.do?Type=TA&Reference=P6-TA-2007-0576&language=EN> [Accessed March 25, 2012].

⁴³ In its seventh session, in Barcelona, the AWG-LCA integrated for the first time a sub-section on IP Rights (albeit in brackets) in its negotiated text. From this time being, the IP debate has never left the negotiation table until the recent development in Cancùn. See ss.33-36 of the AWG-LCA negotiating text.

of developing countries took language from the Doha Declaration and made two proposals on this basis: first, “any international agreement on intellectual property shall not be implemented in a manner that limit or prevent any party from taking any measure to address climate adaptation or mitigation”; secondly, “developing countries have the right to make use of the full flexibilities contained in the TRIPS Agreement, including compulsory licenses”.⁴⁴

On the other side, developed countries acknowledged the inefficiencies of the current technology framework and stressed the need for the engagement of the private sector. With regard to IPR, the United States recalled that IPR is “an essential component” in the market of innovation, including green innovation. For that reason, it is important to be clear on IPR costs. In their view, the IPR costs in the energy sector are marginal.⁴⁵ On this matter, a 2006 UNFCCC report on the priority needs and economic barriers to TT for non-Annex I respondents found that IPR is a factor of minimal significance. Other factors, such as a lack of financial resources, high investment costs, subsidies and tariffs were considered greater barriers to accessing technologies.⁴⁶ Moreover, empirical studies showed that competition existed in the market for green technologies and that basic approaches to solving the specific technological problems in ESTs have long been off-patent.⁴⁷ On that basis, the United States and the other major developed countries (the European Union and Japan) advocated for the maintenance of a “status quo” with regard to IP in the climate negotiations. Accordingly, due to the continuous misunderstanding on the role of IP in the transfer of green technology (barrier or incentive?) and the generalized lack of goodwill from all the governments, the delegates left Copenhagen with this issue pending, hoping for a favourable outcome the following year for COP 16 in Cancun.

Box 2: IP chapter in the AWG-LCA negotiating text⁴⁸

Any international agreement on intellectual property shall not be interpreted or implemented in a manner that limits or prevents any Party from taking any measures to address adaptation or mitigation of climate change, in particular the development and enhancement of endogenous capacities and technologies of developing countries and transfer of, and access to, environmentally sound technologies and know-how;

Specific and urgent measures shall be taken and mechanisms developed to remove barriers to the development and transfer of technologies arising from intellectual property rights protection, in particular:

- (a) Creation of a Global Technology Intellectual Property Rights Pool for Climate Change that promotes and ensures access to intellectual property protected technologies and the associated know-how to developing countries on non-exclusive royalty-free terms;
- (b) Take steps to ensure sharing of publicly funded technologies and related know-how, including by making the technologies and know-how available in the public domain in a manner that promotes transfer of and/or access to environmentally sound technology and know-how to developing countries on royalty-free terms;

Parties shall take all necessary steps in all relevant forums to exclude from Intellectual Property Rights protection, and revoke any such existing intellectual property right protection in developing countries and least developed countries on environmentally sound technologies to adapt to and mitigate climate change, including those developed through funding by governments or international agencies and those involving use of genetic resources that are used for adaptation and mitigation of climate change;

Developing countries have the right to make use of the full flexibilities contained in the Trade Related Aspects of Intellectual Property Rights agreement, including compulsory licensing;

⁴⁴ Jayashree Watal, “Trade, Technology and Climate Change”, presentation at the Side Event of the Conference of Copenhagen, Faculty of Law, University of Copenhagen, December 16, 2009, available at http://jura.ku.dk/english/webcast_wto/ [Accessed March 25, 2012].

⁴⁵ The lack of infrastructure is often seen as the main challenge to applying ESTs in developing countries. “Many developing countries simply do not have some of the infrastructure requirements in place to apply promising new technologies. Importation, fabrication and assembly may be quite difficult, for example. Therefore, less-developed countries may tend to implement clean technology in whatever form is readily available—the existence of a patent or a license are likely irrelevant with respect to ultimate value.” Mark V. Muller and Annemarie Meike, “Patents and Licensing as Metrics of Technology Transfer: An Example from Clean Technology”, *Les Nouvelles (Licensing Executives Society International)*, December 2011, pp.319-322.

⁴⁶ UNEP-EPO-ICTSD, “Patents and Clean Energy” (2010), p.20.

⁴⁷ Barton, “Intellectual Property and Access to Clean Energy Technologies in Developing Countries” (2007) ICTSD Trade and Sustainable Energy Series, Issue Paper No.2.

⁴⁸ AWG-LCA negotiating text, twelfth session, Tianjin, October 4-9, 2010, FCCC/AWGLCA/2010/14, available at <http://unfccc.int/resource/docs/2010/awglca12/eng/14.pdf> [Accessed March 25, 2012].

The Technology Executive Committee shall recommend to the Conference of the Parties international actions to support the removal of barriers to technology development and transfer, including those arising from intellectual property rights.

IP kicked out of the climate deal in Cancun.

In the run-up to COP 16, and in reaction to the agitation around IP in Copenhagen, both the United States and the European Union made it clear that they would not agree on any UNFCCC decision that would interpret or weaken the international IPR regime; it is a red line for them.⁴⁹ In their view, IPR is not a barrier to TT, but on the contrary a pre-requisite for innovation. This vision goes in conjunction with the concept of “green growth” that is abundantly used in the developed countries and that induces the protection of green jobs while promoting the creation and diffusion of environmentally-sound inventions.⁵⁰ In this vein, three US Congressional bills expressly prevented the US administration to relax IPR rules or enforcement in the global climate talks, in line with the US Chamber of Commerce policy.⁵¹ The latter, in a letter to the President of the European Commission, M. José Manuel Barroso, urged the European Union to follow its path and to join their forces in order to oust the G77 proposal that was on the table.⁵² Additionally, the unconditional support of the developed countries to the patent system coupled with their commitment to dramatically reduce their emissions of GHG gave birth to a so-called “accelerated procedure” for green inventions in various parts of the world, with the United States and the United Kingdom leading.⁵³ The fast tracking of green invention reflects the prevailing ideology in the developed countries: the patent system, when appropriately applied, is an inescapable tool to promote, develop and transfer green technologies throughout the world.

Are the TRIPS flexibilities sufficient or is there a need for special rules in the context of ESTs?

Article 27 of the TRIPS Agreement states “patents shall be available for any inventions . . . in all fields of technology”, thus including the field of green technologies. While being neutral at first sight, some observers from the South have argued that art.27 unjustifiably impedes the access, deployment and transfer of clean technology contrary to the objective of “widest possible cooperation” required by the UNFCCC

⁴⁹“Joint Resolution of BUSINESS EUROPE, IIPPF [International Intellectual Property Protection Forum, Japan] and the Global Intellectual Property Center [US] on Climate Change, Technology Transfer and Intellectual Property Rights”, September 28, 2009, available at <http://www.thecied.org/files/2010/10/FinalJointGreenTechnologiesClimateChangeStatementSept2809.pdf> [Accessed March 25, 2012].

⁵⁰ Copenhagen Economics, *Clean Technology and European Jobs* (Copenhagen: 2009), study prepared for the Coalition for Innovation, Employment and Development, available at <http://www.thecied.org/files/2010/10/CleanTechandEuroJobsFullReportFINAL1.pdf> [Accessed March 25, 2012]. See also Garten Rotkopf, *Intellectual Property Protection and Green Growth: Analysis and Implications for Climate Negotiations* (Washington: 2009), report for the Global Intellectual Property Center, available at http://www.thecacp.org/sites/default/files/reports/documents/gartenrothkopf_ipr_greengrowth_0.pdf.

⁵¹“Of concern are three laws: The American Clean Energy and Security Act 1978 (amended 2009), the Foreign Operations and Related Programs Appropriations Act 2010, and the Foreign Relations Authorizations Act for fiscal year 2010 and 2011, recently approved by the House of Representatives and pending in the Senate.” Sangeeta Shashikant, “Climate-Technology Protectionism and IPRs: Three US Congress Bills Prevent the US Administration from Agreeing to relax IPR Rules or Enforcement in the Global Climate Deal, Thus Posing Barriers to Technology Transfer” (2009) 40 *South Bulletin* 10, available at http://www.southcentre.org/index.php?option=com_content&task=view&id=1086&Itemid=279 [Accessed March 25, 2012].

⁵²“Clean technology, moreover is key to European economic recovery, growth and jobs. Indeed, in your recently announced ‘Political guidelines for the next Commission’ you argue that ‘first-mover advantages can be gained by exploiting the potential of EU environmentally-friendly industries, services and technology through fostering their uptake by enterprises, especially [small and medium enterprises], and designing the appropriate regulatory environment.’ This can only occur if the incentives to innovate in this field are fostered and if IP rights are effectively protected.” American Chamber of Commerce to the European Union (AmCham EU), “Position Letter on Protection of IPR in Climate Change-Related Technologies”, September 29, 2009, available at http://www.amchameu.eu/Documents/DMXHome/tabid/165/Default.aspx?Command=Core_Download&EntryId=4467 [Accessed March 25, 2012].

⁵³ These procedures include the “Accelerated Examination” in the United States (<http://www.uspto.gov/patents/process/file/accelerated/index.jsp>) and the “Green Channel” in the United Kingdom (<http://www.ipo.gov.uk/p-pn-green.htm>). Similar initiatives have been launched in Japan (http://www.jpo.go.jp/torikumi/t_torikumi/souki/greensouki.htm), South Korea (http://hanyanglaw.com/eng/news/newsletter_preview.asp?curPage=1&ca=116), Australia (http://www.ipaustralia.gov.au/patents/process_expedited.shtml), Israel (http://www.israel-patents.co.il/index.php?page_id=272) and Canada (<http://www.cipo.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr02462.html>) [Accessed March 25, 2012].

in its Preamble.⁵⁴ They claim that IP is a barrier that must be overcome by relinquishing the rights of the IP holder in the public domain. The positive or negative effect of the TRIPS framework rules is thus under discussion.

TRIPS Agreement v TT.

The TRIPS Agreement, in its attempt to set a minimum standard of IP protection, took care to not focus excessively on the protection and enforcement of IPR, but tried to maintain an eye on the promotion of other public policy objectives, such as the transfer of technology. This approach was indeed necessary in order to avoid sub-optimal situations where the scope or the level of protection of IP is such that it may stifle innovation or make access to knowledge more difficult or costly. The so-called “balancing feature” of the TRIPS Agreement stems principally from arts 7 and 8(2), both of which appreciate the protection of IP in the light of the TT requirement.⁵⁵ Furthermore, art.66.2 imposes explicit obligations on the developed nations aiming at facilitating the transfer of technology to LDC Members via a scheme of incentives directed to their national industry “in order to enable them to create a sound and viable technological base”. In 2003, following the repeated criticisms made by the LDCs on the misuse or insufficient use of art.66.2 by the developed countries,⁵⁶ the TRIPS Council took a Decision on the Implementation of Article 66.2 of the TRIPS Agreement.⁵⁷ This document specifically required developed country members to submit

“full reports on activities undertaken to meet the obligations [of Article 66.2] every three years, beginning in late 2003, with annual updates to be provided in intervening years”.⁵⁸

Unsurprisingly, while very persuasive in theory, some observers have stressed the considerable gap that exists between the intentions expressed by the parties and the resulting actions.⁵⁹ Last but not least, the “exhaustion principle” set forth in art.6 of the TRIPS Agreement may aid or hinder the transfer of technology depending on the model the Members may adopt. The “universal exhaustion scheme” nurtures the public domain on a global scale and is actively promoted by the developing countries. Whereas the “territorial exhaustion regime” extensively limits the scope of this principle and is vigorously defended by international corporations, and thus developed countries, they fear the abusive use of parallel imports in the first scenario. In between these two factions are the calls to establish a system of “regional exhaustion” that would reconcile the two opposite views mentioned above.

⁵⁴ The preamble of the UNFCCC notes: “[T]he global nature of climate change calls for the widest possible cooperation by all countries and their participation in an effective and appropriate international response, in accordance with their common but differentiated responsibilities and respective capabilities and their social and economic conditions.”

⁵⁵ Article 7 of the TRIPS Agreement states that the objective of the protection and enforcement of IP should be to 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”. Article 8 also recognizes that measures “may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which ... adversely affect the international transfer of technology”.

⁵⁶ “Many developing countries have stressed the difficulties that they have faced in putting into practice the massive legislative changes required by the TRIPS Agreement, and the little support received from developed countries. In this context, the issue of the implementation of Article 66.2 to the benefit of LDCs has been raised by Egypt (WT/GC/W/109), India (WT/GC/W/147) and the African Group, which noted that no concrete steps have been demonstrated by developed countries with regard to the fulfilment of their obligations under that article (WT/GC/W/302).” Carlos Correa, “Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries” (1999) 2(6) *Journal of World Intellectual Property* 939.

⁵⁷ See Council for Trade-Related Aspects of Intellectual Property Rights, “Implementation of Article 66.2 of the TRIPS Agreement—Decision of the Council for TRIPS of February 19, 2003”, IP/C/28, available at http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm [Accessed March 25, 2012].

⁵⁸ Suerie Moon, “Meaningful Technology Transfer to LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2” (2011) CTSD Programme on Innovation, Technology, and Intellectual Property, Policy Brief No.9, p.2, available at <http://ictsd.org/downloads/2011/05/technology-transfer-to-the-lDCs.pdf> [Accessed March 25, 2012].

⁵⁹ “The country reports do describe a range of programmes that certainly may benefit LDCs. However, they do not provide sufficiently detailed data to determine whether article 66.2 led to any additional incentives beyond business as usual foreign aid”. See Suerie Moon, “Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999–2007)” (2008) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Policy Brief No.2, p.8, available at http://www.unctad.org/en/docs/iprs_pb20092_en.pdf [Accessed March 25, 2012].

The in-built flexibilities of the TRIPS Agreement.

Around 75 per cent of the parties to the UNFCCC are also parties to the TRIPS Agreement. This sole finding explains why so much emphasis has been put on the flexible provisions of the TRIPS Agreement in the climate negotiations. Generally speaking, some tend to consider that the TRIPS Agreement found quite a good balance between the obligations it imposed on the Member States and the leeway it conceded to them. On the one hand, the TRIPS Agreement instituted minimum standards of IP protection applicable to all Member States. On the other hand, some provisions, best known as the “TRIPS flexibilities”, allow them to frame their IP national regimes in accordance with their public policy objectives and priorities—in this case, the protection of the environment. Nevertheless, the recourse to these flexibilities has not proven easy in the past,⁶⁰ and the WTO-TRIPS panels have yet to clarify the scope of these flexibilities.⁶¹

There exist three main “flexibilities” in the TRIPS Agreement, namely: (a) the “morality clause”; (b) the “unauthorized use exception”; and (c) the “compulsory license”.

(a) Article 27.2 — the “morality clause”.

This provision allows the Member States to exclude from patentability, within their borders, every invention that might cause some “serious prejudice to the environment”. While very useful at first sight, this flexibility is too vague, for now, to be effectively put in practice because it fails to specify the level of prejudice that might be actual or potential, as well as the degree of seriousness required to take action against an inventor. This loophole stems from the fact that this provision has never been tried by a WTO panel, leaving the Members in their uncertainty as to the risk of implementing it the wrong way.⁶² Beyond that assertion, patent offices of the Member States that would successfully incorporate the content of art.27 into their own legal orders would have the opportunity to exclude CO₂ emitting inventions on this sole basis.⁶³ It must be noted that this alternative is actively promoted by the Group of 77 and China within the climate talks.⁶⁴

(b) Article 30 — the “unauthorized use exception”.

Article 30 of the TRIPS Agreement highlights the fact that the exclusive rights conferred to the patent owners are not absolute by nature and that WTO Members may provide “limited exceptions” to them. This means that countries may, under certain circumstances, automatically allow the use of the patented

⁶⁰ ICTSD, “Climate Change, Technology Transfer and Intellectual Property Rights”, presentation at the Trade and Climate Change Seminar, June 18–20, 2008, Copenhagen, Denmark, p.7, available at http://www.iisd.org/pdf/2008/cph_trade_climate_tech_transfer_ipr.pdf [Accessed March 25, 2012].

⁶¹ How far-reaching the flexibilities are in practice has only been tried in a few cases. The WTO-TRIPS panels have rather confirmed the scope and strength of IP right. For more information, see Bruno de Vuyst, Alea M. Fairchild and Gunther Meyer, “Exceptions to Intellectual Property Rights: Lessons from WTO-TRIPS Panels” (2003) 10(4) *Murdoch University Electronic Journal of Law*, available at http://www.murdoch.edu.au/elaw/issues/v10n4/meyer104_text.html [Accessed March 25, 2012].

⁶² The EPO, on the other hand, in its role of the watchman of the European Patent Convention (EPC), has already been confronted several times with disputes where environmental considerations took the precedence over the rights of the patent owner in accordance with art.53(a) of the Convention. In *Plant Cells/Plant Genetic Systems*, it asserted that “applying these principles to global warming, it could mean that the cost-benefit analysis test could be used only if there is evidence that a specific invention causes actual damage or disadvantage to the environment. In that case, if the risk outweighs its benefit(s) to society, then it should not be patentable under Article 53 (a) of the EPC ... but only to the extent that the damage is ‘sufficiently substantiated at the time the EPO makes its decision to revoke the patent’”. *Plant Cells/Plant Genetic Systems* (T-356/93) [1995] OJ EPO 545.

⁶³ Please note that the requirement of seriousness will be appraised in significantly differing ways depending on the interpretation advanced by the Members: A broad view would lead the Member States to exclude from patentability ANY inventions that emit CO₂, while a more restrictive and reasoned view would encourage the States to make a “cost-benefit analysis” in terms of the value of the invention for society and the level of CO₂ emitted. The last one seems more appropriate and was shared by the EPO on several occasions. Estelle Derclaye, “IP and Global Warming” (2008) 12(2) *Marq. Intell. Prop. L. Rev.* 270.

⁶⁴ See §.13 of the Copenhagen version of the AWG-LCA negotiating text: “Parties shall take all necessary steps in all relevant forums to exclude from Intellectual Property Rights protection ... in developing countries and least-developed countries on environmentally sound technologies to adapt to and mitigate climate change”. UNFCCC, “Report of the Ad Hoc Working Group on Long-term Cooperative Action under the Convention on its eighth session, held in Copenhagen from 7 to 15 December 2009”, FCCC/AWG/LCA/2009/17, available at <http://unfccc.int/resource/docs/2009/awg/lea/eng/17.pdf> [Accessed March 25, 2012].

invention by a third party without consent of the patent holder. An example is provided by the “experimental use exception”, which permits use of the patented invention for research or experimental purposes by parties other than the patent owner. This exception, which has been incorporated in most European patent laws, illustrates the latitude conferred by the TRIPS Agreement. But it might not be helpful for developing countries as it presupposes that there is some local capability in the technological field. This might not be the case for all ESTs and other difficulties might occur: even if they can be locally produced in the South, there might be some bottlenecks in the technology or some components which require more sophisticated processes that are not available outside a few developed countries. For instance, the basic technology for solar panels is quite simple and no longer protected by patents, but there might be a bottleneck as the process for enriching silicium needed for the solar cells is still very complex and only a very few companies can efficiently perform this.⁶⁵

(c) Article 31 — the provision on “compulsory license”.

This provision covers various situations where the patent owner has expressly refused to license its invention to a third party that “has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time”. In this situation, art.31 requests the Member State to provide for a mechanism specifically designed to grant compulsory licences on certain conditions—conditions left to the discretion of the States. Consequently, by leaving to the States the latitude to define the grounds for which a compulsory licence could be granted as well as to determine what constitutes national emergency or other circumstances of extreme urgency, this provision provides technology-dependent nations with a significant means to gain access to patented ESTs. However, the implementation of the compulsory license scheme has proven to be very controversial in the past and has encountered vivid reactions from the European Union and the United States in the context of climate change negotiations.⁶⁶ Advocates of this corrective mechanism argue that compulsory licensing is a common practice in many countries; they highlight the fact that the United States has various provisions in its own legislation,⁶⁷ which have the same effect as a compulsory license. The same mechanism is also enshrined in various European laws.⁶⁸ One of the myths defended by those advocates and some countries of the South is that “technology transfer can occur in a one way flow”,⁶⁹ referring to the assumption that the removal of the alleged IP barrier would extensively foster the transfer of ESTs. Under this view, IPRs obstruct the access to green technologies and the urgency of the situation calls for the application of compulsory licenses. This vision has been translated into the wording of para.13 of the AWG-LCA negotiating text: “Developing countries have the right to make use of the full flexibilities contained in the TRIPS Agreement, including compulsory licensing” (see box p.12). Nevertheless, compulsory licensing is not necessarily the right solution because ESTs are capital and

⁶⁵ Arnaud de la Tour, Matthieu Glachant and Yann Ménière, “Innovation and International Technology Transfer: The Case of the Chinese Photovoltaic Industry” (2010) CERNA, Working Paper Series No. 2010-12, p.14, available at http://www.cerna.enscm.fr/images/Documents/WP/cerna_wp201012.pdf [Accessed March 25, 2012].

⁶⁶ Business Europe, IIPPF, and the US Chamber of Commerce, “Joint Resolution of Business Europe, IIPPF, and the US Chamber of Commerce on Restrictions of IP rights and Compulsory Licensing”, December 9, 2008, available at <http://www.jetro.go.jp/theme/ip/iippf/pdf/press081222.pdf> [Accessed March 25, 2012].

⁶⁷ The US Clean Air Act (42 U.S.C. s.7608) specifies that the United States can require the owner of a patented technology necessary to enable another party’s compliance (i.e. technology needed to meet agreed standard) to license the technology in exchange for a reasonable royalty set by a federal court. The same way, the “march-in rights” disposition under the Bayh-Dole Act (35 U.S.C. s.203) provides that the government may, under a set of specific circumstances, march in and take over rights from the patent holder, which developed a drug, device, therapy, or technology using government funds.

⁶⁸ “Compulsory licensing is permitted in Europe (called ‘public interest’ compulsory license) but there are no recorded examples of its use, as it is generally regarded as a ‘nuclear option’ by both governments and business, who will come to an agreement without its use being invoked.” Ian Harvey, “Intellectual Property Rights: The Catalyst to Deliver Low Carbon Technologies” (2009) The Climate Group, Braking the Climate Deadlock, Briefing Paper, available at <http://www.theclimategroup.org/assets/files/Intellectual-Property-Rights.pdf> [Accessed March 25, 2012].

⁶⁹ Cynthia Cannady, “Access to Climate Change Technology by Developing Countries: A Practical Strategy” (2009) ICTSD Intellectual Property and Sustainable Development Series, Issue Paper No.25, available at <http://ictsd.org/i/publications/58385/> [Accessed March 25, 2012].

labour intensive, and a lot of transformations—in terms of capacity building. for example—should happen before some ESTs can be transplanted and work properly. Similarly, compulsory licensing only applies to patented technology, but in many areas, one knows that the real value might reside in the know-how surrounding the invention. Imposing a compulsory licence might thus sever the access to this know-how, potentially limiting the usefulness of the technology. The ready-made mechanism of compulsory licensing, which might be attractive at first sight, is thus not the panacea, and its overall efficiency in promoting a true transfer of technology remains unlikely.⁷⁰

ESTs are very different from pharmaceuticals.

Member States of the South have advocated the amendment of the TRIPS Agreement in the same way as for the access to medicine through the Doha Declaration.⁷¹ The effectiveness of the new compulsory licensing schemes for certain medicines following the Doha Declaration is not yet clear—this is a complex issue that goes well beyond the present contribution. A transposition of compulsory licensing in the context of ESTs raises even more problems. The products (medicines v ESTs) and the markets have distinctive features that may call for a different treatment. Let us just point to some of the differences. Unlike pharmaceuticals, climate technologies are not a stand-alone product, they are a “bulk product”. Contrary to the “single-supply business model” that predominates in the pharmaceutical market where small volume pills may be sent worldwide from one single place of production, climate technology has to be done locally in cooperation with local industries. ESTs generally form part of a larger product or unit of operation such as a car, a power station or even the energy grid which integrates various elements that should best work together. The transfer of ESTs is thus not likely to produce the expected results if the larger product or unit cannot be adequately produced or replicated. For many ESTs, the technology is already in the public domain, and patents are not relevant at all. For patented technologies, it is likely that patents do not exist in many countries—in particular, in less developed countries (contrary to the pharmaceutical sector where innovative substances tend to be patented in many countries). Relying on compulsory licenses for ESTs is thus not likely to produce a “quick fix” to the problems for many reasons.

The concept of special and differential treatment.

While the TRIPS flexibilities outlined above are available to all countries, the special and differential treatment provisions (SDTs) offer alternatives specifically designed for the developing and least developed country members and only available to them. The idea behind the “differential and more favourable treatment provisions” that transcend both the GATT, the WTO Agreements and many multilateral environmental agreements (including the UNFCCC and the Kyoto Protocol)⁷² is that the developing countries and LDCs should benefit from a different set of rules allowing them to reach a sufficient level

⁷⁰ Maskus, “Differentiated Intellectual Property Regimes for Environmental and Climate Technologies” (2010) OECD, Environment Working Papers No.17, pp.26–27.

⁷¹ Very recently, India contended that “[a]dequate commitments are also required in order to ensure that IPRs in themselves do not become a barrier for transfer of technology ... To give effect to this commitment especially in the context of critical EST required by a WTO Member, innovative mechanisms would need to be conceptualized to allow for compulsory licensing for export of such technology to another Member. The Doha Declaration on Public Health could provide the basis of one such innovative mechanism.” WTO Committee on Trade and Development, “WTO Negotiations on Environmental Goods and Services: Addressing the Development Dimension for a ‘Triple-Win’ Outcome: Communication from China and India”, April 15, 2011, TN/TE/W/79.

⁷² Principle 7 of the Rio Declaration states: “States shall cooperate in a spirit of global partnership to conserve, protect and restore the health and integrity of the Earth’s ecosystem. In view of the different contributions to global environmental degradation, States have common but differentiated responsibilities. The developed countries acknowledge the responsibility that they bear in the international pursuit of sustainable development in view of the pressures their societies place on the global environment and of the technologies and financial resources they command.” Similarly, the Preamble of the UNFCCC states that Parties should act to protect the climate system “on the basis of equality and in accordance with their common but differentiated responsibilities and respective capabilities”. Krishna Ravi Srinivas, “Climate Change, Technology Transfer and Intellectual Property Rights” (2009) Research and Information System for Developing Countries, Discussion Paper, p.29, available at http://www.ris.org.in/images/RIS_images/pdf/dp153_pap.pdf [Accessed March 25, 2012].

of economic development before being subject to stringent international obligations. Applied to the TRIPS Agreement, this would mean that developing countries and LDCs-friendly provisions should adequately balance the rights and obligations applicable to them with their less favourable economic situation. The TRIPS Agreement contains four references to the SDTs that can be regrouped under two headings: first, the extension of the implementation periods (called the “transition period”—arts 65 and 66.1 of the TRIPS Agreement) for the above-mentioned countries; secondly, the various commitments by developed countries to promote TT and technical and financial assistance to developing countries (arts 66 and 67 of the TRIPS Agreement).

Box 3: Summary of the provisions contained in the TRIPS Agreement for the differential and more favourable treatment of developing countries and LDCs⁷³

Article	Provision for developing country members	Provision specifically for least-developed country members
Preamble	Recognition that objectives of national systems of IP protection include developmental objectives.	Recognition of special interest of LDCs in respect of maximum flexibility in implementation of domestic regulations in order to enable the creation of a sound technological base.
65.2 and 65.4	Four year transitional period additional to one year available to all original members (applicable to most but not all TRIPS obligations). Further five year extension in cases where Agreement requires extending product patent protection to areas of technology not so protectable by end of general transition period.	
66		Delay for up to 10 years for most TRIPS obligations. Possibility of extension following duly motivated request.
66.2		Developed country members to provide incentives to enterprises and institutions in their territories for purpose of encouraging transfer of technology to LDCs.
67	Provision by developed members of technical and financial cooperation.	

The SDTs remind us that different levels of development call for adequate and differentiated level of IP protection. To be fair, the TRIPS provisions should have taken into account the specificities of each Member States before determining the length of the “transition period” while, at the same time, creating a solid and effective framework for the “technical and financial cooperation” supposedly coming from the developed countries.⁷⁴ In the climate change context, it is no longer the idea of development that justifies such SDTs, but more the observation that countries have “common but differentiated responsibilities” that justify the setting up of different stages of GHG commitments. Unlike in the TRIPS-alike debate, the interests at stake are crucial for every country; it is no longer about an asymmetrical balance of economic and political power that distorts the rules of the game. As a matter of fact, while the transfers of ESTs will be, unsurprisingly, the cornerstone of any climate deal in the near future, such transfers are, through the “Mechanisms” instituted by the Kyoto Protocol, not only environmental-friendly,

⁷³ World Trade Organization, “Annex II: Summary of Provisions Contained in the Uruguay Round Agreements for the Differential and More Favourable Treatment of Developing and Least Developed Countries”, available at http://www.wto.org/english/tratop_e/devel_e/annexii_e.doc [Accessed March 25, 2012].

⁷⁴ Constantine Michalopoulos, “Special and Differential Treatment of Developing Countries in TRIPS” (2003) Quaker United Nations Office, International Affairs Programme, TRIPS Issues Paper No.2, available at <http://www.quno.org/geneva/pdf/economic/Issues/Special-Differential-Treatment-in-TRIPS-English.pdf> [Accessed March 25, 2012].

but also, and mainly, commercially viable. Indeed, each time a green technology is transferred through these mechanisms, a reward, in terms of GHG emissions (e.g. “carbon credit”), is given to the Member State involved.⁷⁵

Therefore, aside from the stringent commitments imposed on the historically most polluting nations, there is room for SDT measures that would favour both the technology-dependent nations by way of transfer of ESTs and the transferors through the decrease of the GHG commitment. With this in mind, the delegates of the States could, on the occasion of the UNFCCC Climate Negotiations, draw inspiration on the TRIPS Agreement and discuss further SDTs with regard to IP and the transfer of ESTs. This, in turn, would allow some differentiation in the global IP framework at a time when the adverse effect of the TRIPS harmonization are experienced in various parts of the world in a multi-disciplinary landscape (public health, environment, and traditional knowledge). More importantly, in a post-2012 scenario, the developing countries and the LDCs, which were previously exonerated from any GHG commitments, will be asked to participate in the global effort to mitigate the effect of climate change. All in all, there is an urgent need to create IP-friendly mechanisms for the benefit of the technology-dependent nations in order to allow the leapfrogging of various stages of technological evolution (i.e. get access directly to the most advanced ESTs). We might question why an IP-related tool is not yet attached to the existing “Mechanisms” in order to bring back the cost of IP to the IP-exporter countries that would earn GHG credit from the operation while opening new markets to their national industries.⁷⁶

Prospects: Can we expect something on IPR from the COP in the future?

COP 15: “Hopenhagen” and the onset of climate Realpolitik.

The presence and personal investment of the world leaders in the decision-making process at the “Copenhagen Summit” featured the international recognition and consecration of global warming as an inescapable challenge. Many Heads of State realized that

“there is more at stake at Copenhagen than the climate.... [T]his is the most important forum in several years. What seems to be an environment discussion is more a political and economical negotiation”.⁷⁷

The many Head of States have planted, in Copenhagen, the foundations of a long-term oriented agreement on the basis of which further commitments can be grafted. Indeed, even if the “Copenhagen Accord” had no legally binding force for the States because it only constitutes a “statement of intent”, it was the first time that the issue of climate change outreached the level of NGOs or delegates of the governments.

⁷⁵ UNFCCC, “The Mechanisms under the Kyoto Protocol”, available at http://unfccc.int/kyoto_protocol/mechanisms/items/1673.php [Accessed March 25, 2012].

⁷⁶ It must be noted that this idea is in line with the creation of a “Green Technology Package Programme” proposed by the Japan Intellectual Property Association (JIPA), under the auspices of the World Intellectual Property Organization (WIPO)—also known as the “WIPO Green Programme”. This project has been presented on the occasion of the Conference on Innovation and Climate Change organized by WIPO in Geneva on July 11–12, 2011 (<http://www.wipo.int/climate/en/>). The basic idea is to give carbon credit to country members that would, in exchange, partially finance the acquisition of IP licenses by developing country companies to developed country licensors, the latter obtaining the full royalty prices ultimately through tax reductions. For more information, see Dr Rama Rao, “WIPO Green: the Sustainable Technology Exchange”, presentation at the Conference on IP and Green Tech: “Accelerating Commercialization & Promoting Global Innovation”, organized by the USPTO and Diplomacy Matters Institute, Alexandria, US, June 1, 2011, available at http://www.diplomacymatters.org/programs/ip_greentech/index.php [Accessed March 25, 2012].

⁷⁷ Morten Andersen, “Copenhagen Was More Than the Accord”, available at <http://www.denmark.dk/en/menu/Climate-Energy/COP15-Copenhagen-2009/Selected-COP15-news/Copenhagen-was-more-than-the-accord.htm> [Accessed March 25, 2012].

COP 16, COP 17: The TM and the Green Climate Fund, no mention of IP.

From the time the Copenhagen Accord was decided, the setting up of the financial mechanism and a parent institution on TT and development were at the heart of the many discussions that animated debates in the various climate fora throughout the world. During 2010, two meetings took place in Bonn⁷⁸ where

“it appeared that some issues—such as REDD-Plus, the Technology Mechanism, Capacity Building and, to some extent, financing—were coming together faster than others and some countries consider these could be early harvest items for Mexico, should parties then not be ready for a full package deal”.⁷⁹

The two Bonn meetings served as a barometer to assess the feasibility of the above-mentioned treaty project in the short-term. Yvo de Boer, the former UNFCCC chief, invited “countries to put their money where their mouths are”.⁸⁰ Having this in mind, it was crucial to reach an agreement in Cancun on how to operate what had already been decided, but not unanimously approved in Copenhagen with regard to those two institutions. The “Cancun Accord”, by setting aside the many contentious issues (IP was one of them), resolved to focus exclusively on short-term practical achievements that would propel the negotiations on a higher stage. Again, according to Yvo de Boer, “developing countries especially would want to see what an agreement would entail for them before they are willing to turn it into a legally-binding treaty”. This statement was further reflected in the outcomes of the Durban Agreement the following year, which included a decision by parties to adopt a universal legal agreement on climate change as soon as possible, and no later than 2015. Moreover, in Durban, parties agreed on key arrangements to make the TM fully operational in 2012.⁸¹

IP in the future: A dormant opposition on the lookout for a call for justice.

TT and the protection of IPR have, from the outset, been associated with the climate change negotiations. The Bali Plan of Action, which called for enhanced action on TT, already resulted in the creation of the IP minimalist movement that asserts the need for a more adequate IP regime in relation to climate issues. However, the recurrent criticisms of various groups of countries (Group of 77, BASIC countries⁸² and BRIC countries) have not led so far to concrete references to IP in the numerous texts that have been negotiated by the delegates of the Parties to the UNFCCC. As time goes by, *from Bali to Copenhagen, from Copenhagen to Cancun, via Bonn*, there are no apparent signs of a solution to the IP debate. Bolivia, one of the strongest opponents to the inequities stemming from the TRIPS Agreement, voiced strong objections in Cancun and challenged the UN Climate Deal on the grounds that it was not encouraging the spread of clean technology by weakening IP rights.⁸³ By standing alone and strongly insisting on the weakening of the IP system as a prerequisite to any climate deal, Bolivia made sure that IP will not be so easily removed from the UN Climate Agenda.⁸⁴ A few months later, India followed Bolivia’s lead and

⁷⁸ Bonn Climate Change Talks, April 9–11, 2010, available at http://unfccc.int/meetings/intersessional/bonn_10/items/5533.php [Accessed March 25, 2012]; Bonn Climate Change Talks, May 31–June 11, 2010, available at <http://unfccc.int/meetings/sb32/items/5573.php> [Accessed March 25, 2012].

⁷⁹ ICTSD, “Climate Deal in Cancun in Question as Bonn Gets Underway”, *Bridges Trade BioRes*, May 31, 2010, available at <http://ictsd.org/i/trade-and-sustainable-development-agenda/76950/> [Accessed March 25, 2012].

⁸⁰ ICTSD, “Climate Deal in Cancun in Question as Bonn Gets Underway”, *Bridges Trade BioRes*, 2010, p.195.

⁸¹ UNFCCC, “Outcome of the Work of the Ad Hoc Working Group on Long-term Cooperative Action under the Convention”, Draft decision [–/CP.17], available at http://unfccc.int/files/meetings/durban_nov_2011/decisions/application/pdf/cop17_lcaoutcome.pdf [Accessed March 25, 2012].

⁸² BASIC countries refer to the combination of Brazil, South Africa, India, and China.

⁸³ Other countries, such as Venezuela, Ecuador and Cuba, first supported this vision, but backed down at the last moment because they realized they were standing in the way of a historic agreement. Simon Crompton, “Bolivia Rejects Cancun Deal on IP Grounds”, *Managing IP*, December 15, 2010, available at <http://www.managingip.com/Article/2737358/Bolivia-rejects-Cancun-deal-on-IP-grounds.html> [Accessed March 25, 2012].

⁸⁴ See the speech made by Ambassador Pablo Solon of the plurinational State of Bolivia at the Cancun Conference, December 4, 2010, available at <http://boliviaun.net/cms/?p=1889> [Accessed March 25, 2012].

issued a proposal for the inclusion of additional agenda items in the provisional agenda of COP 17, including IP-related items such as the treatment and delivery of climate technologies and their IPRs as public good.⁸⁵

To conclude, although it seems very unlikely that a decision on the role of IP in the transfer of ESTs will be adopted in the short term (COP 18 in Qatar in 2012), this issue will most certainly remain the subject of a series of informal meetings in the future. We have barely seen the tip of the iceberg. IP and TT must go hand in hand in the climate discussion.

⁸⁵ UNFCCC, "Proposals by India for inclusion of additional agenda items in the provisional agenda of the seventeenth session of the Conference of the Parties (item 11: Accelerated access to critical mitigation and adaptation technologies and related intellectual property rights)", September 21, 2011, FCCC/CP/2011/INF.2, available at <http://unfccc.int/resource/docs/2011/cop17/eng/inf02.pdf> [Accessed March 25, 2012].

Patents for Humanity

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☞ Developing countries; Humanitarian aid; Intellectual property; International law; Patents; Pharmaceuticals; United States

This article evaluates two policy initiatives by the United States Government to address access to essential medicines—Priority Review vouchers and “Patents for Humanity”. Such proposals are aimed at speeding up the regulatory review of inventions with humanitarian uses and applications by the United States Food and Drug Administration, and the United States Patent and Trademark Office. It is argued that such measures fall short of international standards and norms established by the World Intellectual Property Organization Development Agenda 2007; the World Trade Organization’s Doha Declaration on the TRIPS Agreement and Public Health 2001 and the WTO General Council Decision of August 30, 2003; and the World Health Organization’s declarations on intellectual property and public health. This article concludes that there is a need for broader patent law reform in the United States to address matters of patent law and public health. Moreover, there is a need to experiment with other, more promising alternative models of research and development – such as medical innovation prizes, a Health Impact Fund, the Medicines Patent Pool, and Open Source Drug Discovery.

Introduction

The topic of intellectual property (IP) and access to essential medicines is a large field of jurisprudence, policy-making, and scholarly work.¹ There remain fiercely contested debates over patent law, public health, and access to essential medicines in a number of international fora—such as the World Intellectual Property Organization (WIPO),² the World Trade Organization (WTO)³ and the World Health Organization (WHO).⁴

In 2011, the Delegation of South Africa put forward a submission on behalf of the African Group and the Development Agenda Group to the WIPO Standing Committee on Patents.⁵ The submission emphasized:

“The issue of patents and its impact on public health has been the subject of discussion in many fora. In 2003, the 56th World Health Assembly of the World Health Organization (WHO) had urged Member States ‘to reaffirm that public health interests are paramount in both pharmaceutical and

¹ For an overview of the area, see Frederick Abbott and Graham Dukes, *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow’s World* (Cheltenham: Edward Elgar, 2009); Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (eds) *Incentives for Global Public Health: Patent Law and Access to Medicines* (Cambridge: Cambridge University Press, 2010); Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford: Oxford University Press, 2011); Duncan Matthews, *Intellectual Property, Human Rights and Development* (Cheltenham: Edward Elgar, 2011).

² *World Intellectual Property Organization Development Agenda 2007*, available at <http://www.wipo.int/ip-development/en/agenda/> [Accessed March 25, 2012]. For commentary, see Jeremy de Beer (ed.), *Implementing the World Intellectual Property Organization’s Development Agenda* (Ottawa: Wilfred Laurier University Press, 2009).

³ See World Trade Organization, “Doha Declaration on the TRIPS Agreement and Public Health”, November 14, 2001, WT/MIN(01)/DEC/2; World Trade Organization, “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, Sept. 1, 2003, WT/L/540. For commentary, see Sarah Joseph, *Blame It on the WTO? A Human Rights Critique* (Oxford: Oxford University Press, 2011).

⁴ World Health Organization, *Public Health, Innovation and Intellectual Property* (Geneva: 2008); World Health Organization, “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property”, May 24, 2008, WHA61.21.

⁵ “Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group”, May 18, 2011, SCP/16/7, p.16.

health policies,’ and ‘to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).’ Furthermore, the 2001 Doha Ministerial Declaration on the TRIPS Agreement and Public Health affirmed, *inter alia*, that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.

The WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property adopted in 2008 states that while international IP agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries, they may face obstacles in the use of flexibilities. Thus, there is a need to address this problem and remove obstacles faced by developing countries in making full use of the public health related flexibilities.”

The Delegation of South Africa concluded:

“In order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement would need to be incorporated in the national legislation”.

The Delegation further insisted: “There is equally the need to ensure that international commitments, including regional and bilateral arrangements, do not restrict these flexibilities and safeguards”. South Africa also emphasized that “these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine”.

In December 2011, the US Government made a submission to the WIPO Standing Committee on Patents on the topic of patents and health.⁶ Espousing a position of intellectual property rights maximalism, the US Government maintained that the patent rights of pharmaceutical drug companies should receive strong and unyielding protection:

“Weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets not only removes or reduces the incentive to develop new medicines, but also leads manufacturers to keep already developed medicines out of those markets. It has been shown that more goods become available in developing countries when IP rights are strengthened there. In the particular case of medicines, it has been shown that all else being equal, a new drug is more likely to be launched in a country where patent protection is strong, rather than one where such protection is lacking.

To successfully employ a technology such as manufacturing of medicines, know-how and specialized skills are often required in addition to the detailed disclosure found, for example, in a patent. Resorting to a compulsory license or other non-voluntary mechanism would not gain the cooperation of the patent owner, and the recipient of the compulsory license may not easily be able to successfully manufacture the medicine.”

In this statement, the US Government disparaged access mechanisms—such as compulsory licensing, Crown or government use and acquisition, and technology transfer—even though such measures have long been recognised and accepted as legitimate under international law. The US Government expressed a preference for alternative voluntary licensing and funding mechanisms—such as patent pools, advance market commitments, corporate social responsibility programmes, and philanthropic donations.

⁶ “Patents and Health: A Proposal by the Delegation of the United States of America”, December 7, 2011, SCP 17/11.

At the international level, there has been a concerted push by the United States to impose TRIPS Plus standards in respect of patent protection for pharmaceutical drugs through the means of bilateral and regional free trade agreements.⁷ The United States has been pushing for TRIPS Double Plus agreements in new fora—particularly with the Anti-Counterfeiting Trade Agreement⁸ and the proposed Trans-Pacific Partnership Agreement.⁹

Nonetheless, at the domestic level, the US Government has experimented with measures designed to address access to essential medicines—most notably, priority review vouchers and fast-track mechanisms for humanitarian patents. Such mechanisms are worthy of closer analysis and scrutiny.

This article provides a critical evaluation of two measures promoted by the US Congress and the US Government to address access to essential medicines—priority review vouchers and “Patents for Humanity”. It seeks to assess whether these measures are appropriate and well-adapted to be applied elsewhere in other jurisdictions, or incorporated into international schemes. This article does not seek to survey or cover the large field of access to medicines. It has a narrow scope and a particular focus—namely, the use of vouchers and fast-track mechanisms in the context of access to medicines. I have considered a number of policy issues related to access to essential medicines elsewhere and do not intend to repeat or cover that same ground.¹⁰ Part I looks at the development of priority review vouchers under the US Food and Drug Administration (FDA). Part 2 considers the programme of the US Patent and Trademark Office (USPTO) to provide fast-track mechanisms for “Patents for Humanity”. This article concludes that such measures provide minor incentives for the manufacturers of pharmaceutical drugs and medicines, and do little to provide or ensure access to essential medicines. It is argued that the US Government’s measures fall well short of implementing the WIPO Development Agenda, the WTO’s Doha Declaration on the TRIPS Agreement and Public Health, the WTO General Council Decision of 30 August 2003, and the WHO declarations on intellectual property and public health. The conclusion flags the need for a consideration of alternative mechanisms for research and development in respect of access to essential medicines.

I. Priority review vouchers

The FDA is a key institution in respect of the regulation of pharmaceutical drugs and medicines.¹¹ Under the Orphan Drugs Act 1983, the FDA has traditionally sought to advance the evaluation and development of products for the diagnosis or treatment of rare diseases and conditions. The Drug Price Competition and Patent Term Restoration Act 1984—the Hatch-Waxman Act—establishes a process to allow for generic pharmaceutical drug manufacturers to file for regulatory approval from the FDA. There has been much discussion as to whether the FDA could provide greater incentives for the regulatory review of neglected diseases.

⁷ See e.g. United States-Singapore Free Trade Agreement 2003; United States-Chile Free Trade Agreement 2003; Australia-United States Free Trade Agreement 2004; United States-Dominican Republic-Central America Free Trade Agreement 2005.

⁸ Anti-Counterfeiting Trade Agreement 2011, not yet in force. For commentary on ACTA, see Brook Baker, “ACTA—Risks of Third-Party Enforcement for Access to Medicines” (2011) 26(3) *American University Journal of International Law* 579; Andrew Rens, “Collateral Damage—The Impact of ACTA and the Enforcement Agenda on the World’s Poorest Peoples” (2011) 26(3) *American University Journal of International Law* 784; Peter K. Yu, “Six Secret (and Now Open) Fears of ACTA” (2011) 64 *SMU Law Review* 101.

⁹ Department of Foreign Affairs and Trade, “Trans-Pacific Partnership Agreement Negotiations”, available at <http://www.dfat.gov.au/tpa/> [Accessed March 25, 2012]; Deborah Gleeson, Kyla Tienhaara and Thomas Faunce, “Challenges to Australia’s National Health Policy from Trade and Investment Agreements” (2012) 196(5) *The Medical Journal of Australia* 1.

¹⁰ See Matthew Rimmer, “The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines” (2004) 5(2) *Melbourne Journal of International Law* 335; Matthew Rimmer, “The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid” (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889; Matthew Rimmer, “Race Against Time: The Export of Essential Medicines to Rwanda” (2008) 1(2) *Public Health Ethics* 89; Matthew Rimmer, “The Lazarus Effect: The (RED) Campaign, and Creative Capitalism” in Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010); Thomas Pogge, Matthew Rimmer and Kim Rubenstein, “Access to Essential Medicines: Public Health and International Law” in Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010).

¹¹ See John Braithwaite and Peter Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000); Marcia Angell, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (New York: Random House, 2004); Fran Hawthorne, *Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat* (Hoboken: John Wiley & Sons, 2005).

A. A new incentive

Some academics have suggested reforms to drug marketing and regulatory review mechanisms. In 2006, David Ridley, Henry Grabowski and Jeffrey Moe from Duke University proposed a system to give pharmaceutical companies incentives for developing drugs for neglected diseases.¹² The authors noted the scale of the problem, which they sought to address:

“Infectious and parasitic diseases accounted for more than half of healthy years lost in Africa in 2002, but only 3 per cent of healthy years lost in developed countries. Communicable diseases that disproportionately affect people in developing countries include malaria, leishmaniasis, Chagas disease, tuberculosis, dengue fever, and African trypanosomiasis. Lack of scientific knowledge is not the major barrier to drug development for many of these diseases. Scientists know more about the biology, immunology, and genetics of leishmania and trypanosomes than any other parasites. Rather, successful compounds often do not enter costly clinical development. The barrier is a lack of financial incentive. Because most people suffering from these neglected diseases live in low-income countries, there is little financial incentive for private pharmaceutical companies to invest in research and development (R&D) for new treatments.”

Under the proposal, a drug developer with a treatment for a neglected disease would receive a “priority review voucher” from the FDA for an expedited review of a second treatment of its choice. The voucher could be sold to another company or acquired as part of a buyout of its owner. Summarizing the proposal, the authors argued:

“We propose a novel pull mechanism in which a voucher is awarded for creating and licensing a drug that treats neglected diseases in the developing world. The transferable voucher would give the bearer priority-review status at the FDA for another drug. If the voucher speeds FDA approval by a year, it could increase the present value of sales of a blockbuster drug by more than US\$300 million. The developer also would be eligible for orphan drug tax credits. In a well-functioning voucher market, drugs that consumers and payers value more would reach the market sooner. We estimate that the additional cost of faster FDA review would be US\$1 million and could be passed on to the manufacturer. The cost to the government would be the additional cost associated with any drug for a neglected disease (that is, orphan drug tax credits).”

The authors conclude that the priority review voucher could provide benefits in developing countries and the United States at relatively low cost:

“The voucher would appeal to pharmaceutical manufacturers, consumers (who appreciate faster access to blockbuster drugs), the military (whose personnel operate in developing countries and might be exposed to neglected diseases), and advocates for health in developing countries.”

The lead author, David Ridley, observed:

“Tropical and infectious diseases cause enormous suffering, but because the victims are in poor countries there is little or no profit for pharmaceutical manufacturers. Our plan makes it commercially viable to develop new therapies for neglected diseases.”¹³

¹² David Ridley, Henry Grabowski and Jeffrey Moe, “Developing Drugs for Developing Countries” (2006) 25(2) *Health Affairs* 313.

¹³ Duke University, “Duke Faculty Propose Incentives for Developing Drugs for Neglected Diseases”, March 7, 2006, available at http://today.duke.edu/2006/03/developing_drugs.html [Accessed March 25, 2012].

Moe commented: “Our concept has benefits for U.S. consumers, discovery-driven companies and neglected disease sufferers”. The researcher added: “Those of us who have benefited so greatly from the fruits of innovative research and development shouldn’t accept ‘market failure’ as insurmountable when so many suffer globally.”

This work has undoubtedly had a high impact, and tapped into the zeitgeist. Not only has it been widely cited amongst researchers and scholars,¹⁴ the notion of priority review vouchers have been picked up by legislators. No doubt part of the appeal and attraction of the proposal was that it transcended the deadlocked debates over patent law, public health, and access to essential medicines.

In 2007, the US Congress adopted this proposal as part of the Food and Drug Administration Amendments Act 2007.¹⁵ Section 1102 of the amendments introduces a new s.524 to the Federal Food, Drug, and Cosmetic Act 1938. Section 524(a)(1) defines “priority review” as

“review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007”.

Section 524(a)(2) defines a “priority review voucher” as

“a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351 of the Public Health Service Act after the date of approval of the tropical disease product application.”

Section 524(a)(3) provides that the term “tropical disease” can include tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue, dracunculiasis (guinea-worm disease), fascioliasis, Human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis, yaws, and “any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary”.

Section 524(b)(1) provides that “the Secretary shall award a priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such tropical disease product application”. Section 524(b)(2) states:

“The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under s.505(b)(1) or s.351 of the Public Health Service Act will be submitted after the date of the approval of the tropical disease product application.”

Section 524(c) contains a limitation—providing that priority review vouchers cannot be granted in respect of tropical disease product applications made prior to the date of the enactment of the legislation. Section 524(c) address priority review user fees.

In April 2011, Senator Robert Casey, a Democrat from Pennsylvania, introduced a bill called the Creating Hope Act 2011.¹⁶ The legislation was designed to expand the priority review voucher scheme to apply to tropical and rare paediatric diseases. Senator Casey said of the initiative:

¹⁴ Google Scholar identifies 72 citations of the paper, and the Web of Knowledge notes 34 citations of the paper, as of March 15, 2012.

¹⁵ Food and Drug Administration Amendments Act of 2007 s.1102, 15 U.S.C. s.301 (2006).

¹⁶ For a discussion of the legislative proposal, see Edward Connor and Pablo Cure, “‘Creating Hope’ and Other Incentives for Drug Development in Children” (2011) 3(66) *Science Translational Medicine* 66. There have also been earlier initiatives like this—for example, Senators Sam Brownback (R-Kan.) and Sherrod Brown (D-Ohio) put forward the Creating Hope Act of 2010, s.3697.

“Millions of Americans are affected by rare diseases and neglected conditions for which there is currently no hope because there is no treatment. The Creating Hope Act brings light where there is now only darkness by providing an incentive, at no cost to taxpayers, to develop treatments for these illnesses. The broad support for this legislation speaks to the need to solve this problem.”¹⁷

Casey’s press release noted:

“Despite this significant unmet medical need, private companies seldom pursue new therapies for tropical illnesses or rare diseases because it requires making an investment in products that will likely not recoup the high costs associated with their research, development, marketing and distribution.”

It also elaborated: “Developing products for children is particularly challenging because of the difficulties associated with conducting clinical trials on this population.”

The legislation contained a number of measures to reform and revise the priority review voucher scheme. First, the scheme would expand priority review vouchers to include treatments for paediatric rare diseases. Secondly, the Bill would prevent companies from receiving a voucher for products that they already market in other countries. Thirdly, the Bill would allow for vouchers to be transferable and tradable (which is controversial). Fourthly, the Bill would allow sponsors to seek a designation from the FDA before they submit their new drug application that the drug, if approved, will qualify for a voucher. Fifthly, the Bill would strength reporting and marketing requirements. Sixthly, the Bill would add the Chagas disease to the FDA’s list of neglected tropical diseases.

The legislative proposal was supported by advocates for children’s health. Nancy Goodman, Executive Director of Kids v. Cancer, observed:

“I want to ensure that one day, children like my son, Jacob, who are diagnosed with brain cancer and other serious and rare diseases, will have drugs available for safe and effective treatments.”

Dr. Peter C. Adamson, Chair of the Children’s Oncology Group at the Children’s Hospital of Philadelphia, commented:

“As a pediatric oncologist who leads the Children’s Oncology Group, a nationwide team of physicians, scientists, nurses and others dedicated to treating children with cancer, I know that improving the outcome for children with cancer will require development of new, more effective anti-cancer drugs. With cancer remaining the leading cause of disease related death in children in the United States, the Creating Hope Act of 2011 will provide a critically important new way to help engage scientists in the biopharmaceutical industry to help develop better medicines for the children we care for.”

Peter Saltonstall, President and CEO of the National Organization for Rare Disorders (NORD), commented: “By expanding priority review vouchers to include pediatric rare diseases, this legislation would encourage the development of treatments for children with serious rare diseases.” The legislation has been referred to the Senate Committee on Health, Education, Labor, and Pensions for consideration.

In September 2011, Representative Michael McCaul, a Republican from Texas, introduced legislation (H.R. 3059) to amend the Federal Food, Drug, and Cosmetic Act to “improve the priority review voucher incentive program relating to tropical and rare pediatric diseases”. The Bill has 24 co-sponsors. The legislation was referred to the House Energy and Commerce Committee.

¹⁷ Robert Casey, “Casey Introduces Bipartisan Bill to Help Develop Treatments for Rare Diseases”, March 17, 2011, available at <http://www.casey.senate.gov/newsroom/press/release/?id=a8deb1ac-6ffd-424b-84b9-c166b4d6ff7> [Accessed March 25, 2012].

The issue of antibiotic resistance is a particular issue for pharmaceutical innovation.¹⁸ There has been some discussion as to whether a priority review voucher scheme would be effective in encouraging the development of drugs with antibacterial resistance. Ramanan Laxminarayan and John Powers comment that

“without clear eligibility criteria related to novelty and ability to address public health needs, application of a similar scheme for antibacterials might encourage manufacturers to develop ‘me-too’ antibacterials solely to earn the vouchers, which are economically valuable”.¹⁹

There has also been consideration of whether priority review vouchers could be adapted to the field of biosecurity and promote the clinical development of medical countermeasures—including drugs and vaccines—effective against chemical, biological, radiological and nuclear threats to the United States.²⁰

David Ridley and Alfonso Calles Sánchez have also argued that a priority review voucher scheme should be established in the European Union to be awarded by the European Medicines Agency or the European Commission.²¹ The authors contend: “For each new neglected-disease therapy approved, the developer would be awarded a voucher for priority marketing authorisation and accelerated pricing and reimbursement procedures for a medicine of the developer’s choice.” Ridley and Sánchez comment:

“The pricing and reimbursement feature differs from the US version of the programme, which only accelerates FDA scientific review; the US Government plays a small part in negotiating prices with manufacturers, whereas pricing and reimbursement negotiations in Europe are important and time-consuming features of government involvement.”

Ridley and Sánchez conclude that “European governments have made substantial contributions to research and development of medicines for orphan and neglected diseases” and that “the introduction of a priority review voucher scheme in the EU similar to that in the USA would be a useful additional contribution”. The authors maintain: “The use of similar systems in the two regions could help to expand incentives for developing new treatments for neglected diseases.” However, this proposal has found little favour with the European Union—especially at a time when it has been grappling with the global financial crisis, and austerity measures in various Member States of the European Union.

There has also been a push to include priority review vouchers at the international level. In 2010, the WHO Expert Working Group on Research and Development Financing considered whether the concept of the priority review voucher should be implemented.²² Rightly in my opinion, the Group was of the view that the proposal was flawed:

“This proposal offers ‘priority regulatory review’ of a commercial product in return for registration of a drug for a neglected disease in the United States. Priority review allows a company to bring a product to the market faster, resulting in many hundreds of millions of dollars of additional sales if the product is successful. It has been estimated that a reduction in the review time from 19.4 to 6.4 months for a drug receiving priority review could be worth US\$322 million to developers. The vouchers can be traded. The design of the priority review voucher has, however, major flaws and it could be of substantially greater value if these were addressed. A neglected disease product need not

¹⁸ Kevin Outterson, “The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation” (2010) 31(3) *Cardozo Law Review* 613.

¹⁹ Ramanan Laxminarayan and John Powers, “From the Analyst’s Couch: Antibacterial R&D Incentives” (2011) 10 *Nature Reviews Drug Discovery* 727.

²⁰ Jason Matheny, Michael Mair and Bradley Smith, “Cost/Success Projections for US Biodefense Countermeasure Development” (2008) 26 *Nature Biotechnology* 981.

²¹ David Ridley and Alfonso Calles Sánchez, “Introduction of European Priority Review Vouchers to Encourage Development of New Medicines for Neglected Diseases” (2010) 376(9744) *The Lancet* 922.

²² World Health Organization, *The Report of the World Health Organization Expert Working Group on Research and Development Financing* (Geneva: 2010), p.75.

be suitable for use in developing countries, and developers need only to register the product in the United States. Thus, firms can register products in the United States that have already been used in other countries for many years (as was the case with the first product to receive a priority review voucher); and there is no link between award of the voucher and actual uptake of the product in developing countries, i.e. the firm does not have to register or sell the product in developing countries in order to receive the voucher.”

The report observed:

“The priority review voucher may be worth further consideration because of its attraction for small-to-medium enterprises; it may be one of the more potent ‘pulls’ to bring these firms into the field, including firms in innovative developing countries.”

However, it noted:

“This would only be the case, however, if the priority review voucher was redesigned to address the flaws described above in order to deliver far better value for money for both the funders and the recipients (patients in developing countries).”

A 2011 meeting of the WHO Expert Working Group on Research and Development Financing rated priority review vouchers as a middling policy option amongst the wide spectrum of choices.²³ Higher priorities included patent pools, open source strategies, prizes, and direct grants to small-to-medium enterprises.

B. Advocates of priority review vouchers

Republican Senator Sam Brownback was one of the supporters of priority review vouchers, which create a market-based approach to eliminating neglected diseases by encouraging pharmaceutical companies to invest in developing treatments for such diseases. Brownback commented:

“In the developing world, millions of people suffer from curable diseases that many of us think no longer exist. The biggest challenge to finding cures for these diseases is the lack of a market. The lack of interest in finding treatments for neglected diseases has led to only a few new drugs in the market. Between 1975 and 1997, only 13 new drugs were developed for neglected diseases. Because pharmaceuticals are expensive to develop, companies have fewer incentives to pursuer [sic] therapies when the purchases are primarily poor people. We can encourage pharmaceutical companies by granting a patent extension for a lifestyle drug or a neglected disease product if they make the investment to develop a treatment for a neglected disease. A drug company can recoup costs incurred by developing drugs for a neglected disease by securing these new patent rights.”²⁴

The Senator observed that “too many people in the developing world suffer and die from diseases that for the most part are both preventable and curable”. In his view, “the main obstacle to responding to the needs of those suffering is insufficient incentive for companies to produce drugs that treat and prevent neglected tropical diseases”.

Senator Joseph Lieberman also supported the introduction of priority review vouchers:

²³ World Health Organization, “Report of the Second Meeting of the Consultative Expert Working Group on Research and Development: Financing and Coordination”, July 2011, available at http://www.who.int/phi/news/cewg_rd_2nd_meeting_report.pdf [Accessed March 25, 2012].

²⁴ “Lieberman Calls for Incentives for Research on Disease Treatment: Senator Joins Colleague in Introducing Neglected Diseases Act”, May 2, 2006, available at <http://votesmart.org/public-statement/169327/lieberman-calls-for-incentives-for-research-on-disease-treatment> [Accessed March 25, 2012].

“We have the technology and brain power to bring about cures for these damaging diseases, but what’s lacking is a market incentive to tackle them. This bill will help bring relief to thousands of people suffering from ancient diseases in a world with contemporary medical capabilities. The technology and brain power behind cures should not be limited to the privileged and our bill aims to remove the barriers that have too long prevented these cures from reaching the nation’s underprivileged. The financial benefit companies would receive from the patent incentives in our bill can help offset the cost of crucial R&D investments needed to combat these neglected diseases, which can be as high as US\$1 billion dollars per drug.”

The amendment provides a significant financial incentive for pharmaceutical companies to produce neglected tropical disease treatments by awarding them with a FDA priority review voucher for bringing to market such products. The priority review vouchers could be applied to any drug in a company’s production pipeline and would reduce the FDA review time from roughly 18 months to 6 months. The 12 month shorter review process would be worth more than US\$300 million if applied to the top 10 per cent grossing drugs.

Bill Gates has enthused about the priority review vouchers at the 2008 World Economic Forum:

“Some of the highest-leverage work that government can do is to set policy and disburse funds in ways that create market incentives for business activity that improves the lives of the poor. Under a law signed by President Bush last year, any drug company that develops a new treatment for a neglected disease like malaria or [tuberculosis] can get priority review from the Food and Drug Administration for another product they’ve made. If you develop a new drug for malaria, your profitable cholesterol-lowering drug could go on the market a year earlier. This priority review could be worth hundreds of millions of dollars.”²⁵

He lauds the initiative as an instance of “creative capitalism”:

“Of course, governments do a great deal to help the poor in ways that go far beyond nurturing markets: they fund research, subsidize health care, build schools and hospitals. But some of the highest-leverage work that government can do is to set policy and disburse funds in ways that create market incentives for business activity that improves the lives of the poor.”

Tim Wells of the Medicines Malaria Venture in Geneva was optimistic about the value of the priority review voucher:

“Even if only one in ten of the vouchers were deployed successfully, it would still have a book value of tens of millions of dollars. This is enough to help drive innovative clinical development.”²⁶

BIO Ventures for Public Health recommended that the WHO should consider the virtues of this US legislative measure at the international level:

“By taking advantage of existing market forces, patients in the developing world can have faster access to lifesaving products that may not otherwise be developed. And sponsors of neglected disease drugs can be rewarded for their innovations. This new financial incentive complements other market-based incentives to stimulate investment in global health R&D. Donor countries have recently committed to other new initiatives. Earlier this year, for example, five leading industrialized countries along with the Bill & Melinda Gates Foundation committed US\$1.5 billion to a pilot Advance Market Commitment that guarantees a developing world market for pneumococcal vaccines. To create the

²⁵ Bill Gates, “Creative Capitalism”, delivered at the World Economic Forum, January 24, 2008, available at <http://www.gatesfoundation.org/speeches-commentary/Pages/bill-gates-2008-world-economic-forum-creative-capitalism.aspx> [Accessed March 25, 2012].

²⁶ Bethan Hughes, “Priority Voucher Flops” (2011) 29 *Nature Biotechnology* 958.

next generation of medicines for the developing world, we need to continue to develop and support these types of market incentives. And we need to ensure that we have appropriate tools in place to measure and improve their impact.”²⁷

The organisation emphasized that “new market-based solutions are needed to leverage industry expertise and encourage greater investment in innovation for these neglected diseases”.

The economist Nicola Dimitri contended that priority review vouchers “tend to increase R&D efforts, notably if a firm obtaining a voucher has in its portfolio a particularly valuable compound to prioritize”.²⁸ Dimitri maintained:

“When this is so the bearer is, in some sense, outperforming the market because the value it can create internally, by prioritizing a drug, is higher than what it could obtain by selling the voucher.”

C. A critique of priority review vouchers

The priority review voucher mechanism can be criticised on a number of theoretical grounds.

First, there have been concerns expressed as to whether the incentive provided by a priority review voucher is an efficient means of encouraging R&D in respect of neglected diseases. Aaron Kesselheim argued that “priority-review vouchers represent an inefficient and potentially dangerous way of encouraging research into tropical diseases”.²⁹ He maintained: “It is inefficient because the program does not directly connect the incentive with the innovation”. Kesselheim maintained:

“Relying on these sorts of transactions to spur innovation is speculative as well, and the deals between small and large pharmaceutical companies affecting agents of great importance to global health will lack transparency.”

He wondered whether access to essential medicines would be inhibited by side deals within the pharmaceutical industry: “Such deals may include other payments or exchanges of intellectual property that raise the cost or restrict the future availability of the products.”

Secondly, there is some uncertainty as to the value of an expedited review. Ian Spatz of the pharmaceutical company Merck has commented that the benefits were overstated:

“Unfortunately, their particular prescription—a transferable voucher for an expedited review within the U.S.—is built on faulty assumptions that make the success of their plan questionable. The authors base their estimates of the value of an expedited review on an estimate of standard FDA review of 18.4 months compared to 6.4 months for priority review. According to the FDA, in fiscal year 2003, the actual difference was 13.8 months compared to 6.4 months. Perhaps more importantly, under the Prescription Drug User Fee Act (PDUFA) program, the FDA has committed to delivering action on 90 percent of applications within a time frame of 10 months for standard reviews and 6 months for priority reviews. For companies like Merck, these are the review periods that we count on for planning purposes.”³⁰

²⁷ BIO Ventures for Public Health, “New Market Incentive to Encourage Innovation for Global Health FDA Bill Creates Priority Review Voucher for Neglected Tropical Diseases”, available at http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_BVGH_Full_Contribution.pdf [March 25, 2012].

²⁸ Nicola Dimitri, “The Economics of Priority Review Vouchers” (2010) 15(21–22) *Drug Discovery Today* 887.

²⁹ Aaron Kesselheim, “Drug Development for Neglected Diseases—The Trouble with FDA Review Vouchers”, (2008) 359 *The New England Journal of Medicine* 1981.

³⁰ Ian Spatz, “Benefits of Expedited Review Likely Overstated”, *Health Affairs*, March 13, 2006, available at <http://content.healthaffairs.org/cgi/eletters/25/2/313> [Accessed March 25, 2012].

There has also been criticism that priority review vouchers will be an additional windfall for pharmaceutical drug manufacturers, in addition to the benefits of patent rights. Aidan Hollis of the University of Calgary notes that “firms which are developing very profitable products will be rewarded even more”.³¹

Thirdly, the priority review vouchers mainly target certain neglected diseases—including tuberculosis and malaria, but not HIV/AIDS. As Kevin Outterson has noted, developing countries would benefit from essential medicines related to Type I diseases, as well as Type II and Type III diseases.³²

Fourthly, there is a concern that priority review vouchers do nothing to enhance access to essential medicines. Hollis has commented that the proposal does not address “the access problem, but helps to increase incentives through creating distortions in markets in developed countries”.³³ He notes that such an approach “would encourage research investment, but the net impact on consumers is uncertain, as they would benefit from more innovation, but at greater cost”.

Finally, there has been criticism that the priority review voucher scheme is open to strategic behaviour and gaming by self-interested applicants. In 2009, the FDA approved Coartem tablets for the treatment of malaria infections in adults and children.³⁴ Dr. Murray Lumpkin, deputy commissioner for International and Special Programs of the FDA, commented: “Malaria is a global life-threatening disease. It is encouraging to have new treatment available, particularly for children.” The FDA awarded Novartis—the manufacturer of Coartem—a one-time priority review voucher to use towards a future new drug application. It noted that the voucher could be transferred by the company to another manufacturer, if need be.

Bethan Hughes recounts the tribulations of Novartis, the first company to deploy a priority review voucher.³⁵ Novartis of Basel recently used the only priority review voucher to have a “priority” review of their supplemental biologics license application to the FDA for Ilaris (canakinumab). Eric Althoff, head of global media relations, commented: “We decided to utilize our PRV for ACZ885 (canakinumab) in gouty arthritis because of the significant unmet need that exists despite standard treatment options.” Bethan Hughes observes of the Novartis application:

“Unfortunately, Novartis received a complete response letter from the FDA requesting additional clinical data to evaluate the benefit-risk profile for use of Ilaris in refractory patients. As Novartis used their PRV (which cost an additional fee of US\$5,280,000 on top of the sBLA fee) but did not achieve approval of the supplementary indication for Ilaris, industry observers have been quick to suggest that use of this first PRV has been a failure. This is because the potential value of the PRV has been predicted based on additional sales revenue that a company would theoretically receive if approval was achieved at an earlier date.”

Novartis is a controversial applicant—especially given its litigation against provisions of India’s unique patent regime and its treatment of pharmaceutical drugs.³⁶ Médecins Sans Frontières (MSF), in alliance with patient groups and affected communities, has appealed to Novartis to drop its case against the “pharmacy of the developing world”.³⁷

James Love of the Knowledge Ecology International commented that this application was an abuse of the system:

³¹ Aidan Hollis, “Optional Rewards for New Drugs for Developing Countries”, February 23, 2005, available at http://www.who.int/intellectualproperty/submissions/en/Optional_rewards.pdf [Accessed March 25, 2012].

³² Kevin Outterson, “Should Access to Medicines and TRIPS Flexibilities Be Limited to Particular Diseases?” (2008) 34 *American Journal of Law and Medicine* 279.

³³ Hollis, “Optional Rewards for New Drugs for Developing Countries”, 2005, available at http://www.who.int/intellectualproperty/submissions/en/Optional_rewards.pdf [Accessed March 25, 2012].

³⁴ Food and Drug Administration, “FDA Approves Coartem Tablets to Treat Malaria”, April 8, 2009, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149559.htm> [Accessed March 25, 2012].

³⁵ Bethan Hughes, “Priority Voucher Flops” (2011) 29 *Nature Biotechnology* 958.

³⁶ See *Novartis AG v Union of India* (2007) 4 *Madras Law Journal* 1153; see also Hafiz Aziz ur Rehman, *The Pharmacy of the Developing World: Indian Patent Law and Access to Essential Medicines*, Ph.D. thesis, ANU College of Law, 2012.

³⁷ Médecins Sans Frontières, “Novartis’s Day in Court Set for 28 March, Campaign to Drop the Case Continues”, March 1, 2012, available at <http://www.msfaccess.org/content/novartis%E2%80%99s-day-court-set-28-march-campaign-drop-case-continues> [Accessed March 25, 2012].

“While the [priority review voucher] was designed as an incentive to develop new drugs, Coartem was developed and put on the market outside the United States years before the PRV legislation was proposed.”³⁸

II. “Patents for Humanity”: A fast-track for humanitarian patents

The US President Barack Obama appointed David Kappos—previously, an intellectual property expert with IBM—as the head of the USPTO. Kappos has certainly sought to experiment with new policy models—within the constraints of his role. He has been interested in improving the quality of patent examination and the time taken for patent examination. He has, for instance, trialled fast-track examination,³⁹ the Peer-to-Patent project,⁴⁰ a scheme for clean technologies,⁴¹ and a project for humanitarian inventions, entitled “Patents for Humanity”.⁴²

In September 2010, Kappos announced that the USPTO would introduce a new fast-track pilot program for patents, with humanitarian applications.⁴³ Under the proposal, patent holders who made their technology available for humanitarian purposes would be eligible for a voucher entitling them to an accelerated re-examination of a patent. This proposal was in part inspired by the priority review voucher scheme.

Kappos commented: “A voucher for fast-track re-examination of a patent is a valuable incentive for entities to distribute humanitarian technologies through licensing or other means.” It was envisaged that the range of subject matter covered by the new fast-track pilot program would be broad:

“Among the technologies which address humanitarian needs that would be eligible for the program are treatments for tropical diseases, diagnostic medical tools, crops with higher yields or better nutritional value, and treatments for sanitation or clean water.”

A fraction of such technologies—such as, for instance, climate-ready crops and water purification—would include clean technologies. The scheme was designed “to increase the diffusion of technologies that address humanitarian needs through market forces” through creating “an incentive to provide patented technologies for humanitarian research, which in turn may spur the development of new technologies to address humanitarian needs”.

In the *Federal Register*, the USPTO sought public comments on proposals to incentivise the creation and wider distribution of technologies that address humanitarian needs.⁴⁴ Promoting the scheme in Geneva, Kappos maintained:

“We feel the right to a fast-track re-examination could be a very valuable right, allowing a patent owner to affirm the validity of his or her patent more quickly and less expensively.”⁴⁵

³⁸ James Love, “Novartis Games the FDA Priority Review Voucher”, Knowledge Ecology International, April 10, 2009, available at <http://keionline.org/blogs/2009/04/10/novartis-games-the-fda-priority-review-voucher> [Accessed March 25, 2012].

³⁹ Kristen Osenga, “The Patent Office’s Fast Track Will Not Take Us in the Right Direction”, *Patently-O Patent Law Journal*, June 3, 2010, available at <http://www.patentlyo.com/osenga.pdf>; see also Kristen Osenga, “Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office” (2005) 33 *Florida State University Law Review* 119.

⁴⁰ Peer to Patent project, available at <http://peertopatent.org/> [Accessed March 25, 2012].

⁴¹ For an analysis, see Matthew Rimmer, *Intellectual Property and Climate Change: Inventing Clean Technologies* (Cheltenham: Edward Elgar, 2011), pp.163–169.

⁴² “Patents for Humanity”, available at http://www.uspto.gov/blog/director/entry/patents_for_humanity [Accessed March 25, 2012].

⁴³ USPTO, “USPTO Launches Effort to Incentivize Humanitarian Technologies: New Initiative Encourages Businesses to Develop and Disseminate Technologies that Address Humanitarian Needs”, September 20, 2010, available at http://www.uspto.gov/news/pr/2010/10_41.jsp [Accessed March 25, 2012].

⁴⁴ USPTO, “Request for Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System” (2010) 75(181) *Federal Register* 57261.

⁴⁵ David Kappos, “Press Conference on Intellectual Property”, United States Mission to the United Nations and Other International Organizations in Geneva, September 23, 2010, available at <http://geneva.usmission.gov/2010/09/23/press-conference-on-intellectual-property-protection/> [Accessed March 25, 2012].

However, in my view, such a scheme would appear to only offer a minor incentive to patent holders to disseminate technologies to address humanitarian concerns.

A. Comments

The proposal from the USPTO received a somewhat mixed reaction from key stakeholders in the field of patent law and access to essential medicines. A range of comments were received from governments and international agencies; non-profit and aid organisations; academic and research institutions; industry groups; law firms and associations.

i. Non-profits and aid organizations

A joint submission was made by Knowledge Ecology International, Doctors without Borders, Oxfam, and Public Citizen.⁴⁶ The civil society groups congratulated the “USPTO for considering new mechanisms to encourage innovation and licensing of technologies for humanitarian purposes”. The joint submission made the point:

“The USPTO’s proposal recognizes implicitly that the patent system as presently implemented fails to adequately serve the needs of neglected populations around the world.”

Indeed, the civil society groups emphasize that

“new mechanisms are needed to incentivize technological advances responsive to the needs of developing countries, and to ensure that these technological advances can provide meaningful benefits to disadvantaged populations”.

The civil society groups warned: “The voucher program must be carefully designed if it is to deliver real humanitarian benefits, and avoid becoming a public giveaway of valuable rewards for little in return.” Moreover, the organisations worried that, “if the mechanism is improperly designed or implemented it could have unintended, harmful consequences that would undermine its purported benefits”.

The submission expressed concern about the strategic gaming behaviour which had taken place in respect of priority review vouchers:

“The voucher program should be designed as a pure incentive program to incentivize the development of both meaningful technological innovations and significant humanitarian dissemination practices. In order to achieve this goal, the mechanism should try to eliminate abuses that may arise.

For instance, patent holders should not be able to apply for a humanitarian voucher if the invention has already been used or licensed for the humanitarian purpose that the applicant is seeking under a new application and does not offer additional and important humanitarian benefits. Improvements to existing technologies that do not confer a new purpose should not be eligible for vouchers.

Also, the USPTO should ensure that companies with many patents do not merely donate low-value patents in order to accelerate the re-examination of high-value ones. The proposed competitive prize mechanism plus minimum standards for voucher awards can help prevent such a giveaway.”

⁴⁶ Knowledge Ecology International, Doctors without Borders, Oxfam, and Public Citizen, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_sanjuan2010nov19.pdf [Accessed March 25, 2012].

Citing the example of Novartis obtaining a priority review voucher for Coartem, the submission emphasizes that “the USPTO program must eliminate these and similar efforts to ‘game’ this new initiative”. The submission emphasizes that a prize-based approach, an independent review mechanism, and an opportunity for public comment may help limit the risks of “gaming the system”. The submission recommends that the USPTO’s scheme should embrace open licensing and technology transfer to developing countries.

AVAC, which engages in global advocacy for HIV prevention, commented on the USPTO proposal.⁴⁷ The group discussed its particular interest in the topic:

“AVAC has advocated for responsible IP practice and policy in the service of facilitating HIV prevention biomedical research and development for a number of years. In 2005 and in 2010, AVAC published results of its IP evaluations and policy recommendations affecting large molecule HIV vaccine biologics. We assembled the first significant database of the underlying HIV vaccine patent landscape—a field characterized by issues of a patent thicket, uncertainty with regard to research tools, and complexity in sharing voluminous data sets and biological samples that are necessary for discovery and which underpin the application for many new patents. Copies of these reports are cited here with request that USPTO focus its development of humanitarian purposes policies on the AVAC recommended principles for collaboration, sharing and harmonization directed at the public good.”

This group was uncertain as to whether a re-examination voucher program would have a material effect or include a sufficient range of “humanitarian purposes”. It was also concerned that the definition of “humanitarian purposes” was too limited. The group worried that there was insufficient incentives for public researchers and institutions, especially given their involvement in the area of HIV/AIDS research.

The group, Incentives for Global Health, led by Professor Thomas Pogge, was supportive of the proposal:

“We share the USPTO’s view that incentives can help to stimulate more useful and more accessible innovation, and we strongly support the USPTO’s effort to creatively advance innovation using IP system incentives.”⁴⁸

It emphasizes the need for a simple, reliable method of assessing humanitarian impact; the importance of the “last mile” problem; and the need for technological, financial and geographic neutrality.

The Medicines Patent Pool was mildly hopeful that the “Patents for Humanity” project would encourage patent holders to participate in patent pools and share essential medicines:

“The Medicines Patent Pool welcomes the initiative of the USPTO to improve access to important technologies, such as pharmaceuticals, in developing countries. If designed well, we believe the Voucher could have an important impact on the willingness of patent-holders to generate innovation with potential benefits for populations in low- and middle-income countries, and contribute to ensuring that the fruits of scientific progress are accessible to those who need them. We hope the Voucher initiative will encourage pharmaceutical patent-holders to share their patents with the Medicines Patent Pool.”⁴⁹

Nonetheless, the Medicines Patent Pool was concerned about threats to the integrity of the regime. The group makes the sensible point that there is a need to ensure that the quality of patent examination is not adversely impacted by an accelerated process:

⁴⁷ AVAC, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_fisher2010nov23.pdf [Accessed March 25, 2012].

⁴⁸ Incentives for Global Health, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_lipkus2010nov19.pdf [Accessed March 25, 2012].

⁴⁹ Medicines Patent Pool, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, p.8, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_moon2010nov19.pdf [Accessed March 25, 2012].

“In general, it will be important to avoid creating perverse outcomes, such as the reinforcement of weak patents through hurried re-examinations or encouraging more widespread patenting in developing countries.”⁵⁰

Indeed, it noted “two key risks have been identified with the analogous US FDA priority review voucher program that bear mentioning here: first, a priority review obligation may put additional burden on the agency and thereby extend the waiting time for other applicants; secondly, the accelerated deadline may negatively affect the quality of regulatory decisions”.⁵¹

ii. Industry

In its submission, PhRMA—the peak industry body for pharmaceutical drug manufacturers—questioned whether such a scheme was appropriate.⁵² First, it emphasized that “PhRMA members devote substantial resources to humanitarian endeavors”. Secondly, it maintained that patent rights are essential to pharmaceutical innovation. Thirdly, PhRMA contended that it was not the function of the USPTO to run humanitarian programmes:

“The PTO’s goal of incentivizing humanitarian invention is laudable; however, PhRMA questions whether the proposed initiative is the best way to achieve the goal. This proposal may present challenges to the fundamental principle of non-discrimination and the smooth functioning of the patent process. Other incentive programs, such as those undertaken by other government agencies with different core missions, may be better suited to incentivizing R&D or other activities in this area.”

PhRMA raises the questions about eligibility criteria, the use of vouchers and decision-making.

The Biotechnology Industry Organization (BIO) also supported strong patent rights protection: “In order to provide innovative technology to the marketplace, strong intellectual property rights are the key to a successful business model.”⁵³ Bio

“commends the USPTO for likewise exploring creative and market-oriented ways to incentivize the development and distribution of humanitarian technologies, a goal that BIO and its members have long shared and are working hard to achieve.”⁵⁴

BIO maintained that any regime should be technology-neutral:

“The United States Government is free to create technology-specific or problem-specific incentive and reward programs to address developing-country needs in the particular areas of, for example, education, medical care, nutrition, pollution, animal health, transportation, communication, and the like. Such programs would be developed and implemented by agencies with specific technology expertise and legal and policy mandates in these areas. In contrast, the patent system is primarily concerned with furthering the progress of technological innovation, without regard to the applicability of inventions in specific policy areas. Maintaining the strict technology-neutrality of the patent system

⁵⁰ Medicines Patent Pool, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, p.2.

⁵¹ Medicines Patent Pool, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, pp.2–3.

⁵² PhRMA, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_korn2010nov19.pdf [Accessed March 25, 2012].

⁵³ Biotechnology Industry Organization, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_sauer2010nov19.pdf [Accessed March 25, 2012].

⁵⁴ Biotechnology Industry Organization, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, p.1.

is critically important to BIO's member companies from an international comparative, trade, and treaty obligation perspective as well. Accordingly, BIO members still have many open questions about the inclusiveness of the proposed program and how its technology-neutrality can be ensured."⁵⁵

There seemed to be a lack of consensus amongst the stakeholders of BIO about the relative merits and disadvantages of the scheme proposed by the USPTO.

AdvaMed, a medical technology association, was roundly hostile to the proposal, maintaining that the USPTO straying from its right and proper institutional role:

"The role of the USPTO, with regard to medical technology, is to determine the patentability of what is often a limited aspect of a medical device. Although obtaining patent protection directly impacts the ability to command investment capital to further a medical technology's development, the proposed voucher program's potential to consistently bring new medical technologies to patients sooner would be tenuous, as obtaining patent protection is an early step in developing a medical technology and bringing it to market. Accordingly, the proposed program would not directly benefit patients. More importantly, AdvaMed is concerned that adding additional complexities and workload to an already-overburdened USPTO staff will have an adverse impact on all technologies."⁵⁶

The Association maintained:

"While the voucher program is a noble idea, it will not lead to any increase in humanitarian technology and could actually impede such technology along with other technologies by diverting scarce resources within the PTO from handling the normal application work load."⁵⁷

Gilead Sciences is a pharmaceutical drugs company, with a strong emphasis upon the development of therapeutics for the treatment of HIV/AIDS.⁵⁸ The company observes that "Gilead believes in a system of strong intellectual property protection" and "Gilead also believes that along with intellectual property comes responsibility to vulnerable populations". Gilead Sciences "strongly supports the creation of a fast-track ex parte re-examination voucher pilot program to incentivize technology creation or licensing to address humanitarian needs". Interestingly, the company thought that there would be diplomatic benefits arising from the programme:

"In addition, we endorse this program because it strengthens the diplomatic hand of the United States Government. This program provides the United States with strengthened credibility in the developing world to show that the intellectual property policies of the United States encourage responsible use of intellectual property rather than merely protecting the monopoly of patent holders having no regard to broader humanitarian implications. Importantly, a commitment to humanitarian use helps to protect the underlying innovation."

The company stressed that "award recipients would ideally be those innovators that make strides in reducing the prevalence of a disease or reducing the impact of diseases".

The company Novartis put in a short submission, stating its belief that "the USPTO's proposal is a meritorious and worthwhile endeavour", and that it hoped that "a robust conversation between the healthcare industry and the USPTO will ensue to establish specific parameters to further define this new initiative".⁵⁹

⁵⁵ Biotechnology Industry Organization, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", 2010, p.3.

⁵⁶ AdvaMed, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", November 19, 2010, p.2, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_chang2010nov19.pdf [Accessed March 25, 2012].

⁵⁷ AdvaMed, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", 2010, p.1.

⁵⁸ Gilead Sciences, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_lis2010nov19.pdf [Accessed March 25, 2012].

⁵⁹ Novartis, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_ryberg2010nov19.pdf [Accessed March 25, 2012].

The health-care company Sanofi-Aventis commented:

“Although, such a voucher could be valuable under the right circumstances, we believe that alternatives to the fast-track ex parte re-examination voucher could provide greater incentives and thereby better incent humanitarian efforts and would help us justify continuing and increasing our humanitarian efforts in the face of the disparate needs of the company’s stakeholders.”⁶⁰

Although not united in their opinions, the industry groups suggest that regulatory institutions should not concern themselves with matters of humanitarian aid and that such matters are better left to other agencies. I would dispute this. It is entirely proper and appropriate that patent offices such as the USPTO consider the implications of the examination and grant of patents for access to essential medicines. Professor Brad Sherman has observed that the patent system is not a system of regulation purely designed for instrumental economic ends:

“While there is no denying the important role that patents play in macro-economic policy, there is no reason why the patent system, as a regulatory tool, should only be used in the pursuit of economic ends, nor any reason why “external” factors such as the impact of technology on the environment or health should not fall within the core remit of the patent system. That is, there is no compelling reason why the various practices, rules and concepts that have been developed and fine-tuned over the last couple of centuries or so should only be used for economic ends. Given that modern patent law already performs a number of, sometimes surprising, non-economic roles, this is not as alien a proposal it might first appear.”⁶¹

Indeed, patent offices would be justly criticised for failing to properly engage with public policy concerns—such as access to health-care and essential medicines.⁶² The patent system is not hermetically sealed off from larger questions about development, access to knowledge, and access to essential medicines.

iii. Academic and research institutions

Professor Susan Sell considers the role of academic and research institutions in the development and licensing of humanitarian intellectual property:

“Universities may feel caught between the conflicting imperatives of attracting private sector funding and generating revenue through patenting activity on the one hand, and promoting public goods through ‘humanitarian intellectual property’ policies on the other. It is clear that universities have an important role to play in preserving the balance between exclusion and access as well as paving the way to more informed, effective, and socially responsible agricultural intellectual property policies.”⁶³

It is notable that a number of academic and research institutions commented on the USPTO’s proposal for “Patents for Humanity”.

The Association of American Universities and the Council on Governmental Relations emphasized that

⁶⁰ Sanofi-Aventis, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_farquharsontorres2010nov19.pdf [Accessed March 25, 2012].

⁶¹ Brad Sherman, “Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery” (2003) 25(7) *European Intellectual Property Review* 301.

⁶² Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge: Cambridge University Press, 2010).

⁶³ Susan Sell, “What Role for Humanitarian Intellectual Property?: The Globalization of Intellectual Property Rights” (2004) 6(1) *Minnesota Journal of Law, Technology, and Science* 191, 211.

“the university community strongly supports the goal of USPTO to explore strategies that would use the patent system to incentivize activity addressing humanitarian needs, and encourages USPTO to pursue a pilot program as proposed in the Federal Register notice”.⁶⁴

The submission provided a qualified endorsement of the scheme:

“While we support the goals of the USPTO proposal, we are concerned that some aspects may need to be carefully considered to avoid unintended consequences and potential exploitation. We believe that USPTO should consider instituting a competitive review process for voucher issuance to assure quality and effectiveness. We also suggest that the number of vouchers issued on an annual basis be substantially limited, at least until the results of the pilot program are known. While possible transferability of the re-examination vouchers on the open market would substantially enhance their value, auctioning the vouchers off to the highest bidder could lead to negative public perceptions and questions about public vs. private benefit. We urge USPTO to consider whether the enhanced value offsets these possible negative consequences.”

The submission noted a number of US universities had endorsed the declaration on *Nine Points to Consider in Licensing University Technology* and a *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies*. The Association of University Technology Managers had also launched a Global Health Initiative.⁶⁵

That University of California has long been a pioneer and path-finder in respect of licensing of patents related to humanitarian inventions.⁶⁶ That university was a driving force behind the statement *Nine Points to Consider in Licensing University Technology*. The ninth point focuses attention on

“unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improve therapeutics, diagnostics and agricultural technologies for the developing world”.⁶⁷

The University of California Berkeley’s Socially Responsible Licensing Initiative seeks to promote the widespread availability of technologies and healthcare products in developing countries.⁶⁸ The University of California provided:

“We feel that it is important for the PTO to carefully consider how best to identify innovative patents that actually address compelling humanitarian needs. Administratively, the challenge the PTO faces is that documenting actual humanitarian use is difficult at patent filing since the data needed is available only after the product is on the market. On the other hand, providing a fast-track voucher only after product introduction acts as a reward rather than an incentive to invest in technologies that address humanitarian need. In addition, the PTO will need avoid rewarding patents that purport to address humanitarian needs but never result in actual humanitarian benefit. The University encourages the PTO to consider a broad view of humanitarian needs that can be met with technologies that extend beyond the pharmaceutical industry.”⁶⁹

⁶⁴ The Association of American Universities and the Council on Governmental Relations, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_norton2010nov19.pdf [Accessed March 25, 2012].

⁶⁵ Association of University Technology Managers, “Global Health Initiative”, available at <http://www.autm.net/home.htm> [Accessed March 25, 2012].

⁶⁶ University of California, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 22, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_foote2010nov22.pdf [Accessed March 25, 2012].

⁶⁷ Association of University Research Managers, “In the Public Interest: Nine Points to Consider in Licensing University Technology”, available at http://www.autm.net/Nine_Points_to_Consider.htm [Accessed March 25, 2012].

⁶⁸ University of California, Berkeley, Office of Intellectual Property and Industry Research Alliances, “Socially Responsible Licensing and Intellectual Property Management”, available at <http://ipira.berkeley.edu/socially-responsible-licensing-ip-management> [Accessed March 25, 2012].

⁶⁹ University of California, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, p.3.

The University of California continued:

“The PTO proposes vouchers for fast-track *ex parte* re-examination, but having a voucher for fast track initial examination might possess greater value for some patent applicants, such as universities.”

Emory University noted in its submission:

“Many universities have given considerable thought to encouraging humanitarian activities through licensing and have come up with certain requirements as part of their licensing practices and in our opinion the USPTO’s proposal can provide additional leverage in securing licensing terms with humanitarian goals.”⁷⁰

The research institution was conscious, though, that the incentive fell well short of the costs involved in developing new humanitarian technologies:

“Although the financial requirements of developing new technologies to address humanitarian needs likely far outweighs the incentive of the USPTO’s proposed voucher, we believe the voucher should be viewed within the context of global efforts within the administration to encourage development of such technologies.”

The University of Mississippi noted that it had a major research program in the National Center for Natural Products Research in the School of Pharmacy to develop pharmaceutical drugs for neglected diseases.⁷¹ The University of Mississippi argued:

“Since it is easier for a university to license the patent rights of an issued patent than of a pending patent application, an accelerated initial review would enhance our chances of commercializing technologies for humanitarian needs.”

Universities Allied for Essential Medicines is a coalition of students from top research institutions from around the world. The organisation

“plays a distinct role in the access to medicines movement because of its unique position in promoting the use of socially responsible patenting and licensing practices, including global access license terms at universities and public research institutions”.⁷²

The organisation urged the USPTO not to repeat the mistakes of the priority review voucher scheme:

“If USPTO issues automatic awards to FDA priority review recipients, the USPTO re-examination award process will inherit the flaws of the FDA priority review. One such flaw was shown with the very first FDA priority review voucher, awarded to Novartis for its antimalarial drug Coartem. Novartis developed Coartem over a decade before the FDA implemented the priority review award. Therefore, contrary to the goal of the FDA program, Novartis was not incentivized to research and develop treatments for neglected tropical diseases. Automatic awards granted to recipients of the FDA voucher would allow these same exploitations to occur with USPTO re-examination vouchers.”

⁷⁰ Emory University, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, p.1, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_hollinger2010nov19.pdf [Accessed March 25, 2012].

⁷¹ University of Mississippi, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, October 27, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_chambliss2010oct27.pdf [Accessed March 25, 2012].

⁷² Universities Allied for Essential Medicines, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_guillen2010nov19.pdf [Accessed March 25, 2012].

Universities Allied for Essential Medicines maintained: “Many examples of global access policies and various innovative mechanisms can provide a solid basis for implementing the proposed USPTO program”. It argued: “Building upon current positive practices while continuing to augment them and learning from potentials for gaming of the system will create the most humanitarian value from the program.”

The Wisconsin Alumni Research Foundation has, traditionally, been supportive of strong protection of intellectual property rights. The Foundation agreed

“that a fast-track re-examination proceeding could allow patent owners to less expensively affirm the validity of their patents, and applauds the USPTO for its leadership and vision on this proposal”.⁷³

The Foundation argued “that the greatest opportunity to facilitate humanitarian efforts related to patented technologies is not in the re-examination stage, but in the initial examination stage”.

iv. Law firms and legal associations

The American Intellectual Property Law Association—led by Q. Todd Dickinson, a former director of the USPTO—was unenthusiastic about the scheme, arguing:

“The current proposal . . . is unlikely to achieve the desired results, and may create the undesirable impression that re-examination is a necessity because issued patents are inherently unreliable or defective.”⁷⁴

The Intellectual Property Owners Association (IPO) was also rather dour in its assessment of the regime:

“Although the proposed voucher program may provide a mechanism to gather information about ongoing humanitarian uses of technology, IPO believes other, more efficient ways of gaining this information can be developed which could offer viable alternatives to incentivizing additional development or patenting of such technologies.”⁷⁵

IPO complained that “the proposed program raises significant concerns regarding access to and availability of re-examinations for all patent applicants and risks unintended consequences”. IPO also worried:

“By creating a market for vouchers, the Notice might also incentivize parties to obtain marginal or low-quality patents, or could encourage the filing for patents on inventions that would otherwise be made available to the public.”

Thomas Kowalski of the law firm Vedder Price questioned the design of the scheme:

“What will the USPTO do to ensure that those in the developing world as well as the poor in the developed world can gain access to the technology? Also, the voucher should be tied specifically to the technology with the humanitarian use instead of being independent and transferable.”⁷⁶

Howard University School of Law suggested that there was a need for the USPTO to obtain assistance from humanitarian agencies and institutions in assessing the credentials of applications:

⁷³ Wisconsin Alumni Research Foundation, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, Department of Commerce, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_sullivan2010nov19.pdf [Accessed March 25, 2012].

⁷⁴ American Intellectual Property Law Association, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, available at http://www.uspto.gov/patents/law/comments/humanitarian_g_garlock2010nov19.pdf [Accessed March 25, 2012].

⁷⁵ Intellectual Property Owners Association, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, http://www.uspto.gov/patents/law/comments/humanitarian_g_muthig2010nov19.pdf [Accessed March 25, 2012].

⁷⁶ Michael Francisco, “USPTO’s Do-Good Vouchers” (2010) 28 *Nature Biotechnology* 1226.

“To ensure that the USPTO is not overburdened by researching these issues, it should elicit the assistance of humanitarian aid organizations, such as the World Health Organization (WHO), that are likely to have on hand information and data on the various humanitarian issues outlined.”⁷⁷

B. Pilot programme

In 2012, after much consultation, the USPTO launched a 12-month pilot program entitled “Patents for Humanity”.⁷⁸ In his blog, Director David Kappos discusses his ambitions for the scheme:

“Sweeping revolutions in technology continue to fundamentally redefine the way we connect with one another and interact with the world. Today, an entrepreneur can do business with a remote village across an ocean just as quickly as a student in Boston can video-conference with a professor in Beijing. Political rallies can be organized by the click of a button, while gripping images of that rally can be shared across continents with a cell phone.

And while an ever-shrinking and increasingly interconnected world allows technologies and information to spread in unprecedented ways, it also reminds us of the unique challenges we face as a planet. That’s why the United States Patent and Trademark Office, during a global development event today at the White House, announced the *Patents for Humanity* pilot program. Because while 21st century challenges are global in scope, so too are their solutions.”⁷⁹

Kappos contends:

“By building smarter irrigation systems in towns plagued by drought, by delivering cost-effective medicinal vaccines to communities without hospitals, and by engineering weather-resistant crop strains to farms ravaged by natural disasters, patented inventions have the power to create lasting solutions for some of the most serious issues confronting the world’s poorest and underserved regions.

He maintains:

“By offering strong incentives for businesses of all sizes to engage in these humanitarian efforts, *Patents for Humanity* encourages up to 1,000 applicants to demonstrate how their patented, or patent-pending technologies, are advancing research and results in four categories: Medical Technology, Food and Nutrition, Clean Technology, and Information Technology.”

He observes:

“Not only will the faster processing help technologists move solutions to the marketplace faster; it will also demonstrate that humanitarian endeavors and smart economic growth can work hand in hand.”

Kappos concludes: “By harnessing the power of science and technology with research and development, *Patents for Humanity* plays a key role in advancing President Obama’s global development agenda.” He observes:

“By collaborating with parts of the world in ways unimaginable just a few years ago, and by unleashing broader prosperity in emerging economies, this important new USPTO initiative demonstrates that the power to innovate is the power to lead, by design and by solution.”

⁷⁷ Howard University School of Law, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_jamar2010nov18.pdf [Accessed March 25, 2012].

⁷⁸ USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544; see also USPTO, “‘Patents for Humanity’ Pilot Programme, Awards Challenge 2012”, available at <http://www.youtube.com/watch?v=35WV6IyeUTw&feature=youtu.be> [Accessed March 25, 2012]; USPTO, “Patents for Humanity”, available at <http://patentsforhumanity.challenge.gov/rules> [Accessed March 25, 2012].

⁷⁹ David Kappos, “Patents for Humanity”, February 8, 2012, available at http://www.uspto.gov/blog/director/entry/patents_for_humanity [Accessed March 25, 2012].

The purpose of the scheme is “to incentivize the distribution of patented technologies to address humanitarian needs”.⁸⁰ The *Federal Register* explains the rules of the competition:

“The pilot program will be run as an awards competition. Participating patent applicants, patent owners, and licensees will submit program applications describing what actions they have taken with their patented technology to address humanitarian needs among an impoverished population or further research by others on humanitarian technologies.

Applications will be considered in four categories: Medical Technology, Food & Nutrition, Clean Technology, and Information Technology. Independent judges will review the program applications, and a selection committee will recommend awardees based on these reviews. Awardees will receive a certificate redeemable to accelerate select matters before the USPTO and public recognition for their efforts, including an award ceremony at the USPTO.

The certificate can be redeemed to accelerate one of the following matters: an *ex parte* re-examination proceeding, including one appeal to the Board of Patent Appeals and Interferences (BPAI) from that proceeding; a patent application, including one appeal to the BPAI from that application; or an appeal to the BPAI of a claim twice rejected in a patent application or reissue application or finally rejected in an *ex parte* re-examination, without accelerating the underlying matter which generated the appeal. *Inter partes* re-examinations and interference proceedings are not eligible for acceleration, nor are the forthcoming post grant reviews, *inter partes* reviews, derivation proceedings, or supplemental examinations.

Certificates awarded in the pilot are not transferable to other parties.”

Such a scheme seems a somewhat impure and eclectic hybrid among a priority review voucher, a patent fast-track system, and a prize regime.

The criteria of the competition focuses, quite strictly, upon humanitarian issues. There are two pathways—“humanitarian use” or “humanitarian research”.

Rules published in the *Federal Register* note that “the *humanitarian use* criteria recognize applying eligible technologies to positively impact a humanitarian issue”.⁸¹ It observed:

“Examples of technologies with potential humanitarian uses include treatments for disease, medical diagnostics, water purification, more nutritious or higher-yield crops, pollution reduction, and education or literacy devices, among others.”

The applicants must address subject matter, targeted population, and demonstrated impact.

The *Federal Register* notes that “the *humanitarian research* criteria recognize making patented technologies available to others for conducting research on a humanitarian issue”.⁸² It suggests:

“Examples of technologies with potential humanitarian research benefits include patented molecules, drug discovery tools, gene sequencing or splicing devices, special-purpose seed strains, or other patented research material.”

This category focuses on contributing needed tools to areas of humanitarian research lacking commercial application. The applicants will have to address the research impact of the technology, whether the area is a neglected field, and whether they took action to share the invention with others.

The White House Office of Science and Technology Policy emphasized that the “Patents for Humanity” project is intended to work in concert with a number of other initiatives.⁸³ In particular, it noted that:

⁸⁰ USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544, 6544.

⁸¹ USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544, 6545.

⁸² USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544, 6546.

⁸³ Quentin Palfrey and Hillary Chen, “Rewarding Inventors Who Work to Solve Global Challenges”, February 8, 2012, available at <http://www.whitehouse.gov/blog/2012/02/08/rewarding-inventors-who-work-solve-global-challenges> [Accessed March 25, 2012].

“Global Access in Action, in partnership with Baker & McKenzie, announced plans to develop and implement a program to educate patent holders and their lawyers about humanitarian use licenses for life-saving intellectual property.”

Moreover, the American Bar Association has agreed to encourage its members to help with the “Patents for Humanity” project. The National Institutes of Health and the US Department of Energy have implemented new programs to expedite and facilitate transfers of global health and clean energy technologies. Such initiatives are intended to be part of the Global Development Policy of the US Government.⁸⁴

In March 2012, David Kappos enthused to the US Congress about the scheme:

“This 12-month pilot advances the President’s global development agenda by rewarding companies who bring life-saving technologies to underserved regions of the world, and by highlighting positive examples of humanitarian actions that are compatible with business interests and strong patent rights.”⁸⁵

Kappos, I fear, overstates his case here. It is indeed hard to reconcile intellectual property maximalism with humanitarian objectives. At the time of writing, the USPTO has extended the deadline for applications to the Humanitarian Awards Pilot Program until the October 31, 2012.

There is a gap between the grandiloquent claims made for the “Patents for Humanity” project, and the decidedly modest scale and nature of the programme. A patent fast-track seems a minor incentive. The “Patents for Humanity” project falls well short of implementing international agreements and declarations such as the WIPO Development Agenda, the WTO’s Doha Declaration on the TRIPS Agreement and Public Health, the WTO General Council Decision of 30 August 2003, and the WHO declarations on intellectual property and public health.

Conclusion

There were high hopes that, under President Barack Obama, the US Government would adopt a constructive approach to intellectual property and access to essential medicines. However, there has been little in the way of progress in terms of the US Government’s stance on patent law and public health. In some respects, there has been backsliding and regression from the position of the Bush Administration. Sean Flynn notes that the United States replaced “the May 2007 access to medicine policies included in the Peru Free Trade Agreement with its new ‘access window’ (aka ‘team’) approach requiring TRIPS-plus data exclusivity, linkage and patent extensions”.⁸⁶ Hans Lofgren despairs that in some respects the Obama administration has gone backwards, with its support of the Anti-Counterfeiting Trade Agreement and the Trans-Pacific Partnership Agreement:

⁸⁴ White House, Office of the Press Secretary, “U.S. Global Development Policy”, September 22, 2010, available at <http://www.whitehouse.gov/the-press-office/2010/09/22/fact-sheet-us-global-development-policy> [Accessed March 25, 2012].

⁸⁵ David Kappos, “USPTO FY 2012 Budget Request”, testimony before the Subcommittee on Commerce, Justice, Science, and Related Agencies, Committee on Appropriations, United States House of Representatives, March 1, 2012, p.4, available at http://www.uspto.gov/news/speeches/2012/KapposTestimony120301_FINAL.pdf [Accessed March 25, 2012].

⁸⁶ Sean Flynn, “Intellectual Property Trans-Pacific Partnership Agreement Talks Stall in Melbourne”, March 12, 2012, available at <http://infojustice.org/archives/8847> [Accessed March 25, 2012]. Zach Carter and Sabrina Siddiqui, “Obama’s Global Health Policy Undercuts Reform at Home”, The Huffington Post, 10 July 2012, available at http://www.huffingtonpost.com/2012/07/10/obamas-health-policy-global-health-reform_n_1659742.html [accessed August 17, 2012]; and *Global Commission on HIV and the Law, Risks, Rights and Health* (New York: UNDP and HIV/AIDS Group, 2012) available at <http://www.hivlawcommission.org/> [accessed August 17, 2012].

“Remarkably, the US position under Obama represents a step back from the 2001 Doha Declaration on TRIPS and Public Health, the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and even the policy adopted by the Bush Administration in 2007.”⁸⁷

This article has considered two key initiatives deployed by the US Government: priority review vouchers and “Patents for Humanity”. The proposals are both designed to accelerate the regulatory review of patents with humanitarian purposes. It is certainly pleasing that the FDA and the USPTO have shown initiative in crafting policy solutions to address access to essential medicines. It is right and proper that such institutions play a leadership role in addressing innovation in respect of matters of public health and access to medicines—such as infectious diseases, neglected diseases, and pediatric diseases. Credit should be especially given to the innovative leadership of David Kappos, who has been willing to overcome resistance from certain stakeholders in order to pursue such development goals.

It is the contention of this article that, for all their grand intentions and humanitarian ambitions, the use of vouchers are shadow solutions, because they are not an effective means of addressing the magnitude of the problems associated with access to essential medicines. For its noble ambitions, the priority review voucher scheme has been a disappointment, especially given that it has been the subject of strategic gaming behaviour by pharmaceutical drug manufacturers. I am somewhat more positive about the “Patents for Humanity” project—partly because it had a stronger deliberative process and partly because it displayed a greater awareness of the complexities of crafting a policy instrument. At best, such regimes could serve as a minor or incidental incentive for public research institutions, not-for-profit entities, and pharmaceutical drug manufacturers, given both the costs involved in R&D, and the sheer scale of the problem in respect of access to essential medicines. At worst, such mechanisms are vulnerable to gaming and strategic behaviour. Fast-tracking regulatory approval may also have an adverse impact upon the quality of granted patents. Vouchers could well be hoarded by intellectual property owners, and stacked on top of a variety of intellectual property rights, such as patent, trade mark, and data exclusivity rights. It is of concern that the schemes are influenced by a larger ideology that strong intellectual property rights protection, coupled with other incentives, are the best means of promoting health-care and development. There is little engagement with the view that nation states should be able to make use of flexibilities within the intellectual property regime to address matters of development, access to medicines, and access to knowledge.

No doubt some commentators might consider such a verdict harsh or tough. Nonetheless, it is argued that there are more flexible and effective measures of promoting the research, development, and deployment of medicines for humanitarian uses and purposes. As Aaron Kesselheim comments:

“Though Congress should reconsider the usefulness of the voucher program, there are more direct ways to encourage drug development for medical conditions for which current incentives have proven inadequate.”⁸⁸

There is well-founded criticism that priority review vouchers and the “Patents for Humanity” project are a poor substitute for substantive patent law reform. The US patent system has been the subject of recent revision. Campaigning to become the US President, Barack Obama vowed to “Reform the Patent System”.⁸⁹ He pledged: “A system that produces timely, high-quality patents is essential for global competitiveness in the 21st century.”

In September 2011, President Obama signed the America Invents Act 2011 commenting:

⁸⁷ Hans Lofgren, “The Trans-Pacific Partnership Agreement: A Threat to Affordable Medicines and Public Health” (2011) 4(2) *Southern Med Review* 2.

⁸⁸ Kesselheim, “Drug Development for Neglected Diseases” (2008) 359 *New England Journal of Medicine* 1981.

⁸⁹ The Obama Campaign website has since been archived. Quoted in Matthew Rimmer, “Reform the Patent System” *Australian R&D Review*, October 2009, p.10.

“I am pleased to sign the America Invents Act. This much-needed reform will speed up the patent process so that innovators and entrepreneurs can turn a new invention into a business as quickly as possible. I’m also announcing even more steps today that will help bring these inventions to market faster and create jobs. Here in America, our creativity has always set us apart, and in order to continue to grow our economy, we need to encourage that spirit wherever we find it.”⁹⁰

However, the reforms contained in the America Invents Act 2011 did not address the question of patent law and access to essential medicines. The US regime has a weak defence of experimental use.⁹¹ The safe harbour for research leading to the approval of pharmaceutical drugs has been interpreted by the United States Supreme Court somewhat more broadly.⁹² The MSF Intellectual Property Expert Group has argued that there should be exceptions to patent rights for humanitarian uses.⁹³ The patent regime has not facilitated public sector licensing in respect of essential medicines. The US regime lacks effective mechanisms for compulsory licensing, government use and state acquisition for domestic use.⁹⁴ The US Congress and the Obama administration still have not implemented the WTO General Council Decision 2003 to allow for the export of pharmaceutical drugs to developing countries. There is not a strong record of technology transfer in respect of essential medicines. The US Government could do more to aid the UNITAID patent pool programme. There needs to be a better system of public sector licensing. The next generation of patent law reform in the United States needs to consider such outstanding matters.

Furthermore, it is worthwhile to consider a number of other alternative proposals in respect of encouraging R&D in medical innovation. The economist Joseph Stiglitz and the civil society group Knowledge Ecology International have recommended the use of monetary prizes as an alternative mechanism to stimulate private investment in R&D.⁹⁵ The civil society group suggests that donors and governments should consider prizes as an alternative to marketing monopolies as a reward for successful R&D investments. The US Government has been quite enthusiastic about the use of prizes in other technological contexts, such as promoting innovation in respect of clean technologies.⁹⁶ It is mysterious why the US Congress thus far have not embraced proposals such as Senator Bernie Sanders’ The Medical Innovation Prize Fund Act 2011 and The Prize Fund for HIV/AIDS Act 2011.⁹⁷ There have also been proposals for a Health Impact Fund, which links rewards to the impact of a pharmaceutical drug.⁹⁸ Such a project is worth trialling. The Medicines Patent Pool established by UNITAID has sought to encourage the sharing of patented inventions related to essential medicines.⁹⁹ The US Government could do more to

⁹⁰ White House, “President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs”, September 16, 2011, available at <http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim> [Accessed March 25, 2012].

⁹¹ *Madey v Duke University* 307 F.3d 1351 (2002).

⁹² *Merck KGaA v Integra Lifesciences I, Ltd.* 545 U.S. 193 (2005).

⁹³ Knowledge Ecology International, “Humanitarian Uses of Patented Inventions”, available at <http://keionline.org/patents/humanitarian> [Accessed March 25, 2012].

⁹⁴ Rimmer, “The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid” (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889; Rimmer, “Race against Time: The Export of Essential Medicines to Rwanda” (2008) 1(2) *Public Health Ethics* 89; Ellen t’ Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (Diemen: AMB Publishers, 2009); Abbott and Dukes, *Global Pharmaceutical Policy* (2009); Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010); William Fisher and Talha Syed, “Global Justice in Healthcare: Developing Drugs for the Developing World” (2007) 40 *University of California Davis Law Review* 581.

⁹⁵ Joseph Stiglitz, “Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations” (2006) 333 *British Medical Journal* 1279; James Love and Tim Hubbard, “Make Drugs Affordable: Replace TRIPS-Plus with R&D-plus” (2004) 6 *Bridges* 3, available at <http://www.cptech.org/ip/health/rnd/bridges042004.pdf>; Knowledge Ecology International, Selected Innovation Prizes and Reward Programs, *KEI Research Note 1*, March 7, 2008, http://www.keionline.org/misc-docs/research_notes/kei_rm_2008_1.pdf [Accessed March 25, 2012].

⁹⁶ For an analysis of environmental patents, see Rimmer, *Intellectual Property and Climate Change* (2011), p.343.

⁹⁷ James Love, “Senator Sanders Introduces Two Medical Innovation Prize Bills in U.S. Senate to De-link R&D Costs from Drug Prices”, May 27, 2011, available at <http://keionline.org/node/1147> [Accessed March 25, 2012].

⁹⁸ Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Available for All* (New Haven: Yale University, 2008).

⁹⁹ Medicines Patent Pool, <http://www.medicinespatentpool.org/> [Accessed March 25, 2012]; Geertrui Van Overwalle, *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (Cambridge: Cambridge University Press, 2009); Dianne Nicol and Jane Nielsen, “Opening the Dam: Patent Pools, Innovation and Access to Essential Medicines” in Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010).

support this important initiative. Finally, groups based at Yale University, Duke University, and elsewhere have proposed an “open source” gift approach to drug development.¹⁰⁰ They have envisaged a decentralised, web-based community wide effort where scientists from both the public and private sectors can work together for a common cause.

Generally, there is a need to avoid “shadow solutions” in respect of intellectual property and global issues. The philosopher Stephen M. Gardiner has commented:

“In a perfect moral storm, we should expect 'shadow solutions' to the problem at hand that reflect only the limited concerns of those with the power to act. Such 'solutions' are morally problematic. Not only are they typically inadequate as a matter of substance, but they also create the dangerous illusion of real action, and this serves as a distraction through which continued buck-passing can be perpetrated.”¹⁰¹

In dealing with Patents for Humanity, we need real solutions, and not merely shadow solutions.

¹⁰⁰ Stephen Maurer, Arti Rai and Andrej Sali, “Finding Cures for Tropical Diseases: Is Open Source an Answer?” (2004) 1(3) *PLoS Medicine* 183; Amy Kapczynski, Samantha Chaifetz, Zachary Katz and Yochai Benkler, “Addressing Global Health Inequities: An Open Licensing Approach for University Innovations” (2005) 20 *Berkeley Technology Law Journal* 1031; Stephen Maurer, “Open Source Drug Discovery: Finding a Niche (or Maybe Several)” (2007) 76(2) *University of Missouri—Kansas City Law Review* 405; Yann Joly, “Open Biotechnology: Licenses Needed” (2010) 28 *Nature Biotechnology*, p.417.

¹⁰¹ Stephen M. Gardiner, *A Perfect Moral Storm: The Ethical Tragedy of Climate Change* (Oxford: Oxford University Press, 2011), 76.

Reform Proposals on the Geographical Indications of the European Union for the Protection of Traditional Knowledge

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☞ Cultural property; EU law; Geographical indications; Origin marking; Protected designations of origin; Traditional knowledge; Traditional specialities guaranteed; Transparency

This paper focuses on the revision of the “sui generis” system of geographical indications in the European Union, one of the most debated instruments protecting intellectual property. Here, we suggest fundamental improvements to increase the transparency and thereby the information-economic function of geographical indicators (Protected Designation of Origin, PDO; and Protected Geographical Indications, PGI) and to incorporate in their goals the protection of traditional knowledge about distinctive features of local food culture. The paper firstly proposes to abolish the category of Traditional Speciality Guaranteed (TSG), which shares many characteristics with geographical indications and can therefore lead to confusion among consumers. In addition, two potential alternatives for reform are discussed from an information economic and cultural property perspective, concluding that a concentration on PDO as the sole form of

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protected status is preferable over the alternative of transparently displaying the origin of the raw materials and differentiating the forms of protection PGI and PDO. With this recommendation, this paper contradicts the reform proposal previously suggested by the European Commission.

The “Regulatory Choice Problem”—Introduction

Geographical indications (GIs) are instruments that provide consumers information about special qualities of a product that are not identifiable either before or after a product’s consumption. Thus, they constitute a special kind of credence good.¹ As consumers cannot determine the real origin and the specific traditional manufacture of a product, producers have to credibly convey information on the product’s attributes in additional ways. GIs are meant to resolve this situation of information asymmetry by protecting consumers from being misled and by reducing the consumer’s costs of obtaining information similarly to trademarks,² thus supporting a well-informed decision. GIs therefore generate additional value for consumers and facilitate price premiums for producers. The extent to which producers can obtain the price premium depends on the consumers’ willingness to pay. This is determined by the market value of the products, which is again influenced by the information-providing effect of GIs. In addition, GIs can offer a high level of protection against imitation, thus maintaining producers’ income which benefits rural regions as it counteracts rural depopulation by providing jobs.³

Current research on GIs is based on Regulation 510/2006 on the Protection of Geographical Indications and Designation of Origin for Agricultural Products and Foodstuffs.⁴ That Regulation has replaced its similarly titled predecessor Regulation 2081/92⁵ which was not conforming to the international trade rules of the WTO. Currently, a further amendment is being discussed in the European Union,⁶ which is also dealt with in this article.

By implementing GIs beyond the original provision of information on a product’s quality, reputation and traditional production method, Regulation 510/2006 enables producers to differentiate their products from others in many ways.⁷ Nevertheless, it comes as a surprise that neither the original 1992 Regulation nor the currently effective Regulation address the protection of traditional knowledge, although many international fora discuss GIs in this context.⁸ To some extent the Regulation Proposal of 2010 compensates for this by aiming to preserve the quality and diversity of traditional products as “living cultural and gastronomic heritage”.⁹ Thus, GIs are seen as an instrument enabling commodification, but by no means forcing it.

¹ For the classification of goods into search, experience, and credence goods based on information asymmetry, see Phillip Nelson, “Information and Consumer Behavior” (1970) 78(March-April) *Journal of Political Economy* 311; Michael R. Darby and Edi Karni, “Free Competition and the Optimal Amount of Fraud” (1973) 16(1) *Journal of Law and Economics* 67.

² For the economic function of trademarks, see William M. Landes and Richard A. Posner, *The Economic Structure of Intellectual Property Law* (Cambridge, Mass: Harvard University Press, 2003), Ch.7.

³ Roland Herrmann, Thilo Maruhn and Ramona Teuber, “Der Schutz geographischer Herkunftsangaben: Herausforderungen für agrarökonomische, rechtswissenschaftliche und interdisziplinäre Forschung” (2008) 57(7) *Agrarwirtschaft* 321.

⁴ Council Regulation 510/2006 of March 20, 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (Regulation 510/2006) [2006] OJ L93/12.

⁵ Council Regulation 2081/92 of July 14, 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1992] OJ L208/1.

⁶ European Commission, “Final Proposal for a Regulation of the European Parliament and of the Council on agricultural product quality schemes” (Regulation Proposal), December 10, 2010, COM(2010)733.

⁷ Dwijen Rangnekar, “The Socio-economics of Geographical Indications: A Review of Empirical Evidence from Europe” (2004) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No.8, available at <http://ictsd.net/downloads/2008/07/a.pdf> [Accessed March 25, 2012].

⁸ As part of the WTO’s Review of GIs under art.24, members “have highlighted the relevance of human factors to matters such as quality, traditional methods of production, vinticultural practices and methods of production, preparation and cultivation”. See World Trade Organization, “Review under Article 24.2 of the application of the provisions of the section of the TRIPS Agreement on geographical indications”, November 24, 2003, IP/C/W/253/Rev.1, p.44. See also World Trade Organization, “Issues related to the extension of the protection of geographical indications provided for in Article 23 of the TRIPS agreement to products other than wines and spirits”, May 18, 2005, TN/C/W/25, pp.13 and 18, directly raising the issue of traditional knowledge.

⁹ See Regulation Proposal, p.13, para. (1).

While a GI does not save products from having to prevail on the market, it makes it easier, as reliable information on origin, production and quality generally facilitates a higher price. Specific preferences on behalf of consumers for authentic, traditionally manufactured products are documented in the Regulation Proposal¹⁰ and also in the empirical literature.¹¹ Precisely for this reason, GI goals should also focus more on the traditional knowledge. GIs support the sustainability of traditional knowledge or cultural heritage, but they rather indirectly encourage valuing such knowledge instead of directly protecting it. They achieve this by identifying the content or the production method of products in the product specification. GIs safeguard such products by protecting them from free riding on the product's reputation, thus maintaining their existence. But the definition and the protection of food-cultural particularities does not imply a preservation strategy freezing methods of production and thus local knowledge similar to a museum. Instead they rely on the market to determine which goods prevail. Therefore, a well-functioning market is a basic requirement to successfully use the GI instrument.¹²

Unlike in other contexts of cultural property, GIs do not aim to directly protect particular actors and groups of actors such as indigenous groups. They rather provide protection rights for a certain region, thus also allowing external actors to benefit from protection if they move to the area and conform to the code of practice.¹³ Moreover, not only small scale producers are able to apply for GIs, but industrial producers are also able to do so. In practice, this occurs frequently—for example in the case of the largest French dairy firm Lactalis,¹⁴ the Swiss Emmi AG and the Swiss sausage company Bell AG. All of these leading international actors aim to enrich their products' portfolio with attractive GIs. As a result, the regions benefit in terms of employment. At the same time, cultural idiosyncrasies are preserved if traditional production knowledge and regional pre-products lead to particular specialties for the end consumer.

In summary, GIs provide a different protection potential than other "sui generis" rights that are based on copyright law.¹⁵ While the former favour actors generally in a specific region when manufacturing certain products, the latter protect the rights of specific actors identified as the carriers of cultural practices.¹⁶ Precisely the fact that GIs are not ascribed to specific actors provides further potential to maintain and protect knowledge and the associated products that are already in the public domain and whose actual creators are not identifiable.¹⁷ Nonetheless, GIs offer considerable protection potential for cultural property, as they facilitate a commodification of entirely different products than the "sui generis" rights derived from copyright law. In this context, they complement the instruments available for the protection of cultural property below the level of formal property rights like those for material property.

By analysing and evaluating the EU regulations, this article develops ideas for improvement and possible alternatives, which were partly discussed by the European Union.¹⁸ It arrives at a recommendation contradicting the Regulation Proposal previously suggested by the European Commission. This article

¹⁰ See Regulation Proposal, p.2, art.1.1 (Grounds for and Objectives of the Proposal).

¹¹ See e.g. Sean Beer, "Authenticity and Food Experience—Commercial and Academic Perspectives" (2008) 19 *Journal of Foodservice* 153; Stephen Brown, Robert V. Kozinets and John F. Sherry Jr, "Teaching Old Brands New Tricks: Retro Branding and the Revival of Brand Meaning" (2003) 67(July) *The Journal of Marketing* 19.

¹² David R. Downes, "How Intellectual Property Could Be a Tool to Protect Traditional Knowledge" (2000) 25 *Columbia Journal of Environmental Law* 253; Shivani Singhal, "Geographical Indications and Traditional Knowledge" (2008) 3(11) *Journal of Intellectual Property Law & Practice* 732.

¹³ C. Bramley and J.F. Kirsten, "Exploring the Economic Rationale for Protecting Geographical Indicators in Agriculture" (2007) 46(1) *Agrekon* 69, available at <http://ageconsearch.umn.edu/bitstream/10128/1/46010069.pdf> [Accessed March 25, 2012].

¹⁴ See Alexander Wirsig, Adriano Profeta, Anna Häring and Roman Lenz, "Indigenous Species, Traditional and Local Knowledge and Intellectual Property Rights" (2010) 9th European IFSA Symposium, Vienna, p.1724.

¹⁵ E.g. Tunis Model Law on Copyright for Developing Countries 1976 (UNESCO); Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions 1985 (UNESCO and WIPO); Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *The Protection of Traditional Cultural Expressions/Expressions of Folklore: Outline of Policy Options and Legal Mechanisms* (Geneva: WIPO 2004).

¹⁶ See Kilian Bizer, Matthias Lankau, Gerald Spindler and Philipp Zimbel, "Sui Generis Rights for the Protection of Traditional Cultural Expressions" (2011) 2 *JIPITEC* 114.

¹⁷ Singhal, "Geographical Indications and Traditional Knowledge" (2008) 3(11) *Journal of Intellectual Property Law & Practice* 732.

¹⁸ For an overview of the discussed alternatives of the EU, see European Commission, "Impact Assessment on Geographical Indications", December 10, 2010, SEC(2010)1524, Commission staff working paper; European Commission, "Impact Assessment on Traditional Specialities Guaranteed", December 10, 2010, SEC(2010)1525, Commission staff working paper.

examines the regulations from two different perspectives: an information economic perspective and a cultural property perspective. The article proceeds as follows: after discussing the EU system of origin-labelling, different reform proposals are derived. Finally, alternatives and policy recommendations are evaluated and summarized.

The EU system of origin-labelling for food specialties

As one of the strongest supporters of GIs on the international level,¹⁹ the European Union commands three instruments to obtain the goals previously outlined: Protected Designations of Origin (PDO), Protected Geographical Indications (PGI) and Traditional Speciality Guaranteed (TSG).²⁰ These elements of the European Union's quality policy provide information on the specific characteristics and the associated quality of the products. In the narrow sense, only PDO and PGI are considered qualified GIs²¹; TSG designates traditional characteristics of a product and not necessarily the product's actual origin²² even if the denominations often point to a region. Therefore, only a qualified label of origin requires a close link between the geographically (and traditionally) identified origin and specific product characteristics (such as quality, production method, reputation) (*terroir*).²³ This enables a labelled product to differentiate itself from products from other regions or countries. The fact that this close relationship (cf. "intrinsic link")²⁴ cannot be clearly measured poses a central problem for the origin-labelling system.²⁵ In practice, scientific links in terms of a measurable correlation between origin and qualities are more the exception than the rule.²⁶

On the demand side, these three instruments should convey different information on origin, quality and traditional production method of the protected products to consumers. It is compulsory to use the indications PDO, PGI and TSG or their symbols where the associated products are marketed under the registered name.²⁷ However, the respective EU labels are very similar to each other and only differ slightly.²⁸ The difference between the content of the labels is not recognizable without additional information. The risk of confusing consumers is correspondingly high and empirically confirmed.²⁹ Further, various studies have already pointed towards a lack of public awareness and the low recognition level of GI labels.³⁰ To

¹⁹ See e.g. Christophe Geiger, Daniel Gervais, Norbert Olszak and Vincent Ruzek, "Towards a Flexible International Framework for the Protection of Geographical Indications" (2010) 1(2) WIPO J. 147, discussing the EU position in the WTO; see also Tim Josling, "The War on Terroir: Geographical Indications as a Transatlantic Trade Conflict" (2006) 57(3) J. Ag. Econ. 337, 349–359.

²⁰ Regulated by Council Regulation 510/2006 of March 20, 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [2006] OJ L93/12, and Council Regulation 509/2006 of March 20, 2006 on agricultural products and foodstuffs as traditional specialties guaranteed (Regulation 509/2006) [2006] OJ L93/1.

²¹ See Regulation 510/2006 art.2 (Definitions of PDO and PGI).

²² See Regulation 509/2006 art.2 (Definitions) and art.4 (Requirements as Regards Products and Names).

²³ For an extensive discussion on the French concept of "terroir", see e.g. Justin Hughes, "Champagne, Feta, and Bourbon: The Spirited Debate about Geographical Indications" (2006) 58 Hastings L.J. 299; Josling, "The War on Terroir" (2006) 57(3) J. Ag. Econ. 337.

²⁴ See Regulation Proposal, p.16, para. (17).

²⁵ See the argumentation in Adriano Profeta, Richard Balling, Volker Schoene and Alexander Wirsig, "The Protection of Origins for Agricultural Products and Foods in Europe: Status Quo, Problems and Policy Recommendations for the Green Book" (2009) 12(6) J. World Intell. Prop. 622.

²⁶ See the discussion to apply the multi-isotope analysis in the wine sector and its contradictory results in Simon Kelly, Karl Heaton and Jurian Hoogewerff, "Tracing the Geographical Origin of Food: The Application of Multi-element and Multi-isotope Analysis" (2005) 16 *Trends in Food Science & Technology* 555, 563.

²⁷ See Regulation 510/2006 art.8.2; Regulation 509/2006 art.12.2.

²⁸ Commission Regulation 628/2008 of July 2, 2008 amending Regulation 1898/2006 laying down detailed rules of implementation of Council Regulation 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [2008] OJ L173/3, has introduced different colour schemes for GIs. Accordingly, the PDO label is identifiable with the combination of colours of red and yellow, while PGI with colours of blue and yellow. Nonetheless, as the labels are used in black and white or in negative, the difference between PDO and PGI remains only in the small wording inside the symbols. Interestingly, TSG labels use the same colours as PGI labels. Further, regarding the style and the design of the GI labels, there are no distinguishing characteristics, and TSG labels differ only slightly from them.

²⁹ See the analysis of the impacts on consumers in London Economics, *Evaluation of the CAP Policy on Protected Designations of Origin (PDO) and Protected Geographical Indications (PGI): Final Report* (London: 2008).

³⁰ Such as Ramona Teuber, "Producers' and Consumers' Expectations towards Geographical Indications—Empirical Evidence for Hessian Apple Wine", presentation at the 113th EAAE Seminar: "A Resilient European Food Industry and Food Chain in a Challenging World", Greece, 2009; Christos Fotopoulos and Athanasios Krystallis, "Quality Labels as a Marketing Advantage: The case of the 'PDO Zagora' Apples in the Greek Market" (2003) 37(10) *European Journal of Marketing* 1350; London Economics, *Evaluation of the CAP Policy on Protected Designations of Origin (PDO) and Protected Geographical Indications (PGI)* (2008).

a certain extent, the great differences in the ways in which Member States utilize the system depends on a country's particular agricultural background, as those with a strong tradition in agriculture feature products with a high awareness level regardless of the EU labels. To initiate a protection procedure the awareness level of a product among consumers and the reputation of a product should be measured. Some authors point out the necessity of consumer surveys as suggested in the Guide to Community Regulations of the Commission Services.³¹

In addition, the labelling of origin system bears problems on the supply side as well—for instance, the low participation of small scale producers due to arduous efforts, costly controls and the necessity to implement specified requirements.³² To some extent, the European Union has recognized the challenge of harmonizing competition conditions for products of the same category and balancing or counterbalancing the cost advantages of established enterprises (monopolists). Therefore, it aims to strengthen and recognize the role of cooperatives (groups), particularly in terms of modifying specifications, supervising the enforcement of the protection of the registered names and complying with the production requirements.³³ Although it is suggested that the registration procedures for PDO, PGI and TSG should be more transparent, the existing reform proposal continues to ignore a substantial problem, as the difference between PDO and PGI remains vague. The same protection level is given for these instruments despite the fact that the regional connection of the product is substantially different between PDO and PGI. Thus, different information should be provided on the actual product origin. This article therefore approaches the fundamental disparities between PDO and PGI and elaborates several reform alternatives, which are presented below.

Possible reform alternatives

GIs can generate additional values for consumers if the instruments are transparent and trustworthy. While the intention of the EU reform proposal to strengthen controls and requirements supports the reliability of the instruments itself, information on fundamental characteristics remains unknown if producers do not provide any further details about the production stages taking place within the region apart from the label. In this case, consumers are not able to clearly distinguish the grade of regional embeddedness of PDO from PGI protected products. Therefore, our analysis focuses on the question of how transparency between instruments of PDO and PGI can be increased and the EU GI system can provide efficient information to consumers as a requirement for higher willingness to pay.

Apart from the fact that TSGs are not technically included as GIs, they also need to be considered as they are closely related to PDOs and PGIs and exhibit similar characteristics. From the consumer perspective the label seems to be very similar although the focus is quite different. For this reason, abolishing the TSG label is seen as an opportunity to clarify the information-providing effect of GIs (PDO and PGI). In addition to abolishing TSGs, this article discusses two reform proposals (see Table 1). While the first alternative aims to increase transparency for PGIs more specifically than currently suggested in the Regulation Proposal, the second recommends further modifying the existing regulation. This also suggests abolishing the PGI category and transforming part of it into PDOs, with the result of maintaining and specifying solely the PDO instrument. Its implementation constitutes a considerably greater challenge for the

³¹ See Adriano Profeta and Richard Balling, "Evaluierung der Übergangsregelung des Herkunftsschutzes bei Agrarprodukten und Lebensmitteln in Europa gemäß Verordnung (EG) Nr. 510/06 und Verbesserungsvorschläge für die anstehende Modifikation" (2007) 56(4) *Agrarwirtschaft* 213, referring to the European Commission, *Protection of Geographical Indications, Designations of Origin and Certificates of Specific Character for Agricultural Products and Foodstuffs: Guide to Community Regulations*, 2nd edn. (2004), Commission services working paper, p.14.

³² See Rangnekar, "The Socio-economics of Geographical Indications" (2004) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No. 8; Stéphane Marette, "Can Foreign Producers Benefit from Geographical Indications under the New European Regulation?" (2009) 10(1) *The Estey Centre Journal of International Law and Trade Policy* 65; Anselm K. Sanders, "Incentives for and Protection of Cultural Expression: Art, Trade and Geographical Indications" (2010) 13(2) *J. World Intell. Prop.* 81; G.E. Evans, "The Strategic Exploitation of Geographical Indications and Community Trade Marks for the Marketing of Agricultural Products in the European Union" (2010) 1(1) *WIPO J.* 159; see also European Commission, "Impact Assessment on Geographical Indications", Commission staff working paper, SEC(2010)1524.

³³ See Regulation Proposal, p.20, para. (57).

community and still leaves many questions unanswered. However, this focus seems particularly reasonable from a cultural property perspective since it provides the greatest commodification potential for regions without risking the establishment of an uncontested monopoly. After all, a PDO can always be challenged by external actors buying regional companies or relocating to the region.

Table 1: Overview of reform options analysed³⁴

Instrument	Option 1	Option 2
	Origin transparency and differentiation based on tradition	Concentration on one protection form (PDO)
<i>PDO</i>	Concentrating on developed specialities (EC Regulation 510/2006)	Maintaining and specifying the EC Regulation 510/2006
<i>PGI</i>	Clearly labelling the origin of raw materials and a stronger focus on developing food-cultural specialities (EC Regulation 510/2006)	Abolition and transformation into PDO
TSG	Abolition (EC Regulation 509/2006)	Abolition (EC Regulation 509/2006)

Justifying the abolition of TSGs

In order to avoid consumer confusion and to keep information on GIs transparent, the abolition of TSGs is necessary. In this light it is important to state that with TSGs' lower level of protection,³⁵ which is limited to the production method without any regional connection, TSGs benefit from the clearly stricter requirements of PDO and PGI, which require an obvious regional link of the raw materials. As TSGs do not need to fulfil this requirement, they could be suspected of free-riding on the other, more demanding categories. If only for this reason, abolishing TSGs seems a legitimate step that could increase the trustworthiness of the other labels.

From the cultural property perspective TSGs also provide the least protection of certain methods of production. They do not even aim to commodify regional raw materials, thus providing neither actor-related nor region-related protection. Under current law, TSGs aim to commodify the production method only, i.e. the recipe. For this reason, abolishing the TSG label is seen as an opportunity to advance the information-providing effect of GIs (PDO and PGI) without notably weakening the protection of cultural property.

In summary, abolishing the TSG is reasonable from an information economic perspective, since the instrument confuses consumers, as is outlined in the following:

Conflict with origin:

According to Regulation 509/2006, products with characteristics based on origin or regional provenance cannot be registered as TSGs.³⁶ TSG labels (which have the same colours blue and yellow and can be mistaken for PGI) do not inform the consumer about the origin of the product, but about their traditional production method as the name "traditional speciality" alludes to. Further, the production does not have

³⁴ The reform alternatives analysed here were partly discussed during the process of the revision of the EU agricultural quality policy: (1) Abolition of TSG was suggested in European Commission, "Impact Assessment on Traditional Specialities Guaranteed", 2010, Policy Options 4.3; (2) "Status quo accompanied with streamlining of procedures and clarification of PDO/PGI rules" (see see European Commission, "Impact Assessment on Geographical Indications", 2010, Policy Options 5.2.3). The option merging definitions of PGI and PDO were also discussed, suggesting the abolition of PDO (see Policy Options 5.5). As it can be assumed from the current EU reform proposal, the EU quality system will further function in its current construction maintaining all three instruments (PDO, PGI and TSG) with slight modifications regarding Regulations 510/2006 and 509/2006.

³⁵ According to Regulation 510/2006 GIs are protected inter alia "against any direct or indirect commercial use of a registered name ... any misuse, imitation or evocation, even if the true origin of the product is indicated or if the protected name is translated or accompanied by an expression such as 'style', 'type', 'method', 'as produced in', 'imitation'" ... (art.13.1(a), (b)). Meanwhile, Regulation 509/2006 leaves the protection of TSG very unspecified stating that "registered names shall be protected against any practice liable to mislead the consumer" (art.17(2)).

³⁶ Regulation 509/2006 art.4(1).

to contain a link with the geographical origin. Accordingly, production is not limited to a certain region, but open to all producers. Precisely for this reason, TSGs are of little economic interest and are not used very much.³⁷

No clear differentiation from GIs:

Eventually, there is no valid reason why an additional category needs to be kept for products without a geographical origin; yet, as Bérard and Marchenay note,³⁸ in every country in the world, a geographical origin is linked to the product. Moreover, the previously mentioned restriction outruling registration of products with a reference to a specific geographical origin in the Regulation Proposal even strengthens the contradiction as GI instruments also reflect the elements of tradition. The differences between PDO, PGI and TSG thus become even more blurred, further increasing the risk of consumer confusion.³⁹

Limited perception of tradition:

In terms of cultural traditions, other problems support the abolition of the instrument: currently the criterion of being a traditional product requires at least 25 years of documented history on the domestic market.⁴⁰ Considering the Regulation Proposal, it seems likely that this period will be extended to 50 years as it demands that only tradition passed on at least over two generations be recognized as culturally significant;⁴¹ PDOs and PGIs on the other hand have no such requirements. Again, GIs and TSGs prove to be inconsistent. In the case of GIs, the existence of a tradition and its meaning does not depend on an arbitrarily set time period, although like TSGs these instruments also describe traditional production methods. From this view, TSGs seem to set higher requirements regarding cultural and traditional connections than GIs. This again can be confusing as the qualitative requirements are otherwise rather less demanding.

In total, given the blurry differences between the GI types and the TSG and the resulting consumer confusion, the continued existence of TSGs cannot be justified. In the end, TSGs are merely “second-class” GIs. Nevertheless, abolishing TSGs requires an adequate transitional arrangement: in cooperation with all possible actors, regulations for companies holding TSGs would have to be modified to enable PGI recognition—or if possible PDO recognition—so as to facilitate transborder nomination as provided also by TSG. This might entail a long negotiation process, but should prove viable in many cases.⁴² Products not fulfilling the requirements of a PDO or PGI nomination could resort to the facultative quality specifications of the EU and international harmonization, i.e. within the Codex Alimentarius (food codex). While their scope of protection may be narrower, they are specifically tailored to preserve product identities without regional delimitation. Building private brands may be another opportunity, especially for industrial processors.

³⁷ To date a total of 37 products are registered as TSG products. See <http://ec.europa.eu/agriculture/quality/door> [Accessed March 25, 2012].

³⁸ Laurence Bérard and Philippe Marchenay, “Local Products and Geographical Indications: Taking Account of Local Knowledge and Biodiversity” (2006) 58(187) *International Social Science Journal* 109, 110.

³⁹ See the current example of Dutch “Boerenkaas”, a cheese from a farm distinguishing itself not with actual qualitative particularities, but a requirement that at least 50 per cent of the milk must originate from the farm producing the cheese. Here, the TSG is used to protect direct marketing (although a proper label for direct marketing products is currently considered, too).

⁴⁰ Regulation 509/2006 art.2(1)/b.

⁴¹ Regulation Proposal, p.23, art.3(3).

⁴² See for instance the case of traditional-type mozzarella cheese. The name “Mozzarella di Bufala Campana” was entered successfully in the DOOR database as a PDO product in 1996. Besides, the name of “Mozzarella” has also been registered as TSG in 1998. For more information, see <http://ec.europa.eu/agriculture/quality/door> [Accessed March 25, 2012].

Option 1: Transparency regarding the origin of raw materials and differentiating the types of protection

In the light of the suggested abolition of the TSG norm, this article discusses a first alternative solution that is dedicated to the differences between PDO and PGI, which is seen as critical in the literature.⁴³ This option aims at considerably improving transparency between PDO and PGI by specifying the differences between the two instruments and highlighting them. This is of great relevance should both instruments be retained as envisaged by the current Regulation Proposal. Only if consumers possess sufficient information on the product identity producers can expect rents appropriate to the product characteristics.⁴⁴

For this purpose, information on protected GIs needs to be fundamentally improved:

Regarding protection criteria:

Protection via PGI can only be granted for the geographical name of a product “which possesses a specific quality, reputation or other characteristics attributable to that geographical origin” and for which “the production and/or processing and/or preparation of which take place in the defined geographical area”.⁴⁵ In contrast, PDO requires that the “quality or characteristics” of the product be “essentially or exclusively due to a particular environment with its inherent natural and human factors”, with “the production, processing and preparation” all taking place in the demarcated geographical area. Both differentiation criteria are problematic. The connection between origin and product characteristics (quality) is challenging in almost all cases—also with respect to PDOs. It is very difficult, if not impossible, to prove that specific characteristics or quality differences are explicitly attributable to the region.⁴⁶ In practice, PDOs strongly rely on the reputation closely connected to the region as initially envisaged for PGIs.⁴⁷ Accordingly, on an international level the instrument is applied unequally: while the same categories of products are registered in northern EU Member States as PGIs, they can be found as PDOs in southern Member States. Moreover, it is not unusual that some PGI products exhibit stricter quality criteria than some PDO products.⁴⁸

If both protection norms are to be maintained, obviously the differentiation cannot be based only on the existing or non-existing link between (scientifically measurable) product characteristics and the region. Instead, a cultural differentiation with respect to a tradition’s link with the region might be a sustainable solution. So far, both concepts include the image of a regional specialty that should be preserved. This contradicts the results of research on cultural property,⁴⁹ according to which establishing a consortium to use the protection rights is the first step to reinventing the regional tradition to be preserved with the GI.⁵⁰ Especially in regions with a low level of food-cultural tradition like in many northern and eastern European Member States, GIs today are a driving force for constituting specialties.

⁴³ See Profeta, Balling, Schoene and Wirsig, “The Protection of Origins for Agricultural Products and Foods in Europe” (2009) 12(6) *J. World Intell. Prop.* 622; Geiger, Gervais, Olszak and Ruzek, “Towards a Flexible International Framework for the Protection of Geographical Indications” (2010) 1(2) *WIPO J.* 147; Evans, “The Strategic Exploitation of Geographical Indications and Community Trade Marks for the Marketing of Agricultural Products in the European Union” (2010) 1(1) *WIPO J.* 159.

⁴⁴ As proposed by Regulation Proposal, p.24, art.4(a).

⁴⁵ Regulation 510/2006 art.2(1); Regulation Proposal, p.24, art.5(1), defining PDO and PGI.

⁴⁶ This fact is especially contested in the wine sector. See Herrmann, Marauhn and Teuber, “Der Schutz geographischer Herkunftsangaben” (2008) 57(7) *Agrarwirtschaft* 321; Rangnekar, “The Socio-economics of Geographical Indications” (2004) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No.8.

⁴⁷ Rangnekar, “The Socio-economics of Geographical Indications” (2004) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No.8.

⁴⁸ Profeta, Balling, Schoene and Wirsig, “The Protection of Origins for Agricultural Products and Foods in Europe” (2009) 12(6) *J. World Intell. Prop.* 622.

⁴⁹ Stefan Beck and Leonore Scholze-Irritz, “Wie der Europäer is(s)t. Europäisierung durch Molekularisierung, Standardisierung und kreative Tradionalisierung von Nahrung und Ernährung” in Susanne Bauer et al. (eds), *Essen in Europa* (Berlin: Transcript Verlag, 2010).

⁵⁰ V. Amilen and A.W. Hegnes, “The Cultural Smell of Fermented Fish: About the Development of a Local Product in Norway” (2004) 2(1) *Journal of Food, Agriculture and Environment* 141.

In this context, a clear differentiation of the two protection norms seems highly recommendable (see Table 2). The PDO should focus on traditions exhibiting a stronger link with the region as all production stages must take place within the region and a corresponding reputation. From a cultural property perspective, that would make PDO the instrument of propertisation of a historically anchored food-cultural speciality. In this case, requirements should be kept high. These could include proof of a traditional production of that good on the domestic market with regard to intergenerational transmission similar to the time period criteria currently suggested in the TSG.

The PGI should then take on the character of an instrument for the promotion of food-cultural diversity. This would imply low requirements for evidence of relevant traditions since this protection scheme would also capture isolated and/or buried knowledge that are only the rudimentary nucleus for the constitution of PGI products. In this light, it is easy to argue in favour of limiting the scope of protection regarding name rights and only allowing for combinations of origin and rather generic product names (when for instance referring to “Allgäuer Emmentaler”). The PGI would also provide a protection for buried knowledge, which is deemed critical by the existing literature.⁵¹

Table 2: Reform option 1: Differentiating the instruments with help of particular criteria

Criterion/Instrument	PDO	PGI
Geographical link	High: entire value added chain is situated in the region	Low: only one of the production steps is required to take place in the region (requirements of labelling the production steps make this transparent)
Traditional linkage	High requirements: profound linkage or tradition across generations	Low requirements: buried or scattered knowledge and isolated traditions
Reputation/prevaling opinion	High level of awareness or high reputation	First nucleus for constitution or recognition

Regarding product labelling:

The PGI also creates consumer confusion as the origin of the raw materials is not common knowledge⁵² and is not legally specified. While it is legally sufficient for one production step to take place in the respective region, many PGI consortiums call for all raw materials to exhibit a regional link and thus do not take advantage of the opportunities of acquiring inexpensive raw materials from low cost regions. However, PGIs are also awarded to products for which it is impossible to obtain all the necessary raw materials from the region, i.e. Lübecker Marzipan. As a result, consumers cannot be sure of how much of the production process takes place in the respective region for PGIs. In future, more information on GIs should be displayed; such display will also act to strengthen the geographical link of the products. This would also require providing information on which part of the manufacturing process takes place in the mentioned region. All important raw materials and production processes for the product should be labelled according to their region (abbreviated on the product as well as in a detailed form in the barcode). This would enable an actual product identity and also a comprehensible origin authenticity supporting the purchase decisions of consumers. In addition, this would provide a further incentive for regionalisation. The product’s origin considerably influences purchase decisions concerning preferences for products from particular countries or regions. Mostly, the PGI’s name refers to the region in which the last production

⁵¹ See e.g. Singhal, “Geographical Indications and Traditional Knowledge” (2008) 3(11) *Journal of Intellectual Property Law & Practice* 732; Downes, “How Intellectual Property Could Be a Tool to Protect Traditional Knowledge” (2000) 25 *Colum. J. Envtl. L.* 253.

⁵² London Economics, *Evaluation of the CAP Policy on Protected Designations of Origin (PDO) and Protected Geographical Indications (PGI)* (2008), p.33.

step took place (e.g. Black Forest Ham). An instrument making it obligatory to localise raw materials and production steps would provide an efficient solution honouring the prevailing opinion of the consumers by PGI products.⁵³

In total, the first option supports two different labels. On the one hand, the value of PGIs for consumers is increased by more information on origin and production steps, which highlights the link between product and region. Because the requirements regarding a tradition described in the product specification as a protection criterion are limited, they provide an opportunity to recognize products based on scattered or buried knowledge. On the other hand, PDOs are recognized for developed specialties with a historical tradition (proved existence of the production on the domestic market) and a corresponding reputation (prevailing opinion of the consumers), which count as existing cultural and gastronomic heritage as proposed by the Regulation Proposal.⁵⁴

Option 2: Concentrating on one protection scheme

The second option results from a drastic proposal of some authors arguing in favour of abolishing both instruments of GIs.⁵⁵ Furthermore, such radical demands were discussed in the course of the Commission's preparatory work as well,⁵⁶ a fact that points to the fundamental regulatory deficits. Apart from the stronger and yet more culturally justified differentiation of the two forms of GIs suggested by option 1, option 2 concentrates solely on one protection scheme, namely the PDO. This stricter alternative argues for maintaining and further specifying the PDO regime while aiming to abolish the PGI instrument.⁵⁷

Information economic aspects:

Concentrating on one protection scheme creates an environment in which the PDO instrument fulfils the function of providing entire or unambiguous information on the product's actual origin. As all production steps take place in the region signalled by the protected name, consumers on the national and international level are not misled in terms of the true product identity as is possible in the case of PGIs. These PDO qualities imply that producers can obtain a higher price level for their products than in case of PGI products,⁵⁸ since their unambiguous authenticity of origin allows for identifying not only the actual origin, but also the original tradition and the alluded reputation. This stronger concept can also be explained by the fact that "consumers increasingly look for authentic products produced using specific and traditional methods".⁵⁹ This option would also prevent weaker instruments from free-riding on the PDO.

Cultural property aspects:

Currently, PDOs theoretically refer to products with "an intrinsic link ... between product or foodstuff characteristics and geographical origin".⁶⁰ However, in reality only a few PDO protected products are able to provide unambiguous evidence that climate and soil determine the product in a specific way rendering

⁵³ See Profeta, Balling, Schoene and Wirsig, "The Protection of Origins for Agricultural Products and Foods in Europe" (2009) 12(6) J. World Intell. Prop. 622; Profeta and Balling, "Evaluierung der Übergangsregelung des Herkunftsschutzes bei Agrarprodukten und Lebensmitteln in Europa gemäß Verordnung (EG) Nr. 510/06 und Verbesserungsvorschläge für die anstehende Modifikation" (2007) 56(4) *Agrarwirtschaft* 213.

⁵⁴ See Regulation Proposal, p.13, para. (1).

⁵⁵ E.g. Profeta, Balling, Schoene and Wirsig, "The Protection of Origins for Agricultural Products and Foods in Europe" (2009) 12(6) J. World Intell. Prop. 622.

⁵⁶ See European Commission, "Impact Assessment on Geographical Indications", 2010, p.33, Policy Options 5.8. Accordingly the protection of geographical indications is suggested through a trademark system.

⁵⁷ This option is in contrast with the EU proposal of focusing only on the PGI scheme. See European Commission, "Impact Assessment on Geographical Indications", 2010, Policy Options 5.5.

⁵⁸ See Regulation Proposal; London Economics, *Evaluation of the CAP Policy on Protected Designations of Origin (PDO) and Protected Geographical Indications (PGI)* (2008).

⁵⁹ See Regulation Proposal, p.2, art.1.1 (Grounds for and Objectives of the Proposal).

⁶⁰ Regulation Proposal, p.16, para. (17).

the product unique. Therefore, it seems necessary for this alternative solution to again focus on strengthening the link between the geographically delimited area and the product on a cultural basis as suggested in option 1. This cultural link should be described in detail in the product specification (“code of practice”) which at the same time represents the codification of local knowledge via interaction with nature and environment,⁶¹ including traditional production process and (traditional) raw materials.⁶²

This option aims to protect the collective reputation of the goods and the region from misappropriation and dilution,⁶³ enabling rights holders to obtain high price premiums. In overall, PDO products must meet three requirements (see fig.1):

This option aims to protect the collective reputation of the goods and the region from misappropriation and dilution,⁶⁴ enabling rights holders to obtain high price premiums. In overall, PDO products must meet three requirements (see fig.1):

1. High geographical link: requiring that the entire value added chain is situated in the region.⁶⁵
2. Traditional anchorage: high requirements are of crucial interest regarding historical anchorage since the boundaries of the region of origin cannot be designated only on the basis of measurable scientific link between product quality and region. Profound linkage between the region and the product relating to the tradition of production across generations must be proved for a demarcated geographical area considering historical data and possible changes in the techniques of production in the past.
3. Corresponding reputational link to the region of origin and high level of awareness on the part of consumers is also an essential criterion for being a product worthy for PDO protection.

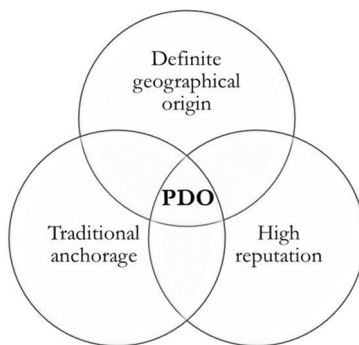


Figure 1: Reform option 2: Maintaining solely the PDO instrument based on a triple criterion⁶⁶

The demarcation of the region of origin is one of the crucial points in a registration process. Even if the delimitation of the authorized area rests upon more objective physical geographical particularities such as climate and geology, there are several disputes over precise boundaries due to the exclusion of potential producers.⁶⁷ In the case of a more subjective cultural factors-based approach, as suggested above, the

⁶¹ Bérard and Marchenay, “Local Products and Geographical Indications” (2006) 58(187) *International Social Science Journal* 109.

⁶² Currently only TSG products must meet these requirements. See Regulation 509/2006 art.4(1).

⁶³ As argued by Rangnekar, “The Socio-economics of Geographical Indications” (2004) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No.8, in general regarding GIs (not only referring to PDOs).

⁶⁴ As argued by Rangnekar, “The Socio-economics of Geographical Indications” (2004) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No.8, in general regarding GIs (not only referring to PDOs).

⁶⁵ An exception can be found in imports of raw materials. See the exemption clause of Regulation 510/2006 art.2(3) and Regulation Proposal, p.24, art.5(2).

⁶⁶ Source: Authors

⁶⁷ See Dev S. Gangjee, “Melton Mowbray and the GI Pie in the Sky: Exploring Cartographies of Protection” (2006) 3 I.P.Q. 291, for details on the complexity of problems relating to the demarcation of a PDO protection area.

restriction of the protection area seems to be of a more complex nature. Since traditions change over time, several factors, such as the different development phases of the product in question or the development of production techniques per se, should be considered.

The case of Melton Mowbray Pork Pie exemplifies these challenges very well.⁶⁸ After a long negotiation process, an area larger than the original area of production has been considered for registration. The rationale behind that lies in the fact that, in accordance with the method of production described in the product specification, a wider area has been engaged in production for 100 years demonstrated by extensive historical research.⁶⁹ This case sheds light on the importance of not only a geographical but also on a traditional delimitation of a production area. This insight leads us to the following limitation regarding the notion of tradition⁷⁰: defining the protection area, historical evidence is recommended for the time period in which a somewhat stable recipe is identified. Specifically, in case the area is determined on a cultural basis, attention should be paid to a particular product (to the first historical disclosure of the associated name to be protected) and not to references about general production of such goods as is currently detectable by several products, thus diffusing the proof of origin. The collective action of all stakeholders is required to take such decisions about the delimitation of region of origin based on historical data. Accordingly, the question arises when the production of a particular product should count as “traditional”.⁷¹ On the one hand, building up a corresponding reputation of a product takes some time; on the other hand, traditions are usually associated with intergenerational transmissions, at least 50 years or a two generation criterion seems to be a suitable requirement for a minimum existence of a product, as also suggested by the Regulation Proposal.⁷²

In order for a single GI instrument (PDO) to be economically worthwhile, measures such as the following should additionally be taken into account:

- The exceptional rule that “certain geographical designations shall be treated as designations of origin where the raw materials for the products concerned come from a geographical area larger than, or different from, the processing area”⁷³ shall be maintained. Here, a labelling of the origin of the raw material seems indispensable: provided that the import of raw materials is an essential part of the traditional production or that the production were not possible without these raw materials (see Lübecker Marzipan) and that this procedure is corroborated by tradition, the origin of these raw materials should be clearly designated to avoid consumer confusion (see above).
- Following up on the stronger focus on traditional links, it further seems meaningful to retain the exception—with a labelling obligation—that “traditional geographic names” can also be registered as PDOs as they define an agricultural product or foodstuff that has its culturally influenced origin in a geographically delimited area.⁷⁴
- For products to which PDO regulations do not apply, facultative quality specifications would provide an opportunity to inform consumers about particular commodifying characteristics and thus differentiate them from other products (see above).

⁶⁸ See Gangjee, “Melton Mowbray and the GI Pie in the Sky” (2006) 3 I.P.Q. 291.

⁶⁹ See the registration document of Melton Mowbray Pork Pie: “Publication of an application pursuant to Council Regulation 510/2006 art.6(2) on the protection of geographical indications and designations of origin for agricultural products and foodstuffs” [2008] OJ C85/17.

⁷⁰ As also suggested by Gangjee, “Melton Mowbray and the GI Pie in the Sky” (2006) 3 I.P.Q. 291.

⁷¹ Apart from the EU’s standpoint, at the national level there are different assumptions on “tradition”. For instance, Austria created a register for Traditional Austrian Specialties on its own initiative, which only regards products as “traditional” when their production exists for at least 75 years or over three generations. See “Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft”, available at <http://www.lebensministerium.at/lebensmittel/qs-lebensmittel/trad-lebensmittel/TraditionelleLM.html> [Accessed March 25, 2012].

⁷² Regulation Proposal, p.23, art.3(3).

⁷³ Regulation 510/2006 art.2(3); Regulation Proposal, p.24, art.5(2).

⁷⁴ See Regulation 510/2006 art.2 (2). This exception clause is not considered in the Regulation Proposal.

- Whereas many PGI products fulfil the criteria for PDO nomination, they are introduced as PGIs for strategic reasons in order to retain the option of switching between suppliers according to the economic conditions.⁷⁵ As a result, many consumer protection watchdogs criticise these producers who decide against obtaining their raw materials from the same region for economic reasons despite its viability.⁷⁶ For these products the “renomination” to PDO is reasonable and justified. Nonetheless, in case of undesirable and unseasonal weather conditions PDO products face a higher risk of insufficient supply of raw materials. Every seasonal product is taking this risk, to some extent.

Summing up, the introduction of only one instrument would entail the following advantages:

Transparent designations of origin:

Abolishing PGIs would prevent, as far as technically possible, production steps from taking place outside the region. Thus, the link between the products and the geographical origin is clearly specified and strengthened on the basis of a traditional linkage.

Reliability:

The extent of controls would apply to all production steps and render the control tasks easy to comprehend. This could enhance consumer trust. By using only one GI label, consumers are protected from confusion due to the existence of various labels with differing information content.⁷⁷ As a “mark of authenticity”,⁷⁸ the label could further convey unambiguous information about the characteristics of the products (clear origin, proven tradition and high reputation).

Spillover effects:

If all production steps take place in a particular region, the product name obtains a collective reputation regarding all production steps. This implies concentrated cooperation of all actors and strengthens rural and regional identity, as well as cohesion. The reputation of a PDO product can have a positive effect on agri-tourism,⁷⁹ as in the case of Italy where the consumption of GI food products encouraged by the national law has turned regional gastronomic traditions into one of the main attractions of farm tourism.⁸⁰ In this way, PDO products provide incentives to commodify regional products as well as traditional knowledge and can thus promote economic development in the region.

⁷⁵ See Evans, “The Strategic Exploitation of Geographical Indications and Community Trade Marks for the Marketing of Agricultural Products in the European Union” (2010) 1(1) WIPO J. 159.

⁷⁶ Profeta, Balling, Schoene and Wirsig, “The Protection of Origins for Agricultural Products and Foods in Europe” (2009) 12(6) J. World Intell. Prop. 622.

⁷⁷ See the discussions on the proliferation of GI instruments in Marette, “Can Foreign Producers Benefit from Geographical Indications under the New European Regulation?” (2009) 10(1) *The Estey Centre Journal of International Law and Trade Policy* 65.

⁷⁸ See Teshager Dagne, “Law and Policy on Intellectual Property, Traditional Knowledge and Development: Legally Protecting Creativity and Collective Rights in Traditional Knowledge Based Agricultural Products through Geographical Indications” (2010) 11(1) *The Estey Centre Journal of International Law and Trade Policy* 68, 99.

⁷⁹ Josling, “The War on Terroir” (2006) 57(3) J. Ag. Econ. 337, 360, pointed this out, namely that particular GIs “are potentially useful in the development of agri-tourism, where the cultural identity bestowed by the mystique of terroir”.

⁸⁰ See Katia L. Sidali, “A Sideway Look at Farm Tourism in Germany and in Italy” in Katia L. Sidali and Birgit Schulze (eds), *Food, Agri-Culture and Tourism* (Berlin: Springer, 2011).

Protection of local knowledge:

Despite the fact that the PDO regime protects the name of the product directly, the vital element of the product specification manifests itself in the production procedure involving local knowledge and practices.⁸¹ Many authors criticise that within a GI system local knowledge remains unrecognised as an object of protection, and therefore rests in the public domain.⁸² Consequently, traditional producers leaving the region cannot be stopped to produce similar or identical products from outside the region. Nevertheless, if requirements of traditional production methods with regional historical anchorage are fulfilled, the PDO does contribute to a certain extent to the protection of local knowledge (codified in the product specification) by protecting its reputation from free-riders.

The product and the associated local knowledge attributed to a geographically delimited area cannot be marketed under the same traditional name by producers outside the region. This creates an environment where culinary heritage is protected and the maintenance and sustainability of traditional knowledge is encouraged. From a cultural perspective it certainly does not imply a monopolization of knowledge or limits access to knowledge and innovation. The knowledge can be used under a different product name.⁸³ The new regime establishes and protects a link to traditional knowledge, significantly influenced by the region,⁸⁴ materialized in the product, and associated with the product name itself. Overall, a PDO system would oblige producers to adhere to the geographical and the stricter cultural limitations contributing to the preservation and persistence of regional traditional knowledge.

Policy recommendation and conclusion

The current Regulation Proposal of the European Community contains some modifications particularly affecting the level of controls, thus increasing the transparency of the GI system. In the eyes of the authors, however, this proposal does not constitute a viable legal basis to solve the numerous, widely discussed criticism by the literature and recognized by the European Union. The critique is focused on sufficiently qualified labels of origin. The previous policy of the European Union faces the dilemma of aiming to incorporate GIs in rural development policy, whereas regional protection rights are only granted in the case of a scientifically based justification for delimiting the product name to its specific region. Otherwise, the baseline of the European Common Market, the prevention of protectionism, is severely challenged. Nevertheless, it is precisely the unambiguous scientific link between origin and measurable product characteristics that is rather the exception than the rule.

The compromises arising from this fundamental contradiction between the previous two regional protection instruments (PDO and PGI) and TSG are not resolved convincingly. In recent years, the number of articles arguing in favour of a stronger differentiation between PDO and PGI⁸⁵ or even in favour of merging or, in contrast, abolishing the two indications⁸⁶ have increased. A study by London Economics, commissioned by the European Commission, shows interesting results⁸⁷: in many Member States, the

⁸¹ Bérard and Marchenay, "Local Products and Geographical Indications" (2006) 58(187) *International Social Science Journal* 109.

⁸² See Sanders, "Incentives for and Protection of Cultural Expression" (2010) 13(2) *J. World Intell. Prop.* 81; Rangnekar, "The Socio-economics of Geographical Indications" (2004) UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No.8.

⁸³ See Bernard O'Connor, *The Law of Geographical Indications* (London: Cameron May Ltd, 2004). See also the successful marketing of Spanish Cava after it was prohibited from calling it "champagne".

⁸⁴ Daphne Zografos, *Intellectual Property and Traditional Cultural Expression* (Cheltenham: Edward Elgar, 2010).

⁸⁵ cf. Profeta and Balling, "Evaluierung der Übergangsregelung des Herkunftsschutzes bei Agrarprodukten und Lebensmitteln in Europa gemäß Verordnung (EG) Nr. 510/06 und Verbesserungsvorschläge für die anstehende Modifikation" (2007) 56(4) *Agrarwirtschaft* 213.

⁸⁶ Profeta, Balling, Schoene and Wirsig, "The Protection of Origins for Agricultural Products and Foods in Europe" (2009) 12(6) *J. World Intell. Prop.* 622.

⁸⁷ London Economics, *Evaluation of the CAP Policy on Protected Designations of Origin (PDO) and Protected Geographical Indications (PGI)* (2008), pp.160–166.

slight differentiation between PDO and PGI is regarded as an additional cost of information gathering for consumers, an opinion shared by consumer associations (Belgium, Germany and Italy) as well as producer cooperatives.

This article argues for a more plausible regulation from an information economic perspective as well as a cultural property perspective. The current debate on an amendment of the GIs regulations of the European Union includes similarly radical ideas, which have, nonetheless, not been incorporated in the final version of the Regulation Proposal. On the one hand, this confirms that international or supranational negotiations produce minimal results, rather than merely radical reforms, a phenomenon apparently also applicable to the European Union.⁸⁸ On the other hand, this minimal reform proposal reveals that an interdisciplinary perspective is required to provide evidence-based insights to the design of criteria for GI with regard to the years in existence, regional delimitation, etc. The pressure on international level in fora such as WIPO and WTO additionally points to the need for a more cultural-economic analysis of the GI regime rather than pure information economics.

As a result, this article argues to drastically modify the existing regulations and suggests keeping only one instrument, namely the PDO, which not only draws on a definite geographical, but also a stricter cultural connection between the product and the region. While GIs generally do not allow for the protection of all types of traditional knowledge,⁸⁹ this reform option would be able to contribute to protect at least one certain kind of traditional knowledge from misappropriation and dilution. The new PDO regime based on tradition could contribute to protecting knowledge attributed to a specific region and manifested in products. In order to evaluate which products fulfil the PDO requirements, it would be helpful to design and regularly apply consumer surveys measuring the perception of PDO candidates. As only agricultural products with a high reputation can prevail on the market, this is an important aspect. The protection of PDO products is justified since only products that have gained high reputation over years are at high risk of being copied and misappropriated.

For all formerly existing products that are no longer produced, acceptable evidence of an undisputed link of the local knowledge with the geographically delimited area should be discussed according to a still arbitrarily set time period,⁹⁰ since in those cases reputation does not seem to be verifiable. How these alternative solutions would support the invention of new regional products and production methods requires further research.

In conclusion, using only one GI instrument (PDO), in contrast to keeping both PGI and PDO as suggested by option 1, facilitates a more efficient exchange of information between producers and consumers. This can help to maintain the price of the so-called “tradition-based, reputable” agricultural products,⁹¹ thus keeping them alive. It simultaneously contributes to the desired promotion of traditional knowledge attributed to products of culinary heritage.

⁸⁸ Matthias Lankau, Kilian Bizer and Zulia Gubaydullina, “Die verborgene Effektivität minimaler Resultate in internationalen Verhandlungen: Der Fall der WIPO” in Regina Bendix, Kilian Bizer and Stefan Groth (eds), *Die Konstituierung von Cultural Property: Forschungsperspektiven* (Göttingen: Universitätsverlag Göttingen, 2010).

⁸⁹ Dagne, “Law and Policy on Intellectual Property, Traditional Knowledge and Development” (2010) 11(1) *The Estey Centre Journal of International Law and Trade Policy* 68; O’Connor, *The Law of Geographical Indications* (2008); Singhal, “Geographical Indications and Traditional Knowledge” (2004) 3(11) *Journal of Intellectual Property Law & Practice* 732.

⁹⁰ The degree of historical ties between GI regions and the product origin is already considered as a decision rule for disputes on whether to register a product as a PDO or a PGI. See Evans, “The Strategic Exploitation of Geographical Indications and Community Trade Marks for the Marketing of Agricultural Products in the European Union” (2010) 1(1) *WIPO J.* 159, 170, discussing the decision over Bavarian beer.

⁹¹ Dagne, “Law and Policy on Intellectual Property, Traditional Knowledge and Development” (2010) 11(1) *The Estey Centre Journal of International Law and Trade Policy* 68, 88.

International Intellectual Property Law and Policy: Can the Caribbean Region Capitalize on Current Global Developmental Trends in Intellectual Property Rights and Innovation Policies?

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☞ Caribbean; CARICOM; Economic partnership agreements; Innovation; Intellectual property

This article addresses the issue of Caribbean Intellectual Property law and policy, and looks at the findings of a recent report titled “The changing face of innovation”, published in the last quarter of 2011 by the World Intellectual Property Organization on the development of Intellectual Property Rights and innovation trends worldwide. In this article, the burgeoning of IP rights and technological innovations is discussed, and the question of the place of the Caribbean region in this new scheme is courted. It examines the historical, socio-political and economic environment in which Caricom operates and proposes the development of a legal and regulatory framework for Intellectual Property that will encourage technological innovations and strengthen the workings of and confidence in the Caribbean Intellectual Property rights, policies and regulation.

Introduction

Recent years have seen developments in innovation in science and technology followed by the rapid development of intellectual property rights (IPRs) regimes and enforcement, both within the locality of individual countries and as international collaborative schemes. It is arguable that both developed and developing countries have played a significant role in this new dispensation, particularly in the cases of China, India and Singapore, which have led the developing world in the creation of innovations and technologies while the African and Caribbean regions have lagged behind. The Caribbean in particular is yet to begin making its contribution to the development of technologies which will create economic growth and development for the region while realizing a higher standard of living for its people and ending the parasitic relationship between itself and the developed world. This article discusses the historical, political and economic background that shapes the current state of Caribbean IPRs. It proposes the creation of a legal and regulatory framework which will accelerate the development of scientific and technological innovations while strengthening regional accountability and increasing international confidence.

Current evidence in the economic data of IPRs registration shows that these registrations have not impacted the economic growth of Caribbean countries whose gross domestic products (GDPs) have shown rates of growth across a period of examination dated 1995–2009.¹ The region, however, remains significantly

¹ *WIPO Statistical Country Profile*, September 2011, available at http://www.wipo.int/ipstats/en/statistics/country_profile/ [Accessed March 25, 2012].

underdeveloped in the fields of science and technology. The recent *World Intellectual Property Report*, published in the last quarter of 2011 by WIPO,² indicates that countries that have implemented enhanced systems of IP protection, along with policies to encourage innovation, have recorded significant scientific technological advancements. This article asks the following question: In view of the current trends in innovation and IP development policies worldwide, how might the Caribbean region capitalize on current developments for economic growth? In order to discuss this issue, the Caribbean IP regulatory and policy framework as well as the statistical data on IP registration of select countries in the region are examined, and the theoretical and practical applications of some of the policies which have led to the reported developmental trends worldwide are discussed.³ It is to be noted that for the purpose of this article the Caribbean region refers to members of the Caribbean Community (CARICOM) which are also signatories to the Caribbean Single Market and Economy (CSME).

The legal, regulatory and policy framework of Caribbean IP

The legal and regulatory framework of Caribbean IP is distinctly characterized by the historical background of the region. With the exception of Suriname and Haiti, the CARICOM region countries all inherited the English common law system and the nomenclature of Commonwealth Caribbean. To much of the world it is that part of the globe familiarly known as the West Indies and much famed for its cricket and soca music. The region comprises both dependent and independent countries of which the independent countries subscribe to a political and increasingly regulatory grouping known as CARICOM or the Caribbean Community, and whose members have also subscribed to the CSME. The CSME initiative is intended among other measures to be responsible for “coordinating and converging of macro-economic policies and performance; harmonising foreign investment policy and adopting measures to acquire, develop and transfer appropriate technology” as well as “the harmonisation of company, intellectual property and other laws”.⁴ There also exists a further sub-grouping of states of the Eastern Caribbean known as the Organization of Eastern Caribbean States (OECS).

This history, though intricate, diverse and multi-faceted, still leaves the Commonwealth Caribbean with a homogenous society. Even in the case of the hybrid and partially hybrid⁵ legal systems of St Lucia and Guyana, which have had some infusion of French and Roman-Dutch laws into their respective legal systems, the homogeneity of the legal system remains undisturbed. Within this framework, however, the individual countries possess differences in socio-economic policies that create the laws of the land. It is these policies that have effected the diverse circumstances creating a Caribbean intellectual policy and law, and the unique socio-economic issues aligned with them.

To begin with, it must be noted that all countries in the region possess laws relating to IP and that these laws are either enforced or enforceable in accordance with government policy. In some instances, as in the case of Guyana there are several pieces of legislation which constitute the main framework for IP, but which are arguably ineffectual (because of their outdated content that does not fit within the context of modern times) and ineffective (for lack of enforcement).⁶ In the case of copyright legislation, the onus rests upon the aggrieved party to take action, since copyright infringement is categorized as a civil wrong and not a criminal offence.

² WIPO, *2011 World Intellectual Property Report: The Changing Face of Innovation* (Geneva: 2011).

³ WIPO, *2011 World Intellectual Property Report* (2011), Ch.2.

⁴ “The Caricom Single Market and Economy (CSME)”, available at http://www.caricom.org/jsp/single_market/single_market_index.jsp?menu=csme [Accessed March 25, 2012].

⁵ R. Belle Antoine, *Caribbean Law and Legal Systems* (New York: Routledge-Cavendish, 2008).

⁶ The relevant pieces of legislation are as follows:

- Trademarks Act 1972 (Cap. 90:01);
- Patents and Designs Act 1972 (Cap. 90:03);
- Merchandise Marks Act 1972 (Cap. 90:04); and
- Copyright Act 1956 (Cap. 74).

It is noteworthy that the copyright law was acquired as a result of reception from Britain after independence in 1966 and that a draft Copyright Act of 2003, which contains some of the more modern elements of legal application remains shelved. The other areas of intellectual property [IP], namely trademarks, patents and designs, and merchandise marks, are all of early 1970s vintage, as a result of the dramatic changes in the landscape of technological developments. They do not encompass the relevant modern issues related to internet communication technologies or other modern developmental issues, which affect all countries in the region to greater or lesser degrees.

A further example of the range of IP regulation lies in the law and policy implementation of St Lucia which has enacted some of the most modern pieces of legislation found across the region. Those pieces of legislation encompass many developmental issues and are modern in outlook.⁷ They include acts dealing with trademarks, patents, industrial designs, copyright and unfair competition.

Jamaica is by far the most actively engaged in the protection and promotion of IPRs, establishment of an intellectual property office (Jamaica Intellectual Property Office (JIPO)),⁸ and the development of stringent government policies. Jamaica's legislation includes acts covering copyright, trademark, patents and designs, and merchandise marks among others.⁹

The CSME is empowered by the Revised Treaty of Chaguaramas to ensure the "harmonisation of Company, Intellectual Property and other laws".¹⁰ Thus far, it has not yet established any mechanism to do so, leaving a significant vacancy in the area of comprehensive regional IP regulation.

The socio-economic background to Caribbean IP

The Caribbean Single Market and Economy (CSME)

On January 1, 2006, the CSME was formally established and adopted by 12 member countries (Belize, Barbados, Grenada, St Kitts and Nevis, St Lucia and St Vincent and the Grenadines, Jamaica, Suriname, Antigua and Barbuda, Guyana, Dominica, Trinidad and Tobago). The schedule of implementation requires a formal framework to be in place by 2008, with the final completion date set for 2015. The CSME was originally proposed by CARICOM in the 1989 declaration of Grand Anse and was conceptually and legally formalized in the 2001 Revised Treaty of Chaguaramas.¹¹ The Revised Treaty included provisions for the establishment of the Caribbean Court of Justice, which was formalized in 2005.

⁷ The relevant pieces of legislation are as follows:

- Trade Marks Act 2001;
- Patents Act 2001;
- Industrial Designs Act 2001;
- Protection Against Unfair Competition Act 2001;
- Copyright (Amendment) Act 2000;
- Geographical Indications Act 2000;
- Layout-Designs (Topographies) of Integrated Circuits Act 2000; and
- Copyright Act 1995.

⁸ Jamaica Intellectual Property Office, available at <http://www.jipo.gov.jm> [Accessed March 25, 2012].

⁹ The relevant pieces of legislation are as follows:

- The Jamaican Intellectual Property Office Act 2002;
- Trade Marks Act 1999;
- Copyright (Amendment) Act 1999;
- The Layout-Designs (Topographies) Act 1999;
- The Copyright Act 1993;
- The Merchandise Marks Act 1985;
- The Designs Act 1976;
- The Patents Act 1975; and
- The Broadcasting and Radio Re-Diffusion Act 1949.

¹⁰ Revised Treaty of Chaguaramas Establishing the Caribbean Community Including the CARICOM Single Market and Economy, available at http://www.caricom.org/jsp/community/revise_treaty-text.pdf [Accessed March 25, 2012].

¹¹ The Treaty Establishing the Caribbean Community, signed at Chaguaramas, July 4, 1973, available at http://www.caricom.org/jsp/community/original_treaty-text.pdf [Accessed March 25, 2012].

The CSME was established with the intention of creating a cohesive framework through which the region could become internationally competitive. The main objectives of the CSME are set out as follows:

“Full use of labour (full employment) and full exploitation of the other factors of production (natural resources and capital); competitive production leading to greater variety and quantity of products and services to trade with other countries. It is expected that these objectives will in turn provide improved standards of living and work and sustained economic development.”¹²

It is arguable that in order for the objectives to be met in terms of growth and sustainable development, IPRs and responsibilities must be moved from their current state of disorder to one of productive engagement and holistic and regulated viability. It is inconceivable that the CSME will be able to achieve a high level of success in its implementation without the establishment of a legal and regulatory framework that promotes development of innovation in science, technology and other areas, while espousing the protection of rights and enforcing responsibilities in IP.

CARICOM and the TRIPs Agreement

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement adopted within the framework of the World Trade Organization (WTO) that establishes minimum standards for many forms of IP. It was negotiated as part of the Uruguay Round of General Agreement on Tariffs and Trade (GATT)¹³ trade negotiations and adopted in 1994.

TRIPS provides requirements for national legislation in the IP area, including copyright, geographical indications, industrial designs, trademarks, patents, and trade secrets. TRIPS also specifies enforcement procedures, remedies and dispute resolution procedures. This agreement introduced IP law into the international trading system and remains arguably the most comprehensive international IP agreement.

An analysis of IP legislation in 11 Latin American and Caribbean countries, *Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation that Favors Public Health?*, determined that these countries are not adequately taking advantage of TRIPS flexibilities. In its analysis, the study considered the term of patents issued, patentable subject matter, transition periods (time until legislation was enacted), reversal of the burden of proof of patent infringement, exhaustion of rights, compulsory licensing and the early working exception (which allows a country to complete all procedures necessary to register a multisource product before the original patent expires). The study concluded that access to medicines might be eroded in the future if new agreements establish more restrictive rules for IPRs. It recommended that CARICOM countries improve interaction between health and patent offices, be given technical support to assist in maximizing public health benefits in national legislation and trade negotiations, and prioritise access to medicines when determining how best to protect innovation.

A 2005 Commonwealth Secretariat report by Dianne Daley titled *Implementation of the Doha Decisions on Access to Medicines at Affordable Prices by Countries with no or Insufficient Manufacturing Capacities: The Caribbean Study*,¹⁴ provides country-specific guidance and information for the following Caribbean countries: Antigua and Barbuda, Belize, Dominica, Grenada, Guyana, St Kitts and Nevis, Saint Lucia, St Vincent and the Grenadines, the Bahamas and Trinidad and Tobago.

¹²“The Caricom Single Market and Economy (CSME)”, available at http://www.caricom.org/jsp/single_market/single_market_index.jsp?menu=csme/ [Accessed March 25, 2012].

¹³GATT was first signed in 1947 and was designed to provide an international forum for free trade among its members by regulating and reducing tariffs on traded goods as well as to provide a forum for dispute resolution. More than 110 countries are members of GATT.

¹⁴Dianne Daley, “Implementation of the Doha Decisions on Access to Medicines at Affordable Prices by Countries with No or Insufficient Manufacturing Capacities: The Caribbean Study”, September 2005, noted in Frederick M. Abbott, Ryan Abbott, Wilbert Bannenberg and Marianne Schürmann, “Regional Assessment of Patent and Related Issues and Access to Medicines: CARICOM Member States and the Dominican Republic” in *Health Research for Action Final Report: Main Report* (2009), Vol. 1, available at <http://ssrn.com/abstract=1909978> [Accessed March 25, 2012].

For each country, the report gives a brief overview of its national pharmaceutical industry, describes its existing production capacity, provides an overview of the institutional framework it has adopted for import and distribution of pharmaceutical products, describes the main features of its national patent laws, and discusses its national procedures for granting marketing approvals. The report provides recommendations for Caribbean countries on compliance with the procedures prescribed in the Doha Declaration, and steps to facilitate trade in essential medicines on a regional basis. It concludes that under the terms of the Declaration, introducing regional patents granted by a regional office could be one way to facilitate regional trade in medicines. A compulsory license to either export or import could be granted on a regional basis without impinging on the territoriality of national patent laws. The report argues that national laws require further revision and harmonization to take full advantage of the facility provided by the Declaration.

All the WTO Member States must abide by the provisions of TRIPS. In general, developed countries had one year (until 1996) to become TRIPS-compliant, while developing countries had five years (until 2000), and least-developed countries (LDCs) had 11 years (until 2006). Developing countries (e.g. India) without existing national pharmaceutical patent protection also had a 10-year transition period (until 2005). In November 2001, the period for LDCs was further extended to 2016 for pharmaceutical (and agricultural) patents.

According to a review conducted by the Centre for Trade Policy and Law (CTPL), *Report on the Status of Implementation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in CARICOM States*, the level of TRIPS implementation in CARICOM countries varies greatly. While all countries have made some progress in reforming their IP regimes to conform to TRIPS obligations, the report finds significant differences with respect to the completeness of implementation. Some countries had not drafted new laws in all areas, while others had drafted a complete set of laws, but those laws were not yet in force. Other countries have fully satisfied their obligations or are very close to doing so. The report provides an overview of TRIPS obligations, assesses the implementation status in each country, provides specific recommendations for individual countries to become TRIPS consistent, and gives recommendations for action at the regional level with a list of priority actions. The final section of the report contains a matrix listing the key categories of TRIPS obligations and the degree to which each country's domestic legal regime is consistent with these obligations. The report discusses the fact that enforcement and administration of IPRs are areas of concern.

Most countries have the basic civil procedures in place for the private enforcement of IPRs; however, there are very few precedents for enforcing these rights in most CARICOM countries. The near absence of precedents implies that the local bar and judiciary may not have had significant exposure to IP laws and their application. The experience of customs authorities and the police is similarly limited. With respect to administration, very few CARICOM countries have well-functioning IP offices. The challenges associated with recruiting professional personnel (e.g. patent examiners) and the cost of establishing or maintaining such an office are significant. Furthermore, offices in the region lack resources (e.g. automation tools and certain databases). The report suggests that efforts be made to explore regional options for the examination of patent and other IPR applications. As far as copyright and related rights are concerned, there are few functioning collectives able to administer these rights in practice.

In 2000, legal officials from 10 Caribbean countries met for three days in Kingston, Jamaica, to discuss IPRs. A concise report of the meeting was presented in the document entitled *Registrar's Report on Attendance at the First Meeting of the CARICOM Working Group on Intellectual Property Rights Held Between May 17–19, 2000 in Kingston, Jamaica*.¹⁵ This report noted that most CARICOM Member States were still in the process of putting TRIPS-compliant legislation in place despite the fact that the time frame

¹⁵ CARICOM Secretariat, "Registrar's report on attendance at the first meeting of the CARICOM Working Group on Intellectual Property Rights held between May 17–19, 2000 in Kingston, Jamaica", May 30, 2000.

for full compliance with TRIPS obligations expired on December 31, 1999. The report contained matrices showing the status of TRIPS implementation in each CARICOM Member State and urged CARICOM Member States to establish new legislative and administrative structures by July 2000. Delegates were asked to ensure that the extreme urgency of the matter was conveyed to the appropriate authorities and the matter of WTO/TRIPS compliance was kept under constant review. The CARICOM Secretariat indicated that slow progress on TRIPS implementation within the Community could be attributed to insufficient political will, as well as to the absence of adequate resources in member states to effectively administer IPRs in the manner required.

Another document for the Centre for Trade Policy and Law, *Implementation of Selected WTO Agreements in the Caribbean Community*,¹⁶ was created to assist Caribbean countries to meet their WTO obligations. This document provided a comprehensive overview of the status of implementation of WTO commitments in selected agreements. It also briefly outlined a set of recommendations to assist CARICOM Member States to fully implement their commitments together with a preliminary work plan for technical assistance to facilitate this process. Among other areas, the report focused on TRIPS commitments and praised CARICOM Member States for “heroic” efforts to meet their WTO obligations in light of structural limitations and resource constraints. However, no state was found to have fully implemented all commitments from all agreements and, for many states, there remained considerable ground to cover. Where structural limitations of size and scale constrained the ability for national governments to fully implement their obligations, the possibility of using regional strategies and shared facilities was suggested.

This document made several recommendations. First, some WTO obligations would be more effectively addressed on a regional or sub-regional level. Secondly, strategic international lobbying was necessary to ensure that the concerns of small economies were addressed, not just LDC concerns. Thirdly, there should be greater coordination between national ministries with trade policy responsibilities and other departments with responsibility for only some areas of WTO requirements. Fourthly, public awareness campaigns should be implemented to improve confidence in the WTO system in the aftermath of the US-EC banana dispute and the burden of post-Uruguay Round implementation. Finally, it recommended advocacy to translate the high level of dedication held by national and CARICOM officials to fully implement WTO commitments into priority items on the political agenda. This article does not intend to give extended analysis of the report since it serves only to illuminate the socio-economic and political circumstances which CARICOM operates under and which affect the development of innovation and IPRs.

At the time of this writing, complete TRIPS compliance for all Caribbean countries had not yet occurred. In 2008 and 2009, the Office of the United States Trade Representative (USTR) placed the Dominican Republic and Jamaica on its watch list. The USTR noted that the Dominican Republic passed IPR laws in 2006 and 2007, enhancing protections for patents, copyrights, and trademarks, and strengthened its IPR enforcement regime. However, the USTR noted problems with data exclusivity in pharmaceutical approval proceedings, unauthorized copies of patented pharmaceutical products, as well as high levels of piracy and counterfeiting. The USTR further noted in 2008 that Jamaica had not yet enacted the Patents and Designs Act, intended to comply with TRIPS and the US-Jamaica Bilateral Intellectual Property Agreement. The United States urged Jamaica to urgently reform its patent law to conform to international standards of protection. This was addressed by adopting the Jamaica Patents Act of 1999.

¹⁶ Centre for Trade Policy and Law, “Implementation of Selected WTO Agreements in the Caribbean Community”, 2002.

CARICOM, the Economic Partnership Agreement and IP

On October 15, 2008, 13 Caribbean countries of CARIFORUM signed a far-reaching Economic Partnership Agreement (EPA) with the European Community (EC). The EPA was meant to serve as a continuation of the Cotonou Agreement, a nonreciprocal scheme under which the EC provided duty-free access to most exports from African, Caribbean, and Pacific (ACP) countries. The new pact covered trade in goods, services and investments, and offered development assistance to the Caribbean countries that joined it. The agreement also established TRIPS-plus IP provisions that commit CARIFORUM countries to higher IPR standards. Guyana and Haiti initially did not sign the EPA with the other CARIFORUM members; however, they later joined the agreement. While other ACP countries have accepted interim EPAs with the EC, no other region has agreed to a comprehensive EPA with IPR provisions. The other interim EPAs are partial and cover mostly provisions related to the liberalization of trade in goods only, potentially with an agenda for further negotiation.

Several potential EPA partners and NGOs (non-governmental organizations) have criticized the EPA, claiming that it would hurt Caribbean producers by exposing them to competition with their European counterparts. EC products may flood CARIFORUM markets and harm domestic industries, and despite promises of assistance from the EC, the costs of implementing the EPA may be high. The then President of Guyana, Mr Bharrat Jagdeo, the most vocal critic of this agreement, argued that the benefits and protection offered by regionalism are undermined by the multilateral EPA, which extends the Most Favoured Nation (MFN) clause to Europe. This, he proposed, might prevent CARIFORUM members from negotiating favourable trade deals with countries within the region or in the developing world, because the same benefits will have to apply to EC Member States. On the other hand, then Prime Minister Bruce Golding of Jamaica, who held lead responsibility for CARICOM's external economic relations, felt that the EPA would strengthen the CSME by forcing the region to be more competitive. An April 2008 report by the Centre for International Environmental Law (CIEL), *Intellectual Property in European Union Economic Partnership Agreements with the African, Caribbean and Pacific Countries*,¹⁷ explored the implications of continuing negotiations for further IPR protection in EPAs. The report analysed potential provisions of future EPAs and discussed the nature of IPR commitments that ACP regions have already made.

The report then examined some of the most important IPR provisions in the EC-CARIFORUM EPA and made recommendations for future EPA negotiations. It argued that the IPR provisions in the EC-CARIFORUM EPA do not support sustainable development for ACP countries, but rather benefit the EC's mercantile interests. Most ACP countries have not committed to negotiating IP provisions in EPAs, and the report recommended that they resist attempts to make the CARIFORUM Agreement the basis for further negotiations on IPRs.

In continuing this discourse, a South Centre policy brief, *Development and Intellectual Property under the EPA Negotiations*,¹⁸ examined the approach of the EPA negotiations with respect to innovation, biodiversity, traditional knowledge, public health, and enforcement of IPRs. The brief focused on some of the TRIPS-plus¹⁹ implications of EPAs and evaluated their possible contribution to the technological development of ACP countries, as well as the effects the EPA would have on access to medicines and the protection of genetic resources, traditional knowledge, and public health. It noted that EPA negotiations

¹⁷ Centre for International Environmental Law, "Intellectual Property in European Union Economic Partnership Agreements with the African, Caribbean and Pacific Countries: What Way Forward after the CARIFORUM EPA and the Interim EPAs?", April 2008, available at http://www.ciel.org/Publications/Oxfam_TechnicalBrief_5May08.pdf [Accessed March 25, 2012].

¹⁸ South Centre. "Development and Intellectual Property under the EPA Negotiations", South Centre, Policy Brief No. 6, March 2007, available at http://www.southcentre.org/index.php?option=com_docman&task=doc_download&gid=18&Itemid=&lang=en [Accessed March 25, 2012].

¹⁹ TRIPS-plus arrangements are those measures taken by developing countries that go further than TRIPS in the implementation of stricter regulations in patent law. These measures have caused additional hardship in access to medicines and other technologies that are considered essential development in these countries.

are likely to result in additional layers of IPR protection, and that this would increase the cost of technological learning and national industrial development. The report recommended that EPA negotiations do not include IPR protections as part of partnership agreements, but rather that agreements should focus on industrial and technological development and aim to address EC policies that have impeded participation of ACP countries in the value chain of products, protection of biodiversity and traditional knowledge and the use of TRIPS flexibilities.

A South Centre analytical note prepared by the Trade for Development Program, *Market Access for Trade in Goods in Economic Partnership Agreements*,²⁰ provides an overview of market access provisions under the interim EPAs between the EC and ACP countries. This analytical note is part of a series of fact sheets designed primarily for ACP countries to promote an understanding of the legal, economic and developmental implications of specific provisions in the texts and to suggest options for improvement. The fact sheet comments on interim EPAs and assesses the extent to which they utilize flexibilities contained in WTO Agreements and identified under regional integration schemes. The EC-CARIFORUM EPA is the principal source of discussion, as it is the only comprehensive EPA to date. The report concluded that EPAs will generate major challenges, both for governments implementing the EPA and for the private sector trying to adjust to new competitive conditions. It also questioned whether the private sector in ACP countries will benefit from the enhanced competition offered by European competitors and notes that the focus of current EPA texts is on binding market opening, not on assistance provisions.

In a work entitled *Implications of the CARIFORUM-EC EPA*,²¹ Professor Norman Girvan of the University of the West Indies notes that the EC-CARIFORUM EPA is more than just a trade agreement: it commits the region to a certain development path. This paper suggests that the region may not completely understand the consequences of agreeing to new obligations in investment, competition policy, government procurement, and TRIPS-plus IPRs. These obligations were pushed by Europe to provide additional protection and opportunities for EC firms and investors, without corresponding commitment to development aid. It states that the EPA will set up a framework for the future evolution of the economic, social, and environmental policies of CARICOM/CARIFORUM states. It recommends that full disclosure of the (then undisclosed) EPA text with an explanation of its meaning and that the implications be disseminated to allow for public discussion and feedback.

The EPA was also discussed in a February 2009 report by the Third World Network, *EU EPAs: Economic and Social Development Implications*. This document made general comments about EPAs, discussed relevant issues such as IP, and then analysed the relevant provisions of interim EPAs and the CARIFORUM-EC EPA. It noted the CARIFORUM-EC EPA was the only ACP-EC EPA that goes beyond goods, and that it appears to be the basis for other EC bilateral/regional agreements. It argued that bilateral agreements between developing and developed countries may be a poor option for developing countries and that multilateral agreements are preferable. However, the report notes that the number of bilateral agreements is increasing. It concludes that TRIPS-plus²² provisions in the CARIFORUM-EC EPA largely achieve EC goals. However, the CARIFORUM goals of facilitating technological development, protecting indigenous knowledge, and obtaining development resources were not met. The report also noted that the costs of implementing the IP provisions of the EPA are likely to be substantial to administer these rights in practice.

In consideration of these factors, it is useful to take a look at the current data from a few of the larger, more economically active CARICOM countries in order to properly grasp the current state of IPRs.

²⁰ South Centre, "Market Access for Trade in Goods in Economic Partnership Agreements", Fact Sheet No. 7, February 2008, SC/AN/TDP/EPA/14, available at http://www.southcentre.org/index.php?option=com_docman&task=doc_download&gid=709&Itemid=&lang=en [Accessed March 25, 2012].

²¹ Norman Girvan, "Implications of the CARIFORUM-EC EPA", available at <http://www.normangirvan.info/wp-content/uploads/2008/08/girvanimplicationsepa21jan.pdf> [Accessed March 25, 2012].

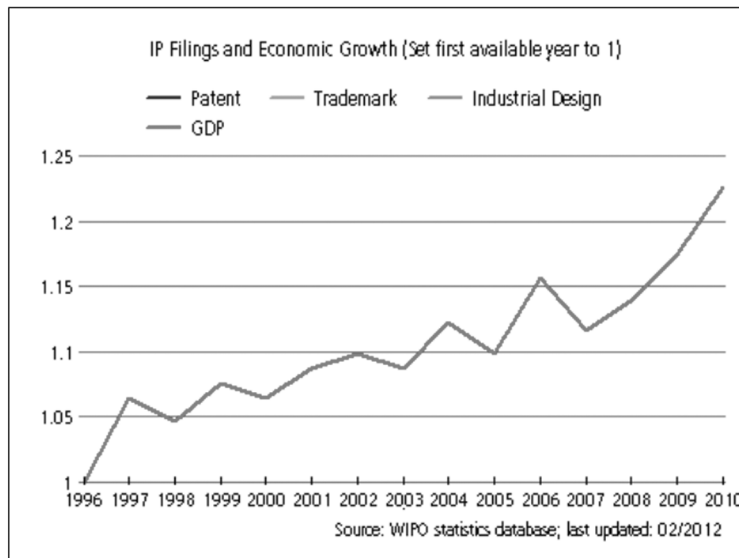
²² EU-CARIFORUM Economic Partnership Agreement, available at http://trade.ec.europa.eu/doclib/cfm/doclib_results.cfm?docId=137971 [Accessed March 25, 2012].

Select country data on IP registrations and economic growth from WIPO statistical country profiles²³

The following data on the IP registrations and economic growth is provided here with the intention of illustrating the pattern of IPRs registrations with the economic growth of select Caribbean countries and with the purpose of discovering whether the trends indicate any correlation between these two factors.

Guyana

Population (Million): 0.76 (2009) (Rank = 156)
 Gross Domestic Product (Billion US\$) (Constant 2005 US\$ (PPP)): 2.11 (2010) (Rank = 143)



IP Filings (Resident + Abroad, Including Regional) and Economy

Year	Patent	Trademark	Industrial Design	GDP (Constant 2005 US\$)
1996				1.72
1997				1.83
1998				1.80
1999				1.85
2000				1.83
2001				1.87
2002				1.89
2003				1.87
2004				1.93

²³ Data retrieved from *WIPO Statistical Country Profile*, September 2011, available at http://www.wipo.int/ipstats/en/statistics/country_profile/ [Accessed March 25, 2012].

IP Filings (Resident + Abroad, Including Regional) and Economy

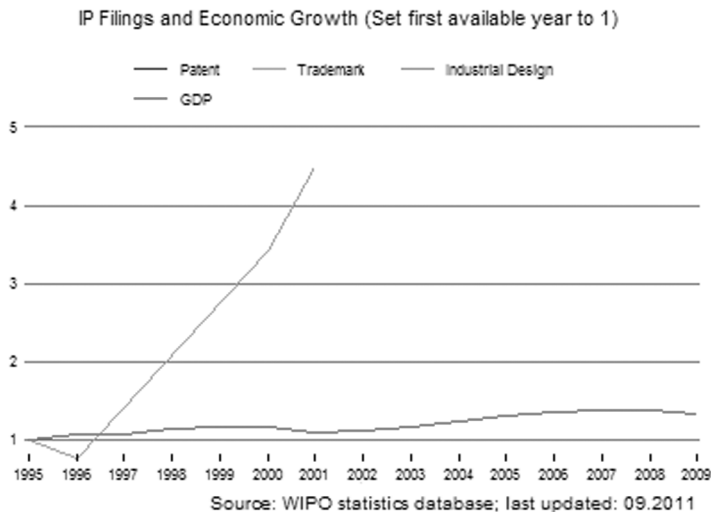
Year	Patent	Trademark	Industrial Design	GDP (Constant 2005 US\$)
2005				1.89
2006				1.99
2007				1.92
2008				1.96
2009				2.02
2010				2.11

The case of Guyana indicates no correlation between GDP growth and IPRs registrations.

St Lucia

Population (Million): 0.17 (2009) (Rank = 175)

Gross Domestic Product (Billion US\$): 0.95 (2009) (Rank = 170)



IP Filings (Resident + Abroad, Including Regional) and Economy

Year	Patent	Trademark	Industrial Design	GDP (Constant 2009 US\$)
1995		12		0.71
1996		9		0.76
1997				0.76
1998				0.81
1999				0.83
2000		41		0.82

IP Filings (Resident + Abroad, Including Regional) and Economy

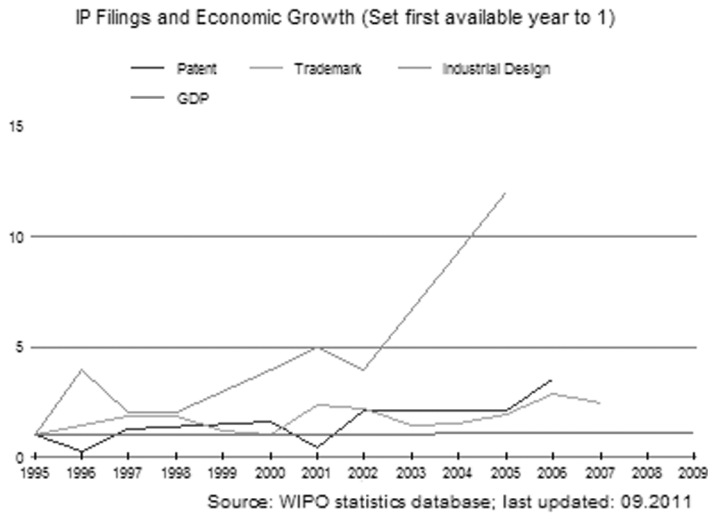
Year	Patent	Trademark	Industrial Design	GDP (Constant 2009 US\$)
2001		54		0.78
2002				0.80
2003				0.83
2004				0.87
2005				0.93
2006				0.96
2007				0.98
2008				0.99
2009				0.95

St Lucia’s statistical data reveal no correlation between GDP growth and IPRs registrations over the period 1995–2009.

Jamaica

Population (Million): 2.72 (2009) (Rank = 135)

Gross Domestic Product (Billion US\$): 12.41 (2009) (Rank = 110)



IP Filings (Resident + Abroad, Including Regional) and Economy

Year	Patent	Trademark	Industrial Design	GDP (Constant 2009 US\$)
1995	7	312	1	11.39
1996	2	450	4	11.43
1997	9	581	2	11.31

IP Filings (Resident + Abroad, Including Regional) and Economy

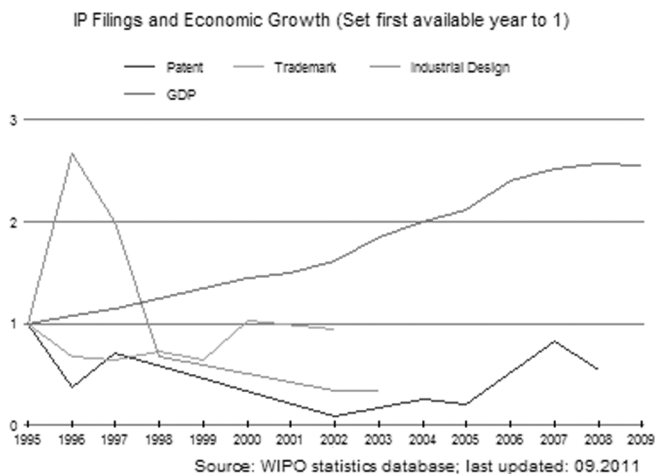
Year	Patent	Trademark	Industrial Design	GDP (Constant 2009 US\$)
1998		585	2	11.17
1999		374		11.29
2000	11	324	4	11.39
2001	3	727	5	11.54
2002	15	682	4	11.66
2003		449		12.06
2004		476		12.24
2005	15	605	12	12.37
2006	25	896		12.74
2007		753		12.92
2008				12.80
2009				12.41

The data indicate no correlation between GDP growth and IPRs registrations for the period 1995–2009.

Trinidad & Tobago

Population (Million): 1.34 (2009) (Rank = 148)

Gross Domestic Product (Billion US\$): 21.12 (2009) (Rank = 94)

**IP Filings (Resident + Abroad, Including Regional) and Economy**

Year	Patent	Trademark	Industrial Design	GDP (Constant 2009 US\$)
1995	24	362	3	8.26

IP Filings (Resident + Abroad, Including Regional) and Economy

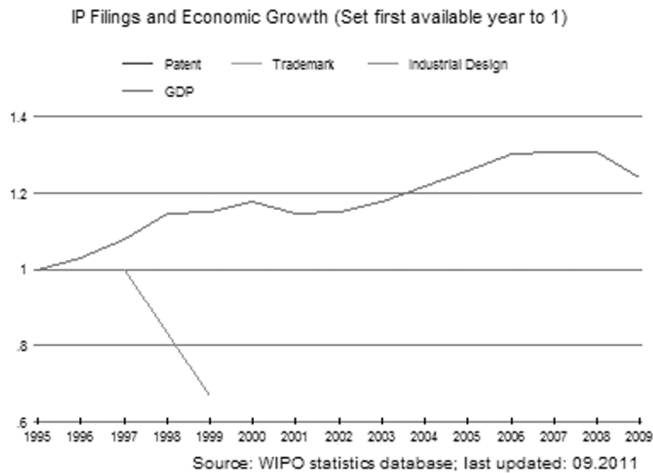
Year	Patent	Trademark	Industrial Design	GDP (Constant 2009 US\$)
1996	9	245	8	8.84
1997	17	234	6	9.52
1998		263	2	10.30
1999		233		11.12
2000		369		11.89
2001				12.39
2002	2	340	1	13.37
2003			1	15.30
2004	6			16.51
2005	5			17.54
2006				19.91
2007	20			20.83
2008	13			21.31
2009				21.12

The data on Trinidad and Tobago indicate no correlation between GDP growth and IPRs registrations for the period 1995–2009.

Barbados

Population (Million): 0.26 (2009) (Rank = 172)

Gross Domestic Product (Billion US\$): 3.6 (2009) (Rank = 151)



IP Filings (Resident + Abroad, Including Regional) and Economy

Year	Patent	Trademark	Industrial Design	GDP (Constant 2009 US\$)
1995				2.90
1996				2.99
1997			3	3.13
1998				3.32
1999		140	2	3.34
2000				3.41
2001				3.33
2002				3.34
2003				3.41
2004				3.53
2005				3.65
2006				3.77
2007				3.79
2008				3.80
2009				3.60

The above data taken from the WIPO statistical country profiles clearly indicate little or no correlation between IPRs, registrations and economic growth in Caribbean countries with the larger economies. The lack of such correlation takes place despite those WTO arrangements that required a strong IP regimen through the enactment into national laws of the minimum requirements of the TRIPS Agreement. If it is to be argued that IP rights are a significant catalyst to economic growth, and that it is of signal importance to the CSME, then the missing link of innovation and research policy must be considered. Measures must also be taken to create a legal and regulatory framework to promote innovation while allowing for the protection of IPRs.

An international overview of IP development trends and economic growth: Wither CARICOM?

The 2011 World Intellectual Property Report: The Changing Face of Innovation

The *2011 World Intellectual Property Report*, sub-titled *The Changing Face of Innovation*,²⁴ focused on the growing trend of creation and exchange of IPRs among both developed and developing countries. It found a growing demand for IPRs, which was directly related to the growth in innovation especially in the area of knowledge markets based on IPRs. A key element of this growth is the frequent trading and licensing of IPRs among firms. It was found that royalty and licensing fee revenues derived internationally had grown from US\$2.8 billion in 1970, to US\$27 billion in 1990, then to US\$180 billion in 2009, far greater than the global GDP.

²⁴WIPO, *2011 World Intellectual Property Report* (2011).

There was also the observation of new market functionalities in the business of IPRs, such as brokerages and clearinghouses. Firms had specialized in particular areas of endeavour and had increased their levels of innovation and efficiency while increasing controls over which kinds of information were released or kept confidential. Maximized learning in open innovation initiatives to allow for greater creativity was also found to be a significant factor along with the control of information.

Other key developments include the patenting of complex technologies; these are defined as technologies comprising several different areas, each of which is patentable and may have separate owners. This is especially applicable to communication technologies such as software, optics, audio-visual technology, tablet computers and smart phones. All of these technologies have given rise to companies creating large portfolios of patent rights—to the extent that it is felt that the overburdening of the patent system has significantly slowed the process of innovation. It is proposed that efficient institutions are essential to the functioning of that system in order to avoid hampering innovation.

The report disclosed that several countries established systems and policies which would harness public research for innovation, such as the creation of incentives for universities and other public research organizations. These institutions create patents and take the further step of commercialising them, thus resulting in an increased rate of patent applications. It was also found that filings by universities and public research organizations under the Patent Cooperation Treaty (PCT) increased from minimal in the 1980s to more than 15,000 in 2010. Such an increase could be attributed to the high income economies such as France, Germany, Japan, the United Kingdom, and the United States, even though middle-income countries have also made significant contributions to this trend.

Among the important developments in this area suggested by the report is that while the high income countries maintain high levels of investment in research and development (R&D), low- and middle-income countries have increased their levels of participation and R&D spending by 13 per cent between 1993 and 2009:

“While high-income countries still dominate global R&D spending, the geography of innovation has shifted. Global R&D expenditures almost doubled in real terms from 1993 to 2009. Most R&D spending still takes place in high-income countries—around 70 percent of the world total. They spend around 2.5 percent of their gross domestic product (GDP) on R&D, more than double the rate of middle-income economies. Low- and middle-income economies have increased their share of global R&D expenditure by 13 percentage points between 1993 and 2009. China accounts for most of this increase—more than 10 percentage points—propelling China to the world’s second largest R&D spender in 2009.”²⁵

The report also found increased publications in peer-reviewed journals in the relevant fields of science and technology, with co-authorship of an international nature and a list of patents with inventors from more than one country, thus providing a clear indication of increased international collaboration in those fields. The report concluded that societies benefited greatly from collaboration in R&D, which lead to IPR creations and new technologies. It stated that joint IP production was usually the result of R&D alliances and that multilateral firms increasingly locate their R&D facilities within other countries. Such production has resulted in increased economic activity and growth in middle-income countries.

Among the difficulties with the data acknowledged in the report is that in the first instance,

²⁵ Sacha Wunsch Vincent, “The Changing Face of Innovation”, *WIPO Magazine*, February 2012, available at http://www.wipo.int/wipo_magazine/en/2012/01/article_0006.html [Accessed March 25, 2012].

“[i]t is difficult to draw a clear distinction between open innovation strategies and long-standing collaborative practices, such as joint R&D, joint marketing or strategic partnerships. For another, certain elements of open innovation strategies—such as new policies internal to firms or informal knowledge exchanges—cannot easily be traced.”²⁶

The argument is made, however, that IP protection can shape creative and innovative policy in a substantial way:

“IP protection is a policy initiative that provides incentives for undertaking creative and innovative activity. IP laws enable individuals and organizations to obtain exclusive rights to their inventive and creative output. Ownership of intellectual assets limits the extent to which competitors can free ride on problem-solving and related information, enabling owners to profit from their efforts and addressing the appropriability dilemma at its heart.... IP rights are an elegant means for governments to mobilize market forces to guide innovative and creative activity. They allow decisions on which innovative opportunities to pursue to be taken in a decentralized way. To the extent that individuals and firms operating at the knowledge frontier are best-informed about the likely success of innovative projects, the IP system promotes an efficient allocation of resources for inventive and creative activity.”

This document propounds that R&D policies implemented by governments have in a large part been responsible for fuelling the growth of IP registrations, technical innovations and advancements that have benefited societies across the world. The report is notably silent on the CARICOM states as being involved in any of developmental trends and leaves open the question of the future of the region in this new state of world affairs.

The Caribbean Community has devised a centralized mechanism in the form of a secretariat,²⁷ which is responsible for regional policies devised by the Heads of government and implemented through specialized organs in the fields of science and technology (including medicines and agriculture), arts and culture, and economics, among others. Its two prominent regional tertiary institutions, the University of the West Indies and the University of Guyana, along with the Institute of Applied Science and Technology of Guyana, comprise some of the resources available in the areas of innovation and technology. It leaves the curious onlooker with the burning question of whether it is for lack of foresight or political will that there have yet to be any notable developments in policies and programs, which will lead the region to claim its share in this sector of the global economy.

There is obvious scope and dire need for the collaboration of scientists and policy makers from the mentioned institutions, and there is a need for the investment of adequate resources to develop competitive technologies. There is even greater scope for private investment in this area, but which must be supported by the necessary and relevant legal and regulatory framework and promoted as viable economic investments to those willing to do in and outside the region. It is clear that the issue of IPRs cannot be wished or explained away since it is now an integral part of modern international economic developments and that CARICOM is faced with the choice to either sink or swim.

²⁶ Vincent, “The Changing Face of Innovation”, *WIPO Magazine*, 2012, available at http://www.wipo.int/wipo_magazine/en/2012/01/article_0006.html [Accessed March 25, 2012].

²⁷ Information about the CARICOM Secretariat is available at http://www.caricom.org/jsp/secretariat/secretariat_index.jsp?menu=secretariat [Accessed March 25, 2012].

Making the Caribbean connection

Because of some of the regional issues discussed before, the making of the Caribbean connection to this trend of growth and development is, admittedly, a hardly simplistic exercise. In addition, there is the recent addition of the global recession which has severely affected the GDP's of several Caribbean countries. As Professor Norman Girvan stated in a lecture entitled "Existential Threats in the Caribbean: Democratising Politics, Regionalising governance" in May 2011:

"In 2007 Caricom countries were resisting some of the most unreasonable demands of the European Union in the Economic Partnership Agreement. The EU threatened to impose tariffs on imports from the Caribbean; and Caricom caved in. The agreement will remove tariffs on the majority of imports from Europe and will bind government policies in trade, services, investment, intellectual property and government procurement; indefinitely. It commits Caricom countries to negotiate further liberalization in 2013."²⁸

These comments provide a succinct description of the external forces that have taken a hold of shaping the immediate, and perhaps long term, future of some of the CARICOM members. Professor Girvan continued by describing the Jamaica situation as follows:

"Since the onset of the crisis four Caricom countries have entered into major IMF programmes. The IMF Jamaica agreement is one of the most stringent cases imaginable of financial supervision of an independent state. There are nine listed conditionalities covering Government Finances, Public debt management, Public entities, Institutional Fiscal Reform, and Financial sector reform. Jamaican officials are required to report to IMF staff resident in Jamaica on a daily basis in some instances. There will be quarterly reviews: for example 'the first ... review will focus on the FY 2010/11 budget and the implementation of the fiscal responsibility framework; ... examine the plans for recapitalizing financial institutions. The second will focus on fiscal reforms, specifically in the debt management, tax, and public financial management areas. It will also review progress in the various initiatives aimed at strengthening financial system regulatory and supervisory framework. The third review will focus on public bodies and employment reforms as well as progress in financial sector reforms."²⁹

While reflective of the economic and policy constraints that are part of the CARICOM experience at this time, these comments certainly do not preclude the creation of initiatives at the level of the CARICOM governance organization in the development of a comprehensive legal and regulatory framework for IP which will include mechanisms for dispute resolution and comprehensive reporting systems while developing regional, and encouraging national, incentives for innovation and IPRs creation.

Creating a regional patent and trademark registration system

The evidence is substantial in favour of the promotion of innovation and IPRs as a means of encouraging financial growth and scientific and technological development. It is also clear that the regional abeyance in the creation of a regulatory framework in spite of recognizing its importance to the development of the CSME has kept it out of the emerging group of rapidly developing countries in this area. It is here proposed that the development of a regional patent registration system, which will give protection to registrants in the signatory countries, will immediately alleviate some of the difficulties investors face in protecting their innovations in the Caribbean.

²⁸ Norman Girvan, "Existential Threats in the Caribbean: Democratising Politics, Regionalising Governance", available at <http://www.normangirvan.info/wp-content/uploads/2011/05/girvan-clr-james-lecture-revised.pdf> [Accessed March 25, 2012].

²⁹ Girvan, "Existential Threats in the Caribbean", available at <http://www.normangirvan.info/wp-content/uploads/2011/05/girvan-clr-james-lecture-revised.pdf> [Accessed March 25, 2012].

The PCT provides a workable model for the universal protection of patent system needed for the region. The PCT is open to states that are signatories to the Paris Convention for the Protection of Industrial Property. It allows the nationals of signatory states to simultaneously gain protection in all other signatory. A CARICOM system of this kind may be implemented through the creation of a Protocol to the Treaty of Chaguaramas, which will allow for the creation of a patent and trademark registration system to be administered by a special agency created by CARICOM for this purpose. It is also possible for signatories to such an arrangement to incorporate special exceptions that will allow them greater autonomy than in the case of a simple uniform patent with region wide application. Countries will be able to adjust their patent application provisions to account for policy and economic considerations while affording a substantial level of protection to rights holders.

Alternative Dispute Resolution

The creation of a holistic legal and regulatory framework must, of necessity, encompass the mechanisms of alternative dispute resolution in order to attain maximum efficiency. The use of ADR in the form of an arbitral tribunal that will deal exclusively with IP matters has been proposed by this author at different fora, in some detail. This is a concept which has been tested and proven in the European Union with the creation of the European Civil Service Tribunal³⁰ and which will provide a means for resolving disputes efficiently and effectively. Applied in the Caribbean, it will serve as the central CARICOM dispute resolution forum for IP matters and provide IPR investors with a high-level judicial forum of international standing, equipped with qualified, impartial, international jurists. This measure must be undertaken concurrently with the establishment of IP registration systems in order to provide a comprehensive, manageable and accountable system of administration for Caribbean IP.

Conclusion

While the Caribbean region faces some unique difficulties as a result of its historical, political and economic issues, and in the face of stark financial issues, it is proposed that the creation of a legal, regulatory and policy framework that promotes the growth of IPRs and that encourages innovation as has been done in other parts of the world will have significant impact on the development of the region. Incorporation of such initiatives into the goals of the CSME—firstly, by the creation of a patent and trademark registration system and administration office, and then by the promotion of national and regional incentives for creativity and innovation—will have an immediate impact on the growth and development of science and technology. The areas of traditional knowledge, climate change, the low carbon development strategy proposed by Guyana and the offspring industries from the low carbon initiative will experience a significant thrust and create forward movement nationally and regionally, both in the creation of IPRs and economic growth.

³⁰ The EU Civil service tribunal was established to deal specifically with issues arising between the European Union and its civil servants: see http://curia.europa.eu/jcms/jcms/T5_5230/ [Accessed March 25, 2012].

Trends of Patent and Utility Model Activities in Asia and Africa: A Comparison of Regional Innovation, FDI and Economic Activity

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☞ Africa; China; Economic development; India; Innovation; Malaysia; Patents; Philippines; Research and development; Technology transfer; Thailand; Utility models

The 21st Century is characterised by the knowledge economy in which wealth creation emanates from information, knowledge and intangible assets. This article undertakes comparative analyses of trends in innovation using resident and non-resident activity in patents and utility models in five newly industrialising countries in Asia and thirty two member countries of the African Regional Intellectual Property Organisation (ARIPO) and the African Intellectual Property Organisation (OAPI). It also explores relationships among patenting, investments in R&D, Foreign Direct Investments and economic activity in the two regions. This is necessary to help policy makers, practitioners and scholars consider the relative levels of local innovation and the contribution of Intellectual property to economic activity in the two regions. The results have profound contributions to the debate on whether the formal IP system is appropriate for measuring progress in innovation activity in these regions.

Introduction

The 21st century has been characterised by the knowledge economy in which contemporary wealth creation emanates from information, knowledge and intangible assets¹ (intellectual property (IP)). This article undertakes comparative analyses of trends in innovation activity in five newly industrialising countries (NICs) in Asia (China, India, Philippines, Thailand and Malaysia) and 32 member countries of the Africa Regional Intellectual Property Organisation (ARIPO) and the African Intellectual Property Organisation (OAPI). The article also explores relationships amongst patenting, investments in research and development (R&D), foreign direct investments (FDI) and other economic activities in the two regions. Such exploration is necessary to help policy makers, practitioners and scholars consider the relative levels of local innovation and the contribution of IP to economic activity in the two regions. The article uses patent and utility model applications for both residents and non-residents obtained from the World Intellectual Property Organisation (WIPO) online databases and economic performance indicators such as real gross domestic product (GDP), net FDI flows, population, manufacturing value added and R&D expenditure data obtained from the World Bank.

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¹ D. Dang and K. Umemoto, "Modeling the Development toward the Knowledge Economy: A National Capability Approach" (2009) 13(5) *Journal of Knowledge Management* 359.

IP system, innovation and the knowledge economy

When discussing patents and utility models in any context, it is important to remember that the patent system is a component of the broader IP system at the national, regional or international level. An IP system can be described as a triple system encompassing:

- IP mechanisms such as patent and petty patent law, trademark law, industrial design law, copyright law and other IP laws and regulations;
- IP administration such as IP offices and infrastructure and their level of efficiency and effectiveness; and
- IP enforcement such as efficient law enforcement systems like courts, the police and customs authorities.²

This comparative analysis focuses on the patent and utility model mechanisms and their activity levels in the ARIPO and OAPI regions and in NICs in Asia (NICA).

For any country, strengthening and modernising the IP system is one response to the fundamental need to improve participation in the knowledge economy. This entails creating and improving national institutions that enable the production, access and use of knowledge.³ Some scholars have argued that the knowledge that is going to be of immediate use to least developed countries and developing countries is knowledge concerned with such basic things as development of medicines and responses to deal with food insecurity. Additional arguments have been made that

“IPR and patents are not a central issue here since the absence of business opportunities is not related to insufficient or incomplete legal systems to enforce patents but is clearly linked to poverty”.⁴

In countering these arguments, other scholars have noted that it is possible to re-orient the IP system to take advantage of its incentive philosophy by allowing the protection of limited but useful innovations through a utility model or petty patent system.⁵ This entails the development of less stringent standards for the protection of less advanced innovations. Similarly, simplified patent protection might be made available to those projects that address neglected needs, such as the development of medicines for tropical diseases or the development of tools and gadgets that may have less advanced inventiveness in them and yet still be very useful in developing countries. The creation of conditions for low-cost research activities in developing and least developed countries can be an important means of stimulating the knowledge economy in those countries.⁶

For many years, economists have tried to provide an explanation on why some economies grow fast while others do not, i.e. why some countries are rich and others are not. It is generally agreed that knowledge and innovation have played an important role in recent economic activity. The renowned economist Paul Romer theorised that the accumulation of knowledge is the driving force behind economic growth.⁷ For countries to promote growth, their economic policies should encourage R&D investments and subsidise programmes that develop human capital.⁸ Rapid knowledge creation, including the emergence of new technologies, results in and from, among other things, policy changes regarding IP and the adoption of new knowledge asset management practices.⁹

² D. Yang, *Intellectual Property Benchmarking* (2006), study prepared for WIPO.

³ M. Blakeney and G. Mengistie, “Intellectual Property and Economic Development in Sub-Saharan Africa” (2011) 14(3–4) *J. World Intell. Prop.* 238.

⁴ Blakeney and Mengistie, “Intellectual Property and Economic Development in Sub-Saharan Africa” (2011) 14(3–4) *J. World Intell. Prop.* 238.

⁵ D. Foray, *Knowledge, Intellectual Property and Development in LDCs: Toward Innovative Policy Initiatives* (2007), study prepared for UNCTAD as a background paper for *The Least Developed Countries Report*.

⁶ Blakeney and Mengistie, “Intellectual Property and Economic Development in Sub-Saharan Africa” (2011) 14(3–4) *J. World Intell. Prop.* 238.

⁷ K. Idris, *Intellectual Property: A Power Tool for Economic Development*, 2nd edn (Geneva: WIPO, 2003).

⁸ R.C. Acharya and W. Keller, “Technology Transfer through Imports” (2009) 42(4) *Canadian Journal of Economics* 1411.

⁹ T.O. Awokuse and H. Yin, “Intellectual Property Rights Protection and the Surge in FDI in China” (2010) 38(2) *Journal of Comparative Economics* 217.

Since the 1990s, an increasing number of policy makers in emerging economic powers recognise the important role the IP system plays in encouraging private R&D investments and FDI, especially in the industrial and scientific fields.¹⁰ Many studies suggest that a healthy IP system is a key element in encouraging FDI.¹¹ This article undertakes comparative analyses of trends in R&D investments, trends in resident and non-resident patent and utility model activities in NICA and 32 countries in Africa that are members of the two regional IP organisations, ARIPO and OAPI. The article conducts correlation analyses as a basis to understand some of the factors contributing to differences in the level of innovation and economic development between Africa and Asia.

Technology transfer and economic development

By providing recognition and economic benefits to the inventor and owner(s) of an invention, a fair and modernised patent system constitutes an incentive for inventiveness and innovative activity. That system also creates a favourable environment for the transfer of technology through the security it provides for the patentee, licensee and licensor.¹² Patent laws require that an application for a patent describe the invention so clearly and completely in terms of all the technical details that anyone having ordinary skill in the field should be able to carry out the invention by reading the description. In addition, patent laws require that the details of the patent should be published as a condition for granting a patent for an invention. In other words, at the very latest, when the patent for an invention is granted, the invention will be “disclosed”, i.e. its essence and mode of exploitation will be brought to the knowledge of anyone who wishes to know through publication in the patent office’s journal or gazette.

The use of information available through this disclosure avoids wasteful duplication of effort and the multiplication of costs that research aimed at finding solutions to technical problems can entail. In addition, disclosure acts as an impetus for further inventions, and this contributes to advancement in science and technology.¹³ A search for the state of the art or prior art through existing patent and utility model documents will usually identify the solutions to a technical problem that have been proposed in the past.¹⁴

Park and Lippoldt, in their paper entitled “The Influence of Intellectual Property Rights (IPRs) on Technology Transfer to Developing Nations”, argue that IPRs could have market expansion effects in that they enable rights holders to better exclude imitators and enjoy a larger market for their technologies.¹⁵ However, IPRs could also have market power effects which in theory may enable rights holders to increase the rents earned on their technologies—for example, by constraining the quantity supplied, thus causing increased prices.

Other studies show that stronger IPRs in developing countries can be associated with increased technology—intensive FDI. However, in some countries with weak IPRs, there may also be substantial flows of FDI, although these tend to be for the purpose of establishing sales and distribution outlets, rather than high-value production and R&D facilities.¹⁶

¹⁰ T. Broude, “It’s Easily Done: The China—Intellectual Property Rights Enforcement Dispute and the Freedom of Expression” (2010) 13(5) J. World Intell. Prop. 660.

¹¹ K. Saggi, K. Maskus, and T. Puttitanum, “Patent Rights and International Technology Transfer through Direct Investment and Licensing” in Keith E. Maskus and Jerome H. Reichman (eds) *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005).

¹² L. Yang and K.E. Maskus, “Intellectual Property Rights, Technology Transfer and Exports in Developing Countries” (2009) 90(2) *Journal of Development Economics* 231.

¹³ WIPO, *IP Handbook, Policy, Law and Use* (Geneva:2004).

¹⁴ WIPO, *IP Handbook, Policy, Law and Use* (2004).

¹⁵ W.G. Park and D.C. Lippoldt, “Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries” (2008) OECD, Trade Policy Working Paper No.62.

¹⁶ Yang and Maskus, “Intellectual Property Rights, Technology Transfer and Exports in Developing Countries” (2009) 90(2) *Journal of Development Economics* 231.

The empirical results from the Park and Lippoldt study show that, when focusing on technology transfer to developing countries, stronger levels of patent protection are positively and significantly correlated with inflows of high technology products, like pharmaceutical goods, chemicals, aerospace, computer services, information, and office and telecommunications equipment. This relationship, they argued, holds for all groups of countries: developed, developing and least developed.¹⁷

Nunnenkamp and Spatz argue that exports of high technology goods and services and FDI inflows are also significantly and positively correlated with foreign patenting in developing countries. Thus, stronger patent rights in developing countries appear to have the potential not only to stimulate international technology transfer, but also to provide incentives for foreigners to transfer new technologies.¹⁸ In Brazil, Russia, India and China, technology transfer via trade and FDI has been one important input (among other factors) into developing local technological capabilities. Thus, the inflows of goods, services, capital and patent applications have been a source of knowledge spillovers as well as a source of inputs with which to conduct innovation (such as laboratory equipment). The effect of this has been enhanced by governments' own efforts to fund R&D in their own countries.

In light of the foregoing, while many studies have been undertaken to establish the various indicators of technology transfer worldwide, there is scarcity of comparative studies for Africa (categorized as the ARIPO and OAPI regions) and Asia, focusing on the patent and utility model systems. Countries which are renowned with a phenomenon of high economic growth rates in Asia include China, India, Malaysia, Philippines and Thailand.¹⁹ Alongside increased economic growth, these countries seem to be experiencing an increase in the level of registration of utility models (petty patents), patenting activity, R&D investments and FDI. A detailed comparison with Africa would be insightful for the ARIPO and OAPI regions to learn lessons from the Asian region on what needs to be done to increase participation in the formal IP system and knowledge economy in order to contribute to raising the regional living standards.

The context and background issues in the ARIPO and OAPI regions and NICA

ARIPO is one of the two regional organisations dealing with IP protection in Africa.²⁰ It was established under the auspices of the United Nations Economic Commission for Africa (UNECA) in 1976. Its establishment was supported by WIPO, and these two institutions formed the interim Secretariat of the Organisation at its inception. ARIPO

“pledges to develop, promote, harmonise and protect industrial property and ensure that this contributes to the social, cultural, economic and technological development of its member states.”²¹

As of December 2010, ARIPO had 16 Member States, namely Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. The observer states included Angola, Burundi, Egypt, Eritrea, Ethiopia, Liberia, Mauritius, Nigeria, Rwanda, Seychelles and South Africa. It should be noted that observer states are not members and cooperation with them entails giving them an observer status in meetings to help them gain an understanding of how ARIPO functions as they consider whether to join or not.

¹⁷ Park and Lippoldt, “Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries” (2008) OECD, Trade Policy Working Paper No.62.

¹⁸ P. Nunnenkamp and J. Spatz, “FDI and Economic Growth in Developing Economies: How Relevant Are Host-economy and Industry Characteristics” (2004) 13(3) *Transnational Corporations* 53.

¹⁹ United Nations Conference for Trade and Development (UNCTAD), *Global Economic Statistics*, available at: http://www.unctad.org/en/docs/tidstat36_en.pdf [Accessed March 25, 2012].

²⁰ G. Sibanda, *The Africa Intellectual Property organization (OAPI) and the African Regional Intellectual Property Organization (ARIPO): Origins and Functions* (Harare: ARIPO 2008).

²¹ Lusaka Agreement on the Creation of the African Regional Intellectual Property Organization (ARIPO) 1976.

OAPI, which was formed in 1961, is the older of the twin sub-regional organisations entrusted with the protection of IPRs on the African continent. Its membership comprises mainly Franco-phone countries in Africa. OAPI was created and established with the support and assistance of the French National Industrial Property Offices.²² OAPI is a supra-national IP organisation of a sub-regional character created by the transformation of its predecessor upon the adoption of the Libreville Agreement on March 22, 1977 at Bangui, Central African Republic.²³ As of December 2010, OAPI had 16 Member States, namely Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad and Togo.

Newly industrialising countries in Asia

NICs are countries whose economies have not yet reached developed country status, but have, in a macroeconomic sense, outpaced their developing counterparts.²⁴ Another characteristic of these countries is that they are undergoing rapid economic growth (usually export-oriented). On-going industrialisation is an important indicator of an NIC. The term began to be used in the 1970s when the “East Asia Tigers” of Hong Kong, South Korea, Singapore and the Republic of China (Taiwan) rose to global prominence with rapid industrial growth since the 1960s. In particular, the combination of an open political process, high per capita GDP income and a thriving, export oriented economic policy has shown that these countries have now reached the ranks of developed countries. There is a distinction between these countries and the countries that now are considered as NICs. Table 1 below lists the countries that were categorised as NICs in each continent as of 2008.²⁵ For the purpose of this comparative study, the NICs focused on were the Asian block comprising China, India, Malaysia, Philippines and Thailand as depicted in Table 1 below according to the IMF classification.

Table 1: NICs by continent²⁶

Continent	Country	GDP (PPP) (millions of USD 2008 IMF)	GDP Per capita (USD 2008 IMF)	GDP Per Capita (PPP) (USD 2008, IMF)	GDP (real growth rate)	GDP (real growth rate per capita)
<i>Africa</i>	South Africa	495,990	6,170	10,187	4.50	4.92
<i>North America</i>	Mexico	1,550,257	10,747	14,582	3.00	3.30
<i>South America</i>	Brazil	1,975,904	8,676	10,298	5.40	4
<i>Asia</i>	China	7,890,277	3,180	5,943	11.10	9.95
	India	3,305,435	1,043	2,787	9.70	7.02
	Malaysia	388,313	7,866	14,225	5.40	3.65
	Philippines	319,773	1,108	3,539	7.50	7.40
	Thailand	556,410	4,099	8,380	4.40	3.93
<i>Eurasia</i>	Turkey	937,143	11,463	13,447	5.20	4.10

²² Sibanda, *The Africa Intellectual Property Organization (OAPI) and the African Regional Intellectual Property Organization (ARIPO)* (2008).

²³ Libreville Agreement 1962; Bangui Agreement Relating to the Creation of an African Intellectual Property Organization, Constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property (Bangui (Central African Republic) 1977).

²⁴ UNCTAD, *World Statistics Report 2008* (2008).

²⁵ International Monetary Fund, *Country by Country Statistics on Development* (2008).

²⁶ Source: International Monetary Fund (IMF), 2008

Theorising patent system, technology transfer, FDI and economic activity

Economic growth theories developed in the 20th century focused on contribution of technology to economic growth.²⁷ This section discusses relevant IP related economic theories and then reviews empirical literature that lends support to the postulations from these theories. The section then considers the expected differences between Asia and Africa regarding patent and utility model activities and their relationships with economic variables like FDI, GDP growth and R&D investments.

Economic growth theories

Economic growth theories related to IP may be grouped into two models known as endogenous and exogenous growth theories. Both theories agree that technology is a key to growth, but differ on how to treat technological progress as a factor in economic growth.²⁸

(a) Endogenous growth theories

In these theories, technological change is included in the new capital stock and is induced by previous economic conditions. This entails that economic growth emanates from within the system, usually a nation. Thus, technological progress is regarded as an endogenous factor. From this perspective, R&D investments would lead to development of new technologies resulting in new products or methods. Endogenous growth theories allude to education, on-the-job training and development of, hitherto, novel technologies for the local and global market as catalysts for increased economic activity.²⁹

(b) Exogenous growth theories

In these theories, technological changes contribute to increased GDP without change to the input of labour and capital in the production process. This entails that output increases while using the same amount of labour and capital as a result of technological progress. The theories do not specify any particular transmission mechanism by which technological progress occurs; rather, such progress is assumed to fall like “manna from heaven”. Technology is viewed as being an external factor. While FDI is not a technology transfer activity per se, it is a driver or a factor in technology transfer. Thus, technology transfer activities resulting from FDI and exchange of expertise between parent and subsidiary companies may lead to new products and production methods that become the catalyst for economic growth. This “manna from heaven” would in present understanding be likened to non-resident patenting activity and FDI and other sources of technology transfer.

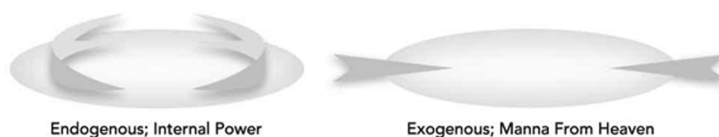


Figure 1: Endogenous and exogenous growth theories (Source: Adapted from Idris (2003))

²⁷ J.B. De Long, “A Short Review of Economic Growth: Theories and Policies”, November 1996, available at http://econ16.berkeley.edu/econ-articles/ACCF_Growth/Growth_ACCF4.html [Accessed March 25, 2012].

²⁸ Idris, *Intellectual Property* (2003).

²⁹ E. Denison, *The Sources of Economic Growth in the United States and the Alternatives Before Us* (New York: Committee for Economic Development, 1962).

(c) Schumpeter's growth theory

Joseph A. Schumpeter laid some ground work for endogenous growth theories and later exogenous growth theories. His contribution centred on innovation and entrepreneurship. Entrepreneurs took advantage of a basic invention, whether new product or process (technique), transforming it into economic innovation. Inventions were economically irrelevant until entrepreneurs got involved to make them operational and to market them.³⁰ The primary motive for entrepreneurs was profit. While working these innovations and the imitations that follow in the process result in increased economic activity, imitators reduced the entrepreneurial profits.³¹ Indeed, entrepreneurial zeal for profits was the driving force of most innovations.

Given the free riding possibility from imitators, Schumpeter proposed that some degree of monopoly power would be necessary to enable entrepreneurs to continue innovating. In modern approaches, this monopoly power would be in the form of IPRs. Later, Schumpeter predicted the demise of the smaller entrepreneurs and the emergence of a new mode of economic organisation in which innovation and R&D would be conducted by large firms. This conclusion led some economists to see two Schumpeters: Schumpeter I, who saw entrepreneurs playing a critical role in technological progress; and Schumpeter II, who saw scientific and technical activities being undertaken by large firms.³² According to Schumpeter II, large monopolistic enterprises would become the principal engines of technological progress as they had the necessary resources to undertake complex technological research and investment activities. However, these firms would also be threatened by what he termed creative destruction, i.e. superior innovations displacing inferior technologies. In modern parlance, this can also be observed in FDI activities where large multinational firms invest in developed and developing countries having created inventions and turned them into innovations in their home countries. This in turn drives out inferior technologies as customers switch to superior technologies. Recently, economists like William Baumol have postulated that an IP system is to be regarded as an important factor influencing the behaviour of the entrepreneur in encouraging inventions, applying the innovations, introducing them into an economy, and marketing the product in an innovative or creative way.³³

(d) Technological progress—An important economic variable

In the 1950s, neoclassical economists continued focusing on technological progress as a key variable in economic growth. Based on his study of GDP data for the United States from 1909 to 1949, Robert Solow suggested that the growth in capital stock contributed less than 20 per cent of the growth in GDP per person employed.³⁴ He argued that growth in labour and capital explained only half of the growth in GDP. He concluded that the remaining unexplained portion of growth, which came to be known as the Solow Residual, resulted from technological progress.³⁵

³⁰ A.J. Schumpeter, *Theory of Economic Development* (Cambridge, Mass.: Harvard University Press, 1934, 1954).

³¹ Schumpeter, *Theory of Economic Development* (1934).

³² F.W. Rushing and M.A. Thompson, "Intellectual Property Protection, Entrepreneurship and Economic Growth" (1996) 4(3) *Journal of Enterprising Culture* 267.

³³ D.B. Audretsch, W.J. Baumol and A.E. Burke, "Competition Policy in Dynamic Markets" (2001) 19(5) *International Journal of Industrial Organization* 613.

³⁴ R.M. Solow, "A Contribution to the Theory of Economic Growth" (1956) 70(1) *Quarterly Journal of Economics* 65.

³⁵ R.M. Solow, "Technical Change and the Aggregate Production Function" (1957) 39(3) *Review of Economics and Statistics* 312.

Solow's findings were later supported by Edward Denison who concluded that between 1929 and 1957, 40 per cent of the increase in per capita income in the United States was due to the "advance of knowledge".³⁶ Basically, the Solow model focuses on four variables—namely, output, labour, capital and knowledge.³⁷ The theory explains how capital, labour and knowledge combine to produce output, the level of which can determine the growth of an economy over a period of time. This model assumes that technological progress occurs when there is an increase in the amount of knowledge and that the production function constantly returns to scale in relation to capital and effective labour.³⁸

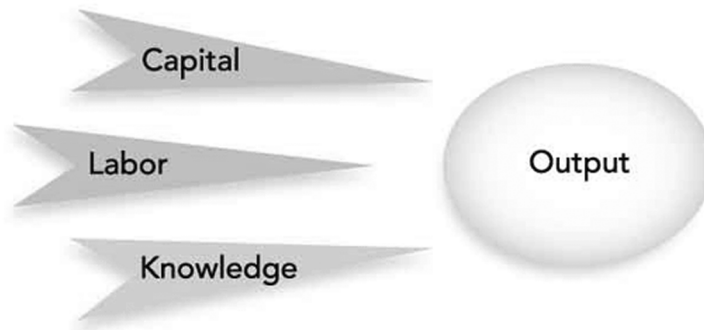


Figure 2: The Solow model (Source: Adapted from Idris (2003))

According to Solow, economic growth depends on the rate of growth of capital, labour and technological improvement. He argued that an economy would grow if a large share of its total output was devoted to R&D investments or if there was a rapid growth of technology. Technological progress was the key factor leading to economic growth. Growth had little to do with the state of the internal economy, and progress in science and technology depended little on monetary or fiscal policies (i.e. economic policy).

The foregoing findings meant that treating technological progress as exogenous implied that the implementation of economic policy alone did not directly influence technical progress, but technical progress could influence economic growth. This was why the Solow model did not attempt to define where technology was coming from. Thus, a country with higher rates of technological growth, and hence greater productivity growth, would experience an increasingly higher standard of living than those countries without such growth. Specifically, in relation to the rising standard of living as far as output and consumption growths were concerned, Solow introduced an assumption of technology growth as being exogenously determined, thus increasing the productivity of labour. This assumption meant that the natural growth rate was composed of not only the biological rate of population growth (necessary for increased labour force and increased consumption demand), but also the rate of technological progress. This was known as effective labour. Solow elaborates that technological progress is at least partially endogenous to the economy and identifies the patent system as one of the instruments used to attract more resources into the research for new products and processes leading to further growth in the economy.

³⁶ Denison, *The Sources of Economic Growth in the United States and the Alternatives Before Us* (1962).

³⁷ R.G. Lipsey and K.A. Chrystal, *An Introduction to Positive Economics* (Oxford: Oxford University Press, 1995).

³⁸ E.F. Denison, *Trends in American Economic Growth, 1929–1982* (Washington: Brookings Institution Press, 1985).

(e) 1980s endogenous growth theories

Paul Romer in his 1986 study, *Increasing Returns and Long Term Growth*, assumed a monopolistic competitive environment and suggested that R&D activities and the accumulation of human capital through education and training played a key role in economic growth. Romer postulated that technological progress in industry required concerted, profit oriented activity that yields two distinctive components: (a) specific technical features embodied in products that can be patented and produced, excluding rival firms from the same activity; and (b) the knowledge that those features were essentially for the public good.³⁹ Thus, in order to encourage people or institutions within or outside an economy to be involved in knowledge creation and transfer, the principle of excludability had to be invoked. He argued that two ways can be used to exclude others: first, by keeping the knowledge as a secret; and second, by invoking effective IP laws. Thus, Romer concluded that for countries to promote growth, their policies should:

- encourage investment in research for new products and processes as opposed to encouraging investment in physical capital accumulation; and
- subsidise the accumulation of total human capital as the higher the level of human capital a country possesses, the higher its productivity which translates into sustained economic growth.⁴⁰

Empirical literature supporting the theories

Literature review on empirical studies testing the preceding theories of economic growth has shown that where there is an increase in technological progress, there is likely to be an increase in the level of output at both the firm (micro) and national levels (macro). Literature has also revealed that there is an empirical relationship between IPRs and technology transfer.⁴¹ Technology transfer can be evidenced and can occur in many ways including imports of high technology products, exchange of staff between parent and subsidiary companies, and transfer of production capacity and know-how through FDI flows. The bedrock of technology transfer is, however, the IP system.⁴² This is because IPR owners would like to be assured that their rights will not be infringed in the country from which they seek to operate.

Furthermore, literature shows that a relationship between technological progress and growth in output is expected. Empirical economic literature is increasingly lending support to the view that international trade and FDI provide means by which technologies can be spread internationally.⁴³ International technology transfer activities can explain cross-country differences in per capita incomes as well. Such transfers help recipient countries develop their own capacity to produce and export high-technology goods.

Other studies explore the mechanism by which FDI transfers knowledge to the local economy. The transmission of technology can also occur through labour mobility between subsidiaries and parent enterprises.⁴⁴ Markus et al provide a more focused survey of IPR policies and regimes, noting in particular that they affect incentives for engaging in international technology transfer, influencing the volume of flows via different mechanisms of transfers as well as the choice of means of transfer of technologies.⁴⁵

³⁹ P.M. Romer, "Increasing Returns and Long-run Growth" (1986) *Journal of Political Economy* 1002.

⁴⁰ Romer, "Increasing Returns and Long-run Growth" (1986) *Journal of Political Economy* 1002.

⁴¹ Saggi, Maskus and Putitanum, "Patent Rights and International Technology Transfer through Direct Investment and Licensing" in Maskus and Reichman (eds), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (2005).

⁴² Acharya and Keller, "Technology Transfer through Imports" (2009) 42(4) *Canadian Journal of Economics* 1411.

⁴³ Acharya and Keller, "Technology Transfer through Imports" (2009) 42(4) *Canadian Journal of Economics* 1411.

⁴⁴ Park and Lippoldt, "Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries" (2008) OECD, Trade Policy Working Paper No.62.

⁴⁵ Saggi, Maskus and Putitanum, "Patent Rights and International Technology Transfer through Direct Investment and Licensing" in Maskus and Reichman (eds), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (2005).

From these studies, it is expected that patent and utility model activities would be influenced by R&D investments. In addition, foreign patenting activity would be somewhat correlated with FDI and means of technology transfer.

This article empirically investigates the comparative trends in innovation and the relationships amongst patent and utility model activities, R&D investments, FDI and economic activity in NICA and two groups of countries in Africa under ARIPO and OAPI. The study does not attempt to evaluate the strength of IPRs registered in the countries of interest nor does it attempt to investigate the various other means of technology transfer in the two regions.

Hypothetical questions regarding the expected differences between Asia and Africa

In light of the background theoretical and empirical literature reviewed, this article asks the following questions:

- (i) since literature suggests a positive association between R&D Investments and innovation, are differences in patent and utility model activity between Asia and Africa explained by differences in these investments?
- (ii) since literature suggests a positive correlation between foreign patenting activity and FDI, are differences in FDI flows between Asia and Africa explained by differences in foreign patenting activity?
- (iii) since literature suggests that the higher the FDI flows, the higher the rate of economic growth, are differences in economic growth rates between Asia and Africa explained by differences in FDI flows?
- (iv) since literature suggests a positive correlation between innovation activity and economic activity, are differences in economic activity between Asia and Africa partly explained by differences in patent and utility model activity?

Relevant data and procedure for the analyses

To answer the questions raised in this article after the theoretical and empirical literature review, time series data were collected for comparative trend and correlation analyses.⁴⁶ This being a comparative study of 32 member countries of the ARIPO, the OAPI and the NIC comprising China, India, Malaysia, Philippines and Thailand, comparative annual time series data were collected for the following constructs:

- patent applications for both residents and non-residents;
- utility model applications for both residents and non-residents;
- R&D investments as a percentage of GDP;
- manufacturing value added data;
- population, the real GDP and GDP per capita data; and
- FDI data both as monetary figures and as a percentage of GDP.

The data were obtained on an annual basis from WIPO, the United Nations Conference on Trade and Development (UNCTAD), the Organisation for Economic Cooperation and Development (OECD), the International Monetary Fund and the World Bank for the period 1995–2005.

It is worth mentioning that the GDP data were collected on purchasing power parity (PPP) basis as of 2005. Purchasing power parities are required for monetary values for purposes of cross-country comparisons because similar goods and services have widely varying prices when converted to a common currency

⁴⁶ J. Hanke and A. Reistch, *Understanding Business Statistics* (Homewood: Irwin, 1991).

using market exchange rates.⁴⁷ Differences are greatest in sectors not commonly traded internationally such as housing, construction, health and education services. Price differences are smaller for widely traded products such as machinery and equipment after allowing for taxes, distributor margins and transport costs. PPP includes the prices of tradable and non-tradable goods using weights that reflect their relative importance in total GDP.

Thus in a nutshell, the variables concerning the number of patent and utility model filings per million population were analysed to establish trends over the 10-year period from 1995 to 2005. Apart from trend analyses, these variables were also investigated for correlation with R&D investments as a percentage of GDP on a PPP basis and lagged by two years.

Trends in resident and non-resident patenting activity in Asia and Africa

Analyses of the statistics on patent filings revealed that the NICA experienced phenomenal growth in total filings from 35,225 patent applications filed in 1995 to 212,809 in 2005, representing a 504 per cent growth over the 10-year period and an average growth rate of 50.4 per cent per annum. The share of resident patent applications filed to the total applications filed also increased from 34 per cent in 1995 to 47 per cent in 2005. China had the largest share in 2005 of the non-resident patent filings and resident patent filings for the region at 71 and 93.8 per cent respectively, followed by India at 18 and 4.5 per cent respectively. Figure 3 below shows the foregoing trends.

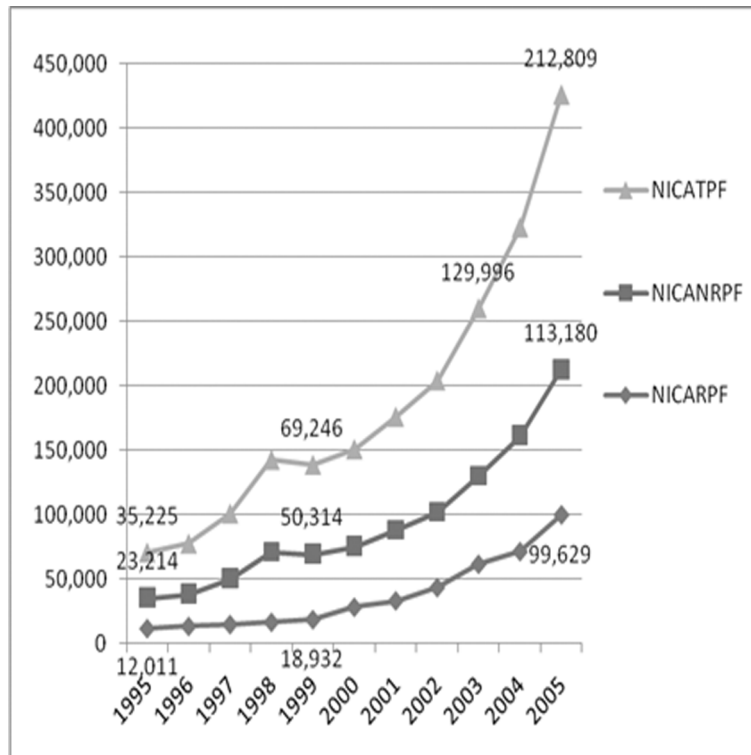


Figure 3: Patent applications trends in Asia⁴⁸

⁴⁷ World Bank, *World Development Indicators 1997–2008* (Geneva: 1997–2008).

⁴⁸

In contrast to the marked growth in patent applications filed in NICA, the ARIPO and OAPI regions experienced a decline in total patent applications filed from 336 for ARIPO and 444 for OAPI in 1995 to 3 for ARIPO and 0 for OAPI in 2005. The share of resident patent applications filed also declined from 70 for ARIPO and 27 for OAPI in 1995 to 3 for ARIPO and 0 for OAPI in 2005. Figure 4 below depicts this decline.

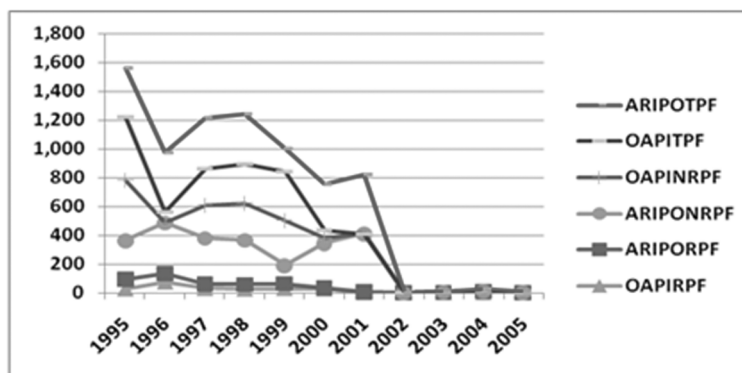


Figure 4: Patent applications trends in Africa⁴⁹

Trends in utility model applications in Africa and Asia

Utility models are an important alternative in countries where they are available for the domestic market, and they may be a key catalyst to economic growth because they encourage less advanced but locally useful innovations. In the period 1995–2005, the NICA experienced an increase in resident utility model applications from 43,473 to 139,646 representing 221 per cent increment over the entire period and an average increase per annum of 22.1 per cent. Non-resident utility model applications were negligible at about one per cent of total applications in 2005. This is expected since utility models are normally meant to encourage innovation for residents of particular jurisdictions and may not need to have universal novelty. Figure 5 depicts these trends of utility models in Asia.

Legend:

NICATPF (Total Patent Applications Filed)

NICANRPF (Non-Resident Patent Applications Filed),

NICARPF (Resident Patent applications Filed)

⁴⁹

Legend:

ARIPOTPF, RPF, NRPF (ARIPO Total Patent Filings, Resident Patent Filings, Non-Resident Patent Filings respectively)

OAPITPF, RPF, NRPF (OAPI Total Patent Filings, Resident Patent Filings, Non-Resident Patent Filings, respectively)

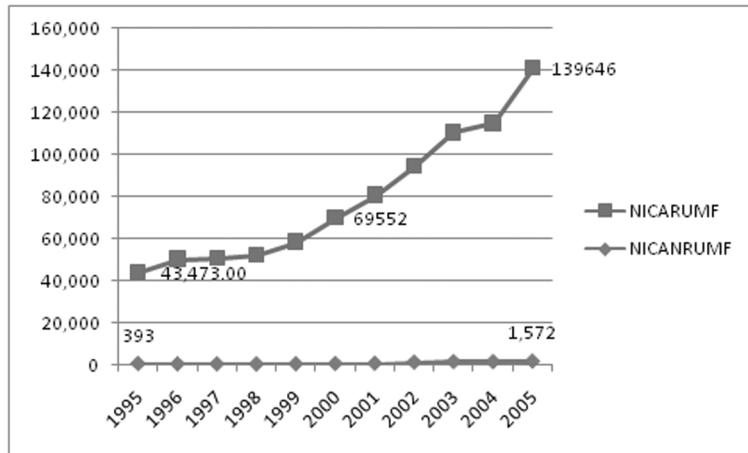


Figure 5: Utility model applications trends in Asia⁵⁰

In Africa, the performance was very different from that of Asia. Africa experienced stagnation in such performance from 1995 to 2005. Less than 12 utility model applications were filed per annum in the ARIPO and OAPI regions, and local innovation activity by the residents was much lower among the 32 countries compared with the Asian countries. Figure 6 below shows this.

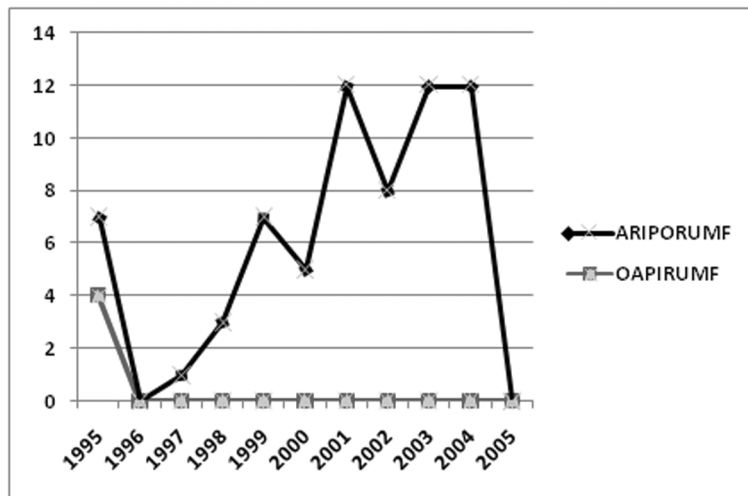


Figure 6: Utility model applications trends in Africa⁵¹

50

Legend:
 NICARUMF (Resident Utility Models Filings)
 NICANRUMF (Non-Resident Utility Model Filings)

51

Legend:
 ARIPORUMF (ARIPO Resident Utility Model Filings)
 OAPIRUMF (OAPI Resident Utility Model Filings)

Resident patent and utility model applications per million population

To improve comparability of performance between countries and regions, patent and utility model applications to population ratios were used. Statistics for the NICA on resident patent and utility model applications per million population show an increase of 184 per cent for utility models (an average increase of 18 per cent per annum) and 630 per cent increase for patents (an average increase of 63 per cent per annum) over the period 1995–2005. These trends are clearly seen from Figure 7 below.

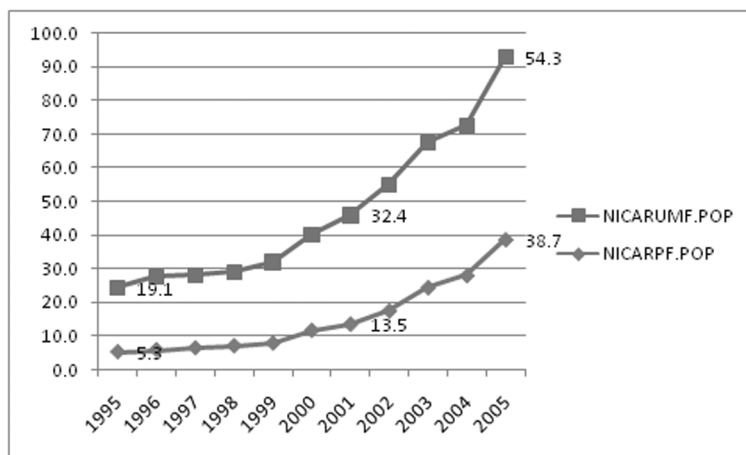


Figure 7: Resident applications per million population trends in Asia⁵²

The statistics on the 32 countries in Africa with regard to resident utility model applications per million population and resident patent applications per million population revealed a decline from slightly over one to close to zero over the period 1995–2005. Figure 8 below shows this decline.

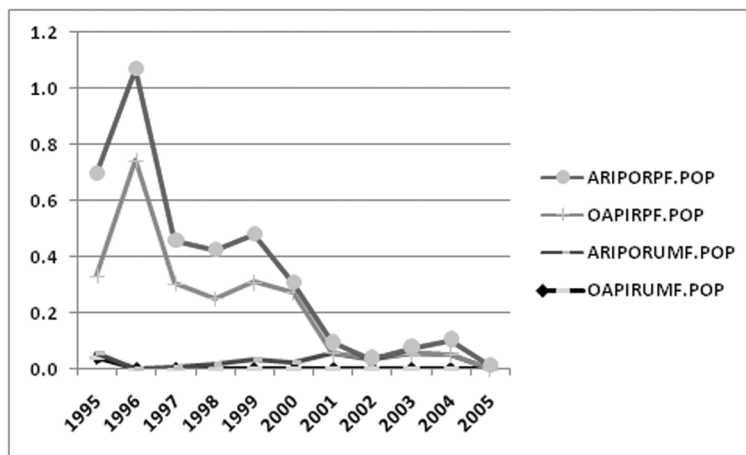


Figure 8: Resident applications per million population trends in Africa⁵³

52

Legend:

NICARUMF.POP (Resident Utility Model Filled per million population)

NICARPF.POP (Resident Patent Filings per million population)

53

These results are consistent with recent studies that even though most sub-Saharan African countries, including least developed countries, maintain a patent or industrial property office that is responsible for the registration of industrial property rights, these countries contribute less than one per cent of patents registered in their own countries.⁵⁴ Using these results, if the level of innovation in a region is to be measured by the level of activity in patent and utility model filings by the residents, then clearly Asia has been increasing in its levels of innovation activity. Conversely, the African countries have exhibited a declining trend in innovation activity. This stagnation in patent and utility model activities could be a result of a number of factors.

This article suggests three possibilities. First, it could be that the level of R&D investments in Asia is higher than Africa since theory predicts that R&D positively correlates with patenting activity. Secondly, it could be that the level of awareness in the economic value of IP is lower in Africa than in Asia. If the level of awareness is low, it affects generation, protection and commercialisation of IP. Thirdly, and related to the second possibility, it could be that there may be some level of innovation taking place, but the residents are not aware of the use of the formal system to protect their IP to aid exclusive commercialisation. If this is the case, then assessing the level of innovation activity using the patent system may not be appropriate for Africa. For an economic system that thrives on informal means of innovation and creativity, WIPO and patent statistics and similar sources of formal data will be inappropriate for assessing progress in innovation. This would then seriously affect comparability with other countries or regions in the globe that use formal systems. The questions that follow from this possibility then is: What innovation and creativity is taking place in Africa? What are the means of recording it? How is it being protected if these formal systems are not being used? Answers to these questions, of course, are beyond the scope of this article, but the questions are important for scholars, policy makers and even IP offices in Africa and beyond. The next section presents a comparative analysis of R&D investments between Asia and Africa.

R&D Investments

Having discussed the trends in patent and utility model activities between the NICs in Asia and Africa, trends in R&D investments as a percentage of GDP were analysed and compared. Figure 9 below shows that over the years from 1995 to 2005, Asian countries invested more in R&D with an increase in the rates (from 0.40 to 0.60 per cent of GDP) than African countries, whose rates were stagnant (between 0.02 and 0.16 per cent of GDP). Since both theoretical and empirical literature reviewed suggests that an increase in R&D investments has a positive impact on innovation activity, these results seem to provide part of the evidence on why Asia has had more resident patent and utility model filings than Africa. Asia has been consistently investing more in R&D than Africa.

Legend:

ARIPORPF.POP (ARIPO Resident Patent Filings per Million Population)
 ARIPORUMF.POP (ARIPO Resident Utility Model Filings per Million Population)
 OAPIRPF.POP (OAPI Resident Patent Filings Per million Population)
 OAPIRUMF.POP (OAPI Resident Utility Model Filings per Million Population)

⁵⁴ Blakeney and Mengistie, "Intellectual Property and Economic Development in Sub-Saharan Africa" (2011) 14(3-4) J. World Intell. Prop. 238.

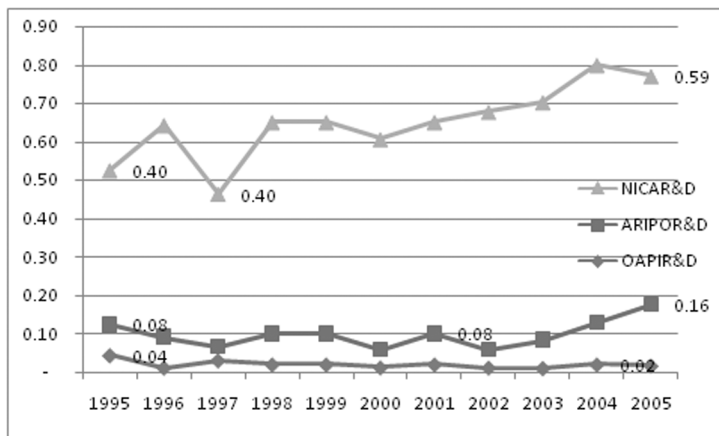


Figure 9: R&D Investments as a percentage of GDP in Asia and Africa⁵⁵

Patenting, utility model filings and R&D investments in Asia and Africa

It is expected that where the local innovation levels are increasing and where the IP system is being used by the residents to protect their innovations to enable exclusive rights for commercialisation, the resident filings of patents and utility models will be higher. It is also expected that with an increase in R&D investments, there will be an increase in patent and utility model filings by residents. Table 2 below presents correlation analyses between resident patents, utility model filings and R&D investments. Shown in the same table are the correlation coefficient (R), coefficient of determination (R^2), and the significance level at which the statistical evidence is sufficient to warrant a conclusion that the two variables are related.

Table 2: Patent and utility model activities and R&D investments

Region	Correlation with R&D	R	R^2	Significant (1 tailed) @
NICA	Resident Patent Filings	0.659	0.434	0.05
ARIPO	Resident Patent Filings	-0.114	0.012	-
OAPI	Resident Patent Filings	0.021	0.000	-
NICA	Resident Utility Model Filings	0.719	0.517	0.01
ARIPO	Resident Utility Model Filings	-0.121	0.0146	-
OAPI	Resident Utility Model Filings	0.735	0.54	0.01

Beginning with the NICA, the results shown in Table 2 above indicate that there was sufficient statistical evidence to conclude that the number of resident applications for patents and utility models, on the one hand, and R&D investments, on the other hand, were positively correlated for the applicable data. The

⁵⁵

Legend:

NICAR&D (Asian R&D Investments);
 ARIPOR&D (ARIPO R&D Investments);
 OAPIR&D (OAPIR&D Investments).

coefficients of correlation (R) were positive for resident patent applications (65.9 per cent) and utility model applications (71.9 per cent). The coefficients of determination (R^2) were 43.4 per cent for resident patent applications and 51.7 per cent for resident utility model applications. This implies that the 43.4 and 51.7 per cent of the changes in resident applications for patents and utility models, respectively, could be explained by changes in the levels of R&D investments as a percentage of GDP, while 56.6 and 48.3 per cent of the changes in these applications (filings) were caused by factors other than R&D investments. Thus, by putting in place policies that affect the level of R&D investments, a nation or region can affect its propensity for resident patent and utility model applications.

With regard to African countries, in OAPI the correlation was significant between R&D investments and resident utility model applications with a positive correlation coefficient of 73.5 per cent and a coefficient of determination at 54 per cent. The correlations between resident patent filings were positive though statistically insignificant for resident patent applications for OAPI. For ARIPO the correlations were statistically insignificant for resident applications for both patents and utility models. This is not surprising because the actual numbers of patents and utility models are close to zero over the period investigated.

Trends in FDI between Asia and Africa

With regard to trends in FDI, the NICA reported an increase from US\$46,495 million in 1995 to US\$93,350 million in 2005. This represents an increase of 100 per cent over the 10-year period and an average growth of 10 per cent per annum. In 2005, China had the highest share of 83 per cent followed by India at seven per cent. The least in the region was Philippines, which had a share of only one per cent. The aggregate statistical trend in FDI in the five NICA is shown in Figure 10 below.

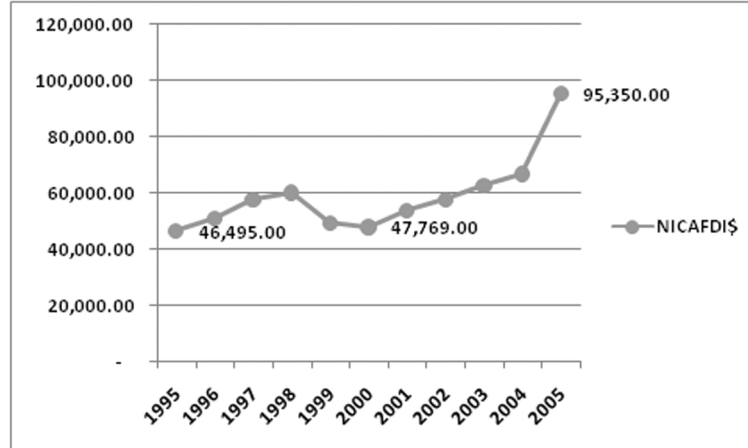


Figure 10: Asian trends in FDI⁵⁶

For Africa, the ARIPO region experienced an increase from US\$712 million in 1995 to US\$4,387.8 million in 2005 in net FDI. This represented an increase of 516.26 per cent over the period 1995–2005 with an average increase of 51.6 per cent per annum. The highest recipient was Sudan at 54 per cent of the total for the region in 2005, followed by Tanzania at 11 per cent. The last one in the region was Somalia, which had no inflows at all.

56

Legend:
NICA FDI\$ (FDI in Million US Dollars).

For the OAPI region, the total net FDI received was US\$4,317 million in 2005 compared with US\$347 million in 1995, which represented an increase of 1,144 per cent over the 10-year period and an average growth of 114 per cent per annum. Equatorial Guinea had the largest share, with 43 per cent of the total, followed by Mauritania at 20 per cent. Countries with the least share were Guinea Bissau and Central African Republic, both of which had zero receipts in 2005. Figure 11 below shows the trends for the OAPI and ARIPO regions in millions of US dollars.

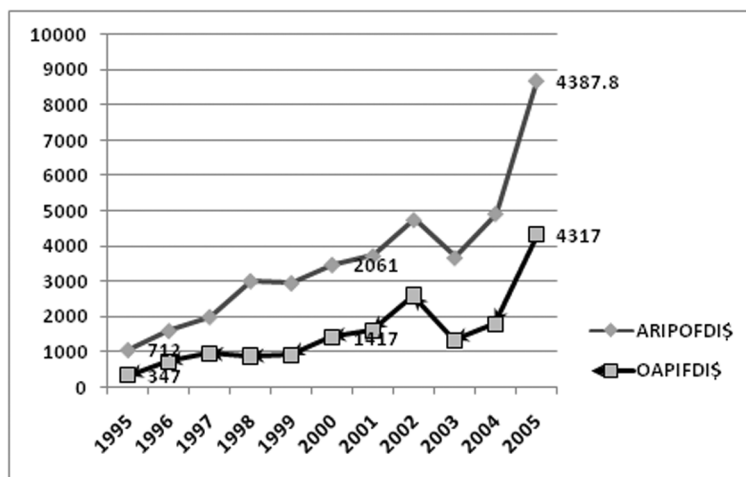


Figure 11: Trends in FDI in Africa⁵⁷

FDI and patenting activity in Asia and Africa

The results regarding correlation analyses of FDI and Foreign patenting activity between Asia and Africa are shown in Table 3 below.

Table 3: Patenting activity and FDI

Region	Correlation with FDI PPP	R	R ²	Significant (1 tailed) @
NICA	Non-Resident Patent Filings	0.885	0.78	0.01
ARIPO	Non-Resident Patent Filings	-0.654	0.43	0.05
OAPI	Non-Resident Patent Filings	-0.57	0.32	0.05

From Table 3 above, statistics for the NICA reveal a very strong positive correlation (R) at 88.5 per cent and a coefficient of determination (R²) of 78 per cent between FDI and foreign patenting activity. The coefficient of determination entails that 78 per cent of the increase in non-resident patent applications was associated with net FDI inflows.

The Asian phenomenon shown above notwithstanding, the ARIPO and OAPI analyses show that there was a moderately strong negative correlation at 65.4 per cent between FDI inflows and non-resident patent applications for ARIPO and a negative correlation of 57 per cent for OAPI. These rather surprising results for the African region could have some plausible explanation from the nature and purpose of patents for

⁵⁷

Legend:
ARIPOFDI\$ (ARIPOFDI in Million US dollars);
OAPIFDI\$ (OAPIFDI in Million US dollars).

foreign investment. Patents and utility models generally have their biggest impact on the manufacturing sector because they are concerned with inventive and innovative products or production techniques. The results on OAPI and ARIPO entail that non-resident patent applications reduced as FDI increased. This is because the FDI flows into African countries have little to do with manufacturing. Rather, they are investments toward the primary sector, not the intermediate or tertiary sectors. Economic activity in many African countries is mainly in the extractive industries such as mining of base metals and crude oil. Thus, FDI flows are used by foreign investors to buy equipment for these primary industries which export raw or primary materials. This perspective may be supported by the statistics on trends in manufacturing value added between Africa and Asia in Table 4 below.

Table 4: Manufacturing value added trends for Africa and Asia

Region	Manufacturing Value Added 1995 (US\$ million)	Manufacturing Value Added 2005 (US\$ million)	Growth over 1995 to 2005 Period	Manufacturing Value Added as % of GDP 2005	Sectoral Average Annual Growth Rate
NICA	420,341.71	1,013,574.85	141%	29.80%	14.1%
ARIPO	5,835.77	9,229.96	58%	11.50%	5.8%
OAPI	4,455.72	5,553.63	25%	7.81%	2.5%

From Table 4 above, over the 10-year period analysed, the manufacturing sector grew from US\$4,455.72 million in 1995 to US\$5,553.63 million in 2005, representing a 25 per cent growth and an average growth of 2.5 per cent per annum for the OAPI region. The previous trend analysis for FDI noted that in OAPI, FDI flows grew by 114 per cent per annum over the same period, implying that these investments did not affect the manufacturing sector. Moreover, the average contribution of manufacturing sector to GDP was 7.81 per cent in 2005, meaning that the bulk of the GDP was in other sectors including the primary sector.

When it comes to ARIPO, the average contribution of manufacturing to GDP was 11.50 per cent in 2005. Over the 10-year period, the manufacturing sector grew from US\$5,835 million in 1995 to US\$9,229.96 million in 2005, representing a 58 per cent growth and an average growth of 5.8 per cent per annum. The previous FDI trend analysis observed that net FDI flows grew by 51.6 per cent per annum for the ARIPO region. This entails that most FDI in Africa goes toward non-manufacturing sectors which do not have much to do with patenting. In primary industries in developing countries—like copper ore mining in Zambia, for example—technology transfer still occurs between a parent company and its subsidiary except that such transfer is limited to staff, expertise mobility and training as well as importation and learning how to use the heavy machinery required for extracting the primary product.

Another example concerns multinational companies involved in the extraction of crude oil. Here the technology transfer occurs through mobility of staff and learning new oil extraction, and sometimes refining, technologies brought in by the parent company to be used by the subsidiary. Patenting in the FDI host country only becomes important to control distribution of the finished product. Control of distribution through foreign patenting and the related patent registration and maintenance costs only becomes attractive for the producer of a finished product if they consider the territory large enough to make commercial sense and if they consider that competitors might free ride on their technology or invention. This is very rare in least developed economies in Africa.

The performance of the manufacturing sector in the ARIPO and OAPI regions with respect to FDI flows is sharply contrasted with the performance of the Asian region. Asia had growth in manufacturing value added from US\$420,341.77 million in 1995 to US\$1,013,574.85 in 2005, providing a 141 per cent growth over the 10-year period and an average of 14.1 per cent per annum. This growth of 14.1 per cent

per annum compares well with the 10 per cent annual growth in net FDI for Asia. In addition, Table 4.3 above shows that the contribution of manufacturing to GDP was averaging 29.8 per cent in Asia as of 2005. This growth in manufacturing sector compares well with growths in FDI and non-resident patenting activity. The relationships discussed between annual growth rates in FDI and the manufacturing sector over the 10-year period from 1995 to 2005 are depicted in Figure 12 below.

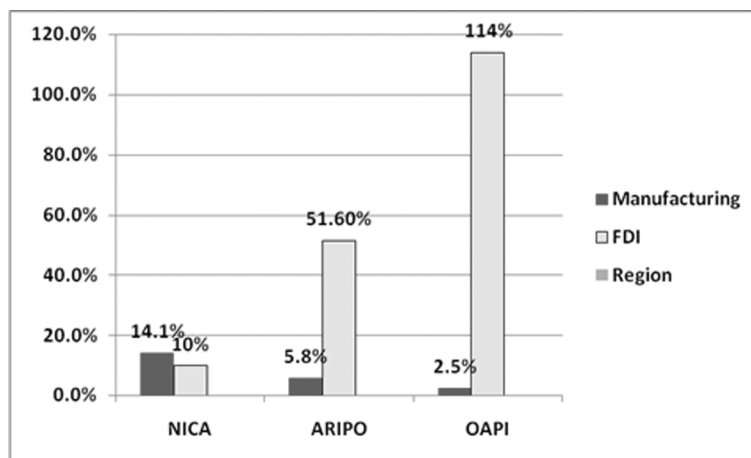


Figure 12: Annual growth rates in manufacturing and FDI (1995–2005)

FDI and economic growth in Asia and Africa

Comparability of economies is improved once the real domestic product figures have been adjusted to per capita levels to take into account the size of the population for each country or region. In addition, comparability of patent and utility model activities can also be improved by taking into account the size of each country or region's population. The total population for the selected NICA was 2.572 billion as of 2005 with China having the highest at 1.3 billion, followed by India at 1 billion, and Malaysia the least at 25 million. In the ARIPO region, the total population was 239 million as of 2005 with Tanzania having the highest at 38.3 million, followed by Sudan at 36.2 million, and Swaziland being the least populated in the region at 1.1 million people. In the OAPI region, the total population was 137.1 million as of 2005—with Cote d'Ivoire having the highest at 18 million, followed by Cameroon at 16 million, and Equatorial Guinea as the least populated with fewer than 1 million people.

Figure 13 below shows that the Asian region had a marked increase in per capita GDP from US\$666 in 1995 to US\$1,340 in 2005, representing 101 per cent over the 10-year period with an average growth of 10 per cent per annum. The OAPI region had a 10.75 per cent growth in per capita GDP over the same period from US\$418 in 1995 to US\$463 in 2005, representing an average growth of 1.1 per cent per annum. The ARIPO region had a 29 per cent growth in per capita GDP over the same period from US\$300 in 1995 to US\$387 in 2005, representing an average growth of 2.9 per cent per annum.

The 2008 world statistics report of UNCTAD indicates that before the year 2000, Asian countries like India and China were ranked among low incomes (with per capita income below US\$1000). This classification was the same as that for countries in ARIPO and OAPI. However, the 2005 statistics show that the Asian counterparts have moved to middle income level with per capita income way above US\$1000.

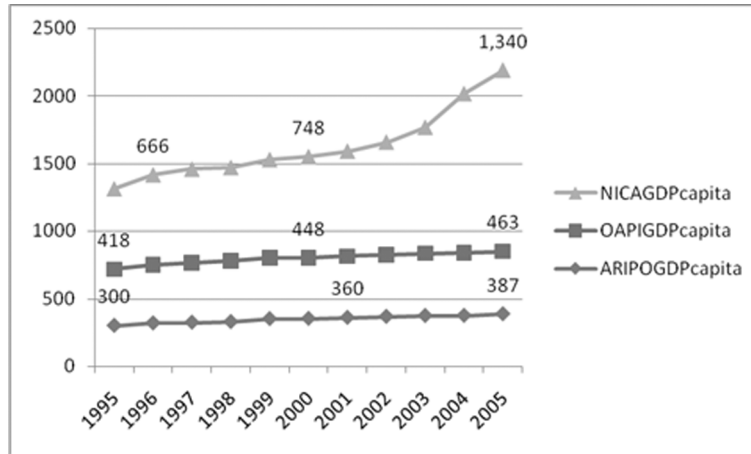


Figure 13: Real GDP per capita trends in Asia and Africa⁵⁸

FDI and economic growth were positively related in both Asia and Africa. The correlation coefficients were positively very strong at 88.5 per cent for Asia, 91.6 per cent for ARIPO and 82.3 per cent for OAPI. The implication of this finding was that efforts and policies by governments to improve the business environment in their own countries to attract FDI would result in increased non-resident patent applications (if the FDI is driven by the manufacturing sector) as well as in economic growth.

Patent and utility model activities and economic growth in Asia and Africa

An increase in patent and utility model activities, assuming most of the inventions protected are being worked, entails an increase in the level of productivity and thus economic activity in a country or region. It follows therefore that GDP per capita was expected to increase with an increase in patent and utility model activities in a country or region. While simple correlation analyses show that these activities are positively correlated with GDP and even GDP per capita at (R) 97.8 and 94.7 per cent respectively, the relationship between economic activity and patents is generally a complex one and may not be determined by simple linear regression models. For ARIPO and OAPI, the negative correlation or non-significant correlation between patenting and economic activity may be said to be spurious at best, since the level of patenting and utility model registration stagnated in the period under review. This result is spurious because it was clear that utility model and resident patent applications for the region were declining to almost zero activity over the period 1995–2005. In addition, the manufacturing sector, which would be the significant beneficiary of patent and utility model activities, had made a very small contribution to GDP. This therefore meant that these activities could not have significantly impacted the per capita GDP. In a nutshell, based on the data from Asia, where resident patent and utility model applications are rising, a significant contribution to GDP through the manufacturing sector is to be expected.

⁵⁸

Legend:
 NICAGDP per capita (Asia US\$ GDP per capita);
 OAPIGDP per capita (OAPI Africa region US\$ GDP per capita);
 ARIPOGDP per capita (ARIPO Africa region US\$ GDP per capita).

Conclusions

NICA comprising China, India, Malaysia, Philippines and Thailand experienced phenomenal growth of 50.4 per cent per annum and 22.2 per cent per annum over the period 1995–2005 in total patent and utility model applications respectively. Total patent applications stood at 212,809, while total utility model applications stood at 139,646 for the five countries in 2005. The share of resident patent applications increased to 47 per cent of total applications by the end of 2005, while over 98 per cent of utility model applications were by residents. In contrast, however, the ARIPO and OAPI regions experienced a decline in total patent applications from 336 for ARIPO and 444 for OAPI in 1995 to 3 for ARIPO and 0 for OAPI in 2005. The share of resident filings of patent applications also declined from 70 for ARIPO and 27 for OAPI in 1995 to 3 for ARIPO and 0 for OAPI in 2005. Utility model applications were less than 12 per annum by residents for both regions in Africa.

When these statistics are put in cross-country comparable terms per million population, statistics for the selected Asian countries on resident applications for patents and utility models per million population show an increase of 18 per cent per annum for utility models (54.3 from 19.1) and 63 per cent per annum for patents (38.7 from 5.3) over the period 1995–2005. The statistics on the 32 countries in Africa with regard to resident patent and utility model applications per million population revealed a decline from slightly over one to close to zero over the same period. The selected Asian countries invested more in R&D with an increase in the rates (from 0.40 to 0.60 per cent of GDP) than the African counterparts which stagnated (between 0.02 and 0.16 per cent of GDP).

Both in Africa and Asia, there was significant statistical evidence that as the R&D investments increased, the number of resident applications for patents and utility models also increased. Part of the reason why Asia experienced increased resident applications for patents and utility models was the increase in R&D investments, compared with African countries that were not doing much.

With respect to trends in FDI, the selected countries in Asia reported an increase from US\$46,495 million in 1995 to US\$93,350 million in PPP terms (10 per cent per annum). The ARIPO region experienced an increase from US\$712 million in 1995 to US\$4,387.8 million in 2005 in FDI (51.6 per cent per annum). The OAPI region had total FDI received as US\$4,317 million in 2005 compared with US\$347 million in 1995 (114 per cent growth per annum). Statistical evidence was sufficient to conclude that a positive correlation existed between non-resident patent applications and FDI inflows for Asia, but not for the OAPI and ARIPO regions. The results for OAPI and ARIPO, though significant, were deemed spurious based on the slight increase in the manufacturing value added as a percentage of GDP over the 10-year period. FDI in Africa mainly benefited the extractive primary industries and not manufacturing.

The NICA experienced growth in economic activity as represented by the GDP from US\$1,348,276 million in 1995 to US\$3,446,000 million in 2005 (156 per cent growth). For the African continent, the ARIPO region experienced growth in GDP, albeit low, from US\$57,466 million in 1995 to US\$92,456 million in 2005 (60 per cent growth). The OAPI region in Africa experienced the least growth from US\$41,094 million in 1995 to US\$63,435 million in 2005 (54 per cent growth). There was a significant statistical correlation between FDI and economic growth in Asia and Africa. The Asian region had a marked increase in per capita GDP from US\$666 in 1995 to US\$1,340 in 2005 (an average of 10 per cent growth per annum). The OAPI region had modest growth in per capita incomes from US\$418 in 1995 to US\$463 in 2005 (1.1 per cent per annum). The ARIPO region grew from US\$300 in 1995 to US\$387 in 2005 (2.9 per cent per annum).

On the whole, it can be concluded that there is a positive relationship between expenditure on R&D investments and local innovation reflected through resident filings of patents and utility models. It can also be concluded that the NICA have experienced an increase in innovation activity among the residents more than the African region, partly because of an increase in R&D expenditure. As R&D investments increased, resident applications for patents and utility models also increased.

In addition, the article has also shown that as non-resident patent applications increased, FDI also increased. A number of companies from developed countries have moved their manufacturing activities to Asia, especially China and India, to take advantage of cheaper labour costs. This is also reflected in the marked increase in manufacturing value added and exports from Asia. In Africa, FDI mainly goes to the extractive and primary industries, and hence there is a minimal growth in the manufacturing sector.

The article has also shown that there was a strong positive relationship between FDI and economic growth. The economy is impacted positively when FDI increases. The study concluded that as resident and non-resident patent and utility model activities increased, the economy was impacted positively. Nevertheless, this depended on the characteristics and nature of the economy in terms of its emphasis on primary or secondary industries.

Limitations, areas for further study and recommendations

In light of the foregoing conclusions, before making recommendations, this article highlights some limitations of the study which may prompt further research and debate. Firstly in Africa, South Africa is the largest economy followed by Nigeria. These two nations are not members of any of the two regional IP bodies. In Asia, countries like Indonesia have made tremendous progress economically in the recent past to deserve to be on the NICs list, though they were not part of the analyses. Including them in the analyses would have been insightful, though it is unlikely that the conclusions on a comparative basis would have been significantly different. The level of patent and utility model activities in Africa was so low that the article has raised questions concerning whether the formal system is appropriate for measuring the level of innovation in Africa. What innovation and creativity is taking place in Africa, and how is it being measured and protected? This question is important, and it requires urgent investigation by researchers, policy makers and IP offices in light of the dismal comparative results shown using the formal system of tracking progress in innovation.

The foregoing limitations notwithstanding, this article makes a number of recommendations. First, since resident patent and utility model activities increased with an increase in R&D expenditure, governments should encourage increased inventiveness and innovation by taking fiscal and other policy measures to increase R&D funding for both the private and public sectors.

Secondly, governments should put in place policy and legislative measures that impact on non-resident patenting activity because this would generally positively impact on FDI and subsequently on economic growth that is linked to the manufacturing sector. Furthermore, seeing the correlation between utility model and patenting activities and increased economic growth, governments should come up with national IP policies and legislation and take fiscal policy measures to encourage the development and commercialisation of inventions and other IP assets. Patents and utility models need to be supported by R&D investments, clear IP policies and legislation and a vibrant manufacturing sector. Africa needs to shift from focusing only on primary industries to growing value adding sectors such as manufacturing.

Finally, the OAPI and ARIPO regions should make statistics on patent and utility model activities more available on their websites so that researchers can undertake comparative studies easily. The availability of reliable statistics would help inform scholars and policy makers.

The results discussed in this article have provided a basis for debate and further research concerning the enquiries on what should be used to measure progress in innovation activity in Africa, why the IP formal system is not being used for protecting, recording and tracking progress in innovation, and indeed why there is low innovation activity on the African continent.