

# Intellectual Property Rights in a Changing Political Environment: Perspectives on the Types and Administration of Protection

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Intellectual property rights (IPRs) have been critically reassessed in recent years. This paper evaluates several of those analyses in detail. With regard to patent quality in the United States, analysis indicates that rising numbers of patent grants are a consequence of demand for patents rather than changes in patent examination standards. Internationally, protection options for living organisms (seeds, plants, and animals) are more limited than for other products, suggesting a relative underinvestment in the sector. In particular, the recent "initial/essentially derived" system, intended to provide incentives for background plant breeding, is judged to be inoperative. Finally, with regard to IPRs and foreign direct investment (FDI), the "strength" of national IPR systems was found to be strongly associated with levels of FDI for 44 developing countries in the post-TRIPs world. The limited US research exemption for patents was identified as a major potential restrictor of public-sector access to germplasm for future breeding.

**Key words:** FDI, foreign direct investment, intellectual property rights, IPR, patent quality, plant variety protection.

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## Introduction and Objectives

Intellectual property rights (IPRs), largely overlooked by the public in earlier periods, have caused mixed reactions over the past decades. At the domestic governmental level, patentable subject matter has been expanded greatly to include living organisms (microorganisms, plants, animals), software, and business methods, while internationally, with the establishment of the World Trade Organization (WTO) in 1994, some 140 countries made commitments to adopt minimum harmonized levels of IPR protection. In the case of developing countries, those minimum standards represent a substantial expansion of IPR over previous standards.

The Bush administration, through then-Attorney General Ashcroft, has also been aggressive in protecting private IP rights. For example, the rights of music copyright owners have been upheld against file-sharing systems such as Napster. Medicare medicine benefits prohibit government groups from negotiating over prices, which enhances the partial monopoly rights granted under patents.

Concurrent to this apparently pro-IPR governmental position, numerous individuals and groups have been raising serious issues about the implementation of those policies and their consequences (see citations below). At one level, the United States Patent and Trademark Office (USPTO) has been criticized repeatedly for inadequate examination procedures that lead to frivolous patents, which serve only to impede research, or alternatively overly broad ones (compared to the nonobvious-

ness contribution), which thwart subsequent inventive activity. Internationally, IPRs have been linked with blocking access by the poor to lifesaving medications—most notably AIDS therapies. For systems that are intended to provide public benefits by granting private incentives for research and development (R&D) investments, these are indeed damning critiques.

However, while serious, many of the charges made against IPR are poorly supported by analysis—for example, the notion that patentability standards have declined. Evidence that patent grants have expanded rapidly (trebling from 1980–2000; Figure 1), and some sectors have experienced high levels of infringement suits, is certainly consistent with the charges but is by no means conclusive. The stakes of setting the proper balance between public and private IPR benefits, though, are high in an economic system where the private sector provides two thirds of total plant breeding research spending and the public sector increasingly looks towards marketing technology as a revenue source (Traxler, 1999).

The objective of this paper is to review the evidence regarding the effects of IPR in three specific areas: (a) patent quality and USPTO standards/practices; (b) protection granted for living organisms; and (c) the effects of IPR on developing countries. These topics touch on only a few of the IPR-related issues under broad discussion at this time. Of course, nothing can be inferred about those other issues from what is concluded here.

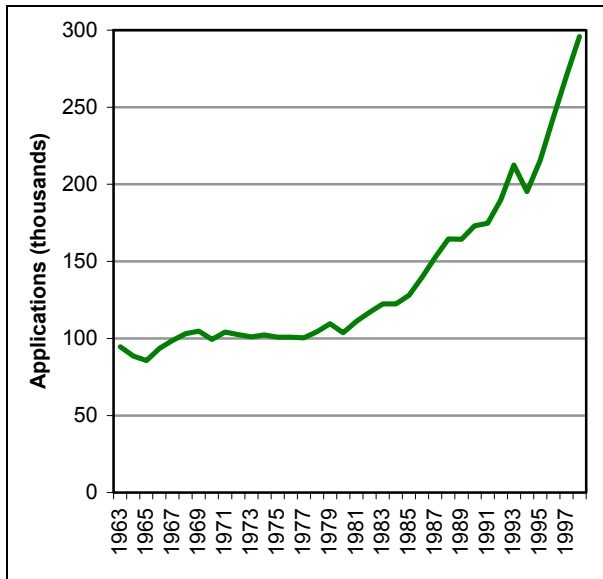


Figure 1. Utility patent applications excluding reissues, 1965–2000.

The intent is to have a US and an agricultural/biotechnology IPR policy focus. Nonagricultural and international issues, though, cannot be entirely excluded from consideration. For one thing, agriculture is an international sector—differences in IPR systems (real as well as perceived) have a direct bearing on the United States and our IPR practices. Second, and more pragmatically, much USPTO data are aggregates, so individual sectors (patent classifications) can be analyzed only in particular ways.

### Has the Quality of Patents Been Declining?

#### Literature Review

The number of USPTO patent grants tripled from 1980 to 2000, increasing at a rate greater than the expansion of R&D spending (Figures 1 and 2). Quillen and Webster (2001) computed that the proportion of US patent applications that eventually mature into a patent is as high as 97%. This contrasts with a long-term nominal rate (grants/applications lagged to account for examination delays) of about two thirds. An obvious inference is that patentability standards in the United States are low. Their analysis was subsequently revised (Quillen, Webster, & Eichman, 2002), leading to an estimated grant rate of 85%. Ebert (2004), however, raised an issue with the earlier assumptions that the claims in the several forms of “continuation” patents allowed in the United States are necessarily the same as in the initial applications, meaning that the issued patents are for different

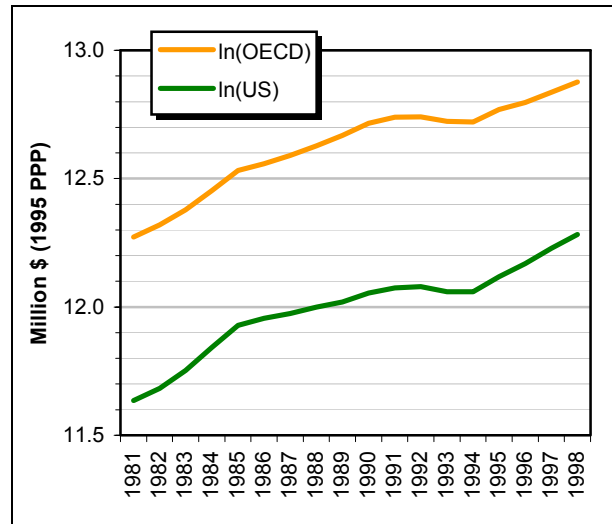


Figure 2. R&D in US and total R&D in OECD (US, UK, France, Germany, Japan), 1981–1998.

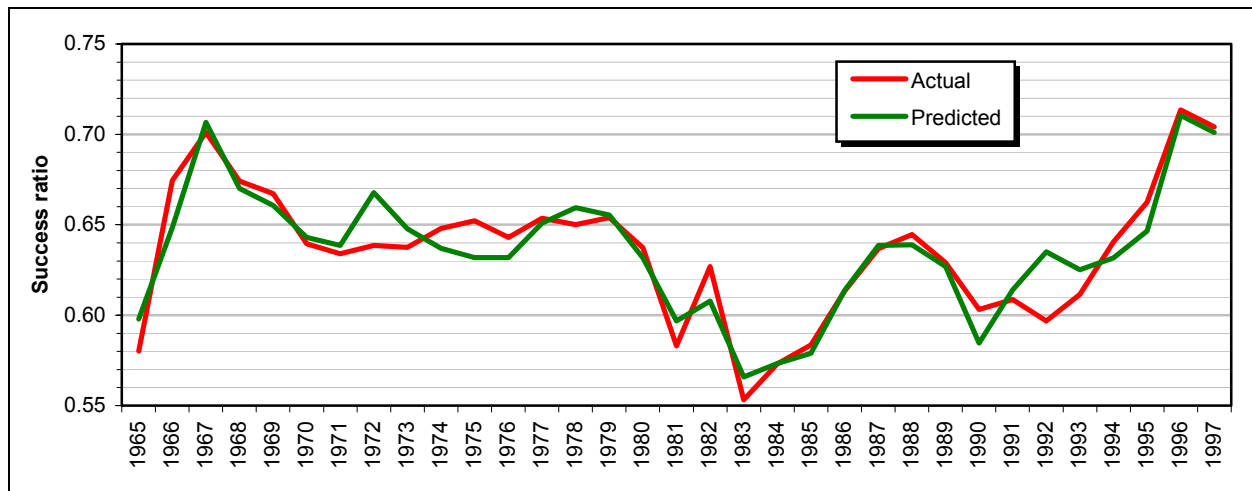
Note. Data from Lesser and Lybbert (2004).

inventions. On that basis, the grant rate for the USPTO is about 75%, in line with other major patent offices.

Barton (2000) focused a critique of USPTO practices on the quality, training, and allowed time of patent examiners. “The best way to improve patent validity is for the PTO to issue better decisions in the first place. This is a matter of the quality of the PTO staff and of the time that staff can allocate to each application” (p. 1933). No support for those positions is offered beyond general statements about brief examination periods and staff turnover.

Cockburn, Kortum, and Stern (2003) tested that assertion by examining a subset of 182 patents in 1997–2000 that were subjected to a validity review by the Court of Appeals for the Federal Circuit (CAFC), to which patent issues are referred. All granted patents for the period were subsequently evaluated to identify the productivity and experience of examiners in different technology areas for those examiners whose patents were invalidated by the CAFC. Regression analysis indicated no relationship between examiner experience and examiner workload and the likelihood of the invalidation of a patent. The small number of litigated patents is in no way a random sample of all patents, so the sample used in this analysis was not indicative of all examiners. Pertinently, though, the study provided no support for contentions that examiners’ characteristics are the cause of declines in patent quality.

King (2003) also evaluated examiners’ practices over time and technological areas. He first examined the number of examiner hours adjusted for experience



**Figure 3. Actual and predicted success ratio, 1965–1997.**

Note. Data from Lesser and Lybbert (2004).

available for evaluating individual patents. Over 1985–1998, available hours remained largely constant, even though applications were rising at a faster pace than examiner hours. The differential was reflected in a longer backlog/pendency period. Although those findings apply overall and within technology groupings, the average hours applied to examining a patent varied substantially across technologies. Furthermore, those groups with longer examination hours available experienced fewer legal challenges to issued patents. That finding is consistent with a conclusion that the examination process could be improved, but does not sustain claims that the examination process overall has deteriorated over the past two decades.

### Analysis

Although the preceding studies provide no support for the hypothesis that examiner quality or time availability has declined, there are other possible sources of diminished patent standards, such as a reduction in nonobviousness requirements or an increase in scope granted. We sought to examine that hypothesis by evaluating responses to changes in policy (Lesser & Lybbert, 2004). That is, recognizing that the USPTO has a tightly managed examination process controlled through the Examiners' Manual (USPTO, 2004), we hypothesized that changes in standards would not be evolutionary or random but would rather follow a particular internal policy action or court decision. Six such changes were examined over the 1965–1997 period, ranging from the 1982 creation of the single court to address patent issues (the CAFC, often considered to be “pro-patent”) to the

1993 internal decision by the USPTO to become more service-oriented.

The analysis used the success rate—the proportion of applications which eventually mature into grants. Modeling the patent application decision, it is possible to predict how each of these factors would affect the success rate in the long and short run (the period during which application rates would adjust to changes in the expected likelihood of a grant). Those expectations are shown in Table 1. The analysis (Figure 3) does not contradict the predictions in Table 1, so there is no evidence that patent-granting standards at the USPTO have changed.

### Policy Conclusions

Our analysis finds no evidence to support the frequently stated conjecture that the USPTO has a flawed and declining patent examination process. That is not to say there are no issues regarding patent management that do not require further scrutiny. For example, errors are clearly made in patent grants, and further steps should be taken to reduce further those errors.<sup>1</sup> Or, there may be errors in selecting patentable subject matter. But overall, the principal explanation for the ongoing rise in patent applications seems to be a result of demand fac-

1. *The Optional Inter Parties Reexamination Procedure Act of 1999 (amended by the 21<sup>st</sup> Century Department of Justice Appropriations Authorization Act of 2002 introducing and further modifying Ex parte reexamination procedures) is a promising approach to correcting granting errors. See Knowles, Vanderbloemen, and Peeler (2004).*

**Table 1. Anticipated effects of changes in practices on patent applications and success ratios.**

Year	Application	Change	Long-term success rate	Short-term success rate
1980	Chakrabarty: "Everything under the sun..."	Rise	?	?
1982	Creation of CAFC	Rise	Fall	Rise
1984	Reduce novelty standard	Rise	—	Rise
1987	Reduce invention standard	Rise	—	Rise
1991	Reduce nonobviousness standard	Rise	—	Rise
1993	USPTO commitment to service	Rise	Fall	?

Note. — = no change; ? = inconclusive. Data from Lesser and Lybbert (2004).

tors and not changes in supply requirements or standards.

## IPR Protection for Seeds, Plants, and Animals

Whereas the previous section applied to all patents, this section focuses specifically on protection for higher life forms, particularly those with agricultural uses. Higher life forms have presented vexing IPR issues for a considerable time; indeed, the 1930 US Plant Patent Act (limited to asexually propagated plants) was the first-ever protection system for that important class of products. Options have expanded to the point in the United States that inventors have several options: plant patents for asexually propagated plants only, utility patents for plants and animals, and plant variety protection (PVP) for plants.

### Strategic Choice of Protection System

As is immediately evident, there are overlaps in protection choices, and US plant breeding firms have clearly experimented with their options (Figures 4 and 5). Interpreting Figure 4, it helps to know that PVP was first available in 1970, but for hybrids beginning only in 1994. Therefore, prior to 1994, PVP corn certificates applied to pure lines. Figure 4 shows that interest was marginal until the 1980s, when a court decision (*Pioneer v. Holden*, 1987) indicated that trade secret protec-

tion was inadequate—especially for the female line, for which some small portion of the pure line would predictably be found in marketed hybrid seed.

Conversely, patent protection first became available in 1985, and firms used both systems for some years; recently, a reliance on patents has dominated. There are reasons for that choice, despite the higher cost of utility patents. PVP allows farmer reuse of seed (although not an issue for F-1 hybrids) as well as open breeding access. Patents allow neither. Moreover, underfunding and resultant delays in issuing certificates reduced the value of PVP for breeders.

The situation for soybeans (Figure 5) is similar, except that as a nonhybrid crop, there is no pure line protection to consider. The use of utility patents began in the early 1990s and seems to correspond to the introduction of transgenic soybean seed. With PVP protection only, the breeders' exemption allows the insertion of a gene construct into a protected variety, thus allowing little control by variety owners.<sup>2</sup> Although both PVP and patents were used for a time, in recent years patents are clearly the form of choice. For the record, it should be noted that Pioneer Hi-Bred is the dominant user of both patents and PVP certificates.

In contrast to the situation in corn and soybeans, there are very few utility patents for lines, varieties, or hybrids of other agronomic or horticultural crops. This is not due to a lack of interest in protecting materials, as these crops are well-represented in PVP applications. Nor is it due to a lack of awareness of the potential of patents for protecting materials. Rather, economics is the likely explanation; returns on seed of even the top varieties of noncorn and soybean crops are small in comparison, so the seed industry is less able to support the costs of obtaining and enforcing patent protection.

A review of plant variety patents quickly indicates standardized application language, wherein a distinction in variety performance and morphological features is drawn with a standard reference variety. Claims have increased from about 10 in 1996 (patent #5,545,811) to 31 (patent #6,797,869) in 2004 involving the line, pollen, ovule, tissue, and method incorporating the line. The dual aspect of dubious nonobviousness and expanding claims (if only to make explicit what is being protected in contrast to an expansion in scope) have raised questions about the management of variety patents in the USPTO. The Patent Office is said to be reviewing

2. This is an oversimplification—see the analysis in following subsection.

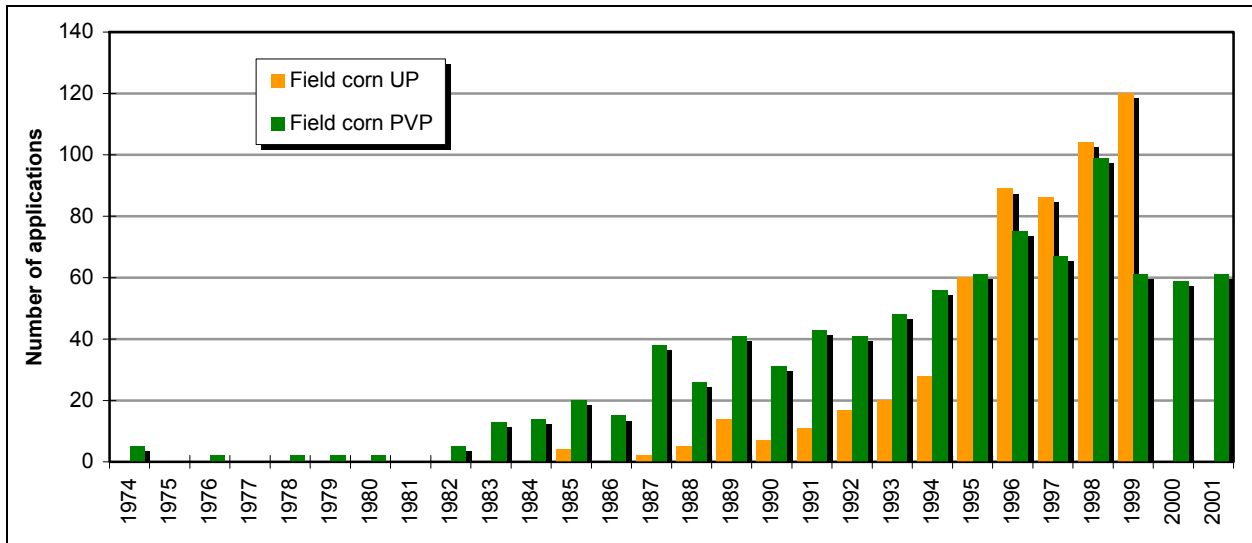


Figure 4. UP and PVP applications on field corn.

Note. Data from Lesser and Mutschler (2002).

the patent standards for varieties, but being an internal evaluation, the extent and timing is unknown.

**Initial and Essentially Derived Varieties**

The patenting of plant varieties is not permitted in most countries outside the United States. In the European Union, the prevailing standard language is Article 53(b) of the European Patent Convention, which prohibits patents for “plant or animal varieties or essentially biological processes for the production of plants or animals.” Over a multiyear evaluation process, the EU interpretation evolved to allow patents when an invention applies to more than the fixed form of a variety, such as genetically modified traits (European Directive on the Legal Protection of Biotechnological Inventions, Directive 98/44/EC, Rule 23b(5)).

Most developing countries, though, are even more restrictive. For most, protection for varieties was adopted only in conjunction with the WTO TRIPS (trade-related aspects of intellectual property rights) appendix in which, under Article 27.3(b), countries have the option of excluding from patentability “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof” (World Trade Organization, 1994, p. 331). In most cases, the sui generis option has been chosen. That is, patents for plant varieties—even transgenic ones—are disallowed. This is a matter of some concern to the plant

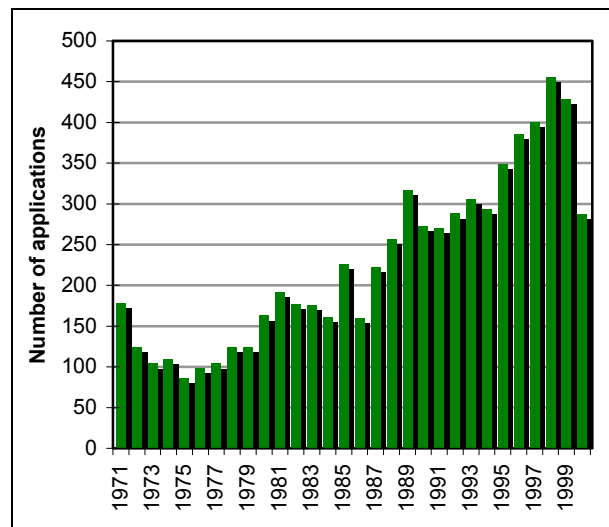


Figure 5. Applications for UP and PVP on soybean.

Note. Data from Lesser and Mutschler (2002).

breeding community, because the “breeders’ rights” exemption (a form of research exemption) would allow the transfer of a gene construct to a protected variety, giving the variety no ownership rights.

To prevent that negation of variety rights, in 1991 the concept of a *dependent variety* was added (International Union for the Protection of New Varieties of Plants, 2002, Article 14.5). In many cases, a variety transformed by the insertion of a gene construct would be dependent, and commercialization would require the permission of the variety rights holder. However, the dependency concept is also intended to provide incen-

tives for “prebreeding” or “germplasm enhancement,” the decade-plus long process of breeding traits from a wild species or landrace into commercial breeding stock. In the absence of dependency, the breeders’ exemption means that the benefits of the expensive prebreeding process can be appropriated in the next generation of seeds. As a result, little background breeding has been done outside the public sector.

In Lesser and Mutschler (2004), we examined the current dependent variety system and determined it to be unworkable. The underlying problem is the functionality of PVP as protecting the entire plant and not specific traits (as is possible with patents). As a result, dependency considers what portion of the germplasm was derived from the purported initial variety (51% is the minimum, as a dependent variety can have but one initial variety)—something we refer to as *relatedness*. In addition, the allegedly dependent variety must express the essential characteristics of the initial variety. The complexity arises because traits transferred to a variety may involve few genes (e.g., disease resistance—a simple trait) or multiple genes (e.g., sprouting resistance in onions—a complex trait). The complication arises when the degree of relatedness is set. If it is set high (90%), then there is an incentive when the trait is discrete to engage in unproductive “cosmetic” breeding to circumvent the dependency standard. Conversely, if the relatedness is low (75%) and the trait discrete, then it is possible that an independently discovered trait will be identified as dependent, greatly expanding the control of the initial variety owner over varieties he or she made no contribution to. Overall, we conclude that a single relatedness requirement for a species cannot equitably be applied to both discrete and complex traits.

### **Patent Protection for Animals**

The USPTO, in an internal 1987 decision, declared higher animals to be patentable subject matter. The first animal patent was granted in 1988, and approximately 500 higher animal patents have been issued to date (Lesser, 2005). The vast majority are medical models (for medical research) with as yet no patented livestock used for food production (although some fish for food and pets have been so protected). Internationally, only the EU, Australia, New Zealand, and Japan allow (or, more correctly, do not prohibit) patents for animals. Some 75 animal patent applications are presently on file in the EU states (not all of which will lead to a grant).

Because PVP is limited to plants only, and the geographic scope of countries allowing patent protection

for animals is also restricted, investment in animal biotechnology is likely below what it would be otherwise. Most critically affected would be applications to food production; medical uses tend to be physically controllable and distributed among a small group of easily identified users, meaning that patent protection is less essential. At the same time, food uses are the most controversial and subject to great regulatory review. Species that might escape and acculturate (like some fish species) are in need of additional scrutiny.

### **Research Exemption**

At a one-day conference held in association with the Crop Science Society in 2003, the focus was on identifying policy issues related to IPR protection for plants. Receiving considerable attention was the functioning of the research exemption—broad under PVP and essentially nonexistent for patents. Although public-sector representatives tended to support the research exemption, the private-sector spokespersons were divided; those focusing principally on corn and soybeans generally resisted the exemption, whereas firms concentrating on other crops supported an exemption. The policy, it should be noted, is a highly sensitive one.

### **Policy Conclusions**

Protection preferences for plants is bifurcating to patents for corn and soybeans (the two highest valued seed sector components), and PVP otherwise. The seemingly routine granting of utility patents for varieties is problematic, so the review of protection standards said to be underway at the USPTO should proceed and be concluded with some urgency.

The initial/essentially derived protection system for plants first adopted in the United States in 1994 appears to be unworkable in its present form. Consideration needs to be given to alternatives, particularly in most developing countries, where PVP is the only form of protection available. Opportunities and returns for US plant research are indirectly affected. The situation with animals is even more limited internationally, for although animals are generally excluded from patents, there is no PVP-like system for animals.

From the policy conference, the following public issues were identified:

**Plant variety protection (PVP).** As a result of the trade-related aspects of IPR (TRIPS) under the WTO, PVP is becoming the most common international form of IPR

for plant varieties and hence warrants additional examination. Recommendations include the following:

- Legislation limiting support of the PVP office to fee-based funding should be reevaluated. The time to process PVP applications averages three to four years and may require up to eight years. Even with interim protection, this creates uncertainty, which could reduce private-sector investment.
- Descriptors required for securing protection should be sufficiently flexible to allow breeders to present the most consistent and significant bases of distinctness.
- The breeders' research exemption under PVP, which follows that under UPOV, is a major departure from patent systems; some believe it should be limited in light of technological advances. However, with widespread support for the breeders' exemption in both the public and private sectors, any change would be very controversial.

**Utility patents.** In the United States, broad research access for breeding exists under PVP but not under utility patents. There is debate on the need for and degree of research use exemption. Some feel that providing the most complete protection to lines and varieties is necessary to protect continuing investment in breeding activities. However, in the United States, the unique blend of an expansive scope of protectible subject matter for patents with a very narrow research exemption could reduce future germplasm access, hampering breeders in the long term. Recommendations include the following:

- Patent Office considerations of nonobviousness and claims supportable by the application applied to lines and varieties should continue.
- Possible errors on improper utility patent grants for plant varieties may be further reduced by increasing use of (a) foreign databases, including SINGER (the System-wide Information Network for Genetic Resources) used by the Consultative Group on International Agricultural Research (CGIAR); (b) crop advisory committees; and (c) USDA/public-sector expertise.
- US Federal Trade Commission proposals for reducing the costs of challenging questionable patents are another approach to consider to correct possible granting errors.

**Reduce transaction costs.** One source of costly negotiations is the multiple forms of Material Transfer Agreements (MTA) in use. The United States Department of Agriculture (USDA) could contribute to standardization

by mandating a limited number of MTA forms for use with USDA grants (as the National Institutes of Health presently do for grantees). Examples for accessing "unimproved" materials are available from CGIAR and the International Treaty.

**Bayh-Dole.** The Bayh-Dole Act was intended to increase public use of inventions derived from publicly funded research. Although IPRs are often necessary for commercialization, the protection costs to universities often exceed revenues generated. Presently, only a few university licensing programs are in the black, and those cases are due only to a small number of very valuable inventions. A means of providing public funding for the cost of more routine technology transfer, including IPR, should be considered. It should not impact research funding.

**Future of crop genetic improvements.** Universities provide key breeding services, including (a) training; (b) development or adaptation of cutting-edge breeding techniques; (c) germplasm utilization, enhancement, and transfer; (d) variety development for minor crops; and (e) continuity and competition in a volatile investment environment. Some suggest that public-sector IPRs can generate sufficient funds to support public breeding, but this suggestion is not borne out by experience. Furthermore, pressure on public programs to be self-supporting through generation of intellectual property has the potential to shift university breeding from complementing to competing with private-sector breeding. To better achieve the goals of public programs, current funding needs to be augmented. Expanded funding could be used more effectively by:

- focusing attention on declining programs for minor crops of major national significance, such as vegetables, fruit, forage, and wheat;
- competitively identifying centers of excellence for such crops and granting stable long-term funding (5–10 years); and
- allowing public breeding-based projects to be funded competitively within USDA programs.

### Do IPRs Benefit Developing Countries?

At one level, this is a nonissue for the 140 signatory countries to the WTO (the majority of which are developing economies) who have committed to a minimal level of IPR protection and are in the process of meeting those commitments. However, under TRIPS, countries have latitude in implementation (such as the options for

protecting plants). Critically, countries can choose to enforce laws more or less strictly and immediately. Overall, then, there is a distinct benefit to US researchers if international policy makers embrace IPR as beneficial rather than responding grudgingly to a commitment.

### Literature Review

In general, the benefits of IPR are measured in the macroeconomic aggregates of contributions to foreign direct investment (FDI) and the enhancement of imports. That kind of analysis requires an index that reflects the relative strength of IPR protection. Two forms of indexes have been used over time: one based on a survey of judgments of practitioners and another using a subjective interpretation of the legislation. The former approach is limited by the choice of respondents (who will have more experience with some parts of the world than others), the uncertainty of aggregating subjective ratings, and the inability to recreate the same index over time. The latter approach is perhaps more flawed, because it excludes any consideration of the enforceability of the laws—always a key matter under the law.

In general, prior studies support the hypothesis that stronger IPRs increase both FDI and imports (see Lesser, 2002; Maskus, 2002). All studies are limited by the possibility that the strength of IPR is an indicator of a well-functioning economy or legal system rather than the role of IPRs per se. However, available subanalyses indicate that the strongest effects are in high-technology sectors, which are typically most sensitive to IPR protection, suggesting that it is the property rights systems that are operational and not other associated factors. All studies applied to the pre-TRIPS era.

### Analysis

The relationships between IPR and FDI were reestimated in the post-TRIPS period—the period of obvious interest for developing-country policymakers (and those who supply those markets). The analysis included a novel indexing system that drew on public data and is hence recreatable. Weighting utilizes internally generated factor weights rather than judgment-based ones.

On average, the results for 44 countries in 1998 indicated that a one-point increase in the IPR scores (about 10%) increases FDI by \$1.5 billion (about 50% of the mean) and imports by \$8.9 billion (40% of the mean). Those numbers are larger than prior estimates but reflect all sources, not US sources only, as is the case for many prior reports. The analysis was repeated for high-tech

goods and license fees (with only 35 countries due to data limitations). The results, while all having the proper signs, were not as statistically significant as for the all-sector analysis.

### Policy Conclusions

Our analysis (as well as prior analyses) supports the theory that in general, stronger IPRs are associated with stronger IPR protection. Those results seem to be particularly robust in the TRIPS period. A key component of the results emphasizes the significance of a well-functioning court system. One role of the United States would be to provide additional assistance to countries for upgrading their courts.

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