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**Policy Space for Development in the WTO and Beyond:
The Case of Intellectual Property Rights**

Ken Shadlen

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Tufts University
Medford MA 02155, USA
<http://ase.tufts.edu/gdae>

Policy Space for Development in the WTO and Beyond: The Case of Intellectual Property Rights

Ken Shadlen¹

Abstract

Global governance in intellectual property (IP) has changed dramatically in the last two decades, and these changes have profound – and worrying – implications for late development. What was once principally an instrument of national policy is now increasingly subject to international disciplines, as the world moves ever-closer to harmonization in the area of IP management. But moving toward harmonization and achieving harmonization are different matters, and it is essential to keep in mind that the former and not the latter describes contemporary arrangements: the trend is toward a reduction in policy space, a feature that many scholars and activists point to with great concern (Gallagher, 2005), but the outcome remains one where countries retain space for autonomous IP management.

This paper examines the relationship between IP and development, presenting a framework for assessing IP regimes both cross-nationally and over time. It is then shown how the trend toward harmonization places new and significant restrictions on developing countries' opportunities for policy innovation in IP management. The implications of harmonization for a range of issues are then considered, including late industrialization, promotion of public health, and protection of biodiversity.

The paper shows that the new regulations are most accentuated at the regional and bilateral level. Thus, for all of the concerns that academics and policy analysts have legitimately and rightly expressed over TRIPS, the biggest threat to using IP policy as a tool for realizing development objectives comes not so much from the World Trade Organization (WTO) as from bilateral and regional Preferential Trade Agreements (PTAs) between developed and developing countries. I demonstrate this by examining various aspects of IP policy: over and over, we see that countries that are parties to such PTAs have significantly less autonomy in their management of IP. In the conclusion, a set of policy recommendations are put forth, at both regional and multilateral levels, for restoring countries' ability to use IP as a tool for economic development.

The policy challenges are twofold: developing countries must utilize and exploit the remaining opportunities under TRIPS to use IP management for national development purposes, and developing countries must be careful to avoid bargaining away their remaining rights under PTAs.

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I. Intellectual Property (IP) and Development: Background

Property rights are rules and regulations regarding the establishment, use, and protection of property. Intellectual property rights (IPRs) are a special subset on account of the distinct characteristics of the property they regulate. Specifically, knowledge is non-rivalrous (i.e. it can be used simultaneously by multiple people) and inexhaustible (i.e. one person's use does not affect the amount left for anyone else to use). These characteristics mean that IPRs perform different economic and social functions than property rights in "normal" goods, and, moreover, that IPRs are the subject of intense political contestation.

Most analyses of IPRs focus on patents and copyrights, with the basic distinction being that the former protect the ideas underlying inventions while the latter protect forms of expression. To provide an example, one can patent a device for recording love songs and one can copyright the melody and lyrics to a love song, but one cannot patent the idea of a love song. In this paper I focus on patents, which are arguably of greatest importance for developing countries.¹

Patents confer limited monopoly rights over inventions that are new, non-obvious, and have technological application. Thus, patents are not available to knowledge that already exists, or that mark only minor steps of innovation, or that are trivial and cannot be put to use. Of course, these criteria are vague, and national patent offices operationalize them differently. As we shall see, this provides countries with a significant amount of policy discretion.

The rights conferred by patents are *limited* in three significant ways, and the politics of IP can be conceptualised as conflicts over these limitations. First, patents are not conferred automatically upon possession. Rather, private ownership rights are granted by the state, typically a national patent office, only where applicants demonstrate that their inventions satisfy the criteria of patentability. With application central to the process of establishing ownership, governments can delineate what ideas and innovations can be owned privately within their territory.

A second limitation is that patent rights always include various exceptions to patent-holders' ability to exert control over the use and distribution of their property. Patent regimes include provisions by which third parties retain automatic access and rights to use the idea. The ability to experiment on the basis of disclosed information is an example: patent-holders cannot prevent it, third parties do not have to obtain permission to undertake such activities, and the exception is not time-bounded. Patent regimes also include non-automatic exceptions, where, under certain conditions, third parties can petition the state for access. A compulsory license, for example, allows a domestic manufacturer to produce a patented good without the authorization of the patent-holder. Because non-automatic exceptions dilute patent-holders' exclusive rights more significantly, they are restricted and time-bounded. Nevertheless, all countries condition the rights of ownership and control of knowledge on the prescription and

proscription of certain activities and practices, and clauses that stipulate the conditions and grounds for issuing compulsory licenses are standard features of IP regimes.

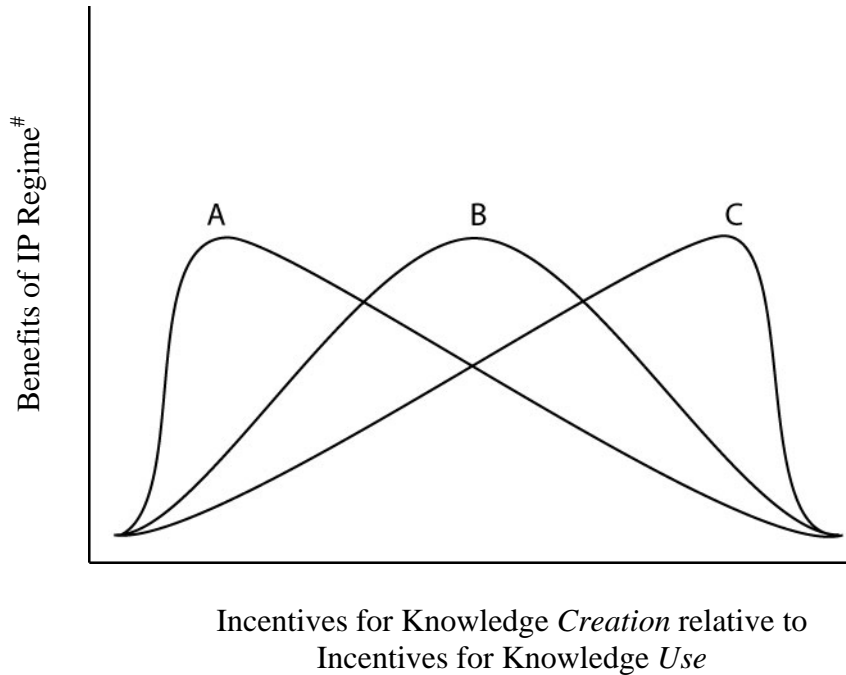
A third limitation is temporal. Patents expire; at some point what is treated as private property enters the public domain, where access to and use of the knowledge is unrestricted. It is worth emphasizing that patent rights are also limited in a territorial sense, in that they are national and the rights conferred end at the border.² This means that potential patentees must apply for patents in each country where they wish to secure protection, and they must defend their patents in each country as well. Even where patents are applied for and granted on a regional basis, e.g. in the European Union, protection and enforcement remains national.

These three limitations constitute axes of variation. When national patent regimes change, the changes can be conceptualised in terms of these dimensions: the processes by which knowledge becomes privately owned, the extent of the rights of patent-holders and third parties, and how long the rights last.³

Designing IP systems entails difficult and unavoidable trade-offs between providing incentives for the creation of knowledge and facilitating the use of knowledge. IPRs can encourage knowledge creation by providing incentives for innovation: innovators can invest their time and resources in attempting to generate new products with confidence that the protection to be granted will allow them to enjoy the returns. In the absence of IPRs, inventions may take on the character of public goods and, subsequently, be subject to traditional collective action problems resulting in underprovision. But IPRs also restrict knowledge dissemination, since they give owners control over the distribution and marketing of the new knowledge, including the conditions under which the knowledge can be accessed and used by third parties.⁴ The trade-off is that without IPRs, some knowledge may not exist; with too much protection, on the other hand, third parties may suffer from reduced access to new knowledge. Limited access, in turn, can rebound negatively on future innovation, to the extent that knowledge creation is an incremental process.

A key point of this review of the basic economics of IP is not simply that countries' IP regimes constitute the balance between incentives for the creation of knowledge and incentives for the dissemination and use of new knowledge, but that a single set of laws and institutions cannot maximize both objectives. That is, IP regimes aim to maximize two desirable – but unavoidably conflicting – social objectives: that knowledge be created, and that knowledge be used. The graphs in Figure 1 present a simple conceptualisation of the trade-offs. Where incentives for either knowledge generation or knowledge use are insufficient, the benefits of the IP regime are minimal. At some point, however, the optimal balance yields maximum benefits, indicated by points A, B, and C. The inclusion of three separate curves is to show that the relationship between IP and knowledge use differs in different settings; the optimal balance of incentives for the generation and use of knowledge depends on a variety of national characteristics that affect the degree to which local actors respond to different sorts of incentives.

Figure 1: Conceptualizing the Trade-offs Generating and Using Knowledge



Benefits are assessed in terms of maximum knowledge generated *and* used

To gain insights on the national distribution of patenting and innovative capacities, Table One provides data on patents granted by the United States Patent and Trademark Office (USPTO), from 1997-2004. A number of points jump off the page. First, firms and organizations from the top ten developed countries account for more than ninety percent of all patents granted. Second, the US, Japan, and Germany alone account for nearly eighty percent. Third, the firms and organizations from the top ten developing and transition economies account for less than seven percent, with greater than five percent coming from Taiwan and South Korea. The combined total of the next eight highest ranking countries is a mere 1.36%, slightly more than Italy.

**Table 1: Patents Granted by USPTO
(1997-2004)**

Top 10 Developed Countries	Percent of Total*
1. USA	53.16%
2. Japan	20.64%
3. Germany	6.50%
4. France	2.39%
5. United Kingdom	2.28%
6. Canada	2.09%
7. Italy	1.03%
8. Sweden	0.91%
9. Switzerland	0.84%
10. Netherlands	0.80%
<i>Sub-Total</i>	<i>90.65%</i>
Top Ten Developing and Transition Countries	Percent of Total*
1. Taiwan	2.87%
2. South Korea	2.24%
3. Israel**	0.57%
4. Singapore**	0.17%
5. Hong Kong	0.13%
6. China	0.12%
7. India	0.12%
8. Russia	0.12%
9. South Africa	0.07%
10. Brazil	0.06%
<i>Sub-Total</i>	<i>6.49%</i>

*Total is greater than the sum of the two sub-totals, which only include patents from the twenty countries in the table.

**High-income country according to World Bank, but classified as “developing country” in TRIPS.

Source: United States Patent and Trademark Office (www.uspto.gov).

How countries prioritize the quests for creating and using knowledge have traditionally affected where the balance is struck in a given country at a given time. Different countries have their own profiles as “creators” or “users” of patentable knowledge. Whereas Table One demonstrates developed countries’ huge advantages in innovative activities (with the important exceptions of Taiwan and South Korea), Table Two, which examines patent applications according to residency of applicant, suggests that developing countries are generally importers of knowledge. Even in the countries that the World Bank classifies as “high income,” non-resident applications overwhelm

resident applications, a reflection of US dominance in this area. But the asymmetries are even greater in the developing world. Residents account for less than three percent of patent applications in middle-income countries and only one-fifth of one percent in low-income countries.

In countries with higher levels of innovation (i.e. where more research and development tends to produce new knowledge), it has made sense for these countries to set incentives to encourage the creation of knowledge.⁵ In contrast, in countries with lower levels of innovation, where most new knowledge that is used is imported from abroad, the incentives were typically set to encourage dissemination and use of new knowledge and ideas.

To be sure, national IP regimes have not always reflected countries' scientific and innovative profiles. Historically, though, diversity in national patent regimes – both cross-nationally and longitudinally – has corresponded to these basic national characteristics. Wealthier countries, with higher levels of innovation (or, more accurately, higher levels of “patentable” innovation), have typically offered more IP protection than poorer countries. Wealthier countries have made patents available and easier to obtain on a wider range of goods, have placed fewer restrictions on what patent-owners must do to retain exclusive rights, and have offered longer periods of patent protection. The relationship between national income and the relative incentives toward knowledge-creation and knowledge-use is best represented by a j-curve (see Figure Two). As countries become more industrialized and thus have greater capacity to use cutting-edge knowledge, their patent regimes tend to facilitate local firms' ability to access such knowledge (hence the dip toward point O); later, as they develop more indigenous innovative capacities, countries' patent regimes tend to emphasize incentives for knowledge-generation (toward point P).

**Table 2: Patent Applications by Residency
(1997-2002)**

Income Levels*	A. Non-Resident Applications as Share of Total Applications
High income	82.28%
Middle income	97.61%
Low income	99.79%

*World Bank Classifications

Source: World Bank, World Development Indicators.

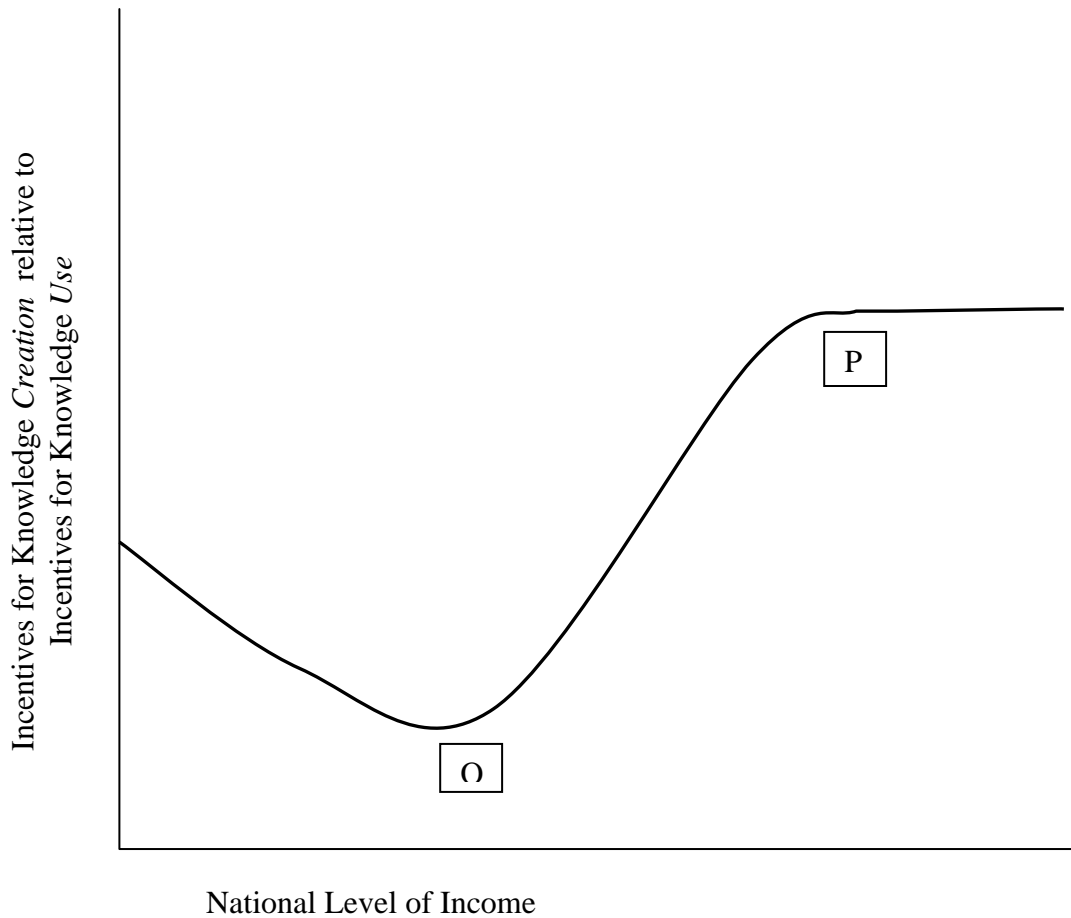
National variation was facilitated by a permissive international regime. Prior to the Uruguay Round, international governance in the issue-area of IP was weak, both procedurally and substantively. Because IP was not considered “trade-related,” the treatment of IP was not regulated by multilateral trade institutions (e.g., General Agreement on Tariffs and Trade [GATT]). Instead, the principal international covenant

for patents was the 1883 Paris Convention for the Protection of Industrial Property, which allowed countries a significant degree of flexibility in designing their patent regimes. Although parties to the Paris Convention pledged to abide by the norms of non-discrimination and national treatment (i.e., they would not treat patent applications and patents differently depending on the country of origin), they retained virtually complete autonomy in designing national patent legislation.

In the 1980s and 1990s, however, global governance in IP underwent a sea change, as developed countries, led by the U.S., pushed for stronger enforcement of a less flexible set of regulations regarding the treatment of IP. The goal, in essence, was to universalise OECD-style IP protection (i.e. to eliminate the trough, illustrated by point O on Figure Two, for all but the poorest countries).

The increased prominence of IP in U.S. foreign policy is a story of sectoral politics, in which well-organized industry groups representing the biotech, chemical, pharmaceutical, entertainment, and software industries pushed the U.S. government to use trade sanctions against countries that were argued to be lax in protecting their copyrights, patents, and trademarks.⁶ In 1984, Congress amended Section 301 of Trade Act of 1974 to make violation of intellectual property rights “actionable.” As the business constituency for stronger IP protection grew, the same coalition succeeded in obtaining another amendment to Section 301 in 1988—“Special 301,” which heightened the United States Trade Representative’s (USTR) authority to act against countries that provided insufficient protection of intellectual property.⁷

Figure 2: Historical Relationship between Level of Development and Nature of Patent Regime



In addition to unilateral strategies of IPR enforcement, the U.S. also insisted on integrating the theme of IP into the Uruguay Round negotiations in order to establish a new set of global standards to guide countries' IP regimes. Integrating IP into the multilateral trade regime would accomplish two goals simultaneously: it would take a giant step toward harmonization of IP, and it would convert the new standards into enforceable international law, where violators could be punished with retaliatory trade sanctions. The product of this campaign is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which creates new global standards regarding virtually all aspects of how countries treat IP.

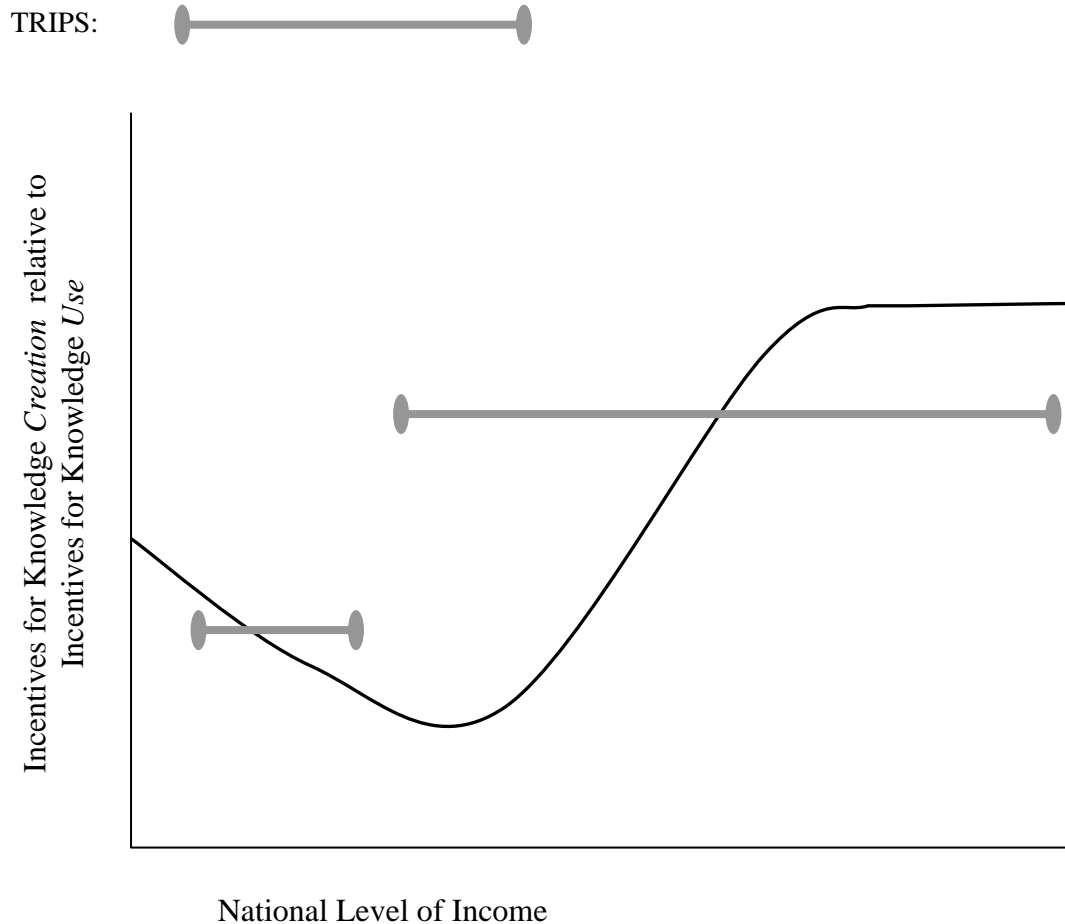
TRIPS places significantly greater limitations on how countries configure their patent regimes. The reduction of policy space under TRIPS is best illustrated with reference to the three axes of variation noted above: establishing private rights over knowledge becomes more automatic, the rights are more absolute, and they last longer. Whereas countries could previously deny patents to certain types of inventions so as to encourage reverse-engineering and lower the barriers to entry in technologically-

intensive sectors, now countries must offer patents in virtually all fields. Whereas countries could include extensive exceptions to patent-holders' monopoly rights in order to facilitate broad access to patented knowledge, TRIPS strengthens the rights of patentees to control access and use of patented information. Whereas countries could make enjoyment of the monopoly rights conferred by patents conditional upon local production or licensing and transferring technology to local users, TRIPS limits how governments regulate patent-holders. And whereas countries could offer patents of short duration to increase the entry of knowledge into the public domain, TRIPS requires that the strengthened rights of patent holders extend for twenty-year patent terms.

Thus, TRIPS makes it more difficult for developing countries to gear the management of IPRs toward speeding the pace of local technological diffusion and spurring indigenous technological development.⁸ Because TRIPS focuses primarily on establishing incentives for innovation and knowledge-generation, activities which occur disproportionately in developed countries, it limits developing countries' rights to design patent regimes to encourage imitation and technological learning. In sum, TRIPS ushers in a new relationship between patent regimes and level of development, as illustrated by Figure Three.

One concession granted to the developing countries regarded transition periods for implementation: 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 2006.⁹ Special transition periods were included for pharmaceuticals and chemicals, and here, too, the least-developed countries are granted additional time. Eventually, when most transition periods are over, developed and developing countries will be subject to the same standards for IP management, with the poorest countries still remaining exempt from many obligations. This new – but still bifurcated – set of obligations is indicated by the lower bar in Figure Three.

Notwithstanding the very real constraints set by TRIPS, the agreement still leaves room for national variation in how countries treat intellectual property. The borders of the upper bar in Figure Three, particularly the bottom border of the upper-right bar, should be viewed as imprecise. Countries may exhibit substantial variation in their patent regimes, all while being compliant with TRIPS; and there is room within TRIPS for countries to develop dynamic patent regimes (CIPR, 2002; Reichman, 1997). To quote a prominent IPR scholar who has also been a 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).

Figure 3: Patent Regimes and Development Levels under TRIPS

II. The New Global Politics of IP: Multilateralism and Regionalism

More than a decade after the introduction of TRIPS, the governance of IP remains one of the most charged issues on the international agenda. On the one hand, many developing countries resent and resist the imposition of new standards for the establishment and protection of IP that go far beyond what countries have typically offered at similar stages of development. At the least they have sought consolidation and confirmation of the flexibilities for IP management that remain under TRIPS. The Doha Declaration on TRIPS and Public Health (WTO, 2001), for example, was the result of a coordinated campaign by developing countries to gain a clear affirmation of the rights set forth in TRIPS.¹⁰ More ambitiously, developing countries seek to retain their ability to use IP management as a tool for achieving broader development goals by, for example, relaxing the standards of IP protection in strategic sectors to facilitate access to foreign

technology or to lower the prices of technologically-intensive consumer and producer goods (e.g. pharmaceuticals, seeds, and software).

On the other hand, most developed countries regard the standards for IP protection established by TRIPS as too weak and too easily circumvented. They seek to harmonize IP protection at a higher level, and thereby guarantee high returns for their own innovative firms that benefit from IPRs. Thus, developed countries – especially the U.S. – have continued to apply direct pressure on countries to exceed their obligations under TRIPS. Most importantly, the U.S. secures heightened IP protection through bilateral and regional preferential trade agreements (PTAs) that offer market access above and beyond what is available in the WTO in exchange for IP practices that are above and beyond what is required under TRIPS.¹¹ Indeed, whereas TRIPS leaves space for countries to tailor their IP regimes to national development objectives, the space under PTAs is *dramatically* reduced.

The subsequent text examines policy space in multilateral and bilateral-regional agreements. The key points are summarized in the accompanying tables. The discussion is organized around the three limitations: the processes by which private rights to knowledge are obtained (Table 3); the extent of and exceptions to the private rights (Table 4); and the duration of the rights (Table 5). Within each sub-section, I discuss the significance for development policy of important policy areas, and I explain the options available to countries under TRIPS, and then under PTAs. As we shall see, PTAs bring IP much closer to actual harmonization.

Before proceeding, a few caveats and points of clarification are in order. First, it is obviously simplistic to discuss PTAs 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 PTAs. PTAs negotiated with the US extend IP obligations beyond TRIPS more consistently than do those with the EU (Pugatch, 2005). I focus on US PTAs.¹² But US PTAs differ not only from EU PTAs, but from each other: all US PTAs are not alike. Indeed, the details of the IP provisions within any given agreement are bargaining outcomes. Thus, general statements regarding IP regulations in PTAs (US or otherwise) run the risk of distorting via oversimplification. That said, with regard to virtually any policy area, the differences between various PTAs tend to be less than the differences between TRIPS and the PTA closest to TRIPS, so there is a good deal that can be illuminated with simplifications. Simply stated, too much analysis of the differences *between* PTAs without considering how the entire genre differs from TRIPS distracts our attention from the big picture; we risk losing the forest for the trees.

Limitation 1: How Private Rights to Knowledge are Obtained

The scope of a patent regime refers to the range of inventions that are eligible to be patented. This has historically been a critical feature that differentiated national approaches toward IP. Many countries refused to grant patents to certain products, and the duration of patent terms often varied by type of product.¹³ Providing local producers

unrestricted access to foreign knowledge in key sectors has historically been a critical dimension of strategies for late industrialization, for it 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 in setting the scope of patent eligibility. Article 27 requires countries to grant patents of twenty years *in all fields of technology*. This is a new definition of the term "non-discrimination," no longer referring to countries' practices vis-a-vis other countries, but rather, vis-à-vis different economic sectors. Of course, any individual patent application can be denied on the standard grounds of novelty, inventiveness, and utility, and countries' national patent offices and courts retain autonomy in how they operationalize these critical concepts (as discussed below); but in principal, IP statutes must permit patenting in all fields.

The new limitations on scope that derive from TRIPS mean that countries can no longer refuse, as a matter of policy, to issue patents to particular classes of goods, such as pharmaceutical products and chemicals. Prior to the Uruguay Round, more than forty countries withheld 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.¹⁴

One contentious issue related to pharmaceutical patents in the TRIPS negotiations regarded countries' obligations for the treatment of already-existing knowledge that was previously ineligible for patenting. As developing countries introduce product patents on pharmaceuticals, must they make protection available to medicines that already exist? The issue involved is that inventions must be "novel" to receive patents. As a result, patent offices generally do not issue patents on goods that have already been patented in other countries.¹⁵ But pharmaceutical companies did not bother applying for patents in countries where their products could not be patented at the time of invention.

The policy question, then, is whether countries should apply "pipeline" protection, granting patents to products that are not new for the duration of the patent in the first country. For example, if a patent was applied for in the US in 1993, a country granting pipeline protection would, at the time its new patent law went into effect, offer protection to that product until 2013, at the time the twenty-year patent would expire in the US. TRIPS does not oblige countries to offer this additional and retroactive form of protection, but PTAs almost invariably do.¹⁶

An important 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 PTAs exceed what is required under TRIPS. In the first regard, some PTAs (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), thus eliminating the Article 27.3.b flexibility. And even where plant patenting is not required, it is strongly encouraged. For example, the US-Chile PTA and 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 PTAs 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, PTAs oblige countries to offer patents or, at the very least, a UPOV system.

In addition to the question of what sorts of knowledge is eligible for patenting, there is the question of how patent offices examine applications. Under TRIPS, countries retain significant prerogatives for making private ownership of knowledge less automatic. Most obviously, 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; 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).

Countries also set their own definitions of an “invention,” and as such can deny patents to “discoveries.”¹⁷ That these are such imprecise terms certainly invites abuse, but it also 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). Likewise, an inter-ministerial committee in India has been constituted to debate whether or not a limited definition of invention could be used to restrict pharmaceutical patents to new chemical entities (NCEs), and thus deny patents to incremental inventions.¹⁸ 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.¹⁹

Countries also retain significant leeway to demand strict disclosure requirements. Recall that in exchange for the 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 the 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.

Disclosure can also provide legal attribution of earlier contributions to knowledge creation. Many developing countries would like to see more benefit-sharing between biotech countries from the OECD, who have the technological prowess to turn genetic resources into commercial goods, and local communities, who contribute to biotech innovations through stewardship of nature. To that end, countries rich in biodiversity might require that patent applicants disclose the origin of the knowledge and materials used – as a number of countries do.²⁰

PTAs can erode these critical areas of policymaking space 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. CAFTA, for example, defines “novelty” in a more expansive way, exporting to all 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).²¹ PTAs are also more likely to limit the sorts of disclosure requirements that national IP offices can place on patent applicants. Again, 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.²²

It is also worth noting that even where countries retain prerogatives on examination and disclosure requirements, using such options presents complex challenges for most developing countries. Patent applications, virtually by definition, include cutting-edge knowledge. Thus, knowing how much disclosure is “sufficient” can be a complex task. Plus, the number of patent applications in most countries has increased astronomically in the last fifteen to twenty years, which means that national patent offices are flooded with applications on highly technical matters. For developing countries, this raises two issues regarded to resource allocation. First, with regard to budgetary resources, having a patent office that is both efficient and effective (i.e. does not take too long on any given patent application and thereby effectively undermine the existence of the system, but does not simply grant patents without undertaking thorough searches and scrutinizing disclosure) is expensive and requires that resources be allocated to the task. Finger and Schuler (2000) note that the combined cost of implementing TRIPS and two other new Uruguay Round agreements would be roughly US\$150 million—and that is merely to implement the minimal standards. Having an efficient and effective patent system would add significantly to this figure. Second, with regard to human resources, the same requirements of efficiency and effectiveness mean that the patent examiners themselves will have to be highly-skilled and well-trained professionals with technical knowledge, normally with engineering and science backgrounds. Given that such skills are, by definition, in short supply in less developed countries (if a country had a surplus of scientists and engineers it would probably be more developed), the obvious question, then, regards the opportunity costs of deploying “the best and brightest” as patent examiners.

Two additional areas of IP policy management must be emphasized in this subsection: patent breadth and utility models. Neither is addressed by either the WTO or preferential trade agreements. Breadth refers essentially to how many ideas (or claims) are protected by a single patent, and it, in turn, affects the terms on which follow-on innovators gain access to the patented knowledge (Merges and Nelson, 1990). Narrow patents can create opportunities for local firms and innovators to “invent around” existing patents without being subject to litigation. Indeed, the granting of narrow patents was a key feature of Japan’s postwar patent regime, one that is commonly cited as a model regime for late-industrializing technological followers (see discussions in Maskus and McDaniel, 1999; Maskus, 2000; Chang, 2002; Kumar, 2003).²³

Utility models (also known as “petty patents”) serve the same basic function as patents, in that they offer protection in exchange for public disclosure of new knowledge, but they offer reduced protection (e.g. seven to ten years rather than twenty) for inventions that meet lower standards of inventiveness (the “non-obvious” criterion). They are typically made available for *incremental* inventions that build on more fundamental discoveries (Maskus, 2000: 39 and 177; CIPR, 2002: Box 1.1 and p. 175). Utility models are of particular interest in considering alternatives for IP management in developing countries because the degree of innovation required for protection is likely to be more appropriate for local firms. The sorts of innovations undertaken by local firms are less likely to meet the inventiveness threshold for patentability. By granting utility models, then, developing countries can reward the smaller and more incremental types of innovation that are common among local firms.

Comparative historical analysis suggests that utility models can be critically important dimensions of patent regimes. The sorts of innovations rewarded by utility models may be developmentally significant and worth encouraging, even if not strictly patentable. Analysts of the role of IPRs in East Asian development typically emphasize not just the narrow scope of patentability, for example, but also the use of utility models in Japan, Korea, and Taiwan (Kumar, 2003; Maskus and McDaniel, 1999). Indeed, a great number of developing countries narrowed the scope of patent eligibility in the postwar era, but one crucial difference that set the East Asian countries apart is that they also actively promoted utility models to encourage local firms to make adaptive and incremental innovations.²⁴

Note that neither multilateral nor preferential agreements address either patent breadth or utility models. However, as with scope and disclosure requirements, the opportunities for policy innovation – though important – are difficult to exploit. Patent breadth, for example, tends not to be a function of statute so much as of administrative and judicial practice (i.e. how patent examiners proceed, and what legal doctrines judges use in deciding infringement cases). Thus, it is “unclear how developing countries can ensure that courts interpret claims in a narrow way, unless this is laid down in detailed guidelines, a stupendous task in itself” (Watal, 1999: 119, note 12). Likewise, an effective system of utility models requires significant government promotion, since many of the smaller, local firms whose innovations might qualify for this sort of protection have little familiarity with IP. Thus, despite the fact that many developing countries now offer utility models, applications tend to be low, suggesting that the systems exist but are not being used. In the case of Argentina, for example, which included utility models in introducing a new Patent Law in 1995, the uptake has been quite slow. In the first year that utility models were available, not a single application was received. Although applications for utility models increased in subsequent years, the number remained orders of magnitude less than applications for patents. From 1996-2002, the National Institute of Industrial Property (INPI) received a total of 1656 applications for utility models and 24,292 applications for patents. In fact, even Argentine nationals, who accounted for less than 20 percent of patent applications but 93 percent of utility model applications, made significantly *more* patent applications than utility model applications in absolute terms (4456 to 1537).²⁵

Table 3: How Private Rights are Obtained under WTO and PTAs

Issue	Significance	TRIPS Obligations	PTAs
Scope	<p><i>What products and processes are eligible for patent protection.</i></p> <ul style="list-style-type: none"> • Historically many countries have reduced patent scope, not granting patents in some sectors • Can facilitate development of local technological capacities via imitation and reverse-engineering • Ethics and biodiversity 	<p><i>Countries must grant patents in all sectors that meet criteria of being new, inventive, and useful.</i></p> <ul style="list-style-type: none"> • Flexibility regarding how countries operationalize patentability criteria (e.g. new, non-obvious, and useful) • Flexibility regarding definitions of “invention” • Article 27.3.b allows for alternative protection system for plant varieties 	<p><i>Further reduction</i></p> <ul style="list-style-type: none"> • Pipeline protection • Removal of operational discretion in patent granting (e.g. defining “novelty” and “utility”) • Further limitations on PGRFA
Disclosure Requirements	<p><i>How much information is required to receive a patent</i></p> <ul style="list-style-type: none"> • Effects nature and amount of information in public domain and thus available to third parties • Can create opportunities for benefit sharing 	<p><i>Not addressed by TRIPS</i></p>	<p><i>Cap on disclosure obligations prohibit disclosure of origin requirements</i></p>
Breadth	<p><i>Number of separate ideas protected by individual patents</i></p> <ul style="list-style-type: none"> • Whether patent authorities grant narrow vs. broad patents affects ability of third parties to use patented knowledge for innovation 	<p><i>Not addressed by TRIPS</i></p> <ul style="list-style-type: none"> • Largely a function of judicial practices 	<p>--</p>
Utility Models (“petty patents”)	<p><i>Provides incentives to innovative activities that would not qualify for patent protection</i></p> <ul style="list-style-type: none"> • Key to postwar technological transformation in late industrializers • More likely to be used by local firms 	<p><i>Not addressed by TRIPS</i></p>	<p>--</p>

Limitation 2: The Extent of and Exceptions to Private Rights

The monopoly rights conferred by patents are not absolute, but, as emphasized throughout this paper, are subject to limitations that are stipulated in national legislation. The limitations include both *general* and *specific* exceptions to exclusive rights. The former are available to anyone at any time, without the need to receive government authorization; they are not subject to time restrictions; and compensation to rights holders are not required.²⁶ The latter, in contrast, require state authorization, apply only to the party indicated by state authorities, are typically subject to time restrictions, and call for compensation. Both sorts of exceptions have critical implications for national development policy.²⁷

TRIPS unquestionably obliges countries to provide IPRs that are stronger and more absolute than in the pre-TRIPS era, in that third parties have less ability to use disclosed knowledge and states must comply with more restrictive conditions for authorizing third-party use (e.g. issuing compulsory licenses). Yet TRIPS permits significant levels of national-level variation with regard to both sorts of limitations, variation that, again, is largely precluded by PTAs. As we shall see, PTAs tend to place even greater limits on third parties' rights to access patented knowledge; in addition, 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. As one observer has noted, "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, emphasis added). Developing countries' flexibilities in this regard are best illustrated by conceiving allowable exceptions along a spectrum. At one extreme would be the preclusion of all third-party access to the patented knowledge. At another extreme would be consent to all third parties to use all patented knowledge for any purpose, including sales. Both of these extremes undermine the goals of an IP system: the first, to the far right in Figure One, grants too much protection, and unnecessarily restricts use; the second, to the far left in Figure One, basically grants no protection at all, and may not provide sufficient incentives for generation and commercialization of new knowledge. Interim points on the spectrum would 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). The key point for the present discussion is that only the final point – permitting commercial production and stockpiling – is proscribed by TRIPS.²⁸

These general exceptions are of tremendous importance in the pharmaceutical industry. Discussions of this issue typically make reference to "early working" (or

“Bolar”) provisions, which allow firms to develop, test, and apply for registration of generic versions of patented drugs, to be put on the market once the protected drugs’ patent terms expire. Early working exceptions are generally thought of as providing important stimuli for the expansion of generic pharmaceutical industries and as measures to reduce 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.

Countries that are members of PTAs with the US sacrifice this flexibility by accepting 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 data, obtained through clinical trials, of the effectiveness of their products. What is at issue is whether producers of generic medicines can use these data to secure regulatory approval. Alternatively, if the data is protected, generic firms must generate their own test data by replicating costly and time-consuming clinical trials, a process that delays the onset of price competition.²⁹

TRIPS leaves developing countries significant leeway with regard to how they treat test data (Correa, 2002; Reichman, 2004; Pugatch, 2005). 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.³⁰

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,³¹ the US has, since the late 1980s, adopted a position that governments should 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 39.³² Unable to secure stronger data protection at the multilateral level, the US negotiators have made this issue a high priority on the bilateral agenda. Concretely, US PTAs 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.³³ Importantly, 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 PTAs. Most countries have objected strongly, arguing that extensive data exclusivity hampers their ability to encourage generic competition and thereby reduce 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,³⁴ have continued to make it a high priority. Chile, for example, sought to ameliorate the adverse effects of data exclusivity included in the US-Chile PTA 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 PTA. 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, 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.³⁵

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), since different policies on parallel imports correspond to differently defined standards on exhaustion.³⁶

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 to allow the adoption of 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.³⁷ 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.³⁸

Here again, the US has been able to secure greater IP protection through PTAs than the WTO by exporting national standards of exhaustion. US PTAs are not common markets. Instead, each country in the “regions” created by US PTAs retain national standards of exhaustion, and thus prohibit importation.³⁹

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 (CLs) 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 the use of CLs (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); it must be non-exclusive; it should 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, under the requirement that "adequate remuneration" be paid to the patentee (Art 31.h), 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. Here it is important to emphasize that TRIPS does not specify any grounds for CLs; countries can issue CLs for whatever reasons they chose.⁴⁰ 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, while previous debates were about the role of CLs in 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.

To understand the importance of the “local working” requirement, recall two points discussed earlier in this paper. First, most patents are held by firms in a handful of wealthy countries, reflecting the extraordinary asymmetries in international technological capacities (see Table 1). Second, patent regimes in the developing world are less about stimulating innovation than about capturing the benefits of foreign innovation through the transfer, absorption, and adaptation of foreign technologies. A partial condition for technological learning is that the technology is used locally. Many developing countries maintain that if patented goods are simply imported, with local use impeded by the rights of foreign patent holders, technological transfer will be minimal. To the extent that governments want to improve local actors’ access to and ability to learn from foreign technologies, there may be a public interest in insuring that the technologies are used locally. One policy instrument to achieve this goal is to condition patent rights on local production.

Whether or not countries can grant CLs in the absence of local production is an unresolved issue in TRIPS, though the answer appears to be that they can do so. On the one hand, the previous discussion, which indicated countries’ freedoms to establish their own grounds for CLs, would suggest that such practices are permissible. On the other hand, the agreement also stipulates that patents “shall be available and patent rights enjoyable without discrimination as to ... whether products are imported or locally produced” (Art. 27.1).⁴¹

We can take some guidance on this issue from a conflict between the US and Brazil over the latter's local working provisions.⁴² Article 68 of Brazil's 1997 industrial property law authorizes the government to issue CLs when manufactured goods are not produced locally after three years from the grant of the patent. The US objected and requested a WTO hearing, accusing Brazil of being in violation of TRIPS. In June 2001, when the two countries signed a joint communiqué announcing the withdrawal of the U.S. challenge in the WTO, they also recognized that the fundamental conflict over Article 68 remains unresolved. In the meanwhile, however, Brazil's law remains in force, and India retained a similar provision in final amendments to the Patent Act. Thus, it is fair to conclude that developing countries can include local working provisions in their patent regimes without violating TRIPS.

Before proceeding, however, more discussion of the US-Brazil conflict is worthwhile, for the entire affair underscores the salience of CLs as tools of industrialization and not just mechanisms to lower drug prices and promote public health. The US challenge to Brazil's IP regime has been portrayed as an attack on Brazil's public health strategy and as an instance where activist campaigning and negative publicity led the US to drop its case. Both interpretations are misleading, and probably wrong. With regard to the substance of the conflict, note that Brazil has two CL clauses, one for public health (Art. 71) and one for local working (Art. 68). The US acknowledges that the former is acceptable under TRIPS, but objects to the latter, which, US officials complain explicitly, is about industrial promotion. According to the USTR's 2001 Special 301 Report on IP practices, "should Brazil choose to compulsory license anti-retroviral AIDS drugs, it could do so under Article 71 of its patent law, which authorizes compulsory licensing to address a national health emergency, consistent with TRIPS, and which the United States is not challenging. In contrast, Article 68 – the provision under dispute – may require the compulsory licensing of any patented product, from bicycles to automobile components to golf clubs. Article 68 is unrelated to health or access to drugs, but instead is discriminating against all imported products in favor of locally produced products. In short, Article 68 is a protectionist measure intended to create jobs for Brazilian nationals" (USTR, 2001: 10). Thus, at the heart of the US challenge to Brazil was a conflict over industrial strategy and developing countries' capacities to mediate their terms of integration into the international economy. In fact, as indicated in the 2000 Special 301 Report, where the USTR explained the rationale for the challenge in the first place, the US sought "to address the concern that other countries may cite the Brazilian 'local working' requirement as a justification for proposing similar legislation" (USTR, 2000: 7).

And with regard to the "resolution" of the case, in particular the US change of strategy, while there is no doubt that the US received relentless criticism from all quarters for its perceived attack on Brazil's HIV/AIDS treatment program, a more plausible explanation for why the US dropped the case is because it feared that Brazil would win. Indeed, the Brazilian government responded to the US challenge by pointing out that various provisions in US patent law also discriminate against non-nationals and violate Art. 27.1 of TRIPS. To be sure, the US government may have been attempting to quiet its

critics when it chose not to press forward with the challenge, but it is also clear that leaving the issue unresolved in the form of a joint communiqué was preferable to losing the case and having a pro-industrial strategy precedent set.

Although developing countries that are compliant with TRIPS retain significant rights to use CLs as policy instruments, these rights are seriously circumscribed in most PTAs. The trick is to fuse the conditions and grounds into specific and exclusive *circumstances* under which CLs can be issue. Although not all PTAs 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.”⁴³ 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 PTAs. The strongest restrictions appear to be in the US-Singapore agreement, though similar language has appeared in drafts of the FTAA and the US-Andean PTA.⁴⁴

With regard to local working requirements, the US gets around the problem revealed by the conflict with Brazil by putting more explicit restrictions on CLs directly into the relevant section of the PTA. To explain, Brazil’s local working requirement is clearly within its CL rights under TRIPS Art. 31, but allegedly violates its non-discrimination obligations under TRIPS Art 27. As indicated, one of the problems for the US was that it too is in violation of TRIPS Art 27. PTAs eliminate this problem by proscribing such practices directly. By explicitly listing the limited and exclusive conditions under which CLs can be granted, local working requirements of the sorts found in Brazil’s and India’s patent regimes are prohibited.⁴⁵

In sum, PTAs 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 PTAs 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 that they take certain measures, some PTAs 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 PTAs 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.

Table 4: Exceptions to Private Rights under WTO and PTAs

Issue	Significance	TRIPS Obligations	PTAs
Exceptions to Exclusive rights	<p><i>Automatic exceptions that are available to anyone without request or authorization or compensation.</i></p> <ul style="list-style-type: none"> • These exceptions allow third parties to use patented goods and the knowledge disclosed in patents. • Degree and nature of exceptions important for local innovation and introducing competition • Early working (Bolar) provisions bring generic drugs into market more quickly and are thus a key part of public health • Third-party access to test data 	<p><i>The language of Art 30 is vague and general, leaving significant room for variation.</i></p> <ul style="list-style-type: none"> • Experimentation allowed, including commercial • Early working does not have to be linked to extension of patent term • Limited protection of test data (Art 39.3) 	<p><i>Extensive data protection</i></p> <ul style="list-style-type: none"> • Minimum five year prohibition on government authorities using submitted data for regulatory approvals • Linking regulatory approvals to patent status
Parallel importation	<p><i>Permits arbitrage and thus reduces ability of patentee to engage in price discrimination</i></p> <ul style="list-style-type: none"> • Question of national or international standards of exhaustion • Can lower prices of patented drugs, so particularly important for public health dimension 	<p><i>Countries can choose standards for exhaustion and allow parallel imports</i></p>	<p><i>Parallel importation prohibited</i></p>
Compulsory Licenses	<p><i>Government allows third party to produce the patented good without the consent of the patentee</i></p> <ul style="list-style-type: none"> • Historically used (or threatened) to combat patent abuse and induce licensing • Key for lowering prices • Important contribution to technological transformation if structured to encourage local manufacturing by foreign patentees 	<p><i>Countries can determine own grounds for compulsory licenses so long as they meet set of conditions</i></p> <ul style="list-style-type: none"> • Compulsory licensing on grounds of public health acceptable. • Legality of “local working” requirements debated but appears acceptable 	<p><i>Compulsory Licenses restricted to extremely limited set of circumstances</i></p> <ul style="list-style-type: none"> • Declared national emergency • Local working requirements prohibited

Limitation 3: The Duration of Private Rights

Lastly, TRIPS makes private rights more permanent as well, by granting longer patent terms of a minimum 20 years from the date of application. Efforts to reduce terms would almost certainly be in violation of TRIPS and invite consultations and dispute resolution at the WTO. Thus, policy flexibility in this area is essentially negative – developing countries cannot shorten terms, but they can refuse to take steps that would 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. While one could only evaluate the merit of such claims on a case-by-case basis, as a matter of policy, developing countries may chose not to grant extensions or to place firm limits on any such extensions.

PTAs 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, or new uses. Again, the issue is not whether or not countries should grant extensions on any given drug at a given time, something that can only be determined on a case-by-case basis, but whether countries should become party to an agreement that obligates them to do so automatically and that restricts their ability to place limits on the full periods of *de facto* protection.

Issue	Significance	TRIPS Obligations	PTAs
Duration	<p><i>Shorter patents bring ideas into public domain more quickly</i></p> <ul style="list-style-type: none"> • Countries typically varied patent duration by product • Key for pharmaceuticals: patenting firms seek to restore time lost while acquiring regulatory approval 	<p><i>Patents for 20 years from date of application</i></p> <ul style="list-style-type: none"> • Minimum period, uniform across sectors • Extensions not required 	<p><i>Automatic Extensions required, generally uncapped</i></p>

Two key points should stand out from the preceding contrast between the space for IP management available under the WTO and that available under PTAs. First, one need not be an enthusiast or advocate of TRIPS to acknowledge that developing countries retain important opportunities for policy innovation in the field of IP. This is the case

with regard to the promotion of public health and biodiversity, as well as technological transformation and industrial development. 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 creative and forward-looking governments can create TRIPS-compatible patent regimes that, by facilitating use and focusing on adaptation and learning, are appropriate for late development.⁴⁶ The second take-away is that these opportunities are radically reduced, if not eliminated, by PTAs. 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 – PTAs place significantly more burdensome and onerous obligations on developing countries than TRIPS does.⁴⁷ Whereas TRIPS represents a worrying step toward harmonization, PTAs step over the line and enter the danger zone. Indeed, the most profound threats to developing countries’ abilities to use IP management for national development purposes are found in PTAs. These agreements threaten the very rights secured under TRIPS.

III. Looking Forward: Policy Recommendations

Recommendation 1: Consolidate Gains

While eliminating or significantly revising TRIPS may not be feasible (though perhaps desirable), efforts should also be made to protect and consolidate the remaining opportunities for policy innovation. This logic should inform developing countries’ approaches toward three of the issues currently on the agenda in the TRIPS Council: public health, patenting life forms, and non-violation complaints.

- Developing countries should continue to seek formalization of the temporary waiver agreed in August 2003 regarding the supply of medicines produced under compulsory license. This is probably not an urgent matter, for the August 2003 settlement is likely to be treated by all WTO members as if it were a formal amendment to TRIPS, but so long as formalization of some sort is on the agenda, developing countries would do well to prevent backsliding. Critically, developing countries must ensure that the waiver to Article 31.f is not limited to a particular set of diseases.
- Likewise, developing countries might wish to make permanent the exceptions to patent scope set forth as temporary provisions in Article 27.3.b. Here too, this is probably not an urgent matter, as the principal demanders of stronger IP protection in PGRFA appear to be comfortable with the status quo. So long as this issue remains on the agenda, however, developing countries need to make sure that their rights to limit patents in genetic resources are not further eroded. Importantly, developing countries must ensure that non-UPOV systems for plant variety protection remain acceptable under TRIPS.

WTO members have agreed that countries cannot be challenged for actions in the area of IP that do not violate TRIPS, even if those actions hurt other parties. TRIPS included a five-year moratorium (until 1999) on such “non-violation complaints,” which has since been renewed. Many developed countries would like to end the moratorium. Developing countries should emphatically reject this proposal. After all, the USTR’s Special 301 report on IP practices is an annual laundry list of non-violation complaints. One (perhaps the only) advantage of integrating IP in the international trade system was to create international standards and multilateral procedures, to make US and European bilateralism less salient. Defending the relevance of TRIPS as the international standard, rather than “TRIPS Plus” standards demanded by the US, has been the developing countries’ major accomplishment in the post-Uruguay Round period (Shadlen, 2004). Opening the door to “non-violation complaints” would mark a major step in the wrong direction.

Recommendation 2: Strengthen the WTO to Dampen Proliferation of PTAs

Developing countries should recognize that the WTO, for all its warts, is the best framework available and, moreover, the strongest bulwark against the proliferation of PTAs. A WTO that works as a forum for coordinating trade policies and resolving disputes can decrease the attractiveness of bilateral and regional accords and give developing countries reliable alternatives to the US. Critically, expanding market access in the WTO by increasing the sectoral scope of trade liberalization and reducing MFN tariffs dilutes the preferential access that comes with PTAs, and thus can diminish enthusiasm for such agreements.

But developing countries will not get better market access for nothing. They will have to make concessions. Thus, to the extent they have an interest in addressing the underlying dynamics driving the proliferation of PTAs, they have an interest in serious bargaining and negotiations at the multilateral level. That means building coalitions, actively participating in negotiations in multiple arenas, and brokering compromises among themselves and with developed countries. Developing countries will not be able to dictate subsequent agreements, of course, but the realization that an unstable WTO contributes to the proliferation of PTAs and an even more threatening global IP environment should focus energies on making the WTO work better.

Of course, broader concessions on services, for example, or symmetrical trade liberalization, may elicit more market access at the multilateral level and thereby dampen the proliferation of IP-excessive PTAs, but it is not at all clear that the subsequent multilateral trade regime that all this bargaining might produce would be propitious for developing countries. Hence the importance of building strong and coherent bargaining coalitions.

Recommendation 3: Clarifying the Link Between TRIPS and the Convention on Biodiversity(CBD)

The relationship between TRIPS and the Convention on Biodiversity (CBD) has been a contentious issue throughout the Doha round. In March 2004, a group of developing countries submitted a formal paper to the TRIPS Council to establish guidelines for subsequent negotiations on three core provisions of the CBD: disclosure of origin, prior informed consent, and benefit-sharing. Specific papers on each topic have been submitted at subsequent quarterly meetings of the TRIPS Council.

The developing countries have pushed the hardest with regard to disclosure of origin. TRIPS allows countries to make disclosure obligations part of national patent regimes (though, as indicated, this is prohibited in many PTAs), but, it is argued, this does source countries little good since the commercialization of the inventions based on biological resources occurs in OECD countries. Thus, to prevent uncompensated use of their genetic resources (“biopiracy”), developing countries seek to amend TRIPS to make disclosure of origin part and parcel of patenting in all countries. This campaign, not surprisingly, has been fiercely resisted by the leading developed countries, particularly the US and Japan, producing deadlock in the TRIPS Council.

Led by Brazil, India, and Peru, the developing countries have continued to keep the CBD-related issues on the WTO agenda. The political reality suggests they are not likely to make much progress on this front, for disclosure of origin obligations would entail amending TRIPS (particularly Articles 27 and/or 29), and the experience of the Doha Declaration on TRIPS and Public Health suggests that developing countries are more likely to succeed in gaining clarification of and compliance with existing regulations than securing changes to the agreement itself. To be sure, developing countries may wish to keep the issue alive, to bring attention to their concerns over fair and equitable use of biological resources. Yet it is worth noting that some scholars – including those who are quite sympathetic to the concerns of developing countries (e.g. Dutfield, 2005a and 2005b) – suggest that pressing ahead on disclosure of origin obligations in the WTO may not be worth the effort. After all, the term “biopiracy” is used to refer to activities that should be proscribed (and Peru submitted a paper to the TRIPS Council in March 2005 which documented its efforts to combat such activities), but it is also used at times to refer to activities that are (or should be) legitimate and encouraged. Moreover, Dutfield (2005a) suggests that careful examination would most likely reveal fewer cases of the former than commonly thought, and even in those instances, it is not clear that amending TRIPS to require disclosure of the source of relevant materials would have had the intended effect.⁴⁸

An alternative (though closely related) proposal is to require patent applicants to submit a certificate from the source country verifying that genetic resources were acquired properly and in conformity with the Bonn Guidelines of Access to Genetic Resources. The certificate would not be included in the specification – i.e. would not be part of the application judged by examiners – but would instead be part of the application process, akin to examination and renewal fees (Dutfield, 2005b). This is close to what

India proposed in October, and developing countries should push to keep it on the agenda.

Ultimately, the bottom line is that the overwhelming share of the world's genetic resources are in the global south, while the technology to commercialize these resources and the markets that make commercialization worthwhile are in the north. The objective, of course, is not to freeze the use of such resources, but to encourage additional research.⁴⁹ Thus, developing countries should continue to seek rules that promote necessary collaboration and develop indigenous technological capacity to maximize the developmental payoffs of national biodiversity. To the extent that multilateral negotiations provide opportunities to advance these development goals, they should be exploited.

Recommendation 4: Reform DSM to make TRIPS a Strategic Asset

Developing countries should also continue their efforts to introduce IPR-linked retaliation in reforms of the dispute settlement mechanism (DSM). Although the DSM's findings are binding, compliance and enforcement remain national-level affairs: if a country does not change its practices and enter into conformity with WTO rules, aggrieved countries are authorized to enact retaliatory trade sanctions against the violator. From a North-South perspective, one of the principal limitations of the DSM is that this enforcement mechanism, trade sanctions, may not be feasible for developing countries to use against developed countries, given the asymmetry in trade dependence. For most developing countries, for example, their imports from the US or the EU amount to a much greater share of total imports than American or European exports to that country amount to their total exports. If a developing country were to enact retaliatory trade sanctions against the US in response to the latter country's violation of a WTO agreement, for example, a large part of the developing country's economy would be affected, for better or worse, but US trade officials would hardly notice.

Some proposals for reforming the DSM focus on giving developing countries more useful enforcement mechanisms, one of those being the ability to withhold or suspend IP protection. Think of the agreements in the WTO as embodying an exchange, whereby developing countries receive improved access to developed countries' markets and developed countries receive improved treatment of their IP in developing countries. Suppose one side fails to live up to its commitments and is judged by a dispute settlement panel to be in violation of an agreement. Developed countries can retaliate by denying market access to the guilty party, thus removing precisely the benefit that makes WTO membership appealing. A reformed system would, in the inverse situation, allow developing countries to retaliate by withholding what the developed country most values: protection of IP. Were a developing country to respond to a US violation in this way, US trade officials would indeed take notice.

The WTO does allow cross-retaliation, such as the use of TRIPS to retaliate against a violation of GATT or GATS, but only when the aggrieved party can demonstrate that it is necessary, because retaliation within the same agreement is either

impossible or would inflict additional damage on domestic interests. Such requests must be approved.⁵⁰ Developing countries should seek a reform to the DSM that would permit cross-retaliation without the need to request permission.

Recommendation 5: Improve TRIPS mechanisms for Technology Transfer

Developing countries should seek to strengthen the technology transfer (TT) requirements that exist in TRIPS. The issue here is that while TRIPS establishes technology transfer as an objective (Article 7) and even requires developed countries to encourage and promote TT toward the Least Developed Countries (Article 66.2), the obligations are not binding in an effective sense. The asymmetry is noteworthy: the threat of DSM looms large for developing countries that fail to meet their TRIPS obligations in terms of adopting and implementing the new minimal standards, but developed countries do not fear such legal sanctions for failing to meet their own obligations in terms of promoting TT.

Often the reason cited for this discrepancy is an asymmetric capacity to use the DSM, but that is probably not a sufficient explanation. After all, developing countries have become regular users of the DSM in other areas, so ability to access the system must not be the impediment. Rather, the problem is derived from the ambiguity of the obligation to promote technology transfer. Unlike the specific obligations for establishing and protecting IP, no such specificity exists in terms of promoting TT. Indeed, the lack of any clear operational definition of TT only furthers the problem. If pressed, officials from developed countries would maintain that they do promote TT via disclosure and promoting secure property rights.⁵¹ In other words, since there is no clear sense of what it means to “promote TT,” nor a strong sense of the relationship between IP and TT (Correa, 2005; Maskus, 2004), it is possible for any developed country government to claim that its actions are intended to have the effect of TT promotion. Developing countries can and should press for clear and specific delineation of developed countries’ obligations in the area of TT.

Recommendation 6: Reforming and Restructuring Technical Assistance

Developing countries should push strongly for fundamental changes to the amount and form of technical assistance. Developed countries have already committed to providing technical assistance, but the amount and form of such assistance is not clear, nor are the mechanisms for providing such assistance adequate.

Most immediately, developing countries should seek to establish explicit targets to use as reference points. Even if these are informal (i.e. not legally binding commitments, which would be unacceptable), such targets can serve as useful reference points.

More critically, developing countries should push for revisions to how technical assistance is provided. Currently, “technical assistance” and “capacity building” takes the form of officials from WIPO, USPTO and EPO (along with aid agencies) advising

relevant officials and judges in the developing world on IP matters and assisting countries in implementing their TRIPS obligations. This assistance is neither “technical,” in the sense of their being a standard set of practices that need only to be understood and implemented, nor “neutral” (May, 2004). To the contrary, “technical assistance” and “capacity building” are intensely political, and their effects are distributional.

A logical recommendation derived from this paper is that technical assistance should not come from developed countries, which push developing countries to exceed their TRIPS obligations, but rather from developing countries that have reformed their IP regimes and thus fulfilled their TRIPS obligations, but have done so in ways that continue to promote development objectives. Again, Brazil and India should be held up as models, and technical assistance and capacity building programs should be geared to assist countries to act similarly.

Given that the WTO lacks the capacity to provide technical assistance, this issue will be referred principally to WIPO. Thus, developing countries should continue to push for changes to WIPO’s orientation and mission.

Ken Shadlen is Lecturer in Development Studies at the Development Studies Institute (DESTIN) at the London School of Economics and Political Science; inquiries can be directed to k.shadlen@lse.ac.uk.

ENDNOTES

¹Other forms of IPRs include plant breeders' rights and utility models, both of which are closely related to patents, along with geographical indications and trademarks.

²This is an important point to note, as it is often overlooked in popular discussions of IP. When policymakers and patent owners from the US complain that the Indians, for example, "don't protect our patents," their complaint is misleading, for by definition patents granted in the US have no legal standing in India. More accurately, the "they don't protect our patents" complaint is shorthand for saying that other countries do not afford the same rights as the US does to knowledge that the USPTO has established to be IP (i.e. "their IP systems are different from ours"!).

³These three dimensions are typically lumped together to form composite measures of "strength" of IPRs. Countries that make private property rights easier to obtain, more absolute, and last for longer periods of time score relatively higher – they have "stronger" IP. My discussion of the three limitations allows me to unpack and disaggregate conventional measures of strength.

⁴Indeed, IPRs aim to stimulate the creation of new knowledge by restricting access to existing knowledge.

⁵For such countries, the relationship between strength of IPRs and innovation is more linear, closer to curve C in Figure One. But even this relationship only holds to a point: even in wealthier countries, if IPRs become too strong, innovation can be stifled (Jaffe and Lerner, 2004; Heller and Eisenberg, 1998; David, 1993; Merges and Nelson, 1990).

⁶See, among others, Drahos (1995); Matthews (2002); Ryan (1998); Sell (1998, 2003).

⁷Although clearly at the forefront of the drive to link IPRs to trade, the U.S. did not act alone. The EU's 1984 "New Commercial Policy Instrument," which is like Section 301 in authorizing trade sanctions against countries involved in acts of "illicit trading," also includes inadequate protection of EU firms' IP as an actionable offense (van Bael and Bellis, 1990: 336-339). Matthews (2002) and Pugatch (2004) both analyze the role of business lobbyists in shaping European policy toward IP.

⁸The reigning (but not unquestioned) logic underlying the new approach is that increasing the security of IPRs will attract foreign investment and make patent holders more willing to transfer technology via licensing arrangements. I discuss this more in the conclusion.

⁹Article 66.1 gives the least-developed countries the right to request a ten-year extension of the transition period.

¹⁰For more discussion, see Shadlen (2004). In contrast to misinterpretations that the Doha Declaration weakened TRIPS (e.g. Pugatch, 2005), I emphasize that this agreement neither added to nor subtracted from developing countries' IP obligations under the WTO (indeed, that was the litmus test that the US applied throughout the entire negotiating process), but clarified and reaffirmed rights that developing countries already had under TRIPS. Both authors argue that the US and EU seek PTAs because they are unsatisfied with the level of IP protection secured under TRIPS, but our different interpretations are informed by different causal logics. For Pugatch, PTAs allow US and EU to compensate for the erosion of TRIPS; for Shadlen, PTAs allow US and EU to compensate for what they regard as the inadequacy of TRIPS. The differences are subtle but crucial. It is not the weakening of TRIPS per se that has driven the US and EU toward PTAs, but rather, the fact that developing countries have asserted (and, at times, exploited) their rights under TRIPS.

¹¹See, among others (and by order of publication), Maskus, 1997; Drahos, 2001; Vivas-Eugui; 2003; Oxfam, 2004; Roffe, 2004; El-Said, 2005; Dutfield, 2005c; Shadlen, 2005a.

¹²In the Americas, the US has agreements with Chile, Mexico and Canada, and five countries of Central America plus the Dominican Republic. Negotiations are underway with Colombia, Ecuador, and Peru (with Bolivia as observer), and also Panama. 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 PTAs 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, Singapore, and Thailand. See www.ustr.gov/Trade_Agreements/Section_Index.html

¹³In the 1800s and early 1900s, many countries did not grant patents at all, and many did so only to nationals. See Machlup and Penrose (1950), Schiff (1971), Chang (2002).

¹⁴Countries that did not previously grant patents on pharmaceuticals and agricultural chemicals were given until 2005 to begin doing so.

¹⁵Typically one year, but the precise time varies.

¹⁶It is important to clarify that TRIPS also has a requirement for pipeline protection for drugs with priority dates after 1995. Countries that were phasing in the introduction of product patents on pharmaceuticals were required to accept patent applications in a “mailbox” and, at the point when patenting became available, consider applications according to their original priority dates. But TRIPS does not oblige countries to grant patents or even accept mailbox applications on drugs that existed *prior* to 1995, only to drugs that came on the market post-1995. Countries with pipeline protection extend retroactive patenting back beyond 1995.

¹⁷The word “invention,” one of the cornerstones of IP, is not defined in TRIPS.

¹⁸Personal communication with Shamnad Basheer, 13 November 2005.

¹⁹Note, 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 and immutable obligation – albeit a new one – and an area where the US exerts considerable pressure (Shadlen, Schrank, and Kurtz, 2005).

²⁰Correa (2003b) discusses options and provides examples of from Brazil, Costa Rica, India, and the Andean Group (Box 1).

²¹Another example of harmonization is the inclusion of the same definition of “utility” that is used in the USPTO’s *Utility Examination Guidelines* into the CAFTA. However, in this particular instance, the definition of utility that all CAFTA parties are obliged to adopt actually raises the bar and provides more grounds to deny patents. It is a rare instance of downward harmonization (Morin, 2004).

²²Not surprisingly, disclosure of origin has been a point of contestation in the PTA negotiations between the US and Colombia, Ecuador, and Peru. The South American countries, as members of the Andean Pact, have requirements that may remain permissible.

²³Note that there is little evidence that the stronger patent protection introduced in Japan in the 1980s increased the level of innovation (Sakakibara and Bransteller, 1999).

²⁴Contrasting India with the rapidly developing countries of East Asia, Kumar (2003) attributes the development of India’s large and robust domestic pharmaceutical industry to the

decision to make drugs ineligible for product patents (an uncontroversial point made by many), but also attributes the comparatively poor performance of the domestic mechanical engineering industries to the absence of utility models.

²⁵Data on file with author, from INPI.

²⁶Because of their open-ended and automatic nature, these sorts of exceptions tend to be limited (e.g. private non-commercial use, educational use, research and experimentation).

²⁷The relevant articles in TRIPS are Article 30 (general exceptions) and Article 31 (specific exceptions).

²⁸In the EU-Canada case, the WTO Appellate Body approved commercial experimentation but ruled that for Canada to permit generic firms to engage in actual production and stockpiling of the new products prior to the expiration of the patent was a violation of TRIPS.

²⁹The emphasis here is on cost. Obviously there would also be critical ethical issues raised by the replication of clinical trials with control groups.

³⁰Reichman, 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” (2004: 11-12).

³¹Estimates 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.

³²Correa (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 a 1990 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, from the “Dunkel Draft of 1991” and from the TRIPS agreement itself.

³³For 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 PTAs (Pugatch, 2005).

³⁴“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 Mickey Kantor (Kantor 2005).

³⁵Related to data exclusivity regulations are provisions included in some PTAs 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 not be illegal), observers have raised a number of concerns. First, they place a legal responsibility on government agencies whose remit is not patent law but health and safety regulation. Second, the burden of defending a patent is partially transferred from the private rights-holder to the public.

³⁶Countries 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.

³⁷Later 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 the former article and in doing so reaffirms countries' freedom to select their own standards of exhaustion.

³⁸Paragraph 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."

³⁹Readers in the US should note the on-going conflict over whether American citizens should be allowed to purchase drugs from pharmacies in Canada and import these drugs into the US. This is a conflict over parallel importation.

⁴⁰In fact, the only time grounds are mentioned explicitly is in Art 31.k, which addresses CLs to remedy anti-competitive practices – and this clause *suspends* some of the aforementioned conditions (e.g. prior negotiations are not necessary and the CL does not need to be "predominantly" for domestic use).

⁴¹Not surprisingly, these apparently contradictory clauses have led to conflicting interpretations. Correa (1999: 9) notes that the preamble of the TRIPS Agreement, as well as Articles 7 and 8, states that the promotion of technology transfer is one of the overriding objectives of the agreement, and that all subsequent articles are to be read in the light of these objectives. To the extent that having the ability to issue a compulsory license on the grounds of the patent holders' failure to work the patent locally can be an effective means to achieve technology transfer, then such measures would be compatible with TRIPS. Furthermore, a number of scholars note that Article 5A of the Paris Convention, which remains in force under TRIPS (Article 2.2 stipulates that nothing in TRIPS derogates provisions of the Paris Convention), allows countries to define non-working in this way. Other scholars reject these interpretations. Watal (1999: 110), for example, though acknowledging the disagreement and ambiguity, points out that during the course of the Uruguay Round negotiations, Art 27.1 was intended precisely to prevent governments from forcing local manufacturing through the use of compulsory licenses, and the Vienna Convention on International Treaties suggests that the original intent of a given clause should be used to guide subsequent interpretations.

⁴²Brazil's patent law provides "a good test on the extent to which working obligations are admissible in the framework of article 27.1 of the TRIPS Agreement" (Correa 2000b: 857).

⁴³Of 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 PTAs.

⁴⁴The language on CLs in the US-Morocco PTA, 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 PTA] 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).

⁴⁵I 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.

⁴⁶Thus, the passages regarding TRIPS in Wade (2003: 623-627 [Gallagher, 2005: 82-86]), which are based on my work and which I co-authored (Wade, 2003: footnote 6 [Gallagher, 2005: 100, note 5]), are incomplete and misleading.

⁴⁷I discuss the differences between WTO and bilateral-regional restrictions on policy space more generally in Shadlen (2005a). Another way that PTAs affect IP management, which does not fit neatly into any of the three dimensions, is that US PTAs include investment agreements with investor-state arbitration clauses. Importantly, investment is defined to include IP, and any regulation on patent-holders’ rights that could be construed as diminishing the value of their assets (“investments”) could be grounds for a lawsuit.

⁴⁸“It may be better to target IP rulemaking in other areas...where the stakes are likely to be much higher than to push aggressively for the introduction of an international disclosure of origin rule that may in fact offer little practical benefit to any national economy or population” (Dutfield, 2005a: 1).

⁴⁹By way of caution, see, for example, the critical comments made by national researchers about Brazil’s tight regulations of genetic resources in “Is Brazil beating biopiracy or biodiversity research?” (*SciDev.net*, 1 November 2005).

⁵⁰Indeed, Ecuador had such a request approved for cross-retaliation against the EU but did not act. More recently, Brazil formally requested permission from WTO to use IP sanctions to punish the US in the dispute over cotton subsidies (“Brazil Asks to Suspend TRIPS, GATS Rules in U.S. Cotton Retaliation,” *Inside US Trade*, October 7, 2005), though this request was ultimately suspended after negotiations between the two countries.

⁵¹Art. 66.2 does not actually refer to IP, so developed countries can claim to be fulfilling their requirements with virtually any action.

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