Policy Space for Intellectual Property Management: Contrasting Multilateral and Regional-Bilateral Arrangements*

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Abstract : Global governance in intellectual property (IP) has changed dramatically in the last two decades. What was once principally an instrument of national policy is now increasingly subject to international disciplines. I contrast the new restrictions placed on IP management that developing countries accept as parties to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) with the constraints they face as members of Regional and Bilateral Trade Agreements (RBTAs) with the United States. I highlight the areas where countries retain opportunities for policy innovation despite their WTO obligations and provide examples of how some countries have introduced and retained measures that tailor IP management to local conditions and needs, all while meeting the new TRIPS obligations. Moreover, I show how these opportunities are circumscribed by RBTAs across all dimensions of patent policy, countries that are parties to such RBTAs have significantly less autonomy in their management of IP. In sum, the proliferation of RBTAs presents the greatest threat to countries' capacities to manage IP for development objectives.

Keywords: governance, intelectual property rights, TRIPS agreement, patent policy, developing countries.

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1. Introduction

National patent regimes have traditionally reflected levels of economic development. Poorer countries, with fewer innovative capacities, have typically made private ownership of knowledge difficult to obtain, and, once granted, the property rights themselves tended to be weaker than in wealthier countries. The logic informing such variation – that national IP practices for managing intellectual property (IP) should be tailored to national economic and social conditions – also informed the international environment. For example, the Paris Convention for the Protection of Industrial Property, the principal international covenant on IP for most of the 20th Century, allowed countries a significant degree of flexibility in designing their patent regimes.

By the end of the century, however, global governance in IP had changed dramatically. Beginning in the 1980s and 1990s, the US and EU campaigned to establish universal rules to guide IP practices. The goal was to universalise OECD-style IP systems. The most visible product of this campaign was the inclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the new World Trade Organization.[1] TRIPS creates new global standards regarding virtually all aspects of how countries treat IP. Although developing countries received transition periods for implementation, when these periods end (as most already have), all but the poorest countries will be subject to the same standards for IP management.[2]

Notwithstanding the constraints on national policy that TRIPS establishes, countries may still exhibit substantial variation. Indeed, some have argued that countries can meet their new international obligations as members of the WTO and still manage IP in accordance with prevailing economic and social conditions (CIPR, 2002; Correa 2000a; Reichman, 1997).[3] In contrast to TRIPS, however, regional and bilateral trade agreements (RBTAs) that many developing countries have signed with the United States threaten to eliminate the capacity to tailor IP management to national conditions.

In this article I contrast policy space for IP management in WTO and RBTAs, with specific reference to patents. I organize the discussion around three standard limitations to the private rights conferred

by patents: (1) the processes by which private rights to knowledge are obtained; (2) the extent of and exceptions to the private rights; and (3) the duration of the rights. Within each sub-section, I highlight the areas where countries retain opportunities for policy innovation despite their WTO obligations, and provide examples of how some countries have indeed introduced and retained measures that tailor IP management to local conditions and needs, all while meeting the new TRIPS obligations.[4] Moreover, I show how these opportunities are circumscribed by RBTAs: on all dimensions of patent policy, countries that are parties to such RBTAs have significantly less autonomy in their management of IP. The greatest threats to managing IP for development objectives come not so much from the WTO as from RBTAs.

Before proceeding, some caveats and points of clarification are in order. It is obviously simplistic to discuss RBTAs as a single entity, as they exhibit considerable differences. The US and EU, the two principal partners for such agreements, have different priorities in integrating IP into such agreements. RBTAs negotiated with the US extend IP obligations beyond TRIPS more consistently than do those with the EU (Pugatch, 2005). I focus on US RBTAs.[5] But not only do US RBTAs differ from EU RBTAs, but all US RBTAs are not alike either. Indeed, the details of the IP provisions within any given agreement are bargaining outcomes. Thus, general statements regarding IP regulations in RBTAs (US or otherwise) run the risk of distorting via oversimplification. That said, with regard to virtually any policy area, the differences between various RBTAs tend to be less than the differences between TRIPS and the RBTA closest to TRIPS, so a good deal can be learned from such oversimplifications. Simply stated, too much analysis of the differences *between* RBTAs without considering how the entire genre differs from TRIPS distracts our attention from the big picture – we risk losing the forest for the trees.

2. Limitation (1): How Private Rights to Knowledge are Obtained

The first important limitation of patents is that private ownership rights are not conferred automatically upon possession of knowledge.

Instead, patents are granted by the state only where applicants demonstrate that their inventions satisfy two sets of patentability criteria: patent examiners must determine that the knowledge is new, non-obvious, and useful; and the knowledge must fall within the range of patentable subject matter. Because patent examination remains national, and with application central to the process of establishing ownership, governments delineate what knowledge can be owned privately within their territory.

Examination

The three standard criteria for patentability – that the idea be new, non-obvious, and useful – are ambiguous terms. How these criteria are operationalized by national patent offices and legal systems affects what sorts of patents are granted. Practices established by the USPTO and EPO tend to establish some precedence in this regard, but this remains an important point of flexibility (CIPR, 2002: 114-119).

Countries can set criteria for "novelty" that makes reformulations or second uses of existing drugs ineligible for additional patents. Likewise, countries retain the freedom to determine what classifies as "non-obvious." India's amended Patent Act is illustrative on both accounts: the Act excludes new uses from patenting by stating that "mere discovery" of new forms of known substances that "do not result in the enhancement of the known efficacy" of the substances are not patentable (section 3.d); and the definition of "inventive step" (used synonymously with "non-obvious") is worded in such a way as to provide administrative and judicial officials with grounds to deny many patent applications and thus effectively narrow patent scope (Basheer, 2006).[6]

Countries also set their own definitions of an "invention," and as such can deny patents to "discoveries."[7] That these are such imprecise terms certainly invites abuse, but this allows policymakers to retain a narrow patent scope. Countries can, for example, deny patents to gene sequences, on the grounds that the technical step was a discovery of an existing entity, not an invention of something new (Demaine and Fellmeth, 2003). Most controversially, restrictive definitions of invention and discovery have been used to deny patents to computer software, under

the argument that programmers are not inventing new processes but discovering (or, perhaps, revealing) underlying mathematical algorithms that are part of nature.[8]

Countries also retain significant leeway to demand strict disclosure requirements. In exchange for exclusive rights obtained by the patent, applicants are required to make their knowledge public. The patent right sets restrictions on what can be done with the knowledge, but anyone can, upon payment of a nominal fee, read and thus learn from patents. Patent applicants, of course, wish to reveal as little of the knowledge as possible in exchange for exclusive rights, but there is a public interest in demanding greater disclosure. The extent to which new knowledge enters the public domain and becomes available for third parties (albeit with serious restrictions on their use of the knowledge), depends on how much disclosure patent examiners demand. This may be of particular importance the case in developing countries, where patents are more often used to block rival imports, and not manufactured locally. Where the patent is not "worked" locally (more on this below), tacit knowledge is not shared, so obtaining the written knowledge becomes that much more essential.

RBTAs can erode these spaces for policymaking by exporting examination guidelines, thus removing the ambiguity that exists under TRIPS, and placing caps on the amount and type of information that patent applicants can be required to submit. DR-CAFTA, for example, defines "novelty" in a more expansive way, exporting to all DR-CAFTA parties the more liberal meaning of "new" that is used in the US, where goods can pass the novelty test and be granted a patent if the knowledge has been disclosed within the year prior to application (Morin, 2004). RBTAs are also more likely to limit the disclosure requirements that national IP offices can place on patent applicants. Again, DR-CAFTA is illustrative, for the agreement proscribes such requirements by establishing an explicit cap on the type and amount of information that countries can demand (Morin, 2004). Were a Central American country to demand more information from an applicant than what is necessary to repeat an invention, the country in question would most likely be in violation of its new regional obligations.[9]

Scope

Even if the knowledge is new, novel, and useful, to receive a patent the knowledge must also fall within the "scope" of a country's IP system: the type of knowledge must be eligible for a patent. Defining patent scope has historically been a critical feature that differentiated national approaches toward IP. Many countries refused to grant patents to certain products. Providing local firms unrestricted access to foreign knowledge in key sectors has historically been a critical dimension of strategies for late industrialization, as this facilitates local firms' abilities to adapt and build upon foreign innovations. Likewise, patents were often denied to restrain prices, facilitate sharing of knowledge, and ensure that local actors (e.g. farmers) could continuously adapt to changing environmental conditions.

TRIPS reduces countries' discretion regarding patent scope. Article 27 requires countries to grant patents of twenty years *in all fields of technology*. The new limitations on scope mean that countries can no longer refuse to issue patents to particular classes of goods, such as pharmaceutical products and chemicals. Prior to the Uruguay Round more than forty countries did not provide any patent protection for pharmaceuticals, while many that did so issued patents only for processes and not for products (WHO, 2002: 15). In many developing countries, the lack of patent protection drove the growth of local pharmaceutical industries, which specialized in making generic versions of drugs – some patented in developed countries, some older drugs whose patents had expired. By 2005, however, all but the least developed countries must grant patents on pharmaceuticals and agricultural chemicals.[10]

One partial exception to expanded scope is in the area of genetic resources. Article 27.3.b allows countries to exempt plant varieties and animals from patentability, provided that they establish "effective" *sui generis* systems of protection for the former. What forms of protection are "effective," however, remains contested. Most countries have adopted forms of plant variety protection in accordance with the conventions of the International Union for the Protection of New Varieties of Plant, UPOV (Llewelyn, 2003; CIPR, 2002: Chapters 3-4; Tansey, 1999). The rights afforded under UPOV conventions differ from patents in a

number of significant ways, most importantly by allowing third parties to use protected seeds and plants for breeding new varieties. The UPOV convention, in its earlier (1978) version, also included a farmers' exception that allowed for the reuse of seeds, but this clause was eliminated in UPOV 1991, which provides much stronger rights to breeders. As the 1978 convention is no longer open for signing, countries that seek to satisfy their requirements under Article 27.3.b by conforming to UPOV standards must use the later convention.

However, TRIPS does not require countries to refer to UPOV. Alternative mechanisms of protection are acceptable (Correa, 2003a; Llewelyn, 2003). Countries have a wide array of options for how they fulfil their obligations for protecting plant varieties. India's Protection of Plant Varieties and Farmers' Rights Act is frequently cited as an example of a non-UPOV system for protecting plant varieties, but India is not unique. According to one international survey of plant variety protection, while 91 countries were reported to offer statutory protection to plant varieties (with legislation under consideration in another 29 countries), only 54 were members of UPOV (Bonwoo, Nottenburg, and Pardey, 2004).

Countries' obligations for protecting genetic resources under RBTAs exceed what is required under TRIPS. In the first regard, some RBTAs (e.g. those between the US and MENA countries and the US-Singapore agreement) explicitly require patents on plants (El-Said, 2005; Fink and Reichenmiller, 2005). And even where plant patenting is not required, it is strongly encouraged. For example, the US-Chile RBTA and DR-CAFTA both include language demanding that parties undertake efforts to develop legislation allowing for plant patents. Nor, in the absence of plant patents, are alternatives to UPOV 1991 allowed. UPOV, which is not mentioned in TRIPS, is referred to explicitly in many RBTAs as the minimum, with deadlines and timetables for accession to UPOV 1991 included as well. Thus, in sum, while a liberal reading of TRIPS would be that countries must provide protection – *but not necessarily patents or UPOV-style rights* – to plant varieties, RBTAs oblige countries to offer patents or, at the very least, a UPOV system.

3. Limitation (2): Exceptions to Private Rights

Patent rights include exceptions to patent-holders' ability to exert control over the use of their property. *General* exceptions are available to anyone at anytime, without the need to receive government authorization, they are not subject to time restrictions, and no compensation to rights holders is not required. *Specific* exceptions require state authorization, apply only to the party indicated by state authorities, are typically subject to time restrictions, and call for compensation. TRIPS permits significant levels of national-level variation with regard to both sorts of limitations, variation that, again, is largely precluded by RBTAs. As I show in this section, RBTAs tend to place even greater limits on third parties' rights to access patented knowledge and they almost uniformly reduce governments' abilities to use compulsory licensing as a policy instrument.

General Exceptions

General exceptions can influence patterns of innovation by affecting the space left for third parties to compete with alternative products.[11] What is allowable? Think of potential exceptions along a spectrum. At one extreme governments prohibit all third-party use of patented knowledge, and at the other extreme governments permit anyone to use patented knowledge for any purpose. Interim points on the spectrum might include restricting access to public and non-commercial use, permitting commercial experimentation in exchange for increasing the length of patent terms, permitting commercial experimentation without any such increases in patent terms, and permitting commercial production and stockpiling (though not commercial sales until the patent expired).

Only the final point – permitting commercial production and stockpiling – is proscribed by TRIPS. Thus, in the pharmaceutical sector, for example, generic firms can use patented knowledge to develop, test, and apply for registration of their own drugs, to be put on the market once the protected drugs' patent terms expire. Early working (or "Bolar") exceptions are generally thought of as providing important stimuli for

the expansion of generic pharmaceutical industries and as measures to lower prices by expediting the entry of competition. In the U.S., the early working exception is linked to easy and simplified extensions of the patent term, though such extensions are not obligatory under TRIPS.

Formally, RBTAs retain this flexibility, but effectively they eliminate these opportunities by imposing more strenuous obligations regarding the protection of test data and regulatory approval of generics. Data exclusivity is most relevant in sectors such as pharmaceuticals (and chemicals more generally), where firms require approval of local regulatory authorities to enter the market. To obtain approval to market drugs, for example, pharmaceutical firms submit clinical trial data to demonstrate the effectiveness of their products. Can generic medicines can use these data to secure regulatory approval for their own drugs? If access to the data is prohibited, then generic firms must conduct their own clinical trials, a costly and time-consuming process that delays the onset of price competition.[12]

TRIPS leaves developing countries significant leeway with regard to how they treat test data (Correa, 2002; Reichman, 2004). According to Article 39.3, countries must protect data that is obtained through "considerable effort" against disclosure and against "unfair commercial use." These requirements are strikingly vague. It is not clear what data is privy to protection (i.e. what is "considerable effort"). Nor does TRIPS specify a term of protection. Most critically, the article does not address whether regulatory authorities can, without disclosing the data, *rely* on the data submitted by one firm for the sake of approving new products. According to many legal scholars, doing so does not amount to "unfair commercial use" and is an acceptable option available to all countries under TRIPS.[13]

US trade policy reflects a different interpretation of "unfair commercial use," one that requires countries to provide more extensive protection of test data. Pushed by the research-based pharmaceutical industry, which seeks to recover the costs of increasingly expensive clinical trials,[14] the US has, since the late 1980s, adopted a position that governments treat the data required for regulatory approval as a form of IP and guarantee the providing firms exclusive rights to "their" data and to the information generated by the data (Brazell, 2004-2005; Dutfield, 2005c; Pugatch, 2005;

Rosenthal, 2005). Indeed, during the Uruguay Round the US attempted – unsuccessfully – to include much stronger language in its proposals for Article 39.[15] Unable to secure stronger data protection at the multilateral level, the US negotiators have made this a high priority on the bilateral agenda. Concretely, US RBTAs generally include five-year periods of exclusivity, beginning at the time the drug is approved by local authorities, during which time all submitted data is protected against both disclosure and reliance.[16] Importantly, this data exclusivity operates independently of the patent status: drugs that are unpatented, because the patent expired or because no patent was obtained in the first place, can receive protection from generic competition for a minimum of five years.

The US insistence on increased protection of test data has been one of the most contentious issues in the negotiations of RBTAs. Most countries have objected strongly, arguing that extensive data exclusivity hampers their ability to encourage generic competition and thereby lower prices, and have proposed less restrictive provisions or sought ways to minimize their commitments. Yet US negotiators, rejecting the argument that data exclusivity might have adverse effects,[17] have continued to make this a high priority. Chile, for example, sought to ameliorate the adverse effects of data exclusivity included in the US-Chile RBTA by passing a law that requires drugs to be registered with local authorities within one year of being approved by the US Food and Drug Authority in order to receive the extended period of data protection offered in the RBTA. Data protection would be available, but only to *new* drugs. Learning from this example, the USTR has, in subsequent agreements, barred Chilean-style requirements. Thus, DR-CAFTA "closes potential loopholes to [data protection] provisions" (USTR, 2003: 5) by explicitly requiring countries to allow up to five years from the time FDA approval is obtained to register the drug locally.[18]

Countries also determine the boundaries of exceptions to exclusive rights with their policies towards "parallel imports," whereby the government allows patented goods to enter the market once the patentee places the good on the market elsewhere. Countries that permit parallel imports typically do so to increase competition, encourage arbitrage, and thus ensure affordability of patented goods. Whether they do so, however, is

a function of national regulations on the "exhaustion of patent rights." Once a good is placed on the market by the patent owner, it can be used by others without permission – the patent rights are "exhausted." The policy question is whether countries adopt national or international standards of exhaustion (or regional, as in the case of the EU), for different policies on parallel imports correspond to differently defined standards on exhaustion.[19]

TRIPS leaves countries with the autonomy to select their own rules regarding exhaustion and parallel imports. This outcome, an "agreement to disagree" (Fink, 1999: 175), was the result of a stalemate during the Uruguay Round negotiations: the US sought national standards, European countries sought to protect the regional standards that are consistent with the common market, and developing countries, expecting parallel imports to serve as form of competition policy and also to open export opportunities, sought international standards. The subsequent agreement (Article 6) gives countries the right to choose national or international standards of exhaustion.[20] Any lingering uncertainty was resolved at Doha Ministerial, as the subsequent Doha Declaration (WTO, 2001) explicitly confirms countries' rights to adopt the exhaustion doctrines of their choice.[21]

Here again, the US has been able to secure greater IP protection through RBTAs than the WTO by requiring countries to adopt national standards of exhaustion, and thus prohibit parallel importation.

Specific Exceptions

Some exceptions to patent-holders' exclusive rights require government action. With a compulsory (or "non-voluntary") license, the host government allows a local entity (a private firm and/or government agency) to produce and distribute a good under patent without the consent of the patentee. Compulsory licenses have historically been part and parcel of countries' patent regimes, and countries have granted them in a wide range of situations (Reichman and Hasenzahl, 2003).

Despite efforts by the US in the Uruguay Round to radically circumscribe their use (Watal, 2000: 320), TRIPS continues to leave countries

with a significant degree of autonomy in this regard. Article 31 of TRIPS establishes a set of *conditions* to be met for governments to issue CLs. For example, governments must proceed on a case-by-case basis, third parties must first seek permission of the patent-holder (i.e. the CL must follow unsuccessful negotiations, though this is waved in case of national emergency), the CL must be of limited duration (and terminated when grounds leading to CL no longer there), be non-exclusive, be predominantly for domestic market, and the patent-holder should be compensated.

When operationalizing these conditions in terms of national law, countries are left with a great deal of flexibility. For example, countries retain significant leeway regarding how much negotiation for a voluntary license is required before a third party can legitimately request a compulsory license from the state. Third parties must attempt to gain authorization from the patentee, and the state may only grant a compulsory license if negotiations are not successful within a "reasonable period of time," but the determination of reasonable is left to individual countries. Likewise the requirement that "adequate remuneration" be paid to the patentee (Art 31.h). Again, countries can establish their own definitions of "adequate." During the Uruguay Round negotiations, the US sought to include a requirement to "compensate the right-holder fully" (Watal, 1999: 114), but this language is not included in TRIPS. And in both instances, with regard to negotiations and compensation, TRIPS (Article 31.j) permits national-level interpretation and adjudication to be *administrative*, not necessarily judicial, which significantly increases the ease of requesting and acquiring CLs.

Beyond the issue of how countries put their Article 31 obligations into national law is the issue of what grounds countries establish for issuing CLs. And here it is important to emphasize that TRIPS does not specify any grounds for CLs: countries can issue CLs for whatever reasons they chose.[22] Although TRIPS stipulates some of the conditions to be met for governments to issue CLs, it leaves the grounds for doing so as matters of national policy. What this means is that so long as these conditions – operationalized locally – are met, countries establish their own grounds for issuing CLs.

Developing countries' rights to issue CLs, particularly with regard to public health, were confirmed in the Doha Declaration on TRIPS Agreement and Public Health (WTO, 2001). Paragraph 5.b., for example, affirms that "each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." Thus, developing countries are only required to abide by the conditions stipulated in Article 31. Furthermore, even some of these conditions can be waived in the context of national emergencies, and paragraph 5.c. of the Doha Declaration stipulates that "each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency...."

While much of the debate over CLs has been related to issues of public health and, in particular, how countries can secure stable and reliable supplies of medicine, the relevance and importance of compulsory licensing goes beyond public health and touches a broad set of issues related to industrialization. Indeed, if one contrasts contemporary debates over CLs with the previous debates over CLs that occurred in the 1980s (Sell, 1998: Chapter 4), it is striking how the overarching issues have changed: contemporary debates are about public health, previous debates were about the role of CLs national strategies to promote indigenous technological advancement and industrial development. In discussing developing countries' flexibilities in this regard, then, it is worthwhile to consider the broader relevance of CLs. Developing countries can make restrictive licensing arrangements grounds for compulsory licenses, as China does, and thus help local firms gain access to patented knowledge on better terms. Or by requiring patent-holding firms to manufacture their inventions locally in order to retain exclusive rights, as many countries did in the past and some (e.g. Brazil and India) continue to do under TRIPS, developing countries can encourage the transfer of non-codified, tacit knowledge that only occurs via the localization of manufacturing operations.[23]

Although developing countries that are compliant with TRIPS retain significant rights to use CLs as policy instruments, these rights are seriously circumscribed in most RBTAs. This is done by fusing the conditions and grounds into specific and exclusive *circumstances* under which CLs can be issue. Although not all RBTAs restrict the use of CLs, the trend

is to allow governments to issue CLs only as remedies for anti-competitive practices, for public, non-commercial use, and in times of national emergency or "other circumstances of extreme urgency."[24] And even then, patent-holders are due "reasonable and entire compensation" (much tighter and stronger language than in TRIPS). The precise language is not the same in all the US RBTAs. The strongest restrictions appear to be in the US-Singapore agreement, though similar language has appeared in subsequent agreements.[25] Likewise, with regard to local working requirements, RBTAs proscribe such measures as well. By explicitly listing the limited and exclusive conditions under which CLs can be granted, local working requirements of this sort are prohibited.[26]

In sum, RBTAs essentially pick up where the WTO leaves off in terms of limiting developing countries' abilities to deploy what historically have been standard tools to regulate patent holders. Neither sort of agreement prohibits CLs, but RBTAs establish clear and unequivocal biases against their use – biases that are significantly stronger than in TRIPS. Whereas TRIPS allows governments to issue CLs on any grounds provided they take certain measures, some RBTAs prohibit governments from issuing CLs except in very strictly and tightly defined circumstances. The discussion of CLs is similar to that discussed above with regard to data exclusivity. In both instances, the provisions that the US insists on in RBTAs are strikingly similar to the more restrictive clauses that the US sought – unsuccessfully – to include in TRIPS during the course of the Uruguay Round negotiations.

4. Limitation (3): Duration of Private Rights

A third limitation to private rights of ownership over knowledge is temporal. Patents expire: at some point what is treated as private property enters the public domain, where access to and use of the knowledge is unrestricted.

TRIPS makes private rights more permanent as well, by granting longer patent terms, of a minimum 20 years from the date of application. Policy space in this regard is negative – developing countries cannot offer

terms of less than twenty years, but they can refuse to lengthen terms. This is of particular importance in the pharmaceutical sector, where much of the patent term is typically exhausted prior to commercialisation. For example, up to ten years may pass from the time a patent application is made until clinical tests are completed and the drug gains approval of health regulators. Not surprisingly, countries face pressures make available extensions to pharmaceutical patent terms, as the US does.

RBTAs do not require that signatories offer longer patent terms, but obligations to extend patents automatically can produce longer periods of *de facto* patent protection. Most agreements include clauses that establish conditions under which extensions must be granted, essentially exporting the most liberal readings of the relevant US legislation. Patents are to be extended on account of "unreasonable" delays on the part of the patent office or health authorities, revised formulations and new uses.

5. Conclusion

One need not be an enthusiast of TRIPS to acknowledge that developing countries retain important opportunities for policy innovation in the field of IP. To be sure, many important policy instruments used in the past are now illegal – TRIPS does indeed usher in a new and more constraining environment for IP management. But governments can, potentially, create TRIPS-compatible patent regimes that, by facilitating use and being geared toward adaptation and learning, remain appropriate for late development.

The opportunities for tailoring IP management, however, are radically restricted by RBTAs. On all three of the dimensions used to assess IP management – governments' abilities to determine which knowledge becomes private property, to provide for exceptions to patent-holders' exclusive rights, and to hasten arrival of the time that private knowledge enters the public domain – RBTAs place significantly more burdensome and onerous obligations on developing countries. Whereas TRIPS represents a worrying step toward harmonization, RBTAs step over the line and enter the danger zone. Indeed, the most profound threats to develop-

ing countries' abilities to use IP management for national development purposes are found in RBTAs.

To conclude, it is worth underscoring that few countries appear to actually take advantage of their legal rights under TRIPS. That is, independently of RBTAs, the *de facto* opportunities for policy innovation in IP may be significantly less than what a legal reading of TRIPS would suggest. Indeed, the few examples provided in this article of countries utilizing their TRIPS flexibilities tend to be from a handful of larger developing countries (e.g. Brazil, China, and India). The concern is that many if not most developing countries either cannot or simply will not exploit the remaining opportunities for policy innovation.

One potential explanation for the low level of "flexibility utilization" may be related to the prevailing form of technical assistance and capacity building in the area of IP. Currently, technical assistance and capacity building tend to take the form of officials from WIPO, USPTO and EPO (along with aid agencies) advising officials and judges in the developing world on IP matters and assisting countries in implementing their TRIPS obligations. To the extent that such missions encourage developing countries to exceed their TRIPS obligations (i.e. not take advantage of flexibilities), this may provide a partial explanation of this phenomenon.[27] In any case, better understanding developing countries' relative capacity and willingness to take advantage of their legal rights in IP management remains a crucially important area for future research.

Notas

[1] See, among others, Drahos (1995); May (2000); Matthews (2002); Sell (2003).

[2] While all countries were required to introduce national treatment and non-discrimination immediately into their existing IPR laws, developing countries had until January 2000 to bring their IPR regimes into full conformity with the WTO, and the least-developed countries were given until 2006. (with the right to request extensions). Special transition periods were included for pharmaceuticals and chemicals (again, the least-developed countries are granted additional time).

[3] To quote a prominent IPR scholar (and strong critic of TRIPS), "Developing countries were able in the pre-TRIPS era to define patent policies with a great degree of freedom. This has changed dramatically, but it is still possible to design patent laws taking into

account broader developmental objectives and, particularly, the creation of a legal environment to promote innovation and technology transfer" (Correa, 2000a: 97).

[4] Of course, many countries do not take advantage of these remaining opportunities; TRIPS flexibilities tend to be underutilized. Explaining this underutilization is the subject of other research I am currently undertaking.

[5] In the Americas, the US has agreements with the following countries: Chile; Mexico and Canada (NAFTA); and five countries of Central America plus the Dominican Republic (DR-CAFTA, with the agreement not yet ratified in Costa Rica at the time of writing). Negotiations have also been completed with Colombia, Panama, and Peru, with each agreement pending ratification. And, of course, there is the hemispheric Free Trade Agreement of the Americas, which would include thirty-four countries (all the sovereign states of the Americas with the exception of Cuba). Outside of the Americas, the list of RBTAs that are either completed or in the process of negotiation includes (by region), the Southern African Customs Union; Bahrain, Jordan, Morocco, and Oman (also Israel, but the US-Israeli agreement does not include IP provisions); Australia, Malaysia, Singapore, South Korea, and Thailand. See www.ustr.gov/Trade_Agreements/Section_Index.html.

[6] After the Swiss pharmaceutical firm Novartis's application for a patent on its anti-leukemia drug Glivec was rejected by the Indian Patent Office in Chennai, on grounds on non-efficacy over existing and known substances, Novartis challenged the TRIPS compatibility of Section 3.d in the Indian courts. It is not clear that the High Court of Chennai is the appropriate setting to judge TRIPS compatibility (and many observers question why Novartis pursued this route rather than enlist the Swiss government to challenge India in the WTO). Amin (2007) provides a concise review of the issues at stake.

[7] The word "invention," one of the cornerstones of IP, is not defined in TRIPS.

[8] Note, however, that not patenting software does not exempt countries from their obligations to provide copyright protection to software as a form of artistic expression. This is a firm obligation – albeit a new one – and an area where the US exerts considerable pressure (Shadlen, Schrank, and Kurtz, 2005).

[9] Not surprisingly, disclosure of origin was a point of contestation in the RBTA negotiations between the US and Colombia and Peru.

[10] Countries that did not previously grant patents on pharmaceuticals and agricultural chemicals were given until 2005 to begin doing so.

[11] "The extent to which third parties can undertake experimentation, including for commercial purposes, is, in particular, an important element to promote innovation based on or around a patented invention" (Correa, 2000b: 854).

[12] The emphasis here is on cost. Obviously there would also be critical ethical issues raised by the replication of clinical trials with control groups.

[13] Reichman (2004: 11-12), for example, cites a number of cases in OECD countries in support of the principle that using regulatory data to allow others to compete with

equal products does not amount to "unfair commercial use".

[14] Estimates of the costs of developing new drugs and bringing them to market spark immense disagreement and conflict, but few disagree that the costs of clinical trials have indeed escalated rapidly.

[15] Correa (2002) and Reichman (2004) both discuss the negotiating history on this issue. The US proposals, which would have prohibited not only disclosure but the use of the data by governments and third parties, were included as bracketed text in a1990 draft of the agreement, the so-called "Brussels draft." But the bracketed text was omitted in its entirety from the subsequent text that formed the basis of the final agreement, the "Dunkel Draft of 1991" and from the TRIPS agreement itself.

[16] For agricultural chemicals the period of protection is ten years. It is also worth noting that the period of data protection in the EU is longer than in the US, but the EU does not require its partners to adopt European standards in RBTAs (Pugatch, 2005).

[17] "Stronger patent and data protection increases the willingness of companies to release innovative drugs in free trade partners' markets, potentially increasing, rather than decreasing, the availability of medicines" (USTR 2004). See also, the statement of former USTR (Kantor 2005).

[18] Related to data exclusivity regulations are provisions included in some RBTAs that bar regulators from approving generic versions of products that are patented and require regulatory authorities to notify patent-holders of any requests for such authorization, regardless of whether the patented drugs are registered and marketed locally. While these requirements seem unproblematic on the face of it (if the drug is patented, then the sale of generic versions would be illegal), observers have raised a number of concerns. First, they place a legal responsibility on government agencies whose remit is not IP law but health and safety regulation. Second, the burden of defending a patent is partially transferred from the private rights-holder to the public.

[19] Countries can use different standards of exhaustion for copyrights, patents, and trademarks. Cottier and Mavroidis (2003) and Fink (1999) provide overviews of the complexities of exhaustion.

[20] Later in the agreement, Article 28.1(a) requires that states give patent holders the right to block their patented goods from being made, sold, or imported locally, which would appear to ban parallel imports. Yet this article includes a footnote that specifically cross-references article 6 and in doing so reaffirms countries' freedom to select their own standards of exhaustion.

[21] Paragraph 5.d of the Doha Declaration: "The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

[22] In fact, when specific grounds are mentioned explicitly in Article 31, it is to release countries from their obligations. For example, Article 31.b, which calls for prior negotiations and reasonable compensation to patent holders, suspends these obliga-

tions when the grounds for issuing the compulsory license is a national emergency (or public, non-commercial use). Similarly, Article 31.k indicates that when a compulsory license is issued to remedy anti-competitive practices, governments need not negotiate first (thus waiving Art. 31.b) and does not need to be "predominantly" for domestic use (thus waiving Art. 31.f).

[23] Note that the US objected to Brazil's local working provision and requested a WTO hearing, but the case was dropped without a ruling by the DSB.

[24] Of course, this allows the US (and other parties) to challenge whether or not countries are experiencing emergencies. Recall that the language of the Doha Declaration, in which countries make their own determinations regarding national emergencies, is not relevant in RBTAs.

[25] The language on CLs in the US-Morocco RBTA, in contrast, is much weaker, a fact that drew the wrath of the US industry group that advises USTR on the IP aspects of trade policy, the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy (IFAC-3). "IFAC-3 notes that the [US-Morocco RBTA] fails to include explicit restrictions on a country's authority to grant compulsory licenses to situations that are needed to remedy anti-trust violations; national emergencies or other circumstances of extreme urgency; and to govern situations of public non-commercial use. IFAC-3 believes that it is critical that future FTAs include these compulsory licensing restrictions, which were found in the Singapore FTA" (IFAC-3, 2004: 14).

[26] I am omitting discussion of Article 31.f, which requires that products produced under CL be "predominantly" for domestic use. This restriction was partially waived in August 2003 in the case of pharmaceutical products to be exported to countries lacking manufacturing capacity (see Matthews 2004). Note that when Canada amended its patent legislation to incorporate this waiver, it did so without violating NAFTA.

[27] Indeed, as number of observers have noted, technical assistance is not at all "technical," in the sense of their being a standard set of practices that need only to understood and implemented (May, 2004; Pengelly 2005).

O espaço para políticas de gestão de propriedade intelectual: o contraste entre arranjos multilaterais e regional-bilaterais

Resumo: A "governança" global na propriedade intelectual (PI) tem mudado fortemente ao longo das duas últimas décadas. O que foi uma vez, principalmente, um instrumento de política nacional, é agora, crescentemente, sujeito a disciplinas internacionais. Eu contrasto as novas restrições que tem lugar na gestão da PI e que os países desenvolvidos aceitam como parte do Acordo sobre Aspectos Relacionados com o Comércio de Direitos de Propriedade intelectual

(TRIPS) da Organização Mundial do Comércio (OMC) com as limitações que eles apresentam como membros do Acordo de Comercio Bilateral e Regional (RBTAs) com os Estados Unidos. Eu lanço alguma luz sobre as áreas onde os países possuem oportunidades de política de inovação apesar de suas obrigações na OMC e apresento exemplos de como alguns países têm introduzido e retido medidas que se adaptam à gestão de PI e às condições e necessidades locais, enquanto discutem as novas obrigações do TRIPs. Mais ainda, eu mostro como essas oportunidades estão circunscritas por RBTAs. Países que são partícipes do RBTAs têm significativamente menos autonomia na gestão de sua PI para todas as dimensões da política de patentes. Em suma, a proliferação de RBTAs apresenta a maior ameaça às capacidades nacionais de gerir a PI para objetivos de desenvolvimento.

Palavras-chave: governança, direitos de propriedade intelectual, acordo TRIPS, política de patentes, países em desenvolvimento.

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