

Patenting of Biological Materials

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1. Introduction

The above passages provide a framework for discussing the patenting of biological materials. The constitution of the United States contains a provision which provides Congress with power to create a patent system to promote the progress of science.¹ Thomas Jefferson's writings confirm that he, as one of the founding fathers of this country, believed in the importance of fostering human ingenuity.² The federal statutes enacted to implement the constitutional provision calling for a patent system reflect the founding fathers' desire to promote ingenuity and the dissemination of information regarding new inventions.³ The Supreme Court of the United States has recognized and re-affirmed the broad role of patents in promoting the progress of science and mankind.⁴

Yet there remains an uneasiness felt by some about the patenting of biological materials. Although perhaps unartfully articulated, the 1995 statement by the religious representatives⁵ reflects the apprehension felt by those who oppose patents on biological materials.

The opposition to patents on this technology appears to be a manifestation of a variety of underlying concerns about biotechnology including, for example, the ethical propriety of this research, a fear of the potential uses of this technology, and a mistrust for the scientific intellectual elite. These underlying concerns may well have validity, and are certainly appropriate topics for informed debate. However, the opposition to patents on this technology is a misdirected and counterproductive means for addressing the underlying social issues. It appears that the opposition to biotechnology patents arises primarily as a result of unfamiliarity with the details of the patent system combined, ironically, with the widespread public awareness of the existence of the patent system. This awareness of the patent system makes it an attractive target for those who, for whatever reason, are uneasy with biotechnology research and its potential uses.

Like many legal topics which relate to morals, ethics, and/or theology, serious consideration of the patentability of biological materials can quickly yield to purely emotional and/or irrelevant arguments if the legal principles are misunderstood or if the metes and bounds of the discussion are not clearly defined. As a patent attorney specializing in biotechnology patent law it is my desire to provide here a summary of the relevant principles of the patent system and provide some insight into the history and current status of biotechnology patent law.

II. Personal Background

In order for the reader to understand my perspective relating to patent law I would like to provide a brief overview of my experience in this field. In addition to my ten years of professional practice in the patent field, I had the good fortune of growing up with my father, Roman Saliwanchik, who is one of the pioneers in the field of biotechnology patent law. I was in my third year of college when my father participated in the 1981 ITEST program on the *Patenting of Recombinant DNA*. I remember well my father sharing his ideas on this topic with our family. In fact, I am not so sure that, at that time, I believed it to be such good fortune to have a father who lectured on patent law at the dinner table and practiced his appellate arguments in the living room to a captive family audience. I now have a much greater appreciation for my father's vision of patent law as he participated in landmark legal decisions which have helped shape the evolution of biotechnology patent laws and, consequently, the development of the biotechnology industry.

As longtime ITEST members will recall, the 1981 conference followed the Supreme Court's affirmance of the decisions by the Court of Customs and Patent Appeals (CCPA) in the Bergy⁶ and Chakrabarty⁷ cases holding that living cells can be patented. In the Bergy case my father had successfully argued in favor of the patentability of "biologically pure cultures." The Chakrabarty decision acknowledged the patentability of cells which had been genetically engineered to confer upon those cells new and advantageous capabilities. These legal decisions were important points in the evolution of biotechnology patent law, and perhaps more importantly, the infant biotechnology industry. These legal decisions provided a critical spark which propelled the fledgling U.S. biotechnology industry forward. In the fifteen years since the Bergy and Chakrabarty decisions, the biotechnology field has rapidly expanded into a multibillion dollar industry employing thousands

and producing products which will benefit all of mankind. This rapid growth could not have occurred without the investment of enormous sums of time, effort, and money. It is extremely unlikely that such investment could have occurred without a legal mechanism for providing some limited protection for the fruits of this highly speculative research. The proper application of the patent laws by both the Patent and Trademark Office and the Courts have provided the necessary environment for this industry to flourish.

Although my background involves extensive experience with the patent system, I have also had significant exposure to the viewpoints of individuals who believe that the role of patents should be limited. My law school intellectual property courses at the University of Michigan were taught by Professor Rebecca Eisenberg. Professor Eisenberg has written extensively on the role of patents in protecting government inventions particularly in the biotech area. One topic which I will discuss in greater detail below is the efforts made by the NIH to patent DNA segments from the human genome. Professor Eisenberg, as well as others, have stated that the efforts by NIH to patent these DNA segments may be inappropriate.⁸ Professor Eisenberg's views are based primarily on economic and market grounds while others have objected to DNA patents on ethical and/or religious grounds.

Our law firm frequently represents foreign clients. We also represent domestic clients seeking to obtain patent protection throughout the world. To effectively represent foreign clients and obtain international patent protection it is important to recognize that, as a general rule, each country has its own patent laws. Patent protection can be obtained in a particular country only if the requirements of that country have been satisfied. Many of the basic requirements for patentability are common to all countries. For example, most patent systems have provisions limiting the availability of patent protection to inventions which are new and involve some significant advance compared to previously known subject matter. Although there are these basic similarities between virtually all patent systems, there are also important differences. For example, there are countries which will not grant patent protection for methods for treating humans.⁹ Other countries do not grant patent protection for pharmaceutical or biotechnology inventions.¹⁰ From my knowledge of foreign patent laws I am aware of the practical implications arising from such limitations on patents.

Even within the United States there are instances where patent protection may not be available for a particular invention or where, even if available, patent protection is not the best option for a particular technology. For example, inventors must often choose between patent protection and trade secret protection.¹¹ Trade secret protection is available for technology which can be kept secret. Once an invention is known to the public it, by definition, can no longer be kept as a trade secret. In sharp contrast to trade secret protection, a critical aspect of the patent system involves *full public disclosure* of how to make and use the invention.¹² This full disclosure occurs when a U.S. patent is granted and/or when a foreign patent application is published.¹³ Therefore, an inventor can initially pursue patent protection while maintaining trade secret protection; however, ultimately, these two forms of protection are mutually exclusive.

Also, our firm represents many colleges, universities, and other non-profit organizations. Some have argued that inventions at such institutions should not be patented and, instead, should be free for the taking. This issue will also be discussed in more detail below. Therefore, although my background includes extensive exposure to, and involvement with, the patent system, I am also very familiar with instances where consideration is given to limiting the role of patent protection.

In order to discuss whether patents should be awarded for DNA and other biotechnology subject matter, it is important to know the basic principles upon which the patent system is based as well as to have an understanding of the procedures through which patents are obtained. Therefore, I will provide here a brief overview of the purposes of the patent system, the legal requirements for patentability, and the administrative procedures which have been developed to enable the patent system to accomplish its goals.

III. Principles of the Patent System

When distilled to its most basic elements, the patent system is simply a means to encourage innovation and promote public dissemination of new ideas and discoveries. As noted above, the founding fathers of our country included within the constitution of the United States a provision calling for patents and copyrights to “promote the progress of science and the useful arts.”¹⁴ Virtually every developed country in the world has some analogous legal system designed to foster creativity and expedite the public dissemination of new innovations. Thus, patent systems are not a product of capitalism or any other economic system, nor is the patent system linked to democracy or any other political system. It is even more basic than that it is simply a means for encouraging creativity and, just as importantly, a means for facilitating the rapid public dissemination of new ideas.

The goals of the patent system are not only admirable, and consistent with the premises of virtually every known religious, moral, and/or ethical system, these goals are crucial to the mental and physical well being of all people. The spirit of innovation which is encouraged by the patent system is behind such disparate accomplishments and goals as the elimination of polio, putting a man on the moon, finding a cure for cancer, improving crop yields to help feed the world population, and the concept of the American Dream itself. Although there will likely always be Luddites and Rifkens who believe in the *status quo* and who are afraid of progress and man’s ingenuity, I have faith in the inherent goodness of people and believe that the prospects for innovation, invention, and advances in technology provide the basis for optimism that the quality of life for an people of the world can be improved.

Although I am a firm believer in the necessity for innovation and creativity, I do not advocate imprudent or careless use of technology. The risks inherent in the development or implementation of all new technologies should be carefully considered and weighed against the potential benefits of the technology. If the risk/benefit relationship is such that a new technology should be developed, then continued efforts should be made to minimize any potential risks. The analysis of the risk/benefit relationship, as well as the promulgation of regulations to ensure public health and safety, is carried out by trained professionals in governmental agencies such as the EPA, USDA, NIH, and FDA. This process of risk/benefit analysis and risk minimization should be carried out with the benefit of as much relevant information as possible. Thus, although the government has ultimate responsibility for many decisions relating to public health and safety, the scientific community, religious and academic leaders, and the general public all can, and should, provide informed input in this process.

In order to provide such informed input it is critical for these sectors of society to have as much access to up-to-date accurate technological information as possible. In this regard patents perform a critical function in providing public dissemination of state-of-the-art technological information. Therefore, rather than seeking to curtail the use of patents in the biotechnology field, anybody who is truly concerned with reviewing and thoughtfully considering relevant scientific information should be seeking ways to *promote* the use of patents as an efficient means to disseminate technological information.

IV. Procedures and Legal Requirements for Obtaining a Patent

Patents are granted only after the Patent and Trademark Office has determined that an invention, and its patent application, meet the strict requirements for patentability which have been established by Congress. The Patent Office employees given the responsibility of reviewing patent applications and making patentability determinations are known as patent examiners. There are hundreds of examiners in the U.S. Patent and Trademark Office. Each examiner has at least a bachelor’s degree in some scientific field; many examiners have doctorates, are lawyers, and/or have significant work experience.

Each patent application received by the Patent and Trademark Office is assigned to an examiner who is trained in the scientific field to which the invention pertains. The patent examiner reviews the application to ensure that all of the requirements relating to the form and the substance of the application have been satisfied. Of

primary significance with regard to the content of the application is the requirement that the applicant provide a complete written description of how to make and use the invention.¹⁵ This description must be sufficiently detailed and complete so as to enable a person skilled in the art to make and use the invention without undue experimentation. Such a full, detailed description is known as an “enabling” disclosure.¹⁶ This complete detailed account of the invention is published when a patent is granted in the United States, and/or 18 months from the filing date if an international application is filed. The publication of this description plays a central role in the patent system. Specifically, this publication enables other researchers and interested parties to have full knowledge of the technology so that they can improve on the technology and combine these teachings with their own knowledge and/or other such teachings, thereby efficiently expanding the store of human knowledge.

In addition to the written description of the invention, a patent application must include at least one “claim.”¹⁷ A claim is a concise statement, found at the end of a patent application, which succinctly states the subject matter which is to be covered by the patent. When a patent is granted, the patent holder can prevent others from making, using, or selling *only* the subject matter *covered by the claims*. Thus, an issued patent may contain a broad disclosure of certain technology but claim only a small aspect of the technology. On the other hand, the claims of a patent can *never* cover more than what has been enabled by the patent’s description. If a patent is granted, the duration of the patent rights is only 20 years from the filing of the application.

In addition to the requirements of the patent application there are, of course, strict requirements on the characteristics of the inventions which can be patented. These requirements have been promulgated by Congress in order to ensure that patents are awarded only for inventions which are the result of *human inventive ingenuity* and which represent substantial advancements of anything which was previously known to man.

In the United States there are three primary requirements which an invention must meet in order to be patentable. These are novelty, non-obviousness, and utility. I will discuss each of these requirements very briefly here and explain how these requirements prevent the patenting of subject matter which is useless, does not involve human intervention, or does not represent a significant advancement over known technology.

Novelty: To be “new” under the patent laws, an invention must not have been known and available to the public prior to the time when the applicant for patent “invented” it.¹⁸ Accordingly, if an uninformed researcher were to independently “discover” penicillin today, a patent would not be awarded because isolated and purified penicillin is already known and in the public domain. Similarly, chemicals, cells, viruses or other entities which exist in nature prior to the date of invention can not be patented because they are not new.

Non-obviousness: The U.S. patent statutes express the non-obviousness requirement as follows:

A patent may not be obtained though the invention [satisfies the novelty requirements] if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.¹⁹

The purpose of the non-obviousness criterion is to prevent the granting of patents for inventions which are merely predictable and/or are small advances over known technology. Therefore, the patent applicant may need to demonstrate that the invention was unexpected, highly advantageous, or otherwise more than the next logical step in the course of research, in order to satisfy the non-obviousness requirement.

Utility: Another requirement for patentability is that the invention be useful.²⁰ Accordingly a chemical molecule for which there is no known use cannot be patented.

The novelty, utility, and non-obvious requirements, together with the enabling description requirement, work in unison to ensure that only the most deserving innovations receive patent protection and, once a patent is granted, the public is provided with full access to the teachings of the inventors.

In the biotechnology field, the patent review process often takes 2-5 years or more, and typically will

involve multiple communications between the applicant and the patent examiner. As a result of the thorough examination given to each application, every granted patent carries with it a presumption of validity.²¹ Despite the presumption of validity accorded to each patent, a patent may be held to be invalid after it has been issued.

With a few exceptions, a patent application must be filed in each country where protection is sought. These patent applications and the inventions which they describe must meet the substantive and procedural requirements of the particular country where protection is sought. Therefore, it is possible that an invention may be patentable in one country but not in another.

V. Patents on Biological Materials

A. The 1995 statement by Religious Representatives

The 1995 statement by religious representatives is the precipitating event for this ITEST workshop revisiting the issue of patenting of biological materials. Therefore, I will briefly specifically address this statement. However, because the statement is short and somewhat unclear, I will also address some of the concerns which are often expressed by those who have reservations regarding the use of patents to protect biotechnology inventions.

The 1995 statement by the religious representatives contains language which is ambiguous regarding the subject matter at issue. First it states that the religious representatives are opposed to the patenting of “human and animal life forms.” It is unclear if human and animal “life forms” are different than “humans and animals.” If these are the same things then it seems that it would have been easier to simply refer to patenting of “humans and animals.” The next sentence adds to the uncertainty by referring to human “body parts.” This clearly suggests that the religious representatives have in mind something more extensive than a ban on the patenting of humans and animals. However, the final sentence of the petition, which provides the rationale for the representatives’ opposition to patents, is restricted to humans and animals. This final sentence of the petition states that humans and animals should not be patented because they are “creations of God.” It is not clear whether the religious representatives believe that plants and microbes are not creations of God. There are many who would argue that divine influence is not limited to the creation of humans and animals, but rather, pervades all that exists and all that is known or done. Thus, divine creation, on its own, does not appear to be a logical basis for asserting the non-patentability of humans and animals.

The wording of the statement of the religious representatives also evidences a misunderstanding of the requirements for obtaining a patent. Specifically, the statement indicates that humans and animals should not be patented because they are not “human inventions.” The U.S. Patent Office has already stated that it will *not* grant patents on humans. To my knowledge, nobody has criticized this decision. With regard to animals, no animal, or any other subject matter, can be patented in its naturally-occurring form. To be patentable, an invention must be new. A microbe, plant, or animal, *as it exists in nature* is not new. Furthermore, for subject matter to be patentable, the characteristic which makes the subject matter new, i.e. different than what exists in nature, must be supplied by human inventive input. Thus, for any invention to be patentable it must involve the “hand of man.”²²

In addition to the novelty requirement which precludes the patenting of subject matter as it exists in nature, the patent laws have additional stringent requirements which prevent the patenting of subject matter which is not a substantial advancement over previously known technology. The most important of these is the requirement that an invention be “non-obvious” in order to be patentable. Thus, in order to be awarded a patent it may not be enough to simply isolate a new protein (or other chemical molecule). The new protein must be non-obvious. Unusual and/or unexpected advantageous properties are characteristics which can help establish that a new protein is unobvious. Also, difficulties in obtaining the protein may make it unobvious. These requirements of novelty, nonobviousness, and involvement of the “hand of man” apply to every invention for which patent protection is sought.

A careful inspection of the valid patents which have issued for chemical compounds, animals, microbes, and

plants would reveal that in each case the inventors have provided society with something that is not only new but is even non-obvious compared to anything previously made by man or known to exist in nature.

As discussed above, a further requirement of the patent law is that the patent applicant must provide a description of the invention in such detail that a person skilled in the art of the invention, reading the description, can make and use the invention without undue experimentation. This requirement is at the heart of the patent system because it ensures that, if a patent is granted, the public will be able to learn from the invention, improve upon the invention, and when the patent expires, practice the invention without any patent restriction.

B. Other Issues Relating to Biotechnology Patents

1. Attempts to Block Biotechnology Research

Some of the opposition to patents on biological materials has come from people who wish to curtail or eliminate research in the biotechnology field. In view of the availability of trade secret protection I believe that such efforts are unlikely to successfully stop this research and, instead, would only have the effect of slowing or eliminating the flow of information to the public.

2. "Ownership" of Life

Another rationale sometimes heard from those who oppose biotech patents is that people should not be allowed to "own" life forms or the basic chemical molecules which are fundamental to life. As discussed above, patents are only granted for inventions which meet the strict novelty, utility, and non-obviousness requirements. These requirements preclude the granting of patents to things as they exist in nature. The "hand of man" must be involved before there is a possibility of issuing a patent. Furthermore, contrary to popular belief the grant of a patent is *not* the grant of an ownership right, rather, the grant of a patent only gives the patent holder the right to exclude others from making, using or selling the patented subject matter for a limited period of time. The grant of a patent does *not* give the patent holder the right to use the invention. The right to use the invention may be blocked or restricted by federal health, safety, or environmental regulations; by another's dominating patent; by contractual obligations; by state laws; by international treaties; and by a host of other impediments and/or safeguards which exist within our society.

In considering the issue of patents and whether inventors should "own" life forms or chemical molecules of basic importance/I> which concludes "But only God can make a tree."²³ I wonder how many of those who are opposed to the granting of patents on mice are also opposed to ownership of real estate including plants and trees.

3. Invention Made With Public Funds

Many have argued that gene sequences, and especially gene sequences identified utilizing public resources (i.e. NIH or Universities), should not be patented and, instead, should be made available to the "public." In these cases, the role of patents in expediting public disclosure is perhaps less critical in view of the tendency for such researchers to publish their results. However, a careful analysis of these situations reveals that, contrary to popular belief, patents can play a crucial role in the effective commercialization of this technology and the equitable distribution of profits which may result from such commercialization.

Take, for example, the NIH discovery of a new gene or protein with potential usefulness as a therapeutic agent. It is my understanding that the current cost of bringing a new pharmaceutical to market is in the neighborhood of \$300 million. Clearly, the NIH does not have the expertise or resources to take this new gene or protein all the way from the laboratory to the market place. Therefore, the technology must be developed by an outside entity. In order for that outside entity to have a realistic chance of recouping its investment it is critical to have a limited period of exclusivity for that product. Without any prospects for patent protection, a new technology is far less attractive to a potential licensee.

Patents can also play an important beneficial role in university technologies which *are* likely to be published *and* are likely to be commercialized even without patent protection. In this regard, consider the process of development of university technologies prior to the use of patents. At universities which did not seek to protect their intellectual property it was common practice for big companies, and other private entities, to directly contact researchers who had promising technologies. Often, for the price of a dinner, that company could have immediate and complete access to valuable technology. When that company developed the technology, no compensation was given to the university. Rather, that company reaps a windfall from publicly funded research. By contrast, if the technology is patented by the university, the company will be required to obtain a license for the technology and share its profits with the university. Typically, the funds paid to the university will be distributed among the inventors, the university department from which the invention came, and the general funds of the university. In this way, the taxpayer's money which originally went towards university research has paid dividends in the development of the technology as well as the enhanced funding of the university.

VI. Conclusion

Although patents have achieved almost a mystical status in our society, the truth is that patents simply provide a limited bundle of negative rights to the inventor who, in turn, discloses his or her invention to the world in complete detail for all to see, ponder, and improve upon.

While arguments against patenting biotech inventions may raise issues of great social moment and/or provide topics for spirited intellectual debate, when carefully analyzed they do not provide any compelling basis for denying intellectual property protection to the fruits of biotechnology research.

References and Notes

* Shareholder, Saliwanchik & Saliwanchik, A Professional Association. This paper reflects only the present considerations and views of the author, which should not be attributed to Saliwanchik & Saliwanchik, or to any of its attorneys or clients.

1. U.S. Constitution. Article 1 Section 8 clause 8.
2. V Writings of Thomas Jefferson, at pages 75-76.
3. See, for example, 35 United States Code 101 (describing subject matter which can be patented) and 112 (describing the requirement for the patent applicant to provide a full written description of the invention).
4. *Diamond v. Chakrabany*, 206 USPQ 193, Supreme Court 1980.
5. This statement was issued by The Joint Appeal Against Human and Animal Patenting. This group was organized by the United Methodist Church and activist Jeremy Rifkin's Foundation on Economic Trends.
6. *In re Bergy*, Court of Customs and Patent Appeals, 201 USPQ 352 (1979).
7. *Diamond v. Chakrabarty*, 206 USPQ 193, United States Supreme Court 1980.
8. See, for example, Eisenberg, R.S., "Limiting the Role of Patents in Technology Transfer," *The Journal of NIH Research*, October 1993, Vol. 5.
9. The European Patent Office, for example, does not grant patent protection for methods of treating humans.
10. India, for example, does not grant patents on pharmaceutical inventions.

11. For a comparison of trade secret and patent protection see R. Saliwanchik, "Protecting Biotechnology Inventions: A Guide for Scientists," *Science Tech/SpringVerlag*, 1988.
12. 35 USC 112 requires the patent applicant to provide a complete written description of how to make and use the invention. This written description is published for all the world to see when the patent is granted.
13. International patent applications are published 18 months from the original filing date, regardless of whether patent protection is granted.
14. The U.S. Constitution, Article I Section 8 clause 8.
15. 35 USC 112.
16. An interesting area of biotechnology patent law pertains to the rules and procedures which have been established for providing an enabling disclosure of technology which utilizes specific biological materials. For example, if a novel process for producing an antibiotic requires the use of a newly isolated fungus, a written description of the process would not be enabling if it did not disclose a way to obtain the new fungus. For this reason, patent applications for biotechnology inventions often contain references to deposited cultures. The cultures have been placed on deposit at a depository which is recognized by the Patent Office. The conditions of the deposit must ensure that the biological material will be viable and available to the public for a period of at least 30 years commencing when the patent issues.

The rules followed in the United States with respect to the deposit of biological materials are derived from, and consistent with, international law followed by many of the developed countries of the world. The primary source of this international law is the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The Budapest Treaty establishes regulations for the deposit of biological materials for patent purposes.

17. 35 USC 112.
18. 35 USC 102.
19. 35 USC 103.
20. 35 USC 101.
21. 35 USC 282.
22. *Diamond v. Chakrabarty*, 206 USPQ 193, United States Supreme Court 1980.
23. TREES

I think that I shall never see
A poem lovely as a tree.

A tree whose hungry mouth is prest
Against the earth's sweet flowing breast;

A tree that looks at God all day
And lifts her leafy arms to pray;

A tree that may in summer wear
A nest of robins in her hair;

Upon whose bosom snow has lain;
Who intimately lives with the rain.

Poems are made by fools like me,
But only God can make a tree.

Joyce Kilmer (1913)