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VIEWPOINT

Limiting The Role Of Patents In Technology Transfer

Rebecca S. Eisenberg*

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 technology transfer and commercial development of those discoveries in the private sector. Whereas policymakers in the past may have thought that the best way to achieve widespread use of government-sponsored research was to make the results freely available to the public, the new pro-patent policy stresses the need for exclusive rights as an incentive for industry to undertake the further investment to bring new products to market.

Although this pro-patent policy may make a good deal of sense for some government-sponsored discoveries, there are reasons to suspect that it makes little sense for others. 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 that patent rights in some government-sponsored discoveries may actually be undermining, rather than supporting, incentives to develop new products and bring them to market. It is time to reevaluate the role of patents in technology transfer—on the basis of more than a decade of actual experience rather than uncorroborated fears—and consider how the present system might be improved.

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In 1980, Congress passed the Stevenson-Wydler Innovation Act, which made technology transfer an integral part of the research and development responsibilities of federal laboratories and their employees, and the Bayh-Dole Act, which reversed the prior practice of some agencies of retaining public owner-



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ship of discoveries made through federal research funding in universities and small businesses (see August 1993 issue, page 45). Later legislative enactments and executive orders have broadened and tightened the provisions of the Bayh-Dole and Stevenson-Wydler Acts wherever loopholes have appeared that might leave potentially valuable discoveries unpatented.

Under the system we have in place today, wherever federally sponsored inventions are made, whether in government, university, or private labo-

ratories, if anyone involved in the research project wants the discovery to be patented, chances are it will be patented. Thus, for example, if a government agency or university has no interest in pursuing patent rights in a discovery, the individual investigator who made the discovery may step in and claim them.

Now, all of this makes a good deal of sense if we want *all* government-sponsored research discoveries to be patented. But do we?

One sign of trouble in paradise for federal technology-transfer policy is the reaction of industry trade groups to the filing of patent applications in 1991 by NIH on thousands of partial complementary DNA (cDNA) sequences of unknown function. 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 Congress 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), contradicted the hypothesis that patents on cDNA sequences are necessary to protect the interests of firms that might develop related products in the future. PMA and IBA both urged that NIH not seek patent protection on cDNA sequences whose biological function is unknown. ABC supported the NIH decision to seek patent protection, but only as a means of generating revenues for the government. Indeed, even ABC urged that the patents be licensed on a nonexclusive basis so as not to block development projects in industry.

These reactions to the cDNA patent applications alone are enough to call into question the strong pro-patent tilt of current policy. It may be that under current law NIH had little choice but to pursue patent rights, but I am at least tentatively persuaded that later product development would probably be better served by leaving the sequence information in the public domain. This seems to suggest at the very least that federal agencies ought to have more flexibility to determine that *some* inventions would be better left in the public domain.

Can we say anything more specific than that at this point? One way of approaching that question is to consider how it is that patents are supposed to promote product development in order to identify circumstances in which the patenting strategy is unlikely to work.

The argument for patenting research discoveries as a means of promoting

their later development into useful products is that patents permit the firms that invest in product development to reap the rewards of their investment through commercially effective monopolies. That argument is generally true when a company obtains a patent on an end product that is sold to consumers.

Somewhat less effective are process patents covering a specific use of an unpatented product. The trouble with these so-called use patents is that as 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 from a variety of sources, it may be impossible to monitor what purchasers are using it for.

Another, even less effective, type of patent covers 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 end product into the United States. Such a patent may also be difficult to enforce because of the practical problems involved in detecting and proving infringement in the manufacturing process.

Weaker still, as a device to keep competitors out of the market, is a patent covering 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 effective remedy will be monetary damages because an injunction against future use of the invention will not thwart the efforts of a competitor who has already finished using it.

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 protecting their market exclusivity. Such patents may generate royalty income, and that prospect may make it profitable to develop further research tools in the private sector, but patents are unlikely to enhance the incentives of firms to develop end products through the use of those research tools.

On the other hand, one firm's research tool may be another firm's end product. This is particularly so in the contemporary biotechnology industry, in which research is big business, and there is money to be made by developing and marketing

research tools for use by other firms. For example, even as PMA and IBA were calling on NIH to dedicate its cDNA sequence information to the public, new firms were being formed to do further cDNA sequencing in the private sector, presumably with the hope of obtaining their own patent rights. 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 and do it. On the other hand, it may make more sense to leave this 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. Competing

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firms may hesitate to request licenses for fear of revealing the directions of their own research. Moreover, a large research project might require access to a great many research tools; if each of these tools requires a separate license and royalty payment, the costs and administrative burden could mount quickly. Another danger is that a company might refuse to make a patented research tool available to competitors at any price. Or, patent holders might find it more lucrative to license research-tool patents on an exclusive rather than a nonexclusive basis, in the process choking off the research and development of other firms.

Basic-research activities might also be affected. 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 significant harm to the overall research enterprise by inhibiting the effective use of existing ones.

Research tools may therefore be one example of the sort of discovery for which exclusive rights do more harm

than good. There are undoubtedly others as well. Certain fundamental inventions with a wide range of applications may be more effectively exploited if left in the public domain or otherwise made freely available to all than if patented and licensed on an exclusive basis. The absence of patent protection on fundamental techniques for producing hybridomas and monoclonal antibodies does not seem to have significantly retarded the development and patenting of commercial products using those technologies.

The time is ripe to take a critical look at the actual operation of our technology-transfer policy over the past decade and see how well it is working. This task calls for more than an examination of aggregate statistics on the percentage of patented inventions that have been licensed. It would be useful to know whether those inventions have led to the development of commercial products, and whether those products are protected by other patents that would provide a comparable degree of market exclusivity even if the government-sponsored invention had been left in the public domain. It would be useful to know what effect those patents have had on the research and development of competitors of the licensee or on other would-be licensees who did not win the exclusive license.

The rhetoric surrounding 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 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. It doesn't necessarily follow that those property rights are on balance creating new social value that will make all of us 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. 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. ■