SCHOOL OF LAW
CASE WESTERN RESERVE UNIVERSITY

Health Matrix: The Journal of Law-Medicine

Volume 12 | Issue 2

2002

BIOTECH IN NORTHEAST OHIO CONFERENCE -- The Role of the Private Sector in Biotechnology: Research and Development

Lila Feisee

THE ROLE OF THE PRIVATE SECTOR IN BIOTECHNOLOGY: RESEARCH AND DEVELOPMENT

Lila Feisee[†]

THIS DISCUSSION WILL PRESENT the perspective of the biotech industry. How can industry interface with entrepreneurs, investors, scientists, and researchers? One of the many services that the Biotechnology Industry Organization (BIO) provides is an annual meeting that will be held in San Diego, California this year. Last year our annual meeting attracted over 12,000 people from a variety of different sectors: private, public, investment, and from different countries. Our annual meeting presents good partnering and education opportunities. Since the completion of the first draft of the Human Genome in June 2000, there have been many questions raised in the ethical and economic realms. These issues have provided a good place to begin discussion. The biotechnology industry, as we all know, is in its infant stages. It will take a lot of work on the part of all of us here to be able to move forward and do things responsibly.

Let me just give you a little background. Since the early 1990s, there have been over 100 biotechnology drugs approved for marketing in the United States and worldwide.[1] There are 350 more in the pipeline ready to be approved or rejected, and 270-million people worldwide have been helped because of these biotech drugs.[2] But that was not always the case. I am going to present a little history to begin the discussion.

[†] Director of Federal Government Relations and Intellectual Property, Biotechnology Industry Organizations (BIO), Washington, D.C.

[1] *See* BIOTECHNOLOGY INDUS. ORG., EDITORS' AND REPORTERS' GUIDE TO BIOTECHNOLOGY 9 (2001) (indicating over 117), *available at* http://www.bio.org/aboutbio/guide2001/letter.pdf.

[2] *See id.*

Most of us know who Alexander Fleming was and that he discovered penicillin. Some of us know that he did it in 1928, but not many people can tell you who Andrew J. Moyer is and why penicillin did not become commonly available until 1941, almost a decade-and-a-half after it was discovered.

Andrew J. Moyer was a microbiologist with the U.S. Department of Agriculture in Illinois. At the start of World War II, the recognition that penicillin could treat wounded soldiers led to international cooperation in looking for a way to mass-produce the drug. In the U.S., Moyer was handed this assignment and he set to work.

He found that by culturing the Penicillium mold in a culture broth of corn steep liquor and lactose, penicillin yields rose dramatically. He also discovered that in this medium, continuous shaking further improved yields and the production rate. Andrew J. Moyer holds patent numbers 2,442,141 and 2,443,989. We'll come back to this story.

One of the questions that is raised as a result of the completion of the Human Genome Project is, who should own biotech inventions and why? This question is vital to the biotech industry. The answers have spurred the growth of biotechnology, and indeed, they will determine its future.

In answering this question we need to focus on a couple of things that have allowed the industry to move forward. One is in the area of the law, specifically patent law; and two, in the area of what government in its infinite wisdom has done.

Okay, most of us know that the patent system took root in the U.S. Constitution, but it really began over 600 years ago in Europe when limited monopolies were granted. The basis in the U.S. Constitution is Article I, Section 8, Clause 8. This is where the government is given the mandate "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[3] I underscore, *Discoveries*.

There have been a few other acts that have been passed which address intellectual property protections; specifically, in 1790,[4] 1930,[5] and the one in 1952,[6] where the Patent Act allows

---

[3] U.S. CONST. art I, § 8, cl. 8.

[4] Patent Act of 1790, ch. 7, 1 Stat. 109 (1845). This was the first U.S. Patent Act, which was amended in 1793 by a slightly longer act that is notable for its defini-

an inventor to patent a composition of matter or improvement on a composition of matter; also a process of making the composition of matter and a process of using it.

The law, however, forbids products of nature from being patented, as well as laws of nature and mathematical algorithms. Nothing in the Act precludes an extraction from nature to be patented as long as it has been formed into a useful composition of matter.

The courts have also upheld this. In 1979, in *In re Bergy*,[7] the Court of Customs and Patent Appeals held that a biologically pure bacterial culture was patentable and not a product of nature because this culture did not exist in nature in its purified form and could only be produced under very controlled laboratory conditions.

In 1980, the Supreme Court also held, in *Diamond v. Chakrabarty*[8]—some believe this was a landmark decision that allowed for the progress of the biotech industry—that genetically engineered bacteria useful for cleaning up oil spills were patentable. In writing for the majority, Chief Justice Burger cited the Congressional Committee Report accompanying the 1952 Act. He stated that, "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[9] So, the law is actually clear, very clear, on who should own biotech innovations.

Interestingly, before 1980, which is when the Supreme Court decision came out, there were only a handful of biotech companies. The innovator at the time was Genentec; then, after that, Cetus Chiron. But after *Diamond v. Chakrabarty*, the biotech industry grew phenomenally. Some say it is a coincidence, but I do not think so.

---

tion of what constitutes patentable subject matter in the United States. *See* Patent Act of 1793, ch. 11, 1 Stat. 318 (1848).

[5] Plant Patent Act of 1930, ch. 312, 46 Stat. 376 (1930).

[6] Patent Act of 1952, ch. 950, 66 Stat. 797 (1952) (specifying, among other criteria, that a composition of matter, or an improvement on the composition of matter, a process of making and a process of using the composition of matter make a discovery patentable).

[7] 596 F.2d 952 (C.C.P.A. 1979), *aff'd in part*, 447 U.S. 303 (1980), *and rev'd in part*, 444 U.S. 1028 (1980).

[8] 447 U.S. 303 (1980).

[9] *Id.* at 309.

There was another thing that helped in spurring the innovation and the biotech industry. That was the work that the government did. The Bayh-Dole Act[10] passed in 1980 by Congress addressed transfer of technology from the public to the private sector.

Since World War II, the U.S. Government had made significant contributions to the world science and technology base. Two of the major beneficiaries of federal spending at the time were universities and U.S.-based corporations. Universities benefited because the government would invest in something that might not necessarily create a product, and business would benefit because they could tap into what was created in universities and federal agencies in order to create a product.

Despite the perceived success, only five percent of the 28,000 patents that the government held at the time were transferred or licensed. That is an incredibly low amount. Most of the research that was done prior to the 1970s sat on the shelf gathering dust because no one had any incentive to do anything with the research.

Bayh-Dole had two purposes. One was to allow universities, not-for-profit corporations, and small businesses to patent and commercialize their federally funded inventions, and also to allow these federal agencies to grant exclusive licenses for their technology to provide more incentive to businesses.

Then we saw the growth of the biotechnology industry. Today there are over 1,300 biotech companies in this country alone. These companies are developing effective new therapies and cures for myriad diseases, including our most intractable illnesses, such as heart disease, cancer, Alzheimer's, Parkinson's, and osteoporosis.

In fact, I read about a procedure that was done in San Diego where transformed cells were injected directly into the brain of an Alzheimer's patient. We do not know what will come of it, but something will happen. This work was the collaborative effort between University of California at San Diego and a small company in San Diego.

The U.S. biotech industry is the world's largest by far and the most successful. It employs more than 150,000 people.[11]

---

[10] Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015.

[11] *See* BIOTECHNOLOGY INDUS. ORG., *supra* note 1, at 9-10 (indicating employment of 150,800).

That is more than the toy and the sporting goods industries together. If you add in the jobs that are generated indirectly by the biotech industry, the industry was responsible for nearly half a million jobs last year and a total of nearly $50 billion in revenue.

In Ohio there are over 350 biomedical companies—which would include just a little broader group than just biotech companies—that generate over $10 billion in revenue and employ 14,000 employees.

It is a sunny day for biotech now, but it is really easy for things to change. The industry is very research intensive and because our companies rely on private investment to support their research, they and their investors on Wall Street are very sensitive to public policy decisions. We saw evidence of this in March of 1999, the day I call the "black day for biotechnology," when President Clinton, along with Prime Minister Blair, said that genetic information should be publicly available. That day the biotech industry lost $5 billion.

That is astronomical, but we recovered. Not as much as we would like to, but we certainly did. And the good news is that a little explaining about intellectual property, especially in the case of gene patenting, can clear up a lot of questions.

Patents are not granted on broad DNA sequences of genes. A patent is awarded only if an applicant or a person or an inventor can describe a gene's role in human health or other commercial applications. This is very clear in the patent office guidelines, published in the *Federal Register*.[12]

A patent does not have any impact on academic researchers as long as they are not involved in commercial activity. Such researchers are free to work without getting licensed from companies or corporations. But without patents or intellectual property protection there would be no biotech industry, there would be no innovative drug development, or it would be dramatically slowed down.

To develop a biotech drug, it takes hundreds of millions of dollars, specifically $500 million, and somewhere between ten and fourteen years time. For every five drugs that enter clinical trials, only one is approved for patient use.

---

[12] Utility Examination Guidelines, 66 Fed. Reg. 1092 (Dep't of Commerce Jan. 5, 2001).

It is not hard to see here that intellectual property enabled companies to sell their treatments and cures in order to raise the revenues they need for further research and development. The biotech industry in 1999 spent over $10 billion on research and development, which is fifty percent of the $20 billion of revenues that they generated in 1999.[13]

The case of penicillin is a perfect case of lost opportunity. Fleming discovered it; he did not patent it; he did not know what penicillin did. But because there was no patent, there was no incentive for anyone to go forward and discover what it did. Eventually a company secured a patent on the manufacturing process and it was developed into a drug and then given to the public.

There are lots of compounds in nature that the biopharmaceutical companies have developed into drugs and biologics; for example, interferons, interleukins, and insulins. They are also all found in nature, but they are not found in a form that is usable as a drug or biologic. If a company extracts one of these from its natural setting and purifies it, identifies its structure, and determines how it affects human health, then they can patent it.

The patent system does not apply purely to manmade or synthetic inventions, because if we did not use what Mother Nature has created, we would not be able to benefit from all that there is in developing the perfect situation for health or for the new century.

It is true that one cannot patent an element found in natural form, but if you create a purified form of it that has industrial use; for example, neon, then you can certainly secure a patent.

The United States leads the world in research and development of biotech products. A key reason for this—and this could be an answer to a lot of the questions that were raised—is the government support of basic research at universities through funding from the National Institutes of Health (NIH).

Breakthroughs in basic research can lead to life saving therapeutics through cooperative efforts of the private and the public sectors. In addition, businesses need the proper environment in order to be able to practice what they do best. If any of you in this room can contact and work with the legislature, you

---

[13] *See* BIOTECHNOLOGY INDUS. ORG., *supra* note 1, at 10 (indicating industry statistics).

can help to create a business environment that will allow biotech industries to thrive. It is simply not enough to have a mechanism here; you also need the environment to be able to create and to grow.

We all know that the NIH is the preeminent American basic medical research agency, but the NIH also knows the value of intellectual property protection. For its contribution to the drug development process in 2000, the NIH was paid $52 million in royalty payments by the biopharmaceutical industry. Also in the year 2000, the NIH obtained 120 U.S. patents, filed 189 applications, and executed 185 licenses and 109 cooperative research and development agreements.[14]

The NIH is doing its share in allowing the biotech industry to move forward. In 1996, according to the Association of University Technology Managers Licensing Survey, of the $478 million in royalties that the universities received, eight-seven percent of it, or $416 million, were from life science inventions, most of which grew out of federal research grants.

As a result of the transfer of technology from the private sector in the last year alone, twenty-three new biotech drugs were approved for marketing in the year 2000.

Much of the basic research that yields these life saving therapeutics could not happen without NIH-funded research. But contrary to public opinion, NIH and government funded research cannot create biotech therapies. They are not equipped to do so. That is not their mission.

The notion that NIH research has spawned a biotech revolution is a real one, though it is a bit oversimplified. In most cases the government's role in bringing a new therapy to market is far upstream from the high risk capital intensive development and testing that biotech and pharmaceutical companies undertake.

The biotech industry, which has more than doubled its revenues in the past six years, spent a greater percentage of those on research and development than any other industry.

Patent protection makes the investment of time and money in biotech possible, and technology transfer allows for the trans-

---

[14] OFFICE OF TECH. TRANSFER, NAT'L INST. OF HEALTH, NIH TECHNOLOGY TRANSFER ACTIVITIES—FY 1993 – FY 2001, *available at* http://ott.od.nih.gov/New Pages/nih.html (last modified Jan. 10, 2002).

fer of the information from universities and federal agencies to the private sector.

Without the ability to exclusively license these particular patents, biotech companies could not raise the hundreds of millions of dollars in capital that is required to create new medicines.

There are some people in Washington that are calling for what amounts to price controls on drugs that are developed from federally funded basic research. Senator Wyden, Democrat of Oregon, has said regarding the cancer drug Taxol: "This was not a drug that came about through the genius of the private sector. It was a drug developed at the National Institutes of Health by dedicated scientists who worked hard and were pushing with every ounce of their strength to come up with new products to help women."[15] He said this in response to the $1.5 billion that Bristol-Myers Squibb had collected on Taxol.

But consider this—to develop Taxol, Bristol-Myers Squibb invested approximately $1 billion. That does not include expenditures for marketing, advertising or sales promotion, while the NIH spent only $32 million. Not that $32 million is a small number, but compared to $1 billion it is. Both of them spent an estimated $65 million to $114 million in the Cooperative Research and Development Agreement (CRADA).

To give you more evidence of how Bristol-Myers Squibb conducted the majority of the research and spent the vast majority of the money to develop Taxol, I offer the fact that the company's employees devoted more than 205 staff years to develop Taxol in 1991 and 1992. This compares to 125 staff years that was listed in the NIH CRADA.

These stats are not presented to discredit the efforts that were put in by the NIH-sponsored scientists, but it is clear that the U.S. system here provides the best vehicle for commercialization of basic research and eventually getting therapeutic drugs to the patients who need them.

In the case of Taxol, the cooperative efforts of the public and private sectors developed and brought to the market a life-saving therapeutic. The lives that were saved due to this cooperative effort more than make up for the return on investment for NIH.

---

[15] 146 CONG. REC. S5823-07 (statement of Sen. Wyden).

The notion of price controls or what is called "reasonable pricing" came up in the early 1990s and again it is beginning to raise its head. Early in 1995 the NIH was told to review the prices that companies set on federally funded research discoveries. The NIH director at the time, Harold Varmus, indicated that the primary programmatic mission, legislative mandate, and expertise of NIH are in biomedical research, not in product pricing. As a result of this, there was a fourfold increase in the NIH CRADAS and creative cooperative research and development agreements with biotech and pharmaceutical companies. This just goes to show that without the looming threat of price control, a lot can be done in the area of biotech research.

In December of 1999, the NIH released the principles and guidelines about NIH funding with respect to transferring research materials and tools.[16] These guidelines indicate that any research tools that are developed as a result of federal funding should be broadly accessible, and the definition of research tools is very broad. It includes monoclonal antibodies, cell lines, animal models, reagents, combinatorial chemistry libraries, clones and cloning tools like PCRs, and even data bases and computer software to the extent that they are used in unique research tools.

In fact, last year a law was enacted that essentially gives these guidelines the force of law.[17] There are a lot of different obstacles that are in the way of the biotech industry. I think a lot can be done by creating a very nurturing environment, through legislation and cooperative efforts with your state legislature to enact tax incentives and research and development incentives to allow for the growth of industry. Work closely with your public officials to make sure that your State provides access to these incentives. More importantly, keep the lines of communication open with the biotech industry by participating in forums such as this one to share ideas and concerns.

---

[16] Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72,092 (final notice Dec. 23, 1999).

[17] *See* Technology Transfer Commercialization Act of 2000, Pub. L. No. 106-404, 114 Stat. 1742.