Defensive Publishing and the Public Domain

SARA BOETTIGER, *Senior Advisor, PIPRA and Chief Economist, M-Cam, Inc., U.S.A.*
CECILIA CHI-HAM, *Director, Biotechnology Resources, PIPRA, U.S.A.*

ABSTRACT

IP (intellectual property) rights can reward innovators and encourage investment in developing new products and services. However, the exclusionary power of IP rights can sometimes have negative effects, making technologies less accessible and, thereby, potentially impeding innovation. To make informed decisions about how to balance access and protection requires an understanding of both the traditional IP rights system (patents, copyrights, trademarks, and trade secrets) and alternative mechanisms for preserving access to technologies. This chapter provides a brief introduction to the public domain and defensive publishing and examines issues concerning the choice behind the choice of whether to publicly disclose or to patent an innovation. Discussing the strategic use of defensive publishing in IP management, the chapter considers both the utility of defensive publishing and its limitations for supporting broad innovation. After an examination of the public domain and how it relates to other open-access concepts, such as open source and the commons, the chapter focuses on the practical considerations involved when using public-domain technologies and defensive publishing to manage intellectual property.

1. INTRODUCTION

A well-functioning innovation system strikes a balance between protecting technologies and preserving access to them. IP (intellectual property) rights can provide incentives that reward innovators and encourage investment in the development of new products and services. However, the exclusionary power of IP rights can also have negative effects. For instance, when research tools or enabling technologies are patented and not available for licensing, the creative and collaborative process of innovation can potentially be impeded. To ensure the balance between access and protection requires an understanding of both the traditional IP rights system (patents, copyrights, trademarks, and trade secrets) and alternative concepts, such as defensive publishing, public domain, and open source.

Debates about IP policy and the need to seek a socially optimal balance between IP rights and the public domain are important for the pursuit of vibrant national and international innovation systems. This chapter's focus, however, is narrower. Rather than examining how policies regarding the public domain might support innovation, we look instead at how, given current IP laws, IP management practitioners can best use the public domain to support particular goals.

The term *public domain* describes a body of work that is freely available, legally unprotected, and not subject to individual ownership. Public domain implies the *absence of individual IP rights.* This definition exemplifies the language associated with the public domain and what remains after all the boundaries of IP rights have been staked. Likewise, we commonly refer to a technology *falling* into the public domain, as if there were never a conscious decision to place something in

Boettiger S and C Chi-Ham. 2007. Defensive Publishing and the Public Domain. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

© 2007. S Boettiger and C Chi-Ham. *Sharing the Art of IP Management:* Photocopying and distribution through the Internet for noncommercial purposes is permitted and encouraged.

the public domain; instead, the public domain encompasses the residuals of the processes of the IP rights system. This chapter, however, does not view the public domain as simply a default for technologies that are not claimed via IP rights. Instead, the chapter aims to promote a broader appreciation of the public domain as a valuable resource. The authors seek to facilitate the discerning use of the public domain as a tool (among a set of tools that include traditional IP rights and related licensing mechanisms) of prudent IP management.

Section 2 provides background that illustrates the importance of the public domain and how it has changed in recent decades. Section 3 briefly introduces two other open-access concepts—the *commons* and *open source*—in order to distinguish three alternatives from one other and defines their relation to the IP rights system. Section 4 uses a narrower, legalistic definition of the public domain to discuss the practical implications surrounding public domain technologies. That section reviews the patent-law concepts necessary for understanding both the construction of a successful defensive publication, how to ascertain whether a technology is, in a legal sense, part of the public domain. Section 5 introduces the practice of defensive publishing, examining how best to place innovations into the public domain. Section 6 considers potential strategies for the IP manager choosing between patenting and defensive publishing. Section 7 outlines practical issues confronted by users of public domain technologies.

2. INNOVATION AND THE PUBLIC DOMAIN

"There is no area in which public concern about intellectual property and the public domain has been greater than in scientific and technical research. Whether it is the controversy over the patenting of, and access to, the humane genome or pluripotent stem cell lines, the appropriate role of intellectual property in university research, or the use of ethnobotany and traditional herbal knowledge in pharmaceutical patenting, the coexistence of science and property rights has been a fairly constant concern over the last 15 years." –James Boyle[1]

In recent decades, many authors have examined how innovation systems have been changing in response to the expanding system of IP rights. As IP rights have become stronger, broader, and more far-reaching, many technologies that might previously have been freely accessible in the public domain are now proprietarily owned. This phenomenon has been particularly noticeable in the fields of health and agriculture.

In 1980, a landmark U.S. Supreme Court decision (Diamond v. Chakrabarty)[2] set the stage for a burgeoning biotechnology industry and an exponential rise in the number of life-science patents. Allowing for the patenting of human-made microorganisms, the decision clarified the Court's position that patentability did not depend on the distinction between living and inanimate things, but instead between inventions made by "man" and those that exist naturally. Among other influences to increased patenting during this period, the Bayh-Dole Act of 1980 has played a role. It set up new rules for the interface between academia, in which publications are the currency of the trade, and the commercialization of university research through patenting and licensing.[3] The rise in the patenting of life-science technologies and the corresponding reduction in the number of technologies remaining in the public domain has been most remarkable in developed countries. Still, in many developing countries, patenting remains sparse.[4] Indeed, despite the strengthening of IP rights policies worldwide through TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) and TRIPS-plus, international disparities in patenting behavior are likely to persist. Understanding these differences can be important for understanding how best to use the public domain.

Substantial differences in patenting behavior can also be found between the public and private sectors within a country. Public sector patenting behavior and the use of the public domain may be influenced by culture (for example, the land-grant universities in the United States, the centers of the Consultative Group on International Agricultural Research, (CGIAR), and many other public sector agricultural research institutions worldwide have a strong history of contributions

to the public domain), a lack of resources relative to the private sector, and institutional structures that often are designed to accommodate different goals. Although there clearly are exceptions, public sector institutions and individual researchers are generally at a disadvantage when it comes to strategically employing the patent system to achieve their research and development goals. In these instances, the public domain can be a crucial resource.

This chapter does not consider whether the shift in the relative strength of the public domain in the life sciences is disadvantageous, and, if so, to whom. Such complex issues have been considered widely in the literature on IP policy. Instead, the chapter focuses on how to use the public domain to achieve individual IP management goals.

Whether research and development goals involve decisions about how to access technologies, how to preserve widespread access to newly developed technologies, or how to ensure that innovations continue along the research and development path toward commercialization unimpeded by IP issues, a solid understanding of the public domain is paramount. It is essential to know how the public domain interfaces with the IP rights system in order to know when and how to use it.

3. DEFINING OPEN-ACCESS CONCEPTS

In this section we compare the concept of public domain with two other concepts: *open source* and *the commons*. These three terms all relate to open-access alternatives to the traditional IP rights system, but they are very different from one another.

3.1 *Public domain*

In its usage to date, the term public domain *is elastic and inexact. A definition can be but one of many definitions, each surely a function of perspective and agenda ...* [5]

Defining the term *public domain* as the absence of individual property rights creates two mutually exclusive sets of technology: one that is protected by some form (any form) of IP rights and another that has no IP rights. Thus, in patent law, a technology is considered to be in the public domain if one can make, use, offer for sale, sell, or import the invention without infringing an active patent and if there are no other types of IP rights that lay claim to the invention. Technologies in the public domain can be used with impunity because, by definition, there is an absence of ownership and therefore free access. This description of the public domain as a distinct set of technologies with a defined boundary, though, is misleading. In fact, the boundary between the two sets can be difficult to discern, can vary from country to country, and is continually shifting. It is no simple task to ascertain whether or not a technology is in the public domain.

3.2 *Open source*

Like the public domain, open source is characterized by free accessibility. However, with regard to open-source technology, free access derives from a different source. Free access in the public domain is defined by an *absence* of ownership, but free access in open source is dependent upon the *presence* of IP rights that enable the use of open-source licenses.

The concept of open source has its origins in computer software. Once computer code has been *fixed in a tangible means of expression*, it is automatically the subject of copyright protection. This copyright protection allows the owner to license the code. A typical (non-open source) license might, for example, contain terms that restrict the use of the licensed product or stipulate fees to be paid. But the terms of an open source license are seen as an unusual reversal of typical licensing terms (so unusual the license is sometimes called *copyleft*). By signing an open-source license, the licensee agrees to ensure that the software will remain available for public use, modification, and redistribution; the licensee is then in breach if he or she privately appropriates the technology and restricts its public availability.

Such legal protection from private appropriation has been used to generate a self-defending commons of software code that is collaboratively added to and improved upon. A technology licensed under an open-source license, therefore, cannot be in the public domain; otherwise there

would be no license and no way of enforcing the commons.

Several versions of open-source licenses are commonly used, and they vary in the restrictiveness of their terms. For instance, there may be a provision that *any* code that is combined with the licensed code will fall under the ambit of the open-source license. Therefore the entire body of code can only be licensed under the same open-source license terms—it cannot be privately appropriated. This *viral* quality limits the utility of the open-source license in certain commercial contexts but increases the potential for growth of the protected commons of code. Other versions of open-source licenses are less viral and have been tailored to different business needs.

In the fields of health and agriculture, open source has been most easily adopted in areas with similar technology characteristics (for example, genomics). Attempts to apply the open-source model to nondigital technology sectors[6] encounter a range of difficulties. Patent law, not copyright law, protects technologies in these sectors of the life sciences. Applying open-source licensing mechanisms in patent law has its own set of legal challenges. Also, there are differences related to the innovation processes of non-digital technologies. The amounts of time, capital, and risk involved in, for instance, the production process of pharmaceuticals, are vastly different from the production process in software production. In addition, some technologies simply lend themselves less easily to the type of collaborative innovation structures that successful open-source models are based upon. Still, the tenets of open source resonate among communities of innovators in a wide range of technology sectors. The search for new applications of the open-source model is surely a worthwhile pursuit.

3.3 *The Commons*

The term *commons* has been used widely in variety of contexts; its meaning, as applied to IP, is less clear cut than those of either public domain or open source. Outside the field of intellectual property, the commons frequently refers to a commonly managed resource (for example, an *ejido* in Mexico describing commonly managed lands). The collective-management concept translates, albeit loosely, into the term's use in reference to intellectual property.

In addition to describing the management of a body of intellectual property, the term *commons* has also been used in reference to characteristics of ownership and access.[7] Whether a commons is defined by lack of private ownership, open access, or collective management seems to vary according to the context in which it appears and to the author's own interpretation of the word. Depending on the choice of definition, commons can apply to the public domain and to open source.

4. REVIEW OF RELATED LEGAL CONCEPTS

Before discussing the use of the public domain in greater detail, this section briefly reviews the relevant sections of patent law. The legal background presented here is important for defensive publishing, that is, intentionally placing a technology in the public domain through publication and thereby preventing future patenting. In addition, understanding these legal concepts will make clearer the discussion in Section 7 on how to ascertain whether technologies are truly in the public domain. Much of this material will be familiar to the reader who has read in this *Handbook* the chapters on freedom to operate (FTO)[8] and on various aspects of patenting and patenting strategies.[9]

4.1 *Patentability requirements and their importance in defensive publishing*

Defensive publishing seeks to preclude future patenting in a technology area by making it impossible for a potential patentee to satisfy one or more of the statutory patentability requirements.[10] A solid understanding of patentability requirements allows for greater success in defensive publishing. In particular, the patent-law concepts of novelty, nonobviousness, and enablement are key.

4.1.1 *Prior art and the patent application process*

In order to meet patentability standards, the claimed invention must satisfy the statutory

requirements of utility,[11] novelty,[12] and nonobviousness,[13] the latter two of which involve an evaluation of prior art. In addition, the patent must be sufficiently described and enabled in the patent application.[14] If the patent examiner assesses the prior art and deems that the claimed invention is either not new, or is obvious, the patent may be denied, or the claims may need to be narrowed in order to account for the documented prior art. It should be noted that the term prior art encompasses both nonpatented and patented prior art. (This chapter does not consider the latter.)

Citations of prior art can be added by either the applicant or the examiner.[15] U.S. patent law does not require the patent applicant to search for prior art (that duty falls to the patent examiner). However, if the applicant or inventor is aware of prior art, it must be included. The duty to disclose exists under the requirement that applicants act in "candor and good faith" when dealing with the U.S. Patent and Trademark Office (PTO) during the patent-prosecution process. A breach of this duty can be considered inequitable conduct and may result in the patent being unenforceable, but there is nothing to prevent intentional ignorance of prior art on behalf of the applicant. In fact, since 2001, when the PTO began to record which citations were added by the examiner, 40% of U.S. patents have resulted from applications in which the applicant has listed no prior art at all.[16]

It is unclear how thoroughly examiners search for prior art. Patents, both domestic and international, are a kind of prior art that allows for relatively easy and expeditious searching. Defensive publishing, however, depends on the ability of patent examiners to find publications in *nonpatent* prior art searches. Sampat[17] discusses the difficulties patent examiners face in searching for nonpatent prior art and notes the *growing concern that these various constraints on effective prior art searching are increasingly binding, and that the PTO is issuing more and more "low quality" patents, [that is,] patents that would not have been issued had the examiner considered the entire universe of relevant prior art.*

So for those seeking to practice defensive publishing, the skills of crafting a good defensive publication must be matched with attention to its prominence in search engines that patent examiners may be more likely to use. Perhaps more importantly, diligent attention should also be paid to newly published patent applications in the field of interest. As these applications are issued, evidence suggests that the author of a defensive publication may need to make the publication known to the patent examiner in order to be considered as prior art and, therefore, limit the claims of the proposed patent. If defensive publications are brought to light *after* a patent issues, recourse through patent invalidation is possible but may be prohibitively expensive. There are provisions within U.S. patent law for the submission of prior art *during* a patent's application process, and this window of opportunity should be strategically utilized.[18]

4.1.2 *Novelty and nonobviousness*

An invention is ineligible for patent protection if it is either not new or obvious in light of existing prior art. The novelty and nonobviousness requirements for patentability define the parameters within which defensive publishing can be implemented. The parameters define how publicly disclosed inventions, as prior art, can be used to support future patentability rejections.

Disclosure of an invention, and the accompanying bar from future patentability due to lack of novelty, is not limited to publications in printed form. An invention can become ineligible for patenting through any public knowledge of the invention, or though its being used or offered for sale. However, it is important to note that U.S. law limits the use of nonprinted evidence in support of a lack of novelty rejection to that which originates *within* the United States. If the intention is to use evidence from other countries to support a rejection on lack of novelty grounds, the evidence must be either a patent or a printed publication.[19] The section of U.S. patent law relevant to novelty and defensive publishing says that a patent application can be rejected on the basis of lack of novelty if *"the invention was … patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or … more than one*

year prior to the date of the application for patent in the United States."[20] In most other countries, the one-year grace period does not exist; public disclosure of an invention immediately bars patentability in those countries.

In addition to understanding the timing of disclosures, a successful defensive publishing strategy should consider the meaning of the words *printed* and *publication*. For example, is a document posted on the Internet considered *printed*, such that the document constitutes prior art and works to reduce future patenting? Sections 5.1–5.4 discuss best practices in regard to the content of defensively published documents, as well as their date and mode of publication.

The nonobvious requirement in U.S. law states that if the existing prior art is such that a person who is *skilled in the art* would not have difficulty coming up with the invention, the invention is not patentable: "*… if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*"[21]

In comparison to the novelty requirement, the patentability requirement of nonobviousness gives a broader range of possibilities for defensive publishing to prevent future patenting. The key difference is that in order to support a rejection under the novelty requirement, the printed publication must include each and every limitation of the claimed invention, either explicitly or implicitly. A rejection under the nonobvious requirement, however, only requires that the content of the prior art publication can be modified in an obvious way to arrive at the claimed invention. In addition, the patent examiner can use *combinations* of prior art to support a nonobviousness rejection, so even disclosures in defensive publishing that are partially complete may still create difficulties for those wishing to patent in the field.

4.1.3 *Enablement*

Careful defensive publishing anticipates how best to support a patent examiner's rejections under the two patentability requirements described above (novelty and nonobviousness). In order to support rejections under the novelty requirement, the publication, or nonpatent prior art, must be enabled. If the reference is supporting a rejection on grounds of nonobviousness, enablement may not be as critical a factor; a nonenabling publication can still be used to support a rejection on grounds of nonobviousness.[22] This section considers enablement for an author constructing a defensive publication.

Although the legal definitions vary somewhat depending on the country in question, in general the enablement requirement is meant to ensure that the document contains enough detail for a person skilled in the art to be able to make and use the invention after reading the document. A key question is whether it is clear that the public possessed the invention prior to the date the patent applicant claims to have invented it. While the burden of proof of enablement for prior art falls to the patent applicant, who must provide facts supporting a purported lack of enablement (this presumption of enablement in prior art is no different for a nonpatent publication than for a patent), it is still worthwhile considering enablement in a defensive publication.

When plants are the claimed inventions that a defensive publication is seeking to protect from patentability, enablement may require that someone of ordinary skill be able to reproduce the plant. Descriptions of the plant variety, however detailed, may be insufficient. In one case, a reference describing a rose was found not enabled, despite explicit detail and evidence that the author was in possession of the rose.[23] In this case the court ruled that, without information on the grafting process, reproduction of the rose was impossible. In other cases, supporting documentation may be necessary to indicate that seeds were publicly available within the time frame necessary to bar patenting.

4.2 *Overlapping claims and dominant patents*

What are the legal concepts used to ascertain whether a technology is in the public domain and therefore freely available? This question is relevant to both scientists and IP managers who

are considering what technologies to choose for a project. These pesrons must proceed with caution, because the use of a technology in a publication, or the decision to in-license a technology under an active patent, may go only part way to providing the right to practice the technology or pursue a certain research project.

A common misunderstanding in this area stems from a belief that patent claims define mutually exclusive areas of technology. In reality, the patent claims overlap each other: the use of one technology can infringe claims in more than one patent. While the issuance of a patent gives the patentee the right to exclude others from practicing the invention, it does not imply that the patentee can *practice* the invention without, perhaps, infringing existing patents. When the rights to existing patents are needed to practice a technology, those patents are considered *dominant patents*.

The existance of broad, pioneering patents illustrate how dominant patents can affect the rights to use downstream innovations. For example, Monsanto's claim to the plant transformation method using *Agrobacterium* means that all patents in which the claims specifically depend on this transformation method are blocked by a previous patent. U.S. Patent No. 6,369,298 is a patent assigned to Pioneer Hi-Bred International, Inc. (now a subsidiary of DuPont) for transformation of sorghum. In this case, the claimed technology depends on the *Agrobacterium* transformation method. A third party intending to practice this technology would likely not only need a license for U.S. 6,369,298 but also for Monsanto's *Agrobacterium* transformation dominant patent(s).[24]

Pioneering patents like the one described above are relatively uncommon, but overlapping claims and dominant patents exist in all areas of patented technology. Understanding the overlapping nature of patent claims is crucial for those who intend to utilize the public domain, because using a technology that *appears* to be in the public domain may involve infringing one or more patents.

The case study of the E8 fruit promoter provides another example (see the timeline in Figure 1 of the chapter by Fenton et al. [25]) An initial search delivers the documents detailed in this figure: several scientific papers and a group of patents. Once the documents are arranged chronologically, we can see that the E8 promoter's DNA sequence was disclosed early in our chronology in two scientific publications. But ascertaining whether the E8 promoter is still in the public domain and therefore available *freely* involves further investigation. Years after the initial publications, several patents were issued that claimed variations on the sequence and the right to use of the *original* E8 promoter sequence when combined with particular genes. Therefore, while the original sequence itself remains in the public domain, when using the sequence care must be taken to avoid infringing subsequent patent claims.

Published scientific literature, trade journals, conference proceedings, abandoned patents,[26] and expired patents are all good sources for finding public domain technologies. In the case of expired and abandoned patents, the boundaries of the forfeited IP rights have been clearly defined by the claims of the patent: the previous owner of the patent no longer has the legal right to exclude someone from using what is set out in the claims of the patent. But these two areas are especially prone to overlapping claims from other patents that may still be active and affect the freedom to use the technology. Companies often file multiple patents in a technology space, or there may be multiple patents in one family that arose from an initial application. Just because a patent has expired and entered the public domain does not mean the technology is available for use.

When seeking to identify whether a technology is in the public domain, one must be cautious because of overlapping claims. Armed with this knowledge, research into a potential public domain technology begins with publicly available patent databases.[27] These databases provide a great deal of information about the boundaries of the public domain. Nonetheless, it can be difficult to understand the interplay between the published scientific literature and patents, as illustrated in the E8 case study. PIPRA offers technical assistance in this regard, analyzing technologies used

in public sector agricultural research to ascertain with greater accuracy the boundaries of the public domain.[28]

5. WHEN TO USE DEFENSIVE PUBLISHING: THE CHOICE BETWEEN PATENTING AND PUBLISHING

Deciding whether to patent or publish is a strategic decision that must take into account a host of variables: the mission of the institution (and/or the funding agency) involved, the goals of the individual project, the financial resources available to spend on IP protection, the nature of the technology, the functionality of the court system in the countries where the technology will be used, and the strategies being employed by other institutions producing similar technologies. Moreover, defensive publishing and patenting inventions each has its limitations and benefits. Other strategies, such as trade secrecy, trademark protection, and bailment[29] need to be considered as options when formulating an IP management strategy.

Defensive publishing is often associated with promoting access, but there are instances where, perhaps counter-intuitively, defensive publishing may not be the most appropriate choice for getting widespread access to either an end-product or a newly developed technology. There are instances, however, where patenting has limitations and defensive publishing may be the better choice.

5.1 *Can defensive publishing promote access?*

Many institutions and/or sponsors, particularly in the fields of health and agriculture, place a high priority on promoting widespread access to developed technologies. Indeed, publishing continues to play a critical role in universities and at other public sector research institutions. Recent changes in the worldwide use of patenting discussed above, however, are forcing these institutions to reassess whether this IP management strategy is the best way to support their goals. This section focuses on promoting access and highlights some instances where the choice to *patent* a technology may be key to achieving the goals of promoting access, primarily by providing important leverage.

5.1.1 *Will the technology need private-sector resources for further development and distribution?*

IP rights provide private economic incentives that can sometimes be critical to research, development, and distribution processes. As an example, consider the investment needed to bring a drug from discovery through to delivery. Although an accurate estimate of the true cost of drug development is the subject of a lively debate, it is inarguably hundreds of millions of dollars.[30] In most cases it is unreasonable to expect the public sector to take on the levels of investment and risk involved in drug development. A parallel example can be seen in agriculture, where regulatory clearance may be needed for a new product, or seed distribution networks may need to be engaged. It is important, therefore, to assess early whether private capital is likely to be necessary, at some point, for research, development, regulatory clearance, manufacturing, and distribution. IP rights can facilitate the private sector's engagement by providing critical assets for bargaining (for example, in product development partnerships).

5.1.2 *Are there benefits to be gained from segmenting the market?*

One benefit of choosing to patent, rather than publish, is that patenting provides an opportunity to segment the market of technology users or licensees. An IP manager may require different licensing terms, for instance, depending on whether the technology will be used commercially or for humanitarian purposes. Alternatively, the license might contain terms to segment the market geographically or by fields of use. An exclusive license may be implemented, for example, to limit the technology's use to one major crop, reserving all other uses of the technology for widely accessible and nonexclusive licensing. Using such an approach, income generation and access may be complementary goals for the IP provider. Or the rights to a technology in, for instance, developed country markets may be exchanged for contractual obligations to deliver the

product to developing countries for a reasonable price. Choosing to protect the technology with IP rights instead of defensive publishing may provide bargaining leverage that ultimately achieves the institution's goals.

5.1.3 *Is the technology a research tool (enabling technology)?*

A body of evidence indicates that the patenting and access restrictions (through exclusive licensing, for example) of enabling technologies can limit the progress of innovation in health and agriculture.[31] Indeed, the existence and effects of patent thicket– or anticommons-dynamics are now fairly well accepted. The task of this section, however, is not to consider the policy question of whether research tools *should* be patentable, but to examine the choice between patenting (notably in the examples given here with widespread *nonexclusive licensing*) and defensive publishing for the IP manager whose goal is to promote access in a context where research tools, and improvements to them, are widely patented. In other words, how can IP management preserve the right to use an enabling technology?

As a first example, consider plant transformation that confers a new trait. Access to several complementary enabling technologies is required to produce a product. A vector that includes a promoter, selectable marker, a backbone, and a gene of interest must be used, as well as a transformation method and germplasm. Lack of access to any one technology may delay research and development or, in some cases, altogether prevent the progress of the project.

In such a case, the complementary nature of the technologies implies that the decision to patent may confer bargaining leverage. If an IP manager chooses not to patent an enabling technology, for example, a novel selection system with wide applicability in plant transformation, the ability to control the technology's applications is lost. Research projects where the selection system would otherwise have been the limiting factor (where all other technologies are owned or accessible) could progress, without impediment, if the technology were to be published. Alternatively, if the IP manager chooses to patent, the essential nature of the technology may place the owner in a position to demand a wide range of contractual obligations in exchange for the use of the selection system. BiOS, for example, operates on this principle by providing patented enabling technologies under licensing terms that support the organizations open-access goals.[32]

A second scenario concerns improvement patents. Here, as in the previous example, suppose the IP manager chooses not to patent the novel selection system. Improvements to the technology are subsequently invented and patented, restricting the uses of the original technology. Had the IP manager patented the technology, the value of the subsequent improvement patents would depend on access to the underlying dominant patent (see Section 4.2 on dominant patents). The E8 case study provides a concrete example where, had the original sequence been patented instead of published, the use of some of the downstream patents would depend on Agritope, Inc. or Epitope, Inc. licensing the original patent. For technologies that do not lend themselves to subsequent restrictions from improvement patents, this is not a concern. Mouse models are an example of this type of technology. The majority of mouse models used in research, for instance, are licensed and *not* patented.

5.2 *Using defensive publishing as a tool in an IP management strategy*

Clearly, the common perception that publishing inherently promotes access may require reconsideration. Still, what are the merits of defensive publishing for supporting a wide variety of IP management goals? And how does it highlight the limitations of using patents to protect innovations?

5.2.1 *The costs of maintaining a patent portfolio*

Patent portfolios are costly to develop and maintain. Moreover, they sometimes require a lengthy maturation period before reaching a point where they return income. Unless a licensee is found who will underwrite the cost before the prosecution process starts, the initial investment in the cost of prosecuting patents can be large,

particularly where protection is sought in multiple countries. Even where licensees are already in place, it can be many years before a license generates a positive cash flow. In examining U.S. university technology transfer offices (TTOs), Heher notes that 40%–50% operate at a net loss and that profitability often depends on income arising from one or more blockbuster patents.[33] In a cross-country comparison of TTOs, he finds that "*the first and foremost requirement for success from technology transfer is a well-funded high quality research system as the benefits from commercialisation of research are directly proportional to the magnitude of the investment in research.*"[34] While direct and indirect economic impacts provide broad benefits from building an institutional patent portfolio and TTO, the investment is long term and high risk. If resources are particularly constrained, the decision to expend money on patenting deserves careful consideration. Less expensive alternatives to patenting may support IP management goals and allow more resources to be directed toward research.

5.2.2 *Transaction costs of licensing*

The transaction costs of negotiating licenses are substantial and may need to be accounted for in the decision to patent. For instance, if the IP management goal is to promote access to a technology, and the choice is either defensive publishing or nonexclusive licensing, the costs of negotiating multiple nonexclusive licenses, or devising licensing language to segment the market of technology users suitably, may outweigh the benefits. Transaction costs can be somewhat reduced in take-it-or-leave-it nonexclusive licenses, but these tend to be rare.

5.2.3 *Enforcement considerations: costs and legal Infrastructure*

The costs (and feasibility) of enforcing the patent may also need to be considered. Because a patent confers exclusionary rights, it may be worthless without the ability to enforce those rights. Enforcement may require litigation against infringers or using the patent to invalidate subsequent blocking patents. In either case, patent litigation is a game for players with deep pockets. Average costs for patent litigation in the United States exceed $2 million dollars per case. Any decision to patent must include an assessment of whether the patentee can afford to enforce the patent. In addition to the expense, the maturity or efficacy of the patent law system in the countries likely to be involved should be considered. If the technology lends itself to bailment, for example, more control over the use of technologies may be found through contract law, particularly in countries where the patent system is not well developed.

5.2.4 *Defensive publishing as an active strategy*

Defensive publishing is most effective as an active strategy. This is a different use of publishing than that found in many research institutions today. The use of defensive publishing requires carefully constructed disclosures with the greatest possible public exposure and diligent worldwide monitoring of new patent applications as they arise in a particular technology field. When a patent application appears for which the defensive publication has the potential to force a narrowing of the claims or a total rejection, the appropriate channels must be used to alert the patent office of the published prior art.

5.2.5 *Using defensive publishing in combination with patenting*

One of the strongest roles defensive publishing can play is when it is used, not as a substitute for patenting, but in conjunction with it. As an example, consider a strategy where an IP manager patents a core technology and then defensively publishes the surrounding, related innovations, thereby reducing the likelihood that others will be able to obtain dominant patents. Obtaining patents on improvements to a core technology as they are discovered may be a poor use of limited resources. In addition to improvements, new uses of the core technology may be discovered as research and development progress. But defensively publishing these improvements and alternative uses will inexpensively and effectively contribute to preserving the right to a wide field of applications for the core technology.

5.3 *Preserving access: ten questions to consider*

For the IP manager deciding on a strategy for preserving public access, considering the following questions should be helpful:

- What are the IP management goals of the institution or inventor?
- Will the technology need the engagement of private-sector resources for further development and distribution?
- Are there benefits to be gained from segmenting the market?
- Is the technology a research tool (enabling technology)?
- Do the benefits of patenting and licensing outweigh the costs?
- How and where might the patent be enforced?
- Are there other viable options for protection—trade secrecy, bailment, trademarks, and so forth?
- In which territories/countries is the technology likely to be used?
- Can the technology be licensed without patenting?
- Can defensive publishing be used in conjunction with traditional forms of IP protection?

6. USING PUBLIC DOMAIN TECHNOLOGIES

Public domain technologies are valuable inputs to research. Indeed, they are a crucial but commonly underutilized resource for researchers. Using research tools or enabling technologies in the public domain reduces transaction costs and mitigates future potential IP impediments in the research and development process.

In developed countries, many of the standard inputs of science in the fields of health and agriculture have been patented. Scientists, however, continue to use these tools because they have a well-known history, including known levels of efficiency and documented use in specific crops. The use of patented research tools, on the other hand, can open the institution to infringement liability and/or create problems in later stages of commercialization. While the maximum use of public domain technologies may be desirable at the outset of a research project, using better-known tools (which are often proprietary) may be important in the initial proof of concept stages of research. In this case, it is worthwhile to identify whether public domain technologies are available for substitution at a later stage.

The identification and promotion of substitute technologies from the public domain is one of PIPRA's important contributions to the field of agriculture. PIPRA's mandate is to assist public sector researchers worldwide in overcoming IP impediments to the research, development, and distribution of staple crops for developing countries and minor crops in developed countries. Because the commercial market for these crops is too small to attract private-sector investment, the public sector primarily pursues research and development with respect to such crops—often without the resources to successfully address IP issues. Public domain technologies are therefore a critical resource for developing these *orphan* crops.

As PIPRA's library of technical and legal information on public domain and patented, but accessible-enabling technologies (including freedom-to-operate opinions from attorneys) in agriculture grows, so does the demand for knowledge of what technologies *are* in the public domain and how they might be employed in place of currently used patented technologies. Some practical considerations for researchers and IP managers with regard to identifying public-domain technologies are laid out below.

6.1 *Patent databases provide only part of the picture*

As the E8 case study illustrates, an investigation must begin with a search through *both* the published scientific literature and patent databases. It is both the comparison of the content and the timing of the publication of each contributing document that will determine whether the technology in question is in the public domain and its limitations for use. A simple patent search may mislead by returning a bewildering number of related patents. But a comparison of these patents with the published literature can reveal that, for instance, the core technology is in the public

domain and that the patent thicket is made up of improvements, and other patents, limiting the utility of the original technology. If this is the case, knowledge of these limitations may be critical in designing a research plan that invents around existing patents and maximizes the use of the public domain technology.

Sequence comparisons may provide another critical piece of information for the researcher seeking to use a public domain technology. As an example, PIPRA's analysis of the Soybean Heat Shock Promoter found that changing the sequence by one nucleotide allowed researchers to avoid infringing the issued patents.[35] It should be noted, however, that this case is somewhat anomalous. The determination by PIPRA's attorneys that altering a single nucleotide avoided existing patents was reached by carefully considering both prior art and patents. Generalizations cannot be made, because it is only through examining how both sets of specific documents interact that FTO can be evaluated. However, the example illustrates how critical the use of sequence analysis tools such as BLAST can be when analyzing patents. In general, careful attention to the prior art and the use of homology measures in patent claims may be necessary to identify the specific public domain sequence.

6.2 *The landscape is continually changing*

The boundary of the public domain changes as new patents are issued. Periodic updates of the analysis are necessary to check for recently issued patents that may restrict the use of the original technology. Searches can be hindered because patent applications remain unpublished—and therefore invisible in patent search engines—for many months after their initial filing dates.

6.3 *Geographical considerations*

Finding out what is in the public domain is made even more complex by the territorial nature of patents. The analysis for the E8 case study considered only the situation in the United States; any other country would require collecting a different set of documents. Nonetheless, because the boundaries of the public domain are more expansive in some countries than in others, opportunities may exist to design research strategies that take advantage of these differences.

For example, the territorial limits of patents have led to suggestions that developing-country research institutions should use technologies that are not patented domestically but are patented in more-developed countries. Legally, a researcher using a technology in a country where no patent has been filed is not infringing. However, an obvious constraint surfaces when the product of the research is destined for export into a country where there is patent protection. In this case, despite the lack of patent protection domestically, it may be necessary to investigate the patent landscapes of export markets.

There are still further considerations. In order to use a technology that resides in the public domain domestically, but is patented elsewhere, a researcher may require the transfer of materials or know-how from the patentee. These often involve material transfer agreements (MTAs) with restrictive terms and reach-through obligations that may hinder research and interfere with broad access for researchers in developed and developing countries alike. Even where no patent rights are found, this situation may involve negotiating agreements (such as nonasserts) with the technology owner. In addition, even when large companies as patentees are not concerned with infringement issues or losing market share, the companies may be concerned about liability and stewardship issues. Finally, developing country research institutions, or the organizations that sponsor their research, may attach considerable value to the building of relationships with the company that has patented the technology. Therefore, despite the lack of patent protection and the legal freedom to use a technology, there may still be important reasons to negotiate a license.

7. THE MECHANICS OF DEFENSIVE PUBLISHING

This last section focuses on the mechanics of defensive publishing: how to best ensure that a disclosure precludes downstream patenting by others.

Elements to consider in drafting a successful defensive publication include: content, language of choice, publication venue, and publication date. The following sections elaborate on best practices in defensive publishing.

7.1 *Content*

The goal of defensive publishing is to prevent patenting in a particular technology area. Therefore, constructing a disclosure specifically designed to create evidence to prevent patentability will increase the likelihood that fewer patents will issue in this technology space. The disclosure should be as complete and detailed as possible. Where relevant, a publication should include descriptions of all parts of the experiment, experimental conditions, diagrams, formulas, procedures, sequences, materials, and methodologies. We indicated earlier that enablement of the publication may be important; a defensive publication should include evidence illustrating possession of the invention and enable a person skilled in the art to make and/or use the invention.

7.1.1 *Consider disclosing the potential for combining technologies*

In addition to a thorough description, defensive publishing should include potential combinations of the target technology with other technologies. This is true even for combinations for which the author may not have detailed documentation. As the case study of E8 revealed, the inclusion of additional combinations can expand the use of the document to support future nonobviousness rejections. Publishing the sequence of the E8 plant promoter did not prevent the issuance of future patents claiming the use of the promoter *combined* with particular genes. If the authors of the original publication had ended their paper by articulating the likely success of the sequence for promoting the expression of broad classes of genes, there may have been stronger grounds for rejecting subsequent patents. To extend this point, a defensive publication may be even stronger if it anticipates not only the promoter-gene combination, but also its potential use in entire systems, such as the transformation method, selectable marker systems, and other elements of a plant transformation vector, as well as its use in particular crops.

Whether the inclusion of certain language in a publication will prevent future patenting in this case is uncertain, and it should be noted that the combination of prior art references in support of a rejection on nonobviousness grounds comes with several caveats. A successful rejection of a claimed invention due to obviousness must show, not only that someone skilled in the art would have been able to combine the prior art references, but that they *would have been motivated* to do so. Second, there must be a reasonable expectation of success for the purported combination. Third, the references taken together must teach or suggest all the elements of the claimed invention. When drafting the content of a defensive publication, it is impossible to anticipate all the possible combinations of the author's technology with that belonging to others, but by using language that acknowledges the caveats above, the author can broaden the subject matter of the disclosure as much as possible.

7.1.2 *Consider disclosing potential alternative applications*

As with potential combinations, it may be worthwhile to include alternative applications of the technology, even if they are not documented in detail. If the technology is a product, the author may want to consider including the current product, potential uses of the product, and derivative products. While defensive publication can place a product technology in the public domain, processes developed later using that product can still be patented. By anticipating potential applications, the author of the defensive publication may contribute to an obviousness-type rejection in the future. If the technology disclosed is a process, the author might consider including details of products derived from the process. These considerations anticipate the patentability of product and process patents. As an example of product and process patents, consider the famous Cohen-Boyer technology. This was not one patent, but three: (1) a process patent for the construction of molecular chimeras, (2) a product patent for proteins made using recombinant eukaryote DNA,

and (3) a product patent for proteins made using recombinant prokaryote DNA.[36]

7.1.3 *Consider disclosing related alternatives*

One way to design around a defensive publication (or a patent) is to alter, even minimally, the structure of the technology. TGo anticipate this, defensive publication can indicate how the technology may be altered while still maintaining the original disclosed functions and characteristics. This follows common practice in drafting patent claims. For instance, a sequence may be published that includes a percentage homology within which the function of the technology remains the same. In addition, it may be useful to include homologies across different species.

7.1.4 *Consider depositing biological materials*

For some inventions involving biological material, we have established that a written description is insufficient to convey the technology in such a way that a person skilled in the art can practice it. For such inventions, the patent system has come to depend on the deposit of biological materials in recognized, publicly accessible culture collections worldwide. As a rule of thumb, if the biological material can be made, or isolated, without *undue experimentation,* or if the material is otherwise known and readily available, it is not necessary to deposit material. In many cases, however, a defensive publication will be stronger if biological materials are deposited (the deposit accession number should be referenced, where relevant, in the publication and sequence information given).

Patent deposits worldwide have been regulated since 1980 when the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure came into force.[37] The World Intellectual Property Organization[38] provides an updated list of the countries that have ratified the Treaty and the collections that are recognized as international depositary authorities (IDAs).[39]

7.2 *Choice of language*

The choice of language (that is, English, or other) in a defensive publication can also be important. The publication language may need to be, for example, one spoken in the countries in which the patent will be barred. It may be important, however, to write at least the abstract and title in English to maximize the chances that this particular disclosure will be brought to the attention of the patent offices in the United States and Europe during prior art searches. Still, given the limitations of nonpatent prior art searching in patent offices, the best post-publication strategy is to monitor the published application in the technology field and alert the relevant patent office to the defense publication.

7.3 *Where to publish*

As noted previously, U.S. law uses the words "printed publication" in its novelty requirement. U.S. courts have adopted a broad definition of the word *printed*, to include documents stored on electronic media, and on microfilm.[40] Documents posted on the Internet may therefore be used to satisfy the printed aspect of the novelty requirement.

The word *publication* has also been fairly broadly interpreted to mean any printed document that is freely available to the public. Peer-reviewed publications are only one option for defensive publication, and their constraints on content may leave the author with a less than complete defense. Printed materials presented at trade shows, conferences, seminars, or on Web sites are all considered to satisfy the definition of *publication*. Indeed, major corporations have used this kind of defensive publishing as part of their IP management strategy for many decades. IBM provides perhaps the best-known example of the use of a technical journal for defensive publishing. The success of that strategy is illustrated by a 2002 search of the U.S. patent database by Bill Barrett that found almost 10,000 patent citings of IBM's *Technical Disclosure Bulletin*.[41] By publishing technical disclosures without the content restrictions of peer-reviewed publications, IBM wields an inexpensive, flexible tool that complements its overall patenting strategy.

A number of companies specialize in publishing nonpatent prior art. The Web site IP.com, for example, provides expertise in defensive

publishing and offers a search engine to make it easy for a patent examiner to navigate through the site's library of disclosures.[42] Disclosing an invention through such a company will increase the likelihood that a patent examiner will see it. The companies, however, may charge hundreds of dollars for such a disclosure. Another method of disclosure is the use of the statutory invention registration procedure, whereby the PTO allows for the registration of an invention that is unexamined. This method, too, can be expensive. The most cost-effective way to defensively publish is to publish for free on the Internet (but dating material published on the Internet can be problematic; see next section). If the Internet is used to publish defensively, there may be a greater need to monitor recently published patent applications in the field of interest.

7.4 *Timing and date stamping*

The date of a defensive publication is a critical piece of information that must be documented and discernible by the patent office. It helps the patent examiner to determine whether the publication brings into doubt the patentability of the subject matter. The dating of material published on a Web site can be a difficult matter: many documents on the Web are date stamped on the date of *access*, not the date of posting. Obviously, this practice can cause problems for a party those attempting to preclude future patenting in a technology area by using the Internet for defensive publishing. Fortunately, there are solutions. Many companies now offer digital time stamping (DTS) or digital notary services. This technology has become accepted legal proof that the contents of a publication existed at a particular point in time and has not changed since that time.[43] Another readily accessible method of establishing the date of an Internet publication is to scan a document that includes a date and a signature, and post the pdf on the Web.

8. CONCLUSION

This chapter has examined how IP managers and researchers can use the public domain and defensive publishing to their advantage. A strategic IP management plan begins by identifying the inputs and enabling technologies used in research. A strategic IP plan also clearly articulates the intended use of the technologies that are produced. Once this framework is established, IP management tools can be used effectively to support the project's goals.

The public domain is a valuable resource for early-stage thinking about a project's research tools. The above practical considerations will hopefully assist in effectively incorporating public-domain technologies into an IP management plan, thus reducing the need to in-license technologies and freeing up resources for more research. Moreover, when managing the products of a research project, one tool to consider alongside more traditional IP rights is defensive publishing, or placing a technology in the public domain. When considering defensive publishing, however, IP managers should keep in mind both its utility and its limitations. ■

ACKNOWLEDGEMENTS

Thanks to Fredh Fredrik, of the Center for Intellectual Property Studies at Chalmers University of Technology, for his research assistance and to Michael Lang of Harness, Dickey & Pierce, P.L.C. for reviewing and discussing an earlier version of this chapter.

SARA BOETTIGER, *Senior Advisor, One Shields Avenue, PRB - Mail Stop 5, University of California, Davis, Davis, CA, 95616-8631, U.S.A. sboettiger@ucdavis.edu*

CECILIA CHI-HAM, *Director, Biotechnology Resources, PIPRA University of California, Department of Plant Sciences, Plant Reproductive Biology Building, Extension Center Circle, Davis, CA, 95616, U.S.A. clchiham@ucdavis.edu*

---

1 Boyle J. 2003. Foreword: The Opposite of Property? *Law and Contemporary Problems* 66(1-2):25. www.law.duke.edu/shell/cite.pl?66+Law+&+Contemp.+Probs.+1+(WinterSpring+2003).

2 447 US 303 (1980).

3 The Bayh-Dole Act (1980) altered incentive structures surrounding the development of publicly funded research by mandating institutional ownership and the ability to exclusively license these inventions. See, also in this *Handbook,* chapter 3.3 by Gregory Graff and chapter 3.2 by Rachel A Nugent and Gerald T Keusch.

4 Because patents are territorial grants of exclusionary

rights, the patent landscape can vary considerably among countries.

5 Lange D. 2003. Re-imagining the Public Domain. *Law and Contemporary Problems* 66(1-2): 463. www.culturaleconomics.atfreeWeb.com/Anno/Lange%20Reimaging%20the%20Public%20Domain%20LCP%202003.htm

6 For example, the Biological Innovation for Open Society (BiOS, www.bios.net).

7 The discussion of the commons here derives from the excellent compilation of collected papers from the Duke Conference on the Public Domain (www.law.duke.edu/pd/papers.html), in Law and Contemporary Problems, 66, Winter and Spring 2003, where readers will find an in-depth discussion of many facets of the public domain.

8 See, also in this *Handbook*, chapter 14.2 by SP Kowalski; chapter 14.4 by GM Fenton, C Chi-Ham, and S Boettiger; and chapter 14.1 by A Krattiger.

9 See, also in this *Handbook*, chapter 10.5 by O Livne, chapter 10.6 by AS Viksnins and AM McCrackin, and chapter 11.8 by S Shotwell.

10 This section refers in particular to U.S. patent law. However, internationally the requirements for patentability tend to be similar.

11 35 U.S.C. § 101.

12 35 U.S.C. § 102.

13 35 U.S.C. § 103.

14 35 U.S.C. § 112.

15 A member of the public can also add citations. See footnote 14.

16 Alcácer J and M Gittelman. 2004. How Do I Know What You Know? Patent Examiners and the Generation of Patent Citations. Working Paper. www.olin.wustl.edu/cres/research/calendar/files/alcacer_gittelman.pdf#search=%22Alc%C3%A1cer%20and%20Gittelman%20(2004)%22.

17 Sampat BN. Examining Patent Examination: an Analysis of Examiner and Applicant Generated Prior Art. Working Paper. faculty.haas.berkeley.edu/wakeman/ba297tspring05/Sampat.pdf.

18 35 U.S.C. §301. Citation of prior art: *"Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential."*

19 §102(g) allows for proof of prior invention in any country that is a member of the WTO, but this is limited to cases where inventorship is disputed in a formal interference proceeding. Outside the scope of an interference proceeding, proof of lack of novelty is limited to printed documents and patents.

20 The one-year period is based on the *priority* date, which is usually the date on which the patent application is filed. It is possible, however, for a patent to have a priority date that is earlier than the date on which it was filed. Continuation and divisional applications, for instance, may retain the priority date of the "parent" application from which they are derived (in these instances it is even possible for one patent to have more than one priority date, as different content in the claims may have entered the patent application process at different times). In addition, the establishment of a priority date must encompass international applications. If a patent is filed on an invention in Japan, and then later a U.S. application is filed, the U.S. application will retain the priority date of the earlier Japanese application. Patent applications can also have earlier priority dates if a provisional application was filed first.

21 35 U.S.C. 103 Conditions for patentability; nonobvious subject matter.

22 *"Even if a reference discloses an inoperative device, it is prior art for all that it teaches." Beckman Instruments* v. *LKB Produkter AB*, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). *"A non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 U.S.C. 103." Symbol Technologies Inc.* v. *Opticon Inc.*, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).

23 In re LeGrice, 133 USPQ 365 (CCPA 1962).

24 Monsanto's patent application(s) for *Agrobacterium* mediated transformation have not yet issued as patents in the U.S. Until this happens, it is impossible to say with certainty which patents will be blocked by the issued claims. In addition, Monsanto's *Agrobacterium*-mediated transformation patents in other parts of the world have already expired; dominance changes by territory.

25 See *supra* note 8.

26 In addition to patents that have been abandoned due to non-payment of maintenance fees, some abandoned patent applications may also be in the public domain. Under a revised law, U.S. patent applications filed on or after 29 November 2000 are to be published within 18 months. Prior to this change in law, patent applications were not publicly available. The new law still contains an option for secrecy up until the point that the patent issues. If the patentee elects to forego foreign patenting, s/he has the right to request that the application remain unpublished.

27 See, for instance, www.uspto.gov.

28 www.pipra.org.

29 If the technology has an element of tangible property, bailment may be used (for example, material transfer agreements) to protect the technology under contract law instead of patent law—a choice that may be warranted in countries where patents are more difficult or prohibitively expensive to enforce in comparison

with contracts.

30 A report by the Global Alliance on Tuberculosis Drug Development on the economics of tuberculosis drug development estimated the cost of drug development for a tuberculosis indication was US$115-240 million. See *The Economics of TB Drug Development* (October, 2001) at www.tballiance.org. These figures are well below many other cited estimates for drug development cost, such as the well publicized study by DiMasi *et al* (DiMasi AA, RW Hansen and HG Grabowski. 2003. The price of innovation: new estimates of drug development costs. *Journal of Health Economics* 22: 151–185).

31 See, for example, BD Wright and PG Pardey. 2006. The Evolving Rights to Intellectual Property Protection in the Agricultural Biosciences. *Int. J Tech and Globalisation* 2(1/2):12-29. While they articulate the complexity of the issues and admit that *"definitive evidence on the effects of IPR on agricultural research will not be available soon, if ever,"* their paper also includes a catalog of examples where the path of research has been altered because of IP rights. Tomatoes with improved shelf-life characteristics, fungus-resistant strawberries, hypoallergenic wheat, as well as herbicide tolerant barley, turf grass, and lupin are all examples where research and development were suspended due to IP roadblocks.

32 www.bios.net.

33 Heher AD. 2004. Economic Modelling of Institutional Research and Innovation. Unpublished Report for SARIMA. SARIMA Project 3. University of Cape Town: Cape Town.

34 See *supra* note 33, page 3.

35 Contact PIPRA for more information on the written FTO opinion for this technology.

36 Intellectual Property Rights and Research Tools in Molecular Biology: Summary of a Workshop Held at the National Academy of Sciences, February 15-16, 1996 (1997), p. 40; www.nap.edu/readingroom/books/property/5.html.

37 The term "microorganism" was appropriate at the time the Treaty was named because the primary uses of biological materials in industry involved bacteria and lower fungi. Today the term is interpreted broadly within the context of the Budapest Treaty to include a wide range of biological materials (for example, bacteria, viruses, isolated DNA, and cell lines, etc. (see Fritz D and V Weihs. 2001. Deposition of Biological Material for Patent Protection in Bio-Technology. *Appl Microbiol Biotechnol* 57:443–450.)

38 www.wipo.int.

39 See www.wipo.int/treaties/en/registration/budapest/pdf/ida.pdf for a current list. Also of relevance is chapter 10.10 by Dennis Harney and Timothy McBride in this *Handbook*.

40 *In re Wyer*, 655 F.2d 221, 226-27 (C.C.P.A. 1981).

41 Barrett B. 2002. Defensive Use of Publications in an Intellectual Property Strategy. *Nature Biotechnology* 20:191-193.

42 www.ip.com.

43 For instance, www.digistamp.com offers non-profit organizations performing medical or environmental public research use of their service at 30 cents per time stamp.