NIH GENE PATENTS: A SOLID FOUNDATION FOR THE INDUSTRY

by Kurt A. MacLean

The U.S. biotechnology industry, I am convinced, is taking the wrong path in objecting to applications by the National Institutes of Health (NIH, Bethesda, MD) to patent its discoveries of thousands of human genes, in most cases without any knowledge of the specific functions of those genes.

The recently discovered genes—really fragments of DNA segments—have been identified as a result of NIH's multibillion-dollar human genome project (HGP), the goal of which is to identify as many as possible of the 50,000 to 100,000 human genes believed to exist.

Although the contents of the NIH patent applications are still confidential, a strong case can be made that the NIH will eventually succeed in patenting most, if not all, of the genes it has identified. Because U.S. patent law protects several categories of invention, including "compositions of matter," the genes certainly fall into the category of patentable subject matter.

Another requirement for patentability is that the invention must have "utility" or practical use. But as the NIH's critics point out, the specific functions of most of the genes the NIH has identified remain unknown. (A gene that, for example, is identified as producing a protein that can treat a specific disease—as genetic engineering is popularly understood—would have an obvious use.) The lacuna of practicality, however, is not likely to present a fatal challenge to the NIH patent applications. Virtually every gene identified will at some point in the future have practical utility in research, either as a genetic probe or as a marker.

As a result, the odds weigh in favor of the NIH succeeding in its patent applications. But would its success prove harmful to the biotechnology industry? On the contrary, I believe that the NIH's actions represent not only sound public policy, but will also provide a solid foundation for the flourishing of the private genetic engineering industry.

The NIH's attempt to patent its gene discoveries represents, above all, sound public policy. A patent cannot be obtained retroactively, so if the NIH is going to keep open the option of patenting any of its inventions, it must act now before the inventions become publicly known. It can always decide later to dedicate its inventions to the public or to issue royalty-free licenses.

If its patent applications are granted, the NIH will also have the option of protecting the fruits of its research by effectually licensing the use of its gene patents to private institutions such as corporations and universities. Fees generated by those licensing agreements could help the federal government offset or recoup the enormous expenditures of the HGP while enabling licensed industries to share in the benefits of its research.

This may prove critical in the fiscal environment dominating Washington today. It is almost certain that the days in which taxpayers routinely underwrite the astronomical costs of Big Science and make the results available free-of-charge are over. So the NIH policy could, in fact, provide a rationale for continuing publicly financed, large-scale scientific projects by proving that they can actually provide a financial return to taxpayers. This would certainly improve the chances that the NIH will succeed in selling its next Big Science proposal to Congress.

That, in itself, would be an enormous benefit to private industry and academic institutions, but the NIH actions also present more immediate advantages to biotechnology firms. For one, the complementary side of the patent law is that the party seeking the patent must publicly disclose its discovery and may not hold what it has learned as a trade secret. That means that the NIH discoveries will become public knowledge that much more quickly.

Private genetic engineering firms should also bear in mind that patent law permits them to apply for patents on any new uses or applications they discover during the course of their research, even on what may eventually become NIH-patented genes. So if a private company learns that a known NIH patented gene can produce a valuable compound or a treatment for a disease, it may patent the new use.

The company would then have the opportunity to conclude a licensing agreement with the NIH for the use of the gene itself and thereby enjoy the exclusive right to market the product for its patented use for 17 years. Of couse, if a competitor found a different commercial application for the gene, it could apply for yet another patent on that use as well.

By attempting to patent its genetic inventions, the NIH is creating a level playing field on which the genetic engineering industry will be able to compete. By making its discoveries known to the industry and responsibly licensing these inventions to qualified institutions and commercial entities, the NIH is firing the starting gun on a race to bring these inventions to the marketplace. Without patent protection, many small, startup biotechnology companies would be unable to compete with the established giants, many of whom are actively patenting their own biotech inventions. In doing so, the NIH provides a good example of how government can nourish a growing industry while protecting the spirit of competition so necessary for its success.

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