The Role of Patents in Technology Transfer in the Human Genome Project

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This project is an empirical investigation of the effectiveness of patents in promoting the commercial development of products emanating from federally-sponsored research discoveries in order to improve understanding of the role of patents in technology transfer in the Human Genome Project.

Federal policy since 1980 has reflected a presumption that the most effective way to promote technology transfer and commercial development of discoveries made in the course of government-sponsored research is to patent them and offer them up for appropriation in the private sector. Yet there are indications that the prevailing pro-patent policy may oversimplify the complexities involved in technology transfer. Of particular relevance to the Human Genome Project, opposition from industry trade groups to the filing of patent applications by NIH on thousands of cDNA fragments suggests that in some circumstances filing patent applications on the results of government-sponsored research may actually be contrary to the interests of the private firms who are the targets of current policy. Technology transfer policy that rests on incorrect or oversimplified assumptions as to the effect of patents on industry incentives could have serious consequences for the success of the Human Genome Project in spawning new products for the diagnosis and treatment of disease. If the information generated in the course of the Human Genome Project is to be put to effective use in the private sector, it is important to understand when that information should be patented and when it should be left in the public domain.

My initial research plan was to identify recent examples of patented and unpatented discoveries emanating from federally-sponsored biomedical research that either had or had not been successfully exploited in the private sector, and then to examine selected inventions in greater detail in order to determine the significance of patent protection or its absence to the course of subsequent research and development of commercial products. As I anticipated in my grant proposal, I have had to adjust the design of my research project somewhat to make most effective use of the information that is available to me and to work around the information that is not available to me, as well as to address specific problems with current policy that have been highlighted by recent developments that I did not foresee when I wrote my grant proposal.

A tremendously significant development for understanding technology transfer in the

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Human Genome Project since the time I formulated my original research plan is the growth of private cDNA sequence databases and the controversy over the terms on which private firms are granting access to these databases. This development raises questions about appropriate mechanisms for transferring technology from the private sector to researchers in university, government, and industrial laboratories, and does not fit neatly into the model of technology transfer that underlies current federal policy, which envisions a linear and largely unidirectional process of moving discoveries from the public sector to the private sector.

I have been keeping close track of the different technology transfer strategies implemented by Human Genome Sciences, Incyte and Merck to achieve utilization of cDNA sequence information. These events provide a real world laboratory for viewing three competing corporate strategies for developing useful products out of an unpatented human genome: exclusive licensing, non-exclusive licensing, and public domain. Human Genome Sciences has entered into an exclusive license for access to its database with SmithKline Beecham; Incyte has entered into nonexclusive licenses with Pfizer and Upjohn; and Merck has taken upon itself the quasi-governmental function of generating a competing database to be placed instantaneously in the public domain. Since each of these approaches comes out of the private sector, one can assume that each of the firms believes, rightly or wrongly, that its strategy will maximize the value it obtains from the information. It is too soon to tell which strategy will pay off in the greatest number of commercial products, but the situation plainly merits continued monitoring.

Meanwhile, I have continued to search for and examine examples of patented and unpatented discoveries emerging from federally-sponsored research that illustrate the value and limitations of patent rights as a mechanism for achieving technology transfer. I have gathered considerable information concerning taxol and ceredase, two unpatented products that were originally discovered with federal funds and have been successfully commercialized. I have had more difficulty identifying illuminating examples of unpatented discoveries that have not been successfully developed into commercial products. Such inventions are generally not salient in anyone's mind. Moreover, the failure of an invention to achieve commercial development is such a common occurrence that it is difficult to say with confidence that a given unpatented invention would have been successfully commercialized if only it had been patented.

In the hope of learning more about how and when the absence of patent rights in a discovery impedes its commercial development, I have turned to evidence from the era before Congress promoted patenting the results of federally-sponsored research under the Bayh-Dole Act. The legislative history of the Bayh-Dole Act contains extensive testimony about both the virtues and the hazards of leaving research results freely accessible, including many anecdotes from both points of view. Moreover, empirical studies of government patent policy from the 1960s and 1970s present aggregate statistical information on the rate of utilization of government- and contractor-owned discoveries during this era. I am in the process of writing up the results of my study of these sources, including a critique of the inferences drawn and arguments made on the basis of the available information.

One of the case studies of a patented invention that I am attempting to pursue in depth is the development of products related to the cystic fibrosis gene. This is an attractive candidate to study because of its obvious relevance to the Human Genome Project, because it is further along in development than other disease genes, particularly with respect to gene therapy, and because key patents on government-sponsored research discoveries are held and administered by my home institution, the University of Michigan. I have already spoken at length with people at the University of Michigan, Genzyme, and Genovo, and have attempted with mixed success to learn the perspectives of other institutions (including commercial firms) that are attempting to develop gene therapy products for cystic fibrosis. I am trying to learn what interests these various institutions have in patents related to cystic fibrosis, what impact the issuance of patents to other institutions--or the licensing strategies followed by such patent-holders--has had on their research or on their incentives to pursue the development of commercial products, whether they believe they would behave any differently if patented discoveries had been put in the public domain, and whether they have any complaints about the way technology transfer has operated in this context. Whenever possible, I try to arrange personal visits rather than relying on telephone conversations, particularly when I do not have a preexisting relationship with the institution.

Other more recently discovered genes are also shedding light on the significance of patents on the results of government-sponsored genome research. The intellectual property stories for some of these genes have found their way into the press, including genes associated with breast cancer, colon cancer, and obesity. I am endeavoring to learn what I can about the significance of these patents to the institutions involved in research and product development, but am somewhat hampered by the reluctance of many firms to talk about their proprietary rights and information with someone who plans to publish her observations. Sometimes I am able to learn a great deal from publically-available patents and SEC filings. With the passage of time, more information becomes available to me, which makes it particularly important that I continue gathering information for a while.

I have recently agreed to chair a workshop for the National Academy of Sciences and Institute of Medicine on intellectual property rights in research tools. I anticipate that this role will give me an opportunity to learn more about the role of patent rights in the dissemination of a type of invention that is very important to the Human Genome Project from sources that might be more willing to disclose information in such a workshop than they would be to cooperate with an academic investigator. In any event, it brings another source of institutional resources to bear on the issues I am studying.

In addition to examining additional inventions and continuing my investigation of previously identified inventions, in the remaining time under my grant I plan to talk to more university technology transfer offices about what they are trying to accomplish by patenting and licensing their inventions, how they select inventions for patenting, how they identify or select licensees and set license terms, and what they see as examples of successes and failures of the present system. So far I have visited the technology transfer offices at the University of Michigan, M.I.T. and Stanford and found some interesting differences among them. I have

also been gaining some insight into the technology transfer process from hearing the perspectives of people in industry who deal with university technology transfer offices.

As the information comes in, I am writing up the results of my investigation to date. I have presented preliminary thoughts in a number of talks, some of which have been written up in press reports or reprinted in records of conference proceedings. I have not otherwise published the results of my research.

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