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# Patents: Help or Hindrance to Technology Transfer?

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# Patents: Help or Hindrance to Technology Transfer?

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"Intellectual property" is a broad heading used to refer to a wide variety of rights associated with inventions, discoveries, writings, artistic works, product designs, and designations of the source of goods and services. Patents and trade secrets are the most important of these sorts of intellectual properties in the field of biotechnology.

One aspect of intellectual property that distinguishes it sharply from other forms of property—and for some people makes it harder to justify—is that intellectual properties may be possessed and used by many people simultaneously. This is not so for tangible property. If someone borrows my car, I cannot use it—nor can anyone else—until the car is returned to me, but if someone borrows my secret manufacturing process or my backup copy of my word processor, I can keep on using it while someone else is using it. In fact, no matter how many people I share my word processor with, as long as everybody can make a copy, it is not going to interfere with my ability to keep on using it. This capacity for simultaneous possession by many people is a feature that is common to all sorts of intellectual property, including computer programs, musical recordings, lists of customers, and self-replicating cell lines or genetically engineered organisms. Many people intuitively feel that they are doing nothing wrong when they make unauthorized use of intellectual property as, for example, when they borrow and copy other people's computer programs.

What, then, justifies a system of exclusive legal rights to ideas and

information that others could benefit from without depriving the owners of their use? In the United States, intellectual property is usually justified in instrumental terms, although some advocates of intellectual property try to justify it in moral or natural-rights terms. The instrumental justification for a patent system is that inventions and discoveries are often costly to make as an initial matter but cheap and easy to copy once someone else has made them. Because the public benefits from new inventions and discoveries, we want to encourage people to invest in research and development, but they might not be willing to do so unless they have some means of preventing competitors from reaping the benefits of their investment without sharing in the initial risk and cost.

## SECRECY AS A WAY TO PROTECT INTELLECTUAL PROPERTY

One way of keeping inventions and discoveries out of the hands of competitors is to keep them secret. As long as no one else knows the company's formula, the company does not have to worry about competition from outsiders who did not share in the cost of developing it. However, secrecy only works for certain types of inventions, such as manufacturing processes, that can be exploited commercially without disclosure. Many inventions and discoveries are self-disclosing once you sell a product that incorporates them. Even if secrecy is feasible, it might not be desirable. We might want to promote disclosure of new inventions and discoveries in the interest of furthering continuing technological progress in the field.

## PATENT PROTECTION

An alternative to secrecy for some inventions is patent protection. A patent gives an inventor the right to exclude others from making, using, and selling the invention for a limited term: 17 years from the date the patent is issued under current U.S. law, 20 years from the application filing date in many other countries. The inventor may choose to make, use, and sell the patented invention; license others to do so exclusively or nonexclusively; or suppress the use of the invention entirely. The one thing the inventor cannot do is to keep the invention secret. To obtain a patent it is necessary to file an application that includes a full disclosure of the invention and of how to make it and use it. In many parts of the world, this disclosure is made public 18 months after the application filing date. In the United States it is made public as soon as the patent is issued. Under either system, an inventor who wants to disclose the invention earlier can do so as soon as the patent application is on file without jeopardizing the prospects for getting a patent. So in addition to requiring

disclosure, patents promote disclosure by providing a property alternative to trade secret rights that survives even after disclosure.

Advocates of patents believe that they promote technical progress both by providing economic incentives to make new inventions and to develop them into commercial products and by promoting disclosure of new inventions to the public. The extent to which the present patent system achieves these goals is not known. Few people would argue that invention and technical disclosure would come to a standstill in the absence of a patent system. Firms that introduce new technologies into the market might find some research and development profitable even without patent rights. The lead-time advantage over competitors gained by being first in the market with an innovation, for example, might be enough to justify continued expenditures on research and development.

## COSTS OF THE PATENT SYSTEM

The prospect of obtaining patent rights undoubtedly increases incentives to invest in research and development, at least in some fields, but the social costs associated with having a patent system have to be weighed against these benefits. The most obvious social cost associated with patents is that they create monopolies that increase the price and reduce the supply of products that are covered by patents. This may be a tolerable cost for socially useful inventions that would not have been made without the incentives of the patent system—we might choose to have these inventions at a high price rather than not to have them at all, but it is a high price to pay for inventions that would have been developed even without patent rights.

It is therefore important to formulate rules of patent law that exclude from protection inventions that would have been made even without the added incentive of the patent system. Most patent systems attempt to do this by requiring that an invention have a certain level of importance before it can be patented. In the United States we require that an invention be new, useful, and nonobvious to be patented. The nonobviousness requirement is a mechanism for distinguishing between inventions that would come about without the patent system and those that need its added incentive. These rules are very difficult to administer and result in a lot of uncertainty in the patent system.

Patent systems also entail considerable administrative costs. These include the costs of determining which inventions are patentable, an activity that consumes the time and energy of technically trained people who might otherwise be adding to the knowledge base more directly. Patent applications also incur costs in procuring and enforcing patents,

and their competitors incur costs in avoiding infringement (including the costs of research efforts aimed at inventing around patented inventions).

Patents may also inhibit inventive activity of people other than the patent holders in fields that are dominated by patents. Patents may distort social priorities by diverting resources toward invention and away from other social problems. They may distort research in favor of making patentable inventions and away from areas in which patent protection is not available, such as basic research or discoveries in fields that are excluded from patent protection but might nonetheless be socially beneficial.

## THE PATENT SYSTEM IN BIOTECHNOLOGY

These costs of the patent system should be remembered when considering the role of patents in biotechnology, particularly the role of patents in publicly funded biotechnology such as the Human Genome Project (Eisenberg 1994a,b). The Human Genome Project is an interesting example because it involves extensive government funding directed toward generating vast amounts of information in the hope that that information will ultimately be put to use in developing new products and processes for the diagnosis and treatment of human disease. Much of this information is generated in government and university laboratories that are not in a position to undertake the research and development necessary further downstream to translate basic research discoveries into commercial products.

## PATENTING AS A WAY TO PROMOTE TECHNOLOGY TRANSFER

Technology transfer to the private sector is a prerequisite for the development of genome-related products, but how to achieve technology transfer in such a project is a complex matter. U.S. policy since 1980 has reflected an increasingly confident presumption that patenting discoveries made in government-sponsored research is the most effective way to promote technology transfer and commercial development of those discoveries in the private sector. Policy makers of prior generations may have thought that the best way to achieve widespread use of the results of government-sponsored research was to make them freely available to the public. Advocates of the new patenting strategy stress the need for exclusive rights as an incentive for industry to undertake the further costly investment necessary to bring new products to market.

This new strategy is justified in terms of both trade policy and technology policy. The trade policy argument is that although the United

States leads the world in basic research and the creation of new technologies, other nations do a better job of commercializing and adopting new technologies in the private sector. As a result, U.S. firms lose sales to foreign manufacturers of goods that are based on technologies pioneered in the United States. The competitiveness of U.S. firms in world markets might be enhanced by leveraging U.S. strengths in research into a stronger position of dominance in applied technology.

The technology policy argument is that government-sponsored basic research discoveries that have been left in the public domain have not been picked up by the private sector and developed into commercial products, or at least not at the rate that one would hope to see. If the economy needs a steady infusion of new technologies to grow and to improve worker productivity, many argue that we need to induce the private sector to tap into the wealth of new information emerging from government and university research. This rationale presumes that inventions made freely available are languishing in government and university archives rather than being actively exploited by all.

## NEW PATENT POLICY OF THE 1980s

The solution to these twin concerns, in keeping with the privatization ethos of the 1980s, was to offer up the results of government-sponsored research for private appropriation by U.S. industry through the mechanism of licenses under government- and university-owned patents. Exclusive patent licenses from a government agency or university would make it profitable for U.S. industry to develop products that would be too risky or costly to pursue if the discoveries were left in the public domain and competitors were therefore free to enter the market once it was established. Technology transfer facilitated by patent rights would generate new products for U.S. consumers and create jobs for U.S. workers while protecting U.S. firms from foreign competition.

Curiously, although the primary motive behind this patent policy appears to have been a desire to benefit U.S. industry, the primary impetus to get it enacted into law seems to have come from the government, with the support of universities, rather than from the private sector. Although industry has been slow to go for the bait of patent licenses to government-sponsored research discoveries, the government has not wavered from the patenting strategy but has instead fortified it by extending it to cover more discoveries made in a wider range of research settings.

Starting in 1980 the presumption in favor of patenting research discoveries was applied to small business and nonprofit organizations making research discoveries with federal funding under the Bayh-Dole Act. In 1983 these provisions were extended by a Presidential memorandum to

large businesses doing government-sponsored research. They were extended by statutory amendments to discoveries made at government-owned, contractor-operated facilities in 1984, then to intramural research and research performed under agreements between government agencies and the private sector under the Federal Technology Transfer Act of 1986. Subsequent legislation and executive orders have continued to broaden and fortify this policy.

Today we have a system that virtually guarantees that wherever federally sponsored inventions are made—whether in government, university, or private laboratories—anyone involved in the research project who wants the discovery to be patented may prevail over the objection of anyone who thinks the discovery should be placed in the public domain. Thus, for example, if a university is reluctant to patent a discovery made in its laboratories with federal funds, the sponsoring agency may insist on obtaining a patent. If a government agency or university has no interest in pursuing a patent, the investigator who made the discovery may step in and claim patent rights. If anyone sees money to be made through patenting a government-sponsored research discovery and has the resources and sophistication to pursue patent rights, chances are it will be patented.

## QUESTIONING FEDERAL PATENT POLICY

Now all of this makes sense if we want all government-sponsored research discoveries to be patented. But do we? Since 1980 federal patent policy has assumed that discoveries left in the public domain will not be used and that granting exclusive rights to discoveries to businesses will ensure their commercial exploitation for the benefit of consumers, taxpayers, and the economy. Our present statutes come close to reflecting a conclusive presumption that this is so. But is it so in fact?

The answer probably will vary from one field to the next and from one discovery to the next. The strong pro-patent tilt of current policy seems like a vast oversimplification of the enormously complex task of achieving technology transfer across the broad spectrum of discoveries emanating from federally sponsored research.

One reason for the complexity is that technology transfer requires extensive back-and-forth communication among different types of institutions and among researchers and technology users who speak to each other across significant cultural divides. The extent of this problem varies among fields. In some fields, researchers in government and university labs share norms of openness that conflict with commercial interests in secrecy. Patent rights may sometimes reduce this difficulty by providing intellectual property rights that survive disclosure. At other times, concerns about preserving the ability to patent future discoveries might for-

tify commercial incentives to maintain secrecy and thereby aggravate the conflict between the cultures of academic research science and industry. Any policy that promotes widespread patenting of the results of government-sponsored research would thus need to take into account and manage the effect of patents on the research enterprise.

Even setting aside the culture of academic research and focusing exclusively on the perspective of industry, current policy seems to oversimplify a complex problem. Patents may make sense as a means of facilitating technology transfer for some government-sponsored discoveries, but there are reasons to suspect that they make little sense for others. The course of scientific discovery and product development is infinitely complex, variable, and unpredictable. Uniformity in technology transfer policy may therefore be a false ideal. Neither the old-fashioned approach of leaving all new discoveries in the public domain nor the newer approach of assigning exclusive rights in such discoveries to private parties should be uniformly applied across the entire range of publicly supported discoveries. In our eagerness to avoid the inadequacies of the public domain approach, we may have moved too quickly and too emphatically in the opposite direction to the point where patent rights in some government-sponsored discoveries may actually be undermining rather than supporting incentives to develop new products and bring them to market.

## NIH APPLICATIONS FOR cDNA PATENTS

One sign of trouble in paradise for federal technology transfer policy was the reaction of industry trade groups a few years ago to the filing of patent applications by the National Institutes of Health (NIH) on thousands of partial cDNA sequences of unknown function identified in government laboratories (Eisenberg, 1992). The research that led to the controversial patent applications consisted of taking randomly selected cDNAs from a human brain tissue cDNA library and finding the DNA sequence for small portions of those genes without knowing what proteins or functions are associated with the genes. Beginning in the summer of 1991, NIH filed patent applications claiming the partial cDNA sequences as well as the full genes of which they are a part, which NIH claimed could be readily obtained with the partial sequence information. An avowed purpose of seeking these patent rights was to be able to offer licenses to firms to promote the development of products related to the sequences.

Some of these patent applications were rejected by the U.S. Patent and Trademark Office, and the new leadership of NIH decided not to appeal the rejections and to withdraw the remaining claims. Although the immediate controversy was thereby resolved, it is nonetheless worth-

while to reflect upon this controversy as a case study of the role of patents in technology transfer. These patent applications generated considerable controversy among scientists throughout the world who charged that the human genome represents the universal heritage of humanity and should be dedicated to the public domain. They argued that intellectual property rights could undermine scientific collaborations and thereby retard progress in the Human Genome Project. Much of the controversy within the scientific community has been a reprise of an old debate about the effect of intellectual property rights on research science norms.

What was striking about this controversy was that the patent applications were also opposed by trade groups from the industry that NIH intended to benefit through technology transfer. These trade groups are not composed of naive, idealistic scientists who have limited experience with patents and limited interest in product development. Their members are the same hard-nosed, profit-maximizing firms that the government is trying to entice into developing products out of government-sponsored inventions. Position statements from the Pharmaceutical Manufacturers Association and from two biotechnology trade groups that have since merged, the Industrial Biotechnology Association and the Association of Biotechnology Companies, expressed views on the NIH patent applications that contradict the hypothesis that patent protection for those particular discoveries was necessary to protect the interests of firms that might develop related products in the future.

The Pharmaceutical Manufacturers Association and the Industrial Biotechnology Association urged that NIH not seek patent protection on DNA sequences with unknown biological function but instead place such sequences in the public domain. The third group, the Association of Biotechnology Companies, supported the NIH decision to seek patent protection, but only as a means of generating revenues for the government and not as a means of ensuring the availability of exclusive rights to those sequences. Indeed, even the Association of Biotechnology Companies urged that the patents be licensed on a nonexclusive basis so as not to block development projects in industry. So although this position is nominally consistent with current federal patent policy, it contradicts its underlying rationale by conceding that, at least in this particular case, exclusive rights to the discoveries could interfere with their effective commercial development.

## INDUSTRY OPPOSITION TO NIH PATENTING cDNA

Why might U.S. industry object to NIH's pursuit of these patent rights and what does that tell us about the role of patents in technology transfer? First, an easy explanation is that the firms may not want NIH to be in a

position to grant or deny licenses to develop genome-related products. There is an essential irony in using government-owned patents to achieve technology transfer. This strategy places a government agency in a licensing role for the purpose of promoting privatization. If NIH holds patent rights to a significant portion of the human genome, it may use its position as licensor to regulate the development of genome-related products, which is the last thing that industry wants.

Exclusive licenses under NIH patents until recently included reasonable-pricing clauses that permit NIH to monitor the reasonableness of prices charged for licensed products. Exclusive and nonexclusive NIH licenses include domestic manufacturing clauses requiring the licensee to manufacture products in the United States or at least granting a preference for U.S. manufacture. Such provisions tie the hands of industry and limit the profitability of products developed even under an exclusive patent license.

Firms may be particularly wary of NIH as a licensor in view of its recent role in authorizing a generic drug manufacturer to pursue NIH's claim against Burroughs Wellcome to patent rights in the use of the drug azidothymidine (AZT) in the treatment of acquired immune deficiency syndrome. This episode highlights the ambivalence of NIH toward profit maximization in the marketing of health-related products.

Second, the patent rights that NIH sought may have seemed unnecessary as a means of protecting the profit expectations of industry. The current government patent policy is based on a simple model of technology transfer in which a patent on a government-sponsored invention is the only source of exclusivity on the horizon for firms seeking to develop related commercial products. However, commercial products in industries that make use of patents, such as the pharmaceutical industry, typically embody multiple patented inventions. If a firm has its own patent rights in a product that are adequate to protect its market position, NIH patent rights covering the same product or covering inventions that are necessary to develop or market the product may be nothing more than an annoyance to the firm. If government patents are not only unnecessary to provide market exclusivity, but also come with burdensome restrictions on pricing and place of manufacture, firms may see them more as a regulatory hurdle than as an incentive to innovation.

Third, NIH patents may have seemed ineffective in protecting the market position of innovating firms. Patent rights are most likely to be effective in promoting product development when they ensure the patent holder of a commercially effective monopoly in the relevant product market. Whether NIH patents would have had this effect depends on the scope of patent rights NIH had been able to obtain from the Patent and Trademark Office. Generally, the most effective commercial protection,

and therefore the most powerful incentive to invest in product development, is provided by a patent on an end product that is sold to consumers. Partial cDNA sequences of unknown function may turn out to be marketable as end products—perhaps in a diagnostic product—but it is more likely that they will be useful as research tools to find the full-length genes to which they correspond and to make the products for which those genes code.

The NIH patent applications included claims to these full-length genes on the theory that, by disclosing how to use the partial sequences as probes to find the full genes, NIH had provided an enabling disclosure of how to make those full genes. Although the NIH patent application did not disclose either the complete DNA sequence for the genes or the proteins for which they code, it did provide a general description of how to use the partial sequences as probes to find the full genes and how to achieve expression of the gene products once the full genes have been found. But under recent court decisions it is unlikely that NIH would have been able to obtain patents on the full genes without setting forth their full sequences (see, e.g., *Fiers v. Sugano*, 984 F.2d 1164 [Fed. Cir., 1993]). Thus, NIH patent rights would probably have been limited to narrower claims to the specific partial cDNA sequences than are actually set forth in the applications. Such limited patent rights would probably not have been broad enough to give effective commercial protection to firms seeking to bring related products to market, and the argument for obtaining patents as a means of promoting product development would lose its force.

## PATENTS ON RESEARCH TOOLS

The partial cDNA sequences themselves are primarily useful as tools for research and development. Not only is it difficult to detect and prove infringements of such patents, but often the only effective remedy even for proven infringement will be damages, because an injunction against future use of the invention at that stage would not thwart the efforts of a competitor who has already finished using the invention. One could argue for a substantial damage remedy, but as long as the competitor no longer needs to use the patented invention in the manufacturing stage, an injunction against future infringement would not serve to keep the competitor off the market. Firms that are interested in developing end products for sale to consumers are unlikely to see patents on research tools used only during research and development as an effective means of promoting their market exclusivity in the ultimate products. Such patents may generate royalty income for their owners, and the prospect of earning royalties may make it more profitable to develop further research

tools in the private sector. However, it is unlikely to enhance the incentives of firms to develop end products through the use of those research tools.

I think there are reasons to be wary of patents on research tools apart from their ineffectiveness in promoting product development. Negotiating licenses for access to research tools may present particularly difficult problems for would-be licensees who might not want to disclose the directions of their research in its early stages by requesting a license. Moreover, a significant research project might require access to many research tools. If each of these tools required a separate license and royalty payment, the costs and administrative burden could mount quickly.

Patent holders, moreover, may find it more lucrative to license research-tool patents on an exclusive rather than nonexclusive basis and in the process choke off other firms' research and development. For years this country has sustained a flourishing biomedical research enterprise in which investigators have drawn heavily on discoveries that their predecessors left in the public domain. Even if exclusive rights enhance private incentives to develop further research tools, they could do considerable damage to the research enterprise by inhibiting the effective use of existing tools. Patents on research tools may offer ineffective commercial protection to firms that use the tools to develop new products for consumers while interfering with research and development within those firms.

The more research that remains to be done to develop a product, the more likely it is that the innovating firm will make further patentable inventions of its own. These subsequent inventions are more likely to be incorporated in the final product, and patents on such inventions are thus likely to be far more important to the firm's profit expectations than exclusive access to any particular research tool.

## CONCLUSION

The present policy of promoting patents on federally sponsored inventions has become rapidly entrenched in U.S. law, although it is not clear that this policy always serves its underlying agenda of furthering the transfer of new technologies to the private sector for commercial development. Patents undoubtedly have a critical role to play in facilitating technology transfer in some contexts, but they can also interfere with technology transfer and with the broader goal of promoting continuing technological process. These goals may sometimes be served by allocating new information to the public domain. Government is uniquely situated to enrich the public domain, and we should be wary of disabling the government from performing this critical function in our eagerness to enhance private incentives to put existing discoveries to use.

## REFERENCES

Eisenberg, R. 1992. Genes, patents, and product development. Science 257:903-908.

Eisenberg, R. 1994a. A technology policy perspective on the NIH gene patent controversy. University of Pittsburgh Law Review 55:633-652.

Eisenberg, R. 1994b. Technology transfer and the genome project: problems with patenting research tools. Risk: Health Safety Environ. 5:163-175.