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Shifting Sands? The Intellectual Property Basis of Biotechnology

As the United States has changed its economic model from the industrial base of the early and mid twentieth century to the discovery and entrepreneurial base that now characterizes large portions of the modern economy, the key role of intellectual property has become critical. Without the ability to patent discoveries in an understandable and predictable fashion, the financial investments in discoveries would not be available to convert them from ideas to demonstration projects and ultimately to economically potent companies. As a result, the United States has long decried other countries which historically have not abided by the rules that the rest of the world used to protect intellectual property.

As an example, China was long thought of as notorious for ignoring patent protections and for changing the rules under which the ownership of ideas could be determined. They still have many issues to resolve over the free flow of information and the use of the Internet, but basic intellectual property as it applies to biotechnology is now is largely regularized. India long sought to avoid intellectual property recognition, for instance on drugs for patients with AIDS, because it had a social need for access to those drugs without the ability to pay for them. Now that the country has itself become a source of intellectual property for the development of drugs, it too has regularized the approach to intellectual property.

All through this period, the United States has had a relatively stable environment for the principles of management of intellectual property as it applies to biotechnology. Starting with the Bayh-Dole Act, which this journal has covered extensively in several issues, and moving on to the discussion of the economic issues associated with companies that patent genes, the scientists, the companies, and the markets have known what to expect. Now this may no longer be true.

—THE MYRIAD CASE

On March 29th, the U.S. District Court for the Southern District of New York announced a decision that patents held by Myriad Genetics on genes associated with breast cancer violated long-standing precedents which prevented the patentability of natural phenomena. The court said that the DNA over which Myriad Genetics Inc. claimed a monopoly via patents could not be allowed since it claimed patents for "the physical embodiment of laws of nature."

The court also rejected Myriad's patent claims on tests that the company had developed in which it compared gene mutations to determine a patient's genetic basis for an increased likelihood for breast or ovarian cancer.

Myriad plans to appeal this decision to the U.S. Court of Appeals for the Federal Circuit, which oversees patent cases. More importantly, this ruling had the effect of casting doubt on other existing patents on other genes in the human genome.

From a practical point of view, this ruling, if upheld, could invalidate large numbers of similar genetic based patents and make the search for genes that cause disease and the ability to develop specific tests to screen patients for these genetic markers more difficult. Financing the discoveries and the development of individual tests might become economically impractical if this ruling is upheld.

On the other hand, mass screening of populations for genetic defects that predispose to illness (personalized medicine) might be enhanced by these developments. From the point of view of mass screening, the idea of negotiating with dozens if not hundreds of companies to acquire the ability to put together a large panel of tests was problematic if the Myriad approach is to be followed. It might never have been possible to put together meaningful panels of tests if the complexity of licensing under different terms from different companies was the model to be used.

As a result, long term implications of the decision are far reaching and intellectual property is now up in the air for a whole host of biologic discoveries.

Editorial

—THE NATIONAL INSTITUTE OF HEALTH/NATIONAL CANCER INSTITUTE INTELLECTUAL PROPERTY POLICIES

Virtually simultaneously with the District Court ruling, the Federal Register of April 6th, 2010 (Volume 75 No 65, p17412-17414) announced a proposed change in intellectual property agreements with certain funding recipients using the Cancer Therapy Evaluation Program (CTEP). As is stated in the Federal Register, "if finalized, (it) would establish that potential applicants for CTEP funding should include an assurance of agreement with the recommended Intellectual Property Option and Institution Notification if they wish to be considered for funding support to carry out any CTEP sponsored clinical trial for which CTEP holds the Investigational New Drug (IND) Application.

The basic issue is that "the current IP option language is silent as to the disposition of intellectual property developed from data and Agent-treated samples. As a result, both Collaborators and Institutions have claimed an ownership interest in inventions generated from these data and materials."

The proposed rules, now open for discussion, are suggested to "clarify" those issues, but there will be much lack of clarity until the rules are finalized and the implementation of them, if approved, becomes reproducible and standardized.

With this as a background, the journal has an issue specifically devoted to the changing landscape of intellectual property in biotechnology and the timing could not have been more appropriate. ■