5

Intellectual Property Rights and Global Policy Challenges

The last chapter aimed to illuminate economic tradeoffs in a range of contemporary issues surrounding the exercise and regulation of intellectual property rights (IPRs) in primarily private goods. Indeed, the current global IPR system was constructed largely to clarify the exclusive rights of creators and inventors seeking to sell such goods in international trade and investment markets. As discussed in chapter 2, there is evidence that real commercial gains are emerging, even if unfortunately they are largely bypassing the poorest countries. However, even in the realm of private goods the system is under considerable stress, whether due to limited administrative resources, increasingly outdated protection models, or basic political economy conflicts. Simply addressing those problems, whether within the World Trade Organization (WTO) or through such external rules-setting exercises as the Anti-Counterfeiting Trade Agreement, raises major challenges.

Far greater controversies arise regarding critical public needs such as nutrition, health, environmental protection, and education. IPRs often involve the very inputs, products, and technologies needed to address these needs, and the clear tendency is toward greater private ownership and control. Exclusive rights may support trade and technology markets but they also raise costs of access to protected information goods, still overwhelmingly developed in the industrialized economies. Further, provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and TRIPS-Plus requirements protect rights owners whose creative goods fit into the traditional paradigm of patents, copyrights, and trade secrets, but offer no protection to the genetic resources and traditional knowledge that make up much of the intellectual wealth of developing economies (Maskus and Reichman 2005a, Dreyfuss 2009, Melendez-Ortiz and Roffe 2009). Because the system falls short in these areas,

policymakers in emerging-market and developing economies are fashioning their own legislative solutions while also looking to institutions outside the WTO, such as the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), to establish new expectations and norms.

These policy interfaces—access burdens in public goods and asymmetric protection—attract the fiercest critics and raise the thorniest analytical questions about IPRs. This chapter addresses several of the most prominent debates through the lens of basic innovation economics and international trade. Once again, economic analysis offers useful insights about basic tradeoffs and some policy recommendations flow naturally. However, these are complex questions and solid empirical evidence would help resolve them more confidently. Unfortunately, in many of the more controversial and difficult areas there is virtually no systematic evidence, leaving us to rely largely on judgment.

Intellectual Property Rights, Policy Space, and Development

There is a massive literature on the role of IPRs in the development process, virtually all of it based on case studies, academic legal scholarship, or treatises by international organizations and nongovernmental organizations (NGOs).[1] There is little point in reviewing this literature here, other than to point to the many complex interrelationships between growth, technological change, economic and social circumstances, public policy, trade, and IPRs.[2] At various points in history and under different circumstances, protection of intellectual property has been seen as a competitive boost to innovation and growth, a drain on learning and source of market power that is inimical to development, or irrelevant.

Thus, simple statements that IPRs always promote development through greater creativity, innovation, and technology transfer are incorrect without greater context. So are proclamations that IPRs harm poor countries via excessive rents paid to powerful foreign companies, costly imitation, and limits on information access. Rather, IPRs are properly conceived as components of national innovation strategies, with the complementary recognition that those rights are subject to regulatory restraint to achieve key objectives in public health, education, competition, and other policy areas.

These are complex problems, some of which are analyzed in later sections. In order to set a foundation for those discussions, this chapter begins with a review of the options available to countries to help regulate and complement IPRs. In this context, note that intellectual property norms are not immutable

1. Among the more prominent source volumes are Commission on Intellectual Property Rights (2002), UNCTAD-ICTSD (2003), Maskus and Reichman (2005a), Fink and Maskus (2005), Gervais (2007), and Wong and Dutfield (2010).

2. See again the case histories in Odagiri et al. (2010).

and should change with development conditions and technological progress.[3] Neither are they fully dictated to developing economies by external factors, as is sometimes suggested. Despite the upward harmonization of standards required to comply with TRIPS and other agreements, developing countries retain considerable residual policy room within which to tilt IPRs toward a competitive orientation.

It is important to note that the policy flexibilities described in this section exist in the laws of nearly all developed economies, though these countries vary in the rigor with which those policies are defined and exercised. Thus, while discussions of policy flexibilities are often couched in terms of developing-country approaches, they apply equally—and may be more often utilized—in the developed world. For developing economies, the question is not whether such policies are legal, but rather how well they fit into their own strategies and resources.

Intellectual Property Standards

Consider the primary options available to developing and emerging-market economies with respect to IPRs. This subsection covers standards, along with limitations and exceptions (L&Es), in basic areas of exclusive rights.[4]

Patents and Regulation

A first observation is that developing economies should avoid practices that encourage filing and approval of low-quality patents. Returning to first principles, patents should be provided only to genuine inventive advances in the industrial and commercial arts. For this purpose, inventions need to be novel (i.e., not known in prior art), nonobvious, and of commercial utility. For example, the newest Chinese patent law, adopted in 2009, has a broader novelty standard for invention patents than in prior Chinese legislation (Gao 2009). It also allows a defense against infringement claims that permits defendants to introduce prior art in court proceedings. Further, developing countries may wish to choose fairly stiff nonobviousness standards, which India did in section 3 of its 2005 patent law regarding new forms or uses of known chemical substances. Finally, a strong utility standard, requiring demonstration that an invention may be reduced to practice of clear commercial benefit, in particular may help keep the results of basic science in the public domain.

Next, while rigorous eligibility standards can prevent excessive patenting, it is sensible for developing countries to employ pre-grant or post-grant oppo-

3. See the discussion in chapter 2. For analysis of the determinants of such changes, see Ginarte and Park (1997), Maskus (2000a), Grossman and Lai (2004), Scotchmer (2004a), and Park (2008a).

4. For further discussion, see World Bank (2001), Commission on Intellectual Property Rights (2002), Maskus and Reichman (2005b), Correa (2007), and Reichman (2009).

sition procedures, or possibly both, so long as they are not used abusively to limit or delay provision of legitimate patents. India has both forms of opposition in its patent law, along with a strict disclosure requirement that is meant to clarify to rival inventors how to implement an invention. Robust opposition procedures may be particularly useful in poor countries that cannot afford their own examination offices and, therefore, rely largely on simple registration procedures or accept the results of novelty examinations done in other jurisdictions.

While applying rigorous eligibility standards for invention patents is worth considering, it is equally important not to extinguish small-scale inventive efforts, particularly by local inventors. Smaller and derivative inventions need not be given full 20-year protection with broad scope. Rather, a robust utility model or petty patents system can be effective. These devices offer shorter-term and narrow protection for adaptive inventions, with limited requirements for demonstrating novelty and inventiveness. Statistical evidence suggests that utility models have contributed to productivity growth in Brazil, South Korea, and Japan (Maskus 2000a, Maskus and McDaniel 1999). More generally, a transparent regime of trade secret protection can encourage commercialization of subpatentable inventions for which firms may prefer not to disclose confidential technical information (Reichman 2000).

These policy rules can help sustain technical information in the public domain while rewarding small-scale innovation. However, countries seeking to encourage domestic competition and build scientific capabilities may wish to supplement them with certain exemptions. One example is the US "Bolar" exemption—passed as part of the 1984 Drug Price Competition and Patent Term Restoration Act—which allows generic drug firms to experiment with protected formulations in order to prepare for regulatory approval upon patent expiration. Similar laws exist in Canada, the European Union, and most other developed economies. Another is a research exception, which permits experimental uses of patented inventions in order to develop new technologies and invent around or significantly improve existing ones. Establishing a research exemption in protected agricultural varieties could be of particular significance in economies with important farming sectors.

Utility Models

As noted above, a system of utility models or petty patents involving narrow protection and short terms can support adaptive innovation at low costs. History suggests it has been deployed effectively in Brazil, Japan, and China, among other countries. Such a regime deserves consideration within the broader system of IPRs in any country striving to encourage incremental innovation.

Utility models still pose difficulties, however. The problems they raise are the same as those with patents, simply written small. Because they are exclusive rights, rival firms cannot legally reverse engineer the protected products,

limiting possible spillovers. Transactions costs in licensing certain technologies may be so high as to make it difficult to launch them in small markets. Enforcement of utility models against infringement requires litigation that may be costly and hard to accomplish in developing economies.

Trade Secrets

Trade secrets are confidential business information such as production processes, formulations, consumer databases, management techniques, or other elements underlying a firm's marketing strategies. They are protected by laws against misappropriation of confidential information through unfair means, including industrial espionage, inducing employees to reveal secret information, and other practices. Regulations protecting trade secrets are often criticized as anticompetitive because they do not require firms to disclose their technologies.

However, trade secret protection supports an important category of competition that is of considerable importance in developing and emerging-market economies. Firms frequently develop new technologies that are not patentable, are not worth paying patent fees to protect, or simply have more value if undisclosed. By opting to keep their information confidential, firms have no exclusive rights to it. However, rival firms must engage in reverse engineering, which is the legal form of learning these secrets, in order to compete with the same or similar technologies. Because reverse engineering takes time and incurs investment costs, the originators have natural lead times within which to gain marketing advantages, register trademarks, and build brand value. Thus, trade secrecy acts as a type of short-term intellectual property right, though the term of protection is uncertain.

Trade secrets protect an important form of innovation: Competitors are free to experiment with a technology, without compensation or license, in order to improve it, so long as their actions are legal. Subpatentable innovation is protected from misappropriation until technologies are reverse engineered and competing products exist. Note that the successful reverse engineer may either keep the knowledge as its own trade secret or publish it, in which case the information goes into the public domain.[5] Originators may also choose to license to potential entrants if it seems reverse engineering is likely to be successful. In these terms, trade secrecy laws can strongly promote competition.

Thus, developing countries seeking to encourage local innovation—in addition to incoming foreign direct investment and licensing contracts—need to establish an appropriate legal framework for protecting confidential business information. Clearly unfair forms of competition, including passing off and industrial espionage, should be illegal. A more complex issue is regulating contractual provisions preventing the use of technical information for some

5. Samuelson and Scotchmer (2001–02) offer a comprehensive analysis of trade secrets and incentives, with an emphasis on semiconductor designs and software.

period of time as employees change positions among firms or start their own enterprises. Rigorous "noncompete" clauses may strongly protect originators, but they also raise barriers to competition, particularly in industries where information spillovers are significant, such as microelectronics, software, machinery and equipment, and business and consumer services. In this regard, authorities may tilt toward more lenient provisions in order to build entrepreneurial activity, even while enforcing legal provisions against stealing trade secrets.

Copyrights

It is evident that countries need not establish copyright terms longer than those required in the Berne Convention and TRIPS, including life plus 50 years for works attributed to authors and 50 years from creation or publication for other works. This is the standard adopted by China, Indonesia, South Africa, and most developing economies, though some go well beyond it. India, for example, offers life-plus-60 and 60-year copyright terms, likely reflecting the strength of its film and software sectors. Colombia's analogous terms are 80 years, while the Ivory Coast extends protection terms to 99 years.[6]

As noted in chapter 3, the scope of copyright protection may be narrowed by provisions for fair use (or fair dealing) and legislated L&Es. Developing countries are presented a wide range of options in this regard, so long as their L&Es meet the so-called three-step test under the Berne Convention and TRIPS Article 13. Specifically, a limiting provision is permissible so long as it (1) is confined to special cases; (2) does not conflict with normal exploitation of the work; and (3) does not unreasonably prejudice the legitimate interests of the rights holder. These provisions restrain governments somewhat in setting their L&Es in copyright. However, legal scholars have argued for a narrow interpretation of these steps in order to sustain wide operating room in promoting the public interest, subject to adequate compensation for rights owners (Okediji 2006). These elements arise most prominently in policy concerning access to scientific and educational materials, as noted later in this chapter.

International Exhaustion

As described in chapter 3, countries may select their own exhaustion regimes, determining the legal scope of parallel trade. In principle, developing nations may prefer international exhaustion, making them open to parallel imports from any other market, where they have limited domestic production capacity. This regime could be beneficial in procuring patented essential medicines and

6. One important reason countries lengthen copyright duration is to establish material reciprocity for their authors in bilateral understandings permitted under Article 7 of the Berne Convention. For example, when, in 1993, the European Union extended its term to life plus 70 years, US copyright interests were anxious to do the same in order to avoid a situation where their works were not protected for the additional 20-year term in Europe. This was accomplished in the highly controversial 1998 Sonny Bono Copyright Term Extension Act.

needed environmental technologies at relatively low cost. The situation is never this straightforward, of course, given the complex economics of parallel trade. Openness may put upward pressure on prices because of reference pricing schemes abroad and strategic decisions by firms to limit parallel imports. Thus, careful analysis of likely market responses is important. One potential means of resolving these difficulties is for regional groupings of developing countries to adopt regional exhaustion regimes, permitting unrestricted parallel trade among their members.

Compulsory Licenses

A compulsory license is an order by public authorities to permit the use by government or third parties of the subject matter of a patent without the authorization of the patent holder.[7] Copyrighted material may also be the subject of implicit compulsory licenses through the fair-use doctrine or similar regulations. This action is taken when the perceived public interest in wider use outweighs the private interests of the exclusive rights owner. In the case of a patent, the users of a compulsory license typically offer a market-based royalty to compensate for the loss in exclusive rights. The compulsory license is generally nonexclusive, permitting the original IPR holder to continue to sell. Such a license may be issued for a variety of public policy reasons, such as providing for government use, dealing with medical emergencies, and counteracting market power.

Regulatory Questions

Article 30 of TRIPS states that governments may provide limited exceptions to exclusive patent rights, so long as the measures do not unreasonably prejudice the legitimate interests of rights holders or conflict with normal exploitation of the patent. While this language may sound narrow, Article 30 offers no restrictions on the use of compulsory licenses. Indeed, some observers claim it offers a broad foundation for issuing such licenses for almost any legitimate public purpose (Correa 1999). Interestingly, attempts to limit the scope of this exception during negotiations ran afoul of legal provisions in the major developed economies, including the United States. For example, efforts to narrow the grounds on which governments could issue compulsory licenses to promote the public interest were inconsistent with US legislation broadly authorizing public use of patented inventions (Reichman and Hasenzahl 2003).

Procedural issues are addressed in Article 31, which lists requirements that must be met to issue a compulsory license. Use must be authorized on a case-by-case basis, limited in scope and duration, be nonexclusive and nonassignable (by the licensee), and the licensee must pay adequate compensation to the rights holder based on the patent's economic value. Further, compul-

7. This subsection draws on Maskus (2012a).

sory licenses are permitted only after prior efforts of potential licensees to gain access to the technology on commercial terms have failed (except in cases of national emergency or public noncommercial use). They are also subject to judicial review and may be terminated after the conditions giving rise to their authorization have ceased to exist. Compulsory licenses may be issued in the case of dependent patents, subject to certain limitations. Finally, under Article 31(f), the use authorized under the license must be "predominantly for the supply of the domestic market," in essence preventing compulsory licenses to build exports. This last limitation was important to multinational firms that did not want to see such licenses used as industrial policy that could support global export competition for their patented goods. As noted in the next section, this rule has been waived in the case of essential medicines for importing countries without production capacity.

Thus, TRIPS leaves developing countries considerable legal room to maneuver in the issuance of compulsory licenses. They are largely unrestrained in cases of national emergencies and orders to offset anticompetitive abuses of IPRs. In other cases they are bound by the requirements of Article 31, but many legal experts believe that these rules may be used flexibly within the bounds of their own legal regimes (Reichman and Hazensahl 2003). For example, authorities may take actions to ensure that licensees under a compulsory license order may continue to produce or be compensated in the event the order is terminated. This is important to encourage licensees to undertake investments without fear of being forced out of the market after some period of time.

Without question, compulsory licenses are an important instrument of public policy in the major developed and emerging-market economies. For example, the United States has essentially two doctrines under which it authorizes such actions. The first is a public, noncommercial use exception for patented technologies. Public-use licenses have often been granted to ensure that critical defense technologies are available, subject to full compensation. Less frequently, the government has taken patent rights in order to support development and infrastructure goals, such as dams and electricity projects. On occasion, US authorities have threatened to issue a compulsory license in order to expand supplies of critical medicines on the market. The most recent, and highly controversial, example came in 2001 when Bayer was threatened with losing its exclusive rights if it did not expand its supplies of the drug Cipro to offset shortages caused by the anthrax scare. In the end, Bayer did so and retained its patent.[8]

The second justification for compulsory licenses is to remedy anticompetitive abuses of IPRs, a frequent practice in US courts (Maskus 2012a). For example, the Federal Trade Commission (FTC) and Antitrust Division of the Justice Department have ordered compulsory licenses as components of consent decrees in a variety of instances to promote competition. Among the more prominent cases were a 1999 FTC order to Intel to stop withholding

8. In fact, Canada did suspend Bayer's patent for a few days. See Resnik and De Ville (2002).

its technical information or demanding unreasonable licensing terms from customers and competitors, and a 2001 FTC mandate to Dow Chemical to license patents and other IPRs related to polyethylenes to two competitors in order to forestall potential market dominance from Dow's merger with Union Carbide.

Japan's patent law recognizes three general justifications for a compulsory license (Kotler and Hamilton 1995). One is a general public-interest exception, which may be invoked in cases of national emergency, medical crises, and the like. A second is to effectuate the exploitation of an improvement invention that requires access to an existing patented technology ("dependent patents"). The third is to remedy nonworking through an unreasonable refusal to produce, import, or license. It should be noted that despite these provisions, compulsory licenses are rarely used in Japan. No such licenses to remedy nonworking of an issued patent have ever been issued. Further, under an agreement reached in 1994 with the United States, Japan pledged not to issue patent compulsory licenses to permit exploitation of dependent patents.

China's patent law offers three reasons for compulsory licenses: the public interest under a national emergency or other extraordinary problem, exploitation of a dependent patent, and refusal to license on reasonable terms.[9] The conditions for issuing compulsory licenses are consistent with TRIPS provisions, including permission of judicial review. To date it appears that no compulsory licenses have been issued since China joined the WTO in 2001.

In India compulsory licenses may be issued in national emergencies and to prevent abuse of a monopoly position.[10] In this context, excessive prices are seen as an abuse that may attract a regulatory response. Indian law also requires working of a patent "in the territory of India," suggesting that importation may not satisfy working, though there is no explicit local manufacturing requirement. A compulsory license may be issued in the case of nonworking three years after the patent is granted. Such licenses may also be authorized where the patented invention is not available to the public at a reasonably affordable price.

Economic Tradeoffs

From this history it is possible to state general conditions under which compulsory licenses may be justified in economic terms. In essence, such licenses exist to resolve several market failures and public needs. First, they may address national emergencies and domestic shortages of critical goods, such as medi-

9. Jon Wood and Raj S. Dave, "Compulsory Licensing of Patents in the U.S., China, Japan, Germany, and India," www.ipo.org/AM/CM/ContentDisplay.cfm?ContentFileID=6521 (accessed on June 1, 2012).

10. Suresh Sukheja, "Compulsory Licensing under the Indian Patent Law," Express Pharma, September 2006, www.expresspharmaonline.com/20060915/management06.shtml (accessed on June 1, 2012).

cines, medical equipment and diagnostic kits, and foods. In principle, there is no legislative restraint on such uses, including for environmental goals and agricultural needs.

Second, there may be needs for public use, including by designated firms operating on behalf of the government. Prominent examples include national defense and public infrastructure (a form of "eminent domain" in intellectual property).

Third, countries may wish to support exploitation of patents on improved technologies. This case may be of particular importance in developing countries, where the bulk of innovation is adaptive and incremental, with the results aimed at meeting local agricultural or industrial needs.

Fourth is the need to offset abusive practices in the private exercise of patents and other IPRs. Commonly recognized definitions of abuse include refusals to supply or license (a form of nonworking); restrictive conditions in licensing contracts, such as required technology grant-backs from licensees; and tied sales or licensing provisions that attempt to extend a patent grant in one area to other markets.

Fifth, compulsory licenses may be necessary to promote competition and the diffusion of technology where widespread use of key technologies is important. Here, competition authorities in developed nations pay attention to the possible need to break up restrictive patent pools and require licensing of IPR-protected critical product or technical standards (see chapter 4).

Those elements are generally seen by economists as appropriate uses of compulsory licenses, though there are substantive differences across countries in their legal status and frequency of use. In essence, they are necessary limitations on patent monopolies in order to achieve important societal goals, including robust competition.

Compulsory licenses become internationally problematic where they are used as instruments of industrial policy, aiming to transfer rights to use IPRs to domestic enterprises. Some governments justify compulsory licenses to force unauthorized technology transfer, even where the patentee makes reasonable efforts to supply the good. Similarly, regulation of technology transfer contracts within foreign direct investment, joint venture, and licensing transactions may require that technology be surrendered to domestic firms within a particular time period. China's indigenous innovation policy has elements of this approach, as discussed in chapter 4.

Policies of this kind are less widely accepted because they are aimed at addressing problems that are not necessarily abuses of patent rights or the result of market failures. Rather, they support strategic industrial policy. Also controversial is the claim that excessive pricing, however defined, is a patent abuse. As an economic matter, using compulsory licenses to pursue such goals is inefficient compared to more direct policies, such as price controls in medicines and subsidies to research and development (R&D) in local innovation and adaptation, though such measures can be difficult to make effective (Maskus and Okediji 2010).

Nonetheless, there are sound public policy justifications for compulsory licenses. In that context, the most remarkable thing about them, particularly in developing countries, is that they are so rarely used. It is difficult to locate cases in which any emerging-market or developing country granted a compulsory license for reasons other than ensuring low-cost access to patented medicines in their markets, and even those situations are scarce.[11]

There are two basic reasons why compulsory licenses go unused, particularly in the poorest countries. The first is that they may be unnecessary or may not achieve much benefit. Few global technologies are actually patented in poor countries with small markets.[12] In those cases there is nothing to issue a compulsory license for, leaving local firms to buy unpatented older technologies or acquire knowledge through imitation. However, if the market is unappealing to foreign investors because of its small size or weak business climate, it is equally unlikely that local firms would undertake the costs of reverse engineering. This also highlights why compulsory licenses may not be effective in small and poor nations: There may not be any domestic private or even state-owned enterprises capable of producing the good.

The second basic problem is that the potential benefits of compulsory licenses may be outweighed by administrative costs, even in countries with larger markets and domestic production capacity. Establishing an effective compulsory license system requires significant legal and administrative resources to answer several complex questions. How long is an appropriate period of time to wait while domestic firms seek voluntary licenses? What are reasonable royalty rates in different sectors and technologies and on what market should they be based? What is the appropriate duration for any particular compulsory license and when should it be vacated? How does the government set up an effective and independent judicial review? Such questions tax the technical and legal expertise of the major high-income and emerging-market nations. Addressing them is likely to require more administrative resources than poor countries are willing to invest.

Next, compulsory licenses may not achieve as much technology transfer as is hoped for. While a country may order domestic use of patent rights, it is not generally possible to order the surrender of confidential trade secrets and information, which may be essential for actually learning the technology. Further, because compulsory licenses are nonexclusive, a potential license recipient may have little real incentive to serve the home market or improve the technology. And unless the courts or authorities prevent it, the patent owner may take over the licensee to reduce competition on the market or refuse to give it access to key imported inputs. An additional problem is that the domestic

11. Some examples are mentioned in the next section.

12. For example, patent scoping exercises find that few climate change mitigation or adaptation technologies are patented in poor developing countries, as noted later in this chapter.

producer operating under the compulsory license may become a monopolist itself, particularly in small markets with weak competition.

One potentially important means of overcoming such difficulties would be for groups of countries to establish cooperative or harmonized regional patent systems in which administrative costs could be shared across members. In the context of compulsory licenses, such a grouping is more likely to support domestic production capacity at some regional location than would be possible within individual countries. Further, the threat of regional compulsory licenses, particularly in concert with joint public purchasing programs, could markedly raise the combined bargaining power of the purchasing authorities, giving them more leverage to negotiate price reductions in medicines and other key products.

In summary, compulsory licenses are a legally justifiable tool for dealing with deficient supplies of critical goods, assuring government use, and disciplining anticompetitive abuses of IPRs. They may also contribute to industrial policy objectives in countries with large domestic markets and effective production capacity, although forcing technology transfer in this way is controversial and may be economically costly. At the same time, compulsory licenses may be subject to misuse and lack of transparency. Finally, they are unlikely to achieve much success in poor countries with limited administrative and production capacity, suggesting that a regional approach may be more effective.

Competition Policy

The last 20 years have seen a significant increase in the number of developing and transition economies enacting or sharpening their competition laws (Brusick and Evenett 2008). According to the International Competition Network, over 100 national authorities in more than 80 countries throughout the world engage in competition enforcement in some form.[13] For example, China adopted a new antitrust law in 2007. In the wake of both TRIPS and general trade and investment liberalization, these countries increasingly see the importance of being able to deal with anticompetitive cartels, dominant market positions, and abuse of IPRs, whether by local firms or international enterprises.

As the discussion of compulsory licenses as a remedy for anticompetitive behavior suggests, there is a deep and complex set of relationships between IPRs and competition policy (Anderson and Gallini 1998, Ganslandt 2008, Drexl 2005). This issue cannot be treated comprehensively here; rather, the focus is on the key questions facing developing countries as they implement and consolidate their competition regimes regarding intellectual property.

The TRIPS Agreement offers broad scope for countering the anticompetitive exercise of IPRs. A general statement is in Article 8.2, which affirms

13. See the International Competition Network website, www.internationalcompetitionnetwork.org (accessed on June 1, 2012).

that countries may take appropriate measures to prevent the abuse of IPRs, so long as they are consistent with other provisions of TRIPS. Measures may also discipline practices that "...unreasonably restrain trade or adversely affect the international transfer of technology." Despite the consistency requirement, which remains largely undefined, some observers see this provision as a broad principle supporting extensive competition rules against a wide swath of anticompetitive behavior (UNCTAD 1996).

Article 40.2 of TRIPS refers specifically to anticompetitive licensing practices, stating that countries may identify in their laws certain activities that constitute an abuse of IPRs and adversely affect competition. Countries may adopt measures that prevent or control such practices. The article provides a nonexhaustive list including exclusive grant-back conditions, provisions preventing licensees from challenging patent validity, and package licensing that compels recipients to purchase rights beyond those needed for the transfer. This language seems to offer considerable freedom to operate in defining abusive licensing conditions. For example, some countries may consider a refusal to license to be abusive if the IPR owner has a dominant market position. This situation could trigger a compulsory license or other remedy.

In this context, the nexus between competition regulation and IPRs remains largely a blank slate in the developing world.[14] The strategy each country selects is likely to differ but some basic principles may be listed here to help guide thinking. First, countries need to determine whether competition regulation should emphasize fairness over efficiency (Reichman 2009). An efficiency emphasis, which is the case in the United States and increasingly in the European Union, sees competition law and IPRs as largely complementary means of encouraging dynamic competition through innovation. In contrast, a fairness ethic, highlighting consumer access and technology diffusion, would argue for a more aggressive stance in which antitrust enforcement largely restrains the scope of IPRs. So long as most developing countries are net importers of new technologies they are likely to favor an access orientation (Sengupta and Dube 2008). Unfortunately, going too far in that direction could work against the dynamic gains envisioned by reforms in the IPR system.

A second issue is that establishing and enforcing competition law is technically demanding and subject to numerous economic uncertainties. In this context, poor countries may be better advised to pursue a more limited strategy for IPR-related competition policy (Janis 2005). One reason is that few such countries can afford to devote the administrative and legal resources needed to study goods and technology markets for adverse effects of behavior on competition and make the case for remedies. History shows that it takes a long time and considerable experimentation for competition authorities to develop meaningful understandings about how best to approach specific cases.

14. See Fink (2009b). Neither is it well settled in the United States, European Union, Japan, or other developed countries (Ganslandt 2008).

A third problem is that aggressive competition enforcement on IPRs may be another debilitating influence on the perceived foreign investment climate, especially in smaller economies. Widespread action of this kind in the developing world could also induce developed countries to push for a set of global standards on patent-related competition rules, perhaps within the WTO. Such a demand could result in adverse outcomes from the standpoint of developing countries and place further stress on the trading system.

Overall, the case for a cautious and incremental approach in developing countries seems persuasive (Janis 2005). In this context, a nascent competition authority should focus in its early stages on advocating for competition concerns to be taken into account in legislating and enforcing IPRs, while also defining anticompetitive licensing practices. For the latter purpose, consulting the US licensing guidelines issued by the Department of Justice and the FTC, along with similar documents from other advanced jurisdictions, could be a useful first step.[15] These guidelines, versions of which could be adapted for use in each national jurisdiction, identify the types of restraints that clearly harm competition the most and that should receive the attention of scarce enforcement resources. Examples include licensing to support restrictive horizontal cartels, price fixing, and tying or related conditions that attempt to extend the scope of IPRs to second markets. Exclusive technology grant-backs and similar practices could be subject to competition regulation but on a more case-by-case basis.

Even this gradualist approach could tax the institutional resources of most developing economies. Recognizing this, governments might collaborate in developing regional antitrust guidelines and standards in licensing and establishing international competition boards that could take actions within the regional agreement and its members. It is possible, for example, that licensing restrictions and cartels could operate across borders of regional neighbors, suggesting that a supranational enforcement body could achieve efficiency gains.

Whether national or regional, competition authorities could gradually build the expertise needed to sustain a competition regime that properly balances innovation incentives and access needs. To many observers, however, gradualism is an inadequate safeguard against anticompetitive patent use (Drexl 2005, Reichman 2009). They argue instead for a fully developed competition authority with the legal ability not only to discipline licensing abuses, as envisioned above, but also to limit misuse of exclusive rights. Patent "misuse" refers to strategic decisions within the scope of protection that generate unwelcome outcomes such as refusals to deal, excessively high prices, and undersupply of a domestic market. A competition doctrine against misuse has existed in Indian law since 1970, while compulsory licenses may be granted under the new Chinese patent law for refusals to deal within a limited time period. The concept of patent misuse has grounding in US competition law but has rarely

15. US Department of Justice and USFTC (1995). See also USFTC (2003) for broader analysis.

been used, based on the philosophy that owners of exclusive rights should be permitted to exercise them as they see fit as long as that exercise is not abusive.

The elevation of misuse into competition regulation in major emerging-market economies is controversial among multinational technology companies. How this controversy works out in the coming years remains to be seen. As a matter of economics it is not possible to argue definitively for any particular approach. However, aggressive reliance on the misuse doctrine in otherwise competitive markets may well inject a chilling effect on local innovation and formal technology transfer. Note that competition enforcement must be nondiscriminatory between international and domestic firms, suggesting that the impact may be particularly problematic for the latter in a rapidly industrializing economy. Again, as with compulsory licenses, it is difficult to foresee much gain in smaller and poorer countries in the costly exercise of this approach.

Administrative Reforms and Policy Experimentation

The analysis to this point indicates that most developing economies could benefit from incorporating and enforcing transparent IPR standards and L&Es that, while consistent with TRIPS conditions, favor rapid diffusion and consumer access. Further, an IPR-linked competition regime is best constructed on basic principles focused on abusive licensing practices and patent-related cartels, while building local capacity through case-by-case investigation and adjudication. Larger and higher-income economies with greater administrative resources are capable of building more comprehensive systems of IPR administration and enforcement, while addressing broader competition questions of market dominance and anticompetitive exertion of IPRs. Ultimately, those policy selections may serve as guideposts for other countries as they build technological capacity.

This suggestion of "regulation light" for poor economies does not mean they should remain passive, however. Developing countries can take a number of active steps in the medium term to make their emerging IPR systems more effective at achieving their fundamental goals. Significant efforts devoted to a more holistic approach bear considerable promise for linking even the least developed economies more fully into global technology markets, while improving domestic processes of creativity and innovation.

It bears repeating that simply reforming IPRs is rarely enough to encourage beneficial economic activity. It is equally important to improve the investment and competition climates through better infrastructure, more responsive government processes, more efficient service delivery, and complementary trade and investment liberalization. The IPR regime must be embedded in an overall development strategy, including investments in education and human capital, improvements in public health, and support for domestic innovation and adoption of technology. These elements are widely discussed in the literature and need no further elaboration here (Maskus 2000a, World Bank 2005, Melendez-Ortiz and Roffe 2009).

Putting Heads Together

However, administrative initiatives focusing specifically on IPRs could readily improve policymaking in poor countries. First is to establish robust interagency procedures to ensure that initiatives in intellectual property are informed by input from a wide range of stakeholders. The practice to date has been largely to gain expert opinion on legal reforms from domestic patent and trademark professionals, whose interests may not align well with overall development policy (Deere 2009). Primary responsibility for formulating IPR policy and legislation often comes from industry ministries, while external relations are handled by trade and diplomatic authorities. These groups tend to emphasize commercial interests and international market access over calibrating IPRs to needs in public health, agriculture, environmental policy, and education. Thus, interagency coordinating councils, established within the context of a broader policy foundation, could usefully advise policymakers about potential economic and social consequences of new IPR laws and regulations (Reichman 2009). Such councils could benefit also from regular consultation with counterparts in other developing economies, perhaps on a regional basis, and would be better positioned to take advantage of available international legal and economic expertise.

Second, the scarcity of administrative resources continues to limit investments that can be made in enforcing IPRs and raising awareness among the population about how to access such rights. To develop funding sources, governments could carefully consider the scope for establishing small levies, with safeguards against diversion of revenues to other purposes, on applications for industrial property rights (patents, utility models, trademarks, geographical indications, and plant varieties) and on certain forms of copyrighted content.[16] In principle, such fees could be scaled to avoid deterring registrations by small inventors and creative persons. These revenues might also be deployed to establish national and regional databases of creative assets owned by domestic firms, musicians, artists, and traditional communities. Such databases could be linked to parallel efforts at the WIPO in order to facilitate international commercialization and protection of rights.

A New Norm for Small and Incremental Innovation

A last possibility is for developing countries with limited technical capabilities to recognize that they can make additional modifications to intellectual property regimes to stimulate local innovation and creativity, while remaining consistent with TRIPS. In such countries innovation tends toward specialized and incremental adaptations of other technologies, often found abroad, to

16. See chapter 4 for further discussion.

meet local needs in agriculture and industry. Domestic firms rarely can muster the resources for large-scale R&D to develop new knowledge, but adaptive work contributes significantly to productivity growth while tailoring technical solutions to local needs.

The roles that various forms of protection can play here were discussed earlier. Patents should have substantive eligibility standards in order to avoid long and broad protection for low-quality innovation. They should be supplemented by utility models or petty patents to establish exclusive rights in small-scale, adaptive inventions, and well-defined trade secrets to protect subpatentable knowledge. Copyrights are important to protect domestic creative activity but should be accompanied by appropriate L&Es. As described later, plant breeders' rights with certain limitations can be beneficial for diffusion in agriculture.

Even this array of IPRs may fall short of an effective innovation model for developing countries, however. As argued persuasively by Jerome H. Reichman and Tracy Lewis (2005), utility models work poorly to stimulate innovation in incremental and cumulative technologies, which may involve small changes in technical designs but need access to existing inventions on which they build. Further, trade secrets may not be enough protection for originators in cases where reverse engineering can be done quickly and at low cost, permitting second comers to free ride on the initial investment. Examples include simple tools, application software, textile and material designs, and basic plant varieties. Invention patents, design patents, utility models, and plant variety protection may limit follow-on innovation for too long, while trade secrets offer too little lead time to incentivize initial R&D.

To stimulate innovation in these areas, an alternative approach, based not on exclusive rights but rather on compensated open licensing, may be promising (Reichman 2000). Such a system is termed a compensatory liability regime (CLR). It gives any firm in the system the choice of using another participating firm's innovation to develop a new version, subject to conditions on how it may be used and for how long, the payment to be made to the innovator (or licensing terms), and the means by which the firms may revise usage terms. Simply duplicating the original product would be prohibited for a designated time period.

Thus, for example, suppose firm A devises a planting tool that works in one kind of soil but could be modified or improved for a different soil condition elsewhere. If the only form of protection is trade secrecy, firm B could free ride by examining and modifying the tool without compensation, generating no investment return for the originator. If firm A had protected itself with a utility model, no reverse engineering could take place, reducing this free riding. However, the originator might prefer not to license its invention to a new competitor, or there may be high transactions costs in doing so. In the first case there is inadequate protection, while in the second case follow-on innovation and use are stifled.

Under a CLR, however, the second firm could legally make the modification and sell the tool without the authorization of the originator. If done during the upfront term of protection, firm B would need to pay a sales royalty, at predetermined rates, for this option. Presumably, given the incremental nature of this process, the royalty rates would be relatively modest, perhaps 3 to 5 percent of follower sales (Reichman and Lewis 2005). Further, firm A would have the right to use firm B's improvement to make further modifications, subject to reasonable compensation. Other competitors could make their own value-adding improvements, subject to payments to firms from which they were derived, implying that all such derivative concerns ultimately would pay the originator some revenues. In this way, multiple improvements to meet varying needs closely related to the original invention could be supported, with the originator gaining income from each higher-value improvement. The initial R&D incentive would remain, and perhaps be expanded, without stifling follow-on uses.

To implement a CLR, further provisions would be needed to identify infringement (meaning simple copying or insufficient technical or design improvement), remedies for infringement, rules linking the regime to unfair competition law, and procedures for arbitration and mediation of disputes (Reichman 2000). Such institutional arrangements could be costly to administer, but presumably the low overall transactions costs of compensated open licensing would attract users to the CLR.

In that regard, firms could opt whether to place their inventions into compensated open licensing or protect them with standard IPRs and trade secrets. The essential reason they might choose the former stems from the general advantages of quasi-open access. At some points in time a firm is likely to be an innovator, while at others it is likely to be a borrower and improver. Ex ante, firms engaged in small-scale and incremental innovation may see higher anticipated returns to R&D if they can freely borrow ideas while sometimes paying for the privilege and sometimes earning royalties (Lerner and Tirole 2004b). The additional anticipated returns come from extended markets and lower transactions costs, while implicitly the costs of R&D are shared across competitors. Further, the reciprocal contributions of multiple players can support cumulative and agglomerative knowledge development. In essence, a well-functioning CLR would create technology pools with compensated access for small innovators.

There are prior examples of CLR-like arrangements in developed nations (Reichman 2000, Reichman and Lewis 2005). These include, among others, provisions in the 1941 Italian copyright law protecting technical drawings under such a regime, similar provisions in the 1988 UK law protecting unregistered industrial designs, and the 1984 law governing US protection of unregistered semiconductor designs. A current example is the US system under which mechanical rights to recorded music are licensed. After purchasing a license from the Harry Fox Agency, music producers are able to record and distribute

copyrighted songs they did not write.[17] License proceeds are then distributed back to original copyright owners.

Systems of liability rules would complement and stand alongside standard IPRs. One particular advantage would be that eligibility standards for invention patents could be rigorous, because the CLR would serve to protect easily copied and subpatentable inventions. Still, they have not been widely introduced into developing countries. This may reflect a concern about potential administrative costs and uncertainty about how well they might perform in stimulating incremental innovation and compensated use. Indeed, it would not be straightforward to determine the boundaries that would characterize innovation that would enter this system versus formal IPRs. Their adoption may also be stymied by local patent attorneys who have an interest in seeing inventions registered as patents or utility models (Deere 2009).

Nevertheless, there seems to be scope for promising experimentation in this regard. Individual countries, or nations in a collaborative regional agreement, could attempt pilot projects for some time period to see how well such rules could work. A role arises also for the WIPO or other interested agencies to provide subsidies for devising and implementing such systems. As Reichman and Lewis (2005) observed, there is little to be lost from such experimentation. If a CLR regime fails, countries would still have their utility models, design patents, and trade secrets in place. If it succeeds, however, the gains to innovators could be significant and the program could become a model for other developing economies considering changes in their innovation systems favoring more open access.

Patent Problems and Progress in Public Health

A fundamental objective of the global community is to ensure that all people have affordable and sustainable access to life-saving medicines. The constitution of the WHO adopted in July 1946 affirms that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...." The United Nations regards as an entitlement for all "[t]he prevention, treatment and control of diseases, including access to essential medicines."[18] One of the UN Millennium Development Goals is to achieve universal access to treatment for HIV/AIDS for all who need it. Thus, the widespread attainment of sound health status, achieved in part by access to drugs and vaccines, is seen as a primary global public good.

Indeed, one of the encouraging global trends is the steady improvement over time in the health status of people in poor countries. For example, life expectancy at birth in the least developed countries rose from 44 years in 1970

17. See Harry Fox agency website, www.harryfox.com/index.jsp (accessed on June 1, 2012).

18. See UN Commission on Human Rights, *Report of the Special Rapporteur*, E/CN.4/2003/58, www.ifhhro.org/images/stories/ifhhro/documents_UN_special_rapporteur/3_4_6.pdf (accessed on June 1, 2012).

to 57 in 2007, while the infant mortality rate fell from 14.9 to 8.1 percent over that period.[19] There are many reasons for these changes, ranging from reduced poverty rates to better nutrition, sanitation, and schooling. Public health interventions also matter, including more widespread access to clinics, larger numbers of medical personnel, and the distribution of such simple items as treated bed nets.

One key policy is to increase the availability of drugs and vaccines for treating and preventing illness. For example, in 1987 the pharmaceutical company Merck began offering the drug Mectizan for free to people in poor countries. This decision has greatly reduced the infection rates and morbidity of onchocerciasis (river blindness). Similarly, in 2009 around 5.2 million people in low- and middle-income countries received antiretroviral therapies (ARVs) to treat HIV, an increase of 30 percent over 2008. This represented about 36 percent of the total population in those countries needing ARVs, a substantial increase in coverage from 10 years earlier (UNAIDS 2010). These access gains were directly related to the remarkable reductions in the prices of key ARVs from 2001 to 2010, as detailed in table 5.1. The cuts were largely the result of price negotiations, generic competition, and public purchasing programs.

Despite such improvements, achieving adequate and sustainable access to medicines in the developing world remains a difficult and vexing problem. This is evident from the skewed distribution of global prescription drug sales. Carsten Fink (2008) estimated that in 2004 the group of low-income economies accounted for about 2 percent of global sales, the middle-income countries 12 percent, and the high-income nations 86 percent. In contrast, the high-income economies accounted for about 16 percent of the global population. Further, the burden of certain life-threatening diseases is highly concentrated: 97 percent of the millions who die annually from HIV/AIDS, malaria, and tuberculosis live in countries with average incomes below $3,600 per year.

To be sure, concerted efforts are made by governments, foundations, and NGOs to address this problem, at least in these three illnesses. Thus, over 5.2 million people received antiretroviral drug treatments in poor countries at low prices, despite the fact that some key therapies are patented (UNAIDS 2010). Still, for many diseases there remain major discrepancies between the needs for medicines and the ability to deliver them. Again, there are many reasons why drugs fail to get to poor countries in volume, including low household purchasing power, weak public procurement budgets, underdeveloped distribution systems and insurance markets, and inadequate medical facilities. Even trade and investment barriers reduce imported supplies in a number of developing countries (Saggi 2007, Olcay and Laing 2005). Patents are prominently implicated by many as a source of this problem because they permit owners to limit supplies, diminish competition from generics, and support prices well

19. Data from World Bank, *World Development Indicators* database, 2012, http://data.worldbank.org/data-catalog/world-development-indicators (accessed on July 18, 2012).

Table 5.1 Price reductions in key antiretroviral medicines, 2001 and 2010 (dollars)

	Originator price		
Drug	**2001**	**2010**	**Percent change**
Zidovudine (AZT) 300 mg	684	161	–76.5
Efavirenz (EFV) 600 mg	346	237	–31.5
Nevirapine (NVP) 200 mg	438	219	–50.0
Lamivudine (3TC) 150 mg	234	64	–72.6
AZT/3TC/NVP fixed-dose combination	1,356	441	–67.5
	Lowest generic price		
	2001	**2010**	**Percent change**
Zidovudine (AZT) 300 mg	193	91	–52.8
Efavirenz (EFV) 600 mg	462	61	–86.8
Nevirapine (NVP) 200 mg	150	34	–77.3
Lamivudine (3TC) 150 mg	91	33	–63.7
AZT/3TC/NVP fixed-dose combination	419	137	–67.3

Notes: Prices (per patient per year) quoted by companies for distribution in eligible developing countries.

Source: Médecins Sans Frontières, "Untangling the Web of Antiretroviral Price Reductions," http://utw.msfaccess.org/drugs (accessed on June 1, 2012).

above marginal production and distribution costs, making protected drugs beyond the reach of poor patients.

Whether in fact patents have had this impact in developing countries is difficult to answer given the many complexities of medical markets. Indeed, their price impact may become more pronounced in the future because new patent laws are still being implemented in many nations. It is clear, however, that the existing global system, built on a foundation of private enterprises developing and marketing drugs with patents in the developed world as the primary incentive for R&D, fails to meet the drug development needs of poor countries. Patents do little to stimulate risky investments in developing new medicines and vaccines for patients who cannot pay for them. But waiting for poor countries to build institutions and distribution systems and for their citizens or governments to have enough money to purchase medicines is not an acceptable option considering their substantial and immediate needs.

Thus, the global public goods problem here is to overcome market failures in the classic quasi-private provision system. There are essentially two major objectives to achieve. The first is to establish sufficient incentives so that research organizations—whether universities, enterprises, or public-private partnership arrangements—focus investments not only on those drugs for

which demand exists in wealthy nations but also on the so-called neglected diseases of poor countries. The second is to ensure widespread access in developing countries to needed medicines at affordable costs. There is an inherently fundamental tension between the dynamic gains of the former goal, which rests largely on temporary market exclusivity from patents, and the static benefits of the latter, which may require limiting those rights. Some economists argue for separating these objectives completely through a variety of mechanisms (Ganslandt, Maskus, and Wong 2001; Barder, Kremer, and Williams 2006). Others argue for a mixed approach (Fink 2008; Dutta, Dutz, and Orszag 2010). These issues are addressed in this section.

Patents and Medicines under TRIPS

The TRIPS Agreement was discussed generally in chapter 3, but it is important to understand its requirements regarding medicines in particular. TRIPS requires countries to provide at least 20 years of patent protection without discriminating between fields of technology. Thus, both drug processes and products have to be protected, along with inventions based on microorganisms, thereby opening key areas of biotechnological research to patenting. As a result, countries may no longer exclude drug products from patent coverage, as earlier had been the case in a number of developing countries, including India, Brazil, and Argentina.

These requirements could be phased in over time, with developing countries given until 2005 to comply. Countries using this delay were required in the intervening period to accept patent applications to be kept in a "mailbox" until they could be reviewed under new laws and to grant them exclusive marketing rights during the transition. A further provision in the Doha Declaration on the TRIPS Agreement and Public Health gave the least developed countries until 2016 to establish and enforce patents for drugs, and those countries may apply for further extensions of that deadline.[20] It follows from these transition periods, and the natural delays involved in approving patents, that the full impact of these exclusive rights may not be felt for a few more years.

The TRIPS Agreement offers prospects for important exceptions and limitations on patent rights for recognized public purposes. Countries can exclude from patentability inventions that would be damaging to human, animal, or plant life and health and also diagnostic, therapeutic, and surgical methods for treating people and animals. They can also exclude plants and animals, except microorganisms, and certain processes. Drug patents are subject to compulsory licensing along the lines described in the last section. Thus, before a nonexclusive compulsory license may be authorized, the various procedures for consultation and review, adequate remuneration, and prior negotiation on a voluntary license must be followed. The latter requirement may be waived in

20. Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, adopted on November 14, 2001.

cases of national emergency and noncommercial public use. The authority of governments to determine the circumstances that constitute a national emergency, or other conditions of extreme need, and to deploy compulsory licenses and other TRIPS flexibilities to protect public health, was explicitly reaffirmed in the Doha Declaration.

As noted above, TRIPS does not prevent countries from establishing competition-based exceptions in patents, including pharmaceuticals. Thus, as is common in the developed world, developing and emerging-market countries may have a "Bolar exemption" that permits generic companies to study the molecular makeup of drugs in order to prepare for marketing approval and entry upon patent expiration. Finally, although TRIPS requires countries to protect confidential test data submitted for marketing approval of certain new pharmaceuticals and agricultural chemicals from unfair use and unauthorized disclosure, it does not specify a minimum time period for this protection.

Paragraph 6 and the TRIPS Amendment

WTO members recognized also at the Doha Ministerial Meeting in 2001 that the requirement in Article 31(f) that compulsory licenses be authorized predominantly for supplying the domestic market raised a major barrier for poor countries with limited or nonexistent pharmaceutical production capacity in finding sources of generic supplies. Thus, Paragraph 6 of the Doha Declaration instructed the TRIPS Council to find a solution to this problem. The succeeding, and highly contentious, negotiations resulted in the August 2003 TRIPS waiver, permitting countries with generic drug capacity to issue compulsory licenses for exports at the request of importing countries without such facilities under specific circumstances.[21]

Specifically, the importing nation must notify the TRIPS Council of its intention to ask for the compulsory license, specify the product and amounts it wishes to import (and from which company), and certify that it does not have sufficient production capacity itself for the drug in question. The exporting country may authorize the compulsory license only for the amounts and destination indicated. The licensee must label the products as intended for the target country, and information must be posted on a website regarding the details of the transaction, any distinguishing features of the goods shipped, and the duration of the license. Further, the exporting country authorizing the compulsory license must pay adequate remuneration to the local patent owner based on the economic value of the import market. Finally, importers must take action within their administrative capacity to prevent reexportation of the drugs, while other WTO members are required to take measures to prevent their importation into their own markets.

21. Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1, September 1, 2003. The United States opposed this decision until the last moment, trying to restrict the list of diseases for which it could take effect (Abbott 2005).

In principle, all WTO members could certify to the TRIPS Council an intention to take advantage of this arrangement as importers, though 23 developed nations have stated they will not do so and 11 other countries have said they would use it only under conditions of national emergency or extreme urgency. In any event, an importing country must demonstrate the absence of effective domestic production capacity. Thus, the agreement applies to all least developed countries and those developing countries willing to make notification as importers.

When this 2003 decision was taken the TRIPS Council was directed to undertake further negotiations in order to make it a permanent amendment to the TRIPS Agreement. That amendment was advanced for implementation in December 2005 but will only take effect upon acceptance by two-thirds of the WTO members, according to their own legal procedures. The United States accepted the amendment protocol immediately but has not ratified it into law. As of May 2011, 34 WTO members (with the European Union counting as one) had accepted the protocol.[22] Until such time as the amendment is accepted, the 2003 decision remains in place.

Some developed countries that have implemented the amendment into their laws have created an explicit basis for their manufacturers to produce exclusively for exports under compulsory licenses. The most notable case is Canada, which introduced its Canadian Access to Medicine Regime in 2007 and is currently considering revising the law to make it easier for firms to export. Others include Norway, Switzerland, members of the European Union, and Japan.[23] India has implemented legislation to serve as an exporter, while several other economies, including China, Hong Kong, South Korea, and the Philippines, have notified laws permitting them to be both importers and exporters under the Paragraph 6 system.

To date, there has been just one use of the system. In 2007, Rwanda notified the TRIPS Council of its intention to import 260,000 packs of Apo-Triavir, a generic copy of a three-drug combination medicine for treating HIV infections. Patents on these drugs are held by GlaxoSmithKline, Shire, and Boehringer Ingelheim. Canada issued a compulsory license to Apotex, a generics manufacturer, which expressed an intention to sell the drug to Rwanda at 40.5 US cents per pill, compared to US$20 in the United States.[24] The license was authorized for two years and Apotex made shipments to Rwanda in 2008 and 2009.

The fact that the system has been used just once seems to validate early concerns that it was too burdensome to be an effective guarantee of access

22. The list may be found at www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed on June 1, 2012).

23. WTO, "Intellectual Property: TRIPS and Health: Members' Laws Implementing the 'Paragraph 6' System," www.wto.org/english/tratop_e/trips_e/par6laws_e.htm (accessed on June 1, 2012).

24. International Center for Trade and Sustainable Development, "Rwanda Tests Public Health Waiver," October 2007, http://ictsd.org/i/news/bridges/4095 (accessed on June 1, 2012).

to medicines under compulsory licensing for exports (Correa 2004). It is difficult for a country envisioning a small and highly specific order to locate willing suppliers with the capacity to produce the particular product once the exporting government has approved the compulsory license. The suppliers themselves may be unwilling to incur the costs of meeting small requests, since they are unlikely to garner economies of scale.[25] Working out which party must pay remuneration to the patent holder is also complex, while gaining regulatory approval can take time. Poor countries may lack sufficient capacity to prevent reexportation of the drugs. Finally, some observers argue that the highly public reporting requirements are themselves a deterrent, for exporting companies may not wish to reveal their operations and importing nations may be concerned about the reactions of patent-owning pharmaceutical companies.

While these concerns are real, it is possible that much need has not yet emerged to deploy the Paragraph 6 waiver. Drug-product patent laws are relatively recent in some major generic producers, especially India, meaning that supplies of such medicines to treat HIV and other major maladies have remained no less available. Indeed, in the Apotex case generic versions existed in India by the time Canada's compulsory license was approved, undercutting the firm's sales in Rwanda. Further, as noted below, a number of global pharmaceutical companies have expanded their donation programs, while international procurement efforts by the World Bank, Global Fund, and other institutions have improved supplies. However, with the introduction of new patent laws the generic availability of new second-line ARVs, cancer treatments, and the like is likely to diminish. Thus, the waiver seems likely to become more widely used in the future, making its access provisions important going forward.

For these reasons, deliberations began recently at the TRIPS Council on finding means to improve the operation of the system.[26] Several developing countries, including countries that would be potential exporters under the system, such as India, China, Brazil, Cuba, and Egypt, suggested that the system is not working effectively. A number of other countries, including the United States, Argentina, Canada, Switzerland, and the European Union, argued for caution in light of the improved market access conditions from greater donations, price concessions, and procurement programs.[27] Ongoing discussions consider obstacles to use of the system, progress of implementation, and support for building capacity in how to use it and related TRIPS flexibilities.

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25. It should be noted that in the Rwanda case it was Apotex that wanted to test the system and it took some time for the company to locate a least developed country with which to partner.

26. "WTO Paragraph 6 Meeting Aims at Improved Use of Health Waiver," *Intellectual Property Watch*, October16, 2010.

27. "Members Discuss Implementation of TRIPS 'Para 6' Solution," Third World Network, TWN Info Service on WTO and Trade Issues, February 22, 2010.

Patents and Drug Markets in Developing Countries

The Paragraph 6 waiver and policy flexibilities notwithstanding, the TRIPS Agreement affirms that the global regulatory framework in developing and distributing new medicines and medical devices is founded primarily on the market-exclusivity rights found in patents. Systems to protect new patentable drugs and vaccines exist now in all developed and emerging-market countries and in most of the poorest nations. More starkly, protecting the interests of patent owners is the primary objective of TRIPS-Plus requirements, as described in chapter 3. The economic implications of this situation are the subject of the remainder of this section.

Clearly the chief concern in developing economies is the potential for patents to raise the prices and reduce the availability of new drugs. By design, exclusivity permits firms to set prices higher than both average and marginal production and distribution costs for a period of time in order to recoup R&D costs. Generic products entering at the end of a patent take major shares of the market and drive prices down toward marginal costs (Frank and Salkever 1997, Reiffen and Ward 2005).[28] As developing countries register and enforce patents on new drugs, the moment when this competition occurs will be delayed, perhaps considerably, and it might not happen at all. Those generic companies, many of which will close, consolidate, or be taken over, will have to wait longer before imitating new medicines. Thus, new patent regimes will raise significant challenges for both health and competition authorities.

There is certainly potential for significant increases in drug prices, according to economic predictions. For example, Shubham Chaudhuri, Pinelopi Goldberg, and Panle Jia (2006) developed a structural econometric model of the Indian market for drugs in the therapeutic class quinolones, a family of broad-spectrum antibiotics, such as ciprofloxacin. Using monthly data on prices and sales by firm from January 1999 to December 2000, they estimated a flexible demand system to account for substitution possibilities across stages and competing products. The endogeneity of prices in identifying demand was accounted for with a series of instrumental variables.

With the estimated elasticities in place, the authors simulated the effects of removing domestic competition in some or all of the quinolones, the assumed outcome of patent protection. For example, eliminating just domestic production of ciprofloxacin would raise prices of three foreign quinolones by somewhere between 98 and 315 percent and also increase prices of domestic versions by more than 100 percent. Removing Indian competition in all four domestic quinolone molecules would raise foreign prices between four and six times. Associated welfare losses would be between 7 billion and 18 billion rupees per

28. Evidence from the United States suggests that while originator firms suffer large market share losses upon entry, the prices of their drugs may actually rise due to brand loyalty built under patent protection.

year, or perhaps $156 million to $400 million at year 2000 exchange rates. The increase in profits to foreign pharmaceutical firms was estimated at just $53 million.

A more comprehensive analysis was performed by Antara Dutta (2011), who used retail data in India for 155 drugs in five therapeutic groups, including 43 products with foreign presence. The sample covered 2001–03, a period when there was free entry by domestic generic firms. A structural model of supply and demand was estimated, accounting for substitution within therapeutic indications. This model also permitted estimation of fixed entry costs. Dutta's results found significant variation across groups in price sensitivity, with demand being significantly higher for branded drugs and those with a foreign presence.

Dutta simulated the price impact of erecting product patents in the 40 goods with foreign presence in India and not facing price controls. On average the drug prices would go up by 18 percent, though the effects would vary considerably across products, ranging from 3.5 to 80 percent. These price effects were considerably smaller than those found by Chaudhuri, Goldberg, and Jia (2006). However, in cases where patents were accompanied by elimination of price controls, the anticipated price increases were considerably larger. Overall, Dutta computed a consumer welfare loss of around $380 million per year, with a potential reduction of 8.5 million patients paying for such drugs.

Both of these studies, and nearly all earlier ones (e.g., Fink 2001 and Watal 2000), focus on the Indian market, where detailed firm-level sales and retail price data are available. India is unique in having built a substantial generic drug industry in the absence of product patents. This implies that, to the extent that such competition is diminished as patents are enforced, the price effects could well be significant. Unfortunately, there are no comparable recent studies of potential effects in other developing countries, so it is difficult to know how generally applicable such computations are. Whether this situation is emerging in other markets in the wake of patent reforms is hard to determine.

One obvious difficulty with such studies is that they are inherently static and do not permit strategic responses by domestic competitors. As noted in chapter 2, however, there is evidence that the largest Indian drug companies are investing significantly more in R&D and product development since it became clear that product patents would be implemented (Arora, Branstetter, and Chatterjee 2011). Indeed, press reports indicate that the industry is growing rapidly and that India is becoming the primary global supplier of low-cost drugs.[29] Several global pharmaceutical concerns have taken over or acquired stakes in competitive Indian companies. At the same time, large numbers of smaller imitative firms are exiting the industry. Moreover, a number of global pharmaceutical firms have set up significant R&D facilities in India in recent years (Linton and Corrado 2008). In this context, the domestic market struc-

29. "India Expands Role as Drug Producer," *New York Times*, July 6, 2010.

ture in India is undergoing a substantial rationalization in a manner that was predicted prior to reforms (Maskus 2000a).

Another fundamental problem is that such studies disguise a basic fact: Governments can deploy a number of policies to diminish the price effects of patents. An obvious one is price controls, about which the TRIPS Agreement is silent. Most major developing economies, including India, China, and Brazil, continue to regulate drug prices on their markets. Another policy choice is to remain open to parallel imports, permitting hospitals to choose the lowest-cost global or regional suppliers of drugs. Yet another is to make use of compulsory licenses in cases where health authorities perceive that patent owners are not offering sufficient access to a drug. For example, government-use licenses were issued by Thailand in 2006 and 2007 on two antiretroviral drugs (Efavirenz and the combination Lopinavir-Ritonavir) and one heart medication (Clopidogrel) and by Brazil in 2007 on Efavirenz. The patent owners, prominently Abbott Laboratories, reacted by threatening to leave the markets and painting these countries as unreliable business locations. However, supplies have not diminished in the wake of these actions. Whether smaller countries would have the clout and expertise to replicate these episodes remains an open question.

In its 2005 patent law revisions India chose to take advantage of such limitations on patent scope, as described in box 5.1. The revisions, known as the Patent Act, try to balance several competing interests, including domestic generic firms, multinational pharmaceutical companies, and civil society groups concerned about preserving access to medicines (Basheer 2005). However, the primary provisions clearly are aimed at supporting the generic industry and sustaining consumer access, largely by limiting the eligibility of incremental innovation and new uses for patents. The law is seen by many in civil society as a model for other developing countries to follow.

Provisions of India's Patent Act are strongly opposed by the research-intensive global pharmaceutical companies. Particularly problematic are the absence of test data exclusivity periods, the existence of pre-grant opposition procedures, and the denial of patents to new uses and derivatives of known substances. For example, Novartis is engaged in a high-profile lawsuit claiming that the exclusion of derivatives from patentability is inconsistent with TRIPS Article 27.1, which requires that patents be issued "...in all fields of technology." Specifically, Novartis challenges the decision of the Indian Patent Office not to grant a patent for its cancer drug, Glivec. The Patent Office found that a new crystalline salt version of the drug (the old version was already patented in the world prior to 2005 and therefore not novel) did not meet the standard of increased efficacy under Section 3.d of the patent law. Novartis submitted additional data showing that the new version was an improvement over the base salt and that only the former could be administered to patients. Nonetheless, the Indian Patent Office rejected this claim, finding no evidence of a sufficient clinical efficacy enhancement.

The case was dismissed in 2007 by the Chennai High Court, which found the law's patentability standard constitutional, while deferring to the WTO the question of the law's compliance with TRIPS. The case was appealed to the

Box 5.1 India's Patents Act of 2005 and pharmaceuticals

As a developing-country member of the World Trade Organization (WTO), India was given until 2005 to bring its intellectual property rights legislation into compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In practice, this meant primarily updating its patent law to permit patentability of pharmaceutical products. In its 1970 act, India had enacted several limitations on patent rights in an effort to encourage local innovation and production. In particular, medical products, food products, and agricultural chemicals were no longer patentable, though processes for making them were eligible. The latter patents are easy to invent around and provide little protection for originators of active ingredients. In the ensuing decades India's generic industry flourished, featuring a handful of major companies supplying both the domestic and foreign markets and hundreds of smaller producers.

The need to establish product patents was the subject of extensive and heated debate in Indian media, industry, academia, and policy circles. A foretaste was provided by the TRIPS requirement that India's health authorities provide so-called mailbox protection for patent applications filed beginning in 1995. The government complied in 1999 after an adverse WTO panel ruling on the issue. This provision established priority dates for those applications and offered exclusive marketing rights to new drugs that were approved for sale. Although the patents would not be reviewed until after 2005, the possibility of their eventual grant was likely a deterrent to generic copying in that period.

Given the importance of the generic drug industry and a heavy representation of civil society in Indian politics, it is no surprise that India's Patents Act of 2005 features numerous provisions favoring competition and access. Among the primary ones are the following:

- The 20-year patent term as required by TRIPS for pharmaceutical products, foods, and chemicals, plus microorganisms. Business methods and computer programs not tied to hardware remain ineligible.

(continues on next page)

newly formed Intellectual Property Appellate Board, which found that the new crystallized form met recognized international patent eligibility standards. However, the patent was still denied, on grounds of both inconsistency with Section 3.d and a finding that Glivec's price was too high in India. The case was then referred to the Indian Supreme Court in October 2011 for expedited review. The Court heard arguments in March 2012 but no decision had been issued as of July 2012.[30]

30. See "India's Supreme Court to Hear Dispute on Drug Patents," *New York Times*, March 6, 2012. For background information, see "Novartis Case: Background and Update," Lawyer's Collective, www.lawyerscollective.org/news/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html (accessed on July 18, 2012).

Box 5.1 India's Patents Act of 2005 and pharmaceuticals *(continued)*

- A high novelty standard, under which the subject matter could not have been published or in prior use anywhere in the world.
- Exclusion of derivatives of known chemical substances from patentability unless they are significantly more effective than the original substance. This provision is meant to prevent "evergreening" of patents by companies seeking patents on new uses of existing molecules.
- Provisions for both pre-grant opposition and post-grant opposition within 12 months.
- Language permitting applications for compulsory licenses three years after a patent is granted if the "reasonable requirements of the public" have not been satisfied, the invention is not available at a "reasonably affordable" price, or the invention is not being worked or produced in India.
- Limiting the period of negotiation between firms for voluntary licensing of a patent to six months before compulsory licensing may be requested.
- Permitting Indian firms to export to any countries issuing compulsory licenses under the TRIPS Paragraph 6 waiver.
- Permitting parallel importation of drugs.
- No provision for exclusivity of clinical test data in the Patent Law. India seeks only to prevent disclosure by unfair commercial means (the TRIPS standard) but offers no formal period of data exclusivity.

Thus, the differences between innovative pharmaceutical companies and government policies in emerging-market economies remain stark. The latter policies are aimed at the medium-term access needs of poor patients. At a broader level, however, economists might question whether rigorous use of price controls, compulsory licenses, and patent limitations in the middle-income and emerging-market countries is globally beneficial. Such countries as China, Brazil, Russia, and India have rapidly growing middle classes that presumably can afford to pay prices above marginal costs, which would contribute to the burden of investing in medical R&D. Further, as drug producers in these locations become more competitive and oriented toward innovation, the disconnect will grow between restrictions on IPRs and the needs of domestic industry. These factors should be taken into account in considering effective international approaches to the provision of medicines.

Global Market Failures and Solutions

The discussion so far has focused on TRIPS requirements and the reactions of developing countries. These are important issues but the broader global debate is about whether the system can achieve sustainable access to new medicines in poor countries. Can we rely on the patent system alone to establish

sufficient incentives for new drug development and to distribute those drugs at affordable prices? In principle, the ability to patent medicines in all WTO countries could help by increasing the profitability of investments in R&D in therapies for poor markets and offering greater abilities for patent owners to differentiate prices in segmented markets. In practice, these hopeful outcomes do not seem to be emerging. Indeed, in the first systematic study of its kind, Margaret K. Kyle and Anita M. McGahan (2012) present evidence suggesting that the pharmaceutical-related patent reforms wrought by TRIPS are not stimulating increases in R&D in medicines to address diseases most prevalent in poor countries.

Taking the R&D question first, the promise of patent protection is not enough to overcome the market failures associated with low incomes, poor medical infrastructure, and weak insurance systems in developing countries (WHO 2006). These problems matter much less for what the WHO labels "type 1" diseases, which exist in both rich and poor countries. Examples are cardiovascular diseases, diabetes, liver ailments, tobacco-related illnesses, and cancers of various types. The large patient loads and high incomes in the Organization for Economic Cooperation and Development (OECD) nations provide incentives for both private and public R&D in these areas. In principle, drugs developed for these maladies could be distributed at lower prices to patients in poor countries, a contentious issue discussed further below.

The investment incentives are much weaker for "type 2" diseases, such as HIV/AIDS and tuberculosis, which exist primarily in developing countries. They are virtually absent for "type 3" illnesses, such as malaria, African sleeping sickness, and dengue fever, often referred to as "neglected diseases" in the literature. The limited evidence available to date finds virtually no private-sector R&D responses aimed at treatments for such diseases since the founding of TRIPS (Lanjouw and Cockburn 2001, Fink 2008, Abbott 2009). Put simply, IPRs provide far more commercial support for R&D in cures for impotence and baldness than for type 2 and 3 diseases.

Paying for Pills

Providing incentives to develop new medicines for type 2 and 3 diseases is essentially a public goods problem that cannot be solved solely with globalized patent protection. Rather, some combinations of public support for research and targeted public-private arrangements are necessary. Of course, governments in both the developed and emerging-market economies provide grants and fiscal supports for basic research and pharmaceutical R&D. As noted in chapter 4, the bulk of this funding has come from US government agencies as grants for medical research at universities and research laboratories, though the European Union, Canada, Japan, and China offer support as well. Again, however, almost by definition much of this research is aimed at treatments for type 1 diseases, since those are important in the developed countries. This bias is changing to some extent. For example, the US National Institutes of

Health have established a funding program for neglected tropical diseases, as has the European Science Foundation. It should be noted that US universities, and several in Europe, seek patents on therapies developed in their laboratories. These patents are generally licensed to pharmaceutical companies and biotechnology firms for late-stage clinical trials and commercialization. Thus, even within the small share of public funding aimed at neglected diseases, the scientific outcomes are unlikely to be free of patents, raising potential access problems.

An important solution to this problem has been for universities and public research institutes to collaborate with pharmaceutical companies and charitable foundations on projects targeted at specific diseases. There are numerous examples of effective product development partnerships (PDPs) working today, such as the Global Alliance for Tuberculosis Drug Development, funded by the Gates Foundation and government donors. Another is GAVI (formerly the Global Alliance for Vaccines and Immunization), bringing together donor governments, UNICEF, WHO, and the World Bank to develop vaccines and encourage immunization. The WIPO recently launched WIPO Re:Search, a global consortium of foundations, research institutions, and pharmaceutical companies.[31] The members agree to voluntarily share intellectual property on a royalty-free basis among members in order to promote development of new drugs and vaccines for neglected diseases.

Pharmaceutical companies seek out such partnerships, whether to meet social responsibility goals or to make money. For example, in 2010 Merck entered an arrangement with the government of Bhutan and a foundation in Australia to provide Gardasil (a vaccine against cervical cancer) to girls at a nonprofit "access price" for six years.[32] Similarly, through its GIPAP initiative, Novartis provides its cancer drug Glivec free of charge to eligible patients meeting certain guidelines in developing countries.[33] Through such programs significant progress in dealing with disease burdens in poor countries has been achieved.

A critical feature of PDPs is that they must find means of allocating IPRs among the partners in order to induce sustainable participation. In this regard, IPRs can facilitate distribution and development of new drugs, rather than raise a barrier to access. This possibility is illustrated in box 5.2, a description of the International AIDS Vaccine Initiative, a particularly successful PDP. Another example is the Drugs for Neglected Diseases Initiative, which recently entered a three-year agreement with the pharmaceutical firm Sanofi.

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31. Ed Silverman, "Drugmakers Join UN Project on Tropical Diseases," Pharmalot, October 26, 2011, www.pharmalot.com/2011/10/drugmakers-join-un-project-on-tropical-diseases (accessed on June 1, 2012).

32. Merck, *2010 Corporate Responsibility Overview*, www.merckresponsibility.com/downloads/2010-Corporate-Responsibility-Overview.pdf (accessed on June 1, 2012).

33. The Max Foundation, "Glivec® International Patient Assistance Program," www.themaxfoundation.org/gipap/default.aspx (accessed on June 1, 2012).

Box 5.2 Sharing of intellectual property rights in the International AIDS Vaccine Initiative

The International AIDS Vaccine Initiative (IAVI) was founded in 1996 to promote development of a globally affordable HIV vaccine. It involves "virtual" research consortia consisting of scientists around the world in academia, nongovernmental research laboratories, and private industry who share their findings across institutions. Funding comes from a variety of sources, including government donors and foundations. The need IAVI fills is largely organizational: No single academic institution would be able to manage the complex and interrelated science needed for this great challenge.

One of IAVI's key structural needs was to develop an intellectual property master agreement that works with each institution's preferences and policies. In return for funding research, IAVI is given an option to license any program inventions, including background-enabling technologies, while granting participating groups a share of future licensing revenues based on agreed-upon formulas. If IAVI exercises its option it pays patent application fees and gets any rights awarded. The inventing institution gets the largest share of any ensuing royalties and the other consortia members get smaller allocations. A sharing arrangement is available for cases where an invention is produced by more than one institution. All new consortia members must agree up front to the research protocols and intellectual property rights arrangement.

IAVI's access model is to provide effective new vaccines to health authorities in poor countries at low prices, while gaining the bulk of any royalty payments from wealthier markets. In the words of the Gates Foundation, an active partner, "Intellectual property rights are critical to IAVI's goal of ensuring that an HIV vaccine reaches developing countries at a reasonable price."

Source: The Gates Foundation, *Case Studies for Global Health: Building Relationships, Sharing Knowledge*, www.casestudiesforglobalhealth.org (accessed on June 1, 2012).

The firm will contribute molecules from its libraries into the arrangement and both sides will collaborate on the research, the results of which will be quickly published. The key element in supporting the partnership, however, is joint management of the intellectual property generated. Both sides will co-own any resulting IPRs.

Another emerging cooperative solution is to convince pharmaceutical companies to contribute their patents to a pool. The most prominent example is the Medicines Patent Pool, sponsored by UNITAID, which encourages pharmaceutical companies and research organizations to license their patents voluntarily. In July 2011, Gilead Sciences became the first firm to participate, signing a license agreement to permit Indian generic companies to produce key HIV medicines for sale in 111 target countries.[34] Notably, some of the drugs

34. "Medicines Patent Pool Boosts HIV Drug Prospects with First License," *Intellectual Property Watch*, July 12, 2011.

are in the pipeline stage, so generic versions may become available in the developing world not long after they enter wealthy markets under patent protection. It remains to be seen how common such arrangements will become.

Publicly funded research, the contributions of foundations, and the work of PDPs are certainly making a significant difference in the medical innovation problem. Even so, only a small share of global biomedical research is targeted to neglected diseases and many observers do not think this effort is adequate to bring enough new treatments to the market. They recommend a number of other approaches for new and innovative funding sources for R&D initiatives, several of which are under consideration by an expert working group at the WHO.

For example, a number of NGOs, such as Knowledge Ecology International, advocate a global biomedical R&D treaty.[35] In broad outline, such a treaty would require each government to contribute financially, in relation to its income levels, to a fund to cover a broad spectrum of R&D costs ranging from basic research to clinical trials. It would also establish open-access medical databases and publishing, ask for transparency in research costs on the part of biomedical companies, and establish norms for managing IPRs that take account of access interests in developing countries. This proposal has gained some traction among poorer countries but faces stiff opposition in the United States and Europe. An expert group established by the WHO plans to recommend that negotiations be launched on a binding R&D treaty with narrower scope.[36]

Less controversial, though not yet widely adopted, are proposals for advanced market commitments (AMCs) and medical prizes. An AMC is a guaranteed minimum purchase, typically funded by public resources, of new vaccines or medicines that meet predefined standards for safety and efficacy. The guarantee reduces the uncertainty associated with future demand and should, therefore, expand the willingness of firms to engage in R&D. Firms that successfully develop a drug would retain its patent rights. However, contracts reached ex ante would ensure that the drug would be available at concessional prices in target markets. For example, UNICEF, the World Bank, and GAVI are collaborating on an AMC project to develop a vaccine for pneumococcal disease, with funding from the Gates Foundation and a number of governments.[37] UNICEF assesses the proposals from vaccine companies and establishes supply agreements. The project is funded at $1.5 billion and each

35. "Proposal for WHO Discussions on a Biomedical R&D Treaty," www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_R_DTreaty.pdf (accessed on June 1, 2012).

36. "WHO Expert Group to Recommend Binding R&D Treaty," *Intellectual Property Watch*, December 14, 2011.

37. Gavi Alliance, "How the Pneumococcal AMC Works," www.gavialliance.org/funding/pneumococcal-amc/how-the-pneumococcal-amc-works (accessed on June 1, 2012).

manufacturer that commits to supply vaccines against pneumonia for at least 10 years on a minimum scale and at no more than $3.50 per dose will share in those proceeds.

Another approach would be for governments and foundations to put up money for prizes that are paid to inventors of treatments for specific diseases. Firms that accept these prizes relinquish any property rights to them, making the drugs freely available in the public domain (Love and Hubbard 2007). Thus, this approach directly solves the access problem by offering drugs to poor countries at marginal cost or less. Some privately funded prizes for biomedical research outcomes have been announced, such as the Archon X Prize for Genomics, which offers $10 million for a technology to rapidly sequence the human genome.[38] Regarding climate change, in 2007 Sir Richard Branson announced the $25 million Virgin Earth Challenge for someone to develop a commercially viable design that helps remove anthropogenic greenhouse gases from the atmosphere. However, these prizes typically have been offered by private industry or foundations and have not generally become elements of public policy.

While AMCs and prizes offer promise for facilitating research and expanding access, they face a daunting economic problem. The outcomes of R&D programs are uncertain and it is difficult for authorities to determine ex ante how much reward to provide. If the reward is too large governments will overpay firms in the form of economic rents, while if it is too small no innovations may occur. Firms may also be wary of investing heavily if they think governments may want to renegotiate a smaller payment after a drug is developed, leading to a classic time-inconsistency problem (Fink 2008).

Sharing the Health

Public funding and PDPs are making notable progress on the difficult scientific and political tasks of building R&D capacity to develop drugs and vaccines for diseases experienced largely in poor countries. While many targets remain, these approaches offer a foundation for solving type 2 and type 3 diseases. Continued progress is primarily a matter of expanding the political will to address a clear humanitarian problem. When such medicines emerge, the need and ability to distribute them at low costs to health authorities in developing countries will remain uncontroversial, because the R&D costs will not need to be paid via large markups over marginal cost. The critical role of IPRs is to support contracts that permit coordination and participation across a large range of actors in the development stage.

Unfortunately, these approaches do not accomplish much with respect to type 1 diseases. Heart ailments, cancer, diabetes, and pulmonary problems are common in both rich and poor nations. Here, the problem is not building

38. For information about the prize, see www.genomics.xprize.org (accessed on June 1, 2012).

incentives for R&D, as it is for neglected diseases. Government grants and the prospect of patents in the developed world accomplish that, although the science is becoming increasingly difficult and costly. Rather, the economic problem is finding means of distributing new patented medicines to public health authorities and low-income patients in poor countries at affordable prices. Where a drug has global application there is an inevitable tension between market exclusivity rights and the needs for widespread access.

One early proposal was essentially to force drug inventors to choose between protection in major markets and other countries (Lanjouw 2001). The idea was to make pharmaceutical and biotechnology companies declare in their patent applications in the developed world whether they wished to pursue patent rights in poor countries. If they did, the original patent application would be rejected, leaving them open to rapid generic competition in the United States and Europe. Clearly, if this proposal became law the applicants overwhelmingly would opt out of seeking protection in developing countries, "solving" the access problem. Unsurprisingly, this proposal was met with strong opposition from both the research-based pharmaceutical sector and universities. Beyond any legal difficulties with national and multilateral patent rules, it foundered on how to designate target countries. If only least developed countries with limited production capacity were included, it would not much matter because patents are unlikely to be taken in those locations anyway. Thus, to be economically meaningful the targets would need to include emerging-market economies with generic capacity, such as India. Pharmaceutical companies were unwilling to surrender their patents so quickly. As an economic matter the proposal raised troubling questions about how much it might damage innovation incentives from patents.

How then to resolve the tension between patents and accessibility to type 1 medicines when originators wish to acquire IPRs in countries where they might face generic competition without them? There are three possible approaches beyond relying on philanthropy. The first is to work within the existing system of rights outlined by TRIPS to sustain as much generic competition as possible, with products made available through international trade. There is already significant competition from India, Israel, Brazil, Thailand, China, and other locations in off-patent and unpatented drugs. Going forward this process will become more difficult as new treatments achieve protection in more markets. As described earlier, such mechanisms as compulsory licenses and parallel trade can sustain some competition under certain circumstances. However, these elements bear costly administrative burdens, may largely transfer benefits to parallel traders rather than consumers, and may not be that effective.

A second possibility is to rely on stronger global patents to support incentives for firms to differentiate prices across markets. In principle, nationally defined patents segment markets and permit manufacturers to set prices according to willingness to pay. So-called tiered pricing should then result in

substantially lower prices in poor countries than in rich ones. Pharmaceutical companies should be willing to sell drugs at prices just over marginal production and distribution costs in developing nations, a strategy that contributes to global profitability, while making their highest returns in developed countries. Older economic studies failed to find evidence of substantial differences in pricing across markets at different income levels (Scherer and Watal 2002, Maskus 2001, Danzon and Chao 2000).

There are many potential reasons for this situation. Patent owners may find it more profitable to sell to higher-income patients, perhaps covered by insurance plans at private hospitals, than to lower-income patients. Health authorities in poor countries may not have sufficient resources to bargain for low prices on high volumes of drugs. Price-control regimes based on reference prices may reduce the incentives of drug firms to offer low prices anywhere. Perhaps most fundamentally, pharmaceutical companies may be concerned that if they sell type 1 drugs at very low prices in poor countries, those drugs may escape their distribution control and be diverted to richer markets through parallel trade. Or, more simply, such sales may encourage patients in richer countries to demand similar prices, reducing the profitability of those markets.

Despite these factors, there seems to be increasing interest among pharmaceutical companies in differential pricing strategies, at least for antiretrovirals, vaccines, and contraceptives (Yadav 2010).[39] This approach, buttressed by agreements to sell at low prices in targeted markets in return for guarantees that the drugs will not be reexported, bears considerable potential to address a key access problem. A few such programs exist, using differentiated packaging and mechanisms for distribution control, and they are likely to become more common. Still, differential pricing schemes, aimed essentially at charging what segmented markets will bear, cannot be expected to drive prices in poor countries down to marginal production and local distribution costs, particularly in an era of diminished generic competition.

A final approach is to form national purchasing arrangements to bargain with patent owners on lower prices, much as happens with insurance companies and national health authorities in major markets. In many poor countries this is unlikely to be an affordable option for gaining access to drugs in sufficient volumes. It almost surely will not work in cases where drugs are developed at high cost to treat rare diseases. Thus, as noted earlier, regional purchasing programs may offer more scope for negotiation, though they raise difficult coordination problems.

Ultimately, it may be left to the taxpayers in the wealthier nations to engage in such purchases on behalf of the least developed countries. This seems unlikely in light of growing fiscal imbalances and impatience with foreign aid. One promising answer might be for countries with large monetary reserves,

39. See also Waning et al. (2009).

generated from robust current account surpluses, to recycle a small share of those resources into a global drug purchasing fund. It could be one important way for China and the oil-rich Middle Eastern nations to signal their interests in engaging with a serious global concern.

Technology Transfer and Climate Change

No issue is more pressing on the global agenda than dealing with climate change by reducing emissions of greenhouse gases.[40] This is a massive and enormously complex economic and political challenge that will require considerable action beyond the IPR arena. For example, the International Energy Agency (IEA) estimates that investments in clean-technology innovation needed to meet global emission-reduction goals will be around $1.1 trillion per year (in real terms) through 2050, or around 1.1 percent of global GDP.[41] Part of this cost arises from the great heterogeneity of technology needs in particular sectors and countries (Maskus 2010).

Thus, there is a strong need for investing in alternative clean energy resources, means to mitigate the effects of climate change, and technologies to adapt to its effects. Equally important is the effective diffusion and adaptation of new technologies into locations where they are most needed, often countries in the developing world. Indeed, the need to reduce greenhouse gas emissions is underscored by the fact that the share of global emissions coming from rapidly growing developing nations is rising quickly. Emissions related to energy use in non-OECD countries now exceed those from OECD nations (Popp 2008). Much of this increase is due to the rapid economic growth of China and India, but other developing economies are contributing as well. Moreover, the least developed countries face the largest relative costs of adjustment to climate change (Maskus and Okediji 2010).

These factors imply that sustainably transferring appropriate environmentally sound technologies (ESTs) to developing countries, and adapting them to local conditions, is a critical element of addressing the problem. Indeed, finding means for ensuring international technology transfer to developing economies has long been a central issue in global negotiations over climate change. Under Article 4.5 of the United Nations Framework Convention on Climate Change (UNFCCC), developed countries are required to promote access to know-how about ESTs and to help finance technology transfer to help poor countries implement the convention. A proposal was adopted at the December 2009 UNFCCC meeting in Copenhagen to establish the Copenhagen Green Climate Fund to set aside funds for technology transfer and mitigation assistance in developing countries. The accord called for developed countries to "provide new and additional resources" approaching $30

40. This section draws on the analysis in Maskus (2010) and Maskus and Okediji (2010).

41. IEA, "Energy Technology Perspectives 2008 Executive Summary," www.iea.org/G8/2008/ETP_2008_Exec_Sum_English.pdf (accessed on June 1, 2012).

billion in the 2010–12 period.[42] As of this writing, however, the institutional arrangements and financing levels remain unclear.

A Warm Global Intellectual Divide

The most contentious elements of technology transfer in climate change talks are debates over the scope and limitations of IPRs, especially patents. In general, developed countries, led by the United States, European Union, and Japan, view the global IPR system as an inducement to the development of ESTs and their effective diffusion and transfer to developing countries. Accordingly, they see no need to place any limitations or exceptions on the scope of patent rights. Many developing nations, led by China and India, instead see patents as a significant barrier to technology transfer. They argue for specific measures that would remove such barriers, including compulsory licensing of patented technologies, pooling and sharing publicly funded technologies and placing them into the public domain, and changing the TRIPS Agreement to permit a solution to EST transfer akin to the special arrangement on compulsory licenses for public health. Some countries call for exempting least developed countries altogether from obligations to patent climate-related technologies and banning patents on genetic resources and plant and animal varieties if they are important for adaptation. Another group of developing countries, including Bolivia, the Philippines, and Indonesia, has argued for permitting countries to exclude ESTs altogether from eligibility for patents (Maskus 2010).

This impasse reflects the fundamental conflicts between countries in making global IPR policy. At one extreme sit the United States and like-minded developed economies. Firms in those countries are still the owners and creators of the vast bulk of patentable inventions across the range of ESTs, though this is changing rapidly. Investments in these technologies are supported by major public grants to basic research at universities and government laboratories. The knowledge created may be directly channeled to private industry through commercialization arrangements in which some licensing of intellectual property is paramount. Both private firms and universities want to protect their potential revenue streams through IPRs as their technologies are licensed or otherwise transferred abroad.

At the other extreme are the least developed countries and many emerging-market economies, where innovative activity lags behind and governments are incapable of investing in basic agricultural improvements or environmental cleanup, much less public research supports. Small firms and inventors may be highly innovative but generally cannot develop large-scale research programs to address basic environmental problems. Their environmental needs and ecological vulnerabilities are large and must, in the main, be met by global

42. Sourcewatch, "Copenhagen Green Climate Fund," www.sourcewatch.org/index.php?title=Copenhagen_Green_Climate_Fund (accessed on June 1, 2012).

public funding and access to appropriate ESTs. In addition, privately motivated investments in their particular environmental needs are likely to be small or nonexistent due to their small market size.

Somewhere between these poles lie countries with rapidly emerging technological capabilities, such as Brazil, India, and China. These nations are capable of undertaking R&D in novel and adaptive ESTs. China, in particular, is a global leader in the development and implementation of several new technologies, and its enterprises hold a significant and rising share of patents in major countries covering solar energy and fuel cells (Copenhagen Economics 2009). Nevertheless, significant environmental problems plague those countries, giving them an interest in pushing for significant L&Es on patent scope. Policymakers see various L&Es as a means of acquiring relevant technologies from abroad at relatively little cost, in turn encouraging information diffusion and spillovers into their broader economies. On a broader scale, to the extent that China and similar countries take advantage of restrictions on patents they may more rapidly become significant sources of competing green technologies (Maskus and Okediji 2010).

Of course, what is seen by Chinese and Indian authorities as sound industrial strategy and environmental policy is seen by Western firms as an attempt to steal expensive technology. It has proved impossible so far to bridge these positions and this impasse is one of the impediments to achieving a global agreement on emissions reductions. It is a key example of the seeming intractability of current international controversies over IPRs.

The Patent Landscape

Global patenting in green technologies is increasing rapidly. The WIPO reports that solar-energy-related patent applications filed under the Patent Cooperation Treaty tripled between 2004 and 2008, rising to over 1,400 (Castonguay 2009). Another analysis found around 215,000 patent applications worldwide between 1998 and 2008 in seven key environmental technologies: waste, solar, ocean, fuel cell, biomass, geothermal, and wind power (Copenhagen Economics 2009). Of these, perhaps 22,000 applications were in a sample of developing economies. However, virtually all of this growth was in a small group of emerging-market economies, including Argentina, Brazil, Russia, Ukraine, India, China, and the Philippines. Fewer than 10 applications per year were submitted in the sample of poor countries. It is also noteworthy that more than one-third of the applications in these emerging-market countries were registered by inventors actually from those countries, primarily China. Indeed, China is a significant source of new environmental technologies and its enterprises and research institutes hold major shares of global patents in solar energy, fuel cells, and clean coal technologies (Jessup 2008).

The most comprehensive analysis was performed by the United Nations Environment Program, European Patent Office, and International Center for Trade and Sustainable Development (UNEP, EPO, and ICTSD 2010). These

organizations reviewed all recent applications and described the existence and ownership of patents in major clean-energy technologies. They found that patenting rates in these technologies have gone up by 20 percent a year since 1997, faster than the rate in traditional energy technologies. This activity remains dominated by developed nations but several emerging-market economies are now important technology developers, including Mexico in hydro/marine activities and India in solar photovoltaic inventions, in addition to those listed above.

Despite this rapid rise in patenting there is little indication yet that it raises access barriers to ESTs. For one thing, patents cannot be a direct impediment to technology transfer to the poorest countries, since virtually no patents have been registered in those countries. For another, ownership within any of these technology groups tends to be spread broadly across countries and firms, suggesting there is little risk of monopoly pricing or anticompetitive behavior (Copenhagen Economics 2009).

John H. Barton (2007) reviewed patenting behavior in solar photovoltaic, biofuels, and wind technologies, reaching similar benign conclusions. In ESTs many of the foundation technologies have long been off-patent, while existing patents typically protect moderate improvements and specific features. These incremental changes compete with numerous substitute technologies both within and across invention classes in sectors with relatively free entry. Thus, licensing opportunities are available from multiple sources and competition restrains pricing power in reasonably competitive markets in developing economies. In this context, the real barriers to technology transfer arise from impediments to trade and investment and from limited adaptation capabilities in poor countries.

The Essential Problems

Thus, the evidence to date is that patents do not unduly hold up technology transfer, primarily because usually ample substitutes are available. Going forward, however, this sanguine situation could change as additional investments are made in new forms of environmental technologies. One specific concern is that there will be extensive patenting of the enzymes and microorganisms that will become the basis for second-generation biofuels and synthetic fuels (Barton 2007). This possibility is similar to the current situation in biotechnology, where many observers claim that patent thickets and high transactions costs deter R&D and impair access to knowledge (Newell et al. 2008). More generally, patents could raise future access problems in technologies that address specific local ecological needs or market conditions.

Note also that governments in a small number of countries finance much of the basic research in ESTs at universities and public laboratories (Maskus 2010). These countries also effectively subsidize innovation and commercialization by domestic firms in the name of global competitiveness. Thus, another potential concern is that the deployment of technologies emanating

from publicly funded research programs will take on protectionist elements. For example, US innovation policy encourages patenting of technologies developed under public support and the rules favor commercialization approaches that discriminate in favor of domestic firms (Barton 2007). The European Commission's Environmental Technologies Action Plan, succeeded by the Eco-Innovation Action Plan in December 2011, provides fiscal support to firms bringing green technologies to market. Many other developed and emerging-market economies offer similar commercialization subsidies. The risk is that nationalistic favoritism will raise the costs of access to ESTs developed from public research.

Deeper structural problems, however, form the core of North-South debates in technology transfer in climate change. To begin, there is an acute timing mismatch between the immediate needs to deploy technology and lengthy global diffusion processes. One extensive investigation over the last 30 years of patent ownership and market adoption rates of six energy technologies—wind, solar photovoltaic, concentrated solar power, biofuels, cleaner coal, and carbon capture and storage—found that innovation and international adoption are both lengthy processes, often taking 20 or 30 years (Lee, Iliev, and Preston 2010). This slow diffusion rate cannot meet short-term global needs for rapid technology transfer and local adaptation, suggesting that additional supports will be necessary as new technologies come on line.

Next, the fact that IPRs may not yet constitute an access problem does not mean that the current regime is the most effective mechanism for encouraging innovation and diffusion of clean technologies. In this context there are a number of concerns. First, the existing IPR system evidently does not provide enough profit incentives to motivate the extensive amounts of R&D needed for developing effective new technologies. Indeed, in real terms R&D spending by IEA member countries on alternative energy sources and mitigation technologies fell in the 1990s (Barrett 2009). More recently these expenditures have increased, but primarily due to public investments. Second, relatively little of either the public or private investment is aimed at the particular conservation and mitigation needs of poor countries because their markets are too small. Third, even where general-purpose ESTs could be deployed in those countries, resources are insufficient to pay for the costs of adapting them to local soil, climate, production, and living conditions (Maskus 2010). Fourth, the poorest countries generally have the least capacity to invest scarce development resources in costly solutions to domestic ecological issues, much less those with a global payoff.

Finally, fundamental fairness issues are at play. Authorities in developing economies point out that most of the accumulated greenhouse gases in the atmosphere were emitted by the developed economies and, accordingly, see little justification for paying royalties to firms located there. At the same time, policymakers in the developed world see attempts in developing economies to limit patent rights as an unfair strategy to expropriate expensive knowledge for domestic firms and create competitive industries.

Potential Solutions

It is misleading to blame the patent system for limited progress in private sector development of novel technological solutions to environmental issues in the developing world. Available evidence indicates that five factors are driving the bulk of investment in ESTs: anticipated market demand, relative prices of alternative energy sources, costs of investment, regulatory incentives, and public research subsidies (Popp 2006; Johnstone, Hascic, and Popp 2008; Maskus 2010). Like other engineering-oriented manufacturing sectors, in most green technologies the promise of patents per se is not a major spur to innovation, though IPRs are important for earning market returns and facilitating commercialization (Cohen, Nelson, and Walsh 2000).[43] As for international technology transfer and local investments in adaptation, IPRs likely play a supporting role at best in developing economies that face problems of resource scarcity, limited domestic capacity to absorb and improve technical information, and ineffective governance.

In this context, at least two basic conditions are required to provide general incentives for technological development and diffusion. Most important would be a large and sustained rise in global costs of emitting greenhouse gases or using fossil fuels to make R&D in conservation and alternative energy sources more profitable. This might be accomplished through coordinated energy taxes or cap-and-trade systems—both globally problematic due to extensive free-riding problems. Also necessary would be improved and transparent innovation policies and investment climates in developing countries that can bring down the costs of transferring and modifying new technologies.

In the absence of these facilitating conditions, it is doubtful that tinkering with IPRs would have decisive effects. Even if progress were made in those directions, many countries still would have unattractively small markets, while certain technology needs are sufficiently different to limit prospects for cross-country economies of scale. Thus, there is scope for deploying useful complementary approaches—involving both patent modifications and broader supports—that global and national policymakers might consider to ease some of the structural difficulties in motivating development of ESTs and their dissemination in poor countries.

In this context, the greatest need is for a shared vision and cooperative approach to expanding access to ESTs in a way that actually enhances incentives for investment. As a matter of economics, there is considerable scope for establishing and consolidating conditions that are mutually advantageous for both technology developers and those needing access. Several ideas are described in the following subsections.[44]

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43. Patents are likely to be increasingly important inducements to R&D in biofuels, synthetic fuels, and other bioengineering solutions.

44. Abbott (2009), Bollyky (2009), and Maskus (2010) offer more extensive ideas.

Access Tools Already Exist

First, it is important to have parties at the UNFCCC negotiations recognize that existing L&Es permitted under TRIPS apply to environmental technologies. As a result, there is little need to develop a global accord specific to ESTs that would further weaken the scope of IPRs under TRIPS. For example, countries are free to employ robust and rigorous standards of patentability. Protection should be given only to genuine inventive improvements, with minor inventions and modifications eligible for lesser protection, such as utility models, or relying on trade secrecy. Because rigorous eligibility standards are of little value in countries that do not examine patent applications, developing countries may deploy pre-grant or post-grant opposition procedures.

For purposes of supporting local adaptations and improvements to patented ESTs, nations may also establish a research exemption for experimental use by domestic firms and research organizations. This offers scope for reverse engineering to develop noninfringing domestic or regional versions of patented technologies. Having a limited research exemption in agricultural varieties may be of particular importance as developing economies deal with greenhouse gases by deploying drought-resistant crops or plants for biofuels.

Further, countries have authority almost without restraint to grant compulsory licenses, subject to certain procedures and requirements, and government-use licenses. Procedural limitations on compulsory licenses in TRIPS may be waived in cases of a national emergency, extreme urgency, or public noncommercial use. Each country may decide for itself what constitutes a national emergency, since this term is not defined in TRIPS. Some observers claim that the potential future consequences of climate change could create a near-term situation of extreme urgency (Adam 2009). Further, countries may exercise competition policy to grant nonvoluntary licenses as remedies in cases of anticompetitive practices, as discussed earlier in this chapter. Under certain circumstances such licenses may also permit use of a prior patent to effectuate a dependent EST of particular importance in a country.

Because all of these provisions exist in the patent laws of major developed economies they are not radical departures from accepted practice. However, compulsory licenses generally have been of limited effectiveness in the developing world and extensive resort to their use could diminish incentives for global firms to transmit technologies. Moreover, effective use of complex patent standards, compulsory licenses, and accompanying judicial procedures requires significant administrative and judicial expertise. For these reasons they may not help much in the poorest countries to expand access to ESTs, though countries might benefit from establishing regional cooperation. In any case, it is important to build expertise and capacity in these complex procedures, calling for increased technical assistance from abroad.

The primary point is that, because such authority already exists, there are no compelling legal or economic reasons to significantly alter TRIPS as a means of encouraging technology transfer to combat climate change. In par-

ticular, there is little argument for excluding ESTs from patent eligibility. One exception might come into play later if it seems that the poorest economies cannot gain access through market channels to essential patented bioengineered technologies and do not have sufficient domestic production capacity to produce under a compulsory license. In that event, multilateral consideration of another TRIPS waiver, parallel to that in essential medicines, may become necessary (Maskus and Okediji 2010).

Useful Differentiation of Patent Terms

There may be more promise in modifying patenting conditions as a means of expanding access (Maskus 2010). For example, virtually all newly developed and patentable ESTs seek protection in the major developed economies. Patent authorities in those jurisdictions could be instructed to differentiate application and renewal fees and length in response to demonstrated commitments to effective technology transfer and adaptation. Expedited examinations and mutual recognition of granting decisions across major patent offices would extend effective patent length and increase returns to investment. Limited extensions to patent duration in developed and major emerging-market economies, granted midway through an invention's term and with a high renewal fee, might be offered in return for a commitment to low-cost licensing in poor countries.

As always, the difficulty with reduced upfront patent application fees and patent term extensions is that patent offices cannot easily discriminate among technologies. Without a restrictive definition of eligible ESTs many other industries can be expected to label their inventions accordingly in order to qualify for preferred treatment. However, a narrow (and inevitably bureaucratic) definition would risk excluding broader technologies, such as computer programs that drive and monitor environmentally sound equipment, even if that is not their only purpose.

This problem could be overcome with an appropriate fee structure. Since the objective is to favor inventions that would be transferred to uses in developing countries, effective fee discrimination could be achieved through a partial rebate upon adequate demonstration that the technology has been made available for licensing on reasonable terms. Such treatment could be made available to inventions that facilitate environmental mitigation or adaptation without reference to the underlying patent classification. Another approach would be to offer a lower initial application fee to any invention that claims a useful environmental use and an intention to license but raise renewal fees at later periods. The latter approach would offer a disincentive to inventors hoping to benefit from misclassifying their applications and would also tend to bring patented technologies more quickly into the public domain. In principle each major patent office could develop a fee structure along these lines and there could be coordination among them.

Facilitating Alternative Access Mechanisms

A promising complementary approach would be to support voluntary patent pools or networks into which patent holders would deposit their relevant intellectual property.[45] Users could then acquire the licenses needed for specific mitigation and adaptation technologies from members of the network in return for royalties paid at ex ante determined rates. These rates could be differentiated in favor of uses in developing nations. Such patent cooperatives can greatly reduce the costs of licensing to multiple markets (Lerner and Tirole 2004a, Picker 2006). They are especially helpful where there are multiple patents on complementary inputs, which is often the case in such cumulative inventions as solar photovoltaic energy and biofuels. Structured properly, patent networks would amount to open licensing in return for an agreed payment, effectively a liability rule regime (Flynn, Hollis, and Palmedo 2009). Indeed, such an arrangement has been established by UNITAID in the area of antiretroviral drugs (Weilbacher 2009).

The biggest problem with voluntary licensing pools is that inventors may refuse to deposit certain patents, particularly for inventions with high global commercial value. Thus, the ability of licensing pools to promote technology transfer depends on how much they reduce transactions costs, the size of potential markets, and the nature of relevant technologies (Lee 2006). In some cases public subsidization of license fees may be needed to build markets where the technologies in question bear external environmental benefits. Importantly, even if voluntary pools failed to attract enough participation by private firms, universities and public research institutes could be encouraged to place their technologies into public repositories, accessible to all users in return for licensing fees differentiated by development levels and needs.

Fiscal Supports

Whatever may be advanced in the IPR arena, significant new funds must be deployed to facilitate development of new technologies and, most importantly, to pay for their adaptation to specific needs in countries that cannot afford them. As noted above, the Copenhagen Green Climate Fund commits the developed countries to establishing a fund by 2012 for climate change mitigation, though it is left unspecified whether this money would be largely publicly provided or arise from private investments. This is a useful beginning but it needs specificity in terms of how these funds will be provided, toward what objectives they will be directed, and how they will be managed.

Fiscal supports are essential for transferring green technologies and ensuring their diffusion throughout local economies. In this context, a series of regional or functional (subject matter) Global Emissions Reduction Funds

45. Such approaches have been advocated also for genetic inventions and diagnostic kits (van Zimmeren et al. 2006, Verbeure et al. 2006).

could be established that operate in ways similar to the Global Fund to Fight AIDS, Tuberculosis and Malaria and create incentives to meet the specific mitigation needs of poor countries. Also promising are prizes or advanced-market commitments that are awarded on the basis of demonstrated local needs and effective solutions (Maskus 2010).

Such funds should adopt principles and guidelines for the management of intellectual property in ways that ensure reasonable access, encourage local adaptation, and permit private partners to profit from participation. Because such arrangements are complex, each fund would need a set of transparent yet flexible principles to which partners would adhere. Such principles would include, for example, conditions for acquiring existing IPRs, determining whether newly developed technologies would go into the public domain or be partly privatized, working out ownership and royalty shares, and establishing concessionary prices and license fees in developing countries. As appropriate, contractual arrangements could ensure that technology developers would be able to profit from sales in nontargeted markets. Universities, firms, and public authorities wishing to avail themselves of these funds would need to respect these principles and develop effective mechanisms for transfer and diffusion.

Global Cooperation

This multipronged approach has numerous advantages over the existing global approach to climate change and IPRs. It would reduce the political momentum in the developing world toward reliance on compulsory licensing as a solution. In some circles compulsory licenses are seen as the counterpart to "border tax adjustments" or "green tariffs" proposed by major developed countries to offset perceived production-cost advantages in developing countries with weak environmental standards and high emissions. Developing economies view border tax adjustments as unfair and costly protectionist measures that will slash their export prospects. Indeed, if such adjustments were to come into wide use, the reduction in market access would almost surely reduce technology transfer prospects, while diminishing incentives in the developing world to cooperate on climate change initiatives.

More fundamentally, a cooperative approach would set a better framework for enhancing future technology transfer as new technologies come on line. For example, patents and plant breeders' rights may become more prevalent as second- and third-generation biofuels, synthetic fuels, and emissions-absorbing bioengineered crops are developed. These technologies will be more like medicines and software in their vulnerability to reverse engineering and copying. Financing mechanisms with transparent principles for rent sharing and transfer are more likely to encourage their development and global use than are IPRs under the existing regime, where rights are territorial, fragmented, and subject to uncertainty.

Agriculture and Genetic Resources

Economists routinely use farming to illustrate an industry with static technology and constant returns to scale. Whatever may have been the accuracy of this characterization in the distant past, today it is a highly misleading caricature. Agriculture is both the source and rapid adopter of major technological progress, ranging from genetic and molecular innovations to improved plant characteristics and the sophisticated use of weather data and satellite images to manage harvests and select crop rotations.

Consider some basic examples. Universities and research institutes invest billions of dollars annually in chemical and biogenetic agricultural research aimed at inventing crops that are more resistant to droughts and pests and inputs that enhance the nutritional or health value of foods. Critical agricultural inputs, such as technologically advanced fertilizers and pesticides and genetically modified seeds, are developed in and produced by major agribusinesses with global reach. So-called industrial farming, in which beef cattle, hogs, chickens, and fish are kept in close quarters in huge numbers in order to produce animal proteins efficiently, is itself a major form of technical change but is possible only with the application of modern antibiotics. The wine industry rests on a veritable treasury of scientific information regarding soil conditions, pest resistance, and juice-blending characteristics to produce new varieties.

The importance of developing new technologies in agriculture and transferring them to developing countries with significant potential for expanding farm outputs can scarcely be overstated. The world just passed a population of seven billion and is moving rapidly toward nine billion by 2050.[46] Finding means of feeding them, while also meeting the needs of growing middle classes around the world for better foods, is a central question. There remain land areas in forests and cold regions that could be developed for this purpose, though they would be less productive than existing resources and their exploitation would raise questions about global environmental stewardship. Thus, the primary answer must be found in technological improvements that continue to raise nutrition generated per hectare of land. This process requires more science, extension work, private R&D, and incentives for adoption and adaptation.

Again, we can ask whether reliance on private and exclusive IPRs is sufficient to manage this transition. Certainly they must play an important role. As in other industrial sectors, IPR reforms should procure significant gains in market efficiency, international technology transfer, and productivity in agriculture. As farmers in more locations embrace new agricultural biotechnologies, they can expect gains in yields and product qualities that provide more income while helping to feed the world. This sanguine outcome would be more likely if complemented by trade policy actions to open world markets to

46. "Feeding the World: The Nine-Billion People Question," *Economist*, February 26, 2011.

new crop and animal varieties and break down resistance to consuming them in certain locations over time.

There are good reasons to doubt that IPRs alone can sufficiently incentivize productivity growth. First, some argue that expanding legal protection will raise the costs poor farmers face in procuring seeds and other inputs, while limiting their freedom to replant and exchange varieties. Put differently, stronger IPRs could reduce diffusion rates while worsening rural poverty. Second, private rights by themselves cannot readily overcome the costs of adapting new agricultural technologies to specific soil and weather conditions in poor countries, suggesting the need for public extension services and adoption incentives akin to those regarding environmental innovations. Third, as described later, private IPRs do little to encourage investments in basic natural resources.

Furthermore, deep questions of global public policy surround the application of IPRs to agriculture. For example, many observers worry about the fundamental implications of globalized private rights for sustaining the global plant-genetic commons from which crops have been improved over many generations of science and experimentation. If IPRs permit inventors to develop standardized "super-crops" that replace or supplant the natural variation of strains in produce, cereals, and grains there could be negative impacts on plant genetic biodiversity. A similar process could characterize the development of industrialized "super-animals" that embody particular genetic traits rather than natural evolution. Ultimately the concern is that such inventions would threaten global food security in the event that those dominant strains face a debilitating disease or natural disaster.

A more immediate concern is that, as in medicines, the development of new bioengineered crops and plant varieties often uses specific genetic resources frequently found in developing nations without adequate legal protection against unauthorized appropriation. Many civil society critics argue that this use threatens a further reduction in natural biodiversity.

As usual, whether such problems are truly the result of stronger global IPRs is the subject of heated debate and little solid evidence, as noted later in this section. There are always tradeoffs between innovation, licensing, and access, and it is difficult—and probably too soon—to determine the net effects on adoption and poverty in poor countries. Similarly, it is far from clear whether the effect of IPRs is likely to be development of dominant crop and animal strains or increasing experimentation to produce finer technical variations tailored to specific climatological needs and consumer preferences.

Intellectual Property Rights in the Countryside

The historical evolution of research, technological change, and IPRs in agriculture is fascinating (Evenson 2005, Ruttan 2001). Roughly speaking, five major technical revolutions moved farming from a small-scale subsistence activity to a research-based industry. First was the widespread implementation of mecha-

nization in the 19th and early 20th centuries, with the introduction of a variety of plows, mowers, reapers, tractors, and combines. Public science played only a small role but patents were important in protecting and commercializing these inventions, which came overwhelmingly from private industry. Patents also played a role in the introduction of agricultural chemicals, such as new fertilizers, herbicides, and insecticides, in concert with the development of chemically based pharmaceuticals in the 20th century. Agricultural chemicals were heavily patented and today remain highly dependent on the IPR system.

In contrast to these earlier revolutions led by the private sector, publicly funded and performed research first became critical in scientific cross-breeding programs to improve the genetic structure of crops. The participation of US universities and public agricultural extension stations first became prominent in the development of hybrid varieties of corn and other grains in the 1930s and later. Importantly, these hybrids did not generally require IPRs because the methods of producing them yield sterile seeds that cannot be replanted, thereby acquiring their own natural protection from future competition. With this natural barrier in place, private seed firms quickly dominated the industry and there was rapid diffusion of seeds to US farms (Griliches 1957). However, many other crops did not have such natural protection and inventors demanded legal protection. As a result, IPRs were introduced in the United States, first through the Plant Patent Act in 1930 and next via the Plant Variety Protection Act in 1960, with similar legal processes emerging in other developed countries.

This process of crop genetic improvement later supported the famous Green Revolution, as public research institutes applied these techniques to crops that would succeed in developing countries. In the 1960s, scientists in two public International Agricultural Research Centers (IARCs) released modern high-yielding varieties of wheat and rice, developed from freely available stocks of genetic resources and using knowledge from private breeding experiences. These varieties, which featured shorter and stiffer stalks (to permit more plant energy to go into producing grains), were rapidly adopted in a number of countries in Latin America and Asia, often supported with public investments in irrigation. They were followed by new varieties of many other crops, with more than 8,000 released by 2000. It is noteworthy that the bulk of these new varieties were developed in IARCs located in developing countries, with little participation from institutions in developed nations or private firms (Evenson 2005). The Green Revolution was a product of public research and extension efforts with little presence of formal IPRs.

The fourth major form of technological change was the shift to industrial livestock production, which relies on improvements in animal genetics and animal pharmaceuticals in addition to organizational changes in processes and marketing. In particular, specialized livestock operations exist in vertical relationships with agribusinesses that supply feeds and vaccines and antibiotics while selling processed meats to contract retailers. Both improvements in animal breeding and inputs rely on patents and other IPRs, with the bulk of these technical changes emerging from the private sector.

Where intellectual property is most prominent is in the fifth revolution, involving bioengineering to introduce living organisms into plants to improve their drought resistance or yields or for other useful features. This so-called Gene Revolution is well under way but still evolving. It involves significant collaboration between basic and applied science, often funded publicly at universities and extension stations, and private developers. An early and highly significant invention was the method for stably inserting DNA from external organisms into a host genome, which earned a US patent for two scientists at Stanford in 1980. The Cohen-Boyer patent for recombinant DNA techniques is often described (along with the *Diamond v. Chakrabarty* Supreme Court case in the same year) as the foundation of IPRs in biotechnology (see chapter 2).

In the wake of this legal foment emerged many applications of basic science to new genetic technologies in pharmaceuticals and agriculture. These applications supported the development of university-industry collaborations in agriculture and licensing of genetically modified organisms in many countries. An important factor was the growth of such major multinational life science companies as DuPont, Monsanto, and Novartis, which came to dominate global plant biotechnology markets.

As this brief review suggests, IPRs have long been associated with parts of agriculture but they have taken on much greater importance in recent decades. As noted elsewhere in this volume, there are three canonical forms of legal protection of IPRs in this sector. First, plant breeders' rights (PBRs) give the developer of a new, distinct, uniform, and stable variety of plant exclusive control to sell and license the propagating material and outputs for a fixed number of years, typically 20 (or 25 for trees and vines). Thus, these rights function much like patents and, indeed, may be the subject of compulsory licensing. However, they are generally more limited, since breeders cannot claim protection of similar varieties or those derived from similar techniques. Moreover, variety rights may be limited by the farmers' privilege, permitting storing and replanting seeds, and a research exception permitting experimental use by rival breeders.[47] These exceptions form a regime of fair use akin to that in copyrights (Swanson and Goeschl 2005).

International protection of plant varieties is governed by TRIPS, which demands at least a sui generis form of legal right. TRIPS makes reference to the systems set out in the treaties managed by the International Union for the Protection of New Varieties of Plants (UPOV). As of December 2011 the UPOV had 70 members, with 25 having joined since 2000. UPOV membership is not necessary to satisfy TRIPS, however. For example, India has a sui generis law, passed in 2001, that maintains farmers' rights to stock, replant,

47. See chapter 2. It is curious that no parallel system of animal breeders' rights has emerged, though the logic is largely similar (Temmerman 2011). In several countries it is possible to patent particular animals that are invented to display useful traits, such as a predisposition to a disease for facilitating medical research.

and even exchange and sell seeds. Note the use of the phrase "farmers' rights" as opposed to "farmers' privilege."

The second form of protection is patents for new plants and animals that meet criteria for patent eligibility. Patents have broader scope than PBRs and, in particular, do not generally permit a farmers' privilege or research exception. Several countries, including the United States, Canada, and Australia, feature both types of protection, which has caused legal uncertainties about overlapping claims and what behavior truly constitutes infringement. Relatively few developing countries opt to provide patents for new plants, which is not required by TRIPS.

The more direct and widespread use of patents in agriculture relates to protection for biogenetically engineered seeds and other biotechnological inputs, such as vaccines, antibiotics, and pesticides. Again, the TRIPS Agreement, Article 27.3(b), states that WTO members must provide patents for microorganisms and microbiological processes. Thus, in countries with a market for using biotechnological agricultural inputs, patents need to be defined and enforced. Note also that seeds and other agricultural technologies may be protected commercially through trade secrets.

The third form of IPRs relevant for agriculture is geographical indications, discussed extensively in chapter 4. Again, a considerable debate remains about whether to globalize protection of geographical indications through a multilateral registry with legal force.

Sowing Money

It may seem surprising that seeds require IPR protection for their development and market transfer. However, these technologies share with medicines the feature that they are relatively easy to reverse engineer, making them vulnerable to copying. More than that, seeds have the peculiarly self-destructive (for breeders) characteristic that they quickly and automatically create their own competitors (Swanson and Goeschl 2005). For example, a breeder might develop a new variety of rice that resists pests and generates plumper kernels. With marketing efforts the breeder could sell the seeds to farmers at an initial markup. If those farmers could retain and sell seeds to neighboring producers, it would not take long before the market price of seeds would approximate that of rice. The original breeder would quickly find itself in competition with a large number of competitive seed sellers.

The technological issue here is that most agricultural seeds embody their own reproductive blueprints via biology. All that is needed to reproduce the blueprint in volume is to grow the plants and use the seeds. Put differently, selling a new plant variety without protection implicitly transfers a license to replicate and produce the crop without compensation beyond the first year. Breeders would rarely earn a return sufficient to pay for their R&D costs, slowing innovation in agriculture. This problem would be particularly damaging in farming, where there is a constant biological race to develop vari-

eties that cope with pest infestation and disease epidemics. Thus, in agriculture as in medicines, there are strong externality-based arguments for providing exclusive marketing rights for a defined period of time. Plant breeders' rights in some form are a key market support for dynamic evolution and can bear high social returns (Evenson 2005).

As noted above, some hybrid crops carry their own technical protection through the production of seeds that generate crops but are infertile and cannot be replanted. More recently, life science companies have developed genetic use restriction technologies (GURTs), which essentially transfer specific sterilization genes to other crops, such as wheat and rice, without eliminating production of the desired variety. Companies such as Monsanto view these GURTs, which would automatically eliminate the farmers' privilege as the relevant seeds are adopted, as technical means of defeating weakly enforced IPRs in many countries. However, farmers groups and NGOs quickly tarred these technologies with such labels as "terminator genes" and "suicide seeds" to emphasize their potential impact on access to low-cost seeds. Unsurprisingly, the idea of GURTs-protected crops met with substantial opposition from such groups in many locations, including in the developed world, and Monsanto pledged in 1999 not to commercialize them. However, the company requires customers who buy their seeds in many locations to sign a pledge not to save or sell them for further cultivation, planting, or breeding.

There is little systematic econometric evidence about the roles played by IPRs in promoting innovation and diffusion in new plant varieties and biotechnological crops. Again, the economic tradeoffs are familiar: Temporary exclusive rights provide price premiums that pay for R&D costs but increase the charges farmers pay for seeds. However, those seeds could offer significant gains in terms of higher productivity, reduced uncertainty, and greater crop quality. History suggests that where such benefits exist farmers are quick to appropriate them by adopting the new technologies. Griliches (1957) demonstrated that within the United States replacement of traditional maize with hybrid corn varieties was especially rapid, though it varied across states. More recent evidence found that hybrids have met with variable adoption rates across countries but have slowed the growth of crop yields only in the poorest countries with weak agricultural infrastructure (Goeschl and Swanson 2000).

With respect to the ongoing Gene Revolution, adoption rates are similarly rapid by farmers in countries where conditions are conducive to using new genetic crops. For example, in Argentina survey evidence indicates that the widespread adoption of Roundup Ready soybeans (a crop with a genetic trait permitting reduced use of toxic herbicides) raised productivity by around 10 percent, generating substantial consumer gains (Qaim and Traxler 2005). More broadly, worldwide planting of biotech crops rose from 1.7 million hectares in 1996 to 160 million hectares in 2011.[48] In 2011, 16.7 million farmers in 29

48. "Global Status of Commercialized Biotech/GM Crops: 2011," ISAAA Brief 43-2011, www.isaaa.org/resources/publications/briefs/43/highlights/default.asp (accessed on June 1, 2012). This

countries grew such crops, with most of these producers being small farmers in 11 developing countries who planted Bt cotton.[49] In the developing world the leading producers are China, India, Argentina, South Africa, and Brazil, which together planted 63.4 million hectares of genetically modified crops in 2010. These five countries, and a growing number of smaller and poorer developing nations, see a variety of potential benefits from expanding their use of biotech crops, including greater food security, enhanced exports, and lower fertilizer and pesticide use. They also have a wide variety of legal systems for protecting new seed varieties and genetically modified crops. Perhaps the most warranted conclusion to draw is that while there may not be much statistical correlation between laws and the adoption of technology, the gains from use are great enough that implementation of IPRs is no barrier to technical change.

The Public Goods Questions

As noted above, there are basic questions about the ability of private markets, buttressed by IPRs, to engage in sufficient innovation and international technology transfer to meet global demands for nutrition, food security, and biodiversity. In some dimensions these issues are similar to those in medicines and green technologies. Indeed, there are significant policy and commercial overlaps among these areas, as biotechnology supports both new medical treatments and genetically modified seeds, and addressing climate change includes developing crops that use less water, place reduced stress on local soil conditions, and adapt to changing weather patterns. A major difference, however, is that the need for public R&D support and technology transfer through extension services has long been recognized in agriculture. Moreover, the global policy architecture is more highly developed in agriculture and genetic resources, though it is far from being smoothly coordinated.

Research and Extension Services

Agriculture has long been the subject of publicly funded research, education, and extension activities in the United States, Japan, Germany, Brazil, and numerous other countries (Evenson 2001, Ho 2011). One influential study places research and extension at the center of agricultural development, itself often a precondition for sustained economic growth (Birkhaeuser, Evenson, and Feder 2001). Supports range from research grants to universities and public research institutions to information programs at extension offices. Empirical meta-studies find a high social return to public research and exten-

source is hardly disinterested but its international data on biotechnology production in agriculture are the figures used by the US Department of Agriculture.

49. Bt stands for *Bacillus thuringiensis*, a soil-dwelling bacterium that is commonly used as a biological pesticide. Bt genes have been inserted into cotton, wheat, corn, potato, and other crops to make them resistant to insects, thereby raising productivity.

sion, though with a wide range of estimates (Birkhaeuser, Evenson, and Feder 2001; Raitzer and Kelley 2008).

The externality-based arguments for this support are familiar: Farmers are too small and diffuse to organize expensive R&D with significant spillovers, crop and livestock prices and farming incomes are subject to extensive uncertainty that reduces investment, the costs of achieving reliable information are high (which can discourage individual farmers from being early adopters), and a plentiful supply of foodstuffs is important for national well-being and security. Note that IPRs are not suited to resolve these problems, except where agricultural research may be efficiently undertaken in organized life science companies that may license basic inventions from university laboratories. Thus, certain fiscal and structural supports in agriculture remain justifiable as a public good.

These observations hold wherever farming is a significant economic sector. However, some problems, such as the unwillingness of farmers to undertake risks and be early adopters of new technologies, pertain especially to poor countries. Further, much like essential medicines, private profit incentives are generally insufficient to induce development of new seeds that meet the particular needs of low-income farmers in specific locations.

Thus, the global community has invested in an extensive public international infrastructure for funding R&D and encouraging adaptation and adoption through local extension services. Most prominently, 15 IARCs engage in research on farming issues ranging from tropical agriculture to rice, corn, potatoes, livestock, food policy, biodiversity, water management, and forestry and fisheries. Most of these centers are located in developing countries and aim to find sustainable solutions to resolving economic and technical problems in agriculture. Two of them, the International Maize and Wheat Improvement Center in Mexico and the International Rice Research Institute in the Philippines, played crucial roles in fostering the Green Revolution.

These centers are currently organized into an international consortium called the Consultative Group on International Agricultural Research (CGIAR), which permits them to share funding sources and information. A new source founded in 2010, and somewhat parallel to the Global Fund to Fight AIDS, Tuberculosis and Malaria, is the CGIAR Fund, which supports agricultural research programs seeking to reduce poverty and hunger, improve health and nutrition, and contribute to sustainable resource use. Funding for this effort and for the IARCs generally is provided by governments in both developed and developing countries, foundations, and international organizations.

Through their research the IARCs develop intellectual assets such as improved germplasm, enhanced seed varieties, and other technologies. An immediate question is whether to manage these assets through assertion of IPRs or models based on more open access. In parallel again with public institutions working on medicines and vaccines, IPRs, including patents and variety rights, are often deployed by these centers as useful means of sharing obligations and benefits, particularly where they enter partnerships with foun-

dations or private firms. However, the CGIAR has a set of principles regarding this issue that clearly favors widespread access.[50] In particular, the consortium regards the results of its R&D work to be international public goods and is committed to sharing them on a widespread basis to benefit poor farmers. It also seeks to respect the promotion of farmers' rights to preserve and exchange seeds.

Biodiversity and the Genetic Commons

This policy principle of CGIAR is woven into the broader question of how best to use and conserve the global supply of plant genetic diversity (Helfer 2005, Gerstetter et al. 2007). Here is where the debate over IPRs looms greatest in agriculture and natural resources. Those who support a private property approach argue that permitting private ownership of scientifically isolated and commercially developed products of plant genetic resources (PGRs), emanating largely from wild materials, would encourage more rapid innovations in bioengineered crops and medicines. Others advocate a pure global commons regime in which farmers, breeders, and researchers would have free access to all PGRs, whether held privately or in seed banks or public collections. This is a primary debate over finding an appropriate balance in the IPR arena and determining where to draw the dividing line between the public domain and private ownership.

As is often true in intellectual property, there is no easy answer to this question. One obvious reason is the stark difference in economic interests between certain developing countries, in which the great bulk of PGRs are found, and developed nations where the universities, biotech companies, and life science concerns wishing to develop them are overwhelmingly located. Put simply, entities in the former group wish to control and gain economic benefits from global development of the resources they harbor. That control may well mean developing these assets at a slower pace than preferred by innovators in private markets. For their part, inventive interests in the developed world prefer unfettered access to PGRs combined with global property rights on the products they create, typically after incurring considerable investment costs. Added to this tradeoff are global interests in sustaining biodiversity, in both natural raw materials and public seed banks.

As a matter of economics, there are major potential gains from trade if the basic ownership and sharing problems are properly worked out. Poor countries are the primary suppliers of PGRs emanating from great biodiversity, yet generally lack the scientific infrastructure and commercial mechanisms to develop them, even as they aspire to do so in the future. Companies and research institutions in developed countries wish to have access to sources of highly diverse genetic materials to support the production of new medicines,

50. CGIAR, "CGIAR Principles on the Management of Intellectual Assets," March 2012, www.ciat.cgiar.org/AboutUs/Documents/cgiar_principles_management_intellectual_assets.pdf (accessed on June 1, 2012).

plant varieties, crops, other biotechnological products, and cosmetics. Leading experts have described the potential for a "grand bargain" in materials, technologies, and products that could support growth of markets based on biodiversity and genetic resources (Ten Kate and Laird 1999). On the basis of crude statistics and methods, these authors calculate that the world markets for products developed from genetic resources already amounted to between $500 billion and $800 billion in 1999, a figure that is surely much larger today.[51]

The industrial complex supported by PGRs is technologically sophisticated and deeply vertical (if not vertically integrated). The basic inputs are lands and naturally occurring genetic resources. These resources sometimes exist undeveloped in situ and so-called bio-prospectors, which may be agents, companies, or research institutions, scour locations to find them. This search process is often guided by local knowledge of their uses. Indeed, traditional farmers are conduits of information about genetic traits by the planting choices they make. Search agents also look at available germplasm in seed banks and other collections for raw genetic materials. These basic resources are then studied and developed by a complex R&D sector covering basic research at universities and public laboratories, clinical tests, and applied research by plant breeders and life science firms to commercialize products. Note that in the case of plant varieties, farmers are both a source of information and experimentation and a purchaser of new seeds.

Indeed, the biological resource base and its use by farmers is, in essence, the stock of information about key genetic traits such as disease resistance and genomic characteristics that are the fundamental blueprints used in the downstream R&D sector. Thus, efficient development of that biological resource base is critical for success further down the chain (Swanson and Goeschl 2000). One essential economic question is where in this vertical chain to invest ownership of IPRs in order to incentivize an efficient level of investments in both basic resources and marketable innovations. An effective incentive system should induce both more innovation at the product stage and investments in enhancing the basic inputs of land, PGRs, and germplasm.[52]

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51. Such computations are difficult to make with confidence because of the complexities of determining the biological sources of goods and the true uses of genetic resources across multiple markets. Even more difficult is economic valuation of biodiversity in genetic resources, a process that entails estimation of the extinction of species, potential technological uses of plants, social valuation of land in situ, and numerous other factors (OECD 2004).

52. There is an extensive but inconclusive theoretical literature on the optimal stage of patent protection in cumulative invention, where the outcomes of basic research are needed to achieve second-stage product development. Some argue for strong protection of the basic invention because it enables subsequent innovation and should share in the dynamic rents (Scotchmer 1996; O'Donoghue, Scotchmer, and Thisse 1998). Others claim first-stage protection should be weak because monopoly provision could stifle second-stage product innovation (Merges and Nelson 1990, Denicolo 2000, Nelson 2005). However, this literature fails to consider the distinct problem of sustaining an open natural-resource base at the initial stage.

In fact, private ownership rights have favored the output stage through technical hybridization, PBRs, and patents in biological life forms. As noted above, the major developed economies have long had such systems in place and an international policy architecture, made up of the UPOV and TRIPS, supports them. Available evidence suggests that PBRs can help overcome the inherent appropriability problem in new seeds. For example, Carl A. Pray and Mary Knudson (1994) found that firm entry and R&D in the US wheat-breeding sector greatly accelerated after legislation introducing such protection, though this finding has been contested (Alston and Venner 2002). Similar protection in Latin America in the 1990s expanded access to new international varieties and reduced unauthorized sales, even in the presence of a continued farmers' privilege, while also raising seed prices (Jaffe and van Wijk 1995). A recent qualitative survey of five developing countries found little evidence of increased investment by domestic seed companies, though registrations by foreign developers generally rose (Tripp, Louwaars, and Eaton 2007). Thus, while the appropriate scope of such protection remains controversial, PBRs—and by extension TRIPS—offer room for solving the end-stage information problems.

However, there is virtually no evidence that the expansion of IPRs has increased private investments in biodiversity, genetic resources, or seed collections. Indeed, the period from 1960 to 2000 saw a sharp reduction in measured biodiversity of PGRs, even as systems of PBRs and plant patents were being implemented (Swanson and Goeschl 2000). Much of this decline was the result of increasing conversions of natural habitat to modern agriculture in response to growing world food demand. In short, IPRs as implemented to date have not generated incentives for conserving PGRs in situ to supply the downstream R&D sectors or for farmers to experiment with and improve natural varieties. This is hardly surprising, for there are no private property rights in naturally occurring substances, and farmers are not engaged in R&D to isolate and stabilize new varieties. One possible solution would be for global plant breeders and life science companies to integrate vertically by acquiring large tracts of land in developing nations in order to preserve the needed diversity. However, there are substantial information costs in procuring and protecting such ventures, and local populations and authorities generally see this as a diversion of farmland from more appropriate uses. Further, a purely private approach to resource ownership raises questions about equity in the use of the genetic commons. In brief, the single instrument of downstream IPRs cannot readily resolve the vertical innovation problem, let alone resolve the difficult politics of where to set the boundary between the public domain and materials that could usefully be privatized.

The Grand Bargain Policy Framework

This economic conundrum found practical expression in the 1980s when governments in poorer nations first raised objections to the increasing flows of PGRs from repositories in the developing world to plant breeders in the

developed countries (Helfer 2005). The primary concern was that these raw materials were being taken without compensation paid to their original sources and used to develop plant varieties with exclusive IPRs. This practice quickly was labeled "biopiracy" to connote the uncompensated extraction of genetic materials to produce goods from which even the original suppliers in principle could be excluded. In 1983, the Food and Agriculture Organization (FAO) Commission on Genetic Resources for Food and Agriculture adopted a nonbinding International Undertaking declaring that all PGRs—whether plants found in nature, materials stored in genetic seed banks, or cultivated varieties—should be freely available for scientific research, plant breeding, and conservation.[53] Under this principle of open access, international gene banks, many of them in the system of IARCs, issued genetic samples freely for research and industrial breeding but instructed recipients not to claim IPRs in those materials.

The International Undertaking, despite being nonbinding, was opposed by the United States and a number of European countries. They pointed out its inconsistency with UPOV (and TRIPS by extension), which permits exclusive PBRs, and their own national patent laws protecting both genes and plant varieties. From this legal uncertainty emerged a binding agreement, the International Treaty on Plant Genetic Resources for Food and Agriculture, commonly called the PGRs Treaty, which entered into force in 2004. As of March 2012, 56 countries had ratified it with another 101 nations having signed it or an accession document.[54] The countries ratifying the treaty come largely from the developing world, including Egypt, India, Turkey, and Brazil, along with larger EU nations. The United States signed the treaty but has not ratified it. Other notable omissions include New Zealand, Japan, and China, which have not signed, and South Korea, which has not ratified.

The essential compromise in the PGRs Treaty stems from recognizing that particular genetic sources should be in the public domain, while participants should establish a dedicated funding mechanism to sustain the genetic commons. In particular, the treaty puts in place a novel multilateral system that places 64 food and feed crops, comprising most of the plant sources of human nutrition, into a common property resource (Helfer 2005).[55] Member states and their nationals, such as breeding companies and universities, are granted "facilitated access" to these materials held in public and international seed banks, which may be used for research, training, and breeding. In return, participants must follow a standard materials transfer agreement, under which

53. International Undertaking on Plant Genetic Resources, Report of the Conference of the United Nations Food and Agriculture Organization, Document C/83/REP, 1983.

54. FAO, "International Treaty on Plant Genetic Resources for Food and Agriculture," www.fao.org/Legal/treaties/033s-e.htm (accessed on June 1, 2012).

55. Commission on Genetic Resources for Food and Agriculture, "The International Treaty on Plant Genetic Resources for Food and Agriculture," www.fao.org/AG/cgrfa/itpgr.htm (accessed on June 1, 2012).

private entities that use these genetic resources to develop commercial products must pay a percentage of their profits into a trust fund. Payments are voluntary if the developers make the product freely available for further use but mandatory if they assert proprietary control and limit such access. Funds generated in this way are used to promote benefit sharing, particularly with respect to farmers in poor countries, and defray the costs of further materials conservation. Regarding the farmers' privilege to save, replant, exchange, and sell seeds, the treaty simply recognizes the sovereignty of member countries to decide the matter according to their own laws.

Concerns were raised early that the ability to take out private IPRs in new seeds and isolated genes could effectively privatize the most valuable and productive materials in the gene banks despite the funding mechanism. Thus, language was included in the final treaty directing that "Recipients shall not claim intellectual property or other rights that limit facilitated access to PGRs, or their genetic parts and components, in the form received from the multilateral system."[56] The last part of this sentence, demanded by the United States, raises the critical question of just how much a piece of genetic material must be transformed from its basic form in the materials transfer agreement in order to qualify for IPRs. Presumably new plant varieties and genetic insertions into new plants meet this bar, but debate persists about isolating a gene from basic material. The United States, European Union, Canada, and Australia insist that nothing in this treaty may conflict with rights established under TRIPS and national laws.

In sum, the PGRs Treaty attempts to strike a balance that resolves the vertical R&D dilemma described above and, in principle, could achieve the twin goals of encouraging downstream innovation and promoting upstream conservation and expansion of the genetic commons. However, a major and ambiguous gap persists between its proscription against privatizing extracted genetic materials and legal systems in many developed countries. Time will tell how well it is suited to its dual tasks, which are inherently difficult to reconcile. It is evident that continued vigilance by the global public sector regarding the stock of genetic materials is warranted.[57]

Brief mention should be made of another major agreement, the Convention on Biological Diversity (CBD). This accord recognizes biodiversity in all forms as a "common concern of humankind" and therefore seeks to conserve it and promote sustainable use of the environment and natural resources. With respect to IPRs, two primary principles of the CBD are relevant. First is the recognition that countries have the sovereign right to control exploitation of their own resources, including PGRs and traditional knowledge.[58] Second is

56. PGRs Treaty, Article 12.3(d).

57. Some legal commentators think this system needs to be buttressed by a sui generis intellectual property regime in PGRs to avoid further misappropriation (Cottier and Panizzon 2005).

58. Traditional knowledge is discussed in the following subsection.

that there should be "fair and equitable sharing of the benefits arising from the use of genetic resources."[59]

The latter provision prompted the adoption in 2010 of the Nagoya Protocol to the CBD, which sets out a framework for encouraging access and benefit sharing. Countries are supposed to adopt transparent and fair rules and procedures for providing access to genetic resources, while ensuring that firms seeking such access gain the prior informed consent of affected parties, such as farmers, villages, or national governments. Those who gain permits under a prior informed consent are expected to enter into benefit-sharing arrangements on mutually agreeable terms, which could include the payment of royalties, access to research outcomes, capacity building in agriculture, or other outcomes. Numerous developing countries, including China, India, and, in a shared regime, the Andean nations, have developed access and benefit-sharing laws under these basic principles.

Regulations for prior informed consent and access and benefit sharing are often burdensome for those seeking access to PGRs. Further, such laws can be confusing in their detailed requirements, while identifying the necessary local partners can be difficult. Nonetheless, they do reflect an appropriate balance among stakeholders. Such requirements embody concerns for an equitable distribution of monetary gains from resource exploitation and R&D, especially on behalf of farmers and indigenous peoples who might otherwise be incapable of representing their interests. They ensure that some compensation is paid for the valuable information implicit in farmers' experimentation with seeds and the particular knowledge of locals regarding the nutritional or medical benefits of plants. The need for prior informed consent deters extraction of resources and knowledge that stewards in poor countries would rather see left untouched. Requirements for payments to local or national governments are akin to extraction taxes used commonly in developed economies to manage the supply of natural resources over time.

Thus, in combination with the PGRs Treaty, the CBD and related laws governing extraction, consent, and benefit sharing do much to fill the gaping hole in vertical R&D incentives discussed earlier. The sensible approach is to permit IPRs on downstream R&D outcomes while keeping the basic genetic resource base as open as possible. However, benefit-sharing charges and requirements for funding the genetic commons imposed on those taking private rights should avoid overuse of these resources and encourage critical investments in conservation and biodiversity. This is the true grand bargain that provides a framework for improving national and global procedures and incentives going forward.

To complete this discussion it is worth reiterating an earlier point about whether to extend this framework to a WTO rule under which all countries would require applicants to disclose, as a condition for patent eligibility, the

59. European Commission, "The Convention on Biological Diversity: Implementation in the European Union," http://ec.europa.eu/environment/biodiversity/international/pdf/brochure_en.pdf (accessed on June 1, 2012).

source and country of origin of biological materials and traditional knowledge employed (see chapter 3). This idea is touted by many developing nations and even a few developed countries but is strongly opposed by governments of countries that have major research-oriented life science and biotechnology companies. As an economic matter, placing such a requirement with the WTO would be a step too far. One reason is that it would force patent applicants to reveal confidential information, potentially chilling innovation. A second is that it would add a new eligibility condition to patents, risking the delicate legal structure developed over many decades. The more limited approach of national requirements for prior informed consent and access and benefit sharing, combined with the ability of interested parties to challenge the validity of patents ex post, strikes a better and more flexible balance.

Trading in Traditions

Many of these same issues are central to the closely related question of finding appropriate means to protect traditional knowledge, including cultural expressions. Many of these items, such as traditional medical treatments, oral histories, linguistic expressions, and music, exist in an international commons that may be mined to develop valuable products. One needs only to think of the Disney movie *Mulan* (from a Chinese folk tale) or the Weavers' hit song *The Lion Sleeps Tonight* (from a South African traditional song) to understand the economic value of such knowledge. Traditional medicines, already a significant commercial industry in China and India, are becoming globally traded products. The "grand bargain" surely includes the potential for combining this rich supply of intellectual—if perhaps informal—creations with modern commercialization processes.

The essential problem is how to devise a system, based perhaps on concepts of intellectual property, that efficiently and equitably achieves this goal. Of course, commercial monetization may not be the only objective. For historical and sacred reasons, tribal peoples, musicians, and artisans might prefer not to see their knowledge enter the marketplace at all. Yet another goal might be for authorities to archive such knowledge without necessarily releasing it into commerce. This situation is much like that of PGRs, for such traditions act as an information commons that needs to be preserved and expanded even as it serves as a source of economic inspiration.

The Concept of Traditional Knowledge

Because of this fundamental similarity with PGRs, the economics of traditional knowledge will be treated relatively briefly here.[60] There are, however, important distinctions worth noting. To begin, it is difficult to draw a line defining

60. The subject is far more complex than this discussion would suggest, with deep issues ranging over traditional concepts of religion, science, anthropology, and the law. See Nader (1996), Dutfield (2005), and Coombe (2005).

the boundaries of traditional knowledge. The most common use of the term refers to knowledge and practices applied to the conservation of biodiversity, including traditional farming and medicinal substances and procedures. However, scholarly work and global policy discussions have expanded the concept to incorporate cultural dimensions, such as expressions, oral histories, and music. In terms of geographic scope, many refer to traditional knowledge as existing in the practices and customs of tribal peoples in rural areas, hence the related term "indigenous knowledge." However, much of this knowledge is shared with urban dwellers and important forms of traditional knowledge exist among specific cultures in developed countries, such as the aboriginal peoples of Australia.

Traditional knowledge is often conceived of as being collectively held procedures and cultural goods passed down from prior generations, but even those ideas are misleading in practice (Dutfield 2005). Still, they offer a useful point of departure for posing questions relevant for linking traditional knowledge to IPRs. First, ownership of knowledge in traditional societies may not be well defined. In some cases there might be an individual creator but many groups do not recognize authorship or attach it to ownership, attributing creativity to a gift of nature. As a result, control over the knowledge, if any, may reside with tribal leaders or other social conventions. Many societies view their roles as joint custodians of knowledge and cultural traditions, to which each individual has access rights but must exercise stewardship responsibilities.

Can Intellectual Property Rights Help?

These characteristics suggest that the potential relationships between traditional knowledge and IPRs are not straightforward. On the one hand, unlike PGRs, which function as a commons to support basic research and multiple end uses, expressions of culture in principle are more readily codified and translatable into final cultural goods. Thus, standard intellectual property ownership concepts could well offer sufficient rights to sources of traditional knowledge to ensure their supply. On the other hand, if ownership is in collective hands or not even recognized it may be impossible to use IPRs to achieve contracts for use or determine claims on rents paid. In this case concepts based on public cataloging, collective management, and benefit sharing seem more appropriate.

Some scholars argue that IPRs are sufficient to manage these problems effectively. Daniel J. Gervais (2005, 2009), for example, finds little legal incompatibility between standard intellectual property and collective ownership of traditional knowledge. He thinks that collective marks, commonly in use in the United States, for example, may feasibly be extended to community or even government ownership. Even registration of patents or copyrights as community ownership is possible, though identification of an "inventor" and transfer of rights to a public entity could be quite difficult. In such cases issues of attribution and assignment rules would have to be worked out but the issue

of collective traditional knowledge per se should not be a bar to ownership and commercialization. There is scope as well for communal registration of geographical indications to protect some forms of traditional knowledge. Indeed, community ownership of recognized IPRs could facilitate agreements on prior informed consent and benefit sharing, while managing licenses for content use abroad.[61] It is not difficult to imagine private traditional knowledge brokerage markets emerging under the appropriate legal framework.

Other authors doubt that a standard intellectual property approach could be effective or sufficient for the task (Dutfield 2005, Cottier and Panizzon 2005). For example, the concepts of novelty and industrial applicability for patent eligibility may not fit well with inventions arising from traditional knowledge that relies on long-standing information. Perhaps the greatest difficulty is that certain elements of traditional knowledge may not fit readily into the usual confines of patents, copyrights, or trademarks. Traditional medicines require protection, for example, but may not rise to the level of patentability. A copyright could prevent unauthorized use of sacred material, but under existing strictures that protection would end after duration of the right. Many believe that the ability to control such materials, or indeed all traditional cultural expressions, should be indefinite.

In consequence, there are numerous proposals for different approaches to protecting traditional knowledge (Dutfield 2003). These consist of both "defensive measures" and "positive measures." There are several aspects of defensive protection, advocated by numerous NGOs and governments in developing countries, designed to prevent misappropriation of traditional knowledge. First is compulsory disclosure of genetic resources and associated traditional knowledge in patent applications, as discussed earlier. Second is to compile databases of traditional knowledge, preferably in digital and searchable formats, to serve as prior art in patent applications. Few patent offices recognize oral tradition as prior art, which must be in published form, suggesting that databases could serve this function.[62] India, for example, has established a database concerning traditional health information associated with medicinal plants and the Ayurvedic system (Dutfield 2005). Third is for governments to enact laws against misappropriation, which would feature sanctions against unfair competition, obligations to pay compensation for use of traditional knowledge, prior informed consent, and recognition of moral and cultural rights (Correa 2001). Moral rights, a concept borrowed from European copyright systems, would permit traditional knowledge owners to be identified as authors of cultural goods and to object to future alterations in their use, in essence providing permanent protection against unauthorized use. Cultural rights, such as "the right of a people to its own artistic, historical and cultural wealth," have no counterparts in standard intellectual property doctrine.

61. Recall the case of Ethiopian coffee and public trademarks discussed in chapter 4.

62. The WIPO offers an online portal to a collection of traditional knowledge databases at www.wipo.int/tk/en/databases (accessed on July 18, 2012).

While protective measures may deter misappropriation and unfair competition, they do little to permit farmers and indigenous peoples to profit from the use of their traditional knowledge. Thus, as a basic positive measure governments and NGOs offer technical and fiscal support to inventors and creators to register and license traditional knowledge-based products abroad. However, given the problems noted above with standard IPRs, some analysts have suggested tailoring new sui generis systems of rights to overcome problems with standard IPRs. One idea is to establish a special database right for traditional knowledge databases, the contents of which may not be sufficiently protected by copyrights. This special right would permit controlling actual use of materials in the database without predetermined terms of protection, much like the EU database system. A second is to explore compensatory liability regimes, under which traditional knowledge is subject to open access but users must pay ex post compensation into a fund for appropriate distribution to those providing it (Reichman and Lewis 2005). Such a system may be of particular utility for transferring benefits where much traditional knowledge is already in circulation and cannot be controlled by the original holders. In this setup Disney presumably would have had to pay a fee, perhaps established up front or as a share of royalties, to a traditional knowledge fund in China for its use of the *Mulan* story.

It is evident that the development of protection systems for traditional knowledge remains in flux and may best be resolved through policy experimentation in a variety of national settings. At the WIPO an effort is under way to negotiate an international agreement, or series of agreements, to promote the effective protection of traditional knowledge, traditional cultural expressions, and genetic resources. However, these underlying approaches remain highly controversial and reaching consensus on such legal instruments will be particularly difficult. Because these issues entail significant cultural, historical, and religious practices that cannot be valued in market terms, economics regrettably has little to say about their appropriate resolution.

Knowledge as an International Public Good

One of the most difficult elements of sound technology policymaking is determining what is basic knowledge, and therefore properly in the public domain, and what is commercial information that can usefully be marketed with the assistance of IPRs. In some cases this question seems straightforward: Such fundamental knowledge as mathematical theorems, the structure of atoms, and the periodic table of elements are completely nonrival and so important for advancing science that they are not patentable. In contrast, the idea of how to construct a long-lasting, energy-efficient light bulb is a specific and commercially valuable application, the very essence of what patents should protect.

Between such extremes lie many types of knowledge that are not as easily characterized. What about data from meteorological research, if it is compiled in a way that would make commercial weather reporting more efficient? Or

the structure of specific genes, if tagging them makes it easier to detect likely dispositions toward certain diseases? Or a laboratory animal that is genetically programmed to become cancerous? What about the biogenetic research tools that make identifying genes and developing animals possible? Each of these technologies combines the purest of basic science with an economically valuable outcome.

Deciding where to draw the line between the public domain and private ownership rights has never been easy, even when there seemed to be a linear path from basic science to industrial application. In today's scientific environment the distinctions between basic scientific inventions and marketable innovations are becoming increasingly blurred. Research involves feedback effects and complex loops from early-stage science to later proofs of concept and field trials, often in complex networks across national and international institutions. In the middle of this complexity, policymakers need to decide the stage or stages at which to invest in patents or other forms of ownership rights to knowledge. It is a delicate decision. Granting exclusive rights to fundamental science may incentivize more science but might also raise blockages to important further research and diminish downstream access for students and applied researchers. And there is an international dimension: Should scientific results, paid for largely by public grants in a few wealthy countries, be made freely available to users everywhere? It is one of the great questions of our time.

Pricing Knowledge

There are clear origins of policies investing private property rights in knowledge so fundamental that it might, at other times and in other legal regimes, be considered part of the intellectual public domain (Nelson 2005). The primary movers in the United States both happened in 1980. First, the Supreme Court decision in *Diamond v. Chakrabarty* ruled that genetically engineered organisms invented for a particular purpose (in this case, a bacterium that could break down oil spills) could be patented.[63] This decision is widely cited as a basic launching event for the biotechnology industry. Second, Congress enacted the Bayh-Dole Act, which strongly encouraged universities to register patents on their research results. The logic was that knowledge developed in university laboratories was not being commercialized sufficiently to support economic growth. By clarifying the rights of universities to own and license patents, even on an exclusive basis, this problem would be solved. Whether Bayh-Dole actually has had this impact, in comparison with what would have happened in its absence, is a much debated, if unresolvable, counterfactual (Mowery et al. 2004). Undeniably, however, the growth in university patenting and licensing since the 1980s has been dramatic (Thursby and Thursby 2008). It has also fundamentally changed the basic knowledge-sharing norms of university

63. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

scientists, who work for institutions that are increasingly focused on patent licensing as a source of revenues.

Beyond patents, additional rights have been attached to forms of scientific expression (David 2005). Largely this is the result of copyrights being applied to digital information, with protections against unauthorized downloading, file sharing, and copying, even for classroom use. These restrictions are facilitated by legislation, such as the US Digital Millennium Copyright Act, and are strongly supported by the academic publishing industry.

Compilations of data are generally protected by copyrights, as set out in TRIPS. However, the European Union's 1996 directive created a sui generis form of protection for databases, whether electronic or nonelectronic.[64] This provision directed member states to create a broad and comprehensive new form of intellectual property, which is free from many L&Es normally provided by copyright law. Protection is available for a broad definition of databases, including the compilation of facts that had been in the public domain. For example, meteorological data generated by government research stations are now sold by commercial firms (Barton and Maskus 2006). The EU Database Directive leaves little scope for L&Es to its exclusive rights. Further, because there is little need to demonstrate originality or novelty in achieving protection, which may be renewed indefinitely, database protection in the European Union is effectively more rigorous than patents, despite its application to expressions rather than commercially useful ideas.

The motivations underlying this increasing privatization of knowledge are both technical and economic. First, a very large share of current university science lies in what is called "Pasteur's quadrant," which means deploying basic research methods to solve problems that involve difficult science but nevertheless have commercial utility. Examples include computer science, materials engineering, nanotechnology, photovoltaic cells, agricultural biogenetics, cellular biology, pathology, and immunology, among many others. Research is aimed at developing deeply scientific answers, which in turn support particular solutions to practical technologies. In the United States, Western Europe, and Japan, the greatest share of government funding goes to support these applied sciences (Nelson 2005). This ever-increasing melding of basic science with practical outcomes has pushed patenting further into the university realm.

Second, and closely related, this kind of "big science," often involving large teams of researchers and networks distributed across public and private institutions, is increasingly expensive to perform. Early-stage research requires buildings with exacting specifications, particular instrumentation, and complex materials, requiring large investments. For example, US federal and state funding for nanotechnology research was over $2.2 billion in 2010 (Cientifica 2011). At the same time, public support for research funding seems

64. Directive 96/9/EC of the European Parliament and of the Council of March 11, 1997, on the legal protection of databases.

to be waning, leaving universities more dependent on private sources. Patent licensing offers one attractive avenue toward paying for the increasingly costly scientific enterprise.

A third factor arises from basic political economy. Lobbied by digital content industries, life science companies, and universities, governments increasingly view protecting knowledge with IPRs as a means of increasing international competitiveness for domestic enterprises. In this case, enhanced competitiveness means greater strategic advantages associated with exclusive rights. For example, the Bayh-Dole Act requires that licensees of patented technologies that are developed by universities using publicly funded grants commit to substantially producing the commercialized products in the United States (Barton 2007). In 2002, the European Union established a European Research Area, with several reservations for EU firms in using publicly funded research results.

For its part, the EU Database Directive was devised as a strategic policy response to the commercial development of electronic databases in the United States (David 2005). Its strategic nature may be seen from the inclusion of reciprocity provisions, which would have threatened foreign nationals with retaliatory copyright infringement of their materials in Europe if their governments did not sign the then-proposed draft WIPO convention on databases, which was never concluded. Several unsuccessful legislative attempts have since been made to move US database protection beyond copyright law.

As for disseminating scientific results, strong copyrights in digital goods directly benefit the commercial academic publishing industry, as much as they do other content providers. This is surely one of the most unusual industries in existence in terms of its economic structure (Bergstrom and Bergstrom 2004, Edlin and Rubinfeld 2004). The inputs—scientific articles and peer reviews—are paid for by grants, university faculty salaries, and research fellowships. The publishers obtain copyrights from authors via exclusive licenses, generally without charge, making the inputs free. Indeed, in the natural sciences it is common for authors to pay a publication fee. These copyrights are generally comprehensive, permitting the publishers to prohibit authors from putting finalized versions of their articles on their websites or otherwise sharing them with other researchers.

Copyrights, and the related concentration of the for-profit academic publishing industry, also support rapidly rising subscription prices for academic journals. For example, the average cost per title of journals listed in the science citation index rose from around $1,100 in 2005 to nearly $1,600 in 2009 (Van Orsdel and Born 2009). The institutional price of *Analytical and Bioanalytical Chemistry* in 2011—in essence the cost of a site license for a university—was listed as $9,440 per year.[65]

65. Price information from the Springer website at www.springer.com/librarians/price+lists?SGWID=0-40585-0-0-0 (accessed on June 1, 2012).

Efficient Exclusion or Costly Rents?

As in other areas of intellectual property protection, it is possible to justify the increasing application of exclusive private rights to scientific tools, genetic codes, engineering data, and research results. These rights exist to encourage academic scientists to invent new techniques that support multiple engineering applications and to incentivize universities to license this knowledge into the marketplace. Patents overcome any uncertainty about ownership that might otherwise characterize research knowledge in more open systems, thereby encouraging licensing. Copyrights compensate publishers for the costs of organizing and printing academic journals. Advocates of strong IPRs in academia and public research argue that they unlock knowledge that would otherwise languish in the ivory tower, expanding innovation.

The empirical evidence supporting such claims is mixed, even in the United States, where the policy has been pushed farthest. David C. Mowery et al. (2004) express doubts that the Bayh-Dole Act has significantly encouraged more scientific outcomes and applications than would have been the case otherwise. After all, university researchers have ample career incentives to engage in research and disclose their findings through publications. The vast bulk of basic scientific research remains funded by federal granting agencies, which arguably would have spent at least the same budgets in the absence of Bayh-Dole.

As for innovation and commercialization, however, US universities now register far more patents than in the past. In 1965, just 96 US patents were granted to 28 universities, but by 2006 these figures had risen to 3,384 grants to over 150 universities.[66] This may not be solely the outcome of Bayh-Dole, since evidence suggests academic patenting would have grown due to other incentives arising from the patentability of biotechnology, software, and other disciplines (Thursby and Thursby 2008). Universities also devote considerably more resources to technology transfer and licensing. Indeed, the number of exclusive and nonexclusive licenses from universities to faculty spinoffs and broader industry has also grown rapidly. Thus, whatever the root causes, academic institutions and faculty have become much more entrepreneurial in managing research outcomes from their laboratories in the recent pro-patent US environment.

In light of this perceived success, other OECD countries have emulated the US legal environment in an effort to foster university-to-industry technology transfer, with mixed results. Mowery and Bhaven Sampat (2004) claim that these efforts are likely to have modest success at best, due to substantial differences in technology institutions, cultural barriers between universities and industry, and the difficulty of replicating the large scale of US university research and government funding. Indeed, Finn Valentin and Rasmus Lund

66. See Henderson, Jaffe, and Trajtenberg (1998) and data from the USPTO at www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table_1_2008.htm (accessed on June 1, 2012).

Jensen (2007) present evidence that the 2001 Denmark Law on University Patenting actually reduced collaboration by shifting IPR ownership from industry to academia. As noted by Anthony D. So et al. (2008), numerous developing countries are adopting related legislation to invest patent rights in universities and public research institutes.

A Commons Problem

Despite its advantages in some commercial dimensions, the growing tendency toward strengthened proprietary rights in scientific tools, basic research results, digital knowledge, and data raises fundamental concerns. A prominent one, much debated in the scientific community, is the extent to which research may be impeded by the high transactions costs associated with licensing patented research. Applied technological progress is competitive and cumulative, with multiple researchers dependent on a readily available body of basic scientific knowledge to guide their inventive choices and offer technical illumination (Nelson 2005). Exclusive licensing of a basic research tool, diagnostic method, or scientific material can slow or block follow-on innovation or push academic research into less promising avenues of inquiry (Murray and Stern 2007).

Put differently, the traditional economic role of basic science has been to foster a knowledge commons, from which industrial researchers could develop commercially valuable applications. For this process to work effectively, university scientists need to have ready access to essential results and data, both to verify research outcomes and use basic techniques in their own work. This knowledge commons, which regenerates and improves itself through cumulative research in an ethos of sharing, is a key supporting infrastructure for applied innovation and growth. Basic science is therefore strongly complementary to applied technology development and dynamic competition. Indeed, public funding of early-stage research at universities raises the private returns to downstream commercial R&D. This effective subsidy is most effective when access to knowledge is widely available at low cost (David 2005).

The essential difficulty is that poorly designed protection systems can limit access to this pool, diminishing its ultimate productive support function. For example, the United States grants patents on basic research tools and scientific methods of discovery in genetic sciences.[67] In doing so, the classical utility standard, under which an invention had to be reduced to a commercially useful product or process (as opposed to a scientific method), has been eroded significantly as a bar to gaining exclusive proprietary rights to basic knowledge.

67. This principle was narrowed in the Ariad Decision of 2010, in which the Federal Circuit Court affirmed that broad claims to all potential molecules achieving a particular outcome could be ruled invalid in the absence of a written description of the specific technologies claimed (reported at 560 F. 3d 1366).

US policy also permits broadly written patents on research tools and genetic materials that allow inventors to assert reach-through claims to other uses. This practice effectively extends property rights on basic inventions to multiple potential channels of applied innovation and raises fundamental concerns about "anti-commons" effects in biotechnology and materials sciences as the transactions costs of acquiring licenses rise (Heller and Eisenberg 1998, David 2005). Furthermore, a US court decision in 2002 greatly narrowed the research exemption in patent law that long afforded to university researchers unfettered access to the intellectual advances of other scientists in order to conduct related experiments.[68]

The academic scientific enterprise is now freighted with the responsibility of acquiring and paying for licenses to use basic tools and materials, which may or may not be granted at reasonable costs. Further, many competing claims across universities or their licensees may need to be resolved, another contentious form of patent thickets described earlier in the volume.

The Global Dimension[69]

The increasing application of IPRs to basic knowledge outcomes and data developed through public funding is not overly problematic in advanced nations such as the United States and the European Union, where the bulk of such research takes place. Research universities and large firms in those countries may be able to engage in sufficient patent pooling and cross-licensing that their research programs are not greatly inhibited (Walsh, Arora, and Cohen 2003). They also can acquire site licenses for expensive academic journals, permitting their faculty and graduate students reasonable access to scientific articles.

These hopeful outcomes are hardly universal, however. For example, startup firms and small enterprises in developed countries are at a distinct disadvantage in using patent-protected basic knowledge (Reichman and Uhlir 2003). University libraries, especially outside research institutions, find it increasingly burdensome to subscribe to high-cost journals. Gaining access to copyrighted educational materials can be out of reach for classrooms at many universities and schools.

Such problems are compounded with respect to research processes and education in most developing countries. Public research institutes, university science and education, and the development and diffusion of applied technologies all are dependent on access to basic knowledge, which is overwhelmingly generated in the developed nations. Increasing privatization of basic data by entities in the developed countries threatens to slow the diffusion of such knowledge into science and competition in developing countries. Few of the

68. *Madey v. Duke University,* 307 F. 3d 1351, Court of Appeals for the Federal Circuit, 2002.

69. This subsection draws on Barton and Maskus (2006) and Maskus (2006c).

developing countries are able to invest significant public funding for basic research at their own universities and institutions. Neither can their universities or education ministries afford scientific journals and copyrighted educational materials. Thus, one significant deleterious outcome of IPR policy in the United States and the European Union is higher costs for, and diminished access to, the fundamental scientific results that have been a foundation for technical change, even in developing economies.

On a broader level, knowledge is a global public good because its nonrivalry clearly transfers across borders. Thus, widespread international access to basic knowledge generates multilateral gains in terms of science, education, technological change, and dynamic competition, even as it reduces the profits that might be available to those institutions controlling its diffusion. Seen in this light, it is not surprising that those technologically advanced countries generating the major share of global knowledge increasingly view it as a source of competitive advantage if it can be protected on a preferential basis.

As an economic matter, however, consider that basic science and technology are an essential component of the public and global commons. It follows that national governments will not invest sufficiently in knowledge creation to provide the optimal international level of it. Indeed, governments may fail to provide enough resources to support nationally optimal levels of basic science and technology research even for their own economies. Greater priorities for limited budgets or political-economic structures may be discouraging the public provision of national public goods, forcing most countries to rely on access to international science. Certainly, most poor countries have inadequate education and research infrastructures, and make little effort to promote scientific research. Both their national innovation systems and research institutions depend on adequate access to international knowledge.

A more fundamental problem is that national governments, acting on their own to establish support policies for basic science and technology, will jointly underinvest in that area from a global standpoint. Again, the essential difficulty is the nonrivalrous nature of basic science and technology. In setting their own subsidies to the development of basic knowledge, individual countries do not take into account the spillover benefits to other countries (Drahos 2004). That is, each country would rationally fund research up to the point at which the marginal cost of developing knowledge equals the sum of the marginal valuations of all domestic users. From a global view, however, the domestic marginal cost would be less than the sum of international valuations in any nationally determined equilibrium. As a result, too little investment in basic knowledge would be undertaken, even in the absence of free riding. That is, even if international valuations were known, individual countries would be loath to fund additional knowledge to meet international needs. If we add free riding—an unwillingness of importing countries to reveal their social valuations for knowledge—to this equation, the situation is made yet worse.

In asserting private ownership rights to basic knowledge, the United States and the European Union essentially are trying to solve the international

free-riding problem, but in an inefficient manner. The policies extract some international surplus for the fruits of their investment, but on behalf of private interests rather than the public purse. More importantly, private exclusive rights can be expected to reduce international access to information and, if transactions costs are raised sufficiently, to inhibit future investments in technology. Put in the language of economics, strong IPRs endowed upon basic research results are the wrong instrument for meeting the dual targets of expanding investments in knowledge as a global public good and making that knowledge widely available as a platform for applied R&D.

Solution Concepts Applied to Science

In principle, there are two approaches to resolving this problem: improving the instruments of protection and working toward a coordinated international provision model. The remainder of this section offers some ideas about each, ranging from achievable changes in policy emphasis to more ambitious global coordination.

Protection Norms and Licensing for Differentiated Access

One can begin by examining why IPRs potentially raise roadblocks to access. The essential difficulty is not the existence of patents in basic science or copyrights in data per se. As noted earlier, patents perform the critical function of sorting out ownership claims and facilitating the transfer of technologies, while copyrights encourage investments in complex digital goods. The real problem is that excessively protective intellectual property standards shift incentives toward an imbalance favoring access restrictions and high transactions costs. It follows that basic IPR policy in knowledge goods, especially in the United States, European Union, and other high-protection jurisdictions, could be modified to restore a better balance. Equally, as emerging-market economies such as India, Brazil, and China devote more resources to basic science, the standards they select will significantly affect the pace and direction of global science.

For example, in the United States, endemic structural problems continue: insufficient resources for patent examination and an institutional bias that discourages challenges to patent validity. Arguably, these practices have diminished patent quality in academia, as they have in industry (Maskus 2006a, Thursby and Thursby 2008). Presumably, these difficulties will diminish over time as the 2011 patent reforms kick in (see chapter 4).

A more fundamental problem stems from basic patent standards. First, more care should be taken to uphold the basic principle that discoveries that are primarily natural phenomena are not patentable (Nelson 2005). Second, the progressive weakening of the utility standard for patentability has rendered too much of basic science eligible for protection, diminishing the public-domain intellectual commons. Reconsidering a tighter definition of this stan-

dard should occupy policymakers and the courts in the coming years.[70] Third, the legal permission of broad claims on all potential uses of a research tool and other elements of basic science has generated as much confusion about actual ownership among overlapping patents as it has incentivized commercialization. Competing claims in academic patent thickets significantly raise transactions costs for follow-on science and applied research. Again, legislators, the courts, and patent offices should revisit the question of appropriate patent scope in the area of basic science. The essential goal is to prevent broadly written patents from blocking widespread participation in specific research areas. Third, the elimination of a robust research exemption for universities and public laboratories leaves scientists wondering about their freedom to conduct investigations in protected areas. It would be useful to establish an explicit research exception for purely scientific endeavors (Dinwoodie and Dreyfuss 2005).

For its part, the EU's system of database rights is unbalanced even in normal IPR terms, since it offers "patent plus" protection to presentations (data compilations), thereby diminishing the important distinction between ideas and expressions. This problem is compounded by the legal authority to incorporate facts already in the public domain into a protected database. Appropriate legal reforms here would see the European Union scaling this protection back to copyrights in databases, the global standard under TRIPS and the WIPO.

Turning finally to publications and digital content, authors and publishers certainly should benefit from copyright protection. The essential question here relates to the scope of allowable L&Es, along with the specification of noninfringing behavior under fair-use provisions. This balance remains hotly contested in the developed countries, with libraries and schools pushing for greater freedom to post, distribute, and copy materials for research purposes and classroom use. Overall, they have reached accommodations with publishers on means of paying for access under varying license terms.

However, this issue remains fluid in key developing countries, which retain the ability to establish their own public-interest exceptions, subject to the limitations of TRIPS (Okediji 2006) (see chapter 3). Some have adopted strong copyright protection for scientific and educational materials to comport with developed-country norms. Others prefer more open-access models, with a liberal distribution policy as regards research and educational use. In practice, this can be difficult to achieve legally if the original content, such as scientific journals, textbooks, and research data, is expensive or unavailable.

70. In a notable case, the UK Court of Appeal ruled that a patent on a nucleic acid molecule issued by the European Patent Office to a firm called Human Genome Sciences was invalid because the applicant failed to demonstrate industrial applicability, a ruling that would have raised the utility bar if upheld. In November 2011, however, the UK Supreme Court overturned that decision. See *Human Genome Sciences v. Eli Lilly,* [2011] UKSC 51.

In light of this large international regime variability, the WIPO Development Agenda may offer some avenues toward greater global balance (see chapter 3). For example, WIPO members are nearing the end of negotiations on a treaty that would expand access to copyrighted materials on behalf of the visually impaired and reading disabled, wherever they reside. The proposed agreement would require signatories to establish minimum exceptions in copyright laws to facilitate access to copyrighted works by such persons. Notably, it would also permit people and institutions to share copies of such accessible works with visually impaired persons in other countries. This provision for open international access would be novel in global copyright treaties and has been opposed by major publishers.

Ultimately, however, the most sustainable solutions to the deep problems of knowledge investments and diffusion are likely to be found in facilitating access-oriented licensing models. Publishers oppose treaties expanding copyright L&Es largely because they eliminate control of content distribution, while generating no revenues. Approaches similar to those described in chapter 4 for global music and media licensing offer a more positive route for supporting licensing on differentiated access terms. Regarding patented research results, more universities are opting for nonexclusive licensing, with preferential terms for scientists in developing countries and public international research organizations. This tendency could be usefully advanced by facilitating patent pools with reasonable licensing terms and even upfront compensated licensing contracts permitting usage rights to participants in a form of knowledge "semi-commons" (Reichman and Uhlir 2003).

A Global Access Treaty?

The second general approach to meet the dual targets of expanding investments in knowledge as a global public good and making that knowledge widely available as a platform for applied R&D would be to achieve greater global coordination in the provision of primary science and the ability to use basic research results, tools, and data. In this context a strong case can be made in favor of a multilateral agreement on access to basic science and technology (ABST), as a complement to the global IPR system (Barton and Maskus 2006, Maskus 2006c). This would place into access pools the patented results of publicly funded research that has developed knowledge capable of supporting applied science and R&D. In essence, funding agencies in participating nations would certify that, as a condition of receiving a grant in specific areas of primary science, the university and scientists must agree to place resulting patents into common-resource pools. These patents would then be available for license to all competent agents from other member countries under terms worked out ahead of time.

A basic model would be to license on "fair, reasonable, and nondiscriminatory" (FRAND) terms, taking a page from standard-setting organizations. In this context, however, there should be scope for offering concessional terms to

researchers from poor countries, so long as there is no discrimination between applicants within country bands that would be graduated by some mix of income levels and technological development.

The idea is to preserve and enhance the global commons in science and technology without unduly restricting private rights in commercial technologies. Moreover, the agreement could encourage researchers from other countries to participate in or compete with local research teams for grants and subsidies, possibly combined with increased opportunities for temporary migration. It could also give researchers in other countries access to nationally generated science and data.

An ABST agreement would presumably be negotiated within the WIPO, given its competence in IPRs and focus on specialized treaties. Other possibilities might be UNESCO and the World Bank, or even a new multilateral entity focused on the governance of knowledge. It is conceivable that enough countries would participate to make an agreement reached within one of those organizations effective.

However, for several reasons, the best home for an ABST agreement would be at the WTO. First, without a multilateral agreement to discipline free riding, any plurilateral agreement, as is common in the WIPO, may not be sustainable. Second, the WTO already has responsibility for major agreements governing intellectual property, subsidies, standards, and trade in services, all of which would be interrelated strongly with the transfer of scientific results. Third, the WTO offers a recognized format for arbitrating and settling disputes arising between governments, which would be primary players in this treaty. Fourth, the organization has a dynamic negotiating process that permits tradeoffs in concessions across sectors and functional agreements. Finally, many of the essential WTO principles may be applied to an ABST agreement, as discussed next.

In terms of format, several provisions would need to be addressed in the treaty. The first would be its scope in terms of subject matter and processes. The term "basic" science and technology is used here, but it is not easy to determine the dividing line between basic and applied research. In principle, one would describe basic knowledge as that which is truly nonrival, has limited (if any) commercial utility, and is an intellectual input into other science. Another class of basic technologies would be those supporting the provision of global public goods, such as environmentally sound processes and health care. It is evident that reaching an agreement on this element would be highly controversial.

Ultimately, there is no practical sense in which these characteristics might be universally defined. One way to manage the distinction would be to include, as elements of the treaty, research processes and results and data that are both fundamental knowledge inputs and largely publicly funded, whether through direct research in government laboratories or grants to universities, NGOs, or other institutions. This distinction between technological characteristics and funding may not be overly critical, for presumably most basic and public goods

technologies require public financing in any event. Thus, focusing primarily on publicly funded research and data may be sufficient for most purposes, subject to safeguards mentioned below.

A second question relates to the forms in which access is to be granted, or the nature of liberalization. In principle, three levels of commitment could be entertained. First, "input liberalization" would permit researchers from other countries to participate in or compete with local research teams for grants and subsidies. This could be combined with increased opportunities for temporary migration of scientific personnel and additional student visas, an important means of increasing global technology transfer. However, under this alternative, governments could choose to reserve their research results for preferential use by local firms and the registration of IPRs. While this approach could expand research efficiency and transfer more skills abroad, its scope for raising access to new information would be limited.

Next, "output liberalization" would entail offering researchers in other countries access to nationally generated science and data, without increasing their ability to compete for underlying funding or use research facilities. This approach would usefully expand the public commons and increase knowledge diffusion, but would not directly expand efficiency or transfer research skills. A key provision here would promote access to scientific databases and ensure that intellectual property regulations not limit access to basic scientific knowledge deposited in commons pools. The United States, for example, could meet terms of an ABST agreement by offering, as a liberalization concession, to modify the Bayh-Dole Act to require access-oriented, nonexclusive licensing of publicly funded basic research results.

Finally, "full liberalization" would combine these approaches, both expanding international flows of research contracts and personnel and increasing global access to outcomes. As an economic matter, full liberalization is optimal to the extent that it is politically feasible. In getting there, however, it may be necessary to adopt something like the approach used for the General Agreement on Trade in Services (GATS), permitting governments to reserve sensitive areas of technology and designate different levels of commitment to open access.

A treaty of this kind would need to be balanced by safeguard clauses. One issue involved in international scientific and technological collaboration relates to the equitable and efficient distribution and management of intellectual property that could emerge from subsequent applied innovation. To what extent would originator universities depositing basic research results be able to benefit from downstream applications? Another issue is that concerns regarding national security and technology proliferation would need to be addressed. For example, the United States has moved to establish new security classifications for biological data and restrict some foreign students from studying particular areas of biotechnology. Such restraints need to be balanced with the advantages of promoting the scientific and technological commons, a balance that could be set out in an international agreement.

It would also be possible to build in preferential advantages for the developing economies. For example, where data and research results are to be made available in licensing pools at some cost, differential pricing schemes for governments and institutions in poor countries could be encouraged. Efforts to encourage research participation by scientists and engineers from developing countries could be written into proposals.

Two other issues arise for the construction of an ABST agreement. First, careful consideration is needed of how its provisions relate to other WTO agreements and even such non-WTO accords as the Convention on Biological Diversity. Within the WTO, efforts to reconcile an ABST agreement and TRIPS would be required. In effect, an ABST agreement would be an attempt to rebalance the strong privatization of rights in information implicit in TRIPS. Similarly, specification of an ABST agreement could usefully sort out the meaning of precompetitive research subsidies and how they might be provided internationally.

Second, there would need to be provisions for regular meetings, a small secretariat or council to evaluate the extent of scientific and technological cooperation and its benefits, and ongoing negotiations. These negotiations could provide a forum for scientific and technical communities to pursue further expansion of the global information commons.

Can It Work?

If successfully concluded, an ABST agreement would increase global access to the fruits of public research funding. An obvious difficulty is that research decisions are endogenous and funding might decline if authorities in the major countries perceive that an ABST agreement would dilute the ultimate economic benefits from such investments without reciprocal benefits from abroad. Thus, analysis of national economic interests in the accord is relevant for considering its construction and feasibility. Mutual trade liberalization in the WTO has been achieved through a mercantilist agenda in which countries have been willing to offer greater market access to foreign firms in return for reciprocal access abroad. A similar reciprocity, in which access of foreign researchers to grants and research results is provided in return for related opportunities abroad, could appeal to competitiveness concerns. A broader scope of opportunities and research competition presumably would expand the efficiency with which public science and technology are generated, resulting in mutual gains from trade. And the opportunity to negotiate liberalization will focus the attention of those in the scientific and technological communities to press politically for the benefits of liberalization. Moreover, with a wider set of basic technologies available, largely in the public domain, the scale of product innovation built on such information should increase.

At the same time, countries are highly asymmetric in terms of their abilities to finance and develop basic science and technology. The United States, European Union, and Japan may see some complementarities in mutually

integrating access to these resources. Some large developing countries such as Brazil, India, and China could be attractive as well. However, small and developing countries with limited research resources offer little in the way of "export" interest to researchers in the main technology-developing nations. In consequence, a WTO treaty might require technology importers to offer other, perhaps complementary, concessions in such areas as services, investment, and product market access. Alternatively, each country might be tasked in the agreement to offer some financial contributions to a global fund that could be used to supplement national programs in basic science.

An important point here is that firms in the poorest countries pose little or no competitive threat as technology developers in the medium term. Permitting those nations to join an access treaty on a preferential basis could help develop their research and innovation capabilities, in line with other development assistance. Indeed, this may be one of the most affirmative approaches for developed countries to meet their obligations under TRIPS to facilitate meaningful technology transfer.

There is another reason to believe that powerful economic interests might support such an agreement. Unlike the situation 30 years ago, multinational enterprises now often transfer technology in order to build export products in developing countries. The costs of doing so would diminish were local researchers to have access to basic technologies and be able to effectively deploy them. Thus, multinational enterprises might be expected to lobby for such an agreement, particularly to the extent that it can be accompanied by appropriate policy responses in recipient countries regarding governance and infrastructure. Further, the treaty would provide legal certainty about the scope of the public and private domain across countries, which would benefit global enterprises.

Ultimately, a bargaining approach in the WIPO or WTO could permit countries to exchange concessions about access to their own basic technologies, recognizing that their domestic educational and technological enterprises would benefit from reciprocal access. The reciprocity would mitigate some of the spillover and free-riding problems deterring investments in public science. At the same time, there may be some decrease in the political incentives of wealthier nations to invest in public research, because the competitiveness motivations would be less intense. Still, this decrease would be minimized by the reciprocity requirement, and any ultimate deleterious impacts in the applied-technology markets should be counterbalanced by the increased productivity of the global research enterprise. Moreover, to the extent that bargaining permits rationalization of basic research, in the sense of avoiding wasteful duplication of similar programs, bargaining can mitigate the underlying provision problem as well.

Despite this logic, there are good reasons to be skeptical of the feasibility of an approach to knowledge creation and sharing within the WTO. Commitments made might be weaker than needed for effective liberalization, similar to the situation in GATS. Adding yet another fundamental issue to

negotiate could distract resources from making progress on unresolved issues in market access. Most problematic, the WTO, despite its expansion into IPRs and regulatory issues, fundamentally remains a pact about disciplines on commercial policies. It is not well suited by history and expertise to become the world's knowledge governance institution.

In this context, perhaps the best that can be hoped for is an agreement at the WIPO or a new knowledge organization, structured along the lines sketched above. Such an accord could facilitate discussions among the world's research-funding agencies about opening competition for grants across borders and facilitating licensing by their universities and research laboratories. That alone could be enough to reverse the unfortunate tendency toward privatization of basic knowledge, which threatens to diminish the global intellectual commons.

Summary

The global strengthening of IPRs is often viewed by civil society groups as an unwarranted and costly assault on the ability of governments to take actions to provide their societies with needed public services. Even more, it is seen as a roadblock to coordinated international action to deal with such problems. These views are misleading in that IPRs certainly can play important and positive roles in facilitating important public objectives.

Nonetheless, there are areas where private rights can interfere with the efficient provision of public goods, as described in this chapter. Dealing with these interfaces raises complex challenges for public policy in areas as disparate as public health, environmental technology transfer, agriculture and biodiversity, and knowledge scarcities. A great many of these challenges have been addressed by various conventions and treaties arising from key international organizations, though it is important to expand coherence across these agreements.

Other problems have not been resolved, though numerous ideas have been advanced by academic scholars, NGOs, international organizations, and interested private businesses and providers. The analysis here offers a number of suggestions, both new and borrowed from these sources, to deploy economic logic to address a broad group of fundamental problem areas. Whether such proposals see the light of day depends on more than economics, of course, but perhaps the discussion about them here will help stimulate further policy attention.