



Complications In Patenting Biotech Inventions:
A Peek At US Law.

Author: Kalyan C. Kankanala¹ , Chief Knowledge officer, Brain League IP Services

Introduction.....	2
Substantive Patentability Requirements and Modern Biotechnology	2
Patentable subject matter.....	2
Utility.....	4
Novelty	5
Nonobviousness	6
Generic Patent Model for Biotechnology inventions	8
Conclusion	9

¹ The views or arguments expressed in this article are that of the author and not the company. Please send your feedback to kalyan@brainleague.com

Introduction

Article 1, Section 8, Clause 8 of the American constitution gives congress the power to 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. In furtherance of the power granted to it by the constitution, the congress has enacted the Patent Law, which has been codified under Title 35 of the United States Code. The objective of the US patent law as stated in the constitution is to promote the progress of science and technology. The patent system promotes progress by providing exclusive rights to the inventor in exchange for disclosing his invention to the public. It operates on the principle of 'quid pro quo' or 'give and take'; the inventor gives an invention to the society and gets exclusive rights over it for a limited period of time (20 years) in the form of a patent. A patent gives an inventor the right to exclude others from making, using, offering to sell or selling his patented invention within United States or importing his invention into United States during the term of the patent. The rights granted by the patent are negative rights as it only gives the right to prevent others from doing the aforementioned acts but does not give the right to perform anything. The exclusive rights granted by a patent gives incentives to invent, invest, disclose and design around, which in turn promote rapid progress of science and technology.

Though patent law has been very successful in promoting the progress of science and technology and its scope has extended to every conceivable field, biotechnology is testing the limits of traditional patent law. The evolution of modern biotechnology and the complexities it poses with regard to requirements under patent law has demonstrated the need for a new patent framework for biotechnology. This paper discusses the problems posed by modern biotechnology to traditional substantive patent requirements and suggests a generic framework to overcome them.

Substantive Patentability Requirements and Modern Biotechnology

In order to get a patent in United States, an invention has to satisfy the following requirements:

- a. Patentable subject matter
- b. Utility
- c. Novelty
- d. Nonobviousness
- e. Specification

The first four are the substantive patentability requirements.

Patentable subject matter

The first and the most basic requirement for patentability is that the invention should fall within the scope of patentable subject matter as defined by the patent statute. Section 101 of the patent statute provides that any invention or discovery which is a new and useful process, machine, manufacture, or composition of matter, or any new and

useful improvement thereof is patentable². The scope and extent of patentable subject matter is very broad and open in United States. Unlike in Europe and India, there are very few limitations on its scope. Only laws of nature, physical phenomena, and abstract ideas fall outside the scope of patentable subject matter³.

In *Diamond v. Chakrabarty*⁴, which is the most important biotech case relating to patentable subject matter, the United States Supreme Court by holding that everything under the sun made by man is patentable, cleared all doubts and opened the gates for patentability of biotech inventions. The case involved Chakrabarty's discovery of a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single *Pseudomonas* bacterium, which by itself has no capacity for degrading oil. Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprising of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves. The patent examiner accepted the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: (1) that microorganisms are "products of nature," and (2) that as living things they are not patentable subject matter under section 101. The court discarded both the arguments. It rejected the product of nature argument by stating that Chakrabarty has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility patentable under section 101. The court rejected the second argument by holding that the microorganisms are patentable as compositions of matter under section 101.

After Chakrabarty's decision, a large number of patents have been issued on living organisms and other biotech inventions including a patent on a genetically modified mouse⁵. In another case, *J.E.M. AG Supply, Inc.*⁶, the US Supreme Court held newly developed plant breeds to be patentable subject matter under section 101 though they had separate protection under the Plant Protection and Plant Varieties Protection Acts. The USPTO (United States Patent and Trademark Office) and the courts have extended patent protection to isolated DNA, RNA and proteins under section 101 stating that gene and protein sequences are new compositions of matter resulting from human intervention as opposed to naturally occurring products, which are not patentable. USPTO considers gene and protein sequences as large chemical compounds patentable as compositions of matter. Today, under the United States Patent Law every biotech invention is patentable subject matter as long as it can be proved that it has been made by man.

The broad and expansive interpretation of patentable subject matter given by the US Courts increased the investment into Research and Development in the biotechnology industry, which as some scholars claim, is one of the reasons for the dominance of United States in the field.

Though the broad approach seems to be promoting the progress of biotechnology, it gives rise to significant disadvantages. There is an inverse relationship between the scope

² 35 USC Section 101 (2004).

³ *Parker v. Hook*, 437 U.S. 584 (1978)

⁴ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

⁵ [U.S. Patent No. 4,736,866 \(issued April 12, 1988\)](#)

⁶ *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 122 S.Ct. 593 (2001).

of statutory subject matter and size of public domain. With the broadening of the scope of patentable subject matter the size of public domain diminishes because it takes twenty years (patent term) for many inventions to fall into the public domain. Such a phenomenon tilts the balance in favor of the patentee, which is not good for the ends of patent law. It results in the Tragedy of Anti-commons⁷, by bestowing unnecessary rights on too many inventions/inventors, the result of which is blockade of information and materials from the public by conditioning access on cost. Without free access to the existing technology, research would receive a huge set back. Though it might be argued by some jurists that research exemptions⁸ would facilitate research despite a broad subject matter, that is not possible because of the very narrow scope of research exemptions, which are confined to philosophical use and idle curiosity. It is important for policy makers to realize and act upon these facts, by bringing about a balance between the scope of subject matter and the size of public domain.

Utility

Section 101 provides that an invention or discovery should be useful in order to be eligible for a patent grant⁹. Usefulness is a very subjective enquiry and is not considered strictly by the USPTO¹⁰ while dealing with biotech inventions. To satisfy this requirement, an invention should have some practical utility in the form of immediate benefit to the public. In *Brenner v. Manson*¹¹, the US Supreme court while invalidating a patent for process of making a novel steroid compound for lack of any demonstrable utility held that utility could not be established until specific benefit exists in currently available form. It further stated that a patent is not a hunting license; it is not a reward for the search, but compensation for its successful conclusion¹².

On January 5, 2001, the PTO released the Utility Examination Guidelines. The PTO guidelines require an invention to have "specific, substantial, and credible utility" in order to meet the requirements of section 101. Credibility of utility is judged from the perspective of someone who is skilled in the relevant art, with the applicable question being whether that person would appreciate why the invention is useful.

A biotech invention would be eligible for patent protection if some present, substantial and credible utility judged from the perspective of a person with ordinary skill in the art could be shown. Though speculative or prospective utility would not be acceptable for the purpose of satisfying the utility requirement, the USPTO and courts

⁷ The Tragedy of Anticommons occurs when many individuals have rights of exclusion in a scarce resource. Heller, M.A. "The Tragedy of Anticommons." Harvard Law Review, January 1, 1998.

⁸ 'Research Exemption' is an exception from the infringement of a patent for the purposes of conducting research activities. This allows a person to make use of the patented invention without the permission of the patent owner if the use is meant for 'research' as defined by the patent law.

⁹ "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor...", 35 USC Sec. 101 .

¹⁰ US Patent and Trademark Office

¹¹ *Brenner v. Manson*, 383 U.S. 519 (1966).

¹² *Id.* at 235-36.

have diverted from the established principle by granting patents to genes, proteins and others whose utility is only for research, which might or might not prove to be useful. Granting of such patents based on future usefulness delineates from the established standards in patent law and gives way to obstruction of research. Though the existing policy on the utility requirement seeks to encourage rapid advancement in biotechnology, the relaxed requirements have a potential of blocking progress by allowing futile patents.

Novelty

Novelty means newness. An invention in order to be patentable should be new in the light of the prior art (what exists at the time of conception of the invention). If an invention falls under any of the categories under section 102, it would not be novel and is therefore not eligible for a patent. The novelty under section 102 is not different from the newness required under section 101. Section 102 lays down a non-exhaustive list of circumstances that would deny newness to an invention.

Under section 102¹³, a person shall not be entitled to a patent if:

- (a) The invention is known or used by others in United States or patented or published in a printed publication in United States or in a foreign country before the invention thereof
or
- (b) The invention was in public use or public sale for one year prior to the date of application for a patent in United States
or
- (c) The inventor has abandoned the invention or
- (d) The inventor has filed an application more than twelve months of a foreign application on the same invention or
- (e) If the invention was described in a patent granted on an application for patent by another filed in the United States before the applicant invented, or on an international application by another before the applicant invented.
- (f) The inventor derived the invention from another or
- (g) Another who had not abandoned, suppressed or concealed the invention made the same invention. While Determining the first inventor, the date of conception and reasonable diligence to reduce the invention to practice shall be considered.

Early conception and reasonable diligence to reduce the invention to practice would always prevail over later conception and quicker reduction to practice. If the biotech invention falls under any of the aforementioned categories, it is said to be anticipated by the prior art and is therefore not patentable. In relation to biotech inventions, conception of the invention is not always considered sufficient for anticipation or prevalence under section 102(g) unless the invention is reduced to practice. As the field is highly

¹³ 35 USC Sec. 102, (2003).

unpredictable mere conception would not enable a person with ordinary skill to reduce the invention to practice.

Though prior art includes everything under section 102, it is not limited to those entries. In order to be denied patentability by anticipation under section 102, the prior art must contain all the elements of the invention in a single reference.

The existence of proteins, genes, enzymes, etc., in nature would not anticipate their artificial isolation or preparation. In patent applications for gene sequences, anticipation could be avoided if a claimed composition is of increased purity that is sufficient to distinguish the product from its unpurified, naturally occurring form¹⁴. Likewise, claims to biotechnology products Demonstrating increased activity, distinguishing physical characteristics or physical form may be considered novel, despite previously known, naturally occurring forms, and despite utility that is identical to that of the previously known product. Similarly, if a claim to a biotechnology product is narrowly limited by referencing a specific nucleic acid or protein sequence, anticipation is avoided if the claimed sequence differs only slightly from the sequence found in nature or the prior art, regardless of activity or structure.

The threshold of novelty to be cleared by biotechnology inventions is very low when compared to other inventions. Discovery of one additional nucleotide in a gene sequence or one new amino acid in a protein sequence is sufficient to avoid anticipation under section 102. Such a low threshold might encourage speedy progress but the inventive activity in such inventions is generally very low, which might not be enough to credit patent protection. Sometimes, the small novelty hurdle for biotech inventions would result in the grant of very general patents that might impede progress in the field by anticipating valuable inventions.

Nonobviousness

An invention in order to be patentable should be nonobvious in the light of the prior art. The invention would not be patentable 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 pertains¹⁵. While deciding upon the obviousness or nonobviousness of an invention the court or the USPTO has to determine the scope and content of prior art, ascertain differences between prior art and claims at issue and resolve the level of ordinary skill in pertinent art¹⁶. Secondary indicia such as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented and they may have relevancy in determining obviousness or nonobviousness¹⁷.

The Obviousness standards required for biotechnology inventions have been interpreted by courts to be different from the generally accepted principles. In Hybritech

¹⁴ Id.

¹⁵ 35 USC Sec. 103 (2001).

¹⁶ William T. GRAHAM et al. v. JOHN DEERE COMPANY OF KANSAS CITY et al., 15 L.Ed.2d 545 (1966).

¹⁷ Id. at 18.

v. Monoclonal¹⁸, a case involving a patent over "Immunometric Assays Using Monoclonal Antibodies", the court held the patent non-obvious despite the existence of twenty prior art references because the prior art as a whole did not make the invention obvious at the time the invention was made. Though some references seemed to anticipate the invention, they were made after the date of conception of the invention, thus taking them out of the scope of prior art. The court in this case reiterated the importance of secondary indicia by determining the sandwich assays using monoclonal antibodies to be nonobviousness because of the commercial success, unexpected advantages and praise from experts of the diagnostic kits made by Hybritech.

In *Amgen v. Chugai*¹⁹, a patent for DNA sequences encoding erythropoetin (EPO) was claimed to be invalid based on section 103 along with other claims. The Federal Circuit held the patent nonobvious by reasoning that it might have been feasible, perhaps obvious to try, to successfully probe a human gDNA library with a monkey cDNA probe but it does not indicate that the gene could have been identified and isolated with a reasonable likelihood of success. Neither the DNA nucleotide sequence of the human EPO gene nor its exact degree of homology with the monkey EPO gene was known at the time the claimed invention was made. According to the court, though the idea of using the monkey gene to probe for a homologous human gene might have been obvious to try, but the realization of that idea was not obvious. Finally, the court stated that hindsight is not a justifiable basis on which to find that ultimate achievement of a long sought and difficult scientific goal was obvious.

In *In re Deuel*²⁰, a case involving an invention relating to isolated and purified DNA and cDNA molecules encoding heparin-binding growth factors, the Federal Circuit held the invention non obvious despite Bohlen and Maniatis references disclosing a group of protein growth factors and a general gene cloning method. The issue raised in this case was whether the combination of a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, would render DNA and cDNA molecules encoding the protein prima facie obvious under Section 103. The court held that the subject matter of the invention cannot be conceived based on the teachings in the references because, until the claimed molecules were actually isolated and purified, it would have been highly unlikely for one of ordinary skill in the art to contemplate the claimed invention. The court further stated that 'What cannot be conceived cannot be obvious.'

In the aforementioned cases, the court clearly pointed out that existence of prior art references suggesting a biotechnology invention wouldn't make the invention obvious, until it is reduced to practice. With regard to biotechnology the rule is that 'Obvious to try' wouldn't make the invention obvious. Which means that it is very easy to cross the Obviousness hurdle because even if there are a large number of prior art references suggesting a particular invention, it would be non obvious if it can be proved that no one has actually reduced the invention to practice. Such reduced standards of obviousness make it easy for biotech inventions that pass through the filter of subject matter to attain the status of a patent. Inherent danger in such a policy is that inventions in the public

¹⁸ *Hybritech, Inc., v. Monoclonal Antibodies*, 802 F.2d 1367 (Fed. Cir. 1986).

¹⁹ *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200 (Fed Cir. 1991)

²⁰ *IN RE THOMAS F. DEUEL, YUE-SHENG LI, NED R. SIEGEL and PETER G. MILNER*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed Cir. 1995).

domain that have been clearly described in references or which are obvious from the references would be pulled out of the public domain, thus precluding the right of public to have free access. The result would be shrinking of the public domain and obliteration of progress in the field. Though it might be argued that the lacuna arising out of the existing policy can be filled through imposition of stringent specification requirements, that strategy won't work well as those procedural requirements have been incorporated with a totally different objective, which is primarily notice of the rights of the inventor and enablement of the invention.

Generic Patent Model for Biotechnology inventions

It can be seen from the aforementioned problems that the courts are struggling to apply the traditional principles of patent law to the fast evolving field of biotechnology. Though a few judges at the Federal Circuit believe that biotechnology doesn't require a different set of standards, they have implicitly made attempts towards that end through their decisions. While it is always a good idea to determine patentability on a case to case basis, the decision making process would be made easy if generic principles can be evolved based on the unique nature of biotechnology.

Patentability requirements work like filters arranged in succession. An invention has to pass through the first filter i.e. patentable subject matter in order to get to the determination of the second i.e. novelty and it has to pass the second filter in order to reach the third and so on. If it successfully passes through all filters, the invention would be conferred the honour of 'patent'. If these filters are not configured properly, as it exists now, the result would be grant of frivolous patents, which potentially block progress. In order to ensure optimum progress of biotechnology without obstructions, a policy that would balance the rights of the patentee and that of the public has to be made.

The model suggested here would prove very useful in framing a generic regime that would be best for biotechnology. A very broad scope of patentable subject matter is always fatal to the ends of patent law if the scope of exemptions for research is narrow. The scope of exemptions for research should be proportional to the scope of subject matter. If subject matter is narrow, exemptions for research could be broad or narrow and if the subject matter is wide, exemptions for research should also be wide. Such a policy would bring about a balance between rights of the patentee over his invention and the rights of the public to access it, which is very essential for the best possible advancement of the field. Having said that, too broad and too narrow subject matter/ research exemptions is also not too good and such a scope would provoke litigation. It would be very well balanced if the subject matter is just enough to allow appropriate inventions and if the research exemptions are sufficiently broad to allow research activities. The determination of such a balance is a tough one but it can be worked by framing a generic policy, which gives enough latitude to make decisions on a case-by-case basis.

The problems due to broad or narrow scope of subject matter can be clearly understood with the help of an Illustration on proteins.

Illustration: The scope of subject matter could be broad or narrow in relation to proteins. If the law lays down a ban on patenting of proteins per se, the subject matter is too narrow. In such a case, incentives to invest and invent offered by the patent regime would not be available for proteomics and other protein related fields, which would result in slowing down the progress of research in that field. In such a scenario, it doesn't make a difference whether the research exemptions are narrow or broad because there will be no patents on proteins.

If the law lays down that all proteins, which are the outcome of human intervention are patentable, it is a very broad policy. The result would be patenting of a large number of proteins and related inventions. In this case, if the research exemptions are narrow, the public would not get an opportunity to freely use the patented proteins for their research during the patent term, which would result in blockade of research. So, in order to facilitate progress in a broad patent regime, the exemptions should be broad to permit public use of the patented invention for research. Though broad subject matter and research exemptions seem to be good, the problem with such a policy is that it results in a lot of litigation because of increased use of patented proteins for research without permission from the patentee. The outcome would again be blocking of progress due to fear of litigation.

If subject matter is not too broad and allows patents over products i.e. proteins isolated by a particular process, it would encourage progress by granting patents over proteins and by not blocking use of the patented proteins themselves made by a different process. Furthermore, if the exemptions for research are just broad enough to allow academic and experimental activities, public would have enough latitude to use the patented invention. The result of such a policy would be optimal progress of research and development on proteins and related fields.

Coming to Utility, high standards need to be strictly implemented and only inventions that have clear substantial, credible and current utility should be allowed. Such a high utility standard would avoid lot of patents, which might block research. With regard to the Novelty and Non-obviousness standards, the relaxed standards need to give way to higher and tougher requirements. As it exists today, conception is not considered as reduction to practice and 'Obvious to try' is not considered 'Obviousness', which permits patenting of inventions well-known to the public. It is important to do away with such a principle and to increase the hurdle to pass through obviousness as that would prevent pertinently known inventions from being granted as patents.

To summarize, reasonably broad subject matter with proportional exemptions for research, higher standards to pass through utility, novelty and non-obviousness requirements would provide a balanced framework to encourage the progress of biotechnology. A coordinated and balanced effect of all filters i.e. requirements would give rise to best results.

Conclusion

The application of patent law to Modern Biotechnology has been causing problems to the objectives of the patent system and instead of promoting progress, its result is the

blockade and obstruction of progress. The problems existing in every patentability requirement necessitates a change in the law. It demands a balanced approach involving a proportional arrangement between subject matter and exemptions for research and increased standards to pass through the requirements of utility, novelty and non-obviousness. Enough latitude should also be given to courts in order to make decisions based on specific case situations. Implementing a generic model incorporating the aforementioned standards would result in a regime that would be well tuned to promote the progress of biotechnology. As courts in countries other than USA tend to follow the seemingly evolved standards in US Patent Law, they should be wary of the complications involved in borrowing or copying the principles, which are being applied now.

Copyright © 2005, Kalyan Chakravarthy Kankanala, Brain League IP Services