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ACCESSING OTHER PEOPLE'S TECHNOLOGY: DO NON-PROFIT AGENCIES NEED IT? HOW TO OBTAIN IT

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ABSTRACT

As patents and other forms of intellectual property become more pervasive in the next generation of biotechnologies, designing polices and practices to ensure sufficient freedom to operate (i.e., the ability to practice or use an innovation) will be crucial for non-profit agencies in the developed and developing world, especially those intent on developing improved seed varieties and other technologies destined for commercial release. Are non-profits exempt from intellectual property claims? What constitutes infringement of a patent? How does a non-profit establish its freedom to operate? We address these issues in this paper and evaluate various options for accessing other people's technologies. Options include cross-licensing agreements, research-only or cost-free licenses, market segmentation strategies, mergers or joint ventures, and patent pooling or clearinghouse mechanisms. Responding creatively to the new intellectual property environment will have far reaching consequences for the future of non-profit research.

KEYWORDS: research, agricultural biotechnologies, patents, intellectual property

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1. INTRODUCTION

Interest in intellectual property no longer belongs just to the private-sector realm of inventors, authors, artists, and the firms that deal in their output. Public and private non-profit institutions around the world are becoming increasingly evident on the intellectual property scene, interacting more closely with the for-profit sector and even spawning private entities of their own.

Universities have traditionally been considered ivory-tower institutions and bastions of "pure" academic pursuits, but they are increasingly active in claims for patents, copyrights, and other forms of intellectual properties. For example, from the years 1981-1985, a total of 1,887 United States patents was awarded to inventors who assigned their rights to entities containing the word "University" in its name, comprising only 0.59 percent of total United States patents during these years. From 1986-1990, this number increased to 4,027 or 0.96 percent, from 1991-1995, to 7,314 or 1.47 percent and from 1996-2000 to 13,940 or 2.15 percent of total patents awarded. At least some of this increase may be attributed to the Bayh-Dole Act of 1980, which mandated that the United States Government cede ownership of intellectual property, emanating from government-

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sponsored research, to the recipient institution (Mowery et al. 2001). Notably absent from the group of non-profit institutes that seek patent protection are the Centers that form the Consultative Group on International Agriculture Research (CGIAR, or CG for short). Of these 16 Centers, located primarily in developing countries, only a few have obtained patent protection for their inventions (Binenbaum, et al. 2001).

Non-profit research institutions are not in the business of selling products to consumers. If they are to realize a return on their investment (rather than make it available gratis), they essentially have to sell rights to their technologies to commercial entities or other research institutions. For example, the technologies may be exclusively out-licensed to a commercial partner or form the basis for a company that is spun off from the institute. Alternatively, an institution may choose to out-license the technology itself on a non-exclusive basis. Some highly publicized patents have been licensed in this manner, generating a very substantial income for the host institution. For example, in 1997, Stanford University received over $43 million from licensing the now-expired Boyer-Cohen patent, which represented over half of its total licensing income.

The importance of licensing and technology transfer for non-profit organizations is also reflected in the large membership of the Association of University Technology Managers (AUTM). AUTM represents over 300 universities, research institutes and teaching hospitals mostly from the United States and Canada. In a recent licensing survey conducted by AUTM (1999), 190 United States and Canadian universities, teaching hospitals, research institutes, and patent commercialization companies reported that more than 400 new products were introduced from about 100 of these institutions,

that over 340 new companies based on an academic discovery were formed in 1999, and over 18,600 licenses and options were active, up 9 percent over 1998. Moreover, the adjusted gross license income received was $862 million.

Non-profits also receive substantial funding from the private commercial sector. In the same AUTM survey, industry-supported research increased 13 percent over 1998 to $2.7 billion. This money may or may not be encumbered with intellectual property constraints, such as an obligation to license or assign resulting technology and inventions back to the funding agency.

For all these benefits that non-profit institutions receive from intellectual property, these same institutes are notorious for using other people's patented technologies without permission. A review of the intellectual property policies of several large universities in the United States with very active licensing offices reveals that none discusses the need to obtain permission to use patented methods and materials and only one presented guidelines on copying material that is copyright protected. All the policies focused on the university's rights to inventions, the procedures that researchers need to follow to inform the university of an invention, and the distribution of licensing income. Very little factual information about intellectual property rights is provided in these policy documents. Thus, in their intellectual property policies non-profit institutions appear to be concerned mostly, if not exclusively, with generating income, and are neglecting internal monitoring and compliance with respect to other people's technologies. In contrast, for-profit entities, especially in biotechnology, are not only generally more cognizant of intellectual property rights and rules, but are also pro-active

in obtaining licenses, options for licenses, or collaborations that will assure them of "freedom to operate" (i.e., the ability to use or practice an invention). For-profits are also usually less interested in generating income from a particular piece of intellectual property; they are more interested in developing a suite of intellectual property that supports their final product.

Despite widespread belief to the contrary, however, non-profit organizations are not immune to intellectual property laws. There is no general research exemption from infringement, and the exemptions in the United States, for example, are very limited and based in statutes.[4] Non-profit research organizations need to develop and implement policies to make decisions regarding use of other people's technologies. Without such policies, researchers and investigators will continue to be confused about patent laws, act inappropriately and propagate misinformation, possibly subjecting their host institution to financial liability or damage to their reputations.

With a special emphasis on agricultural biotechnology, this article discusses policies of intellectual property protection, de jure and de facto research exemptions, and the ways that research at non-profit institutes fit with and are at odds with these policies and exemptions. We also present an overview of the steps necessary to abide by other's intellectual property rights and show how most non-profits are ill-equipped to undertake such measures. Consequences of ignorance or inaction of a non-profit are presented as a risk analysis. Finally, we present strategies for pursuing different options of obtaining

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[4] One notable exception is that State institutions in the United States cannot be sued in Federal courts. Very likely, the United States Congress will find a constitutionally acceptable means of correcting the anomaly that allows State institutions to enjoy the benefits of the patent system but not the consequences.

rights to use other people's technologies with special emphasis on the international implications of these issues.

2. FORMS OF INTELLECTUAL PROPERTY PROTECTION

Over the past few decades, there has been a proliferation of intellectual property emanating from agricultural technologies and the sciences that generate these technologies. By way of background to our discussion of intellectual property options for non-profit institutions, we provide a brief description of the various forms of legal protection used to protect agricultural technologies, seeds, and the science that gives rise to these technologies.

The major forms of legal protection available for agricultural biotechnology are patents, Plant Breeders' Rights (known in the United States as Plant Variety Protection Certificates), trademarks, and contracts. Trademarks, however, have relatively little impact on non-profit institutions and so will not be discussed here. Protecting and controlling the use of intellectual property can also be achieved by technical means, like hybridization of crops such as corn and rice, and genetic use restriction technologies (GURTs). These methods have the greatest impact on farmers by rendering the seed unsuitable for replanting or suppressing the expression of certain introduced traits in saved seed. They are not discussed here, but are dealt with in detail by UNEP/CBD/SBSTTA (1999).

A web of proprietary claims now envelops the transfer and use of patented biotechnologies, thereby limiting the freedom to operate of public and private agencies alike. Biotechnologies covered by these claims include:

- Parent germplasm in the form of individual plant varieties
- germplasm constructs that include trait-specific genes controlling specific “input” characteristics such as tolerance of biotic and abiotic stresses, output traits such as increased content of starch, oil, amino acids, proteins, vitamins, and minerals, or decreased content of traits that are harmful (for example, allergens) or contribute to environmental pollution (such as phytates that increase the environmental damage from manure), and
- enabling technologies that include transformation technologies by which a gene coding for a specific characteristic is inserted into plant cells, promoters that are used to control expression of the gene in plants, selectable markers that are genes used to determine which plant cells have been successfully transformed to show the desired characteristic, and gene silencing or regulating technologies that can be used to suppress or modify gene expression in plants.

Depending on the complexity of the transgenic product, there can be dozens of identifiable proprietary claims involved in its development.

Patents[5]

A basic understanding of the nature of intellectual property inherent in a patent is a prerequisite to thinking about the appropriate public R&D role in an increasingly proprietary agricultural science world. Patents protect inventions of tangible things and confer a legally enforceable right on their owners to exclude others from practicing the invention described and claimed in the document. However, these rights apply only for a limited period of time, generally 20 years from the date of filing, and only in a specific legal jurisdiction, and the scope of the property protection is circumscribed by the claims made in the patent. Especially in the United States, the validity of a patent, and its scope, is often unclear until many years after issue, when final legal rulings are issued after a court challenge.

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 extends only to the national

[5] Utility patents on inventions related to machinery, chemicals, and pharmaceuticals have been around for many years. By early 2001, 111 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, which protected asexually reproduced plants (like grape vines, fruit trees, strawberries, and ornamentals, which are propagated through cuttings and graftings). In 1985, the U.S. Board of Patent Appeals ruled in ex parte Hibberd, 227 USPQ2d 443 (Bd. Pat. App. & Interf. 1985) that utility patents could protect asexually and sexually propagated seeds, plants, and tissue culture, although the broadening of patentable subject matter due to ex parte Hibberd (resulting in "double protection" by utility patents and plant variety certificates) has been challenged recently in a case involving Pioneer that is due to be heard late 2001. The expansion of means to protect plants may be observed as well in Europe. Plants distinguished by a single recombinant DNA sequence (as distinct from plant varieties per se) are now patentable in the European Union, according to a recent decision of the European Board of Patent Review (Harbison and Wailes 2000).

jurisdiction in which the patent is awarded. If an innovation is patented in the United States but not in, for example, Australia, then anyone is free to use it in Australia, although importation into the United States of a product embodying the patented IP, or resulting from it, might well be subject to legal challenge in the United States. The nature of patents and the implications of their geographic limitations is pursued in greater detail in Binenbaum et al. (2000).

To protect an innovation in more than one country, a patent must be awarded in each. The cost of obtaining a patent varies from country to country; the cost of obtaining protection in all important markets can be very substantial--hundreds of thousands of dollars. Thus, most inventions are patented in just one or a few developed countries with large markets; the chance that many of these patents have been awarded in developing countries is small.[6]

Plant breeders' rights / Plant variety protection certificates

The United States introduced a Plant Variety Protection Act in 1970 designed to strengthen intellectual property protection for varieties (that lack the natural protection against replanting possessed by hybrids), and are not clones protected by the Plant Patent Act. Forms of plant breeders' rights (PBRs) consistent with the International Union for the Protection of New Varieties of Plants (UPOV) now exist in most OECD countries, and since 1989 in Australia. Developing countries are adopting either UPOV standards or other forms of plant variety protection to comply with the requirement of TRIPS to

[6] 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).

grant a so-called *sui generis* form of protection to plant varieties.[7] By early 2001, a total of 47 countries (including, most recently, Bolivia, Brazil, China, and Kenya) have enacted PBR legislation. Unfortunately, the implementations of *sui generis* protection are heterogeneous and institutionally complex (Egelyng 2000).

To be granted a PBR, an applicant must demonstrate the variety is new, distinct from other varieties, and genetically uniform and stable through successive generations.[8] The holders of a plant breeders' right have a legal monopoly over commercialization of their varieties for a prescribed length of time. Although the details of protection vary from country to country, in general, the sale, reproduction, and importation of new varieties of plants are encompassed. Under this scheme, use of plants for further breeding is unrestricted, and the progeny are eligible for PBR protection provided they are distinct from the parents (where distinctiveness may be, in a notorious example, a difference in flower color in a soybean, where flower color is irrelevant commercially). In contrast to a patent, utility or usefulness is not required for a PBR.

In this paper we focus on the implications of intellectual property protected by patents (and related commercial contracts and licenses) for freedom to operate by researchers at non-profit institutions. However, it is important to remember that access to

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[7] Alston and Venner (2001) provide convincing evidence that the United States PVPA did not stimulate private investment in wheat breeding nor an increase in experimental and industry wheat yields as was intended by the Act, despite an increase in the wheat area sown to private varieties from 3 percent in 1970 to 30 percent in the early 1990s. The PVPA apparently served primarily as a marketing tool, which might have increased appropriability of rents on branded cultivars, and this encouraged their diffusion, but did not increase their productivity.

[8] Distinctiveness is a measure of the differences in the variety's phenotype, or physical traits, compared with all other protected varieties. Uniformity is a measure of similarity among individual plants of the same variety. Stability refers to the degree to which individual plants of a variety remain similar across generations.

intellectual property is shaped by the interactions among all available forms of intellectual property protection (including trade secrets and contracts, discussed briefly in this context by Binenbaum et al. 2000).

3. DO YOU NEED PERMISSION TO USE OTHER PEOPLE'S TECHNOLOGY?

The nature of the patent right allows the patent holder to exclude others from making, using, selling, offering for sale or importing the patented invention. The principal public policy rationale for patent rights is that they provide direct socially beneficial incentives, to innovate as well as facilitate further innovation by mandating public disclosure of the patented technology. As new ideas are disseminated through publication, licensing, or other means, this information stimulates further rounds of innovation and technological advances. Inherent in this scheme, however, is a tension between the goal of providing incentives for innovation and the goal of allowing innovators to build upon one another's work. Recognizing that it is desirable to allow use of patented processes and products for basic research purposes, countries sought to facilitate access and provide researchers some level of certainty of avoiding an infringement suit. The means they have chosen include a statutory exemption, a common law (judicially fashioned) exemption, and compulsory licensing. It is beyond the scope of this paper to discuss the merits and disadvantages of each of these approaches. Rather, to illustrate research access issues in concrete terms, the following discussion focuses primarily on the situation in the United States, which arguably has only a common law exemption. This is in direct contrast to the situation in Europe, which has an explicit

research exemption.[9] As more countries implement patent laws and engage in more basic research, the debate will widen over research exemptions in relationship to patent rights. The extent of government control in these areas is limited. In the discussion below, we point out some possible ways in which exemptions can be modified, subverted or overridden.

There is no general research exemption from infringement

The right to use a patented invention for research is a concern in both non-profit and commercial settings. Many, if not most, university scientists assume that patent law does not apply to their basic research. This perception is reinforced by the academic culture. Furthermore, governmental granting agencies and foundations in the United States do not claim ownership of inventions they fund, and do not solicit information from the applicant as to whether their research will use patented technologies. Thus, academic researchers are often shocked to discover that, except for some very limited statutory exemptions that do not generally apply to them, there is no general research exemption in the United States for using other people's patented technologies.[10]

Awareness of the consequences of using other people's protected technologies is increasing in some countries. In Australia, where much of the R&D funding emanates from statutory corporations seeking to fund research ultimately resulting in

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[9] European Patent Convention Draft, Article 27(B).

[10] In contrast to patents, the U.S. Plant Variety Protection Act (PVPA, 7U.S.C. §2321 et seq) provides for a research exemption. Under the Act, a protected variety may be used and reproduced in plant breeding or other bona fide research. The UPOV Convention, and most if not all of the countries that are signatories to that convention, have a similar exemption.

commercialization, grant applicants are asked for a statement about intellectual property considerations (e.g., freedom to operate for the final product).

In the course of the development of patent law in the United States, courts have faced the issue of examining whether there is a research or experimental use exemption. Many of the cases involved infringement actions against the United States Government, where there is a clear absence of a profit motive for using the patented inventions. Overall, as long as the use was for the "legitimate interests" of the government, the courts held the activity was infringing.[11] In other words, when the government was using an invention during its normal activities, even though its activities are non-commercial, it was infringing. As a rule, the Federal Circuit court, or its predecessor court, only found exemptions when use was for idle curiosity or purely philosophical pursuits. In this landscape, research at a university or other non-profit organization, even if performed without any profit motive, would be infringing, as it is difficult to imagine research that is outside the scope of business interests (e.g., perform scientific research) of an organization. So, for example, a university researcher's use of polymerase chain reaction (PCR) to assist in cloning a plant gene would require a license from the patentee owning rights to PCR. It is unclear whether a researcher can successfully deflect a charge of infringement to the Government by asserting that the alleged infringing use occurred under the auspices of federal funding, such as a National Science Foundation grant. It is possible, however, that use of PCR in educational activities might escape a finding of infringement (Parker and Stafford 1998).

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[11] Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1976), cert. denied, 434 U.S. 1051 (1978)

The U.S. Congress has the authority to legislate a general research use exemption, but so far has only enacted a few very narrow exemptions. In 1984, the Drug Price and Patent Term Restoration Act allowed drug companies to proceed with pre-market approval testing of a drug during the life of the relevant patent.[12] The main policy consideration that drove adoption of this exemption was to ensure that consumers received the advantages of generic drug prices. Without the exemption, the patent term of a drug was inadvertently lengthened because a generic manufacturer could not otherwise begin testing a product until the patent expired. Although not yet definitively resolved by the Federal Circuit Court, it is unlikely that this exemption would apply to patented assays or genes or other inventions that are not themselves the product for which government approval is being sought. In addition, very recently Congress has legislated a very limited exemption for certain users of patented inventions. 35 U.S.C. § 287 (c)(1) grants exemption to medical practitioners performing a medical or surgical procedure that would otherwise be an infringement. Among other limitations of this exemption, it does not include uses of patented machines or compositions of matter, nor patented uses of compositions of matter, nor "practice of a process in violation of a biotechnology patent."

While many commentators favor a more expansive research use exemption in the United States, Congress has failed to act. A policy consideration that would drive enactment of such an exemption would likely be based on a need for the exemption in

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[12] 35 U.S.C. 271(e)(1): It shall not be an act of infringement to make, use, or sell a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products. However, use of patented herbicides to test new herbicide-tolerant cultivars, for example, would not fall within this exemption.

order to promote continued innovation or to remove university and non-profit research institutions from the risk of infringement actions. Even if there was a demonstrated need for an exemption, workability of an exemption could be extremely difficult given the often poor distinction between "pure" (non-commercial) research and research with a commercial interest in non-profit organizations. This particular issue is discussed in more detail below.

In jurisdictions that have adopted research exemptions, the exceptions are usually limited to research on improvements of the invention and do not extend to use of the invention in research. For example, in Europe, the Community Patent Convention provides a research exemption relating to European Community patents: patent protection does not extend to "acts done privately and for non-commercial purposes" and "acts done for experimental purposes relating to the subject matter of the patented invention."[13]

Even assuming that absolutely no research exemption exists, it is unlikely, however, that non-profit organizations have more than a very minor risk of infringement exposure.[14] It would be poor public relations for a patentee company to sue a non-profit organization for infringement, and it is likely that a jury would sympathize with the defendant. In addition, the type of remedy imposed is unlikely to be severe from the

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[13] European Patent Convention Draft, Article 27(B). Individual European Countries such as Germany, United Kingdom, France, Switzerland, Sweden, The Netherlands and Italy have enacted laws granting research exemptions, many with similar language to EPC 27(B). Interpretations of these laws indicate that the exemption would be restricted to research relating to invention, and would not encompass research using the invention.

[14] This opinion is limited to patent rights. Recently, universities have been subject to accusations of copyright infringement in the highly publicized Napster case. See The Standard (2000).

institute's point of view. In Rocke Products v. Bolar Pharmaceutical Co.,[15] a key experimental use exemption case, the patent owner urged that the data generated during the infringing activity be confiscated and destroyed. The Court, however, expressed a preference for monetary damages and admonished that injunctions are an equitable remedy and by no means a mandatory remedy. Although difficult to predict with certainty, damages owed by a non-profit infringer would likely be limited, possibly to the cost of a license, as use of the technology within a non-profit organization would not generally cause a company to lose profits.[16] Thus, weighed against the significant expenses of litigation, a corporation is unlikely to pursue such a suit except for very significant matters. Furthermore, patentee corporations stand to gain some advantages by having researchers do some of their research and widely adopt technologies that the corporation can then license. For example, the Center for the Application of Molecular Biology to International Agriculture (CAMBIA) owns rights to β-glucuronidase (GUS), which was widely used by researchers in non-profit organizations who ultimately moved to corporations and continued using GUS. While CAMBIA grants non-commercial research in non-profit settings a cost-free license, fees are charged for using GUS in commercial research.

In actuality, there does appear to be a de facto exemption in the United States. The number of patent suits filed in United States District Courts against non-profit organizations is extremely small. For example, a search of patent suits recorded in the

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[15] 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984).

[16] Infringement can be very costly in the United States, since willful infringement can invoke treble damages.

Court Link database[17] uncovered a possible five lawsuits against non-profit institutions,[18] of which two appear to be pre-emptive actions (declaratory judgments) requesting a finding of non-infringement, one is unclassified, and only two appear to be infringement suits. Congress also does not believe that universities suffer a high or actual risk. In 1990, the House Committee on the Judiciary, which has jurisdiction over patent matters, recommended a broad research exemption,[19] but in opposing the exemption, one Representative questioned the need for the exemption and challenged universities to come forward to show how the existing patent law was harming them.[20] We assume that the evidence simply was not there because the exemption was never passed. Moreover, in the United States, the 11th Amendment of the Constitution protects State institutions from being sued in federal courts unless they consent to the suit or implicitly waive their immunity. Congress attempted to subject States to infringement suits in passage of §296(a) of the Patent and Plant Variety Protection Remedy Clarification Act. Recently, the United States Supreme Court found this section unconstitutional.[21] Undaunted, the most recent session of Congress initiated, but failed to pass, another bill to ensure that State entities would be subject to patent infringement laws. Eventually, Congress is

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[17] See www.casestream.com

[18] These suits were identified as those in which the only defendant was a "university", "college" or "institute." The exact nature of the suits was not investigated. Many more suits were identified in which a corporation was a co-defendant. In these instances, the non-profit is likely co-joined as the owner of the patent and a required party in suit under Federal Rules of Civil Procedure and is not likely to be cited as the infringing party.

[19] H.R. Rep. No., 960, 101st Cong., 2d Sess. (1990).

[20] Ibid.

[21] Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank et al.119S.Ct.2199(1999) (in which College Savings Bank filed a patent infringement suit against Florida Prepaid, a Florida state entity).

likely to succeed in passing legislation that will abrogate States' rights and withstand the scrutiny of the Supreme Court.

Thus, although there is no research exemption for most non-profit institutions, it is unlikely that infringement suits will be filed against universities and research institutes regardless of their geographic location, in cases where the nature of the research is clearly non-commercial.

Commercially oriented research

While the risk of infringement liability appears to be essentially nil for non-profit organizations doing non-commercial research, it is the opinion of the authors that the risk may be higher when commercially-oriented research or services are performed. In these situations, the organization may receive a letter requesting the activity cease and desist, an offer for a commercial license, or notice of an infringement action.

Commercial services performed by a non-profit organization may well attract unwanted attention from a patent holder. For example, in Florida Prepaid, the alleged infringer, an entity created by the State of Florida that administers tuition prepayment contracts, was sued by College Savings Bank for direct and indirect infringement of its patent claiming a financing methodology to guarantee investors sufficient monies to cover college tuition. And several years ago, the holder of PCR patent rights contacted a prominent non-profit cancer research institute about a commercial license for use of PCR to tissue type patients, a service for which the institute charged.[22] In both of these examples, the organizations provided and charged for a service, which is arguably

[22] Personal communication to one of the authors.

indicative of a commercial activity. Thus, activities that are commercial in nature may provoke patent rights holders to take some sort of action against even non-profit institutions.

But what exactly is commercial research performed by non-profit organizations? And where is the line drawn between commercial and non-commercial research? Some commentators broadly define commercial research as research having some commercial purpose, but in some sense this is a circular definition. Trying instead to define non-commercial research leads to similar difficulties. At some level, all federally funded research in the United States has a commercial component due to the Bayh-Dole Act that encourages use of the patent system to promote a number of goals, one of which is "to promote the commercialization and public availability of inventions…."[23] To achieve the goals, recipients of federal funds may retain title in any subject inventions.

Indeed, an increasing amount of research is performed as part of a private-public sector alliance. In year 2000 at one university, University of California at Berkeley, seven percent of externally funded research projects for research, education, and public service were in the form of grants of contracts from private industry (University of California, Berkeley 2000). This amounted to $14 million out of a total of $430 million. In 1999, industry awarded $35 million out of a total of $432 million (University of California, Berkeley 1999). Much of the increase in 1999 was due to a single corporate sponsorship at UC Berkeley that constituted over $25 million of funding for a five-year period. This alliance between Novartis Agricultural Discovery Institute and the

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[23] 35 U.S.C. § 200 et seq. implements the Bayh-Dole Act of 1980 and amendments.

Department of Plant and Microbial Biology has been highly publicized and much criticized (e.g., Press and Washburn 2000). Some aspects of the agreement are discussed below.

Non-profit organizations are not the only entities doing deals with the corporate world. Substantial private-sector funding also supports research at U.S. Government departments under the auspices of Cooperative Research and Development Agreements or CRADAs (Day-Rubenstein and Fuglie 2000). A CRADA is a contract between a private company and a government agency to work together on a project, in which the private collaborating partner agrees to provide funds, personnel, services, facilities, equipment or other resources needed to conduct a specific research or development effort while the Federal government agrees to provide similar complementary resources. Also, the parties can mutually agree to keep research results emerging from the CRADA confidential and free from disclosure through the Freedom of Information Act for up to 5 years. The government and the collaborating partner may share patents and patent licenses, allow one partner to retain exclusive rights to a patent or patent license, or assign licensing rights to facilitate licensing to third-party users. CRADAs are specifically designed to speed the commercialization of federally developed technology.

While CRADAs are restricting unfettered access to federally funded research, the National Institutes of Health (NIH), which, like the USDA, transfers technology through CRADAs, is also trying to rectify and restore access to research materials. Recognizing the difficulties encountered by some researchers in obtaining access to research tools, NIH has attempted through the recently-issued final rule on "Sharing Biomedical

Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts"[24] to provide encouragement and guidance for provision of access to basic research tools.

What is "free access"?

Given that there is some risk to using other people's patented technologies, some in the non-profit research world may want express permission to use the technologies. As discussed in detail below, permission may be obtained in a variety of ways, but the recipient should be vigilant for the "hidden costs" of access. Sometimes agreements widely characterized as onerous, such as the Novartis-Berkeley deal, are far less restrictive than apparently "free" deals and traditional consulting arrangements with academics. For example, access to Monsanto's (Pharmacia) rice genome sequence database has multiple restrictions, such as it is limited to publicly funded research at non-profit research organizations and government research agencies, data downloads are limited to the amount of data submitted up to 26 kb per request (thereby severely curtailing the applications or research possible with these data), any resulting intellectual property, although vesting in the institution, must be reported to Pharmacia along with a copy of the patent filing. Furthermore, the institution must grant Pharmacia a right to negotiate a non-exclusive license and agree that Pharmacia may use the research results in its internal programs.

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[24] Federal Register Notice, published on Thursday, December 23, 1999, [64 FR 72090].

In consulting arrangements with individual faculty, private funders typically retain complete control over the nature of funded research, and any resulting patents, and often constrain the publication of results adverse to the funders' interests. Frequently, research reagents such as cell lines, vectors, and clones, are transferred between investigators by material transfer agreements (MTAs). The form of an MTA can range from a formal document setting out the conditions of transfer to a simple letter accompanying the reagent that states conditions for acceptance. In the academic world, MTAs commonly specify that the materials are not to be transferred to third parties, but may also specify sharing of results obtained using the material, particular acknowledgement in publication, or even co-authorship. We are aware of cases in which the sender of the material was not the originator of the material but still attempted to impose conditions on its transfer.

Furthermore, since the vast preponderance of investigators in the United States as well as many other countries are obliged to assign all property rights to their host institution, we question the validity of MTAs signed only by the sender or approved only by the recipient investigator. From a legal viewpoint, it is unclear whether an investigator alone has the authority to agree to conditions of material transfer either in or out of his or her institution. Pragmatically, a cautious approach is to have an official of the institution sign the MTA in addition to the investigator. That approach, by avoiding unwanted difficulties in the future, might well lower the overall transaction costs in the long run.

4. DETERMINING FREEDOM TO OPERATE

Even though the risk of serious consequences for infringement in a non-profit institution is currently quite low, as research becomes more and more commercially oriented the risk may well increase. And as this risk increases, the need to scope out the intellectual property landscape will become more pressing. Who will have, or ought to have, responsibility for determining freedom to operate (FTO) is an issue itself that is beyond the scope of this discussion. In Australia, some government-supported Research and Development Corporations require a grant seeker to discuss FTO as part of the application process. In this situation the onus is placed on the investigator, a person typically ill-equipped to perform the analysis and without funding to hire an attorney or a patent search company. In the current environment, however, many institutions are also ill-equipped to analyze FTO issues.

The discussion below outlines a few of the reasons why determining FTO can be a daunting task, especially for the non-legal professional. Alternatively, determining FTO can be a costly task if the analysis is referred to a lawyer. If neither of these scenarios is appealing to non-profit organizations, then it behooves them to investigate alternatives that might prove more appealing. Some of the available options are presented in the last section of this article.

Dynamic nature of patent landscape

Any FTO analysis is by its design a snapshot of the current patent situation. However, patenting and disclosing inventions is a dynamic process. For most FTO analyses, review of emerging publications is an integral part of the analysis because there

is a continuous stream of patents and applications being published. In addition, new inventors enter an area and those already in the field add to their own intellectual property. For example, in 1996, a FTO analysis was performed by one of us for a small start-up biotech company in the United States. At that time, there were only a few players in the field, with one or two likely to emerge with the predominant rights. Less than a year later, an update of the analysis revealed an extremely crowded field with many players and unfortunately, for the client, additional prior art that anticipated some of its patent claims.

Complicating the challenges imposed by a changing landscape is the difficulty of determining what entity will triumph with what claims. The first view of most patent-type intellectual property is as a publication of a pending application.[25] A pending application has claims but they have not been examined or approved by any Patent Office. Often the published claims are unrealistic compared with the scope that will ultimately be granted. Moreover, depending on the jurisdiction, actual grant of a patent can be a lengthy procedure. Of course, until grant there cannot be infringement. That said, when a product is important it is not necessarily a good idea to wait until grant to try to license or design around the patent.

Interpretation of claims

The claims of a patent, and not the text, define the metes and bounds of the patent right conferred on the patentee. The invention as written in the specification of the patent

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[25] Until 29 November 2000, the United States published only issued patents. At that date, the United States began to publish patent applications 18 months after the earliest priority date, except in limited circumstances when no non-United States patents have been applied for and the applicant petitions for non-publication.

does not establish the extent of the right. For many reasons the claims as granted may not fully cover what is written in the body of the patent.[26] To delineate the extent of the right, claims must be interpreted. Although claims should be interpreted according to the law of the jurisdiction, some basic commonalities apply. For the purposes of this discussion, we refer to United States patent law.

In the United States, claim construction is a matter of law[27] and is focused on an objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean. In the United States, claim scope is established by three factors: the plain language of the claim, the specification (text of the patent) and the prosecution history.[28] While the specification acts as sort of a dictionary, prosecution history is also used to determine the true meaning of the claims, and the use of extrinsic evidence to aid claim construction is discretionary. Therefore, a proper claim interpretation requires skill in reading claims, specification, and prosecution history.

Infringement is determined by examining whether the alleged infringing product or method falls within the scope of the claims. Even if there is no literal infringement, there may still be infringement under the judicially-created "doctrine of equivalents." This overlay of doctrine of equivalents, which is present in some form in major jurisdictions (e.g., United States, Australia, Japan, and Europe) increases the difficulty of

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[26] During the examination of a patent application, the applicant may need to cancel or amend the submitted claims to ensure patentability. In addition, some claims may need to be moved to a new application because otherwise there would be multiple inventions in a single application. Other factors that shape claims include business purposes, clarity, and financial concerns.

[27] As a matter of law, judges, and not juries, determine the meaning of a claim. See also Markman et al. v. Westview Instruments, Inc. et al., 517U.S. 370 (1996).

[28] The negotiation between the Patent Office and the applicant is called "prosecution". The record of this negotiation is called "prosecution history".

firmly determining FTO. Very recently, however, in the United States, the Federal Circuit appeals court, which is the final authority on patent law except for the Supreme Court, has severely limited the scope of the doctrine of equivalents, abolishing all equivalents for claim elements that were amended for reasons of patentability during prosecution.[29] The U.S. Supreme Court has agreed to review this holding, but, at least for now, analyses that consider only literal infringement will afford a fair amount of certainty.

Cumulative nature of biotechnologies

The development of any product in biotechnology requires a multitude of technologies and reagents. This is especially true in agricultural biotechnology, where the delivery system includes germplasm (usually seeds, which themselves embody the results of previous generations of research). Typical reagents include vectors for transformation of plants, components of vectors (e.g., promoters, selectable markers), elite plant varieties and the like. Methodologies necessary for research and development include transformation of plant cells. Because of its high profile, freedom-to-operate was analyzed for GoldenRice™, rice that produces a vitamin A precursor as a result of transformation with non-rice genes. The analysis estimated that 70 patented technologies were used during research and development. Although the number of these that is needed to actually practice GoldenRice is certainly somewhat less, even in the United States (where 44 of the total of 70 patents apply) or major European countries where the

[29] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558 (Fed. Cir. 2000) cert. granted 121 S. Ct. 2519 (2001).

relevant technologies are most frequently patented, this analysis illustrates the complexity of intellectual property in agricultural biotechnology.

Tools for searching patents and applications

In addition to an FTO assessment, scientists and other researchers may want to examine patents as a source of scientific information. Because companies do not always publish results of research that leads to patents in conventional journals, patents and published applications are a rich source of information on data and methods. But how and where does a non-legal professional come by the information?

Several databases[30] that contain differing amounts of information are available by internet access; some are by pay subscription and some are no-cost. For non-legal professionals, a problem common to all the existing databases is the interface, which caters to individuals that have a substantial knowledge base in intellectual property. Another issue is the limited number of searchable fields. Unlike the indexed scientific literature at the National Library of Medicine, patent publications are not indexed, forcing a text-based search. While many would not be put off by the need for a text-based search strategy, the language used in writing patents is very stylistic and to some extent codified by the drafters. A patent title may bear faint resemblance to the subject matter. For example, many published patent applications lodged at the World Intellectual Property Organization (WIPO) office bear the title "Secreted human proteins." Furthermore, with

[30] A non-inclusive list of databases includes: CAMBIA (www.cambiaIP.org); United States Patent and Trademark Office <www.uspto.gov>; Delphion Network <www.delphion.com>; Yet2 <www.yet2.com>; European Patent Office <ep.dips.org>; Dialog <www.dialog.com>; Micropatent <www.micropatent.com>; and STN International <www.fiz-karlsruhe.de>.

the exception of the CAMBIA database, none provides an explanation about patents, how to read a patent, or other information to assist the naï ve user.

Infrastructure in non-profit institutions

An additional hurdle for non-profit organizations and their investigators is the lack of in–house infrastructure. Technology transfer offices appear mostly to be staffed by individuals whose job it is to out-license technology and raise money for the host institution. A perusal of the staff directory of these offices reveals very few patent attorneys. Non-attorneys may be well-versed in patent interpretation and reading, but this is difficult to confirm from the information provided on the internet by offices. As with most administrative departments, these offices operate on a limited budget. It is unlikely that many will have the resources to perform or contract for detailed freedom-to-operate analyses.

5. OPTIONS FOR ACCESSING OTHER PEOPLE'S TECHNOLOGY

There are various options for gaining access to proprietary technologies. Some of the more important ones are discussed here, mainly from the perspective of a non-profit agency. Some emphasis is given to those operating in less-developed countries, although most of the issues discussed are relevant in rich countries too.

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). Similarly, when the Crop Development Center of the University of Saskatchewan developed a commercially viable transgenic flax cultivar, its possession of a U.S. patent on a biolistic transformation process for flax was reportedly important for negotiations to obtain freedom to operate (Stovin and Phillips 2000, p. 687).

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.[31] 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

[31] Normile (1998) describes changes in Japanese patent law that increase the possible rewards for university inventors and relax the grace period for publication.

the United Nation's FAO, which they are committed to make available to the world at 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. Fischer and Barton (1999) propose a model MTA that offers such material at no cost in exchange for access to information about subsequent discoveries (after a lag to allow applications for patents), and zero-cost non-exclusive research licenses to Centers of the CGIAR and agricultural research agencies operating in less-developed countries (LDCs). Further, they propose that a non-exclusive license for commercialization shall be granted to the research centers at a reasonable royalty and at zero cost for subsistence agricultural and other uses not in competition with the private sector. Whether such initiatives can be pursued successfully at sufficiently low cost in money and managerial resources is an open question.

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 U.S. 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. Since 1994 the CG Centers have undertaken to make most of this material freely available to all by way of an in-trust agreement with the United Nation's FAO, effectively taking it out of contention as a basis for bargaining with the private sector. Even if that agreement were modified, Koo, Pardey, and Wright (2001) estimate that although the CG conserves around 30-40 percent of the unique accessions held in the world's 1,300 or so genebanks, much of this material is duplicated and therefore available elsewhere. The CGIAR does have some possible bargaining chips, including its goodwill, access to local institutions involved in the generation and transfer of technologies, and non-designated germplasm, in the form of breeding lines and other material not designated under the FAO Trust Agreement having traits with potential value in commercial markets. The latter are significant only for the major crops that have been subject to intensive breeding efforts.

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 agricultural 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.

Research only licenses and their pitfalls

For scientists, research-only licenses might be attractive, as they allow 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. 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.

In some circumstances the situation might be more favorable to the licensee. If dissemination of successful innovations based on proprietary technology to users in certain markets offers little commercial benefit, a private licensor might be persuaded to license such dissemination *gratis* to a licensee with noncommercial objectives (for example, elimination of hunger among the poor) if it sees some kind of benefit, such as an enhanced public image, from doing so. This is discussed further below.

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.

A survey by Cohen et al. (1998) caused some concern when it revealed that CG Centers are already using research tools and other inputs that are subject to intellectual property rights. What was not obvious from the survey was how many of these were subject to intellectual property in the locations in which Centers operate. All the Centers engaged in agricultural research are in less-developed economies. Patents usually are filed in, at most, a select group of countries. Indeed, until recently, few third world countries allowed patents on life forms. In many cases, research tools and genetic material, and especially plant cultivars, are not covered by patents in the host countries of international centers. Furthermore, as noted above, international patenting is expensive,

and corporations in many, if not most, cases have not obtained patent protection beyond certain OECD countries. Where no patents are held, there can be no infringement.

To the extent that research agencies use technologies and cultivars that are not patented or otherwise protected where they are made, they can and should legally proceed without obtaining permission from the holder of the intellectual property rights. Even after compliance with TRIPs (Trade-Related Aspects of Intellectual Property treaty), the breeding of new cultivars using prior cultivars protected in developed countries may be legal under the *sui generis* protection that is being adopted in many LDCs. These cultivars and associated genetic material might not be legally imported into countries where they are subject to patent claims. But most of the staple food crops of importance for LDCs are largely consumed domestically, as discussed in detail in Binenbaum et al. (2000). Hence the new regime of the World Trade Organization might facilitate a kind of indirect market segmentation, in which LDCs get the new technology for free, and proprietary claims are enforced in developed countries. Further, cultivars incorporating genes patented in LDCs may not be subject to effective intellectual property claims if those countries have neither the legal means nor the will to enforce them (Giannakas 2001). If the policies of agencies like the CG centers operating in LDCs preclude violation of legally valid but practically unenforceable claims, they might consider arranging for their domestic NARS collaborators to address domestic intellectual property concerns.

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 by the CGIAR and its LDC partners 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.

A promising initiative to provide intellectual property information services for third-world research organizations is being pursued by the nonprofit corporation CAMBIA in Australia. 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 feasible by mitigating the difficulties caused by uncertainty about prior claims to useful biotechnology.[32]

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[32] 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.

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).

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, 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 highly 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.

Mergers or joint ventures

As Barton (2000, p.9) notes, "[M]ergers leading to oligopoly may often be an appropriate mechanism of avoiding a patent fight—the merger is the ultimate cross-license." In agricultural biotech, mergers are a prime private-sector solution, to minimize

the private cost of transactions in intellectual property used in research (see, for example, Marco and Rausser 2000.) They can also lead to the private benefits (and public costs) of monopoly. Mergers and outright privatization of previously public research agencies have been a feature of public sector agricultural R&D reforms in some countries like the Netherlands and the United Kingdom over the past decade or so (Alston, Pardey, and Smith 1999). However, much of this change seems to have been driven by policy reforms and public budget cuts, not by a consideration of IP issues *per se.* For many public research institutions in LDCs, including the CGIAR, privatization is neither feasible nor necessarily desirable at this time.

Joint ventures are often viewed as a more promising and flexible alternative. Monsanto is marketing transgenic cotton in China in a joint venture with a provincial public seed-producing organization; their ongoing experience promises to be quite instructive if not necessarily profitable. In 1992/3 the Commonwealth Scientific and Industrial Research Organization in Australia undertook a joint research venture with Monsanto to incorporate the company's Bt technology into locally adapted cotton varieties, which are being marketed through an exclusive licensing agreement by Cotton Seed Distributors, Australia's largest supplier of commercial cotton seed. In the United States, CRADAs (mentioned above) have in some cases been very successful, but also controversial, as the development of Taxol as a lucrative anti-cancer drug by Bristol-Myers-Squibb in collaboration with the United States (Goodman 2001; Koo and Wright 1999).

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.[33] 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 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,

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[33] See, for example, RAFI'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 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.

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. Moreover, Novartis does not control the research done with its support, beyond the appointment of two members of a five-person committee that decides on allocation of the Foundation's funds to individual projects. 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, Monsanto was required to relinquish one of two means of transformation it possessed. 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. (Incidentally, it

is interesting that Monsanto was willing to make this donation soon after the Berkeley-Novartis agreement was announced. Apparently, Monsanto does not view Berkeley as "captured" by its competitor, Novartis.)

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).[34]

Patent pooling

Given the proliferation of IPRs associated with crop breeding and related activities, it will increasingly be necessary to obtain freedom to operate from multiple

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[34] 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.

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 "integrate[s] complementary patent rights", and (b) the "resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program."[35] Thus, patents in the pool must be essential to practice the technology. This requirement may be too big a hurdle for agricultural biotechnology for several reasons, not the least of which is that some very

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

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.[36]

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 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.

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

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[36] 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.

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).

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.

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). Agricultural 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).[37]

The Working Group's recommendations include free dissemination of research tools where possible, use of the Uniform Biological Materials Transfer Agreement (UBMTA), and development of guidelines for reasonable terms of licenses and MTAs. It is clear that biotechnology's intellectual property transactions will continue to be problematic, even when all parties are domestic and share NIH funding.

There is a worldwide perception of the leadership of the United States in setting the pace for the evolution of intellectual property rights. In the views of some, the evolution has proceeded too far, for example in the patenting of gene sequences. However, the United States Patent Office has recently responded by increasing the utility requirement for patenting gene sequences by requiring the applicant to identify a function for the gene (Enserink 2000). Thus, the genome sequences determined by companies or non-profit institutions are unpatentable unless a practical use for the sequence is known. This is not to say that the sequences will be in the public domain though, because they can be treated as trade secrets and accessible only to those willing to pay the going fees and agreeing to the license terms for access and use. Clearly, international research institutions (and public agencies elsewhere in the world) have an interest in following the

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[37] 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).

current debate in the United States and Europe. As shown above, 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 "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 (such as NIH) 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.

6. CONCLUSION

Non-profit access to proprietary biotechnologies used in agricultural research is a growing problem. As more countries become compliant with TRIPs, an increasing number of innovators seek protection for their intellectual property in these markets, and the lines between non-profit and commercial research become more blurred, designing policies and operating procedures to ensure sufficient freedom to operate for public science will become important for public agencies the world over. Freedom to operate will be crucial for public agencies in the developed and developing world intent on developing improved seed varieties and other technologies destined for commercial release, albeit in markets that may generate large social gains but are not necessarily privately profitable. Various options were canvassed in this paper to improve the efficiency of public-private relationships, particularly options that could lower the transactions costs of tapping proprietary technologies for the furtherance of public research.

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.

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, including agricultural biotechnology.

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