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EQUITABLE PATENT LEGISLATION FOR DEVELOPING COUNTRIES

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EQUITABLE PATENT LEGISLATION FOR DEVELOPING COUNTRIES[1]

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My title promises more than I – and perhaps anyone – can treat in a meaningful manner. Among other complications, what is equitable changes from the perspective of the beholder. Thus I shall be examining but one aspect of equity, economic equity at the national level. Specifically, do patents and other forms of intellectual property generate for developing countries more income and employment than they lose through higher prices and negative trade flows attributable to royalties and like payments? In order for patents to have a beneficial economic effect at the national level they must (1) stimulate domestic research and development activities (R&D), (2) enhance access to more efficient products and technologies developed elsewhere and/or (3) not serve as a substitute for domestic economic activity. Enhancing the incentive to invest in inventive activities is the core economic justification for the temporary monopoly rights granted by patents.[2] Countries of course are concerned with <u>where</u> that research is conducted, the obvious preference being for national investment that provides employment and strengthens technological skills. However, in an increasingly interdependent world, <u>access</u> to products and technologies developed elsewhere can be equally significant and will receive considerable attention here.

The methodology used is a review of the economic literature on experiences with patents in developed and developing countries. This is not an easy literature to summarize for it contains numerous opinions but few studies which can be generalized to other countries and times.

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[1]This paper was presented by William Lesser at the IICA Seminar on "Industrial Property Protection of Biotechnological Inventions and Germplasm Use Policies in Latin America and the Carribbean", Caracas, Venezuela, 27-29 November 1990.

[2]There is a second justification for patents based on the concept of personal property, the right of the inventor to her creation. That justification is not considered in this paper in favor of the more pragmatic economic considerations.

My treatment of "biotechnology," one of the subjects of this conference, shall be sufficiently broad to include plant and animal breeding, embryo transplants and tissue culture as well as the "new biotechnology" of genetic transformation. The economic interest in biotechnology, as well as a major societal concern, is with the new products and process this group of techniques can produce To date such approaches as tissue culture have provided more useful products than have the more exotic genetic transformations. Moreover, to commercialize many genetically-altered products it is necessary to deliver them to the market through such vehicles as seeds. This is all saying that intellectual property protection for biotechnology must be considered broadly so as not to foreclose possible areas of development.

In order to narrow matters a bit the focus shall first be on plant breeding followed by a treatment of pharmaceuticals. These seemingly disparate products share the common characteristic of ease of copying. Non-hybrid plants and seeds carry their own mechanism for recreation so that in the absence of legal protection the breeder/inventor has but a season or two before direct competition appears. Copying pharmaceutical products is somewhat more complicated but shares the characteristic that, once invented, they are far quicker and less expensive to copy than to reinvent. Thus both product groups depend on legal intellectual property protection to recover private R&D investments. The similarity though does not end there. Both product groups are the focus of public attention so that any change in policy is controversial. The reason for that public scrutiny is clear: agriculture and medicine have direct impacts on public welfare. At the same time, governments are directly involved in agriculture and health care so that any change in policy is likely to affect the public treasury. Certainly royalty payments for pharmaceuticals would be an additional public expenditure for many developing countries. All this is saying that plant and pharmaceutical intellectual property protection are the most difficult cases; resolve them and the remainder is easy.

Of course that is not completely true so the third section considers the issues involved with product and process patents in general and, following that, additional considerations for

biotechnology. In each area specific recommendations for legislation are put forth. They are presented as amendments/additions to the WIPO Model Patent Law for Developing Countries.

Plant Breeders' Rights

Among the developing countries only Chile, Argentina, Mexico and Peru to my knowledge have active Plant Breeders' Rights legislation in place, and none of these are (nor for that matter is any developing country) presently members of UPOV, the international convention.[3] Up until the present there has been little evaluation of experiences under these laws (but see Gutierrez paper on Argentina in these proceedings) beyond some limited field notes from a USAID-sponsored field visit in 1989 (Pray 1989). Therefore most of the available analysis comes from the developed countries, and especially the United States.

Due to the ease of copying seeds and plants essentially all breeding of non-hybrids was done at public expense until intellectual property legislation was adopted. That occurred for asexually propagated plants (trees, vines, roses, etc) in 1930 with the passage of the Plant Patent Act (presently Sections 161-64 of the Patent Act of 1952) and for seeds and other sexually propagated plants in 1970 under the auspices of the Plant Variety Protection Act (PVPA).

Other papers in these proceedings (see e.g., Espinosa, Bombin) discuss Plant Breeders' Rights (PBR) in some detail. For our purposes here they can be considered as patent-like devices with two major distinctions, as follows:

* Breeders' Exemption – permits the use of protected varieties for further breeding and incorporation in new varieties so long as the use is not repeated as with hybrids,[4] and

* Farmers' Exemption – allows farmers to save and replant seed in subsequent seasons,

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[3]Argentina I understand has applied and expects to become a signature in the near future (Dr. Gutierrez, personal communication).

[4]The parallel research exemption under patent law is less clear. For the United States the general consensus is that a broad research exemption exists even if that research has commercial purposes, but no definitive interpretation has been made. For further information see Bent 1990.

something which is almost certainly an infringement of patent rights (see Lesser 1986(a)).

Because of these two exemptions PBR can be characterized as providing less protection for the inventor than do patents. A further salient factor in the United States is the very limited difference among varieties required for the granting of PBR.[5] In fact I have been told that essentially any difference claimed by the breeder, no matter how economically or agronomically insignificant, is grounds for an award of PBR in the U.S. This limits the scope of protection, increasing potential competition. Thus the responses seen in the United States are the result of very limited incentives and could have been greater had the level of protection available in other UPOV-member states been available in the U.S.

Studies of the PVPA in the United States show the following:[6]

1) Sharp increases in private investment in apparent anticipation of passage of the PVPA (Butler and Marion 1983, pp. 74-75).

2) Increases in numbers of private firm breeders. In the case of soybeans 6 to 63 over 1971-84 (Brim 1987, Table 3).

3) R&D investments were not evenly distributed across crops, with investments in soybeans high and those in carrots and other minor vegetables virtually nonexistent (Butler and Marion 1983, p. 75). Differences in investment can be explained by differences in crop acreage and value, response to breeding, need for local adaptation and other economic factors (Foster and Perrin 1990).

4) Private soybean varieties in 1986 approached half the acres planted in Indiana, a major producing state, suggesting they are at least as productive and profitable as public varieties (Brim

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[5]In Europe and other UPOV-member countries a higher standard of differentiation among varieties, a standard sometimes based on a statistical comparison, typically allows a broader scope of protection (see Lesser 1986(a), 1987(a)).

[6]Only one study known to the author contains an examination of the Plant Patent Act. That study found little incentive effect in fruit breeding due to the difficulty of detecting infringement, although the long lag from the 1930 passage of the Act to the study could have made the analysis more difficult (see Stallmann 1986).

1987, Table 5).

5) Some statistical evidence indicates that private varieties are more productive (Perrin, Hunnings & Ihnen 1983). This is important in the United States where the limited scope of protection led to concerns of "cosmetic breeding" (Claffey 1981).

6) At the same time no evidence has supported concerns of excessive price increases. This is in part attributable to competition from farmer-saved seed (Butler and Marion 1983, p.76).

These results are all quite favorable, but several issues remain which have potential significance for developed, and developing countries. These are discussed below.

* **Genetic Uniformity** – PBR has been charged with enhancing genetic uniformity of crops, and hence their vulnerability (e.g., Claffey 1981). This uniformity is indeed a matter of concern with, for example, but a few genes inducing dwarfing and antilodging (ability to stand erect) in millions of hectares of rice and wheat worldwide. But the connection to PBR has never been made especially as much genetic uniformity exists where PBR are lacking. Uniformity rather appears to be an aspect of market demand and mechanization needs for harvest and handling. Within those requirements PBR would seem to contribute to variability as firms seek ways to differentiate their varieties.

* **Exchange of Germplasm** – in the period prior to the passage of PBR germplasm had no real market value and was exchanged freely among public breeders. With PBR and other property laws comes an associated value for this genetic material which is seen in some quarters as impeding its free flow. Serving as it does as the basic material of any breeding program, loss of widespread access would have distinct impacts on advancements through breeding (see e.g., Kenney 1986).

Surveys which have been conducted do not document any major problems. The most extensive of these completed about 1980 found no overall exchange although the movement from universities to private business increased slightly to compensate for a slight diminution in the reverse flow (Butler and Marion 1983, pp. 67-71). Most recently, although not yet documented in

the literature, exchange is increasingly dependent on the signing of what amounts to a licensing agreement; recipients are in effect acquiescing to pay some royalty in the event the donated materials contribute to a commercializable product. These agreements, to my understanding, apply between universities and private enterprises as well as within the two groups. Breeders are finding these agreements require some understanding and management, but represent a new form of relationship rather than the loss-of-access. Many breeders prefer the earlier system but are accommodating to the new one. Thus there is no evidence to support the loss of access charge against PBR.

Among the group seeking to share in the value of germplasm created through PBR are developing country farmers who have for millennia served as stewards of a major source of genetic variability called native varieties or landraces. These demands have been formalized at an international level under the title "Farmers' Rights", a subject well treated in the Bombin paper in these proceedings. (For additional information and analysis see Sedjo 1988.)

Without attempting to comment on the proposals for Farmers' Rights, it can be noted that PBR are another possible mechanism to the same end. When applied to a distinct new variety identified in cultivation or the wild, PBR can convey the property rights which are often needed to collect payments. That is, whomever identifies and documents a new variety can claim rights to that variety and demand royalties in accordance with PBR legislation. PBR can therefore provide the means for developing countries to claim payment for their germplasm resources (see Straus 1986).[7]

* **Loss of Public Funding** – Concerned individuals in developing countries sometimes express the opinion that private breeding investment stimulated under PBR would have no net

[7]Certain changes in legislation would be required before this approach became workable. In particular, a dependency arrangement similar to that proposed in the UPOV revisions would be needed for the discoverer to receive some ongoing value for his/her variety (UPOV 1990). Also it should be recognized that satisfying PBR requirements would require a detailed exploration of the variety's characteristics to be done by a trained agronomist, something beyond the scope of local farmers operating independently.

additive effect; public funding would simply be reduced by a like amount. This is a difficult matter to comment on in a general matter as it is an issue of national policy. It however can be noted that no such effect has been observed in the United States, Chile or Argentina (Butler and Marion 1983, pp. 40-43; Pray 1989). This does not mean that funding cuts will not follow private investment, only that they need not do so.

It should also be noted that PBR can contribute to public research funding when universities protect and license their varieties. For my university, Cornell University, the annual income is on the order of $250,000 (U.S.) annually (Lesser 1987(b)) while the University of California system is said to earn in excess of $1 million annually. See the Gutierrez paper in these proceedings for an account of the recent experiences in Argentina. In the developing world the approach taken by the international breeding centers, or CGIAR, is probably as important as national funding. Those centers provide basic breeding varieties to the national research systems. Siebeck reports in a paper in these proceedings that these centers are approaching a decision on the exchange and fees for improved and unimproved germplasm. Altogether then there is little evidence that PBR will lead to a reduction in public funding for breeding.

* **Loss of Public Breeders** – this is a small country issue which reflects the concern that private firms in the aftermath of the passage of PBR will hire away all the public sector breeders of key crops. That is a distinct possibility as many countries have but two breeders of a crop, and indeed this has occurred in hybrid maize when private firms enter the market. Program administrators understandably often wish to avoid the entire matter by barring PBR. In my assessment the problem is more one of governmental rigidity than PBR. In private organizations counter offers typically are made when a valued employee receives another job offer. But many governmental systems are too inflexible to do that. The obvious solution is a reform of the social service system, not the barring of PBR. Beyond that change it must be recognized a PBR system has costs as well as benefits; competition for public breeders will be one of those costs for smaller countries.

Synopsis

The available evaluations of PBR systems are highly favorable. They, as economic theory predicts, do lead to increases in the output of productive new varieties. Other observers suggest private firm involvement will enhance seed propagation and distribution, traditionally the weak areas of public programs in developing countries (see Sasson 1988). At the same time, many of the associated problems and costs of PBR have not been documented in practice.

This favorable balance of costs and benefits however depends on the existence of a **competitive breeding sector** (see Butler and Marion 1983, p. 78). Competition is a difficult matter to monitor and measure. However at a minimum a competitive sector would seem to require an active public breeding program and the allowance of imports. Importation can be an effective source of competition, especially in smaller national or product markets. Fostering imports will however require some national governments to ease restrictions on foreign exchange and restructure quarantine practices for some crops.

Recommendations

I make the following recommendations regarding a PBR law:

* Adopt a PBR law along the lines of UPOV.

* Do not include the current exclusion for "double protection", the option of a patent or PBR (UPOV Section 2 (1), 1978 text).[8]

* Take specific actions to preserve competition in the plant and seed sector. One component is to maintain a narrow scope of protection for varieties.

* In the distinctiveness requirement (UPOV Section 6 (1) (a), 1978 text) do not use the term "important characteristics" which has come to be interpreted as one with known economic

[8]The most recent (as of this writing) proposed modification of the Convention drops the ban of double protection (UPOV 1990).

value. I believe strongly that intellectual property offices should not attempt to anticipate how the market values products.

* Do not subject varieties to field trials. That is an exceedingly costly consumer protection practice which does not provide meaningful results in countries with varied climatic and soil conditions (see Lesser 1987(a)).

* A law should require the protection of all genera and species. Allowing for the inclusion of but a subset leads to selective grants based on what is and is not bred nationally (Straus 1986).

Pharmaceuticals

Patent protection for pharmaceutical products is highly contentious because of the obvious human welfare issues and the direct involvement of most national governments in financing health care. Due to these issues, one can imagine, protection is excluded in many countries: 48 of some 99 Paris Convention signature nations worldwide in 1988 and 14 of 19 Latin America countries (WIPO 1988). While most of the excluding countries are developing nations, that is not and has not always been the case. Switzerland did not adopt protection until 1977 while Finland and Australia and a few others still refuse to grant protection.

One view in the developing world of patent protection for pharmaceuticals proposes in essence that it will lead only to paying more for what is already available. That position is really arguing two distinct points, (1) there is no domestic inventive capacity, and (2) major firms (which are in temperate countries) find the potential market in developing countries too small to justify R&D investment in drugs for predominantly tropical diseases. On the price issue there is little debate; in an industry with high fixed (R&D) costs but low marginal (production) costs it is always less costly to pay variable costs only – that is to use generics. Studies of comparative prices support the expectation that prices are higher in countries with patent protection (review in Nogués 1990, pp. 28-30).

What, however, do we know about the impact of patent protection on indigenous research

and external investment? Much of that evidence comes in the negative – what happened when patent protection was withdrawn or limited. In India, R&D investments in pharmaceuticals fell nearly 40 percent from 1964-70 to 1980-81 following the removal of patent protection, something Deolalikar and Evenson (1990, p.237) attribute to the 1970 weakening of protection. The situation in Turkey following the 1961 removal of protection is more complex but does indicate that the mere absence of patents does not spur domestic competition nor encourage domestic R&D (Kirim 1985).

For the implications of enhancements in protection it shall be important to monitor the experiences of Mexico when pharmaceutical products in general become protectable in 1996. Redgrave reported elsewhere in this conference that Canada was able to negotiate with the major pharmaceutical companies an increase in research in Canada and a continuing generic product status for those products currently available when Canada recently granted patent protection for pharmaceutical products. The relevance of that experience to developing countries is however not clear at this time, but it does raise questions about presumptions that patent protection is not important to the decision to invest in research in a country. (For a development of the concept see Firestone 1971, Chaps. 7 and 10.)

A few additional bits of information are available. Regarding national R&D, McLeland and O'Toole (1987, p.246) describe India as having sufficient trained researchers and manufacturing capacity to establish a broad product development program for domestic and export sales. As relates to the interest of established firms in developed countries to invest in R&D for tropical diseases, Behrman (1980, pp. 20-22) notes that these countries now account for one fourth of all pharmaceutical sales. Those nations as a group also have a majority of the earth's population with the fastest growth rates. India for example accounts for but two percent of the world pharmaceutical market despite its population of nearly 800 million. As such these countries represent major potential markets and lack of interest by multinationals cannot be assumed. Greif (1987, p. 209) in fact cites annual expenditures of DM 80 million by six major European

pharmaceutical companies "for research on medical preparations against tropical diseases."

Altogether this information is fragmentary and neither conclusively supports nor opposes patents for pharmaceutical products. What then to do? I propose a middle course, one which allows patents as a means of stimulating private investment but uses compulsory licenses to protect the public from undue price enhancement.

Recommendations

* Allow pharmaceutical products and products by processes as patentable subject matter.

* Provide for compulsory licenses and, in the extreme, patent forfeiture, on the grounds of social well being which in this case would be lack of access or excessive prices.

These recommendations are made in full awareness of the sharp disregard of compulsory licenses held by strict proponents of the patent system. And indeed in the extreme they are correct for very broad compulsory licensing provisions effectively remove all protection as has happened previously with Canadian pharmaceuticals (see Redgrave papers in these proceedings) and India (McLeland and O'Toole 1987, p. 237). Yet some form of compulsory license is a part of every patent law, even that of the United States,[9] and are allowed under the Paris Convention and included in the provisions of the proposed Trade Related Intellectual Property (TRIPs) provisions of GATT. There, as is recommended here, licenses must be duly considered with provisions for adequate compensation allowed for the patent holder[10]. As Scherer, a longtime student of the patent system notes, compulsory licenses are a limited remedy, not a panacea (1980).

This recommendation **should not** be taken to imply that I support compulsory "working" requirements for I do not. The form recommended is intended to assure access at reasonable prices, whether that access is achieved through domestic production or importation. Working

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[9]The Patent Act provides for compulsory licenses for inventions deemed relevant to national security (35 U.S.C. Sections 181-83).

[10]As a practical matter, these requirements are difficult to apply in a mutually agreeable manner, especially the issue of compensation.

requirements have the added intent of stimulating domestic activity and employment. Those are both of obvious national interest but encumber the patent system with an additional objective beyond the central ones of stimulating private investment and enhancing access. From the perspective of the patent holder, a portion of the returns from the patent may come from the economies of centralized production from which many markets are served. A less efficient producer in one of the recipient countries could, with the receipt of a "working license", take away a portion of the returns without providing a lower price for consumers. In this case the incentive for the patent holder would be reduced without any direct benefit to the public. Indeed, part of the problem would be the possibility that any firm at any allowed time could step forward and request such a license, making planning very difficult. My perception is that the rights of the patent holder – and indirectly the incentives of a patent system – should be interceded only when there is a clear public need and benefit, as with excessive prices. The compulsory license recommended above is intended for just such instances.

Other Products and Processes

What now can be said about the remaining group of products and processes which constitute the majority of patents? The patent literature indicates that there are four principal bases of opposition to patents, as follows:

1) predominantly foreign-owned patents displace local industry,[11]

2) Patents are needed only to access the most current technologies which are not needed or appropriate anyway,

3) Technology and, especially, products are available even without patents, and

4) Restrictive patent licensing agreements substantially raise the cost of technology

[11]In developing countries some 5 to 10 percent of patents are held by nationals with the remainder owned by foreigners, including multinationals. By comparison the domestically owned proportion of patents in developed countries are around 17 percent if the extreme cases of the U.S., Japan and Germany are excluded (WIPO data in Lesser et al. 1989, pp. 3-4).

licensing in particular.

*** Displacement of Industry** – On this point there is some statistically-based information, at least for India. Deolalikar and Evenson (1989) found that equations explaining imported and domestically-produced technology moved together (had the same signs), something they interpreted to mean that imported technology and domestic inventive activity tend to be complements rather than substitutes. What seems to be happening is local firms adapt imported technologies to national needs and conditions. Absent that imported technology there is no opportunity for the adaptive work. One might imagine a similar scenario for imported products, but there is no statistical evidence to support that position.

***No Need for Current Technologies** – A frequent complaint form Latin America and elsewhere is the lack of access to current technologies (McLeland and O'Toole 1987, p. 247). Inadequate patent and other legal protection may be a cause of this. But is the latest technology really needed? Certainly it is not always needed, and when it is lower wage rates, energy prices or other factors of production can compensate for some production inefficiencies. But inadequate intellectual property protection can mean current technologies are **never** available. That strikes me as a dangerous position for a national government to take, the choice always to operate with dated technologies. As the world becomes increasingly interconnected and technological evolution accelerates it is questionable if an economy can survive solely on old technologies.

Agricultural technologies are a case in point. Can national economies dependent on a few export crops (coffee, cocoa, sugar, etc.) afford not to access productive improvements which are now becoming available through improved varieties? I believe not, but that is not the real issue. Rather it is significant if the government wishes to make that decision or leave it up to individual industries on a case by case basis. Adequate intellectual property protection, including patent law, fosters access to these technologies without of course requiring it. If older technologies are the most profitable they can be selected anyway; the key is that there is a choice.

***Access is Possible Without Patents** – This point refers to the issue raised by

Siebeck during a discussion period. Patents are but one means to access products and technologies. Indeed, patents may be viewed as but a standardized form of contract with some agreed upon interpretations. Other forms of contracts such as leasing agreements or trade secrets can and do substitute for patents. No claim is made that patents are the sole means of accessing products and technologies. What does need to be recognized, though, is that alternative arrangements have costs also. And those costs may be greater, if less apparent, than patent royalties.

One such potential cost is the cost of enforcement. If contracts are expensive to develop and implement, that cost will be reflected in the fees charged. Trade secrets are particularly expensive to protect because, once lost, the owner has no recourse except against those who improperly gave or received the information. As a result, emphasis is placed on preventing loss, an expensive proposition. Technology renters may reduce their monitoring and enforcement costs by licensing only large, well established firms. Locally owned operations may thereby be excluded. Alternatively, foreign firms may engage in direct investment which reduces the transfer of technical knowhow to national entrepreneurs.

A second hidden cost is that of delay. It may, for example, be impossible to prevent access to new seed varieties. Thus the country saves the royalty payment. But access may come only following some delay. Breeders at a minimum will make an unprotected market a low priority, delaying shipments until other markets are satisfied. At best national breeders must wait until the variety is marketed meaning several years lag while it is adapted and propagated. These delays all have costs as we are reminded in the Barreto de Castro paper in these proceedings. There it is stated that Brazil is losing a million hectares of cotton production annually due to boll weevil infestation. What is the cost of that loss compared with the cost of access to potentially resistent genetic material?

The purpose here is not to provide answers to these questions (although those answers are urgently needed) but rather to identify the costs of not having patents. Those costs should at least

be recognized.

Restrictive Licensing Agreements

It is often charged that the patent monopoly is improperly extended through the appendage of additional requirements such as exclusive supply agreements. Here the reference is primarily to process patents. Data on the frequency with which these clauses are included are tedious to collect and not very current (see e.g., UNCTAD 1975; Vaitsos 1972). Not all such clauses are inappropriate as some stipulations are necessary to insure the quality and functionality of the product (Palmer 1984). Yet despite these qualifications a potential problem exists even if its extent is not clearly documented.

The limiting or prohibition of patent rights does not provide a clear resolution to these problems. The ability to impose such conditions in the first place suggests the patent holder has a desirable and profitable new technology. Should that technology be made available through an exclusive contract agreement then supply requirements could be imposed anyway. But the fundamental point to be made is that inappropriate agreements should be prohibited in their own right, not indirectly through a lessening of patent protection. In the United States these so called vertical restraints are prohibited in the antitrust laws, particularly section 3 of the Clayton Act and section 1 of the Sherman Act (Neal 1974, Chaps. VIII and XI). The use of such controls is sanctioned in Article 40 of the GATT proposal for Trade-related Aspects of Intellectual Property Rights (1990).

Recommendation

Patent laws should prohibit tying and other restrictive agreements within the act if such prohibitions are not otherwise present in national law. Penalties should range from deletion of the offending clauses to civil penalties to compulsory licenses to revocation of the patent. To be included are restrictions on continuing the licensing agreement after the expiration of the patent. It should be noted that these are not easy laws to adjudicate, especially when the courts are called upon to determine if an agreement is based on legitimate business concerns or if it is abusive of the

patent rights granted.

Biotechnology

It is now time to turn attention to biotechnology, a subject matter of this conference. It shall not be necessary for me to address the legal and technical issues involved in biotechnology patenting – those matters were dealt with admirable by Espinosa in his paper. There are however two fundamental attributes of biotechnology which require identification. They are:

* Biotech products are often easily copied – this is particularly true when culture samples are involved[12]. But while perhaps exaggerated this issue is not conceptually different from seeds and pharmaceuticals discussed above which are also heavily dependent on patents for the recovery of private R&D investments.

* Biotechnology appears to be a major potential source for new products and technologies in numerous sectors, especially agriculture – the significance of biotechnology combined with its need for patent protection for recovering private investment expenditures argue strongly for the extension of strong protection to these products.

A related point needs to be added here. Much attention to biotechnology is focused on the major products. In agriculture bovine somatotropin (bST) with its potential to increase milk production per cow by 15-20 percent and reduce livestock feeding costs by like amounts has received a great deal of attention.[13] Yet in my experience this is the only, or at minimum one of a few, agricultural products promising such dramatic results. Agricultural biotechnology will rather provide an ongoing series of modest new products or less expensive means of producing existing products. This point is of significance because it is just these minor improvements requiring a long pay back period for which patent protection is particularly significant (Jewkes, Sauers and

[12]See Lesser 1986 (b) for a brief treatment of this matter.

[13]See e.g. Molnar and Kinnucan 1989 for several views.

Stillerman 1969). Patent protection is further important for domestic inventions by small firms. With adequate incentives we can anticipate major biotech industries developing in at least the larger of the developing countries, including Brazil and India, among others. Biotechnology at this stage in its development is trained personnel intensive, not capital intensive. It is possible to think of small companies in developing countries making significant contributions to R&D.

Can Developing Countries Afford to Operate a Patent System?

Any country considering the adoption of a patent system or the extension of protection into a new, technological area must consider the trained manpower needs and costs of such a system. They are not trivial as the $300 million annual budget of the U.S. Patent Office indicates. There are nonetheless less costly alternatives to the operation of patent offices.

***Use a Registration rather than an Examination System**

Examination systems require technically trained patent office personnel who can make judgments about the satisfaction of the inventive step requirement of an application, as well as other technical matters. This is slow and costly. Alternatively, a registration system reduces the patent office to a clerical role which records patents after certifying that certain administrative matters are satisfied. This is both quick and inexpensive as well as eliminating the need for technically competent personnel. The decisions of validity and scope of patents are made by the courts if and when a patent is challenged. Note that registration is distinct from reregistration of patents granted elsewhere, generally in developed countries. Reregistration is an additional burden for developing country inventors who must overcome the costs and exacting requirements of pursuing a patent in a developed country.

Registration systems do create their own problems, particularly the potential for many invalid patents being issued which discourage additional research in the area (see Hodkinson and Quest 1985, p. 110 for a discussion of this issue). Registration does however provide an opportunity to initiate a patent system with a minimum of cost and complexity.

***Rely on International Searches on a Fee Basis**

Typical patent office procedures call first for a search of prior art. The search provides information on the novelty of the application as well as assisting in the examination procedure. A thorough search is a critical part of the patent granting process. Searches, which rely primarily on printed materials including existing patents, do require an extensive reference library of international documents. This exceeds the reasonable scope of many developing countries and at minimum involves the duplication of materials. As a less costly and complex alternative, countries can rely on international searches at an existing patent office. The fee for this service is minimal. One alternative is the international search procedure set up under the Patent Cooperation Treaty (refer to Espinosa's paper on international agreements elsewhere in these proceedings). Secondarily, the International Patent Documentation Center in Vienna provides searches on a fee basis. Countries would still wish to collect and search national and possibly regional materials, but that would involve a fraction of the effort of a full international search.

***Use Regional Patent Offices**

Small patent offices offering examination are in the difficult position of needing to provide technical competence in a broad range of technologies at a time when application numbers are likely to be low. This creates a costly dilemma. Alternatively, countries can join together to form regional offices. The major one of these, and a very successful undertaking, is the European Patent Office in Munich and The Hague. Among the developing countries regional offices exist in Africa, the African Regional Property Organization (ARIPO) in Zimbabwe for the English speaking countries and the Organisation Africane de la Properiete Intellectuelle (OAPI) in the Cameroon for the former French nations (see Juma and Ojwang 1989). I have read of a Central American Patent Union but it appears to be inactive. The operation of these offices is not well documented in the literature but they do suggest an alternative to multiple national offices.

***Use Outside Technical Experts**

One concern of developing countries is the technical expertise required in infringement and

other court proceedings. Such competence is beyond the internal resources of many countries. That really need not be such a grave problem. Experts can be hired internationally and, while expensive, are less costly than developing national competence which is seldom called upon. Judges need not be technically competent themselves but rather have logical minds able to measure the merits of testimony from both sides. It is however critical that the court be perceived of as fair and impartial; a patent system cannot function without that requirement. To that end, a specialized court would seem to be advantageous.

Summary

Much remains to be learned about the economic impacts of patent and Plant Breeders' Rights systems, especially in developing countries. At a time when many countries are being pressed under GATT to enhance intellectual property protection, further understanding of these matters is critical. Additional research should receive the highest priority. Despite this, there are a number of issues for which reasonable conclusions can be drawn. These, combined with my personal recommendations, are listed below.

* Patents do appear to stimulate local R&D activity. In particular, domestic investment in research seems to be a complement to patenting foreign products and technologies, not a substitute.

* Intellectual property protection is particularly important for plants and many biotechnological inventions where legal sanctions are often the only form of protection available to the private inventor.

* Patents are important for stimulating national R&D as well as enhancing access to products and technologies developed elsewhere. The role of patents in fostering access to technologies is too often overlooked or minimized in discussions of the implications of patents.

* Patents are not the only means of accessing foreign inventions; licensing and direct foreign investment are among the alternatives. These alternatives however have associated costs also which should not be overlooked just because they are not as viable as royalty payments.

* Protection should be encompassing, for example covering microorganisms, genes and plants. This will allow inventors to identify the most appropriate form(s) of protection and not influence the direction of technological development.

* Countries have understandable concerns about the potential abuses of patent monopolies. In my view, they can and should be addressed within a patent law through provisions for compulsory licensing and prohibitions for unjustifiable extensions of patent rights.

* Numerous systems are available which reduce the cost and complexity of operating patent and PBR offices, as well as the need for technical competency. These alternatives should be considered. An impartial court system is however essential.

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