Keith E. Maskus

Reforming U.S. Patent Policy
Getting the Incentives Right

The U.S. patent system comes under much criticism these days. In a lightning-rod case, the maker of the popular BlackBerry communication device, Research in Motion (RIM), chose to pay a $612.5 million settlement in order to avoid a court-ordered shutdown. In this case, the judge supported a patent infringement case brought by NTP Inc. despite the fact that the U.S. Patent and Trademark Office (USPTO) had preliminarily ruled that all five NTP patents were invalid. Moreover, NTP did not provide email service or compete with RIM. In an April 2005 speech, Brad Smith, Microsoft's general counsel, said that his company spends $100 million per year defending itself against thirty-five to forty lawsuits at a time.[1] He observed a "need to ensure that high-quality patents are approved and low-quality patents are not." Microsoft has called for patent law to be reformed in order to make it easier to challenge the validity of patents after they are issued and to reduce runaway patent litigation costs. The company has also cited a need to increase

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funding to improve patent examination procedures at USPTO. The BlackBerry case and Microsoft's calls for reform symbolize an American patent system that is increasingly inefficient and costly for innovative firms. Its numerous structural problems are rooted in two fundamental misconceptions:

- The view—predominant in Congress and the courts—that patents are like tangible property and that owners of such property have the basic right to sell and license it (or not) as they wish; and
- The virtually unchallenged view that more patent protection necessarily provides greater incentives for innovation and commercialization of technologies.

Neither view makes for good policy.

Patent policy needs to be balanced to protect the investments of original innovators as well as to encourage access to technologies and products. Ever stronger exclusive rights generate overlapping claims, monopoly power, and litigation costs that actually discourage competitive innovation. Striking the proper balance requires that U.S. policy relax the modern notion that intellectual property rights are basic rights and return to the tradition of limiting the scope of patents in order to encourage the use of new technologies and information.

Failure to rein in the patent regime could have global repercussions. To hinder innovation is to hinder the dynamic competitiveness of U.S. companies. While some aspects of the IPR system (such as copyrights) for American firms largely remain sound, significant problems with patents put the U.S. system at a disadvantage vis-à-vis more balanced and less costly foreign ones.

At present, Congress is considering whether to reform domestic patent law. In 2005, Representative Lamar Smith (R–TX) introduced HR 2795, which would enact a number of reforms, some of which are advocated later in this report. That legislation has languished in the House of Representatives.

In the upper chamber, Senators Orrin Hatch (R–UT) and Patrick Leahy (D–VT) jointly introduced a Patent Reform Act in August 2006. The proposed act has the support of the information technology and financial services sectors, but it is viewed warily by pharmaceutical and biotechnology companies, which are concerned that large changes to the system—especially the possibility of patent challenges long after a patent is issued—may reduce their patents' value. The proposed reforms would be the most sweeping in many years, but they still would not do enough to improve the functioning of the clogged and costly patent system. The final section of this report will give suggestions for more comprehensive reform.

In contrast to the proposed domestic reforms (limited as they are), there seems to be little interest in achieving greater balance in the U.S. approach to international patent rules. The United States continues to pursue an aggressive trade strategy to harmonize global patent standards at U.S. levels. The approach achieved its first major victory in 1995 with the adoption at the World Trade Organization of the TRIPS agreement, which requires all members of the WTO to implement and enforce a comprehensive set of minimum standards protecting the intellectual

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property of both domestic and foreign firms. For many developing countries, TRIPS forced a strengthening of their patent laws.

However, it permits members substantial flexibility in limiting the market power of patent holders. U.S. trade authorities still found the agreement insufficient for protecting the international economic interests of major American companies in certain industries, so they have pushed the harmonization agenda far beyond that level.

Such extensive harmonization is difficult to achieve. It is not surprising, therefore, that the efforts have only borne fruit in a series of bilateral trade agreements with small nations. Even when the efforts have succeeded, they have made questionable contributions to global development and have generated resentment among citizens in trading partners—resentment that bodes ill for the rest of the U.S. trade agenda. It is advisable to abandon this high-level harmonization agenda. Unfortunately, at present there are few major economic interests pushing for such rationalization in trade policy.

The current U.S. trade strategy appears even more senseless when we consider the fact that the problem for most major U.S. companies is not that patent laws abroad are inadequate, but that they are poorly enforced. A more effective strategy to protect international economic interests would be to increase the pressure on major developing countries, such as China, to improve their record on enforcing patents and other forms of IPR.

A combination of carrots and sticks could be used to achieve this end. The carrot would be to collaborate more fully with other developed economies and international organizations to increase the amount of technical and financial assistance available for improving enforcement. The stick would be for the United States and other major developed economies, especially the EU and Japan, to marshal evidence and arguments for a formal complaint at the WTO that specific countries have failed to meet their enforcement obligations under TRIPS. A coordinated effort would reaffirm that the United States is committed to a multilateral approach to resolving tough trade problems and would deflect criticism that the United States is a solitary and aggressive demander in global patent policy.

PATENTS AND INNOVATION

Innovation results from the interaction of norms, markets, incentives, regulations, and infrastructure for the creation and use of technology. Education systems encourage skills and technical competence. Venture capital markets finance the investments of small U.S. companies in biotechnology, software, and related new technologies. Mass communication systems foster access to knowledge. These and other elements contribute to the skills, talents, capital, and competition that support innovation.

Most importantly for our purposes, innovation thrives under openness to dynamic competition. Open markets encourage firms to enter and exit, restructure through efficient takeovers, gain access to important inputs and suppliers, and

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develop and sell new products and process technologies. Information and new products diffused throughout the economy generate greater competition and spur more innovation. Finally, openness to international trade, investment, and licensing is essential for facilitating technology transfer across borders.

Patents—the focus of this report—and other forms of IPR are only one part of this system. Nevertheless, they often play a vital role in fostering innovation, a role that becomes apparent after considering what would happen without IPR protection. Without protection, an inventor could spend considerable money, time, and effort developing an idea that a rival could easily copy and sell for a fraction of the cost. The inventor may be left not only without a profit but also with a sizable loss—and a clear disincentive against future innovation.

Patents are the most direct incentive for developing commercially useful new technologies and products. They facilitate dynamic gains—new products and greater variety—by temporarily supporting exclusive market power. That is the classic trade-off in the traditional view of patents, which sees innovation as the discrete birth of a single-idea technology covered by a patent. Whether actual patents match this view is widely debated and will be examined in the next section.
Patents also help to ensure the adoption and diffusion of innovative ideas. The publication of patent applications guarantees that inventions are disclosed and not kept secret.

Commercialization—turning a new idea into a marketable product, service, or technology—can be costly. Exclusive rights provide an incentive for firms to shoulder those costs. The exchange of technologies is made easier because patents provide a legal foundation for that exchange. Without that foundation, contract negotiations over the terms of agreement might prove difficult or impossible. This is also true for the specialized technology transfer services that are made possible by patents.[2] These economic roles—sufficient innovation, commercialization, and diffusion— could be achieved in a number of ways. A major advantage of patents and other IPR is that they work through the markets themselves. If new products fail to attract consumers, the associated patent is virtually worthless, and consumers do not suffer monopoly prices.

IPR therefore channel investment into new knowledge goods that are anticipated to provide consumer benefits.

Patent Standards

Despite the dynamic innovation that patents can facilitate, they also inject new monopolies into markets. Accordingly, it is essential to develop the standards under which patents are granted and protected with an eye to achieving the right balance. In general terms, the major patent standards are eligibility rules, length and breadth of patents, and limitations on rights.

Eligibility rules cover the elements of knowledge that may not be patented. Most countries exclude fundamental scientific discoveries flowing from basic

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physical laws of nature, including mathematical algorithms. Other subject matter may be excluded in order to preserve national security or public health.

In all countries where patents are awarded, for an invention to be patented it must: (1) be novel (that is, previously unknown), (2) contain an inventive step (that is, a step that is not obvious to one skilled in the area of technology it represents), and (3) demonstrate utility by being reduced to an item of commercial applicability. Determining whether an invention meets these criteria is the job of patent examiners. To be declared novel, an invention must survive a search of the prior art, which is the total of relevant published knowledge. The inventive-step standard is important to prevent obvious inventions from being patented. The utility standard determines the dividing line between unpatentable knowledge derived from basic science and patentable applied arts. Clearly, it is possible for examiners to make mistakes and issue patents that do not truly meet one or more of these standards. To mitigate that risk, most systems permit interested parties to bring prior art to the attention of examiners before a patent award, contest the validity of a patent after it is issued, or both.

Patent applications are published within a certain time period in order to disclose the technical claims made and the mode of operating a technology or making a product.

Timely publication is important for diffusing new technical information into the economy and informing firms that particular technologies are protected.

After eligibility standards come standards determining the length and breadth of a patent. The global standard for duration is twenty years from the filing date. In terms of breadth, inventors make claims about the protectable novelty of their inventions, although examiners can narrow or reject those claims. Some countries permit only narrow claims on singly defined uses of information while others permit multiple claims of novelty within a patent. To illustrate, a narrow patent on a chemical formulation might claim rights only to a single resulting drug or acid without covering products that use closely similar formulations. A broad and multiple-claim patent could cover the chemical process, specific products it achieves, and close chemical substitutes.

Equally significant is the extent to which inventors can claim rights to uses not specifically listed in the patent. For example, biotechnological research tools may be developed for a particular genetic application, but under a system allowing broad claims, inventors may claim rights to later uses in different research areas. To give another example, genome patents protect claims on long stretches of genetic sequences whose potential future uses are not currently known. Where a country recognizes a "doctrine of equivalents," patent owners may litigate against competing products and technologies shown to rely on techniques that, in essence, perform the same functions in the same ways for the same results as those in the patent grant.

A final set of standards is the set of limitations placed on the exercise of patent rights. These exist for a variety of reasons, most prominently to protect public health and other public goods and to maintain competition. Many countries per-

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mit free use of patented goods by governments. Governments also issue compulsory licenses, which force the patentee to surrender the technology on a nonexclusive basis to another firm in return for a license fee, either to ensure domestic production of essential technologies (such as medicines or environmental inputs) or to enforce anti-monopoly provisions. Some countries recognize a prior-use exception to patents, under which firms that can demonstrate their earlier use of an innovation that was later patented by another firm are able to continue using the technology without having to pay royalties.

EMERGING COMPETITIVE PROBLEMS IN THE U.S. PATENT REGIME

Patent regimes exist along a spectrum, from weak rights that permit consumers and rivals cheap access to new information goods to highly protected rights that favor exclusivity for inventors. Recent trends in U.S. intellectual property protection have increasingly favored those who invent and own patents. At the same time, standards for approving patents are weakening. As a consequence, the number of questionable patents has increased, and litigation and transaction costs have risen for competing firms.

Patent Pathologies

The most important change in patent regulations since 1980 has been the expansion of subject matter eligible for patent protection. In 1980, the Supreme Court ruled in Diamond v. Chakrabarty that genetically engineered bacteria could be patented. This ruling established that virtually all forms of life could be patented, including genetic discoveries and research tools. In 1981, the Supreme Court recognized in Diamond v. Diehr that software could be patented, radically expanding the ability of programmers to assert rights over their computer code. In 1998, a federal circuit court approved the eligibility for patents of business methods and financial service products in State Street Bank & Trust Company v. Signature Financial Group. This case, involving protection of a method of managing mutual funds, opened the door to a proliferation of business methods patents, including Amazon.com's one-click Internet ordering process and Priceline.com's reverse auction for buying Internet products.[3]

The second major development came with the Bayh-Dole Act in 1980, which gave universities control of inventions that resulted from federally funded research. University patenting accelerated, and research universities established technology transfer offices to facilitate licensing to private and faculty-based companies.

The third development was the 1982 creation of the Court of Appeals for the Federal Circuit (CAFC), a special court managing appeals on IPR disputes and other complex business litigation. The goal was to create expertise and predictability in patent cases, but predictability has largely benefited patent holders. Before 1980, 62 percent of cases in which patents were found to be valid and infringed were upheld on appeal; after 1990, that proportion rose to 90 percent. In cases where a patent was ruled invalid or not infringed, the fraction of decisions reversed

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rose from 12 percent to 28 percent. In addition, after the introduction of the CAFC, the rate at which courts issued preliminary injunctions to block the use of patented items during infringement proceedings rose sharply.[4] The final contribution to stronger patents was the lengthening of effective patent terms. To meet the requirements of TRIPS, U.S. patent length was extended from seventeen years (from the date of grant) to twenty years (from the date of application).

The Hatch-Waxman Act of 1984 extended patent terms by up to five years for pharmaceutical products where issuance of the patent had been delayed by lengthy approval processes at the Food and Drug Administration (FDA).[5]

Dilution of Patent Standards

At the same time that policy was strengthening U.S. patent protection, its patent standards were being weakened.[6] It has become common to ridicule the USPTO for issuing questionable patents, such as the J. M. Smucker Company's patent for a "method of making crustless peanut butter sandwiches." A patent is of high quality if it protects an invention that is truly novel, inventive, and commercially useful—requirements that form the essence of a well-functioning patent system. Patents have low quality if they are issued to inventions that are obvious, ignore the prior art, or duplicate existing technologies. The decline in patent quality is exacerbated if patent holders choose not to commercialize their inventions, instead waiting to litigate against other firms that bring a similar technology, independently invented, to market.

Many factors have led to the dilution of patent standards. The first problem is a shortage of patent examiners. The average patent gets only eighteen hours of review, and many are only cursorily examined, yet there is still a backlog of more than 400,000 applications at USPTO. Second, the expansion of patents to biotechnology, software, and business methods means there may not be sufficient written prior art to reject applications on what might seem to be obvious technologies, and examiners may not be adequately trained in those areas. Therefore, both the novelty and nonobviousness standards have diminished sharply as applied, even in cutting-edge technologies.

Third, all patents, even dubious ones, are buttressed by courts and regulation. U.S. courts presume that an issued patent is valid; challenging that validity to defend against infringement litigation is therefore difficult. In fact, it is hard to challenge validity in any forum, as the United States is uniquely hostile to procedures to vacate patents. The USPTO may be asked by interested third parties to reexamine the validity of an awarded patent, but its procedures sharply restrict the scope of the challenge to the patent. No challenges may be made to utility, even though such challenges could, for instance, invalidate certain genome patents. Third parties may challenge a patent by demonstrating a lack of novelty or inventiveness, but only published prior art may be admitted as evidence. Requiring that prior art be in published form can exclude critical evidence of earlier knowledge in elements of new technologies. Software code, for instance, is not ordinarily pub-

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lished but could contain information demonstrating that an invention had already been developed. If the challenge is not upheld upon reexamination, the ability of the parties raising the challenge to vacate the patent in court is greatly restricted.

Moreover, a lawsuit by a rival firm to invalidate a patent is only possible if the patent holder has threatened the rival with infringement litigation.

In addition to concerns about quality, it is increasingly common for patents to be written broadly, covering several technological claims, including "reach-through" claims to uses of research tools. As noted below, in technological areas where products incorporate several interrelated ideas, and technical change builds on earlier innovation, overly broad patents make it difficult for competing innovators to discern the boundaries of what is protected, increase transactions costs in licensing, and raise the market power of individual patentees.

A final concern has to do with the progressive lowering of the utility standard. Technologies are supposed to be reduced to a commercially useful form in order to qualify for patents. However, under Bayh-Dole and legal interpretations of eligibility rules by the courts, patents have been issued increasingly to subject matter that previously would have been considered unpatentable, such as basic discoveries of nature, which have no direct commercial application.

Potential Problems for Innovation

Policy changes have made patents both stronger in scope (broader claims, longer duration, extended eligibility, greater likelihood of prevailing in lawsuits) and cheaper to acquire (diluted standards, lower quality). The resulting proliferation of patent applications and grants in the United States is remarkable, with the former rising from 164,000 in 1990 to 357,000 in 2004 and the latter from 90,000 to 164,000 over the same period.[7] This increase in patents, however, does not necessarily correspond to an increase in innovation. Available evidence does not support the view that enhanced patent protection necessarily stimulates more innovation. For example, surveys of technology officers reveal that, except in pharmaceuticals, biotechnology, and some forms of machinery, inventing firms do not view patents as significant reasons to invest in technology.[8] Rather, they rely more on lead-time advantages, trade secrecy, learning-by-doing, and complementary services. Instead of representing more innovation, then, the recent surge of patents may have created more impediments to innovation from litigation, transactions costs in licensing and research, anti-competitive blockages, and a slowdown in sequential innovation.

The decrease in the quality of patents, as well as the increase in quantity and breadth, has raised uncertainty about the boundaries of the rights owned by patentees. It has also fed an explosion in litigation costs, which may deter small companies from entering the market for fear of infringing on patents with vaguely defined boundaries.

Patent litigation is complex, uncertain, and more expensive than most other civil lawsuits. It is estimated that for patent suits with less than $1 million under

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contention, median discovery costs and legal fees are $790,000; for suits between $1 million and $25 million these costs are $3 million; and for suits with more than $25 million at stake they rise to $6.5 million.[9] These figures do not include damages, which may be treble in cases where willful infringement is found.

In 2000, there were 2,000 patent lawsuits filed involving around 3,000 patents—double the number of lawsuits in 1990. About 2 percent of these lawsuits ultimately went to trial, a rate above that for civil cases in general. It is evident from these figures that litigation costs may be a deterrent for small companies as regards entry into competition that may infringe existing patents. It is also clear that companies generally prefer to settle out of court rather than risk an adverse judgment. Moreover, the United States is unique in providing a right to a jury trial in IPR lawsuits, and juries are more likely than judges to favor patent holders.

In addition to the costs of individual patents, researchers have to contend with "patent thickets." That is, complex technologies, such as biomedical research tools, embody a number of technological inputs, many of which are patented. A different company, in turn, could own each patent. Negotiating these thickets raises the cost of securing rights. Weaker patent standards encourage patent proliferation and an enlargement of the thickets for research in areas such as biotechnology, agricultural chemicals, and pharmaceuticals.

Whether thickets are a significant problem is the subject of much debate. One important survey found little evidence that thickets have prevented biomedical research from fully utilizing the most recent technologies.[10] However, a statistical analysis of citation patterns of publications in biotechnology and life science journals before and after a patent is granted suggested that patents in these areas have a modest research-diminishing effect, with additional evidence of a shift in research priorities toward less protected, and presumably less promising, areas.[11] That suggests patent thickets and transactions costs may slow down the diffusion of scientific research.

This concern was heightened by the CAFC decision in 2002 in Madey v. Duke, which is described in box 1. Prior to this case, universities engaged in research under a traditional research exemption permitting them to use patented technologies freely without paying license fees. The court ruled that research supported potential commercial activities, thereby narrowing the legal scope of the exemption substantially. The decision ultimately could force university scientists to negotiate licenses with multiple patent holders to continue basic research programs. Anecdotal evidence since Madey v. Duke suggests that campus legal offices have become more nervous about their scientists using patented technologies despite the nonprofit status of universities. It remains to be seen whether the case will slow down or shift the priorities of research programs at public laboratories and universities.

A way around these potential problems is licensing patented technologies. Large firms could build extensive patent portfolios that they cross-license with others to avoid infringement and gain access to knowledge. Under cross-licensing agreements, each firm lists a large number of patents it owns and other partici-

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Box 1. Madey v. Duke

John Madey was a tenured professor at Stanford University, where he developed the technology for two patents on an electron laser gun that is important for electron research. In 1988, he moved to Duke University, which built a special laboratory for his lasers. A fallingout caused Duke to remove him as lab director in 1998, but researchers at Duke continued to use machines embodying his technologies, and Madey sued for patent infringement. Duke claimed its use was protected under the experimental use defense for noncommercial entities.

Madey's claim was upheld by the CAFC, which, in essence, ruled that because Duke was using the patented technologies in research that could generate outcomes with licensing revenues, it was a commercial enterprise for this purpose.

Source: Carmella Stephens, "Madey v. Duke University: Federal Circuit Sets Limitations on the Common Law Experimental Use Exemption," Baker Botts LLP Intellectual Property Report 3, no. 27, July 7, 2003.

pants are allowed to use any of the patents listed, with perhaps some net payments to firms with larger portfolios. A related solution is a patent pool, in which two or more firms combine ownership of specified patents but may not license them more widely. Such arrangements may reduce transactions costs enough to offset losses due to greater competition and may avoid litigation costs.

Although such arrangements seem sensible, they pose practical problems. First, they give firms an incentive to build the largest patent portfolio to improve their negotiating positions, a factor underlying the proliferation of patents. Second, patent pools can be operated in anti-competitive ways. For example, Summit Technology Inc. and VISX Inc., which pioneered the development of equipment for laser eye surgery, created a jointly owned partnership that was given control of both companies' primary patents. The partnership could license to third parties but only if both companies agreed, giving each a veto over decisions of the other to license. This agreement eliminated competition between them to offer such licenses.[12] A third problem is that it may be difficult to draft contracts across multiple claims when, as noted above, those claims may be of uncertain validity. Finally, patent thickets may be an entry barrier to the extent that new firms must build a patent portfolio quickly in order to be able to cross-license with other firms.

Of course, cross-licensing also depends on firms' willingness to license their technologies, and holders of U.S. patents have no legal requirement to do so. If companies build portfolios solely for the purpose of extracting payments, they may find it most profitable simply to litigate, especially if lawsuits emerge against a threat of preliminary injunctions and treble damages for willful infringement.

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This possibility limits the willingness of firms to invest in technologies that might infringe patents of even questionable validity.

Similarly, patent holders with broad claims on platform technologies may try to use those claims to discourage competitors through licensing restrictions and litigation against technologies on similar products. A prominent example is the Chiron Corporation, which in the 1980s collaborated with the Centers for Disease Control (CDC) in the discovery of the hepatitis C virus. It was an expensive process, requiring the cloning of the virus through extensive trial and error. The breakthrough discovery, made in 1987, led to a reliable blood test for the disease and sparked further efforts to develop a cure. Chiron applied for a patent on the cloned virus but did not name the CDC or Daniel Bradley, the CDC virologist who had provided essential blood samples from infected chimpanzees, in the patent. Robert Lanman of the National Institutes of Health argued that Chiron should provide the government some control over licensing of the virus and blood test so that other researchers would have access on reasonable terms. Chiron disagreed but in 1990 signed an agreement with the CDC giving Chiron full rights to the patent in return for a payment of $2.2 million. Since that time Chiron has aggressively enforced its patent, and critics claim that its enforcement has held up research by other firms and agencies for years. For example, a French scientist working with bioMérieux stated, "whether you are working on an antiviral or a vaccine, you have to consider that the Chiron patent is going to be a problem."[13] A 2003 study by the National Academy of Sciences also singled out Chiron as a company with a reputation for limiting access to its patents. Moreover, a number of small companies interested in extending research on hepatitis C claim to have abandoned that research because of an inability to license the Chiron patent.[14] Yet another problem with cross-licensing and patent pooling is that patented technologies may be components of technologies that make up important product or technical standards, or become standards themselves. Product interface standards are necessary for various components and programs to work in telecommunications and computer networks. To compete, companies must be able to design products that are compatible with these standards. For example, the application programming interfaces that define compatibility with the Microsoft Windows operating system is a critical industry standard. Yet it is possible that one company may own patents that limit access to the standard or, increasingly, that multiple companies claim rights that cover some portion of it. Indeed, Microsoft's traditional approach has been to keep its patented standards proprietary. Such situations may give the patent holder considerable market power and raise licensing problems similar to those above. Such "holdup" problems in patenting basic technologies can be severe in their effects on follow-on innovation.

The patent system was designed under the classical image of innovation as a discrete technology with clear claims. Yet, as the emergence of these issues indicates, that model increasingly is inconsistent with important new technologies that rely on deep interrelationships across inventions. Firms in high-technology sectors frequently build sequentially on existing inventions to achieve improvements and

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often embed patented technologies into their own products. In this kind of system, future discoveries are more probable if there are more innovators. Stronger patents may thus reduce profits and innovation.

To illustrate this inconsistency between the patent system and modern innovation, one might ask why the U.S. software industry was highly innovative in the 1980s, even though it was not eligible for patents. The sequential, cumulative, and complementary nature of innovation in software pushed product development forward into many areas of technology. The classical view of patents predicts that innovation should have increased after the Supreme Court affirmed in 1990 that computer programs may be patented.

However, the firms that acquired the bulk of these patents actually reduced their research and development (R&D) spending as a proportion of sales, suggesting a flattening of innovation incentives.[15] The reason could be that patents are overly strong protection for the industry. Patents last twenty years, which is far longer than the typical life cycle of a software product. In platform programs with network economies among users, patents can lock in an already significant market advantage, deterring competing innovation.

The Role of Antitrust Policy

Many of the measures that companies take to restrict access to technology fall under the jurisdiction of antitrust authorities. For example, it is anti-competitive to extend market power beyond individual patent claims by tying sales of unrelated or complementary goods to access to patented goods. Under some circumstances, refusals to license a critical enabling technology or important intermediate input may also excessively restrict competition. Antitrust policy could play a role in such cases by ordering licensing.

U.S. antitrust authorities have taken action in some patent cases by issuing nonexclusive compulsory licensing orders and negotiating breakups of patent pools. However, such actions are rare, as antitrust policy has been almost completely benign toward patents. For example, U.S. policy generally will not interfere in cases of "dependent patents," the licensing of which is necessary for the marketing of a later application. This antitrust stance is founded on the same policy presumptions that prevail in U.S. patent law: that patents are property and the state should not limit or order their exploitation, and that technology markets are generally more efficient in the absence of competition regulation.

Given the proliferation of questionable and overlapping patents in an era of rapid technical change, antitrust policy could be a powerful tool for preserving dynamic competition when the patent system fails to do so. The Federal Trade Commission took a step in that direction recently when it raised concerns about the wisdom of maintaining a strong separation between IPR and anti-monopoly policy.[16]

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INTERNATIONAL DIMENSIONS

Difficulties in the U.S. patent regime may be limiting innovation, but it is a problem for international competitiveness only if competitors' systems are more supportive of technological innovation. The first step is to identify variations between the U.S. patent regime and those of other significant countries.

Canada

Taken broadly, the Canadian and American patent systems are similar. Both provide patents for twenty years. Both systems award proprietary rights to exclude others from making, using, and selling the patented processes or products of claimed subject matter.

However, there are significant differences, which reveal the Canadian system to be more cautious in striking a balance between inventors and the users of new information.

Canada has more restrictive eligibility for patents. The Canadian Supreme Court affirmed that transgenic, higher-order animals are not eligible for patents. Canada does not patent business methods, surgical methods, medical treatments, or computer programs. (Computer-related devices that integrate processes and apparatuses may be patented.) Like the United States, Canada publishes all patent applications within eighteen months of filing, but it does not allow inventors to prevent publication if they choose not to file abroad. Canada has stronger standards for what must be disclosed in a patent application. Further, it is possible in Canada for any interested party to challenge patent validity before the patent is granted by making prior art available. And, although procedures exist in both nations to oppose the validity of patents after a grant is made, the U.S. courts have made such challenges difficult to sustain.

For a long time, Canada has viewed compulsory licensing as an appropriate form of transferring technology for purposes of industrial policy (although it has rarely been used), while the United States has confined its use largely to antitrust remedies. The question of interest is whether Canada's approach of more limited rights has generated less innovation growth than has the U.S. approach of strong exclusive rights.

Evidence suggests that this is not the case. During the 1990s, when the United States was considerably expanding the scope of its IPR regime, Canadian R&D expenditures and innovation (as measured by patents registered abroad) rose relative to those in the United States. No definitive inference may be made, because other factors could be at work, but the simple evidence does not favor the hypothesis that the U.S. approach generates more investment in information creation.

European Union

The EU has a strongly protective IPR system. Although traditionally more reluctant about patenting life forms than the United States, the EU has made patents available for biotechnological inventions since 1998. However, the European

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Patent Office (EPO) has taken a more cautious approach than the USPTO in issuing patents with broad claims in core technologies, such as genetic research tools. The EU treatment of software patents is similar to that in Canada. Computer programs, per se, are not eligible for patents, but they can be protected to the extent that they give effect to the operation of a related apparatus or process.[17] This basic principle has supported an increasing number of patents for computer software and Internet programs, although there is no clear definition of what constitutes a "business method" in the EU.

The most important differences are the standards for patents. The EPO tends not to permit overly broad claims in patent applications, and post-grant opposition is more robust in the EU, where there is less of a legal presumption of patent validity. Unlike the United States, the EU recognizes a prior-use exception to patents.

Finally, the EU antitrust body—the European Commission—is more inclined to order licensing or related remedies where it finds excessive use of market power from IPR. A prominent example was the decision in 2004 to order Microsoft to make protocol technologies for Windows available to software firms upon payment of royalties.

Microsoft developed a licensing program, but in July 2006 the commission determined that it was insufficient to meet the terms of the licensing order and issued fines that will remain in place until compliance is achieved.

It is not possible to state definitively whether this approach has limited or spurred innovation growth in the EU relative to the United States, as member countries of the EU vary widely in their innovation capacities. However, in 2003, the United States ranked behind the United Kingdom, Germany, Sweden, Finland, and France in terms of patents received in the USPTO and the EPO per million dollars of R&D spending.[18]

China

Like the United States, Canada, and the EU, China has a system of IPR that is fully consistent (on paper) with the TRIPS agreement. However, China's legal regime makes greater use of TRIPS-consistent authority to limit exclusive rights and encourage access to information. China does not permit patenting of business methods, medical treatments, surgical methods, or plant and animal varieties—in particular, higher-order life forms or biological research tools. (However, one way China does bolster patent rights is by not permitting experimental use of patented materials.) Software users have a limited right to decompile computer code in order to develop new programs, although the government is considering extending patents to computer programs. The country has liberal standards covering government use and compulsory licenses of patented technology.

The familiar problem in China is that patents are poorly enforced, a deficiency that encourages massive copying and imitation. In this context, there is anecdotal evidence, based on interviews of domestic enterprise managers, that China's fail-

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ure to enforce patents is becoming a greater drag on its own firms' ability to innovate and grow.

The remarkable aspect of China's economy is that, despite this weak technology protection and inadequate enforcement, massive amounts of technology have flowed into the economy via foreign direct investment and joint ventures or licensing deals.[19] To date, most such transfers have been second-tier and mature technologies, because foreign firms wished to limit the loss of cutting-edge knowledge. Increasingly, however, international firms are shifting higher-technology production facilities and research centers there. It seems likely that this trend will accelerate as greater enforcement of the new laws takes hold.

Potential Implications

There are two potential implications of these differences across countries that American policy-makers should consider. First, patent systems can provide significant incentives for investments at the same time that they safeguard opportunities for dynamic competition and access. Many countries prefer to strike a balance more in line with the needs of technology users, while transparently recognizing the importance of innovation incentives. In contrast, the U.S. patent system has become so protective of exclusive rights that it diminishes incentives for competitive innovation in some respects.

Second, even if international regimes remain less protective of inventors' rights, the fact that they have become stronger and more transparent in recent decades increases the probability that firms will transfer technology and R&D to international locations.[20] Indeed, numerous software companies and high-technology firms recently have opened research facilities in China and India.

This dynamic poses a challenge for U.S. policy-makers. They are understandably concerned about the loss of technologies to imitation, industrial espionage, and reverse engineering in new industrial competitors. Thus, the United States has a strong interest in pushing China and similar countries to strengthen their patent standards, trade secrets, and enforcement efforts. Paradoxically, though, such a change ultimately would shift technology transfer away from older technology toward first-tier technologies and research facilities as firms feel more confident about their ability to protect proprietary knowledge. Because some portion of this research off-shoring would be due to the competitive problems of the U.S. patent system, the United States would be encouraging excessively rapid technology transfer.

Despite that problem, more active enforcement by China and other nations that misappropriate proprietary knowledge and confidential information would generate significant gains for American technology exporters. Those gains would include higher returns to licensing and longer periods within which firms would benefit from market exclusivity in growing and dynamic economies. Therefore, U.S. trade authorities should place greater emphasis on pushing governments in major developing countries to meet their international obligations to enforce

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patents. As discussed more fully in the recommendations, a positive incentive would be to expand the global resources available for providing technical and financial assistance to these countries in order to improve their judicial systems and enforcement regimes. This relaxation in technical and budget constraints should reduce opposition to investments of scarce development resources in enforcement. However, real progress may require coordinated legal action at the WTO to demand serious efforts to clean up infringement. This combined approach should shift the politics of piracy in developing nations in favor of emphasizing the dynamic gains from stronger protection for domestic and international technologies.

While enforcement initiatives have not been absent from trade policy, the United States has devoted far more effort to negotiating globally harmonized patent standards or, failing that, to markedly strengthening patent regulations in developing countries through trade agreements. Indeed, U.S. trade policy places a strong priority on international patent harmonization at high levels of protection—a questionable ranking of priorities.

International Harmonization

There is a good reason to achieve some harmonization of patent rules, since it could reduce transaction costs of inventive companies. Dealing with different patent standards and fees is costly. There is an alternative to harmonization, however: to increase coordination among patent offices to mutually recognize patent grants and reduce fees.

Mutual recognition would mean that a patent application considered in one major IPR office would, if granted, be ruled presumptively valid in other participating countries, subject to local opposition procedures.

Mutual recognition would not tighten patent standards significantly. The U.S. policy, in contrast, emphasizes the need for far stronger regulations, suggesting that strategic objectives are in play. First, such harmonization would increase the profits of U.S. firms in biotechnology, agribusiness, software, and other industries. Second, a strong harmonization agenda could make competitive differences in the U.S. system and international regimes less glaring.

The harmonization drive has come in three forums. First, the TRIPS agreement established a comprehensive set of minimum standards that all member countries must implement and enforce. For most developing countries, the changes required were significant, particularly regarding patents, the confidential treatment of clinical test data for marketing approval, and compulsory licenses. The TRIPS standards, however, contain room for favoring competitive access over strong exclusive rights. Countries may define their own standards for nonobviousness, utility, and novelty, and many countries (such as Brazil and China) have chosen rigorous standards to prevent awarding property rights to minimal changes in technology. If enforced, these minimum standards provide some certainty for investors but fall well below the U.S. standards in patents. Further, TRIPS has not

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forced convergence of patenting standards and exceptions among the developed economies.

A second important effort has been the currently stalled negotiation of a Substantive Patent Law Treaty (SPLT) at the World Intellectual Property Organization (WIPO). The SPLT would largely harmonize patent examination standards across member nations. U.S. negotiators have pushed for a global regime that would adopt many of the American standards for eligibility, including of subject matter. This negotiation has been an attempt by the United States (and the EU to some extent) to ratchet up patenting standards that were left more discretionary under TRIPS. Many developing countries, led by Brazil and India, have resisted this approach, while difficulties in achieving agreement among the United States, the EU, Japan, and other developed countries have sidetracked the negotiations further.

The third and most controversial U.S. approach has been the negotiation of bilateral free trade agreements with developing countries in order to push patent standards higher than TRIPS levels and closer to the U.S. model. This so-called TRIPSplus agenda (see box 2) has expanded over time, culminating in strong IPR chapters in the agreements with Morocco, Jordan, Bahrain, Singapore, Peru, and Colombia.[21] TRIPSplus requirements have been controversial among health authorities in developing countries because they place strict limits on the ability of governments to encourage generic entry or issue compulsory licenses in pharmaceutical products.[22] They also are resisted by information and education ministries for their restraints on fair use in copyrights.

For all of this controversy, the benefits to innovation are questionable. Most of the markets involved are small, so it is unlikely that research-based international companies would perceive additional incentives for general investments or undertake investments specific to those markets. These policies will not encourage innovation by firms in the signatory countries because they do not provide much additional market access in the United States. It is difficult, therefore, to see much reason to expect more R&D induced by the patent components of these FTAs. A more likely outcome is that local innovation will actually be discouraged by patent standards that exceed what would be sensible for development.

In addition to the damage done to innovation in smaller markets, initiatives to open larger markets to U.S. exports may fall victim to the American focus on patents.

The bilateral FTAs are not likely to go beyond agreements with relatively small economies, as larger and middle-income countries have domestic interests that would resist substantially stronger standards than those in TRIPS, and their governments are better positioned to resist the restrictive aspects of patent policy in TRIPS-plus. Brazil, for example, has resisted negotiating an FTA with the United States—concerns about IPR being a central reason—and has further opposed a hemispheric Free Trade Agreement of the Americas. China in particular sees little need for an agreement that would ratchet up its standards. Clearly, pursuit of harmonization in these cases carries severe costs that merit consideration.

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Box 2. The U.S. TRIPS-plus Agenda

The expression "TRIPS-plus" refers to demands made by the United States and other developed economies that trading partners agree to IPR standards that exceed those required in WTO rules.

In the area of pharmaceuticals, the Doha Declaration clarified TRIPS by permitting the least-developed countries to delay implementation and enforcement of patent rules until 2016, stating that governments could accord priority to public health needs over intellectual property requirements and asserting that developing nations could take full advantage of the flexibilities in TRIPS. In its negotiations of bilateral free trade agreements (FTAs), the United States has systematically ignored these provisions in favor of strong protection in pharmaceuticals in particular and in IPR more generally.

In operational terms, TRIPS-plus means the following. First, for items that are not negotiated within an FTA, the relevant TRIPS standards pertain. Second, the FTA might negotiate standards that exceed those of TRIPS. Third, newer areas of IPR that were not covered by TRIPS may be subject to negotiations in FTAs. This approach meets U.S. negotiating priorities, including requirements that IPR provisions of agreements "reflect a standard of protection similar to that found in U.S. law" and that standards strongly protect new technologies and embodied intellectual property.

Primary items of TRIPS-plus include the following. Regarding patents, the United States prefers that countries provide extensions to patent coverage and scope in a number of ways. One way is to narrow the exclusions from patentability and, in particular, to make eligible life forms, including genetic sequences. Other areas in which patents could be provided are plant varieties, software, and business methods. A second way to extend coverage is to provide patent-term extensions for drugs in cases where health authorities issued patents with undue delay. Another is to issue second-use patents, which effectively extend patent protection for chemical entities beyond original terms. Yet another is to limit experimental use of patented materials and also to restrict their use by potential generic firms in preparation for entry as patents expire. But perhaps the most significant one is the demand that health authorities ban the registration of any generic drugs during the lifetime of a patent. That would effectively end access to compulsory licensing except in rare circumstances.

Next, a central demand of the United States is exclusive use rights for confidential clinical and field trial test data on behalf of original applicants for a period of at least five years for pharmaceutical products and ten for agricultural chemicals. Recent FTAs go beyond that and effectively permit ten-year exclusivity (by giving firms up to five years to apply for marketing approval in the country and then adding data rights) before data may be used. That is a strong restriction on competition, even in medicines where no patent is issued.

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Is Harmonization worth the Cost?

TRIPS-plus raises profits of major U.S. industries selling products abroad, but the agenda offers few innovation benefits for American consumers and may impose costs on citizens in partner countries. In return, however, the United States pays an incalculable, but substantial, cost in terms of its foreign relations. These one-sided demands in patent standards increase suspicion in developing countries that trade agreements are designed unfairly and do not consider development needs. Indeed, concerns about the rules governing regulation of pharmaceuticals held up negotiations with Colombia until the public objections of the health minister could be neutralized. In both Colombia and Peru, the recently signed trade agreements with the United States are unpopular among many citizens primarily because of the IPR provisions.

Attempts to internationalize U.S. patent practices raise considerable opposition more generally abroad. The U.S. Basmati rice patent (see box 3) raised widespread concerns in developing countries, despite the fact that central claims in the patent were overturned, that the American patent system could be used to appropriate traditional technologies. Those countries fear that it will fall to their companies and governments, rather than the U.S. patent examiners, to overturn obviously invalid U.S. patents.

SUGGESTED REFORMS

Based on the analysis in this report, the United States should pursue the following policy recommendations to build coalitions for reform.

Domestic Reforms

Given the evolution of patent doctrine and judicial practice, it is impossible to remove whole technologies (such as software and business methods) from patent eligibility.

Instead, the United States should return, at least in part, to the first principles of examining patents. As noted in the introduction, legislation has been introduced in both houses of Congress that would make some progress in reforming the patent system. The House bill would:

- shift the U.S. system from a first-to-invent patent award to a first-to-file award, thus eliminating litigation to determine the first inventor and making our system more consistent with the rest of the world;
- require publication of virtually all applications within eighteen months of the filing date;
- permit interested parties to challenge the validity of a patent within six months of its granting by filing a petition at USPTO rather than engage in costly lawsuits; and

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Box 3. Basmati Rice

In late 1997, an American company, RiceTec Inc., was granted a patent by the U.S. patent office to grow the aromatic rice known as Basmati and label such rice grown outside India with that name. RiceTec had been trying, with little success, to enter the international Basmati market with brands like Kasmati and Texmati described as Basmati-type rice. However, with the Basmati patent rights, RiceTec would have been able not only to call its aromatic rice Basmati within the United States, but also to label it Basmati for its exports. Farmers in India and Pakistan were outraged because they would lose access to the large U.S. import market and also face greater competition for traditional Basmati exports in such crucial markets as the EU, the Middle East, and west Asia. Many observers in the Indian media suggested that patenting Basmati in the United States was akin to diminishing their history and culture. The Indian government protested three (of twenty) claims in the patent, pointing out that its exclusive titles to growing rice plants with certain characteristics identical to Basmati, the grains they produce, and the method of selecting plants based on a starch index, all related to items that had been known for many years and should be considered prior art. In 2001, the USPTO invalidated these claims in the patent but permitted RiceTec to sustain its patent on rice-breeding innovations unrelated to this prior art of indigenous farmers.

- permit third parties to submit published materials to USPTO prior to its issuing a patent, in order to make sure that patents are not granted on inventions that were already known.

The Senate bill would:

- shift to a first-to-file system;
- provide more structure for judges in determining patent damages;
- permit third-party submission of prior published materials; 33
- limit sharply the definition of "willful infringement" under which treble damages may be awarded; and
- provide a second window for post-grant opposition, during which firms accused of infringement could challenge the patent's validity.

These bills may be as much as can be accomplished due to countervailing political pressures. Unfortunately, they would not go far enough to achieve a fully effective balance in the patent system. Thus, domestic reform should remain on the agenda for the near term until it incorporates all of the following:

- Congress should require that more rigorous standards for determining whether an invention is obvious or novel be applied to patent applications. To this end, it should permit the USPTO to keep enough fees to fund an expansion of examination professionals to serve as a "second set of eyes" for business methods patents, software patents, and other relevant applications. This financial shift would reduce the granting of dubious patents.

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- Third parties should be permitted to submit additional prior art upon publication of patent applications. This requirement would also reduce the granting of patents to inventions that are obvious or not novel.
- Congress should lay the groundwork for an effective and expeditious post-grant opposition system. Legislation to that end should permit any interested party, not just those involved in litigation, to petition the USPTO within nine to twelve months to reconsider the scope and validity of a patent. It should also allow an alleged infringer to request reconsideration of the patent within six months of receiving notice of infringement from a patent holder. The goal is to provide a cheaper and faster means of reviewing patent validity than the current costly and one-sided court procedures.
- Congress should scrap the requirement that a competitor cannot challenge a patent until and unless it is sued for infringement, as it raises substantial uncertainty. It should also weaken considerably the strong legal presumption that issued patents are valid simply because they were issued.
- Congress should eliminate the presumption that preliminary injunctions should be issued by courts in cases of alleged patent infringement and replace it with an approach considering all relevant business factors in deciding whether to issue an injunction or to stay an injunction. For example, plaintiffs should be asked to show that they would suffer irreparable damage that could not be compensated monetarily before a court issues an injunction against a defendant.
- Congress should limit the grounds on which willful infringement is found. For example, the presumption of a willful violation when the infringer did not first obtain a lawyer's opinion should be ended. Generally, punitive damages should be awarded only in circumstances of egregious conduct, not where defendants acted with no intent to infringe. These measures would reduce the hesitancy of researchers to take advantage of published patents and other forms of available information.
- Congress should implement a legitimate prior-use right against patent infringement suits.
- The United States should establish an office of competition advocacy within USPTO to consider the economic implications of broad patent claims before they are granted. This examination should be restricted to patent applications on technologies that would have significant market power, an approach similar to the antitrust role of staff economists at the Federal Trade Commission and the Department of Justice.

International Reforms

- The United States should pursue mutual patent recognition among the United States, the EU, Japan, Canada, Australia, China, and other nations. This would lower overall costs of the global patent regime.

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- The U.S. harmonization agenda should be softened to involve accommodation by the United States at least as much as the other way around. This would include the following steps:
  - A shift in U.S. practice to award patents on a first-to-file (rather than first-to-invent) basis.
  - Pursuit of limited convergence of global patent standards, perhaps through procedures that differ by region or development level. One could imagine a patent application that would cover the United States, Canada, Europe, and Japan and that would be examined in any of those patent offices under a systematized procedures manual. There might also be a single patent application for the Association of Southeast Asian Nations (ASEAN) in conjunction with China, wherein China would undertake primary responsibility for examination under a developing-country set of standards. This technical arrangement would not absolve China of its international obligation to enforce patents.
  - Abandonment of the TRIPS-plus objectives in bilateral trade agreements, especially in regard to patents and procedures in medicines that could negatively affect the ability of developing countries to manage health policy. Specifically, U.S. trade authorities should stop demanding strict concessions regarding compulsory licensing, experimental use, second-use patents, and extended periods of test data exclusivity.

Developing a Consensus

U.S. pharmaceutical companies, biotechnology firms, and others that rely on international patent protection will oppose these international reforms. Firms in other sectors do not place a high priority on these ideas, as they are more focused on domestic patent reforms.

However, all IPR-exporting companies would gain if there were serious progress on enforcement of their rights in major developing countries. Piracy and counterfeiting are important in their own right for many industries but also matter to patent holders, who sell goods using complementary copyrights and trademarks. In truth, there has been virtually no progress in dealing with patent infringement, copyright piracy, and trademark counterfeiting in China and elsewhere. This situation blunts interest in wider reforms and therefore is an important roadblock to achieving them.

Thus, to generate consensus on a relaxation of the international harmonization agenda, there must be serious progress in enforcement. Industry estimates suggest that U.S. firms suffer tens of billions of dollars in lost sales annually to infringement of various kinds. The United States—in concert with the EU and Japan, where firms experience similar losses—should place more emphasis on achieving a global consensus to ensure effective IPR enforcement, particularly in such large markets as China, Turkey, and South Africa. Greater enforcement would have the direct benefit of expanding sales opportunities for international firms and

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the indirect benefit of reducing concerns in Congress about the rapid loss of technologies.

For their part, middle-income and emerging industrial powers have good reason to strive for greater enforcement, since simple piracy and counterfeiting, however profitable, do little to promote technical change and are an increasing burden on the expansion of domestic enterprises. At the same time, the domestic political economy in those countries militates against reforms, because in the short run the primary beneficiaries would be IPR owners from abroad while the losers would be domestic infringing firms, which are often well connected. Further, major enforcement activities would demand large public investments, thereby commanding a greater share of scarce development resources.

A consensus needs to be reached that would coordinate the long-term interests of dynamic firms in developing economies with the medium-term interests of patent-intensive companies in developed countries. This coordinated approach to enhancing enforcement should be built around two basic principles. First, because international firms from all technologically advanced nations suffer losses from infringement, a joint effort among countries in the Organization for Economic Cooperation and Development (OECD) to considerably expand technical and financial assistance for IPR enforcement would be a positive inducement for change. The technical assistance should involve additional training in judicial principles and enforcement procedures. Developed countries should also commit to providing greater financial assistance for effective enforcement procedures in order to relax budget constraints. To a substantial degree this additional assistance could be paid for through nominal fees imposed on international patent and trademark applications at WIPO, which would have the advantage of charging beneficiaries—global patent registrants—a portion of the costs of improving their competitive landscape. In brief, the carrot of substantial assistance, in combination with a relaxation of U.S. pressure for higher global patent standards, should provide positive incentives to developing countries for upgrading enforcement.

Scattered financial and technical assistance of this kind has been offered for years, and the United States has complained strongly about the enforcement issue in China, India, Thailand, and elsewhere. However, neither assistance nor jawboning has been effective in raising the incentives of governments to improve markedly their enforcement activities. It is naive to expect the provision of further assistance to achieve meaningful progress except over a lengthy time period, so an external stick may be required to change domestic politics in favor of rapidly implementing effective enforcement mechanisms. Thus, the second principle is to hold major developing economies accountable for their unwillingness or inability to enforce patents, trademarks, and copyrights in their own laws. China, for example, has undertaken extensive reforms to its laws governing IPR but has made only minor investments in enforcement and continues to turn a blind eye to extensive infringement, piracy, and counterfeiting. A similar situation exists in other large developing countries.

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This lack of progress is inconsistent with commitments made in Part III of TRIPS to "ensure that enforcement procedures…are available under the law so as to permit effective action against any act of infringement of intellectual property rights." Developed countries could use this as the basis for a substantive WTO dispute that their rights have been nullified or impaired by weak enforcement efforts. Demonstrating damages would not be difficult, and such a case could help establish a better framework for improved enforcement.

A WTO case is far more likely to be effective if it is undertaken as a multilateral effort by developed countries. A broader complaint will get more attention from plaintiff countries because any prospective trade sanctions imposed would restrict access to all their most important export markets. It would also spread the costs of preparing the case and suffering the damages from potential trade barriers among multiple countries that stand to benefit from stronger enforcement.

The prospect of better enforcement over the medium term, along with achieving some efficiencies in international patent procedures, may not be sufficient to induce U.S. firms to support the call made here for scaling back the harmonization agenda. Without it, however, the overall reform package advocated here cannot proceed. Ultimately, what should matter is the ability of the domestic and international patent systems to support those firms' ability to compete in technology development and to protect their rights. The needs of innovation will be better served by a more flexible—and better enforced— global regime than by the harmonization agenda being pushed by U.S. trade negotiators.

CONCLUSION

For more than twenty years, the United States has increasingly strengthened the exclusive rights of inventors at the expense of those who need access to new technologies, while patents have been granted too easily and written too broadly. These policies reflect the misguided belief that stronger rights will always expand incentives for innovation.

Instead, the patent system raises roadblocks for licensing and cumulative innovation, becoming a threat to competitiveness and growth.

The dogmatic assertion that "more is better" also drives U.S. trade policy in setting global patent rules. The global trading system cannot thrive under a "one size fits all" approach to any major regulatory regime, including patents. Countries need the flexibility provided under TRIPS—the multilaterally agreed regime—to manage and support their own innovation and competition policies. Pushing a high-level harmonization agenda has not been fruitful but has generated resentment in trading partners and raises risks for the future of U.S. bilateral trade policy.

Thus, the fundamental approach of protecting low-quality patents with ever-stronger domestic rights, while pressing for more harmonized global patent standards, should give way to a framework that emphasizes flexibility and gets the incentives for innovation right. On the domestic front, this requires significant

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reforms in patent law and judicial practice. On the international front, a willingness to relax demands for harmonization and TRIPS-plus standards should be combined with greater assistance for reforms and an insistence on effective enforcement in major developing countries. This two-pronged reformation in the stance of domestic and international patent policy would move a long way toward restoring sense to the patent system and expanding confidence that true innovation will be rewarded, wherever it occurs.

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duration.

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18. Figures from OECD, *Main Science and Technology Indicators 2005* (December 2005).
19. It should be recognized that multinational firms have somewhat greater ability to enforce their patents in China than domestic enterprises.
20. There is substantial evidence that strengthening patent rights attracts more technology flows to middleincome developing countries. For an extensive review and analysis, see Keith E. Maskus, "Encouraging International Technology Transfer," *UNCTAD-ICTSD Project on IPR and Sustainable Development Issue Paper* no. 7, May 2004.
21. Australia also agreed to strengthen its rules in its bilateral trade agreement with the United States.
22. These agreements generally contain a side letter that affirms the ability of partner countries to take actions to protect public health in the event of a health emergency.

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