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The human genome project provides government funds for 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.[1] The recent controversy surrounding the National Institutes of Health (NIH) patent applications on thousands of partial complementary DNA (cDNA) sequences[2] derived in government laboratories highlights some of the complexities involved in achieving technology transfer in such a project.[3] Although under its new leadership NIH has recently changed course and decided not to pursue these patent rights,[4] the controversy nonetheless provides a useful focal point for considering the role of patents in technology transfer.

Federal policy since 1980 has reflected an increasingly confident presumption that patenting discoveries made in the course of government-sponsored research is the most effective way to promote

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1 U.S. Cong., Off. of Tech. Assessment, Mapping Our Genes (1988); Nat'l Res. Council, Mapping and Sequencing the Human Genome (1988).

2 For a brief description of the technology, *See* Christopher J. Harnett, *The Human Genome Project and the Downside of Federal Technology Transfer,* 5 Risk 151, 154 n.12 (1994). [Ed.]

3 *See* Rebecca Eisenberg, *Genes, Patents, and Product Development,* 257 Science 903 (1992); Reid Adler, *Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization,* 257 Science 908 (1992); Thomas Kiley, *Patents on Random Complementary DNA Fragments?* 257 Science 915 (1992); Bernadine Healy, *Special Report on Gene Patenting,* 327 N. England J. Med. 664 (1992).

4 *See* Christopher Anderson, *NIH Drops Bid for Gene Patents,* 263 Science 909 (1994).

technology transfer and commercial development of those discoveries in the private sector. Whereas 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,[5] advocates of the new pro-patent policy stress the need for exclusive rights as an incentive for industry to undertake the further costly investment necessary to bring new products to market.[6] In this new way of thinking inventions that are made freely available to anyone who wants them are presumed to languish in government and university archives rather than to be actively exploited by all.

Yet the reactions of industry trade groups to the NIH patent applications suggest that there are some limits to this approach.[7] 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, pragmatic, profit-maximizing firms that the federal government is trying to entice into developing products out of government-sponsored inventions through its patent policy.

Position statements from the Pharmaceutical Manufacturers Association (PMA) and from two biotechnology trade groups that have since merged, the Industrial Biotechnology Association (IBA) and the Association of Biotechnology Companies (ABC), expressed views on the NIH patent applications that contradict the hypothesis that patent protection for those particular discoveries is necessary in order to protect the interests of firms that might develop related products in the future.[8] The PMA and the IBA both urged that NIH not seek patent

5 *See, e.g.*, Hyman Rickover, *Government Patent Policy*, 60 J. Pat. Off. Soc'y 14 (1978).

6 *See, e.g.*, Healy, *supra* note 3; Adler, *supra* note 3.

7 *See* Eisenberg, *supra* note 3.

8 Letter from Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association, to L.W. Sullivan, Secretary of Health and Human Services, May 28, 1992; Industrial Biotechnology Ass'n, IBA Position Paper: Recommended Federal Policy Concerning Human Genetic Sequences Discovered by Federal Researchers, Contractors and Grantees (June 1992); Ass'n of Biotechnology Companies, ABC Statement on NIH Patent Filing for the Human Genome Project (May 1992). These

protection on DNA sequences whose biological function is unknown but instead place such sequences in the public domain.[9] The third group, the ABC, 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 in those sequences for firms.[10] Indeed, even the ABC urged that the patents be licensed on a nonexclusive basis so as not to block development projects in industry. 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 in discoveries could interfere with their effective commercial development. Generating royalty income for the government has never been among the justifications for patenting the results of government-sponsored research,[11] and it would be a singularly unpersuasive justification inasmuch as the public would have to pay the royalties under such patents as consumers (in the form of higher product prices) to collect them as taxpayers (in the form of NIH revenues).

These reactions to the NIH cDNA patent applications suggest that even if patenting government-sponsored inventions will sometimes promote their subsequent development into commercial products, at other times it will retard progress toward that goal, and that some government-sponsored inventions will be exploited, even widely exploited, if left in the public domain. The course of scientific discovery and product development is incredibly complex and variable and unpredictable. Neither the old-fashioned approach of leaving all new discoveries in the public domain, nor the current approach of assigning exclusive rights in such discoveries to private parties, should be

statements are analyzed in Eisenberg, *supra* note 3, at 907 and in Adler, *supra* note 3, at 912-913.

9 Letter from G.J. Mossinghoff to L.W. Sullivan, *supra* note 8; Industrial Biotechnology Ass'n, *supra* note 8.

10 Ass'n of Biotechnology Companies, *supra* note 8.

11 *See* Healy, *supra* note 3, at 665 ("The rationale is not to make money, but rather to promote and encourage the development and commercialization of products to benefit the public, and to do so in a socially responsible way.")

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 today patent rights in some government-sponsored discoveries may actually be undermining, rather than supporting, incentives to develop new products and bring them to market.

Prior to 1980 the policy and practice of the federal government with respect to patenting the results of government-sponsored research varied among agencies, and sometimes from one institutional agreement to the next.[12] In 1980, Congress passed two statutes that have set the course for government technology transfer policy since that time. The first of these statutes, the Stevenson-Wydler Technology Innovation Act,[13] made technology transfer an integral part of the R&D responsibilities of federal laboratories and their employees. The second, commonly known as the Bayh-Dole Act (Bayh-Dole),[14] focussed more explicitly on the role of patents in technology transfer, reversing the prior practice of some federal agencies of retaining public ownership of inventions made outside the government with federal funds. Under Bayh-Dole, small businesses and nonprofit organizations who were sufficiently diligent in seeking patent rights and promoting commercial development of inventions were to retain patent ownership themselves. In October 1983, President Reagan the benefits that Bayh-Dole had provided for small businesses and nonprofit organizations to all government contractors, including large businesses, so that now they too could retain patent ownership on inventions made in their laboratories with federal funds.[15]

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12 *See* James A. Dobkin, *Patent Policy in Government Research and Development Contracts,* 53 Va. L.Rev. 564 (1967).

13 Pub. L. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-3714).

14 Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-27 (1980) (codified as amended at 35 U.S.C. §§ 201-211).

15 Presidential Memorandum to the Heads of Executive Departments and Agencies, Subject: Government Patent Policy, 1983 **Pub. Papers** 248.

Congress passed a series of amendments to Bayh-Dole in 1984 extending its provisions to inventions originating at government-owned, contractor-operated facilities and repealing limitations on the permissible duration of licenses from nonprofit organizations to large businesses on government-sponsored inventions.[16] Then, with passage of the Federal Technology Transfer Act of 1986,[17] Congress authorized federal laboratories to enter into cooperative research and development agreements (CRADAs) with entities in both the public and private sectors and to agree in advance to assign or license to the collaborating party any patents on inventions to be made by federal employees in the course of collaborative research.

Subsequent legislation and executive orders have continued to broaden and fortify the emerging pro-patent policy,[18] attempting to close any loopholes that might leave potentially valuable discoveries in the public domain. Today, we have in place a system that virtually guarantees that wherever federally-sponsored inventions are made, whether in government, university, or private laboratories, if anyone involved in the research project wants the discovery to be patented, they may prevail over the objections of anyone who thinks the discovery

16 Pub. L. No. 98-620, 98 Stat. 3335 [Trademark Clarification Act of 1984].

17 Pub. L. No. 99-502, 100 Stat. 1785 (amending the Stevenson-Wydler Technology Innovation Act of 1980).

18 *See, e.g.,* Technology Competitiveness Act of 1988, Pub. L. No. 100-418 Title V, Subtitle B, Part I, Subpart B, 102 Stat. 1107, 1433-39; National Technical Information Act of 1988, Pub. L. No. 100-519, Title II, Subtitle B, 102 Stat. 2589, 2594-96; National Competitiveness Technology Transfer Act of 1989, Pub. L. No. 101-189, Division C, Title XXXI, Part C, 103 Stat. 1352, 1674-79; National Defense Authorization Act for Fiscal Year 1991, Pub. L. No. 101-510, Title VIII, Part C, §§ 827-828; 104 Stat. 1485, 1606-07 (1990); American Technology Preeminence Act of 1991, Pub. L. No. 102-245, Title I, § 108, 106 Stat. 7, 13; National Defense Authorization Act for Fiscal Year 1993, Pub. L. No. 102-484, Division C, Title XXXI, Subtitle C, § 3135(b), 106 Stat. 2315, 2640-41; Executive Order No. 12,591, 3 C.F.R. 221 (1987); Executive Order No. 12,618 3 C.F.R. 262 (1987); Proclamation No. 6489, 57 F.R. 47,249 (1992). The trend continues in currently pending legislation. *See, e.g.,* S. 1537 and H.R. 3590 (directing all federal laboratories to assign to their private sector partners the title to any intellectual property arising from a CRADA) and H.R. 3550 (establishing a "Technology Transfer and Commercialization Corporation" to act as the federal government's agent in facilitating the transfer of patents, licenses, processes and technologies for commercialization in the private sector).

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.[19] If a government agency or university has no interest in pursuing a patent, the individual investigator who made the discovery may step in and claim patent rights.[20] If anyone sees money to be made through patenting a government-sponsored research discovery, if they have the sophistication and resources to pursue patent rights, chances are it will be patented.

Now, all of this makes a good deal of sense if we want all government-sponsored research discoveries to be patented. But I think there are reasons to question the effectiveness of patents as a means of promoting technology transfer in some contexts. At their best, patents provide essential incentives to undertake costly investments in product development. At their worst, they can create obstacles to subsequent R&D and add to a thicket of rights that firms must negotiate their way past before they can get their products on the market.

Patent protection is most likely to be an effective device for achieving technology transfer in the case of a patent that covers an end product for sale to consumers. It is least likely to be effective, and most likely to interfere with subsequent research and product development, in the case of a patent on a research tool that is to be used in subsequent stages of R&D but will not be incorporated into the end product as it is ultimately sold.

The essence of the argument for patenting research discoveries as a means of promoting their subsequent development into useful products is that patents permit the firms that invest in product development to reap the rewards of their investment through profits without facing competition from free riders that have not shared in the costs and risks of development. Patent rights enhance incentives to develop products by allowing firms to keep would-be competitors out of their markets for a while. During the patent term, firms can charge monopoly prices,

19 35 U.S.C. § 202(c)(1),(2).

20 35 U.S.C. § 202(d); 15 U.S.C. § 3710d.

and thereby earn an enhanced return on their development costs and compensation for their risks. Thus patent rights are most likely to promote product development when they ensure the patent holder or licensee of a commercially effective monopoly in the relevant product market. Patents on some discoveries lend themselves more readily than patents on other discoveries to protecting the monopoly positions of innovating firms.

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. Subject to the availability of substitute products that are outside the scope of the patent, such a patent confers a right to exclude competitors from the market for the patented product entirely, regardless of how they make it or what they use it for.

Somewhat less effective are process patents covering a specific use of an unpatented product. So long as there are other uses for the product that are not covered by the patent, the patent holder cannot stop competitors from selling the unpatented product itself and thereby driving down its price. If the product is available in the market at competitive prices from a variety of sources, it may be impossible to monitor what purchasers are using it for.

Also less effective are patents on starting materials or processes used in making an unpatented end product. Such patents do not prevent a competitor from making the product from different materials or through a different process, or even from using the patented materials overseas and then importing the unpatented end product into the U.S.[21] Such a patent may also be difficult to enforce because of practical problems in detecting and proving infringing activities in the manufacturing process that are not apparent from inspection of the end product as it is sold in the market.

Weaker still is a patent that claims products or processes that are used only during product development. Not only is it difficult to detect and prove infringement of such a patent, but often the only

21 Amgen, Inc. v. U.S. Int'l Trade Comm'n, 902 F.2d 1532, 1538 (Fed. Cir. 1990).

effective remedy even for proven infringement will be damages, because an injunction against future use of the invention will not thwart the efforts of a competitor who has already finished using the invention. One could argue for a substantial damage remedy if use of the patented product was an essential step in developing a lucrative product, and if infringement was willful the court has discretion to treble the amount of damages.[22] But so 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.

So firms that are interested in developing end products for sale to consumers are unlikely to see patents on research tools as a very effective means of promoting their market exclusivity. Instead, they will see such patents as potential stumbling blocks that they need to negotiate their way past in order to develop their 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, but it is unlikely to enhance the incentives of firms to develop end products through the use of those research tools.

Of course, one firm's research tool may be another firm's end product. This is particularly likely in the contemporary biotechnology industry, where research is big business and there is money to be made by developing and marketing research tools for the use of other firms. So, for example, even as the PMA and the IBA were calling upon NIH to leave its cDNA sequence information in the public domain, new firms were being formed to do further cDNA sequencing in the private sector, presumably with the hope of obtaining their own patent rights.[23] It may well make sense to have this particular task performed in the private sector, and patents may enhance the incentives of firms to step in. On the other hand, it may make more sense to leave this

22 35 U.S.C. § 284.

23 *See* Lawrence M. Fisher, *Mining the Genome: Big Science as Big Business,* New York Times, Jan. 30, 1994, Sec. 1, at 1, col. 3.

information in the public domain, even if that means that the government has to continue to bear the cost of generating it.

There are reasons to be wary of patents on research tools. For one thing, although the ultimate social value of such inventions is difficult to measure in advance, it is likely to be greatest when they are widely available to all researchers who might have a use for them.[24] For years this country has sustained a flourishing biomedical research enterprise in which investigators have drawn heavily upon discoveries that their predecessors left in the public domain. It is in the nature of patents that they restrict access to inventions in order to increase profits to the patent holder. A significant research project might call for access to a great many research tools; the costs and administrative burden could mount quickly if it were necessary for researchers to obtain separate licenses for each of these tools.

Patents are unlikely to interfere significantly with access to research tools by subsequent researchers in the case of an invention such as a chemical reagent that is readily available on the market at a reasonable price from a patent holder or licensee. Many of the tools of contemporary biotechnology research are available by catalog under conditions that approach an anonymous market. Under these circumstances it may be cheaper and easier to obtain the tool from the patent holder or a licensed source than it is to infringe the patent by making it oneself.

But not all research tools are readily available on a licensed basis in an anonymous market. Some esoteric research tools can only be obtained by approaching the patent holder directly and negotiating for a license. In this context patents potentially pose a far greater threat to subsequent researchers. Negotiating licenses for access to research tools may present particularly difficult problems for would-be licensees who don't want to disclose the directions of their research in its early stages by requesting a license. There is also a risk that the holders of patents on research tools will choose to license them on an exclusive rather than

24 *See* Rebecca Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use,* 56 U. Chi. L.Rev. 1017 (1989).

nonexclusive basis, in the process choking off the R&D of other firms before it gets off the ground. Such a licensing strategy may make sense for a start-up company that is short on current revenues, even if it is not value-maximizing in the long run from a broader social standpoint.

Another risk is that patent holders will try to use a device that has been increasingly popular with some biotechnology firms of offering licenses that call for the imposition of so-called "reach-through" royalties on sales of products that are developed in part through use of the research tool, even if the patented invention is not incorporated into the final product. So far patent holders have had limited success with such licenses. Firms have been willing to accept a reach-through royalty obligation for licenses under the Cohen-Boyer patent on basic recombinant DNA techniques, perhaps because the claims of that patent in effect extend to products developed through use of the patented technology. But reach-through royalty terms have met greater market resistance for the patents on the Harvard recombinant onco-mouse and polymerase chain reaction. Licenses with reach-through royalty provisions might appear to solve the problem of placing a value on a research tool before knowing the outcome of the research project, but it takes little imagination to foresee the disincentives to product development that they could create if they become prevalent. Each reach-through royalty obligation becomes a prospective tax on sales of a product. The more research tools are used in developing the product, the higher the tax burden mounts.

For all of these reasons, exclusive rights may be expected to inhibit the optimal utilization of research tools and interfere with product development. Moreover, innovating firms are likely to have other patent rights of their own in new products that are far more significant to their market exclusivity (and therefore to their anticipated profits) than any competitive advantage they obtain as a result of exclusive access to a patented research tool. The earlier in R&D an invention is used, and the more 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 along the road to product development that are likely to be incorporated in the final product. The absence of exclusive rights in research tools is thus unlikely to undermine the incentives of innovating firms to use those tools to develop new products.

A complication arises in the case of inventions that have significant current value as research tools, but might also be incorporated into commercial products at some time in the future. It may be necessary to be able to offer exclusive rights in the ultimate commercial product to innovating firms in order to give them adequate incentives to develop the products. This possibility may argue in favor of patenting inventions even if doing so is unnecessary to facilitate their present use as research tools, and even if it inhibits that use.

Intermediate strategies are possible to minimize any inhibiting effects on research. For example, one might add a research exemption to Bayh-Dole that would protect researchers who later use patented research tools developed with government funds from liability. Patent holders would still be able to enforce their rights against those who make, use or sell the inventions as commercial end products, including competitors who sell the invention to investigators for use as a research tool, but not against those who merely make and use the invention in their own research. Obviously, such an exemption would limit the value of patent rights in any government-sponsored invention that is useful primarily or exclusively as a research tool, although the protection against competitors who would sell the product to researchers provides some measure of protection. So long as other large scale producers can be excluded from the market, the patent holder will be able to reap the benefits of any significant economies of scale in production of the research tool. The lack of a remedy against researchers who make the invention themselves would still set an upper bound on the ability of patent holders to charge full monopoly prices, since at a certain point researchers might find it cost effective to make the research tool themselves rather than to buy it from the patent holder.

A variation on this approach would be to deny patent holders an injunctive remedy against research users, but permit them to recover a

reasonable royalty as damages. This would allow a tribunal to administer a more fine-tuned remedy to ensure that patent holders receive an adequate return where economies of scale are insufficient to induce researchers completely exempt from infringement liability to deal with the patent holder. It has the drawback of creating uncertainty for patent holders and researchers as to the level of royalties that the tribunal will deem reasonable. In an environment where some patent holders demand reach-through royalties for use of research tools, the potential damage remedy might seem intolerable to innovating firms. And opening books to consider how much of a royalty is reasonable is apt to be distasteful to firms on both sides of a dispute.

Of course, both of these approaches amount to compulsory licenses for research users of patented inventions, although only the latter is a royalty-bearing compulsory license. If they are perceived as such, they may be opposed throughout the industry. Universities and biotechnology start-up firms, who are most likely to be in a position to collect royalties on sales of research tools, will have a financial incentive to oppose any change in the law that reduces the value of patents on research tools. Pharmaceutical firms, who derive their profits from selling end products and have the most to gain from a policy that facilitates free access to research tools, oppose any form of compulsory licensing on principle, just as the National Rifle Association opposes any form of gun control. Perhaps the first alternative, which denies a damage remedy altogether, would seem less like a compulsory license provision than the second alternative, which limits damages to a reasonable royalty, although it is ultimately more hostile to the interests of patent holders.

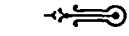
Any retreat from the broad giveaway of patent rights under present law will inevitably be opposed by some people in industry. This does not necessarily mean that a retreat would interfere with technology transfer. The rhetoric surrounding current federal technology transfer policy suggests that whatever is good for industry must be in the public interest. This is a vast oversimplification of the issue. The biotechnology industry is not monolithic. Rights that enhance the profits of small

start-up firms may interfere with the research of established pharmaceutical firms. The private sector responds to the profit incentives created by whatever policies the government puts in place. Whenever the government offers new property rights, one would expect someone to step forward to claim them (and to protest when it threatens to take them away). It doesn't necessarily follow that those property rights, on balance, will make us all better off.

I believe that patents have a critical role to play in promoting technology transfer. But the incentives created by patent rights in government-sponsored inventions would do little to compensate for the damage we could do to our research enterprise if we allocate too much of our new knowledge to private owners and too little to the public domain. To quote a recent opinion by Judge Kozinski:[25]

> ...Private property, including intellectual property, is essential to our way of life. ... But reducing too much to private property can be bad medicine. Private land, for instance, is far more useful if separated from other private land by public streets, roads and highways. Public parks, utility rights-of-way and sewers reduce the amount of land in private hands, but vastly enhance the value of the property that remains.
>
> So too it is with intellectual property. Over-protecting intellectual property is as harmful as under-protecting it. Creativity is impossible without a rich public domain.... Culture, like science and technology, grows by accretion, each new creator building on the works of those who came before. Overprotection stifles the very creative forces it's supposed to nurture.

Government is uniquely situated to enrich our public domain. 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.



25 Vanna White v. Samsung Electronics America, Inc., 989 F.2d 1512, 1513 (9th Cir. 1993) (dissent from decision rejecting a petition for rehearing en banc).