Accessing other people's technology for non-profit research*

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As patents and other forms of intellectual property become more pervasive in the next generation of biotechnologies, designing policies and practices to ensure sufficient freedom to operate (i.e., the ability to practice or use an innovation) will be crucial for non-profit research agencies, especially those intent on developing technologies destined for commercial release. Are non-profit organisations 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 licences, 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.

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.

Among non-profit entities, universities have traditionally been considered ivory-tower institutions and bastions of 'pure' academic pursuits, however, they are becoming increasingly active in claims for patents, copyrights and other forms of intellectual properties. For example, from the years 1981-1985, 1887 USA patents

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were awarded to inventors who assigned their rights to entities containing the word 'University' in its name, comprising only 0.59 per cent of total USA patents during these years. From 1986 to 1990, this number increased to 4027 or 0.96 per cent; from 1991 to 1995, 7314 or 1.47 per cent; and from 1996 to 2000, 13 940 or 2.15 per cent of total patents awarded. At least some of this increase may be attributed to the Bayh-Dole Act of 1980, which mandated that USA government cede ownership of intellectual property emanating from government-sponsored research to the recipient institution (Mowery *et al.* 2001). Notably absent from the set of non-profit institutes that seek patent protection are the Centres that form the Consultative Group on International Agriculture Research (CGIAR, or CG for short). Of these 16 Centres, located primarily in developing countries, only a few have obtained patent protection for their inventions (Binenbaum *et al.* 2001).

Non-profit institutions are not generally in the business of selling products to consumers. If they are to realise 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 publicised 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 claiming basic recombinant DNA technology, which represented over half of its total licensing income.

Non-profits also receive substantial funding from the private commercial sector. 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. Despite widespread belief to the contrary, however, non-profit organisations are not immune to intellectual property laws. There is no general research exemption from infringement, and the exemptions in the USA, for example, are very limited and based in statutes.[1] With a special emphasis on agricultural biotechnology, this article discusses policies of intellectual property protection, *de jure* and *de facto* research exemptions, and the way that research

[1] One notable exception is that State institutions in the USA cannot be sued in Federal courts. Very likely, the USA 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.

at non-profit institutes fits with or is at odds with these policies and exemptions. We consider the consequences of intellectual property on the freedom to operate (i.e., accessing and using others' research) from a non-profit perspective, present an overview of the steps necessary to abide by others' intellectual property rights, and show how most non-profits are ill-equipped to undertake such measures. Ignorance or inaction by a non-profit leading to infringement of other people's intellectual property rights is risky; assessment of the risks is discussed below. Finally, we present strategies for pursuing different options of obtaining 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. The major forms of legal protection available for agricultural biotechnology are patents, Plant Breeders' Rights, trademarks, trade secrets and contracts. Third-party trademarks and trade secrets, however, have relatively little impact on research performed in non-profit institutions and so will not be discussed here. Plant Breeders' Rights in most jurisdictions contain a research exemption and, thus, are not discussed further. Protecting and controlling the use of intellectual property can also be achieved by technical means, like hybridisation 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:

1. Parent germplasm in the form of individual plant varieties,
2. 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 in manure), and
3. Enabling technologies that include methods of transformation of plant cells by insertion of a gene coding for a specific characteristic into plant cells,

promoters that are used to control expression of the gene in plants, genes serving as selectable markers to determine which plant cells have been successfully transformed, 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.

A basic understanding of the nature of intellectual property inherent in a patent is a prerequisite to thinking about the appropriate public research and development (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. Utility patents on inventions related to machinery, chemicals and pharmaceuticals have been around for centuries. 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 Australia, there are two ways of claiming protection for plants: utility patents and Plant Breeders Rights. Patentable subject matter includes new plant varieties, genetically modified plants, plant components and reproductive parts. Generally, similar protection for plants is provided in the USA. In addition, Plant Patents are available for asexually reproduced plants and Plant Variety Protection Certificates for asexually reproduced plants. 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 European countries, according to a decision of the European Board of Patent Review (Harbison and Wailes 2000).

Patent 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 USA, 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 patents are international in scope. However, patents are awarded by national governments and the intellectual protection conferred by a patent extends only to the national jurisdiction in which the patent is awarded. If an innovation is patented in Australia but not in, for example, China, then anyone is free to use it in China, although importation into Australia of a product embodying the patented IP, or resulting from it, might well be subject to legal challenge. The nature of patents and the implications of their geographical limitations is pursued in greater detail in Binenbaum *et al.* (2000).

The cost of obtaining a patent varies from country to country; the cost of obtaining protection in all important markets can amount to 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.[2]

While we focus on the implications of intellectual property protected by patents (and related commercial contracts and licences) for freedom to operate by researchers at non-profit institutions, it is important to remember that access to 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. 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. Recognising that it is desirable to allow use of patented processes and products for basic research purposes, some countries sought to facilitate access and provide researchers some level of certainty of avoiding an infringement suit. Among the means they have chosen are statutory exemptions, common law (judicially fashioned) exemptions, 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 primarily presents the situation in Australia and the USA, which arguably have only a common law exemption. This is in direct contrast to the situation in Europe, which has an explicit research exemption.[3] As more countries implement patent laws and engage in more basic research, the debate will widen over research exemptions in relationship to patent rights. In the discussion below, we point out some possible ways in which exemptions can be modified, subverted or overridden.

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[2] In 1998, the number of patents granted in the USA, Europe and Japan accounted for about 80 per cent of the world's patents (USPTO 1999).

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

3.1 There is no general research exemption from infringement

The right to use a patented invention for research is a concern in both nonprofit and commercial settings. The impression is that many, if not most, scientists in the public sector assume that patent law does not apply to their basic research. In Australia, where a sizeable share of the R&D funding for the Commonwealth Scientific and Industrial Research Organisation (CSIRO), State Departments of Agriculture, and universities emanates from statutory corporations seeking to fund research that ultimately will result in commercialisation, grant applicants are asked for a statement about intellectual property considerations (e.g., freedom to operate for the proposed research). Moreover, these statutory corporations generally retain some share of ownership over resulting intellectual property. In contrast, governmental granting agencies and foundations in the USA rarely, if ever, claim ownership of inventions that result from research they fund[4] 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 either Australia or the USA for using other people's patented technologies.[5]

In the course of the development of patent law in the USA, 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 USA Government, where there is a clear absence of a profit motive for using the patented inventions. Overall, when the Government uses an invention during its normal activities, even though the activities are non-commercial, it infringes.[6] As a rule, the USA Federal Circuit court, or its predecessor court, only has found exemptions when use was for idle curiosity or purely philosophical pursuits. So, for example, a university researcher's use of polymerase chain reaction (PCR) to assist in cloning a plant gene would require a licence from the patentee owning rights to PCR. 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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[4] Funding for non-profits and small business concerns is made by the Government on the proviso that it retains rights to use any resulting inventions. These rights are non-transferable, non-exclusive and irrevocable. 35 U.S.C. §200 et seq. implements the Bayh-Dole Act and amendments. For specific wording of Government rights, see 37 C.F.R. §401.14.

[5] In contrast to patents, Plant Breeders Rights provide for a research exemption. 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.

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

As well, the Australian Patents Act 1990 sets forth exemptions to infringement. These include, use in or on foreign vessels, aircraft or vehicles (§118) and prior use (§119). General legal theory of statutory language suggests that the lack of an explicit research exemption in the Patents Act means that there is no exemption. The USA Congress has the authority to legislate a general research use exemption, but so far has only enacted a few very narrow exemptions that cover drug testing required for government approval[7] and for medical practitioners.[8] While many commentators favour a more expansive research use exemption, legislatures have 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 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 organisations. 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'.[9]

Even assuming that absolutely no research exemption exists, it is unlikely, however, that non-profit organisations have more than a very minor risk of infringement exposure.[10] It would be poor public relations for a patentee company to sue a non-profit organisation for infringement, and it is likely that a jury would

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[7] 35 USC §271(e)(l): 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.

[8] 35 USC §287 (g)(l) granting an exemption for use of patented medical or surgical procedures.

[9] European Patent Convention Draft, Article 27(B). Individual European Countries such as Germany, UK, 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.

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

sympathise with the defendant. In addition, the type of remedy imposed is unlikely to be severe from the institute's point of view. In Roche Products *v.* Bolar Pharmaceutical Co.,[11] 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 licence, as use of the technology within a non-profit organisation would not generally cause a company to lose profits.[12] 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 licence. For example, CAMBIA (Centre for the Application of Molecular Biology to International Agriculture) owns rights to ß-glucuronidase (GUS), which was widely used by researchers in nonprofit organisations who ultimately moved to corporations and continued using GUS. While CAMBIA grants non-commercial research in non-profit settings a cost-free licence, fees are charged for using GUS in commercial research.[13]

In actuality, one might reasonably argue that there is a *de facto* research exemption for non-profit organisations in the USA. The number of patent suits filed in USA District Courts against non-profit organisations is extremely small. Thus, although there is no statutory research exemption for most non-profit institutions, it is unlikely that infringement suits will be filed against universities and research institutes regardless of their geographical location, in cases where the nature of the research is clearly non-commercial.

3.2 Commercially orientated research

While the risk of infringement liability appears to be essentially nil for non-profit organisations doing non-commercial research, it is the opinion of the authors that

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[11] 733 F.2d 858 (Fed. Cir.), *cert. denied,* 469 USA 856 (1984).

[12] Infringement can be very costly in Australia, where the loser must pay legal fees of the winner, and in the USA, where willful infringement can invoke treble damages.

[13] CAMBIA is a private non-profit organisation that relies on revenue from licensing its own technologies as well as grant funding. While its main thrust is developing enabling technologies for agricultural research and development, CAMBIA has also launched an internet-based resource on intellectual property that is designed to assist the user in understanding patents and integrating them with business strategy.

the risk may be higher when commercially-orientated research or services are performed. In these situations, the organisation may receive a 'cease-and-desist' letter, an offer for a commercial licence, or notice of an infringement action.

Commercial services performed by a non-profit organisation 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, and several years ago the holder of PCR patent rights contacted a prominent non-profit cancer research institute about a commercial licence for use of PCR to tissue type patients, a service for which the institute charged.[14] Thus, activities that have a commercial aspect 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 organisations? 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.

Indeed, an increasing amount of research is performed as part of a private-public sector alliance. In the year 2000, at the University of California at Berkeley, seven per cent ($14 million out of a total of $170 million) 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 2000). In 1999, industry awarded $35 million out of a total of $136 million (26 per cent) (University of California 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 5 year period. This alliance between Novartis Agricultural Discovery Institute and the Department of Plant and Microbial Biology has been highly publicised and much criticised (e.g., Press and Washburn 2000). Some aspects of the agreement are discussed below.

3.3 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

[14] Personal communication to one of the authors.

variety of ways, but the recipient should be vigilant for the 'hidden costs' of access. Sometimes agreements widely characterised as onerous, such as the Novartis-Berkeley deal, are far less restrictive than many apparently 'free' deals and traditional consulting arrangements with academics. For example, access to Monsanto's (Pharmacia) rice genome sequence database has multiple restrictions. It is limited to publicly funded research at non-profit research organisations 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 possibilities with these data), and 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 licence and agree that Pharmacia may use the research results in its internal programs.

In consulting arrangements with individual faculty, private funders typically retain complete control over the nature of funded research and any resulting patents, and may 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 (MTA). 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, and 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, because the vast preponderance of investigators in the USA as well as many other countries are obliged to assign all property rights to the host institutions, we question the validity of a MTA 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 orientated 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 analyse FTO issues.

Determining FTO can be a costly task if the analysis is referred to a lawyer. For the non-legal professional, performing an FTO analysis can be daunting due to the dynamic nature of patents, difficulties in claim interpretation, the cumulative nature of biotechnologies, difficulty of searching patent literature and lack of in-house infrastructure. We discuss each of these challenges. If these approaches for determining FTO are not appealing, then some of the alternatives outlined in Section 5 of this article might be worth considering.

Any FTO analysis is, by its design, a snapshot of the current patent situation. However, producing, patenting and disclosing inventions is a dynamic process. For most FTO analyses, review of emerging patent 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 USA. 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.[15] 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.

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

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.

4.1 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 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.[16] 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 USA patent law recognising that many of the key details also hold for other jurisdictions, including Australia.

In the USA, claim construction is a matter of law[17] 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 USA, claim scope is established by three factors: the plain language of the claim; the specification (text of the patent); and the prosecution history.[18] 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., USA, Australia, Japan and Europe) increases the

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[16] 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.

[17] 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.* 517 USA 370 (1996).

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

difficulty of firmly determining FTO. Very recently, however, in the USA, 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.[19] The USA Supreme Court is currently considering this holding, but, at least for now, analyses that consider only literal infringement will afford a fair amount of certainty.

4.2 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 analysed for GoldenRice™, rice that produces a vitamin A precursor as a result of transformation with non-rice genes (Kryder *et al.* 2000). 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 USA (where 44 of the total of 70 patents apply) and major European countries where the relevant technologies are most frequently patented, this analysis illustrates the complexity of intellectual property in agricultural biotechnology.

4.3 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[20] that contain differing amounts of information are available by Internet access; some are by paid subscription and some are at no-cost.

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

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

For non-legal professionals, a problem common to all the existing databases is the interface, which caters to individuals with expertise 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 the exception of the CAMBIA database, none provide an explanation about patents, how to read a patent, or other information to assist the naive user.

4.4 Infrastructure in non-profit institutions

An additional hurdle for non-profit organisations 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. As with most administrative departments, these offices operate on a limited budget. It is unlikely that many will have the necessary 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.

5.1 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 USA 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 USA corporations, USA 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.[21] Many other public and non-profit institutions have similar rules. (See, for example, Phillips and Gustafson 200, table 13 p. 72, for a dramatic contrast between for-profit and public biotech research institutions in Saskatchewan, Canada.)

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 as freely-available under the 1994 FAO Trust Agreement having traits with potential value in commercial markets.[22] The latter are significant only for the major crops that have been subject to intensive breeding efforts.

In an example of cross-licensing by non-profits, 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 a Material Transfer Agreement (MTA) or other contractual agreement. Fischer *et al.* (2000) 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 licences to Centres of the CGIAR and agricultural research agencies operating in less-developed countries (LDC). Further, they propose that a non-exclusive licence for commercialisation shall be granted to the research centres at a reasonable royalty and at zero cost for subsistence agricultural and other uses not in competition with the private sector.

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

[22] The nearly 670 000 accessions of crop and tree species conserved in the 11 genebanks of CGIAR do not constitute the set of bargaining chips or negotiating assets that Byerlee and Fischer 2001 and others seem to suggest. Since 1994 the CGAIR Centres have undertaken to make most of this material, approximately 520 000 accessions, 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.

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 LDC (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 Centres 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 were neither related to biotechnologies nor granted in developed-country jurisdictions). Contrast this with Monsanto who spent $1263 million on R&D that same year and was granted a total of 437 patents during the 5 years between 1994 and 1998.

For public research organisations 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 bring 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 non-profit researchers might well find themselves, like potential private entrants, shut out by the oligopoly defended by cross-licensing agreements.

5.2 Research only licences and their pitfalls

For scientists, research-only licences might be attractive, as they allow them to pursue their intellectual interests using state-of-the-art technology. 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 licence that does not permit commercialisation can make a research tool the 'cuckoo's egg' of technology transfer. If the project succeeds, then the bargaining for permission to commercialise (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 commercialisation, gains information about the technology and its downstream applications that it can use for its own purposes.

In some circumstances the situation might be more favourable 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 non-commercial 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.

5.3 Market segmentation strategies

Before discussion of this strategy in detail, it is crucial to emphasise 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 Centres 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 Centres operate. All the Centres engaged in biological research are in less-developed economies. Indeed, until recently, few developing 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 centres. As already noted, patents usually are filed in, at most, a select group of countries.[23] 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 legally proceed without obtaining permission from the holder of the intellectual property rights. Even after compliance with the TRIP (Trade-Related Aspects of Intellectual Property) treaty, the breeding of new cultivars using prior cultivars protected in developed countries may be legal under the forms of protection being adopted in many LDCs. These cultivars and associated genetic material might not be legally

[23] Because international patenting is expensive, corporations in many, if not most, cases have not obtained patent protection beyond certain OECD countries.

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 at 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).

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.[24] 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 developing-world research organisations 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.

Markets for intellectual property can also be segregated on grounds other than geography. With technology licences, 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,

[24] For the CGIAR (as well as agencies in developing countries heavily reliant on donor funding), a possible drawback of proceeding to use locally unprotected technologies 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 USA, 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 rich countries, the technologies will not be available locally without appropriate licensing. Although such licensing might still leave them with a major share of the benefits, it could decrease the enthusiasm of developed-country donors (especially those that are not home to holders of strong IPR in this area) for such a strategy.

limitations to specific uses of the technology, research use versus commercialisation, or restrictions on third-party services. Another option is to charge licence 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 or heart disease) with large potential markets in both developed and less-developed countries. By her proposal, (discussed in Mallaby 2001; Phillips 2001) patent applicants in, for example, the USA would have to commit not to enforce their patents in a designated list of developing countries when they apply for a 'foreign filing licence' with the USA Patent and Trade Mark Office. This licence is a routine requirement for subsequent filings 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.

5.4 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-licence.' In agricultural biotech, mergers are a prime private-sector solution, to minimise 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. For many public research institutions, privatisation is neither feasible nor necessarily desirable at this time.

Joint ventures are often viewed as a more promising and flexible alternative. In 1992/93 the CSIRO 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.

5.5 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 International Agricultural Research Centres, 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-publicised 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. 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.

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.[25] In the cases referenced, it seems that few if any relevant and valid patents were involved. For example, even though 70 patents were identified by Kryder *et al.* (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 USA (44 patents) and Japan (21), fewer are valid in developing countries such as China (11), Indonesia (6), India (5), Vietnam (9), and the Philippines (1).

5.6 Direct programmatic research support from the private sector

Rather than cooperate in the piecemeal technology transfer described, for-profit corporations might be persuaded to give more general support to collaboration

[25] 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)

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 (SNP), 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 private firms might, on occasion, choose to support public over private research initiatives in areas complementary to their own endeavours.

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 licences) 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 (5 years at $5 million per year), and in particular, much less stringent than appears in typical private-sector contracts with individual researchers.[26] 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.

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 other 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

[26] For example, the Novartis Foundation get 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.

was highly rated in 89 percent of cases versus only 61 per cent of independent studies (Hilts 2000).[27]

5.7 Patent pooling

Given the proliferation of IPR associated with crop breeding and related activities, it will increasingly be necessary to obtain freedom to operate from multiple patentees from various countries. One way to achieve 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 USA, 'patent pools' have been formed either voluntarily or with the involvement of the USA 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 scrutinised 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 (USA Department of Justice and Federal Trade Commission 1995). The two critical features of an acceptable pool are: (i) the pool 'integrate[s] complementary patent rights', and (ii) the 'resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program'.[28] 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 basic and presumably blocking patents still have not been issued because they are subject to ongoing interference proceedings in the USA Patent and Trademark Office.[29] In any case, such joint agreement is probably infeasible as a regular *modus operandi* for pooling technologies on a one-by-one basis.

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[27] 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.

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

[29] When there are multiple contenders for a patent to the same invention, the USA 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.

5.8 Clearinghouse mechanisms

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

5.9 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 operating on their own (especially those operating in developing countries). 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.

5.10 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 non-profit research on biotechnology in the USA, the world leader in this area. Public funding of biotechnology in the USA (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 (NIH 1988). 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 licences and MTA. 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 USA 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 USA 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 licence terms for access and use.

The public debates about patenting do influence patenting standards. 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 faciliated access to the DuPont technology but not only excluded commercial use but also 'any activity associated with higher plants or agricultural applications' (NIH 1998). Making a 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 (non-profit) research, and its dissemination to non-commercial markets.

6. Conclusion

Designing policies and operating procedures to ensure sufficient freedom to operate for public science is becoming increasingly important the world over.

Freedom to operate will be crucial for public and non-profit 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-publicised donations that generate inferences that the multinational life science oligopoly holds extensive portfolios of intellectual property that block further research in those countries. Ironically, in developed countries non-profit researchers often believe themselves exempt from infringement suits. 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, but is becoming a constraint on non-profit research in rich countries. Lack of local investment in science and limited experience and expertise in accessing, using, and regulating modern biotechnologies are the real problems facing many countries and agencies, especially in developing countries. Developed countries are not immune to these problems either. As a rich country that is highly dependent on exports to countries that have strong IP protection (e.g., USA and European countries) but only modest investment in domestic research and development, Australia's agricultural biotechnology industry also suffers. Furthermore, the implementation of TRIPs as currently formulated will likely affect the freedom to operate in the next generation of biotechnologies. 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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