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Reforming and Reinforcing the Revolution: The Post-TRIPS Politics of Patents in Latin America

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Abstract

National policies toward intellectual property (IP) were revolutionized in the 1990s, as countries adopted new systems to conform to the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). TRIPS-style IP regimes make patents available for more types of knowledge, grant long periods of patent protection, and endow patent owners with strong rights of exclusion. This paper analyzes two contrasting patterns of political mobilization and pressures for change that newly-introduced, TRIPS-style regimes became subject to by the early 21st Century. Most governments faced pressures to address aspects of their IP systems regarding pharmaceutical patents; governments came under pressure to *reform* their new patent systems, calling into question the appropriateness and utility of broad and strong private rights of exclusion as tools for disseminating knowledge. Most governments also faced pressures to modify aspects of their patent systems more broadly related to science, technology, and indigenous innovation (STI); governments came under pressure to *reinforce* their new patent systems, buttressing the role of private rights of exclusion as mechanisms to incentivize the creation and distribution of knowledge and technology. I provide a political explanation for the contrasting trajectories of reform and reinforcement by examining how different policy arrangements generate and mobilize interests for continuity and discontinuity. The focus is on asymmetric patterns of interest mobilization: those actors who benefit from policy interventions tend to mobilize more than those who suffer; those actors who suffer retain the capacities for mobilization and resistance more in the area of health-drugs than STI.[*]

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Reforming and Reinforcing the Revolution: The Post-TRIPS Politics of Patents in Latin America

Kenneth Shadlen

Introduction

Throughout the developing world, national policies toward intellectual property (IP) were revolutionized in the 1990s, as countries adopted new systems to conform to the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). TRIPS-style regimes make patents, copyrights, trademarks, and other forms of IP available for more types of knowledge and information, grant long periods of exclusivity, and endow owners with strong rights of control over the use of their knowledge and information. In this paper I examine two different types of political mobilization and pressures for change that newly-introduced, TRIPS-style regimes became subject to by the early 21st Century. Most governments faced pressures to reform aspects of their IP systems regarding pharmaceutical patents.[1] Though the outcomes of this mobilization are not uniform across countries, the common thread has been for governments to address the consequences of stronger patent protection on the price of medicines and access to drugs. At the same time, most governments have also faced pressures to modify aspects of their patent systems more broadly related to science, technology, and indigenous innovation. Here too we witness cross-national variation in outcomes, but all around a common theme of trying to strengthen local actors' capacities to take advantage of the incentives of patent protection and creating new regulatory frameworks to link publicly-funded scientific research with private industry.

These two trajectories of mobilization and change in the areas of drugs-health and science-technology-innovation (STI) are somewhat contradictory: the first trajectory is about *reforming* the now-regnant systems of IP management, as debates in the case of drugs-health are about limiting the extent and strength of pharmaceutical patents; the second trajectory is about *reinforcing* the new systems, as debates in the case of STI are about extending more rights of private ownership over more types of knowledge. In other words, the utility of establishing and extending private rights of exclusion as tools for disseminating knowledge is questioned in one realm and buttressed in the other. Thus, in revisiting the 1990s' revolution in IP, the post-TRIPS politics of patents has featured both reform and reinforcement.

The different patterns of mobilization and policy change around TRIPS-style IP regimes prompt a set of puzzles that are the focal point of this paper. Patent regimes that restrict the use of knowledge would seem to be of questionable appropriateness for developing countries, far removed from the technological frontier. Most experiences of national development have relied on domestic actors benefiting from minimal restrictions on their access to and rights to use cutting-edge knowledge and technologies. These hallmarks of late development – cultivation and refinement of indigenous capacities via imitation, reverse-engineering, and adaptation of foreign knowledge and technology – appear to be greatly circumscribed by TRIPS-style regimes that erect barriers on the use of knowledge by granting strong rights of

exclusion to patent-holders (Kumar 2002; May 2007). Yet, surprisingly, new patent regimes that restrict the use of knowledge have generated fairly robust constituencies for continuity and extension. In contrast to other studies that report broad-based and robust mobilization around "access to knowledge" (see Kapczynksi 2008), my research on the post-TRIPS politics of patents in Latin America reveals that opposition is more the exception than the rule. Indeed, to the extent that pressures to limit patent rights have emerged, the counter-TRIPS (or "A2K") mobilization tends to be rather narrow and limited, oriented primarily (if not exclusively) toward humanitarian dimensions of IP (e.g. health-drugs), rather than more traditional issues of technological transformation and industrialization (e.g. STI).

I explain this puzzling set of responses to TRIPS by examining how different policy arrangements generate and mobilize interests for continuity and discontinuity. I focus on how policy interventions *strengthen* and *weaken* interests, thus creating positive feedback and minimizing negative feedback, respectively. By strengthening interests I refer to the beneficiaries of a policy accumulating resources, which they can then deploy in the quest for continuity. By weakening interests I refer to those actors who are negatively affected by a policy losing resources and thus experiencing diminished capacity to mobilize in search of discontinuity. These different trajectories of interest mobilization make some sorts of policies more (or less) resilient than others, and thus more likely to undergo reinforcement (or reform).

In this paper I use the notions of strengthening and weakening interests as analytic tools to examine the post-TRIPS politics of IP, with a focus on Latin America's three largest and most industrialized economies, Argentina, Brazil, and Mexico. TRIPs-style regimes strengthen interests and thereby are effective in generating self-sustaining constituencies. For the most part TRIPS-style regimes also weaken interests and thereby are effective in minimizing opposition. Distinguishing between the contemporary politics of IP in the realms of health-drugs and STI, however, reveals slightly different patterns. The process of weakening actors has been less pronounced in the realm of drugs-health: coalitions for discontinuity emerge, and these coalitions yield political mobilization for *reform*. In the realm of STI, in contrast, the strengthening of interests in favor of TRIPS-style IP has been complemented by the weakening of opposing interests: the combination of these two processes means that the winners accumulate resources that allow them to push for continuity while sources of opposition and resistance tend dissipate, resulting in *reinforcement*.

One result of these different trajectories has been that patent policy in the area of health-drugs underwent reassessment in each country in the late 1990s and early 2000s. Though resolved differently, in each country questions of how pharmaceutical patents affect the price of essential medicines gained prominence on the political agenda. Another result of these different trajectories has been that each country has introduced changes to STI systems based on increasing domestic patenting, tightening links between public sector research and commercial enterprises, and encouraging licensing of publicly-funded research outputs. Again, the changes vary from country to country (and not all the changes regard patents and IP), yet the overall thrust, common across countries, is to amplify the role of patents and licensing (i.e. private ownership of knowledge) as mechanisms to encourage innovation and technology transfer. Thus, the outcomes analyzed in this paper (reform and reinforcement) do not

map onto countries but rather waves of change in IP policy that are largely similar across countries. Table 1 provides a simple overview of the two divergent trajectories, indicating the nature of the changes introduced and the rough dates in Argentina, Brazil, and Mexico.

Table 1
Reform and Reinforcement in Latin America

Wave	**Nature of Change**	**Countries**
Reform	Pharmaceutical Patents and Drugs • Address public sector's ability to secure price reductions on patented medications • Regulate generic drug market	Late 1990s-early 2000s • Argentina: 2002-03 • Brazil: 1999-2003 • Mexico: 2003-04
Reinforcement	Science, Technology, and Innovation • Encourage public-sector patenting and licensing • Increase university-industry linkages	Early 2000s • Argentina: 2004 • Brazil: 2004 • Mexico 2002

A key finding of the paper is that the processes of strengthening and weakening interests are markedly asymmetrical. I emphasize two types of asymmetries as regards political mobilization in the field of IP. The first asymmetry is that those actors who benefit from policy interventions tend to mobilize more than those who suffer. This finding challenges traditional perspectives on political economy and thus sets the study of IP apart from the standard fields (e.g. trade and fiscal policy) that are the source of most economic theory. That is, most political economists expect "losers" to be organized and strong and "winners" to be diffuse and weak,[2] yet to the extent that is the case it is so prior to the policy change; once TRIP-style IP regimes were put into place, their supporters (immediate beneficiaries and expectant beneficiaries) were strengthened politically while resisters were weakened. The second asymmetry is that while the processes of strengthening interests tend to be uniform across sectors the processes of weakening interests are uneven. In particular, the weakening of interests is much more accentuated in the area of science-technology-innovation than in the area of health-drugs.

In the next section of the paper I show how TRIPS-style patent regimes, once introduced, generate increasing returns by strengthening the interests of actors who benefit (or regard themselves as potential beneficiaries) of more and stronger private rights of exclusion over knowledge. In the following section I then examine the differential – and asymmetrical – processes of weakening interests. In particular I show how TRIPS-style regimes' relative inability to weaken interests in the area of health-drugs facilitates the creation and expansion of coalitions for discontinuity and thus makes the new patent systems susceptible to reform in this area, and how TRIPS-style regimes relative success at weakening interests in the area of science-technology-innovation impedes the creation and expansion of coalitions for discontinuity and thus makes the new patent systems surprisingly robust in this area. Throughout the paper I draw on examples and illustrations from Argentina, Brazil, and Mexico, but space considerations prevent extensive case studies or comparative

analysis.[3] In the conclusion I synthesize the main findings and discuss the implications for understanding the role of IP in late development.

Strengthening Interests under TRIPS-Style Patent Regimes

Although the appropriateness of TRIPS-style regimes for developing countries is widely questioned, they nevertheless appear to generate significant positive feedback and thus build coalitions for continuity. What makes this possible are the mobilizing effects that TRIPS-style regimes have on actors that benefit – or regard themselves as potentially able to benefit – from the new arrangements. Five relevant sets of actors are foreign investors, state officials, local exporters, IP lawyers, and local scientific communities. In this section I examine each in turn.

Foreign investors benefit from and endorse the new TRIPS-style regimes, which make patents available for more types of knowledge and strengthen patent-holders' rights of exclusion. The primary beneficiaries are firms in industrial sectors that had previously been unable to obtain patents (e.g. chemicals, pharmaceuticals, foodstuffs, agro-biotech). This will come as no surprise, as we know that US, European, and Japanese firms in these sectors with concerns over the protection of "their" IP in developing countries were the principal drivers of TRIPS in the Uruguay Round (Drahos 1995; Matthews 2002; Sell 2003). Yet the constituencies for continuity are not limited to these industrial sectors. Foreign investors' support for the new patent regimes tends to be more widespread, notwithstanding studies that reveal differing degrees of importance that IP rules have on TNCs' location and investment decisions (e.g. Mansfeld 1986).

We can appreciate this breadth of support for TRIPS-style regimes by observing patterns of political mobilization of trade associations and interest groups representing foreign investors. To be sure, the associations representing transnational pharmaceutical firms (e.g. AMIIF in Mexico, CAEME in Argentina, INTERFARMA in Brazil)[4], for example, are outspoken and enthusiastic members of coalitions for continuity, supporting the new IP regimes and calling for more resources to be allocated to IP administration and enforcement; but no less active are the explicitly multi-sectoral American Chambers of Commerce. One might expect multi-sectoral associations to be agnostic, or at least somewhat nuanced and tempered, on the topic of IP, since the higher prices that local consumers pay for investors' IP-protected goods in one sector may diminish demand for investors' goods and services in other sectors where IP is less significant, but such inter-sectoral conflicts appear to be overridden by a more general conviction that the introduction of regulations offering more and stronger patent protection is indicative of a propitious environment for investment across the board. Thus, far from leaving the local pharmaceutical and biotech associations to defend their own turf, associations such as the local Amchams continue to make IP a high priority and are critical in mobilizing foreign business communities in support of TRIPS-style policies.

TRIPS-style regimes generate positive feedback within the state too. As expected, IP officials tend to support the new systems and the dedication of additional resources to their departments and offices. And to the extent that IP affects the investment climate, which in turn affects inflows of foreign capital, the coalition of supporters comes to include those ministries and state agencies concerned with attracting investment.[5] Indeed, as having "modern" TRIPS-style IP essentially

becomes a criterion for a country's membership in the global economy, the advocates for continuity include a broad array of state officials involved with integration and external affairs who have come to regard increased (and increasing) IP protection as appropriate. We might expect Finance Ministries to be wary of arrangements that raise the costs of many goods (and thus are inflationary) and compel use of foreign exchange for royalty payments and licensing fees (and thus affect the national balance of payments), but in country after country Finance Ministries offered enthusiastic support for implementing TRIPS-style arrangements and, moreover, opposed efforts to reform such systems.

Among societal actors, important sources of positive feedback come from local exporters. For exporters, more and stronger IP protection is the price to be paid for secure access to critical export markets. This effect is a consequence of how IP was integrated into the global trade regime, in particular the inclusion of TRIPS in the WTO and the inclusion of IP in regional and bilateral trade agreements (RBTAs). In order to have most-favored nation (MFN) access to US and European markets (under WTO) or better-than-MFN access under RBTAs countries have to increase and maintain high standards of IP protection (Shadlen 2005; Shadlen 2008). What this linkage and subsequent IP-market access trade-off accomplish, concretely, is to broaden and enlarge the coalition of actors who are supportive of more and stronger IP by including exporters. Exporters in many light-manufacturing sectors, for example, are unlikely to have an interest in IP policy, particularly as regards patents. But to the extent that their access to the US and European markets depends on national IP practices, they become intensely concerned. In short, making market access conditional on the new IP policies can have the effect of transforming otherwise indifferent actors into IP proselytizers and enthusiastic participants in coalitions for continuity.[6]

The support of local IP attorneys for TRIPS-style regimes requires little explanation. Most professional IP attorneys favour more IP. After all, most IP training is about protecting IP, and more IP means more clients, foreign and national. This is not to say, of course, that all IP attorneys and lawyers share this disposition, and in each of the countries where I have conducted research I have found "public interest" patent lawyers that defend knowledge users. Yet these lawyers are always minorities. Local patent bars and associations of patent agents and patent lawyers are dominated by individuals with strong interests – intellectual and pecuniary – in the maintenance and expansion of IP. Legal journals published by local IP associations are strong supporters of the new IP arrangements. Indeed, in most developing countries, local IP attorneys were among – if not *the* – most outspoken domestic critics of pre-TRIPS IP systems. The changes introduced by TRIPS were welcomed, emphatically, and these actors are also enthusiastic and outspoken participants in coalitions for continuity.

Importantly, the TRIPS-style IP systems generate positive feedback among new societal actors too. Here the key is how local scientific communities come to defend the new systems. The introduction of new IP systems has, not surprisingly, been followed by increases in numbers of patents applied for by residents. The growth is absolute, not relative to patents by non-residents, which of course increases much more;[7] nor does the rate of growth of residents' patents match the rate of growth of non-residents' patents. However, for the purpose of understanding the broadening of coalitions for continuity of new IP systems, it is the absolute growth of residents'

patents that most matters. If one examines data on applications to national patent offices made by countries' residents, the growth throughout all of Latin American and the Caribbean from 1990-2005 is 70%.[8] In Argentina, in the six years following introduction of the new TRIPS-style patent law (1995-2000) the growth figure is 57%; while in Brazil the rate in the six years after introducing the new TRIPS-style system (1996-2001) is 36%.[9] In Mexico, in contrast, the absolute number of residents' patent applications shows little change since 1991, when the new TRIPS-style patent law was introduced.[10] Coalitions for continuity include not just actual but also potential beneficiaries, e.g. scientists and innovators that envision their futures as patenting individuals or enterprises. We can use data on international scientific publications as indicators of the growth and internationalization of local scientific communities. From 1980-1990, the number of publications in each country increased by 87% in Argentina, 86% in Brazil, and 81% in Mexico. From 1990-2000, however, the number of publications increased by 107% in Argentina, 231% in Brazil, and 212% in Mexico.[11] Indeed, scientists (and science associations that articulate "sectoral" preferences and interests) appear to regard themselves as beneficiaries or at least potential beneficiaries under the new arrangements, and in each country I have studied act accordingly by pressing for continuity.[12]

To summarize, then, TRIPS-style IP regimes generate extensive positive feedback among actors in international business, the state, and local society: the winners have been strengthened, facilitating expansion of constituencies for policy continuity. Each of the preceding five snapshot summaries illustrates processes of increasing returns, whereby certain actors benefit from new policy arrangements, which in turn bestow these actors with resources that allow them to mobilize in support of policy continuity.[13] The upshot of increasing returns, then, is a tendency toward self-reinforcement in the area of IP.

Weakening Interests under TRIPS-Style Patent Regimes

Policy reinforcement is not complete, however, because of the mixed and partial presence of the other mechanism that is essential for reinforcement, weakening interests to minimize negative feedback. In this section I examine the processes of weakening the interests of actors who are disfavoured by – and thus expected to oppose – TRIPS-style IP regimes. In doing so I draw attention to the two important asymmetries noted in the introduction to the paper, namely the greater propensity for political mobilization of winners relative to losers, and among losers the greater propensity for political mobilization with regard to health-drugs issues rather than science-technology-innovation issues.

The issues of weakening interests and minimizing negative feedback are really questions of what disaffected actors ("losers") do in response to new policy arrangements. We can think of two different responses by actors who are disadvantaged by policy changes: resist or adjust. Resistance consists of disadvantaged and dissenting actors demanding compensation and attempting to reverse the policy changes. With regard to adjustment, some actors may adapt to the new regulations for using knowledge, for example begin paying license fees to technology owners, while other actors may disappear (firms that cannot adapt, for example, might simply close). Although in economic terms it matters how firms

adjust, if they adapt or disappear, in a political sense the differences are outweighed by similarities: in both scenarios the actors who have (or had) material reasons to oppose policy stop resisting. After all, regardless of their original disposition toward TRIPS, firms that can adapt to the new environment have little incentive to expend resources trying to re-establish the pre-TRIPS status quo; nor do firms that go out of business present significant resistance. Thus, to the extent that we witness adjustment, the effect of the new IP rules is to weaken (if not eliminate) interests that we might expect to present opposition.

It is in the realm of drugs-health where we most witness resistance. Although some pharmaceutical firms have adapted to the new environment and changed their business models to operate in a world of patent protection, and plenty of others have simply ceased operations, most countries' generic pharmaceutical industries retain the capacities to join coalitions of resistance to the new IP arrangements. Adjustment (adaptation and disappearance) tends to be slower in this sector, on account of how pharmaceutical patents were introduced. Developing countries had until 2000 to be in full compliance with TRIPS, and countries that did not offer pharmaceutical patents as of 1995 had until 2005 to begin doing so. And even where countries have pharmaceutical patents, opportunities for generic pharmaceutical and pharmochemical production continue to exist in older non-patented drugs.[14] Few countries used the full ten-year transition period,[15] and important differences remain as to when and how they introduced pharmaceutical patents. In Argentina patents on pharmaceutical products were not introduced until late 2000, so any drug that was in the public domain as of 2000 would continue to be in the public domain. Thus Argentinean firms still accounted for more than half of all pharmaceutical sales as of the early 2000s. Brazil, in contrast, introduced pharmaceutical patents in 1997 and offered retroactive protection to drugs that were not yet on the market (i.e. "pipeline patents"); yet even in Brazil, an "early" implementer in global terms, local generics producers remained sheltered from TRIPS throughout most of the 1990s, and they still could produce older, off-patent drugs. While not retaining as much market share as their Argentinean counter-parts, local pharmaceutical firms in Brazil still accounted for roughly one-quarter of sales and dominated the nascent generics market. What this meant is that in Argentina and Brazil, local pharmaceutical producers and their sectoral associations remained active, if on the defensive; they had not been, "adjusted" out of political existence. Of the three Latin American countries discussed here, only in Mexico, which introduced pharmaceutical patents – including pipeline patents – as early as 1991, did something like a process of eliminating opposition through adjustment transpire. By the early 2000s local firms accounted for less than ten percent of sales and the most important local final-dosage producers had been purchased by foreign firms.[16]

More generally, moving from the pharmaceutical industry to the health sector as a whole, the demand for compensation and assistance can be understood as a function of the simple fact that adjustment in health is not a viable option. Most people in developing countries cannot "adapt" to the higher cost of medicines: ceasing to use the technology is less of an option in the realm of health, and actors in this sector cannot devise strategies to avoid using patented technologies when functional substitutes are absent. Patients who need drugs need drugs, or their conditions worsen and, in many instances, they die. They have to pay for the knowledge and technology, and if they cannot pay for it they lack alternatives. Of course, if those who could not

get drugs died, they would cease to use the technology. This would clearly be a case of adjustment via "disappearance," with policy arrangements weakening interests and minimizing (eliminating) negative feedback. But governments generally try to prevent this from happening, by providing health services. In fact, where the public sector provides health services it is the state, then, that feels the effects of stronger IP. So not only do the losers not go away via adjustment (neither adapting nor disappearing), but as government health bills grow, TRIPS-style IP regimes generate negative feedback in the form of Health Ministries facing exploding budgets on patented drugs.[17]

It is also worth noting that those negatively affected by IP in the realm of health can utilize the legal system. Patients can – and do – press their demands in courts, declaring that access to treatment is a human right or a constitutional right. Indeed, an important phenomenon that we witness in this period is patients groups and health-oriented non-governmental organizations becoming increasingly active and framing their demands in legal and constitutional terms (e.g. Biehl 2007; Kapczynksi 2008). When guaranteeing access to patented drugs becomes a constitutional obligation, governments may be pressed into action as well.

In sum, IP policies in the realm of drugs-health are marked by persistent negative feedback, and thus are *susceptible* to reform. I emphasize susceptible because reform does not look the same from place to place. Indeed, as I shall discuss in the subsequent paragraphs, the actual outcomes of reform in the three countries are quite different, ranging from seemingly technical tinkering in Argentina to substantial health-motivated revisions in Brazil to a case of proposed health-motivated revisions being commandeered and producing patent-strengthening reforms in Mexico. Yet for all the differences, the common thread through the three cases is that the existence of negative feedback kept the issue of patents and drug prices on the agenda and made health-related IP policy politically salient.

In Argentina the reform consisted of retaining – in the face of strong external pressures – a drug approval process that facilitates easy market entry for non-patented products, and modifying a set of seemingly arcane legal provisions on preliminary injunctions in cases of alleged infringement of process patents in such a way as to favour local producers of non-patented medicines. The precipitating events that provide context for these two changes were the deep economic crisis that followed the collapse of the currency board system in 2001 and a case that the US brought against Argentina in the WTO that claimed that many aspects of Argentina's patent system (including the way that health authorities approved non-patented drugs and the system of preliminary injunctions) were in violation of TRIPS. Argentina responded strongly to the US case and negotiated a settlement that included an "agreement to disagree" on the issue of data exclusivity and a pledge to reform the preliminary injunction system to come into compliance with TRIPS. Yet despite constant US threats (e.g. each year Argentina is listed on the USTR's Special 301 list on account of the health authorities use of test data, and Argentina lost GSP privileges to the US in the late 1990s over this issue as well), no significant changes were introduced to the country's practices and policies regarding the use of test data, thus local producers continue to be able to rely on data that producers of originator (or reference) drugs are obligated to supply to the health ministry.[18] In addition, in making the system of preliminary injunctions TRIPS-compliant, Argentinean trade and IP officials worked closely with the local pharmaceutical industry and the Ministry of Health to produce a reform of

the 1996 patent law that effectively raised the bar for patent holders and thus made it more difficult to obtain preliminary injunctions.

In Brazil the reforms consisted of including the Ministry of Health (MH) in the examination of pharmaceutical patent applications and introducing a simpler system for compulsory licenses (CLs). Any pharmaceutical patent application that is approved by the National Institute for Industrial Property (INPI) is then sent to the MH for review. The patent is issued only after IP officials in the Ministry's health surveillance agency (ANVISA) issue "prior consent." Since ANVISA's health-focused criteria are significantly stricter than INPI's, the prior consent requirement makes it more difficult to obtain private rights of exclusion over knowledge for pharmaceuticals. Typically ANVISA uses the prior consent step to prevent the grant of new patents that, by its judgement, would essentially extend the terms of existing patents, and to reduce the breadth of patent applicants' claims. Since the prior consent process was initiated in 2001, 53 applications approved by INPI have been rejected by ANVISA, and in the cases ANVISA has sanctioned INPI's decision (which has happened with roughly 70% of the applications), in 42% of these cases the applicant first had to reduce the breadth of the patent's claims (Miranda Silva 2008). With regard CLs, Presidential directives in 1999 and 2003 reformed the relevant clause of the patent law to make it more useful and thus increase the MH's capacity to leverage price reductions from patent-holding pharmaceutical firms. In particular, the revisions gave clearer definitions of national emergency and public interest, simplified the mechanism for issuing CLs by giving the MH greater authority to act, and stipulated that private firms supplying the government constitutes "public use" and is thus acceptable. The threat of a CL is a bargaining tool used to entice patent-holders to make their products available at lower prices. The effectiveness of the bargaining tool, however, depends on the credibility of the threat. The reforms to Brazil's IP law make the government's threats more credible by making CLs easier to issue and less vulnerable to appeal, and by increasing the government's ability to secure the relevant drugs from alternative suppliers. Indeed, since 2001 the MH has repeatedly negotiated price reductions by threatening to issue CLs on patented HIV/AIDS drugs that consume a disproportionate share of the MH's drug budget, and in 2007 followed through on the threat and issued a CL on a second-line antiretroviral patented by Merck. In fact, while the affordability of HIV/AIDS drugs provided the main impetus for reform, the modifications introduced affect drugs more generally and have yielded lower drug prices across the board (Nunn et al. 2007).

In Mexico the experience of "reform" was somewhat different. Here, efforts to emulate the Brazilian approach to compulsory licensing backfired and ended up producing legislation that strengthened the rights of patent holders (Shadlen 2009). A reform to the patent law was approved by a commission in the lower house in 2003 that aimed to increase the capacity of the Secretariat of Health to issue CLs in the case of health emergencies by making a state of "serious illness" declared by the SH a ground for CLs, by simplifying the process by which "serious illness" is declared, and assuring rapid issue of CLs at low royalties. This proposed bill, similar in many ways to Brazil's CL reform, prompted a counter-mobilization by the transnational pharmaceutical industry and its local representatives. The transnational sector did not just react defensively but went on the offensive, converting the threat into an opportunity. Indeed, the sector's trade association (AMIIF) had attempted to terminate the patent-reform project, though once it was kept alive by the congressional

committee, AMIIF and its allies mobilized to secure a reform that would make the granting of CLs less likely than under the 1991 law.[19] The campaign was successful, as the transnational sector essentially commandeered the initiative. The Executive branch, never compelled by IP reform in the first place, joined the counter-offensive: the Secretary of Government's legislative liaison insisted that the March 2003 version could not proceed and provided the CCyT with a revised text.[20] This new version, which was passed by the full Chamber of Deputies and Senate and then signed into law by President Fox in 2004, *increases* the obstacles to issuing compulsory licenses by making the process by which "serious illness" declared more complicated, removing serious illness as a ground for a CL, and requiring high minimum royalty rates. The changes introduced to Mexico's IP system mean that the prices of patented drugs remain higher in Mexico. Patent-holding pharmaceutical firms do not fear CLs, and thus feel little compulsion to reduce prices. Abbott, for example, prices its patented version of lopinavir/ritonavir at more than five times the Brazilian price, but the Mexican government lacks the instruments to negotiate price reductions. More accurately, such instruments, as they previously existed, were dulled by the reforms of 2003-04.

To repeat, the upshot of these cases of "reform" is not that they are identical in terms of actual outcomes, but rather that the incompleteness of weakening interests in the area of drugs-health meant that these issues remained on the agenda – coalitions for discontinuity remained in tact and active and able to press their issue, though they did not always win (or, depending on context, even press the same issues). So the actual forms of resolution of the issues raised by the coalitions for reform and discontinuity vary from case to case. The reason for this variation is that dynamics within the coalitions for discontinuity are hardly uniform. That is, among the three sets of actors – local pharmaceutical industries, health ministries, and NGOs – the relative weights and capacities of the actors, who is leading the charge for reform, and the relationship among the actors in this coalition, varies from case to case. Thus, the outcome I am pointing in this section is simply a set of underlying pressures that keep the drugs-health aspects of IP on the radar screen.

In contrast to drugs-health, TRIPS-style IP regimes have weakened interests much more consistently and substantially and thus minimized negative feedback in the area of science, technology and innovation. In this realm disaffected actors do tend to either adapt or disappear. Firms (and sectors) that in the past relied on easy use of knowledge either devised new business strategies to survive in the context of the higher cost of knowledge; or they avoided patented knowledge; or they cease to exist. Academics might still clamor about the effects of stronger IP protection on local firms' ability to use knowledge, but most local firms have stopped clamouring about it because those that still exist have either figured out business strategies whereby they either pay for or avoid proprietary knowledge; and those that could not do so do not exist any more. In short, we witness a thinning of "knowledge user communities," which might potentially provide the materials for coalitions for discontinuity.

Measuring these changes in business strategies and industrial structure are exceedingly difficult, to say the least. One indicator could be changing patterns of patent litigation. For example, data on patent nullification proceedings that I have compiled from Argentina and and Mexico show a decline in such cases.[21] If firms are using patented knowledge they are routinely accused of infringement, to which

nullification and invalidity claims regularly follow. The close relationship between use and litigation is a consequence of the uncertain boundaries that are inherent in patents: actors do not know precisely where the private property ends and the public domain begins until patents are litigated in court. Given the great increase in patents that have followed introduction of TRIPS-style regimes, one would expect to see associated increases in litigation. That nullification proceedings are not increasing in a context of increased private ownership of knowledge can be interpreted – tentatively – as indicator of a tendency to avoid the use of patented knowledge.

Thus, within industry and science we witness little evidence of actors demanding compensation and seeking policy change (i.e. resistance). Indeed, it is not just a matter of campaigning to modify TRIPS-style IP regimes. It is rare to find people in science or industry who even articulate an argument that reforming the new IP systems and reducing the amount and strength of patent protection may be beneficial. The result, then, is that as regards science and technology TRIPS-style IP regimes face minimal negative feedback. Here, the self-reinforcing process is more complete.

To illustrate the different propensities for adjustment versus resistance and negative feedback in the realms of drugs-health and STI, consider the following contrast. In health, activist networks grew in response to concerns over how IP affects the price of drugs and thus citizens' access to healthcare. These networks can – and do – make appeals to human rights (e.g. the right to healthcare) and in many countries constitutional rights as well. The ability to make such appeals allows the movements to survive and, in some countries, form alliances with other societal actors (e.g. Ministries of Health, local pharmaceutical manufacturers). Yet the strategies of movement- and alliance-formation that are useful with regard to medicines and health are less viable with regard to industry and technology. Governments do not directly bear the costs of local industrial firms' now-complicated access to technologies. Nor can industrial firms that have lost access to technology on account of IP contest this new reality with appeals to human or constitutional rights: firms do not have rights to use other firms' proprietary knowledge and technology. The inability to rely on the state or to make legal and moral claims reduces the durability of users as political actors. Subsequently, coalitions for discontinuity rarely form. To the contrary, the process of adjustment leads to a progressive thinning of such potential coalitions.

In Brazil, for example, an organization representing local, independent autoparts producers sought – unsuccessfully – to reduce the patent rights of terminal automobile firms through recourse to competition authorities. The case provides an illustration of how much more difficult it is for knowledge/ and technology users outside of the health area to make demands that the IP system should provide less protection to knowledge owners. The comparison with patents on drugs, which the autoparts producers' economists'and lawyers made explicitly in their analyses and legal briefings (on file with author), is striking. To be sure, advancing and defending the rights of knowledge users is not easy in the health-drugs domain either, but at least in that realm there exist sets of actors in state and society that identify a problem caused by the patent system and then make an effort to reduce patent protection to support health. In the case of industry, however, where concerned and interested actors also identify a problem caused by the patent system, they are unable to build the coalitions necessary to introduce changes in the patent system to support local

economic development. The sorts of industry-state-NGO coalitions that have come to exist in the area of health-drugs are nowhere to be seen in the STI realm.

Another vivid illustration of the contrast between the alternatives available to knowledge users in the two realms was revealed in an interview I had with a patent attorney in Buenos Aires (November 2007), when I raised the scenario of a firm that seeks to use a patented technology but cannot reach a licensing agreement with the owner at a rate that makes using the technology feasible. In answer to my question of what recourse the firm might have, the attorney, clearly bewildered by the question itself, responded that the firm had no recourse: the exchange (in this case the exchange of money for the right to use proprietary knowledge) would or would not occur "just like any other exchange in a market economy." But a quick reflection of the case of drugs demonstrates that other sectors of the market economy operate differently. Citizens and governments do indeed demand to use others' proprietary knowledge at reasonable rates; and not only do they frame these demands in terms of their rights to do so, but claims of such rights are generally regarded as legitimate. One might maintain that industrial firms should also have rights to use other firms' proprietary knowledge, but such claims have less intuitive appeal and carry less weight. Thus, in health those negatively affected by TRIPS-style IP regimes can make appeals to constitutional and human rights that have great resonance, but not in industry.[22]

It is important to consider how these dissimilar patterns of political mobilization and coalition formation yield divergence in terms of the contemporary politics of IP. In contrast to the vibrant debates over access to drugs and healthcare, discussions about IP in the realm of STI tend to be thin (in terms of actors involved) and uni-dimensional (in terms of substance). Few local industrial actors express preferences regarding patents and IP. In each country where I have researched, for example, the amount of staff and resources that key trade associations give to IP is remarkably low. What few local firms and associations that do participate in political debates over IP want now is not less IP but more efficient IP systems to support their own aspirations, plans, and strategies to innovate, patent, and license. Outside of the pharmaceuticals and pharmochemicals, it is difficult to find local actors in industry or the scientific community that regard the proliferation of private rights of exclusion over knowledge and technology as an obstacle to their own endeavours. Indeed, those that are at the forefront of political campaigns in the issue-area are those that have their own IP, or at least regard themselves as potential creators and owners of patentable and excludable knowledge. In Brazil and Mexico, leading actors underpinning IP reinforcement in the area of science-technology-industry are private-sector associations that represent innovative (or potentially innovative) research-and-development based firms (transnational and national) from the private sector.[23] Ultimately, the actors that have survived the introduction of TRIPS-style regimes are those that can adapt to the new environments, while others who cannot – and who might provide raw materials for counter-mobilization – are gone.

Consequently, political debates regarding industry and technology are exceptionally one-eyed, about how to create more indigenous IP and how to increase national innovative capacities so that more local scientists and researchers use the IP system as knowledge owners. The result tends to be a panoply of initiatives and policies to restructure systems of science, technology, and innovation: establish

funding mechanisms to increase research and development (public and private); reform higher education and vocational training systems; facilitate linkages between public sector research and private firms; enhance the capacity of university researchers to gain private rights over publicly-funded innovations; modify regulations that impede the movement of scientists between public and private sector; create new (and restructure existing) ministries of science and technology; and so on. One might regard these initiatives as efforts to emulate successful "National Innovation Systems" of the OECD. They often have a "shotgun" feel to them, in that nearly every measure that has been deployed in other settings is deemed worthy of emulating locally.

The IP initiatives introduced in such a context are not so much changes *to* IP systems as they are changes *for* IP systems. That is, countries are not attempting to modify their IP systems to fit national scientific capacities, but rather attempting to improve national scientific capacities and national STI infrastructures to fit their new TRIPS-style IP systems.[24] Consider the following. Most developing countries now have IP regimes of questionable appropriateness for their level of development. In response, a country can modify its IP regime to make it more suited to its scientific capacities (e.g. restrict patenting scope, regulate licensing, facilitate the use of anti-trust measures in IP law, encourage pooling and sharing of knowledge, and so on), and a country can try to increase scientific capacities and upgrade STI frameworks and thereby "grow into" its new IP regime. In practice the latter scenario prevails: the dominant strategy is to leave TRIPS-style regimes intact and to try to "grow into" them. To the extent that changes have been introduced, these almost without exception *reinforce* the new TRIPS-style IP arrangements by extending the range of knowledgeable that is patentable and the range of actors that can obtain patents and relying on private ownership to transfer knowledge.

The political dynamics are illustrated in Figure 1. The top curve (dotted line) presents the relationship between the amount of IP protection and innovation in a "developed" country with high indigenous innovative capacities. As the curve indicates, increased IP leads to increased innovation up to a certain point when diminishing returns kick in on account of too many inputs to further innovation becoming privately owned. The bottom curve (solid line) illustrates the effect that increased IP has on costs. In such a context, a level of IP can be selected such that the benefits (innovation) exceed the costs. This is indicated by the vertical line at point M on the "Strength of IP axis." The middle curve (dashed line) presents the relationship IP protection and innovation in a "developing" country, with low indigenous innovative capacities. Here the innovation curve is significantly flatter: each increment of increased IP yields less innovation, on account of less indigenous capacity, and diminishing returns set in earlier. When the same amount of IP protection is introduced in such a setting, the costs exceed the benefits (compare where line M intersects the two different innovation curves and the cost curve). The two arrows present the alternative responses noted above: reduce the level of IP to a more suitable level (arrow A), alter the shape of the innovation curve to look more like the innovation curve in developed countries (arrow B). Of course there is no reason why a country could not do both, but in practice most of the efforts have been of the nature of arrow B. The reason why the latter response prevails is political: the relative absence of actors pushing to reform the IP regimes removes pressures to follow that path, even when doing so is feasible within international obligations. Why such

absence? Because the TRIPS-style regimes have weakened interests and thus minimized negative feedback, and at the same time they have strengthened the political capacities of their beneficiaries. The result, then, is that coalitions supporting the vertical arrow (B) are greater and stronger than coalitions advocating the horizontal arrow (A).

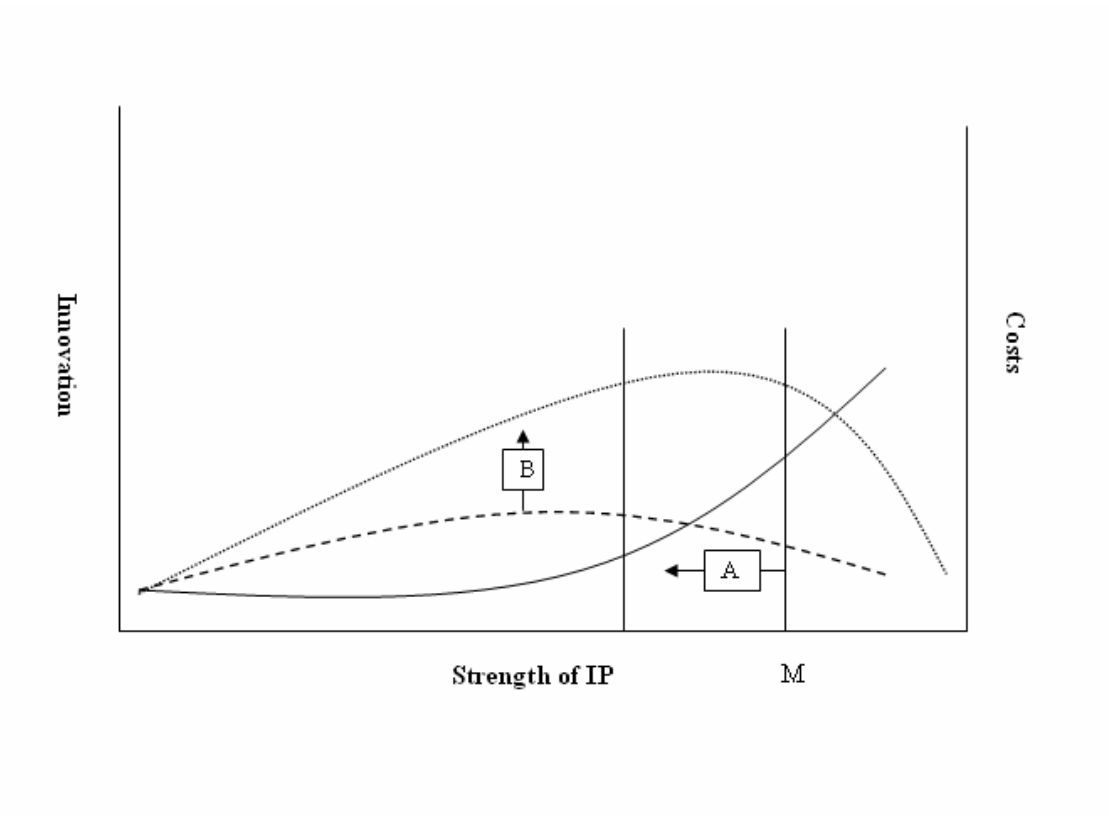

Figure 1: IP and Science-Technology-Innovation: Reform or Reinforce?

Conclusion

If a government implements a policy and the reaction is that beneficiaries demand continuity, we call that positive feedback. If a government implements a policy and the reaction is that those adversely affected demand discontinuity of the policy, we call that negative feedback. All policies tend to elicit both types of feedback, though to different degrees.

In this paper I have used these simple insights to consider how different IP policy changes trigger contrasting patterns of political mobilization in the areas of drugs-health and science-technology-innovation. TRIPS-style regimes have generated growing constituencies for continuity, and negative feedback has been skewed. Where TRIPS-style regimes are less effective in weakening interests they are subject to reform (drugs-health), and where they are more effective in weakening interests they have undergone reinforcement (STI).

Ultimately I attribute the differences to how the "losers" – actors that policies disfavor – react to the new IP environments. In drugs-health, those who are negatively

affected by the new rules can, rather surprisingly, benefit from their inability to adjust. Governments end up bearing at least some of the costs of medicines, and actors make constitutional and also moral appeals to their rights to medicines. These conditions allow political coalitions to form and thus force some reassessment IP policy. The realm of STI, however, tends to be marked by very different combinations of material, legal, and normative factors: firms adjust and go away, with the effects not felt directly by the state; rights to technology have little resonance in legal and constitutional settings; nor does a "right to technology" have much normative weight.

The different patterns of political mobilization lead to two very different approaches to governing knowledge. As indicated, the relationship between patents and health remains a hotly debated topic in many countries.[25] In contrast, policy responses in the realm of STI have almost uniformly been about broadening, extending, and strengthening the role of patents as incentives for the creation, commercialization, and licensing of knowledge. Indeed, the simplest way of summarizing the wave of STI policies in recent years would be that of the global diffusion of the US system based on the Bayh-Dole Act (So et al 2008).

Assessing the effects of this latter approach is exceedingly difficult, but a few observations are in order. To be sure, national patenting rates have increased, as indicated above. Yet this is hardly surprising. The fact that increased IP may lead to increased innovative activities and patenting is to be expected. However, more and stronger IP also increases costs and raises barriers to access. The concern is not that there are no benefits (innovation) derived from TRIPS-style regimes, but that the benefits may be outweighed by the costs (reduced ability to use knowledge). That concern may be misplaced, but one cannot argue against it simply by showing that there are, indeed, benefits. If, for example, a government raises tariffs on shoes by 100% there will be more investment in shoes. One might warn that the benefits of the tariffs (increased investment in shoes) are outweighed by the costs (higher price of shoes to consumers). If one were to try to counter that argument by showing, simply, that high tariffs did indeed lead to increased investment in shoes, the argument would not be taken seriously. The emphasis on increased patenting activities without focusing on how knowledge is used and not used suffers from the same problem.[26]

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NOTES

[1]The focus in this paper is on patents, not other forms of IP such as copyrights and plant breeders' rights.

[2]Indeed, most of the political economy of trade, for example, is about assessing the conditions under which policymakers can overcome the entrenched opposition of organized interests in import-sensitive sectors and mobilize the support of the "invisible majorities" that stand to benefit. For a criticism of such framing in the context of developing countries and an example of how the opposite scenario can materialize, see Shadlen (2008: 14-16) and Thacker (2000).

[3] The three countries provide the empirical basis for my forthcoming book, *Knowledge Gaps, Knowledge Traps: The New Politics of Intellectual Property in Development.*

[4]These associations are the local members of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

[5]In some countries these are one and the same. For example, the director of the PTO in Mexico was formerly the official chiefly responsible for foreign investment.

[6] I call this mechanism "activating agnostics."

[7]This relationship (foreign patents dominating over resident patents) holds in virtually all countries outside of the USA.

[8]The data in this paragraph come from RICYT (www.ricyt.org).

[9]In Argentina, the number of applications decreased after 2000 in the context of severe economic crisis, with 2000 levels re-attained in 2005. In Brazil the upward trajectory continued and the 1996-2005 growth rate amounts to 88%.

[10]What this translates to, politically, is that the push for extending IP in the early 2000s came from the state, academics, and foreign industry. In contrast to Brazil, for example, where local industrial actors were intensely involved in pushing for a revamping of the STI framework, Mexican industry was relatively less active. And even though Mexico has a private-sector organization dedicated to STI (as discussed below), it has small membership (most of its energy comes from MNCs and academia).

[11]The data refer to articles authored by Argentineans, Brazilians, and Mexicans that are cited in the Science Citation Index Expanded. The source is the National Science Foundation.

[12]Both of the types of data presented in this paragraph (patents and scientific publications) are also available on more disaggregated basis, distinguishing by technological class in the case of patents and scientific sub-field in the case of publications. Detailed analysis of the patents and publications data is beyond the scope of this paper.

[13]While the growth and internationalization of scientific communities contribute to processes of increasing returns and strengthening of the interests of pro-IP actors more generally, they are not, strictly speaking, the result of positive feedback from the TRIPS-style regimes themselves.

[14] A useful area for future research might be to examine, comparatively, the extent to which firms can continue to exist and prosper on the basis of older technologies. In pharmaceuticals, not only does the industrial sector continue to exist, but entire sub-sectors emerge around the production and distribution of older off-patent drugs. In most of electronics, in contrast, firms using older technologies cannot compete. But how exceptional is that? In machine tools, for example, can firms continue to prosper using older technologies?

[15] Among developing countries with significant capacity for pharmaceutical production, only India took advantage of the full transition period.

[16] Or to put it differently, Mexico was much further along the "pharmaceutical-denationalization" curve (Shadlen 2009).

[17] Note that variation in national healthcare systems affects the extent to which governments are responsive to the growing advocates for discontinuity. The scenario that I have described (patients and healthcare activists mobilize over prices and access to drugs, and health ministry responds) is a general trait, but there are cross-national differences. For example, in Brazil, the government's commitment to universal HIV/AIDS treatment made the MoH acutely sensitive to prices on patented ARVs, much more than was the case in Mexico (Shadlen 2009).

[18] While policy continuity may not, at first glance, appear to be "reform," one has to consider not just the overwhelming external pressure to alter (i.e. not continue) policy and the fact that during this time the policy became more relevant as more patented drugs were introduced on account of the introduction of product patents in 2000. Effectively, then, this is a case of "reform."

[19]Interview with Director General of AMIIF, 14 August 2007 (Mexico City).

[20]Commission on Science and Technology archives; interview with ex-official from Secretary of Government, 14 August 2007 (Mexico City).

[21]I am still in the process of obtaining systematic and comparative data from Brazil, but at first glance the pattern appears to be consistent with the Argentinean and Mexican cases. Other useful – though imperfect – indicators include diminished number of firms in sectors where patents have increased, size of trade associations in traditional "knowledge user" sectors, and increased license fees.

[22]One place to make such claims might be to competition authorities. Is it easier governments and patients to invoke constitutional and human rights law than for firms to invoke competition law? There is also a collective action issue here. The firm that takes forward a claim against a patent owner, either in competition forums or nullification proceedings, has to bear the costs of doing so, but the benefits become available to all if the knowledge subsequently enters the public domain. For a further discussion of this dynamic as a mechanism that generates increasing returns, see Thambisetty (2009, forthcoming).

[23]I refer to the National Association for Research, Development, and Engineering in Innovative Firms (ANPEI) in Brazil, and the Association of Directors for Applied Research and Technological Development (ADIAT) in Mexico. I am unaware of an analogous association in Argentina. The data on national patent applications discussed above suggests that industrial firms have experienced more growth in

technological-innovative capacities in Argentina than Mexico, but the patenting activities in the former country appear to be much more concentrated sectorally (which might dampen the relevant actors' perceived need and thus demand for establishing a trade association).

[24]Or to put it differently, rather than use IP policy for development, these programs are about increasing scientific capacities and improving STI frameworks (becoming more developed?) to get more out of the new IP policies.

[25]In addition to the cases discussed in this paper, see Krikorian (2009, forthcoming).

[26]Of course, this exercise is easier said than done – measuring the costs is extraordinarily difficult (see Moir 2009, forthcoming). Yet however difficult it is to assess costs and benefits empirically, that does not justify failure to acknowledge both costs and benefits conceptually.

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