



PTO Pulse - March, 2000

Are **Biotechnology** Patents Important?

By Lila Feisee and Brian Stanton

We think so! At the turn of the 19th century, the bulk of all patents covered bicycle- related technology. As the 20th century progressed patents covered space technology, computer technology and the area of biotechnology. Now, we are observing an ever increasing number of patents issuing in the area of Bioinformatics. Bioinformatics is the technology that brings together biology and chemistry into the information technology era, opening the door for an ever-widening array of new discovery.

Biotechnology is one of the most research intensive and innovative industries in the global economy today. While the promise of new discovery is great, this does not come without cost. It takes hundreds of millions of dollars to bring a new pharmaceutical to the marketplace. Without patent protection for biotechnological research, there would be little incentive for investors to risk their capital and many of the potential benefits of biotechnology would not come to fruition. By rewarding inventors for their discoveries for a limited time, the patent system supports innovation while, at the same time, dedicating these discoveries to the public. Thus, both the private sector and the public benefit.

Patent protection in the area of biotechnology also serves the larger economy by providing a forum that encourages both innovation and investment. It also benefits society by providing the means to reduce disease and suffering for both humans and animals. Such results promote and enhance the dignity and quality of life. Moreover, agricultural research holds the key, among other things, to providing sufficient food for the world's ever-increasing population. Biotechnology patents allow for the dissemination of potentially valuable scientific information. The availability of the information disclosed in biotechnology patents enables others in the field of science to build on earlier discoveries. Not only can other researchers use the information in a patent, but by disclosing cutting edge scientific information, the patent system avoids expensive duplication of research efforts. It is only with the patenting of biotechnology that some companies, particularly small companies, can raise capital to bring beneficial products to the market place or fund further research.

In addition, this capital provides jobs that represent an immediate public benefit independent of the technological benefits. Continuing employment opportunities represent a national resource for the future because they encourage the youth of today to become the scientists and inventors of tomorrow. Thus, the patent system not only fosters benefits to our society today, but ensures our future ability to innovate and grow.

Innovations in biotechnology are incremental and have resulted in new areas of research and development in genomics and bioinformatics. This can be seen in the work of the government funded Human Genome Project and the research into genes, expressed sequence tags (ESTs), polymorphisms including restriction fragment length polymorphisms (RFLPs), variable nucleotide type polymorphisms (VNTRs), and single nucleotide polymorphisms (SNPs).

Gene discovery has been a prime area of research in biotechnology, especially as it relates to the determination of the underlying basis of human disease. One specific goal of the Human Genome Project has been to facilitate the discovery of genes that cause or contribute to human diseases. The granting of patents to genes allows inventors to obtain private sector funding for the development of methods of disease diagnosis and treatment. This additional capital obtained from private sources (such as venture capitalists) acts to supplement the increasingly limited funds available in the public sector (such as the National Institutes of Health and the National Cancer Institute). This synergism between private and public sector funding is evidenced by the nature and extent of subject matter that has been the object of patent protection.

For example, [U.S. Patent 5,777,093](#), issued to Shiloh, Tagle, and Collins on July 7, 1998, is directed to nucleic acids encoding mutant forms of the gene that causes ataxi-telangiectasia (AT). AT is a genetic disease that affects the skin, nervous system, and immune system and is present in approximately 2 in 100,000 individuals. The cloning of this gene has allowed the development of diagnostic methods as well as screening procedures to facilitate discovery of drugs that might be valuable for the treatment of this disease.

[U.S. Patent 5,888,722](#), issued to Costa De Beauregard et al., is directed to the gene that causes cystic fibrosis (CF). CF affects approximately 1 in 2000 live births in North America and about 1 in 20 persons are carriers of the disease. This patent is assigned to the Institut Curie of Paris, France and the Centre National de la Recherche Scientifique, Paris, France. The patented subject matter resulted from worldwide research efforts. This patent, while securing intellectual property rights to some mutant forms of the CF gene, did not affect the development of diagnostic methods for screening subjects for the presence of CF related genes. This patent also demonstrates the increasing support that the patent system plays in international commerce and discovery. The international economy and its underlying support in the intellectual property arena, is facilitating cooperation between inventors. This cooperation bridges national boundaries and serves to bring together innovators from around the world. By fostering this type of interaction, cooperation between the members of the brain trust of the world is occurring at an increasing rate, and the ultimate beneficiary is the public. Inventions that serve the public good are commercially successful and provide benefit to everyone.

Agricultural biotechnology is another area where patent protection has been and continues to be valuable incentive. The development of Disease Resistant plants such as disease resistant cucumbers, squash, melons and pumpkins ([U.S. Patent 5,514,570](#)) is a perfect example of how the patent system promotes dissemination of information. [U.S. Patent 5,629,175](#) claims method of producing a mammalian protein in plants and plant cells, i.e. plant bioreactors. [U.S. Patent 5,763,243](#) claims methods of making male sterile plants by reversible nuclear genetic system for male sterility in transgenic plants. [U.S. Patent 5,780,709](#) claims transgenic plants that exhibit increased tolerance to drought and salt resistance. These are just a few of the examples of patents in the area of agricultural biotechnology. With an ever expanding human population coupled with increasingly scarce agricultural resources, agricultural innovation is an essential element of our collective future. The patent system serves as one leg that supports continued growth in this area.

With the growth of biotechnology have come significant changes in the process of research, development, and commercialization and the emergence of entirely new areas of innovation and discovery. For example,

instead of working from the sequence of a known gene, many groups are now focusing on elucidating the significance of unidentified, but uncharacterized cDNA sequences. "Data mining" provides another resource for scientists to identify potentially useful biological molecules. Scientists are also able to discover genetic links to previously untreatable illnesses. These discoveries are not only pushing back the frontiers of medicine, but also challenging conventional assumptions regarding the feasibility of treating such illnesses.

In the United States, since the landmark decision of the United States Supreme Court in *Diamond v. Chakrabarty*, it is clear that patentable subject matter includes "anything under the sun that is made by the hand of man." Therefore, if a product of nature is new, useful, and nonobvious, it can be patented if it has been fashioned by humans. As a result, concentrated, isolated, or purified products of nature are patentable if the resulting concentrate is the product of human intervention and it does not occur naturally in that form. The decision in *Chakrabarty* has since paved the way for a variety of U.S. patents involving living materials, including genetically engineered plants and animals and genetic materials, including DNA fragments.

Are biotechnology patents important? The answer to this question is plainly yes. The reality is that biotechnology research provides us with great opportunities from eliminating and treating debilitating and deadly diseases to providing sufficient food for the world's ever-increasing population. There is every reason to believe that strong and effective patent protection will encourage research and development. As we enter the new millennium, we must continue to support, on an international level, the dynamic forces that hold solutions to worldwide dilemmas and the ultimate beneficiary is the public. New jobs, new discoveries, new therapies, and better life quality, are all supported by a strong patent system. Biotechnology is part of this system and will remain so for the future.

PTO Introduces *PTO Today* An Online Magazine

By Maria Hernandez

PTO TODAY, an online magazine targeted at PTO's external customers was introduced to the public on January 14. The *PTO TODAY* online magazine is published monthly and focuses on inside views and actions of the agency and its leadership.

The contents of *PTO TODAY* are the direct result of customer responses to a survey asking what they would like to see in a monthly publication. In keeping with customer preferences, *PTO TODAY* will offer readers practical information, such as tips to make filing patent and trademark applications easier and a monthly column focusing on the Commissioner's priorities for the agency. In addition, the magazine will feature stories that will keep PTO's customers up-to-date on legislative and policy changes, new programs, and current events. Plans for *PTO TODAY* include a quarterly print version that will be distributed free of charge to subscribers. For information on obtaining a subscription to the print version, e-mail can be sent to Ruth Nyblod, Managing Editor, Office of Public Affairs at ruth.nyblod@uspto.gov.

"I am very excited that the agency now has this ongoing forum to discuss topics that are of interest to our customers," said Q. Todd Dickinson, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks. "I look forward to sharing information on issues that are critical to enhancing the agency's responsiveness to our customers' needs and expectations."

The *PTO TODAY* will appeal to everyone including experienced patent applicants, intellectual property attorneys, and students or teachers learning about patents and trademarks for the first time.