Intellectual Property Rights and Biotechnology Transfer

Prepared for

Asia and the Pacific Industrial Development Forum on Biotechnology

Chengdu, China

16-17 December 2003

Carol Nottenburg
Philip Pardey

CAMBIA, Canberra Australia
University of Minnesota, St Paul, USA

* Carol Nottenburg is Chief Legal Officer and Director, Cambia Intellectual Property Resource at CAMBIA and Philip Pardey is Professor of Science and Technology Policy in the Department of Applied Economics, University of Minnesota.
I. Current state of biotechnology / R&D capabilities between lesser developed and developed countries

The location and structure of R&D worldwide serves as a basis for analyzing the patterns and effects of intellectual property rights and their uptake worldwide. As discussed below, all indicators show that there is a large disparity between lesser developed countries (LDCs) and developed countries (DC) with respect to scientific research and capabilities.

Research Spending. In this section, we examine both total science spending and agriculture R&D spending. Unfortunately, similar data for health R&D spending is not available, however, it is assumed that there is a similar or larger difference in capacity between LDC and DC.

In 1995 about half a trillion (nearly $500 billion, 1993 prices) U.S. dollars were invested in all public and privately financed science worldwide—around 85 percent of it conducted in rich countries (Pardey and Beintema 2001). Of this total, agricultural research accounted for $33 billion or nearly 7 percent of all private and public spending on science.

The public share of agricultural investment has moved over the last 30 years from a period of growth to the current situation of near stagnation. Worldwide, public investments in agricultural research nearly doubled in inflation-adjusted terms from an estimated $11.8 billion in 1976 to nearly $22 billion in 1995. Yet, for many parts of the world, growth in spending during the 1990s slowed dramatically. In the rich countries, public investment grew just 0.3 percent annually between 1991 and 1996 compared with 2.3 percent per year during the 1980s. In Africa, there was no growth at all. In Asia, the annual growth is 4.4 percent compared with 7.5 percent the previous decade.

The fraction of world-wide public spending by developing countries has increased such that in the 1990s, for the first time, developing countries as a group spent more on public agricultural research than the developed countries. But in rich countries as in developing countries, public spending was concentrated in just a handful of countries. In 1995, the United States, Japan, France and Germany accounted for 66% of this public research, whereas just three developing countries—China, India, and Brazil—spent 44% of the developing world's public agricultural research money.
Thus, most of the developing countries spend relatively small amounts on agricultural research.

For private-supported research the spending pattern is reversed. By the mid-1990s about one third of the $33 billion total agricultural research investment worldwide was performed by private entities (Table 1). Strikingly little of this research takes place in the developing world. The overwhelming majority ($10.8 billion, or 94 percent of the global total in 1995) is conducted in developed counties, where private research is over half of all expenditures. In contrast, in developing countries the private share of research is a paltry 5 percent.

Table 1: Private and Public Agricultural R&D Investments, circa 1995

<table>
<thead>
<tr>
<th></th>
<th>Expenditures</th>
<th>Shares</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Public</td>
<td>Private</td>
</tr>
<tr>
<td>(million 1993 international dollars)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Developing countries</td>
<td>11,469</td>
<td>672</td>
</tr>
<tr>
<td>Developed countries</td>
<td>10,215</td>
<td>10,829</td>
</tr>
<tr>
<td>Total</td>
<td>21,682</td>
<td>11,511</td>
</tr>
</tbody>
</table>


Note: Drawing together estimates from various sources meant there were unavoidable discrepancies in what constitutes "private" and "public" research. For example, the available data for Asia includes nonprofit producer organizations as part of private research, whereas Pardey and Beintema opted to include research done by nonprofit agencies as part of public research in Latin America and elsewhere when possible.

In the developed countries, private agricultural research is generally displacing public research and especially in areas like breeding for the seeds of crops with high commercial value. This tendency is especially pronounced in countries like the United States where private agricultural R&D was 90 percent of public spending in 1960, growing to 133 percent by 1996, the latest year for which comparable public-private data are available. Private investments, fueled by agricultural biotechnology research, gravitate to techniques which promise large markets, are protected by intellectual property rights, and are easily transferable across agro-ecologies. Hence, while private research is much more geographically concentrated than public
research, many of its fruits may be more easily transferred across borders and agro-
ecological zones. The transferability is negated however, by the paucity of private
research in products with small markets, weak intellectual property protection, and
limited transferability, precisely the situations in which most poor farmers are found.

**Research Intensities and Stocks of Knowledge.** One way to gauge the commitment
of agricultural research funds, public or private, is to compare them to national
agricultural output, rather than measuring them in absolute terms. This relative
measure captures the *intensity* of investment in agricultural research as a percentage
of agricultural GDP, not just the *amount* of total research spending. In 1995, as a
group, developed countries spent $5.43 on public and private agricultural R&D for
every one hundred dollars of agricultural output compared with just 66 cents per
hundred dollars of output for developing countries. The eightfold difference in total
research intensities illustrates the size of the technological gap in agriculture between
rich and poor countries. Moreover, the situation is growing worse. The difference in
public research intensity ratios was 3.5–fold in the 1970s, compared with 4.3–fold
now (if private spending was factored in, the gap would have been substantially
wider).

As distressing as these trends are, they may actually understate the scientific
knowledge gap. Science is a cumulative endeavor: Innovations beget new ideas and
further rounds of innovation or additions to the cumulative stock of knowledge.
Providing adequate funding for research is thus only part of the science story. Putting
in place the policies and practices to *accumulate* innovations and increase and
preserve the stock of knowledge is an equally important and almost universally
unappreciated foundation.

Stocks of knowledge measures provide a better basis for evaluating the developed
versus developing country capacities for actually carrying out biotechnologies.
Estimates of the stocks of scientific knowledge arising from public and private
research conducted in the United States and Sub-Saharan Africa have been developed

---

1 Discoveries and data that are improperly documented or inaccessible (and so effectively exist only in
the minds of the relevant researchers) are lost from the historical record when researchers retire from
science. These "hidden" losses seem particularly prevalent in cash-strapped research agencies in the
developing world, where inadequate and often irregular amounts of funding limit the functioning of
libraries, data banks and gene banks, and hasten staff turnover. There can also be catastrophic losses,
tied to the political instability that is a root cause of hunger. Civil strife and wars cause an exodus of
scientific staff, or at least a flight from practicing science.
by Pardey and Beintema (2001). Historical research spending (running from 1850 for the United States and 1900 for Africa) was compared with the gross domestic agricultural product for 1995. The accumulated stock of knowledge in the United States was ten times more than the amount of agricultural output produced in that year. In other words, for every $100 of agricultural output there existed a $1,000 stock of knowledge to draw upon. In Africa however, the stock of knowledge in 1995 was actually less than the value of African agricultural output. Furthermore, the ratio of knowledge stock relative to agricultural output in 1995 was nearly 12 times higher in the United States than for Africa. These gaps also underscore the immensity, if not the outright impossibility, of playing “catch-up,” in addition to the need to transfer knowledge across borders and continents.

The location of crop biotechnology research compiled as data on the number of field trials conducted internationally\(^2\) echoes the spending patterns. The number of field trials conducted on bioengineered crops from 1987 through December 2000 are grouped by the regions in the world where the trials were conducted (Table 2).\(^3\) According to these data, a total of twenty seven countries conducted trials on 14 different crops and 183 different “events.”\(^4\)

\(^2\) Precisely what is meant by “crop-related biotechnology research” is difficult to determine. “Biotechnology” can run the whole gambit from conventional breeding, through culturing methods, to genomic and bioengineering (including transgenic) techniques. In addition, and as discussed regarding the patent data reported below, many biotechnology techniques developed with spending directed to the health sciences, for example, have agricultural applications as well.

\(^3\) As indicators of the level of bioengineering research effort, these data must be taken with a grain of salt. To meaningfully assess the distribution of transgenic crops being tested in the ground, one would like the notion of “field trial” to be standardized across countries. One option is to count each location as a separate instance. But in the United States, for example, a “location” can have many sites. For example, test 01-024-26n in the APHIS database contains Pennsylvania as one location, but there are 313 sites comprising a total of 1,838 acres. Likewise, Canada lists field trials conducted at multiple sites within a province as one field trial, but it is not clear if all the data for all the other countries are reported similarly.

\(^4\) An event involves the insertion of a specific gene in a particular crop, resulting in the expression of a trait in that crop. For example, insertion of the Bt cry1(c) protein producing gene into a particular cotton variety is considered an event.
Table 2: Field Trials of Bioengineered Crops by Regions of the World

<table>
<thead>
<tr>
<th>Number of Approved Events/crops(^a)</th>
<th>Field Trials(^b)</th>
<th>Share of Private in-country total (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Countries</td>
<td>Events</td>
</tr>
<tr>
<td>Developed Countries</td>
<td>19</td>
<td>160</td>
</tr>
<tr>
<td>United States</td>
<td>1</td>
<td>49</td>
</tr>
<tr>
<td>Canada</td>
<td>1</td>
<td>49</td>
</tr>
<tr>
<td>All others</td>
<td>17</td>
<td>62</td>
</tr>
<tr>
<td>Developing Countries</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>Argentina</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>China</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>All others</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>183</td>
</tr>
</tbody>
</table>


Note: na stands for not available.

a. Data through to December 2000 where available. For the United States and Canada, and perhaps other countries, a single “trial” may consist of tests conducted at multiple (maybe many) different sites.

As shown in Table 2, 84 percent of the world’s trials were conducted in rich countries; two thirds of the total was in the United States and Canada alone. This points to a biotechnology-research gap between rich and poor countries that is even more pronounced than the gap in overall agricultural R&D spending. Two fundamental factors may account for much of the marked spatial asymmetry in agricultural biotechnology research: specifically, who conducts the research, and the nature of the science itself. First, as indicted in Table 2, the preponderance of these biotechnology trials are conducted by private firms and 94 percent of the world’s private agricultural R&D takes place in rich countries. Second, this type of cutting-edge research requires access to highly skilled scientists, well functioning scientific infrastructure that provides ready access to reagents and a myriad of laboratory equipment and supplies, along with technical information, and the appropriately trained support staff to help carry out the research. Due to the sophistication of the research and its pace of change, “applied” aspects of the biosciences are likely to
receive significant spillovers from on-going basic research and from accumulated stocks of scientific knowledge arising from past research. Both of these elements are much more readily supplied in rich than poor countries. Indeed, localized spillovers from university research directly influences the location of industrialized R&D (Adams 2001).

II. Barriers and challenges to transfer of biotechnology to developing countries

Given the huge disparity of biotechnology capability as shown in the previous section, reducing the barriers and challenges currently a part of technology transfer will be a necessity for LDCs to play technological catch-up. Much of the blame for lack of technology progress has been placed on intellectual properties. The barriers and challenges facing transfer of biotechnologies to developing countries, however, range beyond patents and other intellectual properties to other mechanisms like contracts and regulatory issues. For the reasons stated below however, we propose that other barriers such as contracts account for many, if not most of the barriers to technology transfer.

A. Intellectual property barriers and challenges

Economists, policymakers and even many biotechnologists are largely unfamiliar with the legal aspects and practice of seeking and using rights over intellectual property (IP). To set the stage, we lay out below the basics of IP rights from a legal cum economic perspective, highlighting the primary forms used to protect biotechnologies.

Intellectual property rights are rights to products of the mind—ideas and the way they are represented—be they artistic, scientific, technological, or economic products, that may be afforded legal protection. Such things as inventions, computer programs, publications, videotapes, and music are intellectual properties. Intellectual properties can be protected by means of copyrights, trademarks, utility patents, plant breeders’ rights, trade secrets, and other miscellaneous protection schemes. It is important to remember that access to intellectual property is shaped by the interactions among all available forms of intellectual property protection. In this paper, we discuss the most

---

5 See also Graff, Rausser, and Small (2003).
6 Other forms of intellectual property protection, such as design patents, are not dealt with here.
important forms for biotechnologies and technology transfer, namely utility patents, plant breeders’ rights, (including trade secrets and contracts.

Rationales for granting IP rights include stimulation of new innovations, the provision of incentives for disclosure of new knowledge, ethical considerations of entitlement, and the reduction of transaction costs through clarification of rights. Of these rationales, the first two are perhaps the most important. In the absence of IP protection, new ideas and information that are disclosed are entirely in the public domain. Attempts to benefit commercially from an innovation, or at least recoup the necessary investments, may fail due to imitation. Knowing this, prospective inventors may under-invest in R&D or employ and exploit their inventions in secret.

1. Patents

The patent right is generally considered to be the most powerful in the IP system, enabling the patent holder to exclude all others from making, using, selling or offering to sell the invention in the country that granted the patent right, and importing it or products made as a direct result of the invention into that country for as long as the patent remains valid. Over the past few decades, there has been a proliferation of patents emanating from health and agricultural technologies and the sciences that generate these technologies.

A utility patent, often referred to simply as a “patent,” is awarded for inventions of machines, compositions, and processes. Biotechnology patents may claim vectors, genes, proteins, transgenic plants, animal and plant transformation methods, transgenic animals, pharmaceuticals, and the like. For plant breeding materials in particular, protection may be obtained under two significantly different regimes: plant breeders’ rights, and, in some jurisdictions, the regular patent system. Plant breeders’ rights are discussed in the following section.

Utility patents on inventions related to machinery, chemicals, and pharmaceuticals have been around for many years. By mid-2003, 123 countries with their own patent systems were signatories to the Patent Cooperation Treaty administered by the World Intellectual Property Organization (WIPO) headquartered in Geneva. What is comparatively new, however, is the broadening of the scope of the protection to include inventions involving living things. In the United States, the first step in this direction was taken in 1930 with the passage of the Plant Patent Act. In 1980, in the
seminal case *Diamond v. Chakrabarty*, the United States Supreme Court held that such life forms are patentable. Although the bacterium at issue in *Diamond v. Chakrabarty* was never commercialized, this ushered in a new era for utility patenting of life forms. In fact, under the 1994 TRIPS (Trade Related Aspects of Intellectual Property) Agreement, patents are available for any invention, whether products or processes, in all fields of technologies; members are allowed to implement only limited exclusions, including methods of treating humans and plants and animals other than microorganisms.

Thus, a web of proprietary claims now envelop the transfer and use of patented biotechnologies, thereby limiting the freedom to operate of public and private agencies alike. Depending on the complexity of the product, there can be dozens of identifiable proprietary claims involved in its development. Examples of biotechnologies that may be needed for biotechnology research and development, but subject to patents, include:

- Parent germplasm in the form of individual plant varieties;
- Constructs that include trait-specific genes (e.g., genes whose products control tolerance of biotic and abiotic stresses, increased or altered content of starch, oil, amino acids, proteins, vitamins, and minerals, or decreased content of allergens);
- Diagnostic methods and materials used in the methods; and
- Enabling technologies (e.g., gene transformation technologies, promoters that control expression of transgenes, selectable markers to enrich or identify transformed cells, protein purification, and gene silencing or regulating technologies that suppress or modify gene expression).

Even with the web of patent protection, the situation in less-developed countries is not entirely bleak. The patent system itself contains a number of requirements and limitations that affect their scope. In this regard, patent rights have a number of dimensions that are relevant here, including the requirements for obtaining the rights, the scope of what is protected, the geographical limits to the rights, and the duration of the rights. Importantly, these dimensions vary according to the legal and administrative system of each country.
In order to be patentable, an invention must satisfy certain criteria of novelty, non-obviousness, and utility or industrial application as well as be sufficiently clear and adequately described such that persons skilled in the art can practice the invention. While these criteria are dictated by TRIPs, the interpretation and implementation of the criteria are left to each national legislation. The latitude inherent in TRIPs accounts for why in some countries DNA sequences encoding genes are patentable subject matter and in other countries are deemed "discoveries" and as such, unpatentable. Furthermore, the national standards for each of these criteria can result in some patent regimes being more rigorous (e.g., Europe, United States) or laxer (e.g., South Africa). Another factor that contributes to the scope of granted patents is the training of the patent examiners in national patent offices. Recognizing that hiring qualified examiners and training them can be difficult and expensive for many countries, the international patent application system administered by WIPO (World Intellectual Property Organization) is partly designed to assist these countries.\(^7\)

A common misconception is that a patent awarded in one country, for example the United States, confers property rights in the rest of the world. This is not so. There is no such thing as an "international patent." Patents are awarded by national governments, and the intellectual protection conferred by a patent resides only within the national jurisdiction in which the patent is awarded. For example, if an innovation is patented in Australia, but not in China, then anyone is free to use it in China, although importation into Australia of a product embodying or resulting from the patented IP might well be subject to legal challenge in Australia. The nature of patents and the implications of their geographic limitations is pursued in greater detail in Binenbaum et al. (2000).

Moreover, in practical terms, very few patents are awarded in a multitude of countries, and until recently, very few inventions made in developed countries have been protected in developing countries. The cost of obtaining a patent varies from country to country; the cost of obtaining protection in all important markets can be very substantial, as much as hundreds of thousands of U.S. dollars. Thus, most inventions are patented in just one or a few developed countries with large markets;

---

\(^7\) WIPO provides resources and training in particular for developing countries. In addition, for applications that are lodged at WIPO prior to lodgment in national patent offices, an examination of the application and prior art search are performed and available to the national patent offices.
the chance that many of these patents have been awarded in developing countries is small.⁸

Finally, patent rights apply only for a limited period of time. TRIPs specifies a minimum term of 20 years from the date of filing. While the patent term is calculated from the filing date, enforcement rights do not begin until the patent grants, which can be far into the patent term.⁹

2. Plant breeders rights (PBRs)

Under TRIPs, the status of plants as patentable subject matter is both unclear and controversial. Under TRIPs, a country may exclude from patentability “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.” Protection of plant varieties, however, must still be provided “either by patents or by an effective sui generis system or by any combination thereof.”

An example of so-called sui generis rights is plant breeder rights. Plant breeders’ rights are harmonized internationally through the UPOV (International Union for the Protection of New Plant Varieties) Convention, which as of July 2003 has been signed by 53 countries, including most recently Republic of Korea and many of the former Soviet States.

Forms of plant breeders’ rights (PBRs) consistent with UPOV now exist in most, if not all, developed countries, and developing countries are adopting either UPOV standards or other forms of plant variety protection to comply with the requirement of TRIPS. Unfortunately, the implementations of sui generis protection are heterogeneous and institutionally complex (Egelyng 2000).

To be granted a PBR under UPOV an applicant must demonstrate the variety is new, distinct from other varieties, and genetically uniform and stable through successive generations. In contrast to a patent, utility or usefulness is not required for a PBR.

The holders of a plant breeders’ right have a legal monopoly over commercialization of their varieties for a prescribed length of time, allowing the recovery of the cost of

⁸ In 1998, the number of patents granted in the United States, Europe and Japan accounted for about 80 percent of the world’s patents (USPTO 1999).

⁹ The average pendency of a biotechnology-related patent application ranges widely depending on the country and the complexity of the examination process. It is not unusual for a patent application to sit in queue for seven years in Europe until the first examination.
breeding commercially valuable new plant varieties.\textsuperscript{10} Although the details of protection vary from country to country, in general, the sale, reproduction, and importation of new varieties of plants are encompassed. Exceptions may be made, however, for both research and use of seed saved by a farmer for replanting. Moreover, in some countries, if a protected variety is used as the basis for genetic engineering, the engineered variety may not be used without permission (e.g., licensing) of the holder of the plant breeders' right.\textsuperscript{11}

3. Other classical IP mechanisms: Trade secrets, Trademarks and Copyrights

Trade secret laws in the United States have also been used to protect in-house breeding materials such as the inbred lines of maize used as parents of hybrids. However, trade secret law does not provide protection against independent discovery or reverse engineering of products by their purchasers. Hence, patents afford stronger protection than trade secret law for innovation embodied in most products (Besen and Raskind 1991).

Trademarks are used for the protection of certain names of biotechnologies, such as Monsanto’s Roundup Ready\textsuperscript{TM} technology or Aventis’s Liberty\textsuperscript{®} and LibertyLink\textsuperscript{®} technologies. But trademarks protect only names and other symbols denoting products or technologies. They do not protect the technologies themselves. While they do not constitute a major impediment to the freedom to operate, they may be important elements of private commercialization strategies.

Increasingly, bioinformatics databases are important elements of the currently unfolding biotechnology revolution. Hence, copyrights often applicable to databases and software are likely to become increasingly important in the biotech sector. They do not, however, affect trade in products embodying the protected information.

4. Barriers due to IP: Obtaining freedom to operate

There is a tension inherent in IP between its rationale, the provision of incentives for the development and dissemination of new technology, and the freedom to operate.

\textsuperscript{10} See Alston and Venner (2000) for an analysis of the effects on private plant breeding of the 1970 U.S. Plant Variety Protection Act.

The broader the monopoly rights conferred by IP, the larger the potential threat to the freedom to operate of innovators.

Assuming key technology is subject to a valid IPR in the jurisdiction in question, there are, broadly speaking, two kinds of obstacles to the freedom to operate. First, there may be a large number of licenses to be acquired. Moreover, owners of technology may be unwilling to share or license it, or only do so after costly negotiations (discussed in more detail below in the Contracts section). Thus, it may be difficult to obtain essential research inputs. Second, owners of technology may litigate against alleged infringers, forcing the latter to incur the cost of assessed damages, and, in at least some European countries (e.g., United Kingdom), the patentee's legal defense if found to be infringing. In other jurisdictions, including the United States, even a victorious litigant usually has to pay her legal costs. These two kinds of obstacles are often closely connected. Prospective users of technology may have to weigh the risk of litigation against the costs or difficulties of obtaining licenses.

A further difficulty lies in the diversity of innovations utilized in developing biotechnology products, which can result in a balkanization of technologies due to conflict between the many competing parties holding IP rights, be they patents or assigned use rights via commercial contracts or licenses. This balkanization can seriously threaten to hinder subsequent innovation. Furthermore, as patenting becomes even more prevalent in biotechnology, the number of separate rights needed to produce a new innovation proliferates. If ownership of these rights is diffuse and uncertain, the multilateral bargaining problem can become difficult if not impossible to resolve. This is the "tragedy of the anticommons" noted by Heller and Eisenberg (1998).

The tragedy of the anticommons can be seriously compounded by uncertainty. Those who develop new technology, building on existing technologies, often know neither the extent to which the latter have been claimed as IP, nor the strength of any claims. The conduct of R&D and subsequent commercialization entail navigating a potential minefield of patents and determining the actual scope of claims.

The nature of the patent system in the North, and increasingly in the South, makes it important for all involved in commercialization of products to pay close attention to
freedom to operate in order to avoid infringement. Infringement of a patent involves the unauthorized making, using, selling, or offering to sell the patented invention within the territory that granted the patent, or importing the patented invention into that same country during the term of the patent.\(^{12}\) Because the patent right is exclusionary, it is up to the patentee to defend her right. Her first action upon identification of an alleged infringer is typically to inform him of her patent rights, and either offer to negotiate a license, or ask that the infringement cease. If unsatisfied by the response, the patentee can sue for relief in the appropriate court. The patentee may ask the court for an injunction to prevent the continuation of the infringement and may also ask the court for an award of damages. In response, the defendant can raise the question of the validity of the patent, which is then decided by the court.\(^{13}\) The defendant may also argue that what is being done does not constitute infringement, because what the defendant is making does not fall within the language of any of the claims of the patent.

It can be extremely costly to pursue or defend against a claim of infringement. In the United States, where each party pays its own costs (other than in exceptional circumstances), a minimum estimate for litigation is $500,000, and cases often cost each party several million dollars net of any damages awarded.\(^{14}\) Thus, the stakes are high and it behooves a manufacturer to avoid infringement. Unfortunately, as noted above, in health and agricultural biotechnologies, this can be difficult, as the number of patents is rapidly increasing, and the breadth of claims of some patents, the existence of multiple patents with applicable claims, and the slow pace of legal resolution of validity combine to make practice of basic technologies difficult, or at least legally hazardous.

\(^{12}\) Furthermore, TRIPs allows a patent owner to prohibit importation of products made by processes patented in the importing country. Article 28.1(b) of TRIPs Agreement.

\(^{13}\) In Europe, as well as some other countries, the validity of a patent grant can be challenged within the European Patent Office, but only for nine month period after the patent is allowed. This procedure, known as an opposition, is an inter partes proceeding between the patentee and the challenger. The United States patent law does not allow opposition, but instead has a limited reexamination proceeding, which reexamines the patent only with regard to prior art not considered during examination.

\(^{14}\) Lerner (1995, p. 470) reports that for every 100 United States biotechnology patents, there are six patent suits, an extremely high figure relative to other areas of technology. He further estimates that patent litigation in the U.S. Patent Office and the federal courts initiated in the year 1991 lead to total legal expenditures of $1 billion 1991 U.S. dollars, compared with U.S. $3.7 billion spending by firms on basic research in that year. Note that the cost figure excludes litigation in state courts.
5. Strategies to overcome IP barriers and challenges

The concept of freedom to operate is fundamental to the effective development and commercialization of any innovation and is particularly crucial in biotechnology in light of recent developments. Research providers and commercial entities need to be able to conduct their business without infringing on rights held by others. It should never be assumed that a license to use critical enabling technologies would be made available. If a research program or commercialization proceeds under the assumption that its implementation will ultimately be allowed, future negotiations may be placed in serious jeopardy. The negotiating position of the innovator typically deteriorates as innovation progresses.

Knowledge. There is widespread misunderstanding regarding patents and freedom to operate in developing countries. A survey (Cohen et al, 1998) of the use of proprietary biotech research inputs at selected CGIAR Centers showed considerable confusion on the part of researchers regarding the existence of relevant intellectual property rights and freedom to operate. The report itself does not distinguish local validity of patents from existence of patent rights in some jurisdiction. As emphasized above, patents are valid only in countries in which they are issued.

Many current key technologies for plant breeding and pharmaceuticals appear to be unprotected in developing countries. For example, the key Agrobacterium technology for plant transformation is held in different implementations by numerous patents applied for, and patents awarded in developed country jurisdictions (United States, Europe, Australia, Canada, and Japan) to Monsanto, the Max Planck Institute, AstraZeneca/Mogen, Novartis, Japan Tobacco, and many others. The most widely used selectable markers for cereal transformation, controlled by Aventis/AgrEvo, Monsanto and Novartis, are patented or pending in Australia, Canada, Europe, the United States, Hungary, Ireland, Russia, Japan, Israel, Greece, and Denmark. Other key technologies show similar patterns, that is, patent protection in mainly (or only) developed countries. Thus, there are no IP restrictions in less-developed countries on the use of these commonly employed technologies.

The challenges then for R&D and commercialization by developing countries do not appear to be mainly patents, as long as the products are not geared for export to

\[\text{The filings were made in 1982-83 when neither Greece nor Denmark was part of the European Patent Office.}\]
countries where there is patent protection. Health products are not likely to be exported back to developed countries\textsuperscript{16}, and for agricultural products export is not currently a major inhibiting factor.

**Obtaining rights.** The willingness of owners of agricultural technology to cede use rights, or the minimum price at which they are willing to sell the rights to others is shaped, among other things, by the location and structure of crop production and, particularly, the pattern of trade. There are two, often overlapping, sets of circumstances under which the freedom to operate in agricultural research may not be under serious threat.

First, proprietary technologies that are targeted at commercially unattractive markets may be transferred free of charge. Crops grown for subsistence use in developing countries are clearly of little commercial interest to developed-country multinational companies. In addition, technologies used in crops that are sold primarily to poor consumers in developing countries may not be of much commercial interest to multinationals. Thus, a grant of technologies owned by these multinationals to develop crops growing in those circumstances is, with some caveats, a realistic possibility. In fact, multinationals have, in several prominent cases, donated technologies to nonprofit agricultural research agencies working on behalf of poor farmers in the developing world. Public-relations considerations are likely to play an important role in such cases. Sometimes, more complex market segmentation deals are announced, in which commercially viable uses of the technology are separated from uses that are of humanitarian rather than commercial value.

A well-publicized example of such a complex arrangement is the *GoldenRice*\textsuperscript{TM} Vitamin A Rice Project in which AstraZeneca cooperated with nonprofit organizations to put nutritionally enhanced golden rice seeds containing a gene owned by AstraZeneca in the hands of poor farmers at no charge. *GoldenRice*\textsuperscript{TM} contains enhanced levels of provitamin A in the endosperm of the seed (which remains after the rice is polished), which is potentially of great health benefits to millions of poor farmers and consumers in developing countries. AstraZeneca has acquired the commercial rights to *GoldenRice*\textsuperscript{TM} from Greenovations, a small German company

\textsuperscript{16} The dilemma of parallel importation or export from a country with pharmaceutical manufacturing capabilities to those without such capability was raised at the Doha meeting of the WTO in 1999. The issue has been satisfactorily resolved in the last year and is discussed in more detail below.
acting as an intermediary for the inventors. In return, AstraZeneca has licensed the inventors to enable distribution of the rice on a royalty-free basis to farmers who earn less than $10,000 per year and live in developing countries, leaving the company free to explore commercial prospects for the technology (Tait and Wrong 2000). In addition, Monsanto announced its intent to provide royalty-free licenses for all its technologies that support the further development of GoldenRice™ (Monsanto 2000), and other IP holders have followed suit.

Second, anyone is free to use technologies and know-how in crops that are developed, produced, and consumed in countries where the technology is not subject to local IP protection, irrespective of whether the crop is grown on a subsistence or commercial basis and whether the technology is subject to IP protection in other jurisdictions. This fact appears to be overlooked in discussion of the GoldenRice™ example and makes it difficult to know exactly what is being “donated” in prominent cases. According to Kryder et al. (2000), there are 70 patents associated with this technology, including both process patents (relevant to creation of the technology) and product patents (embodied in the rice itself). This case has been quoted as posing a nightmare with respect to freedom to operate, and so the Monsanto and AstraZeneca donations generated a grateful response. But what did poor rice consumers gain from the donations? Table 1 shows the top 15 importers, and the number of Vitamin A rice technology patents valid in each. It is clear that for most of the developing countries in the list few or no patents associated with Vitamin A rice are valid in each. And these numbers are overestimates. Some of the patents may not cover the application to Vitamin A rice, and others may be later invalidated.
Table 2: Vitamin A Rice Patents in Rice-Producing and Rice Importing Countries

<table>
<thead>
<tr>
<th>Top 15 Rice-Producing Countries</th>
<th>Number of Patents</th>
<th>Top 15 Rice-Importing Countries</th>
<th>Number of Patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>11</td>
<td>Iran</td>
<td>0</td>
</tr>
<tr>
<td>India</td>
<td>5</td>
<td>Brazil</td>
<td>10</td>
</tr>
<tr>
<td>Indonesia</td>
<td>6</td>
<td>Nigeria</td>
<td>0</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>0</td>
<td>The Philippines</td>
<td>1</td>
</tr>
<tr>
<td>Vietnam</td>
<td>9</td>
<td>Iraq</td>
<td>0</td>
</tr>
<tr>
<td>Thailand</td>
<td>0</td>
<td>Saudi Arabia</td>
<td>0</td>
</tr>
<tr>
<td>Myanmar</td>
<td>0</td>
<td>Malaysia</td>
<td>0</td>
</tr>
<tr>
<td>Japan</td>
<td>21</td>
<td>South Africa</td>
<td>5</td>
</tr>
<tr>
<td>The Philippines</td>
<td>1</td>
<td>Japan</td>
<td>21</td>
</tr>
<tr>
<td>Brazil</td>
<td>10</td>
<td>Côte D’Ivoire</td>
<td>10</td>
</tr>
<tr>
<td>United States</td>
<td>44</td>
<td>Senegal</td>
<td>10</td>
</tr>
<tr>
<td>South Korea</td>
<td>10</td>
<td>United Kingdom</td>
<td>35</td>
</tr>
<tr>
<td>Pakistan</td>
<td>0</td>
<td>France</td>
<td>37</td>
</tr>
<tr>
<td>Egypt</td>
<td>0</td>
<td>Indonesia</td>
<td>6</td>
</tr>
<tr>
<td>Nepal</td>
<td>0</td>
<td>United States</td>
<td>44</td>
</tr>
</tbody>
</table>

Assuming Table 2 is correct, importation of Vitamin A rice into Iran from Bangladesh infringes no patents. Crops that are traded among countries in which the technologies are not subject to IP are not liable to claims based on the use of these technologies. But importers of Bangladeshi Vitamin A rice into Japan might be subject to successful prosecution for infringement of claims to any embodied material covered by Japanese patent claims. This could be so even if technologies are unencumbered by IP in Bangladesh.

Specific technologies may have IP protection in some developing countries (like Brazil, China, and Argentina) but not in others. The details would need to be considered on a case-by-case basis. Identification of those countries in which IP has been assigned for a specific technology is an essential task in delineation of traders’ freedom to operate. It is also important to keep in mind the large number of relevant technologies that are typically involved in breeding a modern crop cultivar, as the Vitamin A rice example illustrates.

Thus, in general, developing-world crop breeders have freedom to operate with respect to crops produced in developing countries unencumbered by local IP
protection of relevant inputs, processes, or products, and which, in addition, do not constitute infringing imports into countries in which IP protection prevails. IP problems might arise in technologies destined for crops grown in developing countries unencumbered by IP restrictions if those crops are subsequently exported in a form in which infringement is detectable to countries in which IP is likely to prevail. Note that in such cases it is the importer, not the breeder, who may be infringing on IP.

**Assessing risks.** Due to consumer resistance to agricultural biotechnology, the degree of which varies considerably among different countries, public relations are a serious issue for multinationals active in the field. For instance, a multinational may be reluctant to litigate against a nonprofit research agency for fear of damage to its public image and to its relations with governments and lawmakers of developing countries. In particular, multinationals will try to avoid being seen as obstacles to applications of technologies that benefit poor farmers and consumers. However, it would be a serious mistake to rely on such forbearance as a matter of policy, as implied by RAFI (2000, p. 31). If the stakes are high enough, multinationals have been willing to incur a good deal of opprobrium in enforcing their intellectual property rights against farmers in Canada and the United States. Moreover, owners of IPR include specialized smaller companies that have no reputation or goodwill to protect, and the need for cash that motivates them to protect their IPR wherever infringement occurs. The Enola bean and Texmati rice U.S. patent controversies are instructive here.

Jurisdictions also differ in the extent to which their laws are actually implemented. Knowledge of a country’s IP and biosafety laws is necessary for assessing the local freedom to operate, but may not be sufficient. In addition to the possibility of the official law being implemented imperfectly, or not at all, one must beware of *de facto* rules that are not officially codified as law.

There is widespread apprehension that ignoring the rights of intellectual property holders, even in jurisdictions where they are not valid, could, in at least some cases, incur significant costs, such as loss of fruitful collaborations with the same entities in other areas, and possible loss of support from developed-country donors. However, when private firms are assessing freedom to operate, they ordinarily ignore patents where they are not legally valid in a given jurisdiction, and expect their competitors to
do likewise. Donors should not try to bully nonprofit researchers into respecting claims that would be considered irrelevant in the private sector, nor should researchers feel legally or morally obligated to enter into such agreements. On the other hand, researchers should understand that a cost of using processes or products covered by patents in OECD countries is that none of the relevant innovation, including testing and evaluation, can be conducted where the patents are valid. Thus some of the benefits of research collaboration with agencies located in OECD countries will be foreclosed. In addition, users of biotechnology innovations or products incorporating such biotechnology might export to countries where patents on the innovations are valid. In practice, such South-North trade is not very important for most staple food crops, as demonstrated via analysis of bilateral trade data in Binenbaum et al. (2000).

**Researching existing patents.** The basics and not-so-basics of intellectual property are generally not very well understood by the general public, although the consequences of intellectual property can be far-reaching. In particular, the scientific research community is becoming more involved in intellectual property activities but often without concurrent instruction. When contemplating commercialization, proactive strategy to ensure freedom-to-operate is very wise.

Thus, in order to use intellectual property for benefit, it is imperative that professionals in biotechnology understand patents and their limitations, at least at a basic level, be competent to access patent information from available databases, and the like. Such skills are becoming increasingly important and heretofore have resided in the domain of IP lawyers or other legally-trained individuals.

A promising initiative to provide intellectual property information services for third-world research organizations is being pursued by the nonprofit corporation CAMBIA in Australia (discussed also below). The aim is to develop interactive software that can help researchers to identify prior patent claims and identify areas of freedom to operate and thus travel more safely through the international patent minefield. This type of initiative requires access to personnel with wide experience in international patenting and patent negotiations. Such expertise is quite expensive. If adequately funded on a continuing basis, it could make further international collaboration more
B. Genetic barriers, challenges, and strategies

Some genetic technologies impose technical limits on farmers’ use of seeds from their harvest to replant or to sell for replanting. The most common is production of hybrid crops that generally have a lower yield through loss of “hybrid vigor” if replanted. Modern alternatives include genetic use restriction technologies (GURT) that confer sterility on replanted seeds and are called varietal GURT—popularly dubbed terminator technologies—or that control the expression of specific traits in seeds, called trait-GURT (CBD/SBSTTA 1999).

With regard to strategy for overcoming genetic barriers, there is little to be done except to decide if the technology is valuable enough to adopt. In particular, this decision does not have to be made in the near-future as commercialization of GURT is currently non-existent.

C. Contractual barrier, challenges and strategies

In addition to the legal protection afforded by patents, plant breeders’ rights, trademarks, and so on, contractual provisions may be used to extend or establish IP rights, such as providing reagents under a restrictive technology transfer agreement. In our opinion, such contracts pose a greater barrier for all R&D than does IP (regardless of whether the user is located in a developed or developing country). The reason stems from the different way that law treats intellectual property rights and contracts. First, intellectual property rights are carefully circumscribed by law and have been harmonized between countries by TRIPs. IP rights are highly limited in a number of ways: geographically, time-wise, enforcement, and remedies. In contrast, contracts are treated as negotiated agreements between individuals and therefore, any

17 For the CGIAR (as well as agencies in developing countries heavily reliant on donor funding), a possible drawback of this strategy is that one motivation for developed-country donor support might be prospective spin-offs of research for farmers in their own countries (Tribe 1991). These have been shown to be very valuable for the United States, Australia, and Canada in wheat and rice (Brennan and Fox 1995; Pardey et al. 1996; Thomas 1996). To the extent that CGIAR technology is subject to intellectual property rights in such countries, the technologies will not be available locally without appropriate licensing. Although such licensing might still leave them with a major share of the benefits, it could decrease the enthusiasm of developed-country donors (especially those that are not home to holders of strong IPR in this area) for such a strategy.
limitations are prescribed by the individuals and rarely by statutes. Moreover, the
subject matter of a contract concerning technology can be any aspect of the
technology (e.g., materials, know-how), whether or not it is protected by patent,
trademark, or other legal protection. By the use of contracts, a party that has the
technology can control its dissemination and its use by those receiving the
technology.

Examples of contracts include: *material transfer agreements* between technology
developers and third-parties, which limit the transfer and use of materials such as
vectors, genes, and plants developed by the transferor; *bag label contracts* between
the manufacturer and the buyer of, for example, seed, which limit further uses of
purchased material that would otherwise be allowable; *technology use agreements*
in agriculture between technology suppliers and users, which typically control the
right to plant a given seed on a specific area of land for a certain period of time; and
*licenses* between patent or property holder and licensee, which are negotiated grants
of some or all of the holder’s rights, such as field of use, research, commercialization,
time, geography or a combination of these rights.

*Material transfer agreements* (MTAs) can at times be the most onerous of contracts.
They are one of the most often used contracts in scientific research. In our
experience, many transfers of materials are accompanied by a letter or more formal
contract that puts forth requirements and limitations of use. Some MTAs have
minimal limitations: use according to existing safety laws and do not transfer to third
parties. Too often, the sender inserts clauses prohibiting any use of the material for
commercialization or requires royalties to be paid. This probably reflects the over-
valuation of each scientist’s contribution. In some cases, the material is not subject to
any formal IP rights and may not even have originated with the sender. Due to the
relaxed atmosphere in many science organizations, the MTAs are written and signed
by scientists without consultation by officers of the organization. It is dubious
whether a scientist, as an employee, has the authority to execute an MTA. In our
organizations, we always request that an officer of the company or university sign the
MTA as well as the scientist receiving the material.

---

18 Similarly, the seller of other materials used in biotechnologies may impose restrictions on their use
by mechanisms such as license agreements enclosed with the material. These licenses are not
negotiated and, contrary to the belief of many, are typically enforceable. In the computer industry,
they are known as “shrink-wrap” licenses.
It is possible to negotiate MTAs. If an MTA has one or more onerous provisions, we contact the organization and request that it be changed. Another strategy is to send your own MTA when requesting material. Generally the author of a contract has the advantage.

"Shrink-wrap" licenses such as "bag label" contracts, licenses that accompany purchased materials, and the like, are similar in nature to MTAs. The licenses contain provisions that limit use of the material and in the case of plants, there may be provisions that limit saving seed for re-planting. The validity and enforceability of shrink-wrap licenses have been upheld, at least in the United States. As these licenses usually have a clause dictating what jurisdiction rules the interpretation of the license, the purchaser of the material is sure to find herself in a jurisdiction favorable to the seller.

The main recourse for a buyer of shrink-wrapped material is to not purchase the material if the license provisions are unacceptable. The buyer can also attempt to negotiate a more favorable license. Depending on the seller, this may be a successful strategy. Without a thorough knowledge of local law, it is unwise, however, to rely on the often-heard adage that such contracts cannot be enforced. While it may be true in some isolated cases, it is a poor strategy to pursue when the material is important to commercialization of a product.

Research only licenses might be attractive for scientists, as it allows them to pursue their intellectual interests using state-of-the-art technology. The U.S. National Institutes of Health (NIH) urges provision of such licenses gratis, and indeed such licenses are often freely available. Furthermore, a research license might generate externalities to the licensee in the form of learning-by-doing, and more generally, the development of intangible research capacities that might reduce future dependence on proprietary technology.

However, a free research license that does not permit commercialization can make a research tool the "cuckoo's egg" of technology transfer. If the project succeeds, then the bargaining for permission to commercialize (or release to users at no cost) the fruits of the research effort must begin. The fact that the researchers have already incurred the "sunk cost" of all the research expenditures places them in a highly disadvantageous bargaining position. For instance, the Centre for Legumes in
Mediterranean Agriculture (CLIMA) in Australia developed a transgenic lupin cultivar with tolerance to the herbicide Basta,® but have been unable to reach agreement with AgrEvo (now Aventis) to commercially release the plant (Ewing 2000). On the other hand, the holder of the intellectual property right, even if it refuses to allow commercialization, gains information about the technology and its downstream applications that it can use for its own purposes. In the extreme, the license holder might be able to appropriate for itself the full value of the research output of the licensee, gross of the latter’s costs.

**General strategies.** Some aspects of strategy transcend all the above-discussed contractual barriers. It has been mentioned that negotiation is one avenue to meet contractual challenges and shape the effects of the contract. Negotiation, however, is a skill, and the outcome of a negotiation depends in part upon the relative sophistication of the parties, their relative bargaining strength, and their relative experiences. Any disparities between parties can be reduced by preparation and knowledge. Thus, we recommend training, consultation with professional negotiators, obtaining information from any of a number of web sites that provide guidance on ‘best practices’ for developing country concerns, and arming oneself with at least a basic knowledge of contract law and the rights that arise under contracts. Other preparations can also increase success; for example, an understanding of how the culture of all parties can be addressed will likely lead to a more agreeable and clear outcome.

**D. Regulatory barriers and challenges**

In addition to IP laws, an array of other factors affect biotechnology transfer. Some of these factors are biosafety regulations, public relations, and public perception. Biosafety regulations are closely related to IP in biotechnology. In particular, in some countries official approval is required for the use, sale, and/or importation of transgenic crop or animal varieties. Just like IP or any other laws, biosafety regulations are primarily national in nature, while being affected by international treaties.¹⁹

Due to consumer resistance to agricultural biotechnology, the degree of which varies considerably among different countries, public relations are a serious issue for

---

¹⁹ Such as the Biosafety Protocol, agreed upon in Montreal in January 2000.
multinationals active in the field. For instance, a multinational may be reluctant to litigate against a nonprofit research agency for fear of damage to its public image and to its relations with governments and lawmakers of developing countries. In particular, multinationals will try to avoid being seen as obstacles to applications of technologies that benefit poor farmers and consumers. However, it would be a serious mistake to rely on such forbearance as a matter of policy, as implied by RAFl (2000, p. 31). If the stakes are high enough, multinationals have been willing to incur a good deal of opprobrium in enforcing their intellectual property rights against farmers in Canada and the United States. Moreover, owners of IPR include specialized smaller companies that have no reputation or goodwill to protect, and the need for cash that motivates them to protect their IPR wherever infringement occurs. The Enola bean and Texmati rice U.S. patent controversies are instructive here.

Furthermore, biosafety concerns and public perception of biosafety may limit companies willingness to license technology. Understandably, because many of the companies holding key technologies have ‘deep pockets’, there is a fear of being dragged into litigation if biosafety or the regulations are compromised.

**E. Is access to technologies the binding constraint?**

The short answer is ... only partly. As presented in the first part of this paper, investment into R&D is very poor in most developing countries. When research capabilities are limited, transfer of technology may not always reach its maximal effect.

With respect to intellectual property, for the near term, research agencies in LDCs are likely to have considerable freedom to operate, if they operate judiciously. Retroactive patenting being impossible, most of the technology useable in LDCs over the next half-decade or so is likely to be unencumbered by relevant intellectual property rights. But it would be hazardous to assume general freedom to operate; mistakes could result in catastrophic legal liability. To reliably implement a strategy of obtaining intellectual property only where necessary, those who make research commitments must have access to adequate information on patent rights, and to expert legal counsel. Such access is not widely available at present on an international basis, and does not exist for most LDC researchers and research institutions.
The other side of intellectual property limitation is that when IP regimes are weak, foreign or even local investment is reduced. Much has been written about the inverse correlation and promoting the benefits of strong IP systems. (see, for example, McCalman 2002, and Irdis 2003.)

III. International treaties and regulatory mechanisms in relation to technology transfer

It is vitally important to keep in mind that there is no such thing as an “international intellectual property right.” A patent or other IP right awarded in one country, for example the United States, does not confer property rights in the rest of the world. International treaties and organizations do, however, play an important role in IP rights. The primary purposes of international treaties on IP are to facilitate obtaining protection in multiple countries and to provide a uniform, minimal set of laws and standards in subscribing countries. Through treaties, countries may commit themselves to future changes in their laws and possible deadlines for implementing those changes.

International treaties on IP date back to the 19th century. The Paris Convention (1883) for the Protection of Industrial Property, which covers trademarks, patents, and trade secrets, and the Berne Convention (1886) for the Protection of Literary and Artistic Works, which covers copyrights, are still relevant to IP, although both have been revised and supplemented by later treaties. These treaties are now administered by the World Intellectual Property Organization (WIPO), a specialized agency of the United Nations. The International Convention for the Protection of New Varieties of Plants (known as the “UPOV Convention,” after a French acronym) of 1961 (revised in 1978 and 1991); the European Patent Convention (1977); the Patent Cooperation Treaty (1978), supplemented by the Patent Law Treaty (2000); the Convention on Biological Diversity (Biodiversity Convention, 1992), and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs 1994).

The Patent Cooperation Treaty (PCT) is a special agreement under the Paris Convention among some 108 members of the Convention. The Paris Convention

---


21 While the focus here is on patents and plant breeders’ rights, we are mindful that international treaties, especially for copyrights, can bind parties to granting “full faith and credit” to the rights holder of another member country, thus in effect providing international protection.
provides for the equal treatment toward nationals among member states with respect
to patent rights. The PCT permits an applicant to make a single filing of a patent
specification within 12 months of an initial filing in a national patent office. The
applicant then has up to 30 months from the initial national application to file in
designated countries according to their national procedures and criteria for granting or
rejecting a patent. At the time of conversion, filing fees must be paid in each
country. In summary, the PCT facilitates lodging of patent applications in multiple
countries, but does not furnish an international patent. Recently, member states of the
World Intellectual Property Organization have adopted by consensus an international
treaty that will simplify and streamline procedures for obtaining and maintaining a
patent. The Patent Law Treaty (PLT), which has been opened for signature, will enter
into force once ten countries have ratified it. The PLT achieves a major goal of
international simplification by incorporating the requirements for PCT international
applications into national and regional laws. Thus, under the PLT, the requirements
and procedures for national and regional patent applications, and those for PCT
international applications, will be harmonized. This will eventually lead to
standardized formal requirements and streamlined procedures for all patent
applications worldwide.

The Convention on Biological Diversity (CBD) also contains some provisions on IP
rights, although the main aims of the CBD are conservation of biological diversity,
sustainable use of its components, and the fair and equitable sharing of the benefits
arising out of the utilization of genetic resources. In particular, Article 16(5)
recognizes that intellectual property rights may have an influence on the
implementation of the CBD and further obliges member states to cooperate in order to
ensure that IP rights are "supportive of and do not run counter to" the objectives of
the CBD. So that Parties can gain access to technology, member states must take
appropriate measures, which furthermore are consistent with international law and are

---

22 Patents cannot be sought retroactively; at the critical time-points rights must be pursued. Thus, in
the PCT process, countries in which an applicant might seek protection must be explicitly designated
at the time of PCT application. Likewise, application to a country not party to the PCT but party to
the Paris Convention must be made within 12 months of the initial national filing.


mutually agreed upon.\textsuperscript{25} Essentially, the CBD preserves the rights of intellectual property owners as they are defined in international law, such as TRIPs.

Although aspects of IP protection may vary among countries, the TRIPs Agreement sets out minimum standards that each country belonging to the World Trade Organization (WTO) must implement. These standards have been discussed above. One of the most critical provisions, Article 27(1) of TRIPs, requires member states (about three-quarters of the world’s countries) to allow patents for any inventions, “whether products or processes, in all fields of technology.” While this Article settled the long-standing conflicts over pharmaceutical product patents, Article 27 has created new complications regarding protection for biological matter and agricultural biotechnology in particular. The complications arise from the vagueness of Article 27(1) and exceptions to patentability allowed under Articles 27(2) and (3).

Because TRIPs does not define the term “invention,” countries can determine that biological matter, such as genes, are merely a “discovery” and not an invention. Indeed, some countries are implementing legislation along these lines.\textsuperscript{26} In addition, exceptions are allowed in order to protect order public; human, animal and plant life; and avoid serious harm to the environment.

More importantly, Article 27(3)(b) allows members to exclude from patentability “plants and animals other than micro-organisms as well as essentially biological processes for their production”. The breadth of this exception is hotly debated, and the Article is under review by WTO member states. Thus, there is much uncertainty about what biological matter can be excluded. Although members are not required to allow plants to be patented, they must nevertheless provide protection of plant varieties, either by patents or by an “effective sui generis system” or by combination of both systems. This is a major change for most developing countries, which previously did not provide protection for plant varieties.

Much has been written about what constitutes an effective sui generis system and the latitude that countries have in determining the scope and content of the rights to be granted (see, for example, Leskien and Flitner 1997). Such a discussion is beyond the

\textsuperscript{25} Article 16(3) and 16(4).

\textsuperscript{26} Decision 486, Article 15, promulgated by the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) deems that biological material that exists in nature or can be isolated from any life form is not an invention (Commission of the Andean Community 2000).
scope of this paper. Suffice it to say that while plant protection systems are relatively well established in developed countries, lesser-developed countries are currently struggling with how to comply with this provision of TRIPs. Because developing countries are unlikely to implement patent protection for plants, there will likely be a great deal of variability in rights accorded in each country.

A number of countries, mostly developed countries however, have subscribed to a particular *sui generis* system, the International Convention for the Protection of New Varieties of Plants (UPOV). The rights accorded under UPOV extend not only to the plants but also to plant parts, harvested materials, and “essentially derived varieties.” Moreover, in the 1991 Act, the “farmers’ exemption” that allows farmers to save seed for re-propagation is not required to be implemented by member states, but may be established.

Furthermore, the TRIPs agreement includes a requirement to enhance technology transfer to less developed countries. In Article 66.2, the agreement requires that developed countries provide incentives to their organizations to promote technology transfer. Unfortunately, it appears that this article has not been actively turned into action. In part, it may be due to the lack of specific guidelines and suggestions or the lack of consequences for countries that fail to implement it.

In an effort to ensure compliance with Article 66.2, the TRIPs Council is mandated to develop mechanisms for implementing the requirements. In Doha, at the TRIPs Council meeting, a reporting mechanism was established. The first reports were due from developed countries by the end of 2002. The types of incentives that might be implemented and acceptable include: improving intellectual property rights themselves; and foreign direct investment, which appears to be directly related to the strength of IP in the receiving country (McCalman 2002). Although the relationship between IP and technology transfer is complex, companies seem to be reluctant to invest in technology transfer in a developing country without a strong IP system.

**IV. Mechanisms to facilitate access to technologies**

In this section we explore some mechanisms that may be used to facilitate access to biotechnologies. No one of these mechanisms will always be appropriate; it is important to assess the particular situation and options available.

---

In particular, the mechanisms discussed exclude those that require government intervention, such as strengthening the intellectual property regime of the country or centralizing technology transfer offices or ensuring a suitable regulatory environment. Certainly, changes in national policies may need to be implemented and much has been written about these needs (see, McCalman 2002; Irdis 2003). The brevity of this paper, however, demands a focus, and we have chosen to focus on actions that can be implemented on an individual or private basis.

A. Cross licensing

This is a popular solution for deals among biotech oligopolists. Australia is typical and instructive. “We discovered that research capacity alone was not enough. Research concepts and unpublished data were sometimes interesting for our Industry Associates, but developing collaborative projects based on them was difficult. The breakthrough came when the CRC for Plant Science started to take out patents. Patents are property; property is valuable (or so prevailing wisdom then suggested), and therefore it can be traded. It was as if we had suddenly, almost magically, acquired a stack of chips and could get our feet under the card table. It was then that the tactic of progressive engagement started to pay off” (Buller and Taylor 1999).

In universities, cross licensing is often precluded by the nature of contracts for compensation of university innovators. In contrast to most U.S. corporations, U.S. universities generally have established rules that grant a substantial share of licensing revenues to their employees who patent valuable innovations and other universities in other OECD countries are following their lead. Many other public and nonprofit institutions have similar rules. (See, for example, Phillips and Gustafson 2000, table 13 p. 72, for a dramatic contrast between for-profit and public biotech research institutions in Saskatchewan, Canada.)

Some CGIAR centers have entered into contractual arrangements with other agencies, but the number and nature of those contracts is unknown at present. In any case, at CG centers, licensing would have to be restricted to property other than landraces and other plant varieties designated as “in trust” material under a 1994 agreement with the United Nation’s FAO, which they are committed to make available to the world at

---

28 Normile (1998) describes changes in Japanese patent law that increase the possible rewards for university inventors and relax the grace period for publication.
large. Through an MTA, recipients of in-trust material agree not to seek intellectual property protection on that material but may seek protection for derivatives.

Despite these severe constraints, candidates for cross-licensing have already been nominated. The near-isogenic lines of rice germplasm developed at the International Rice Research Institute (IRRI) headquartered in the Philippines, potentially useful in plant breeding, are examples of technology that might be licensed via an MTA or other contractual agreement. If the above example leads to successful cross licensing, it is likely to be the exception that proves the rule. The number and value of intellectual property chips held by most public agencies operating in or for LDCs (and particularly those operating in the poorer parts of the developing world) that might provide a basis for bargaining with the private sector is often overstated. For example, in 1998 the CG Centers collectively spent an estimated $25 million on biotechnology research (Morris and Hoisington 2000) and held few patents (probably less than 10 in total, and most unrelated to biotechnologies nor granted in developed-country jurisdictions). Contrast this with Monsanto who spent $1,263 million on R&D that same year (Security and Exchange Commission 1998) and was granted a total of 437 patents during the five years 1994-1998. Moreover, the 650,000 accessions of crop and tree species conserved in the CG's 11 genebanks do not constitute the set of bargaining chips or negotiating assets that Byerlee and Fisher (2001) and others seem to suggest.

For public research organizations that are acting independently, cross licensing tends to be much more a part of the problem than of the solution. As the biotech industry matures, it is becoming like many other industries where each major participant “holds an IP portfolio, much of which is regularly infringed by competitors. But none...usually brings suit...because each knows that the defendant would respond with a counterattack based on those of the defendant’s patents that it is infringing. Litigation is too much like a nuclear weapon, and the relation becomes one of mutual assured destruction...But...there is no reason not to use the portfolio against possible new entrants who might affect the oligopoly rents available to the industry leaders” (Barton 2000, p.8). Public or nonprofit researchers might well find themselves, like potential private entrants, shut out by the oligopoly defended by cross-licensing agreements.
B. Market segmentation strategies

Before discussion of this strategy in detail, it is crucial to emphasize that this is not a passive strategy. Rather, it entails devotion of substantial high-quality resources for successful implementation.

Markets for intellectual property can also be segregated on grounds other than geography. With technology licenses, common segmentation strategies include delineating fields of use (e.g., including or excluding particular crops), length of time (e.g., renewable term or end of patent life), certain claims of a patent, limitations to specific uses of the technology, research use versus commercialization, or restrictions on third-party services. Another option is to charge license fees based on an ability to pay or expectation of the profit streams and thus distinguishing between commercial or non-commercial uses, and small startup entities (be they in LDCs or developed countries) versus large national or multinational corporations.

Lanjouw (2001) has developed a creative initiative for market segmentation of pharmaceuticals (such as drugs for global diseases like cancer of heart disease) with large potential markets in both developed and less developed countries. By her proposal, (discussed in Phillips 2001, Mallaby 2001) patent applicants in, for example, the United States would have to commit not to enforce their patents in a designated list of developing countries when they apply for a “foreign filing license” with the United States Patent and Trade Mark Office. This license is a routine requirement for filing in other countries. Producers would effectively be asked to choose between enforcing their patents in developed countries or developing countries but not both. The incentive to develop drugs for diseases that are specific to developing countries such as anti-malarial drugs would not be greatly affected. In developed countries, this initiative would require only an amendment to national patent legislation; no amendment of international agreements is needed. It would be highly desirable if plant biotechnology could be included in this initiative.

C. Cost-free licensing of technologies

For many crops other than wheat, maize, some kinds of rice, soybeans, and barley, private (and public) intellectual property rights holders might be persuaded to allow IARCs, and public research agencies in developing countries, to develop proprietary biotechnology for use by farmers without any direct compensation. This could be
true where there is obviously little risk to the significant commercial markets that are the focus of the intellectual property rights holders’ hopes for profits. Staple crops for poor consumers have low income elasticities of demand, and most will never have large commercial markets even if poor consumers’ incomes increase. As consumers gain wealth, they will substitute more desirable foods, including wheat and meat.

Already, there are well-publicized cases of provision of technology without charge in these non-commercial crops, including several under the auspices of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA). Monsanto Corporation has made its technology available to achieve virus resistance in several non-commercial potato cultivars popular among the poor in Mexico (Qaim 1998). It has also supported the incorporation of virus resistance technology in yams in Africa. AstraZeneca (now Syngenta) and Monsanto have announced they will make technology for the Vitamin A rice, currently under development, available gratis for subsistence farmers (specifically, those earning less than $10,000 per year from farming) in developing countries (Trait 2000). Such collaborations might become increasingly attractive to corporations if international opposition to corporations that market transgenic seeds continues to grow. Technology that helps solve nutritional deficiencies or addresses health problems of poor consumers could generate especially desirable publicity. To encourage private sector participation, it might be very important that ways be found to protect the commercial provider from blame, loss of reputation, or liability for misuse of their technology, hazards that might seem especially serious in countries lacking effective regulatory oversight of technology testing and use in farmers fields.

On the other hand, it is possible that the publicity surrounding recent technology “donations” could lead to an unduly sanguine assessment of corporate generosity with respect to their intellectual property rights.29 In the cases referenced above, it seems that few if any relevant and valid patents were involved. For example, even though 70 patents were identified by Kryder, Kowalski, and Krattiger (2000) as relevant to Vitamin A rice technology, the authors report that none is valid in Bangladesh, Thailand, Myanmar, Iran, Nigeria, Iraq, Saudi Arabia, or Malaysia. Though some of

---

29 See, for example, RAFT’s assertion that “A public appeal to the company to make its technology available to the poor will get an immediately favourable (if begrudging) response from every Gene Giant wanting to be “Mr. Nice Guy” in the media.” (2000, p. 31)
the patents are valid in the United States (44 patents) and Japan (21), and some
developing countries such as China (11), Indonesia (6), India (5), Vietnam (9), and
the Philippines (1), many (26 of the total of 70) are methods patents that apply only to
conduct of research activities as distinct from composition of matter patents that
restrict production, sale, or importation of the transformed seed.

Of course, even if proprietary technology is made available, public agencies must in
turn assess the appropriateness of the technology for their organizations. For
example, the CGIAR decided against adoption of "terminator" technology that
prevents seed saving for re-planting (CGIAR Secretariat 1998, p.53). Whether this
was a judicious decision—beyond its political benefits—for LDCs is less obvious
than many assumed (Srinivasan and Thirtle 2000). Monsanto abandoned
commercialization of the technology in October 1999 (Kaiser 1999), though neither
its erstwhile takeover target, Delta and Pine Land Corporation, nor the United States
Department of Agriculture, seems to have followed its lead.

**D. Direct programmatic research support from the private sector**

Rather than cooperate in the piecemeal technology transfer described above, for-profit
corporations might be persuaded to give more general support to collaboration with
public research. Important examples of such support on the part of corporations with
significant market power have already been observed. In the genomics field, a
consortium of corporations has supported creation of a public database of genome
markers called single-nucleotide polymorphisms (SNPs), in preference to partaking in
a competing private-sector initiative (Marshall 1998a). The motivation for this type
of expenditure, which does not appear to be conditioned on any claim to property
rights, is not clear. But it indicates that the private firms might, on occasion, choose
to support public over private research initiatives in areas complementary to their own
endeavors.

Another example (discussed in a different context above) is the involvement of a
foundation funded by the multinational life science corporation, Novartis, in the
support of plant biology research at the College of Natural Resources at the
University of California, Berkeley (Rausser 1999). This support is conditioned on the
right to be the first to negotiate the rights (as distinct from right of first refusal of
licenses) to innovations arising out of research in plant biology that is supported by
the donor, and the donor also has rights to appoint a minority of the board that directs research funded by the Foundation (Mena and Sanders 1998). But despite prominent expressions of concern the conditions seem surprisingly mild, given the significant commitment (five years at $5 million per year), and in particular much less stringent than appears in typical private-sector contracts with individual researchers. For example, in the agreement, the Novartis Foundation gets rights to first negotiation for only a portion of the patentable discoveries and does not control the research done with its support. Knowledgeable observers conjecture that a major portion of the return envisaged by Novartis consists of the benefits of intimate access to the intellectual resources of the Berkeley campus.

A third example is the donation by Monsanto Corporation of technology for transformation of corn (maize) by Agrobacterium technology to the University of California as part of a divestiture of assets ordered by the U.S. Justice Department as a condition for acquisition of DeKalb, the seed producer. Rather than sell to a competitor, Monsanto, under extreme time pressure, was persuaded to give it to the University, and the University is free to license access to the technology to third parties. The details of this case illustrate the important point that prospective recipients must exercise flexibility and initiative to take advantage of such opportunities.

Other public-private ventures have focused on health issues. Several initiatives have been set up to tackle health problems of the developing world. The International AIDS Vaccine Initiative, begun in 1966, is maximizing the number of promising vaccine candidates in clinical trials. The Global TB Alliance aims to commercialize a new anti-TB drug by 2010. Others include the Malaria Vaccine Initiative and HIV Vaccine Design and Development Teams. Funding for all these organizations is largely from foundations in the United States (Bill and Melinda Gates Foundation; Rockefeller Foundation) as well as from international organizations. These agencies have been termed socially responsible virtual pharmaceutical companies (Lehmann 2001). Similar to regular pharmaceutical companies, these agencies fund work on parallel tracks in the belief that one of them will prove successful. The VPCs, although initially funded by philanthropists, need to create incentives for private industry partners while ultimately providing the drugs at reasonable prices. As a trade-off, the VPCs allow the private partners to use the patents derived from the
collaboration for products aimed at the profitable market in developed countries. (Lehmann 2001). Thus, the money is an investment into the private sector and not a grant.

Other public-private partnerships are aimed at investments in private enterprises in the developing countries themselves. ACIAR (Australian Centre for International Agricultural Research) and the ADB (Asian Development Bank) invest in collaborative projects at the request of Asian partner countries. ACIAR has initiated over 100 biotechnology projects in R&D partnerships with over 15 Asian countries over the past 15 years (Skerritt 2000). The projects concern development of diagnostics and vaccines, especially for tropical livestock. But the state of development of IP protection and the regulatory system with respect to biosafety assessment in these host countries leaves the success of the sponsored programs in a cloud of uncertainty.

Although, in some cases, donations could be motivated by the prospect of tax deductions in exchange for unused and perhaps useless technology, the above examples suggest that it is conceivable that corporations would be willing to exchange access to valuable technology for close contacts with the innovative activities and expertise of non-profits, without making demands for exclusive proprietary rights to the output. Non-profits should search for means of making this kind of transfer easy for the private sector. But they must clearly establish the continued independence of their research mission from undue private-sector influence. The threat of such influence is real. Recently, disturbing (though not conclusive) new evidence appeared regarding the bias that can be induced by private funding of research. For example, Thomas S. Bodenheimer stated that a review of drug trials showed that when the drug owner funded the study, the drug was highly rated in 89 percent of cases versus only 61 percent for independent studies (Hilts 2000).³⁰

³⁰ Likewise, Barnes and Bero (1998) examined 106 articles reviewing evidence on the effects of passive smoking and, after controlling for various other factors, showed that authors who had a financial affiliation with the tobacco industry were much more likely to conclude that passive smoking is not harmful to health than those without industry affiliations. Similarly, Stelfox et al. (1998) showed that authors who supported the use of a certain kind of drug for treating heart ailments were significantly more likely to have a financial relationship with the drug's maker than those who did not.
E. Patent pooling

Given the proliferation of IPRs associated with crop biotechnologies, it will increasingly be necessary to obtain freedom to operate from multiple patentees from various countries. Just as the International Maize and Wheat Improvement Center (CIMMYT) located in Mexico is concerned about giving its technology away if its value might be appropriated by the holder of a blocking patent on a complementary technology (Dalton 2000), corporations are concerned about offering their technology with a no-cost license only to find that their largesse has increased the rents accruing to a less generous owner of another essential enabling technology. One way to avoid this is to obtain a joint grant of freedom to operate in certain markets from all holders of relevant intellectual property rights.

For more than 150 years in the United States, “patent pools” have been formed either voluntarily or with the involvement of the U.S. Government to affect and shape industries. A patent pool is an aggregation of intellectual property rights that are cross licensed and licensed to third parties (Clark et al. 2000). Because of the potentiality that a patent pool can be anti-competitive, pools are scrutinized by the Department of Justice and the Federal Trade Commission. In 1995, these two agencies issued a set of guidelines that set forth policies and examples of acceptable and unacceptable patent pools (U.S. Department of Justice and Federal Trade Commission 1995). The two critical features of an acceptable pool are: (a) the pool “integrates complementary patent rights”, and (b) the “resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program.”

Thus, patents in the pool must be essential to practice the technology. This requirement may be too big a hurdle for biotechnology for several reasons, not the least of which is that some very basic and presumably blocking patents still have not issued because they are subject to ongoing interference proceedings in the U.S. Patent and Trademark Office.

Such joint agreement is probably infeasible as a regular modus operandi for pooling technologies on a one-by-one basis. Far better to coordinate a joint commitment by

31 See Letter from Joel I. Klein, Assistant Attorney General, Department of Justice to Carey R Ramos (June 10, 1999), available at www.usdoj.gov.

32 When there are multiple contenders for a patent to the same invention, the United States determines who is the first in time to have conceived the invention. In contrast, countries in the rest of the world award a patent to the first in time to file for a patent.
the major biotechnology providers and public agencies (including the CGIAR) to provide royalty-free licenses on all intellectual property rights in agreed areas of application (distinguished for example by crop, cultivars, regions, or mode of production). Such licenses could perhaps include a provision for a set of royalty payments to come in force should an owner of a complementary technology used in development of a cultivar demand a positive royalty in the relevant area of application. In negotiating and drafting any such agreement, attention should be paid to the implications of national antitrust laws. This type of negotiation is difficult and costly to all parties, and requires high-quality legal advice. General effective multi-party agreements on technology access are more complex and difficult to achieve than many donors might imagine.

**F. Clearinghouse mechanisms**

An alternate means of lowering the cost of transactions of technology in biotechnology is the creation of an internet-based clearinghouse. This would have the capacity to identify relevant intellectual property in specified technology environments, and identify its availability and how they could be accessed. It could also establish prices or pricing indicators, facilitate negotiations and offer mechanisms for arbitration of disputes and monitoring of compliance. An agricultural biotechnology IP clearinghouse could bundle together sets of complementary patents from different patent holders into complete “biotechnology or agronomic systems” contracts (thus providing upstream technology aggregation). Through active pursuit of such “syndication” strategies it would be possible to create customized licenses that could greatly increase the use of inventors’ technologies and make multi-patent technology systems readily available and affordable to researchers (Graff et al. 2001).

**G. Open source licensing**

As noted above, there has been a huge expansion of intellectual property protection for biotechnology research tools in recent times, which in turn has increased the difficulty of obtaining freedom to operate for commercialization. Open source licensing is a type of intellectual property management that has been successfully used in computer industry and specifically in the development of Linux, one of the major operating systems. In open source environment, access to the technology is available to all and developers of improvements grant back their improvements to the
distributor of the technology. Thus, access is available but commercial involvement is not inhibited.

Open source biotechnology would extend these principles to research tools in biomedical and agricultural biotechnology. The guidelines and recommendations are yet to be made, however, excitement about the concept is growing (Hope 2003; Goetz 2003).

**H. Ally with independent developers of research tools**

A quite different approach is to sponsor creation of substitutes to existing proprietary research paths. This is a task beyond the resources of many non-profits (especially those operating in developing countries) operating on their own. But promising collaborators do exist. For example, CAMBIA in Australia aims to generate new biotechnology tools for agriculture, unencumbered by restrictive proprietary claims. These tools are in turn made available on an ability-to-pay basis. The licensing revenues are used to fund further research and to support transfer of the technologies to developing countries.

Increasingly, the technology paths pursued by plant breeders are being influenced according to their degree of appropriateness by for-profit innovators. Most likely, other paths can be found that score low on appropriateness but high on effectiveness. The discovery of a cheap antibiotic cure for stomach ulcers as a superior alternative to patented pharmaceutical treatments is an example from the health field. (It is notable that this innovation arose on the extreme fringe of mainstream medical research, beyond the support of the pharmaceutical establishment.) University, government, and other nonprofit collaborators are well placed to pursue such opportunities, if they can be sufficiently insulated from powerful private-sector counterparts.

**I. Pressing for sharing of technology**

The kinds of challenges that proprietary claims pose to public-private collaboration in biotechnology are not unique to agricultural applications, and will take time to resolve. They belong to two broad classes. On the one hand are issues of access to innovations useful in biotechnology, which are shared by all other researchers in this general field. On the other hand, problems posed to crop breeders by "farmers'
rights" are similar in nature (but not in degree) to those faced by pharmaceutical researchers interested in access to biodiversity products. These two classes of problems require different approaches.

Access to research tools is a burning issue at the heart of nonprofit research on biotechnology in the United States, the world leader in this area. Public funding of biotechnology in the United States (and, indeed, scientific research funding in general) is dominated by the National Institutes of Health (NIH). Researchers might find the report of the NIH Working Group on Research Tools instructive, if not dismaying (NIH 1998). The report notes that "although competitive pressures have always given scientists an incentive to withhold new research tools from their rivals, past practices allowed for relatively free exchange, typically without formal agreements and without explicit consideration of commercial rights or potential financial benefits...It seems to be increasingly common, however, for the terms of these agreements to interfere with the widespread dissemination of research tools among scientists, either because owners and users are unable to reach agreement on fair terms or because the negotiations are difficult and cause protracted delays" (NIH 1998, Executive Summary p. 1-2)\textsuperscript{33}.

The public debates about patenting do influence patenting standards. Thus, these institutions should continue to press for inclusion of the interests of international and developing country nonprofit research collaborations in measures designed to address the interests of domestic research institutions in the leading countries, including the European Union and the United States. The CGIAR Centers are well placed to assist this effort by coordinating advocacy of the interests of international agricultural research institutions, and the FAO has a central role in the broader policy deliberations.

One form of pressure is a boycott of companies demanding "unreasonable" terms for key enabling technology. This tactic, discussed by Lesser (1999) with respect to plant breeding, would clearly be ludicrous for most non-profits (including the CGIAR) acting on their own. But this tactic appears to have been used with some effect by NIH in a protracted struggle with DuPont over the terms of research licensing of a

\textsuperscript{33} Concerns similar to those expressed by the NIH working group are shared by the Board on Science, Technology, and Economic Policy of the National Research Council. (National Research Council, Board on Science, Technology, and Economic Policy 1999, p. 1).
utical cs of
h on ng of
ig in night
f not have
ivals,
ormal ential ns of
tools
nt on
(NIH
these
and
dress
g the
assist
tural policy
s for plant
AR)
t by
of a
ience, uncit,

“research tool,” mice genetically engineered with the patented “cre-lox” system (Marshall 1998b). Significantly, the compromise ultimately hammered out excluded not only commercial use but also “any activity associated with higher plants or agricultural applications” (NIH 1999). Making common cause with more powerful allies in applying pressure on holders of intellectual property might help ensure that in future agreements, any concessions by holders of proprietary rights are extended to international agricultural (nonprofit) research, and its dissemination to non-commercial markets.

V. Role of private agencies in implementing options
Attention is usually directed to governmental and large public entities and the roles they play in promoting and facilitating technology transfer to developing countries. In the sections above, we outline some of the measures that the larger private concerns, some for-profit and others non-profit, have promoted or participated in to effect technology spill-over. In this section, we discuss a few of the small, private non-profit entities and their initiatives designed to facilitate technology transfer. The initiatives come in several flavors, but all are aimed to assist the developing world in coping with the major advances in biotechnology and intellectual property and harnessing them for their benefit.

A. Public Sector Intellectual Property Resource (PIPRA)
Of patented technologies related to agricultural biotechnology, public sector institutions in the United States own 24% of patents. This represents a substantially larger intellectual property portfolio than that of any single agricultural biotechnology company (Graff et al., 2003). The public sector portfolio, however, is highly fragmented across institutions and much of its intellectual property has been licensed, often as exclusive license.

Because the public research sector itself is increasingly restricted in its ability to develop new crops, a consortium of institutions, including the University of California, the Donald Danforth Plant Science Center, North Carolina State University, Ohio State University, Boyce Thompson Institute for Plant Research,

---

34 Other agencies that bear a mention but are not discussed in this section include Public Interest Intellectual Property Advisors, Inc. (www.pipa.org); Centre for the Management of IP in Health R&D (www.mihr.org).
Michigan State University, Cornell University, University of Wisconsin-Madison, University of Florida, the USDA, Rutgers University, Texas A&M University, and Purdue University in conjunction with the Rockefeller and McKnight Foundations have banded together to form PIPRA; www.pipra.org.

The primary purpose of PIPRA is to explore strategies to collectively manage public-sector intellectual property in support of both U.S. and developing country agriculture. In particular, the strategy of systematically reserving rights to use technologies for subsistence crop development when they issue commercial licenses. For U.S. agriculture, it is also important to retain rights for use in development of specialty crops that are not currently within the commercial interests of large private sector companies. The anticipated benefits of a collective intellectual property management regime are to enable an effective assessment of FTO issues, to overcome the fragmentation of public-sector IPR and re-establish the necessary FTO in agricultural biotechnology for the public good and to enhance private sector interactions by more efficiently identifying collective commercial licensing opportunities.

Specific aims of PIPRA include: develop a series of “best practices” to encourage commercial development of publicly-funded research while retaining public good rights; develop a database of existing IP owned by the institutions, including licensing information; and explore the feasibility of patent pools or other collective arrangements of patents.

**B. African Agricultural Technology Foundation (AATF)**

Another new initiative that is focused on access to private sector technologies specifically for sub-Saharan Africa, is the African Agricultural Technology Foundation (AATF; www.aftechfound.org). It, like PIPRA, is still in its early stages of development. AATF’s goal is to facilitate the sharing of agricultural technologies owned by large private sector companies. The focus is on humanitarian goals, particularly in regions and for crops and markets that do not overlap significantly with their own commercial interests. Still, the transfer is not without conditions imposed by the companies. In particular, the companies insist that 1) the goals of any project using their technologies must be well-defined, scientifically sound, and clearly focused on a goal that can meet a clear need for resource-poor farmers; 2) the project
must have a clear way to ensure proper stewardship for the use of these technologies in ways that also limit the liability of the donor companies; 3) the agreements should allow for clear protection against use of the technologies in ways that interfere in the company's own commercial spheres of interest.

Under the aegis of AATF, private companies in developed nations will be brought together with African stakeholders, including the National Agricultural Research System (NARS) and other agricultural R&D institutions, farmers associations, NGOs and national private sector agribusinesses. The goal is to access advanced scientific and technological resources and adapt them for use in specific projects for the development of agricultural products for sub-Saharan Africa. To ensure that the best interests of Africa will be advanced, the AATF will be an African-based, African-owned and African-led entity.

As a first step, AATF is engaging in extensive consultations with African stakeholders to identify priority crops and traits that are important to poor farmers and to identify scientific partnerships that would be capable of carrying out such projects. AATF will then be the entity that negotiates with the relevant technology providers and potential. In addition, the AATF will negotiate royalty-free licensing agreements with the companies for such projects and will be the primary holder of such licenses. These will then be sub-licensed to the partner institutions in Africa that will carry out the projects. Thus, the AATF serves in the roles of matchmaking, stewardship, and guidance at all levels to ensure the development successful projects that will be carried out in responsible ways.

**C. CAMBIA Intellectual Property Resource**

CAMBIA (Center for the Application of Molecular Biology to International Agriculture) is a private, non-profit research institute located in Australia whose overarching goal is to provide technical solutions that empower local innovators to develop new agricultural solutions. CAMBIA invents, develops, and delivers new technologies in agricultural biotechnology through licensing to companies and transfer to national programs and universities in developing countries. CAMBIA Intellectual Property (IP) Resource (CAMBIA IP Resource; www.cambiaIP.org) is an activity within CAMBIA that is designed to provide tools and information to assist researchers and policy makers in understanding the intellectual property landscape.
influencing research and development in agricultural biotechnology, particularly in issues relevant to international agricultural. The IP Resource provides the background and framework necessary to formulate IP-based strategies for the development and deployment of research activities and in particular targets scientific researchers and business-associated personnel in national programs, universities, small companies and international institutions.

The CAMBIA IP Resource was publicly launched in July 2001 and provides three primary elements: (i) a database containing searchable full-text patent and patent application data that are relevant to biotechnology; (ii) white papers providing overviews of the patents in selected topical areas of interest to agricultural and health-related biotechnologies; and (iii) tutorials designed to bridge the gap between theory and practice of IP.

Four major datasets (United States; Europe; WIPO; and Australia patent documents) are either currently or soon-to-be available. For each of the data sets, that subset of the patents and applications that are most related to life sciences and chemistry were chosen. The search interface is structured to guide the user in making choices. The user can choose one or more of the datasets, whether full text or cover page data is to be searched, and type in terms to query the data. Tutorial and help screens are also posted to assist the user. From the output, a user may select a publication by clicking on the number, which will bring up more details about the particular application, or obtain the entire text of the publication in a format that can be read with a word processing program or in PDF format.

The CAMBIA IP Resource also provides a series of "white papers" that present and analyze the patent landscape in key areas of biotechnology with the top one to three tiers of patents summarized and analyzed for each area. The analyses also contain an introduction, explanation of the science behind the subject matter including schematics and diagrams, and some information about the patent owners. The white papers are available for viewing on-line or can be downloaded in a variety of formats for the user to read. Three papers are currently available: *Agrobacterium*-mediated transformation of plants, antibiotic resistance genes and their uses, and promoters used in biotechnology. In addition, the user will also find several articles on patent policies and their effects on trade of staple crops and on basic scientific research.
Several tutorials have also been developed to provide pragmatic guidance and to assist users in evaluating the significance of patent information. These tutorials provide a concise approach to addressing the lack of legal knowledge in much of the scientific research world.

The outcomes from this project are intended to provide national programs and research institutions with a strategic framework for dealing with both national and international IP issues associated with biotechnologies. In particular, the expertise gained from this resource will increase capabilities for dealing with various IP issues, for negotiating with private companies, raising public awareness and forming policy decisions.

VI. Summing Up

In this paper we have shown that the preponderance of research conducted in science and specifically in agricultural biotechnology is carried out in developed countries, and moreover, much of the product development work is done by private firms. We also drew attention to the comparatively low rates of investment in public agricultural R&D in developing countries, where government revenues may be comparatively expensive or have a comparatively high opportunity cost. Many less-developed countries are characterized by under-investment in a host of other public goods, such as transportation and communications infrastructure, schools, hospitals, and the like, as well as biotechnology.

Even among the rich countries of the world, most have not had very substantial private or public agricultural science industries; so why should we expect the poorest countries of the world to be more like the richest of the rich in this regard? The lion’s share of the public (as well as private) investment in agricultural science has been undertaken by a small number of countries, and these have also been the countries that have undertaken the lion’s share of scientific research, more generally.

What are the barriers and challenges that limit technology transfer to developing countries? Some argue that intellectual property is the major barrier because of the number and breadth of patents, plant breeders’ rights and other forms of intellectual property. Others believe that strengthening intellectual property regimes in poorer countries is one way of stimulating investments in developing-country R&D as well as efforts to commercialize biotechnologies developed elsewhere. In a previous
publication (Binenbaum et al. (2003)) we concluded that for the 15 staple food crops of the world, there was undue concern that intellectual property rights were currently limiting the freedom to operate for research on these crops. In this paper, we reinforce that position and propose that the constraints to conducting modern biotechnology research in developing countries appear to lie largely beyond IP concerns.

Paradoxically, for developing countries the short-run importance of freedom to operate has been exaggerated by well-publicized donations that generate inferences that the multinational life science oligopoly holds extensive blocking intellectual property in those countries. Ironically, in developed countries non-profit researchers often believe themselves exempt from infringement when using protected intellectual property. Worldwide, institutions need to better understand their rights and responsibilities regarding intellectual property.

A number of mechanisms to overcome the barriers are proposed. The mechanisms discussed are those that can be implemented at the organizational or individual level. Some require training in IP management and negotiation skills as well as adoption of a perspective that will plan for and use IP to advantage. In short, different approaches may have to be devised to make it possible for less-developed countries to achieve equivalent access, to tap into technological potentials generated by rich countries; and in many instances less-developed countries may have to extend their own R&D efforts farther upstream, to more fundamental areas of the science.

Additionally, the role of private agencies in facilitating technology transfer is explored. Specifically, we present overviews of several enterprises that were initiated to empower professionals in developing countries.

As things stand now, intellectual property does not appear to be the binding constraint on Southern science. Lack of local investment in science and limited experience and expertise in accessing, using, and regulating modern biotechnologies are the real problems. Nevertheless the implementation of TRIPs will affect the freedom to operate in the next generation of biotechnology. Guiding these changes in intellectual property regimes and responding creatively to the new environment are pressing challenges for those interested in the future of scientific research.
References


Alikhan S. Socio-Economic Benefits of Intellectual Property Protection in Developing Countries WIPO Publication Number: 454, 2000


Ewing, M. Personal communication, CLIMA (Centre for Legumes in Mediterranean Agriculture), Perth, 2000.


