3. Harmonization, differentiation, and development: the case of intellectual property in the global trading regime

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One of the most enduring points of conflict in the global political economy is whether international economic rules and regulations should accommodate diversity or encourage harmonization of regulatory institutions. The logic of differentiation is that optimal regulatory design differs according to national needs and conditions. The logic of harmonization, in contrast, is that the transaction costs imposed by regulatory diversity impede cross-border investment and trade.

Though international economic regimes in the decades following World War II reflected both the logics of differentiation and harmonization, the former largely prevailed. Members of the General Agreement on Tariffs and Trade (GATT), for example, established basic rules and procedures for coordinating ‘trade’ policies, but the issue-area was narrowly defined such that countries retained virtually unlimited discretion over national regulatory institutions – even those regulatory arrangements that might affect trade flows. The logic of differentiation was even more evident with regard to developing countries: many were not members of GATT, and those that were received ‘special and differential treatment’ (SDT). By exempting developing countries from obligations of reciprocity, for example, poorer countries could undertake activities that were prohibited in the case of wealthier countries (Finlayson and Zacher, 1981; Tussie, 1987).

Since the early 1980s, the logic of harmonization has increasingly come to inform international economic regimes. Multilateral trade negotiations have broadened the definition of ‘trade’ and introduced international disciplines on a variety of regulatory practices defined as ‘trade-related.’ Countries now subject to multilateral supervision not just tariffs and other non-tariff measures that have readily observable effects on trade flows (so-called ‘border issues’), but also institutional arrangements that deeply
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affect the way national economies operate. Thus, in addition to a new set of agreements on trade in goods, the Uruguay Round, which led to the creation of the World Trade Organization (WTO), produced new agreements on subsidies, the regulation of foreign investment, trade in services (which addresses investment in financial services, telecom, and utilities infrastructure), and policies regarding intellectual property (Hoekman and Koestecki, 2001). Importantly, the dominant notion of SDT for developing countries that is incorporated into these agreements is not to set different obligations for countries at different level of development (i.e. the logic of differentiation), but rather to establish transition periods for implementation of uniform obligations (i.e. the logic of harmonization).

The trend toward regulatory harmonization is particularly marked in intellectual property (IP). National IP laws, such as those regulating copyrights and patents, affect how private and public actors within countries absorb, adopt, and create new knowledge. Historically, differentiation has been the rule: the treatment of IP was regulated by international agreements that afforded countries a significant degree of discretion and flexibility in designing their national regimes; and national IP institutions typically corresponded to levels of economic development and innovative capacities, with wealthier countries seeking to reward those actors involved in knowledge creation and commercialisation and poorer countries seeking to promote use and dissemination of new knowledge.

Since the 1980s, international governance in IP has undergone a sea change in the direction of harmonization. Reflecting a goal to universalize OECD-style IP protection, the United States and European Union worked to establish a less flexible and more enforceable set of international rules to guide national IP practices. The most important product of this campaign was the inclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as part of the new WTO. The logic of harmonization is clearly visible in TRIPS: rather than expecting variety in IP policies to correspond to levels of economic development, strong protection of IP is regarded as a driver of – and prerequisite for – economic development, and thus uniformity of treatment is deemed appropriate for countries at all income levels.

But moving toward harmonization and achieving harmonization are different matters, and it is the former that describes contemporary arrangements in IP. TRIPS constrains differentiation by establishing universal IP standards, but countries retain a wide degree of latitude with regard to how they implement the standards. Thus, while TRIPS is part of a broader phenomenon of a movement toward regulatory harmonization, a phenomenon that imposes significant constraints on areas of economic policy where countries historically had significant autonomy (UNDP, 2003; Gallagher,
developing countries retain space for autonomous IP policymaking (Reichman, 1997; Correa, 2000; Watal, 2000; CIPR, 2002).

More than a decade after the introduction of TRIPS, the governance of IP, including on-going conflicts between differentiation and harmonization, remains a politically charged issue. Many developing countries, seeking to use IP policies as tools for achieving broader development goals, have sought consolidation and confirmation of the flexibilities that remain under TRIPS. The Doha Declaration on TRIPS and Public Health, for example, was the result of a coordinated campaign by developing countries to gain clear affirmation of rights set forth in TRIPS (‘t Hoen, 2002; Shadlen, 2004). At the same time, many developed countries regard the standards for IP protection established by TRIPS as too weak and too easily circumvented; they are not satisfied with constraining differentiation, and instead seek to harmonize IP standards at a higher level. Thus, developed countries – especially the USA – have continued to apply direct pressure on countries to exceed their obligations under TRIPS. Most visibly, the USA secures heightened IP protection through regional and bilateral trade agreements (RBTAs), which 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 (Shadlen, 2005).

In this chapter I analyse the case of IP as an on-going conflict in the global political economy over harmonization of regulatory institutions. I begin by examining the relationship between IP and development. I then show how the trend toward harmonization places new and significant restrictions on developing countries’ opportunities for policy innovation in IP policy, considering the implications of harmonization for a range of issues, including late industrialization and the promotion of public health. I show that the new restrictions are most accentuated at the regional and bilateral level, where harmonization is not merely a goal sought by more developed countries but increasingly an outcome achieved. Indeed, the proliferation of RBTAs presents the most significant threat to countries’ ability to use IP policies for national development purposes, as made evident by contrasting the IP provisions in the WTO with the obligations incurred by parties to RBTAs.

Before proceeding, a caveat is in order. It is obviously simplistic to discuss RBTAs as a single entity, as they exhibit considerable differences. The USA and EU, the two principal partners for such agreements, have different priorities in integrating IP into such agreements. But not only do US RBTAs differ from EU RBTAs, but all US RBTAs are not alike either. Indeed, the details of the IP provisions within any given agreement are bargaining outcomes. Thus, general statements regarding IP regulations in RBTAs (US or otherwise) run the risk of distorting via
oversimplification. That said, with regard to virtually any policy area, the
differences between various RBTA.s tend to be less than the differences
between TRIPS and the RBTA closest to TRIPS, so a good deal is illu-
minated with simplifications. Simply stated, too much analysis of the dif-
f erences between RBTA.s without considering how the entire genre differs
from TRIPS would distract our attention from the big picture.

INTELLECTUAL PROPERTY AND DEVELOPMENT:
ECONOMIC TRADE-OFFS IN HISTORICAL
PERSPECTIVE

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 regu-
late. For the purposes of economic analysis, the most important attributes
of knowledge, the underlying good that becomes 'property,' are that it
is imperfectly excludable and non-rivalrous. That a good is imperfectly
excludable means that once an actor gains possession, the good cannot
be taken away. That a good is non-rivalrous means that it can be used
simultaneously by multiple people, and one person's use does not affect
the amount left for anyone else.

The distinct characteristics of knowledge mean that IPRs perform dif-
f erent functions than property rights in other types of goods. One of the
potential effects of establishing property rights over excludable and rival-
rous goods is to promote optimal use. That is, intellectual property rights
make knowledge fully excludable, at least in a sense, by providing owners
with legal rights of exclusion over how actors use 'private' knowledge. The
objective, however, is not to promote optimal use, but rather to stimulate
supply, and the means for doing so is to restrict use. Indeed, a side-effect
of providing rights of exclusion over non-rivalrous goods is to generate
sub-optimal use. Thus, IPRs can encourage knowledge generation and
commercialization by providing incentives for innovation: innovators
can dedicate their time and resources toward developing new products
with confidence that their ability to control distribution and use of the
underlying ideas will allow them to enjoy the returns. But IPRs, by giving
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, prevent knowledge from being disseminated and
used as widely and optimally as possible. In short, IP regimes are imbued
with trade-offs between stimulating knowledge generation and facilitating
knowledge use.
A key point of this brief review is not simply that IP regimes perform multiple functions, to encourage both the generation and use of knowledge, but that a single set of institutions cannot maximize both objectives. That is, IP regimes have two desirable – but unavoidably conflicting – objectives, that knowledge be generated and that knowledge be used. A ‘weak’ IP regime that provides high incentives to use knowledge, for example by denying private rights of exclusion over some types of knowledge or simplifying third parties’ access to privately owned knowledge, may not provide sufficient incentives for potential innovators. A ‘strong’ IP regime that gives innovators high incentives, for example by offering private rights of ownership over more types of knowledge or giving owners more rights of exclusion over knowledge, may impede use; and limited use of knowledge, in turn, can rebound negatively on future innovation, to the extent that knowledge generation is an incremental process (David, 1993; Heller and Eisenberg, 1998).

How countries prioritize the quests for generating and using knowledge has, traditionally, affected where the balance is struck in a given country at a given time. In countries with higher levels of innovative capacity, where more research and development tends to produce new knowledge, economic logic supports setting incentives to encourage and reward knowledge generation. In contrast, in countries with lower innovative capacities, where most new knowledge is that which is imported from abroad, economic logic supports setting incentives to encourage dissemination and use of new knowledge (Frischtak, 1995; Maskus and Penubarti 1995).

To gain insights on the national distribution of innovative capacities, Table 3.1 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 90 percent of all patents granted. Second, the US, Japan, and Germany alone account for nearly 80 percent. Third, the firms and organizations from the top ten developing and transition economies account for less than 7 percent, with more than 5 percent coming from Taiwan and South Korea. The combined total of the next eight highest ranking developing and transition countries is a mere 1.36 percent, slightly more than Italy. Whereas Table 3.1 demonstrates the concentration of knowledge-generation capacities in a handful of developed countries (with the important exceptions of Taiwan and South Korea), Table 3.2, which examines patent applications according to residency of applicant, shows the extent to which developing countries are importers and users of knowledge generated abroad. 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,
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but the asymmetries are even greater in the developing world. Residents account for less than 3 percent of patent applications in middle-income countries and only one-fifth of 1 percent in low-income countries.

Historically, diversity in national IP regimes – both cross-nationally and longitudinally – has corresponded to these basic national characteristics. Wealthier countries, with more innovative capacities have typically offered stronger IPRs than poorer countries. The relationship between national income and the strength of protection is illustrated by the j-curve

<table>
<thead>
<tr>
<th>Table 3.1</th>
<th>Patents granted by USPTO (1997–2004)</th>
</tr>
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<tbody>
<tr>
<td><strong>Top 10 developed countries</strong></td>
<td><strong>Percent of total</strong></td>
</tr>
<tr>
<td>1. USA</td>
<td>53.16</td>
</tr>
<tr>
<td>2. Japan</td>
<td>20.64</td>
</tr>
<tr>
<td>3. Germany</td>
<td>6.50</td>
</tr>
<tr>
<td>4. France</td>
<td>2.39</td>
</tr>
<tr>
<td>5. United Kingdom</td>
<td>2.28</td>
</tr>
<tr>
<td>6. Canada</td>
<td>2.09</td>
</tr>
<tr>
<td>7. Italy</td>
<td>1.03</td>
</tr>
<tr>
<td>8. Sweden</td>
<td>0.91</td>
</tr>
<tr>
<td>9. Switzerland</td>
<td>0.84</td>
</tr>
<tr>
<td>10. Netherlands</td>
<td>0.80</td>
</tr>
<tr>
<td><strong>Sub-total</strong></td>
<td>90.65</td>
</tr>
<tr>
<td><strong>Top ten developing and transition countries</strong></td>
<td><strong>Percent of total</strong></td>
</tr>
<tr>
<td>1. Taiwan</td>
<td>2.87</td>
</tr>
<tr>
<td>2. South Korea</td>
<td>2.24</td>
</tr>
<tr>
<td>3. Israel</td>
<td>0.57</td>
</tr>
<tr>
<td>4. Singapore</td>
<td>0.17</td>
</tr>
<tr>
<td>5. Hong Kong</td>
<td>0.13</td>
</tr>
<tr>
<td>6. China</td>
<td>0.12</td>
</tr>
<tr>
<td>7. India</td>
<td>0.12</td>
</tr>
<tr>
<td>8. Russia</td>
<td>0.12</td>
</tr>
<tr>
<td>9. South Africa</td>
<td>0.07</td>
</tr>
<tr>
<td>10. Brazil</td>
<td>0.06</td>
</tr>
<tr>
<td><strong>Sub-total</strong></td>
<td>6.49</td>
</tr>
</tbody>
</table>

Notes:
a. Total is greater than the sum of the two sub-totals, which only include patents from the 20 countries in the table.
b. High-income country according to World Bank, but classified as ‘developing country’ in TRIPS.

Table 3.2 Patent applications by residency (1997–2002)

<table>
<thead>
<tr>
<th>Income levels*</th>
<th>(%) Non-resident applications as share of total applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>High income</td>
<td>82.28</td>
</tr>
<tr>
<td>Middle income</td>
<td>97.61</td>
</tr>
<tr>
<td>Low income</td>
<td>99.79</td>
</tr>
</tbody>
</table>

* World Bank classifications


Figure 3.1 Differentiation: historical relationship between IP regime and level of development

in Figure 3.1. 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).

TRIPS makes it more difficult for developing countries to tailor their IP regimes to national conditions. Because the new standards focus primarily
on establishing incentives for innovation and knowledge-generation, they limit developing countries’ opportunities to design IP regimes to encourage imitation and technological learning. 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, the least-developed countries were given until 2006 (with the right to request extensions), and special transition periods were included for patenting pharmaceuticals and chemicals (with the least-developed countries also granted additional time). Eventually, when most transition periods are over, developed and developing countries will be subject to the same standards for IP policy, with the poorest countries still remaining exempt from some obligations – a clear reflection of the logic of harmonization. Figure 3.2 illustrates the new relationship between IP regimes and level of development, with the thick grey bars indicating the obligations established by TRIPS.

Notwithstanding the real constraints set by TRIPS, the agreement still leaves room for national variation in how countries treat IP. The borders of the upper bar in Figure 3.2 should be viewed as imprecise. The reasons for this are that the agreement is not self-executing (i.e. countries need to change their own national legislation to enter into compliance), and a number of the most important clauses are ambiguous and open-ended. When countries introduce new laws and institutions to meet their TRIPS obligations, they do so with a great deal of latitude. The result, then, is that countries may exhibit substantial variation in their patent regimes, all while being compliant with TRIPS.

In contrast to TRIPS, regional and bilateral trade agreements tend to eliminate ambiguity and establish very clearly defined obligations on how parties manage IP; and these obligations go beyond those required by even the most ambitious interpretations of TRIPS. The top line in Figure 3.2 represents the harmonization of IP institutions introduced by RBTAs. In the remainder of this chapter I contrast opportunities for IP policy innovation under TRIPS and RBTAs, with specific reference to patents. I organize the discussion around two standard limitations to the private rights conferred by patents: (1) the processes by which private rights to knowledge are obtained; (2) the extent to which private rights are subject to exceptions in the form of compulsory licenses. Within each subsection, I highlight the areas where countries retain opportunities for policy innovation despite their WTO obligations, and provide examples of how some countries have indeed introduced and retained measures that tailor IP management to local conditions and needs, all while satisfying the

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TRIPS:

RBTAs:

Figure 3.2  Constrained differentiation vs. harmonization: IP regimes and development levels under TRIPS and RBTAs

new TRIPS obligations. Moreover, I show how these opportunities are circumscribed by RBTAs: on all dimensions of patent policy, countries that are parties to such RBTAs have significantly less autonomy in their management of IP.

WHAT KNOWLEDGE BECOMES PRIVATELY OWNED?

The first important limitation of patents is that private ownership rights are not conferred automatically upon possession of knowledge. Instead, patents are granted by the state only where applicants demonstrate that their inventions satisfy two sets of criteria: the knowledge must fall within
the range of patentable subject matter; and patent examiners must determine that the knowledge is new, non-obvious, and useful. Because patent examination remains national, and with application central to the process of establishing ownership, governments delineate what knowledge can be owned privately within their territory.

Scope

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, providing local producers with unfettered access to foreign knowledge in key sectors has historically been a critical dimension of strategies for late industrialization, for this can facilitate local firms’ abilities to adapt and build upon foreign innovations. Likewise, patents were often denied to restrain prices, encourage sharing of knowledge, and ensure that local actors (e.g. farmers) could continuously adapt to changing environmental conditions.

TRIPS reduces discretion in setting the scope of patent eligibility. Article 27 requires countries to grant patents of 20 in all fields of technology. 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 principle, countries must offer patents 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 40 countries did not provide any patent protection for pharmaceuticals, while many that did so issued patents only for processes and not for products (WHO, 2002, p. 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. As of 2005, however, all but the least developed countries grant patents on pharmaceuticals and pharmo-chemical and agricultural chemicals.

Examination

In addition to the question of what sort 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 more or less simple to obtain. 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, pp. 114–19).

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, 2005).

Countries also set their own definitions of an ‘invention,’ and as such can deny patents to ‘discoveries.’ That these are such imprecise terms certainly invites abuse, but it preserves opportunities 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). For example, restrictive definitions of invention and discovery have also been used to deny patents to computer software, under the argument that programmers are not inventing new processes but discovering or revealing underlying mathematical algorithms that are part of nature. In fact, the question of whether to grant patents to software has been extraordinarily contentious not just in the developing world but also in Europe (Haunss and Kohlmorgen, forthcoming).

Countries also retain significant leeway to demand strict disclosure requirements. In exchange for exclusive rights obtained by the patent, applicants are required to make their knowledge public. The patent right sets restrictions on what can be done with the knowledge, but anyone can read and thus learn from patents. Patent applicants typically wish to reveal as little of the knowledge as possible in exchange for exclusive rights, but there is a public interest in demanding greater disclosure. The extent to which new knowledge enters the public domain and becomes available for third parties (albeit with serious restrictions on their use of the knowledge), depends on the amount and precision of disclosure that patent examiners demand.
RBTAs can erode these critical spaces for aligning policy to national conditions by exporting examination guidelines, thus removing the ambiguity that exists under TRIPS, and placing caps on the amount and type of information that patent applicants can be required to submit. DR-CAFTA, for example, defines ‘novelty’ in a more expansive way, exporting to all DR-CAFTA parties the more liberal meaning of ‘new’ that is used in the USA, where goods can pass the novelty test and be granted a patent if the knowledge has been made public within the year prior to application (Morin, 2004). RBTAs are also more likely to limit what sorts of disclosure requirements national IP offices can place on patent applicants. Again, DR-CAFTA is illustrative, for the agreement proscribes such requirements by establishing an explicit cap on the type and amount of information that countries can require from applicants (Morin, 2004). Were a Central American country to demand more information than what is necessary to repeat an invention, the country in question would most likely be in violation of its new international obligations.

It is worth underscoring 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 since the mid-1990s, which means that national patent offices are flooded with applications on highly technical matters. For developing countries this raises an issue regarding human resource allocation. Effective patent examiners are highly-skilled and well-trained professionals with technical knowledge, normally with engineering and science backgrounds. Given that such skills are, almost by definition, in short supply in less developed countries 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 discussed in this subsection, patent breadth and utility models. 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 for late-industrializing technological followers (see discussions in Maskus and McDaniel, 1999; Sakakibara and Bransteller, 1999; Maskus, 2000; Chang, 2002; Kumar, 2003).

Utility models (also known as ‘petty patents’) have shorter periods of
protection than patents (seven–ten years rather than 20) for inventions that meet lower standards of inventiveness (i.e. the ‘non-obvious’ criterion is relaxed). 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 policy in developing countries, for the degree of innovation required for protection may 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 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 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 the East Asian countries apart is that they also actively promoted utility models to encourage local firms to make adaptive and incremental innovations.11

Note that neither the WTO nor RBTAs address either patent breadth or utility models. Here too, however, the formal 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, p. 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 are underutilized.

COMPULSORY LICENSES

Patent rights include exceptions to patent-holders’ ability to exert control over the use of their property. One important exception is the compulsory
license (CL), where the government allows a local entity (a private firm and/or government agency) to produce and distribute a patented good without the owner’s consent. CLs have historically been part and parcel of national patent regimes, granted by countries in a wide range of situations (Reichman and Hasenzahl, 2003).

Despite efforts by the USA in the Uruguay Round to radically circumscribe their use, TRIPS continues to leave countries with a significant degree of discretion. Article 31 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 waived in case of national emergency), the CL must be of limited duration (and terminated when grounds leading to CL no longer there), be non-exclusive, be predominantly for domestic market, and the patent-holder should be compensated.

Operationalizing these conditions in terms of national law leaves opportunities with significant room for national differentiation. For example, countries retain leeway regarding how much negotiation for a voluntary license is required before a third party can legitimately request a compulsory license from the state. Third parties must attempt to gain authorization from the patentee, and the state may only grant a compulsory license if negotiations are not successful within a ‘reasonable period of time,’ but the determination of reasonable is left to individual countries. Likewise the requirement that ‘adequate remuneration’ be paid to the patentee, but countries establish their own definitions of ‘adequate.’ During the Uruguay Round negotiations, the USA sought to include a requirement to ‘compensate the right-holder fully’ (Watal, 1999, p. 114), but this language is not included in TRIPS. And in both instances, with regard to negotiations and compensation, TRIPS 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 implement these procedural obligations are the grounds that countries use for issuing CLs. Here it is important to emphasize that TRIPS is silent: countries can issue CLs for whatever reasons they choose. What this means is that so long as the procedural conditions – defined and operationalized locally – are met, countries establish their own grounds for issuing CLs.12

Developing countries’ rights to issue CLs, particularly with regard to public health, were confirmed in the Doha Declaration on the 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 health and access to medicines, the relevance and importance of compulsory licensing goes beyond health. Indeed, if one contrasts contemporary debates over CLs with the previous debates over them that occurred in the 1980s (Sell, 1998, Chapter 4), it is striking how the overarching issues have changed: contemporary debates are about public health, previous debates were about the role of CLs 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.

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 above. First, most patents are held by firms in a handful of countries, reflecting the extraordinary asymmetries in international innovative capacities (see Table 3.1). 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 exclusion granted to foreign patent holders, technological transfer will be minimal. To the extent that governments want to improve local actors’ access to and abilities to learn from foreign technologies, there may be a public interest in assuring that the technologies are used locally. One policy instrument to achieve this goal is to establish failure to produce the good locally as a ground for a CL.

Whether or not countries can establish the absence of local production as a ground for issuing a CL is an unresolved issue in TRIPS. On the one hand, the previous discussion, which indicated countries’ freedoms to establish their own criteria, 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’ (TRIPS, Art. 27.1). The lack of certainty is illustrated by a conflict between the USA and Brazil over the latter’s local working provisions. 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 USA 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 US 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.

Before proceeding, 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 globally admired public health strategy to provide universal anti-retroviral treatment for people living with HIV/AIDS and as instance where activist campaigning and negative publicity led the USA to drop its case. Both interpretations are accurate on the net, but partially misleading. 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), and at precisely the same time as the conflict with the US over the latter was transpiring, Brazil was reforming the former to make CLs simpler. The USA acknowledges that Art. 71 is acceptable under TRIPS, but objects to Art. 68, which, US officials complain – explicitly – is about industrial promotion. According to the USTR’s 2001 Special 301 Report on IP practices:

‘s 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, p. 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, p. 7).

With regard to the ‘resolution’ of the case, in particular the US change of strategy, while there is no doubt that the USA received relentless criticism from all quarters for its perceived attack on Brazil’s HIV/AIDS treatment program, an equally plausible explanation for why the USA dropped the case is because it feared that Brazil would win. Or more accurately, it might lose by winning. After all, the Brazilian government responded to the US challenge by pointing out various provisions in US law also discriminate require local working and thus would violate the US-favored interpretation of Art. 27.1 of TRIPS. To be sure, in choosing not to press forward with its challenge the US government may have wanted to silence its critics, but it is also clear that leaving the issue unresolved in the form of a joint communiqué was preferable to losing the case and allowing a pro-industrial strategy precedent to be set.

Although developing countries that are compliant with TRIPS retain significant rights to use CLs as policy instruments, these rights are circumscribed in some RBTAs, which fuse the conditions and grounds into specific circumstances under which CLs can be issued. Not all RBTAs restrict the use of CLs, but 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.’ And even then, patent-holders are due ‘reasonable and entire compensation’ (much tighter and stronger language than in TRIPS). The precise language varies across RBTAs, with the strongest restrictions in the US–Singapore agreement. The language on CLs in the US–Morocco RBTA, in contrast, is much weaker, a fact that drew the wrath of the US industry group that advises USTR on the IP aspects of trade policy, the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy (IFAC-3).

With regard to local working requirements, the USA gets around the problem revealed by the conflict with Brazil by putting more explicit restrictions on CLs directly into the relevant section of the RBTA. 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 USA was that it too is potentially in violation of TRIPS Art 27. RBTAs 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.

In sum, RBTAs tend to pick up where the WTO leaves off in terms of
limiting developing countries’ abilities to deploy what historically have been standard tools to regulate patent holders. Neither sort of agreement prohibits CLs, but RBTAs establish clear and unequivocal biases against their use – biases that are significantly stronger than in TRIPS. Whereas TRIPS allows governments to issue CLs on any grounds provided they take certain measures, some RBTAs prohibit governments from issuing CLs except in very strictly and tightly defined circumstances.

CONCLUSION

That opportunities for national differentiation in IP policy are reduced under TRIPS and RBTAs is illustrated with reference to the axes of variation utilized in the previous sections: countries must implement measures to make establishment of private rights over knowledge easier to obtain, and the subsequent private rights must be more absolute. Whereas countries could previously deny patents to certain types of inventions so to encourage reverse-engineering and lower the barriers to entry in technologically-intensive sectors, now countries must offer patents in virtually all fields. And whereas countries could make enjoyment of the monopoly rights conferred by patents conditional upon local production or licensing and transferring technology to local users, governments are now limited in how they regulate patent-holders.

Yet a number of key points should stand out from the preceding contrast between space for IP policy available under the WTO and under RBTAs. First, one need not be an enthusiast of TRIPS to acknowledge that developing countries retain opportunities for policy innovation in the field of IP. To point out that TRIPS ‘merely’ introduces ‘constrained differentiation’ rather than harmonization is not to defend TRIPS. The constraints imposed by TRIPS are serious, and many important policy instruments used in the past are now prohibited. TRIPS does usher in a new environment for IP management that has rightfully caused a great deal of consternation among analysts of IP and development (May, 2000; Drahos and Braithwaite, 2002; UNDP, 2003). But governments can create TRIPS-compatible patent regimes that, by facilitating use and being geared toward adaptation and learning, may be appropriate for late development. The second key point is that these opportunities are radically reduced – if not eliminated – by RBTAs, which achieve outcomes closer to harmonization. On both dimensions used to assess IP management – governments’ abilities to determine which knowledge becomes private property and to provide for exceptions to patent-holders’ exclusive rights – RBTAs place more burdensome obligations on developing countries.
The implications for late development of harmonization – in contrast to constrained differentiation – are profound. Whereas TRIPS represents a worrying step toward the danger zone, RBTAs cross over the line. To understand why, it is worth revisiting the foundations of IP and development discussed earlier in this article. IP regimes constitute trade-offs between incentives for knowledge generation and incentives for knowledge use; and because the same set of institutions are not likely to maximize both functions, differentiation allows countries to tailor their IP regimes to national conditions and development objectives. Harmonization, in contrast, creates a world in which all countries adopt IP regimes that are designed to encourage knowledge generation. This change may, perhaps, lead to more technological generation at an aggregate global level – and by lowering transaction costs may make the global economy more efficient and produce aggregate welfare gains.

Yet harmonization has serious implications for development – for late development is and always has been based on borrowing more advanced knowledge and technology. By definition, late-developing countries are not at the knowledge frontier; they need to adapt foreign innovations for local use. Late development is about learning and adaptation: catching-up in the global economy does not occur via technological breakthrough so much as technological imitation and adaptation. Indeed, one of the defining principles of ‘lateness’ is the imperative to industrialize via learning, by borrowing and improving on technologies already developed by experienced firms in more advanced economies (Amsden, 2001). Harmonization makes this more difficult. The threat to developing countries, then, is not only in terms of resource transfers, in that net users of knowledge will have to pay more to net producers of knowledge for access to technological innovations, but that regulatory harmonization in IP may fundamentally block technological progress – and thus development.

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NOTES

1. See, among others, Drahos (1995); Ryan (1998); Sell (1998, 2003); May (2000); Matthews (2002); May and Sell (2005); Shadlen et al. (2005).
2. In the Americas, the USA has agreements (in force or awaiting ratification) with Chile, Mexico, and Canada, five countries of Central America plus the Dominican Republic, Colombia, Panama, and Peru. Plus, of course, there is the hemispheric Free Trade Agreement of the Americas, which would include 34 countries (all the sovereign states of the Americas with the exception of Cuba). Outside the Americas, the list of RBTAs that are either completed or in the process of negotiation includes (by region), the Southern African Customs Union (negotiations suspended); Bahrain, Jordan, Morocco, and Oman (also Israel; the US–Israeli agreement does not include IP provisions); Australia, Malaysia, Singapore, South Korea, and Thailand. See www.ustr.gov/Trade_Agreements/Section_Index.html
3. The line in Figure 3.2 is placed above the earlier curve, for RBTAs do not just harmonize at the level of the wealthier country (e.g. the USA), but rather introduce new obligations on both parties.
4. Of course, many countries do not take advantage of these remaining opportunities. Explaining this underutilization is the subject of other research.
5. In 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).
6. This article introduces a new definition of the term ‘non-discrimination,’ no longer referring to countries’ practices vis-à-vis other countries but rather toward economic sectors.
7. Countries that did not previously grant patents on pharmaceuticals and agricultural chemicals were given until 2005 to begin doing so.
8. After the Swiss pharmaceutical firm Novartis’s application for a patent on ‘Glivec’ (the brand name for its anti-leukemia drug based on the molecule imatinib mesylate) was rejected by the Indian Patent Office in Chennai, on grounds on non-efficacy over existing and known substances, Novartis (unsuccessfully) challenged the TRIPS compatibility of Section 3.d in the Indian courts.
9. The word ‘invention,’ one of the cornerstones of IP, is not defined in TRIPS.
10. Note, however, that not patenting software does not exempt countries from their obligations to provide copyright protection to software as a form of artistic expression. This is a firm and immutable obligation – albeit a new one – and an area where the USA exerts considerable pressure (Shadlen et al., 2005).
11. Contrasting 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.
12. One place 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).
13. Another policy example is establishing restrictive licensing arrangements as a ground for a CL (as Taiwan does), which can help local firms gain access to patented knowledge on better terms.
14. This is a reference to the Bayh–Dole Act, which facilitates patenting of research generated through public funding.
15. Of course, this allows the USA (and other parties) to challenge whether or not countries are experiencing emergencies. Recall that the language of the Doha Declaration, in which countries make their own determinations regarding national emergencies, is not relevant in RBTAs.
16. ‘IFAC-3 notes that the [US–Morocco RFTA] 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, p. 14).
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17. In Shalden (2005) I explain more generally the developmental implications of the trade-offs involved in RBTAs.

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