Toward a Clear Standard of Obviousness for Biotechnology Patents

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TOWARD A CLEAR STANDARD OF OBVIOUSNESS FOR BIOTECHNOLOGY PATENTS

The term "biotechnology" refers to scientific activity that manipulates living systems and yields useful biological products or processes. Since the discovery of the double-helical structure of DNA in 1959, biotechnology has experienced exponential growth. This unprecedented expansion of knowledge has generated large financial research costs. Accompanying these costs, conflict has arisen over ownership and use of the newly discovered information. During the 1980s, patents have emerged as an important and controversial tool for protecting this knowledge. Rapid scientific advances underscore the need to clarify the legal standards for determining the ownership and use of valuable scientific information. By explicitly acknowledging that patent analysis properly embraces the methods, and not final products, of scientific research, the Federal Circuit can establish a clear standard that will aid the biotechnology industry.

Through a series of four recent cases, the Federal Circuit has attempted to apply the broad statutory language of patent law to the unique needs of biotechnology. The most contentious issue relates

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1 In 1992, the average cost of discovering and bringing a single drug to market exceeded $230 million. This amount has increased as 1990 United States' biotechnology sales reached $2.9 billion. Biotechnology Plant Protection Act, H.R. REP. No. 260, 102d Cong., 2d Sess. 5-6 (1992).

2 See generally Nicholas H. Carey & Peter E. Crawley, Commercial Exploitation of the Human Genome: What are the Problems?, in HUMAN GENETIC INFORMATION: SCIENCE, LAW AND ETHICS 133-47 (Ciba Foundation Symposium 149) (1990) (assessing the industry's need for patents in commercial fields where the high cost and long time frames of research require exclusive ownership rights to achieve an acceptable investment return); Reid G. Adler, Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization, 257 SCIENCE 908 (1992) (summarizing academic and industry positions on patent law and arguing that careful development of policies is needed to successfully encourage commercial product development). "[D]ue consideration must be given to protecting the market exclusivity necessary for the private sector to risk enormous sums of money in product development efforts." Id. at 908.

3 Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987) (assay using monoclonal antibodies is non-obvious); In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988) (expression of fused foreign protein in bacteria is obvious); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir.), cert. denied, 112 S. Ct. 169 (1991) (DNA sequence for the erythropoietin protein is a non-obvious invention); In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991) (expression of an insecticide protein in cyanobacteria is non-obvious). For discussion and explanation of these cases see infra section III.

4 The Federal Circuit is the Federal Court of Appeals for all cases involving patent disputes. Generally, patent disputes arise from either infringement action initiated at the district court level or an appeal from a decision of the Patent and Trademark Office denying a patent application. The Court of Appeals for the Federal Circuit was created in 1982 by the Federal Courts Improvement Act, Pub. L. No. 97-164, 96 Stat. 25 (1982), and
to the standard of "obviousness." This involves a legal determination of whether an invention would have been obvious in light of knowledge in the relevant field at that time. An obvious invention is not patentable.

Despite the crucial importance of obviousness for determining biotechnology patent rights, the Federal Circuit has failed to elucidate a clear test for this analysis. This failure can be attributed to the unique nature of biotechnology and the problems that genetic inventions pose. The Federal Circuit analyzes these cases under the rubric of conventional analysis. However, biotechnology differs from conventional technology in ways that make generic obviousness analysis inapt. The unclear and occasionally confused nature of obviousness analysis leads to misapplication of the law and industry uncertainty in this vital and growing field.

This Note argues that a better approach to obviousness can be drawn from the reasoning underlying the four biotechnology cases resolved in the Federal Circuit. The thesis of this Note is that determination of the obviousness of an invention should hinge on the availability of scientific methods that would have allowed ordinarily skilled scientists to produce the invention. A two-factor legal analysis comprises this standard. First, someone must have already suggested the invention, either implicitly or explicitly, for it to be viewed as obvious to attempt. Second, that suggestion must be coupled with a reasonable expectation of success before the invention can be found legally obvious. The expectation of success can be measured by the availability of techniques that are reasonably likely to accomplish the suggestion. Thus, to be nonobvious, a claimed biotechnology invention must be unattainable through use of reasonably accessible scientific methods.

Confusion may arise because this standard necessitates inquiry into the methods of DNA discovery. Conventional obviousness analysis looks not at the process of invention, but at the obviousness of the invention product itself. By explicitly acknowledging that obviousness analysis properly evaluates the methods of scientific research, the Federal Circuit can establish a clear and workable standard that will aid


5 The holdings of the four cases, see supra note 3, all hinged on the obviousness question. Additionally, a commentator has identified obviousness as one of the the "more commonplace grounds" for patent rejection. Rebecca S. Eisenberg, Genes, Patents, and Product Development, 257 Science 903, 905 (1992) (assessing the controversy surrounding the National Institute of Health's application for thousands of small, functionally-unknown, stretches of DNA).

6 To obtain a patent, an invention cannot have been obvious at the time of invention. 35 U.S.C. § 103 (1988). See, e.g., Monoclonal, 802 F.2d at 1379. For an overview of statutory requirements for patents see infra section II.
the biotechnology industry. In light of the growing investment in biotechnology, the need for a legal standard that will reduce uncertainties about ownership and use of genetic information is readily apparent.

This Note begins by first providing a general overview of molecular biology. Presuming the scientific knowledge of an informed layperson, this section introduces the basic principles and terms of biotechnology research. The second section briefly describes the United States patent system. The third section examines the four Federal Circuit cases to show that a clear analysis for obviousness can be gleaned from the opinions. In each case, the biotechnology invention at issue and the court’s methods of evaluation are closely analyzed. The final section assesses how the proposed obviousness standard can foster efficient processing of applications for biotechnology patents, especially those relating to genetic sequences. Additionally, this section demonstrates how the standard could promote further investment in biotechnology and yet remain flexible to accommodate the changing needs of this growing field.

I

SCIENTIFIC CONSIDERATIONS

The long, thin molecule, deoxyribonucleic acid, or DNA, exists in every cell in every organism. This molecule provides the blueprint for all species of life. Transferred from generation to generation, DNA contains the template for the proteins that are produced in every cell. Proteins provide cell structure. They transform food and light into usable energy. They transport oxygen through blood to muscles. In short, every living action depends on proteins and every protein has a unique and vital function. The selective production and regulation of proteins by the DNA template controls how we grow, develop, and stay “alive.”

The DNA molecule consists of four smaller subunits. These can be arranged in any order along the length of the molecule. This order provides a readable code for an exact protein structure. A combination of three subunits, called a “codon,” codes for one of twenty amino acids.

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7 For an introduction to the vast scope of protein function, see LUBERT STRYER, BIOCHEMISTRY 15-16 (3d ed. 1988) [hereinafter BIOCHEMISTRY].
8 These are adenine, guanine, thymine, and cytosine (A, G, T, and C). See DAVID T. SUZUKI ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 188-92 (3d ed. 1986) [hereinafter GENETIC ANALYSIS] (providing a clear and comprehensive overview of DNA structure); see also WILLIAM T. KEETON & JAMES L. GOULD, BIOLOGICAL SCIENCE 697-701 (4th ed. 1986) (describing the Watson-Crick model of DNA).
9 An astute reader might notice that there are 64 possible combinations of the four bases and yet there are only 20 amino acids. As it turns out, each amino acid can be coded
The order of codons along a stretch of DNA provides a template for a specific protein. For instance, just as each signal of the Morse code corresponds to a letter of the alphabet, each codon corresponds to a specific amino acid. Thus, the specific ordering of Morse code signals creates an understandable message. Similarly, a specific ordering of DNA subunits can create a cohesive, functional protein.

The order of the DNA subunits provides for each protein's structure. The structure of each protein, then, corresponds to a unique segment of DNA. The DNA molecule can self-replicate and passes from generation to generation. In this way, the code for the structure of all an organism's proteins remains stable and guarantees the continued existence of the species.

Genetic diseases arise from mutations in the code sequence of DNA. This gives rise to dysfunctional proteins. The DNA molecule is not completely stable and, thus, is susceptible to alterations, or "mutation." Unfortunately, the mutation of just one base in a gene sequence can have disastrous consequences for the protein.

For example, instead of a three subunit sequence coding for the amino acid Valine, it might, upon mutation of a single subunit, code for Alanine. This results in the insertion of a wrong amino acid into the protein. If the substitution occurs in a vital region, the entire function of the protein may be lost. A vivid example of such a mutation is sickle cell anemia. In this genetic disease, one sequence change results in an amino acid substitution. This substitution alters the physical shape of the protein, hemoglobin. As a result, the abnormal protein transforms the normal "donut" shape of red blood cells into a curved sickle shape. The oxygen transportation function of for by multiple base combinations. For instance, GAA and GAG both code for glutamic acid. Also, there are three combinations called "stop codons" that signal the end of that particular readable sequence. For a discussion of the genetic code, see Keeton & Gould, supra note 8, at 715-17.

A series of incisive studies in the late 1950s and early 1960s revealed that the amino acid sequences of proteins are genetically determined. The sequence of nucleotides in DNA specifies the amino acid sequence of a protein. In particular, each of the twenty amino acids of the repertoire is encoded by one or more specific sequences of three nucleotides [A, G, T, or C].

Biochemistry, supra note 7, at 23.

11 Genetic Analysis, supra note 8, at 212-15 (the order of subunits creates a protein's structure which determines the protein's function).

12 Keeton & Gould, supra note 8, at 615.

13 Id. at 724-26 (describing the inherent instability of DNA).

14 See id. at 717 (this table lays out the entire genetic code which is uniform for all species).

15 See Genetic Analysis, supra note 8, at 212-14.

16 Keeton & Gould, supra note 8, at 673 (describing how the secondary structure of a single protein affects the form and function of an entire blood cell).
the protein is lost and this results in serious medical problems for sufferers of the disease.¹⁷

Scientists can develop treatments for this and other diseases by discovering and manipulating the relevant DNA code sequences. Since the discovery of DNA’s double helical structure, knowledge about DNA’s properties and functions has increased dramatically. Through various techniques, researchers can now locate, decipher, and manipulate DNA sequences.¹⁸ Scientists today are very concerned with locating genes¹⁹ and deciphering their sequences.²⁰ This can be done by a process called “cloning.”²¹ The general idea is to locate and isolate a particular stretch of DNA that codes for a desired protein.

Scientists can analyze a known protein structure to determine the amino acid sequence. Since every protein consists of an ordered chain of amino acids, a known amino acid sequence can be “read” to generate the approximate corresponding DNA sequence. This sequence can then be used to reveal the chromosomal location of the actual gene.²² This gene sequence can then be isolated and purified.

When a DNA sequence becomes known, it may be reproduced. Once reproduced, a sequence can be transferred into another living cell.²³ Scientists can then induce the cell to translate²⁴ the foreign DNA and produce the sought after protein in vast, purified amounts. This protein can then be used for pharmaceutical or other benefit.

An example will illustrate the practical benefit of cloning genes.²⁵ Erythropoietin is a protein that boosts red blood cell production. Persons with anemia have a red blood cell deficiency and some need to

¹⁷ Sickle-cell anemia can cause heart failure, kidney failure, brain damage, and early death. See Genetic Analysis, supra note 8, at 212-13.

¹⁸ See generally id. at 296-328 (describing various current scientific procedures of genetic manipulation).

¹⁹ “Gene” is a surprisingly elusive word to define. See, e.g., Keeton & Gould, supra note 8, at 113 (“the basic units of heredity”); Genetic Analysis, supra note 8, at 578 (“a segment of DNA, composed of a transcribed region and a regulatory sequence, that makes possible transcription”). Thus, the “gene” for a certain protein is that specific stretch of DNA that codes for the protein and allows for its accurate reproduction within the cell.

²⁰ DNA sequence information can lead to the development of useful pharmaceutical protein products. For this reason the sequence information can be very valuable.

²¹ See generally Genetic Analysis, supra note 8, at 298-315 (discussion of the scientific goals and techniques of cloning).

²² Id. at 312.

²³ This process is called “transformation.” Biochemistry, supra note 7, at 193-34.

²⁴ “Translation” is part of the biochemical process that produces an amino acid chain from a DNA template. Keeton & Gould, supra note 8, at 715. Briefly, the DNA sequence is “transcribed” onto an interim molecule, RNA. This interim molecule is then translated into amino acids. Id.

²⁵ This set of facts is taken from the patent dispute between Amgen Co. and Genetics Institute. See Amgen v. Chugai, 927 F.2d 1200 (Fed. Cir.), cert. denied, 112 S. Ct. 169 (1991), discussed infra notes 128-42 and accompanying text.
take erythropoietin as a medical treatment. Potential sales for this pharmaceutical drug exceed $1 billion a year.\textsuperscript{26} Targeting this commercial potential, biotechnology companies can invest in research to discover the genetic basis for the erythropoietin protein. Once the genetic basis is discovered, the protein can be reproduced quickly and cheaply and sold to sufferers of anemia. If a patent issues for the discovery, that company will have the exclusive right to sell erythropoietin and exploit a lucrative market for seventeen years.\textsuperscript{27}

Due to the replicability of genetic information, knowledge and ownership of DNA sequences has tremendous value. The owner of such information can utilize the sequence code to manipulate living systems for commercial benefit. Under the protection of intellectual property laws, the owner of an isolated stretch of DNA can exclusively control all use of that sequence by others.

\section{Basic Elements of U.S. Patent Law}

The Constitution directs that Congress shall have power "[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."\textsuperscript{28} Title 35 of the United States Code codified the granting of patents to inventors for their discoveries.

Incorporated into protectible inventions, specific DNA sequences can be individually owned. Patents provide the tool for ownership of information generated by biotechnology research. A number of statutory requirements exist for patent protection. These include a showing of appropriate statutory subject matter and the usefulness, novelty, and nonobviousness of the invention.

A patent does not give exclusive ownership of an invention to the inventor. Rather, a patent gives the right to exclude others from "making, using, or selling" the invention for seventeen years.\textsuperscript{29} In exchange for this governmental grant, the inventor must fully disclose to the public all aspects of the invention. In essence, a patent is an exchange of a temporary monopoly in consideration for a significant advancement of public knowledge.\textsuperscript{30}

The statutory requirements for granting a patent monopoly are comprised of two main components. First, the threshold inquiry asks

\begin{itemize}
  \item \textsuperscript{26} Edmund L. Andrews, \textit{Mad Scientists}, Bus. MONTHLY 283 (May, 1990).
  \item \textsuperscript{27} 35 U.S.C. § 154 (1988). A patent monopoly lasts for 17 years and then the invention enters the public domain. \textit{See infra} section II for a discussion of the statutory requirements for patents.
  \item \textsuperscript{28} U.S. CONST. art. I, § 8, cl. 8.
  \item \textsuperscript{29} 35 U.S.C. § 154 (1988).
  \item \textsuperscript{30} For an analysis of this exchange theory applied to biotechnology, see Thomas D. Kiley, \textit{Patents on Random Complementary DNA Fragments?}, 257 SCIENCE 915, 915 (1992).
\end{itemize}
whether the claimed invention is patentable subject matter.\textsuperscript{31} Second, although the subject matter in general may be patentable, the specific invention itself must pass a tripartite inquiry for novelty, utility, and nonobviousness.\textsuperscript{32}

A. Patentable Subject Matter

Section 101 of title 35 of the U.S. Code states:

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, subject to the conditions and requirements of this title.\textsuperscript{33}

This describes the entire scope of subject matter that is patentable under United States law. Accordingly, the threshold inquiry of all patent applications is whether the claim can be classified within this range.

Case law has established that patentable subject matter does not include natural phenomenon,\textsuperscript{34} mathematical algorithms,\textsuperscript{35} or products of nature.\textsuperscript{36} Under this precedent, researchers feared that their biotechnology claims would be rejected because they were products of nature.

However, in the landmark case of Diamond v. Chakrabarty\textsuperscript{37} the Supreme Court held that the results of biotechnology research were patentable. The issue in that case was whether a micro-organism genetically transformed with a gene that would break down oil was patentable subject matter.\textsuperscript{38} In deciding that the bacterium was patentable, the Court made three important conclusions that set the stage for future biotechnology patents.

First, the Court was not concerned with whether the bacterium was "manufacture" or "composition of matter" under section 101.\textsuperscript{39} A precise classification of a biotech patent is not necessary as long as the invention falls within the general scope of patentable subject matter.

\textsuperscript{34} Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) (newly discovered natural principles are not patentable).
\textsuperscript{35} Parker v. Flook, 437 U.S. 584 (1978) (mathematical formulas are not patentable).
\textsuperscript{36} "[P]atents cannot issue for the discovery of the phenomena of nature . . . . [They] are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." Funk Bros. Seed Co., 333 U.S. at 130.
\textsuperscript{37} 447 U.S. 303 (1980).
\textsuperscript{38} Id. at 305.
\textsuperscript{39} Id. at 307-08.
Second, the Court defined the general range of subject matter to be wide. The Court noted the presumption that patents exist to provide incentives for research. Genetic engineering then, may have been unforeseen by Congress but was within the broad scope of legislative purpose.

Third, the Court provided a test to limit the bounds of patentable subject matter. The key issue for the Court was that the bacterial strain was nonnatural and a product of human ingenuity. The distinction between patentable and unpatentable claims is that of "products of nature versus human-made inventions."

As a result, biotech claims can be patented where, for example, a transformed organism does not exist in nature. Similarly, a naturally occurring protein that exists only in minute and contaminated quantities can be patented if isolated and purified. Although some biotechnology inventions could conceivably exist in nature, such as by some rare genetic event, the courts and the Patent Board have taken a broad view toward granting patents for this subject matter.

B. Conditions for Patentability

While the general subject matter of a claim may be patentable, the invention itself may not be worthy of a patent if it fails to satisfy the three statutory requirements of usefulness, novelty, and nonobviousness. For example, suppose a certain micro-chip has been on the market for years. Although micro-chips in general are patentable, this

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40 Id. at 307.
41 Id. at 314-16.
42 Id. at 310.
43 Id. at 313.
44 An example of a patented transgenic organism is the transgenic Harvard mouse, patent #4,736,866. A transgenic organism is one that expresses a gene not naturally found in that species. See Biochemistry, supra note 7, at 134 (describing transgenic mice).
45 One example is the purified human erythropoietin, Genetics Institute patent #4,677,195. Although the district court initially held this patent to be valid, the Federal Circuit held that the patent was invalid because GI's claimed method did not in fact result in a pure form of erythropoietin. See Amgen, 927 F.2d. at 1216.
46 The Amgen cases brought to light another serious issue in biotechnology patent law. Genetics Institute received a patent on the purified protein months before Amgen would have been granted a patent on the protein product of the cloned gene. Although both proteins are functionally identical, their discovery and isolation were the result of vastly different research approaches. Current case law only allows a single patent for the protein. A commentator has criticized this system for rewarding the less deserving inventor who is the first to purify small and commercially valueless amounts of a protein at the expense of the inventor who clones the gene so as to produce vast amounts of the useful protein. See R. Stephen Crespi, Inventiveness in Biological Chemistry: an International Perspective, Pat. & Trademark Off. Soc'y 351, 358-59 (1990).
47 See, e.g., Ex parte Allen, 2 U.S.P.Q.2d 1425 (1987), aff'd, 846 F.2d 77 (Fed. Cir. 1988) (denying on obviousness grounds a patent for a polyploid oyster created by a new hydrostatic method. The Board did state that oysters, multi-cellular organisms, were considered appropriate subject matter for patents under Chakrabarty).
particular chip would not receive a patent. Since the microchip claimed as an invention adds nothing new to public knowledge, it would not be patentable. Compare this to a human being, which is not patentable subject matter under any circumstances.\textsuperscript{47} If an application encompasses appropriate subject matter, a tripartite inquiry determines whether that particular claim deserves the granting of a patent.

Since the obviousness of biotechnology inventions has been the most contentious matter, the usefulness and novelty inquiries have not presented major analytical difficulties. This section briefly discusses the usefulness and novelty inquiries before fully analyzing the nonobvious requirement.

1. Novelty

Section 101 of title 35 states that a patentable invention must be “new.”\textsuperscript{48} Section 102 lists the situations in which alleged novelty can be refuted. Novelty analysis seeks to establish whether the claimed invention existed and was available to the public prior to the inventor’s application.\textsuperscript{49}

If the examiner finds that the invention previously existed, the claim fails for lack of novelty.\textsuperscript{50} The patent examiner can scour “printed publication[s] in this or a foreign country”\textsuperscript{51} as well as patents issued in the United States or abroad.\textsuperscript{52} In addition, a patent will be denied for lack of novelty if “before the applicant’s invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.”\textsuperscript{53}

Any prior revelation to the public of the invention will invalidate the claim for lack of novelty. An invention must not actually exist and be publicly accessible for a patent to issue. However, mere sugges-

\textsuperscript{47} Even if this was not the case under the patent statute, patenting a person would violate the 13th amendment, which states that “[n]either slavery nor involuntary servitude . . . shall exist within the United States.” U.S. Const. amend. XIII. Patenting a person would constitute “owning” that person.


\textsuperscript{49} Title 35 grants a 12 month grace period prior to application. 35 U.S.C. § 102. This is intended to protect scientific publications from penalty. For instance, a scientist who published the invention before applying for a patent would not be prevented from applying for 12 months. 35 U.S.C. § 102(b). Other countries are not so forgiving; in some countries, and any entry of an invention into the public domain immediately precludes its patentability.

\textsuperscript{50} 35 U.S.C. § 102 (1988). “A person shall be entitled to a patent unless . . . the invention was known or used by others . . . before the invention thereof by the applicant . . . .”


\textsuperscript{52} Id.

tions of the invention do not make it fail for lack of novelty. Suggestions are evaluated under the inquiry into obviousness rather than novelty.

Because the obviousness of biotechnology inventions has been the most contentious matter for the courts, novelty inquiry has not been a major issue. Additionally, the test is not easily applicable to science as, for instance, each DNA sequence created in the lab is essentially novel. The real issue in biotechnology concerns the related question of obviousness. This will be analyzed after a brief discussion of the utility requirement.

2. Utility

Title 35 states that an invention must be "new and useful" in order to receive a patent. Because the statute does not explain this requirement, the Courts have had to formulate standards on a case by case basis. Recognizing the ambiguity of the word "useful," the Supreme Court in 1966 laid down the criteria for patent utility in Brenner v. Manson.

In Brenner, the Supreme Court reversed the Court of Customs and Patent Appeals (now the Federal Circuit) and upheld the Patent Board's rejection of a claim for lack of utility. The respondent, Manson, had claimed a patent for a synthesized compound. The class of compounds that included his was being tested for possible tumor inhibiting effects. The Court did not consider "current testing" to meet the requirement of utility.

The Court made three statements that have impact on biotechnology applications. First, the Court did not believe that Congress intended the term "useful" to be so broad as to include "any invention not positively harmful." Second, simply being the object of scientific inquiry did not establish utility. Third, the Court expressed concern about the "quid pro quo" of granting a monopoly for a compound with an unknown function.

Since the function of the compound was essentially unknown, the public would not receive anything of substantive value in return for a vast monopoly on future knowledge. By emphasizing the quid pro quo aspect of patents, the Court recognized the immense value of a

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56 For an explanation of the Federal Circuit's jurisdiction, see supra note 4.
57 Brenner, 383 U.S. at 519.
58 Id. at 531.
59 Id. at 533.
60 Id. at 532-35.
61 Id.
62 Id. at 533-35.
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The patent monopoly and the dangers of granting one where public knowledge would not be significantly advanced. The Court aptly concluded that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."\(^{63}\)

Utility has only recently emerged as an issue for biotechnology patent applications. Previous issues, such as the discovery of human protein erythropoietin,\(^ {64}\) reached the courts in large part because of the vast commercial potential and utility of the product. Recent patent applications, however, such as those of the National Institute of Health's for DNA sequences, have diluted the utility requirement.\(^ {65}\) The Patent Office is currently deluged with applications for products that may have little or no commercial utility.

3. Nonobviousness

The issue of obviousness has been the crux of biotechnology cases decided in the Federal Circuit.\(^ {66}\) Title 35 states that

[a] patent may not be obtained . . . 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 . . . .\(^ {67}\)

This statutory requirement asks whether the invention would have been readily apparent to a skilled worker in the particular field. Conversely, inquiry into novelty seeks any previous public knowledge of the invention. Analysis for obviousness examines all relevant prior art\(^ {68}\) to determine whether the claimed invention represents a significant advance beyond what was already known.

In 1965, the Supreme Court set forth the modern test for obviousness in *Graham v. John Deere Co.*\(^ {69}\) This test imposes three requirements: first, the court must survey the scope and content of the prior art; second, it must examine the differences between the prior art and

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\(^{63}\) Id. at 536 (citing *Application of Ruschig*, 343 F.2d 965, 970 (C.C.P.A. 1965)).


\(^{65}\) *See Kiley, supra note 30, at 915-16 (criticizing the National Institute of Health's decision to apply for patents on segments of human genes).*

\(^{66}\) The holdings of the four major biotechnology cases appealed to the Federal Circuit hinged on the obviousness question.

\(^{67}\) 35 U.S.C. § 103.

\(^{68}\) "Prior art" is a term of art that describes sources of information that focus on the same subject matter as the invention. These may include scholarly journals, issued patents, and other analogous material that represent the state of knowledge in the field at the time of the invention. The scope of references analyzed as "prior art" is narrower than that analyzed for novelty. *See generally Hazeltine Research, Inc. v. Brenner*, 382 U.S. 252 (1965) (describing the scope of prior art available to examiners for evaluating a patent claim).

\(^{69}\) 383 U.S. 1 (1966).
the claimed invention; and third, it must determine the level of ordinary skill in the art. The Federal Circuit added a fourth element of secondary considerations to the three-pronged test. The secondary considerations include commercial success, long felt but unsolved need, and the failure of others to create the invention. Although these considerations are not by themselves dispositive, they are highly persuasive of nonobviousness.

Obviousness is currently the major issue in disputes over patent protection for genetic inventions. For the past decade, the Federal Circuit has decided the obviousness question without recognizing, or acknowledging, the underlying mode of its analysis. This Note proposes that the obviousness of an invention incorporating genetic information hinges on the availability of DNA sequences and methods from the prior art.

III
THE FEDERAL CIRCUIT'S OBVIOUSNESS DOCTRINE

Through a series of four cases, the Federal Circuit has confronted the question of obviousness in biotechnology inventions. Despite these four opportunities, the Federal Circuit has failed to elucidate a precise analytic framework. This failure has spawned a confusing framework of analysis for current biotechnology inventions.

As framed by the Federal Circuit's rhetoric, current analysis purports to focus on the actual biotechnology invention; that is, the end product or discovery of scientific research. In each case, the court initially provides a lengthy description of the invention. Then, the court cites conventional precedent that analyzes actual inventions. Notwithstanding the stated attempt at conventional analysis, the court tends to shift focus from the end product of scientific research to the actual research itself. Thus, the court determines obviousness, not by the invention itself, but by the steps that gave rise to the invention.

The resultant confusion is two-fold. First, analysis under the rubric of past nonbiotechnology precedents, while focusing on methods, 70 Id. at 17. 71 See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). 72 Id. 73 See, e.g., Adler, supra note 2, at 910-11 (discussing several decisions regarding the obviousness of genetic inventions). 74 Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987) (assay using monoclonal antibodies is non-obvious); In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988) (expression of fused foreign protein in bacteria is obvious); Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200 (Fed. Cir.), cert. denied, 112 S. Ct. 169 (1991) (DNA sequence for the erythropoietin protein is a non-obvious invention); In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991) (expression of an insecticide protein in cyanobacteria is nonobvious).
fails to provide any guidelines for future biotechnology claims. Second, the court’s unspoken emphasis on scientific methods is far from consistent.

A close analysis of the four Federal Circuit opinions reveals a confused judicial framework. Although the Federal Circuit purports to analyze the claimed invention product, the opinions are better understood as focusing on the techniques and procedures that create the discovery. This Note argues that the patentability of DNA sequences should be considered in the context of the scientific methods employed to define the sequences.

A. Hybritech, Inc. v. Monoclonal Antibodies, Inc. (1986) 75

In this patent infringement case involving monoclonal antibodies, the Federal Circuit court reversed the district court’s finding of obviousness and reinstated the validity of the disputed patent. The case was the court’s first attempt to analyze the obviousness of a biotechnology invention.

1. The Invention

The invention used certain, known proteins to attach to certain molecules in an unknown solution. By their attachment to specific molecules, the proteins can be used to measure the amount of those molecules that are in the solution. Specifically, this was a process that employed monoclonal antibodies in an immunoassay to measure the concentration of certain antigens.

The body’s immune system produces proteins called antibodies. By attaching themselves to foreign molecules, antibodies target “invading” molecules for destruction by the immune system. Each antibody is highly specific for a certain molecule, or “antigen.” Scientists can use this site-specific affinity as “a tool to identify or label particular cells or molecules and to separate them from a mixture.”

Work by Nobel prize-winners Georges Kohler and Cesar Milstein allowed the mass production of a single clone that produces a nearly unlimited supply of identical antibodies for a known antigen. 80 Previously, antibodies had to be purified from natural serum that con-

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76 For a description of Federal Circuit jurisdiction, see supra note 4.
77 For an explanation of monoclonal antibodies technology, see infra notes 78-81 and accompanying text.
78 Monoclonal, 802 F.2d at 1368.
79 Id. at 1368-69.
80 This is achieved by fusing a myeloma cancer cell and spleen cells from mice that have been injected with a particular antigen. The fusion product is called a “hybridoma” and produces identical monoclonal antibodies, See Biochemistry, supra note 7, at 895-97 (describing the development of monoclonal antibodies).
tained thousands of other antibodies. This new technique produces antibodies called "monoclonal antibodies."

Hybritech's invention was an immunoassay that utilized monoclonal antibodies. The goal was to have a process for measuring the quantity of a certain molecule in a solution. Hybritech achieved this by developing monoclonal antibodies with a high affinity for certain antigens. These monoclonal antibodies would sandwich the antigen and create an insoluble complex that could be quickly and accurately measured.

Monoclonal Antibodies, Inc., had developed its own immunoassay and was infringing on Hybritech's patent. Monoclonal challenged the validity of Hybritech's patent for this invention on various grounds. Most importantly, Monoclonal claimed that the immunoassay would have been obvious in light of the prior art.

2. The Analysis

Judge Rich's analysis represented the Federal Circuit's first attempt at evaluating the question of biotechnology obviousness. Purporting to analyze the "claimed invention," the court instead focused its approach on the scientific methods involved. This creates a confusing framework of analysis.

The opinion opens with reference to conventional obviousness precedent. The court cited both the Graham factual inquiries and the need to evaluate secondary considerations before determining obviousness. However, these conventional tests seemed to play little or no role in the actual determination of obviousness. Instead, the bulk of the opinion focuses on the availability of methods from the prior art needed to perfect the invention.

The determination of obviousness hinged on an analysis of the scientific knowledge available in the prior art at the time of invention. In making this determination, the court evaluated three sets of

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81 Monoclonal, 802 F.2d at 1370.
82 Id.
83 Id. at 1371.
84 For an explanation of "prior art," see supra note 68.
85 Monoclonal, 802 F.2d. at 1380.
87 Including the "scope and content of the prior art, level of ordinary skill in the art, and the differences between the prior art and the claimed invention" (footnote omitted).
88 "Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered before a conclusion of obviousness is reached . . . ." Id. at 1380.
89 Id. at 1380-81. This can be generally categorized under the Graham requirements as "the difference between the prior art and the claimed invention."
90 Id. at 1381.
scientific work. First, the court examined a series of four articles that predicted that monoclonal antibodies would be used in immunoassays.\footnote{Id. at 1380.}

These bare predictions "[a]t most, . . . are invitations to try monoclonal antibodies in immunoassays but do not suggest how that end might be accomplished."\footnote{Id.} Although the articles suggested the immunoassay invention, the court stated that "'obvious to try' is [an] improper consideration in adjudicating [the] obviousness issue."\footnote{Id. (quoting Jones v. Hardy, 727 F.2d 1524, 1580 (Fed. Cir. 1984)).}

In other words, the articles did not reveal any scientific methods that could be successfully carried out to create the invention.\footnote{Id. at 1380 ("To the extent the district court relied upon these references to establish that it would have been obvious to try . . . the court was in error.").}

Mere suggestion of an invention does not by itself lead to a finding of obviousness. While the concept of an immunoassay may have been obvious to try, the actual realization of the invention is not obvious without predictable, successful techniques. Without explicitly stating it, the court recognized that the inventive step is not the concept of an immunoassay, but the development of successful procedures for its completion.

The second set of work evaluated by the court included the original monoclonal antibody discovery, an article discussing antibody assays, and a patent for a polyclonal\footnote{Id., 802 F.2d at 1380-81.} antibody sandwich assay.\footnote{Id. at 1380.} The court found that this prior art, however, "indisputably does not suggest using monoclonal antibodies in a sandwich assay in accordance with the invention . . . ."\footnote{Id. at 1380.} While the scientific knowledge revealed various methods surrounding monoclonal antibody and sandwich assays, there was no suggestion to utilize them for the invention.

The court deemed the third set of scientific work the most pertinent.\footnote{Id. at 1381.} This included an article reporting monoclonal antibodies of high affinity and work that described investigating antibody binding sites by use of an insoluble sandwich complex.\footnote{Id. at 1381 ("The [prior art] is directed to mapping epitopes [binding sites] on a known quantity of antigen and the [invention] to determining the presence or concentration of an antigenic substance in a sample of fluid . . . .").} The court concluded that the binding site work was "qualitatively different than the claimed invention [and] . . . the . . . article does not compensate for the substantial difference."\footnote{Id. at 1381.} The prior art, then, does not reveal successful

\begin{itemize}
  \item Polyclonal antibodies are those purified from natural serum. Monoclonal antibodies are those derived from hybridoma technology. See supra note 80 and accompanying text.
  \item Id. at 1380.
\end{itemize}
methods to achieve the invention. Furthermore, the “work in no way suggests using monoclonal antibodies”\textsuperscript{101} such as those used in the immunoassay.

Monoclonal reveals an emerging confusion in the Federal Circuit’s approach to biotechnology obviousness. Although analyzed under the rubric of conventional precedent, the court’s reasoning is better understood as involving a two-factor test that focuses on scientific procedures. First, the prior art must contain a suggestion for the invention. Second, the prior art must reveal predictable techniques that allow for successful realization of the invention. However, this test is not readily apparent from the opinion. Additionally, the court used conventional tests to focus on methods. For instance, the court used objective evidence of commercial success to bolster the finding that the immunoassay techniques were\textsuperscript{102} unavailable.\textsuperscript{102} Commercial success of a product does not necessarily follow from the availability of techniques. Although valuable, techniques are not commercial products. The next case to reach the Federal Circuit failed to clarify this confused framework.

B. \textit{In Re O’Farrell (1988)}\textsuperscript{103}

\textit{O’Farrell} also combined conventional precedent with seemingly unconventional analysis. \textit{O’Farrell} reached the Federal Circuit after the Patent and Trademark Office Board of Patent Appeals and Infringements rejected O’Farrell’s patent application on grounds of obviousness. In this case, the prior art combined an explicit suggestion for the invention \textit{and} the availability of predictable methods to carry out the suggestion. The court’s analysis began to clarify the standard for determining when an “obvious to try” invention is also legally obvious. Although its holding rests on the availability of scientific methods, the court again failed to acknowledge this determining factor.

1. \textit{The Invention}

The invention involved manipulating a bacterium to produce a protein from a completely different species. Specifically, the patent application concerned a method for producing a foreign, fused protein in a transformed species of bacteria.\textsuperscript{104} The process involved isolating the stretch of DNA that codes for that protein and inserting it into the bacterium. As with other genetic inventions, this concept is much more complicated to achieve successfully in practice.

\textsuperscript{101} \textit{Id.} (emphasis added).
\textsuperscript{102} \textit{Id.} at 1382-84.
\textsuperscript{103} 853 F.2d 894 (Fed. Cir. 1988).
\textsuperscript{104} \textit{Id.} at 895.
Bacteria are single-celled organisms whose DNA exists in a simpler form than that of multi-cellular organisms such as humans. A bacterial genome includes small, circular sections of DNA called plasmids. These plasmids allow manipulation of bacterial DNA. Plasmids can be isolated, manipulated, and reintroduced to the bacterial species.

Because the biochemical machinery that replicates and translates DNA is the same among all species, genes from one species can be inserted into the genome of another. Thus, following a successful experiment, a gene for a human protein can be expressed in a bacterium. These genes from a foreign source are said to be heterologous genes. Bacteria that contain foreign genes are said to be transformed.

The claimed invention in O'Farrell was a method to produce successfully a foreign protein in a transformed species of bacteria. This was accomplished by creating a plasmid called a cloning vector. This plasmid includes a portion of a gene indigenous to the bacteria. Linked to this gene is the DNA for the desired protein. Upon successful insertion of the plasmid, the biochemical machinery of the bacteria will recognize the indigenous gene and begin to express it. Since the desired protein gene is physically linked to the host gene, the bacterium will continue reading along the DNA and produce a "fused" protein consisting of the indigenous and foreign protein.

2. The Analysis

The Federal Circuit's opinion evaluated the prior art and found an explicit suggestion for the claimed invention. However, there is some confusion about what the court considered to be prior art. The "prior art" evaluated by the Court consisted of prior procedures and methods. A more conventional approach would have focused on prior inventions. Although the court purported to analyze the prior invention, the opinion focused on the available scientific procedures.

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105 See generally Keeton & Gould, supra note 8, at 741-46 (describing the relatively simple DNA structure of bacteria).
106 The genome is the total sum of an organism's DNA. The genome of eucaryotic organisms (organisms other than bacteria) is wholly contained in complicated structures called chromosomes. See id. at 618-19 (describing the structures of eucaryotic chromosomes).
107 See id. at 730-33 (describing procedures for laboratory manipulation of plasmids).
108 Id. at 738.
109 O'Farrell, 853 F.2d at 895.
110 Id.
111 Not every stretch of DNA is expressed in an organism. Scientists overcome this problem by linking the foreign gene to an indigenous gene that is known to be expressed. Regulation of gene expression remains one of the most topical fields of genetic research. See generally Keeton & Gould, supra note 8, at 742-56 (overview of gene regulation).
In this case, the prior art consisted of a scientific article by the co-inventors that described a method for making a cloning vector with a regulated, indigenous gene. The only significant difference between the article and the invention concerned the nature of the foreign gene used. In the article, the researchers discussed using a ribosomal RNA gene, which is not usually translated into protein, while the invention substitutes a gene for a known, predetermined protein. Importantly, the article reported that the foreign DNA (the gene for ribosomal RNA) was expressed in the form of a fused protein. Thus, the court concluded that the prior art provided detailed methods and techniques that would have made the invention obvious.

The court reached this conclusion by reasoning similar to the Monoclonal opinion. First, the Court found a suggestion for the invention. Second, the court found techniques existing in the prior art that supplied a reasonable chance of success. However, throughout the opinion, the court failed to elucidate its method-based analysis.

The first stage of the court's analysis identified a suggestion for the invention. The court found that the prior art "explicitly suggested the substitution" of a known protein for the ribosomal RNA gene. As was shown in Monoclonal, mere suggestion is not enough for a finding of obviousness. Consequently, the appellants argued that the suggestions were merely invitations to attempt the experiment. Furthermore, rejection of the claim would constitute "an application of a standard of 'obvious to try' to the field of molecular biology." The Federal Circuit had previously rejected the "obvious to try" standard.

The court responded by pointing out that every obvious invention is also obvious to try. An invitation to attempt an experiment may or may not make that experiment obvious. Thus, the court posed the question: "[W]hen is an invention that was obvious to try neverthe-

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112 O'Farrell, 853 F.2d at 899-901.
113 Id. at 901.
114 Id.
115 Id. at 900. Production of a fused foreign protein was the fundamental scientific breakthrough that was claimed in this invention.
116 The article "further predicted that if a gene that codes for a protein were to be substituted for the ribosomal RNA gene, 'a readthrough transcript might allow for extensive translation of a functional eucaryotic polypeptide.'" Id. at 901.
117 Id.
118 Id. at 902.
119 Id. See, e.g., In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987).
120 O'Farrell, 853 F.2d at 903. In this sense, "obvious experiments" are a subset of those experiments that are "obvious to try."
less nonobvious?” The answer lies in the availability of predictable techniques needed to realize the suggestion.

Given an explicit suggestion for an experiment, the court concluded that an invention will be deemed obvious when the prior art supplies “a reasonable expectation of success.” The court gives two scenarios where the given suggestion would not supply the requisite detail.

In some cases, what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. In others, what was “obvious to try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

The scenarios described by the court can be characterized as an analysis of scientific techniques made available by the prior art. Without providing an explanation, the court concluded that neither situation applied to the O'Farrell invention. This Note proposes that this conclusion can be better reached by focusing on the availability of detailed techniques. For instance, in this case, the suggestion provided explicit and detailed methodology, and not merely “general guidance” or “numerous possible choices.” The inventors were denied patent protection because they previously “provid[ed] virtually all of their method to the public without applying for a patent.”

The O'Farrell invention concerned a method for producing a fused protein in transformed bacteria. The court found that the prior art provided both an explicit suggestion and detailed methods to carry out the invention with a reasonable expectation of success. The invention was not only “obvious to try,” but was in fact obvious. A pattern that focused on the scientific methods and procedures thus began to emerge. Underlying the court’s opinion, this pattern of analysis is consistent with the nature of biotechnology research. The inventive step in this research is not the product, but rather the inno-

121 Id.
122 Id. at 904 (citing In re Longi, 759 F.2d 887, 897 (Fed. Cir. 1985)); In re Clinton, 527 F.2d 1226, 1228 (C.C.P.A. 1976).
123 O'Farrell, 853 F.2d at 903 (citations omitted)(emphasis added).
124 Id.
125 The article “contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.” Id. at 902.
126 Id. at 903.
127 Id. at 904.
ervative techniques necessary for its discovery. Without fully recognizing its analysis, the court tended to focus on the availability of these techniques. The next Federal Circuit case extended the analysis even further and applied it to the ownership of actual DNA sequences.

C. *Amgen v. Chugai* (1991)\(^{128}\)

The third case to reach the Federal Circuit again focused on the availability of scientific methods. The contested patent in this case concerned the discovery of the DNA sequences encoding the human protein erythropoietin (EPO).\(^{129}\) Amgen Pharmaceutical Co., Ltd., the owner, sued Genetics Institute, Inc. and Chugai, Inc. for infringing the patent by producing EPO by recombinant DNA technology. Chugai then challenged the validity of Amgen's patent for the DNA sequences.\(^{130}\) The finding of nonobviousness hinged on the availability of the DNA sequences. Indirectly, the court recognized that the discovery of DNA sequences hinged on the scientific methods available for their location and isolation. Thus, the court extended its somewhat confused framework to inventions incorporating DNA sequences.

1. *The Invention*

Erythropoietin (EPO) is a protein that boosts red blood cell production. Persons with anemia have a red blood cell deficiency and some respond to treatment with erythropoietin.\(^{131}\) Through innovative cloning techniques, Amgen scientists isolated and purified the stretch of human DNA that codes for erythropoietin.\(^{132}\) This isolated DNA code constitutes the patent.

Although vitally important to biotechnology, cloning can be a very complex endeavor for scientists. Cloning involves first discerning the amino acid order of the desired protein. An approximate DNA sequence can then be deduced and generated. This DNA sequence, or "probe," can be used to find the exact chromosomal location of the gene which can then be isolated and purified. The difficulty in cloning erythropoietin was that the amino acid sequence was uncertain.\(^{133}\)

The strategy that finally succeeded was to use two sets of fully-degenerate, or variable, probes for two different regions of the EPO gene. Chugai and Genetics Institute contended that their scientists

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\(^{129}\) Id. at 1203-04.

\(^{130}\) Id. at 1204.

\(^{131}\) Id.

\(^{132}\) Id. at 1207.

\(^{133}\) Id. at 1206.
were the first to conceive of this strategy.\textsuperscript{134} They also asserted that the discovery of the EPO gene would have been obvious in light of the prior art.

2. The Analysis

The Federal Circuit’s opinion had two very important repercussions for obviousness analysis. First, the court held that a DNA sequence could not be conceived as an invention until the gene containing the sequence had been isolated. By so limiting the definition of “conception,” the Court’s reasoning necessarily focused on the availability of DNA sequences and procedures. Second, the court treated the scientific process of gene discovery as bearing on the issue of obviousness.

The \textit{Amgen} court’s definition of an invention’s conception is important for subsequent obviousness analysis. Under 35 U.S.C. § 102, the first to conceive of an invention and then reduce that invention to practice is the primary inventor. Having exercised due diligence in reducing the conception to an invention, this person is entitled to a patent.\textsuperscript{135} Genetics Institute claimed that its scientist was the first to conceive of the probing strategy of using two sets of probes and that therefore they should be entitled to the patent and not the Amgen scientist who actually discovered the erythropoietin DNA sequence.

The court rejected Genetics Institute’s claim and held that the conception of a DNA invention requires knowledge of the actual sequence.\textsuperscript{136} The first to invent a DNA invention must be the first to make the sequences available. In this sense, “an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment . . . a simultaneous conception and reduction to practice.”\textsuperscript{137} The court reasoned that “until [the scientist] had a complete mental conception of a purified and isolated DNA sequence encoding EPO and a method for its preparation . . . all he had was an objective to make an invention.”\textsuperscript{138} This assertion recognizes that the inventive step in a DNA sequence discovery is not conceiving the idea of a certain gene product, but creating the actual technical methods needed to realize that idea.

\textsuperscript{134} \textit{Id.} Defendants assert that Amgen’s work was not novel under 35 U.S.C. § 102(g) (1988). By being the first to conceive of the probing strategy, Genetics Institute contends that they were the first inventors. \textit{Id.}

\textsuperscript{135} See 35 U.S.C. § 102(g) ("In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.").

\textsuperscript{136} \textit{Id.} at 1206.

\textsuperscript{137} \textit{Id.}

\textsuperscript{138} \textit{Id.} (emphasis added).
The court also defined biotechnology conception as requiring actual knowledge of the DNA sequences. Although unstated by the court, this definition logically implies that methods are required. Without methods, the DNA sequence needed for conception would be unavailable.

To extend the court's reasoning to its logical conclusion: since conception of a DNA invention cannot occur until the actual sequence is discovered, the invention cannot be obvious until the sequence is obviously conceivable. To be obviously conceivable, the sequence must be readily available by standard, predictable techniques. Obviousness, then, should rest on the availability of the actual sequence. However, the court fell short of reaching this conclusion.

The *Amgen* court still purported to use conventional analysis. The logical extension of the court's definition of "conception" requires an evaluation of methods. However, conventional obviousness analysis looks at the end product of research, not the methods. This contradiction is confusing and produces a tension within the opinion. This tension is apparent in two ways. First, the court briefly acknowledged that obviousness hinged on methods. Second, the court applied a standard of obviousness that began to focus on the availability (by predictable methods) of the DNA sequences.

In *Amgen*, the Federal Circuit briefly recognized the methodological focus of obviousness analysis. In a footnote, the court "note[s] that both the district court and the parties have focused on the obviousness of a process for making the EPO gene, despite the fact that it is products (genes and host cells) that are claimed in the patent, not processes." The court's brief comment acknowledges the methodological focus with neither approval nor disapproval. Nevertheless, the court's subsequent analysis and the holding rely entirely on the scientific methods available for discovery. Thus, the inventive step in these experiments is not the idea of a certain gene discovery, but the actual scientific methods needed to realize that idea.

The court then analyzed the obviousness of the methods to make a finding that the EPO gene was a nonobvious invention. First, the court recognized that prior art had suggested the probing strategy, thereby making the method "obvious to try." This established, the court then agreed with the district court that "there was no reasonable expectation of success in obtaining the EPO gene by the method that [the Amgen scientist] eventually used." Thus, the court found that

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139 *Id.* at 1207 n.3.
140 *Id.* at 1207-08.
141 *Id.* at 1209 (emphasis added).
the many pitfalls and difficulties in cloning techniques made the realization of the suggested idea not obvious.\(^\text{142}\)

The court's conclusion that the invention was not obvious can best be interpreted by focusing on the scientific techniques in the prior art. The DNA sequence for the EPO gene was not readily available by standard techniques. Therefore, the methods of discovery supplied by the prior art would not stand a reasonable chance of success. This approach to obviousness discards the conventional focus on the invention itself. Instead, the approach recognizes that the inventive step in biotechnology is not the end product of research, but the research itself. The final case to reach the Federal Circuit extends the confusion and tension between conventional analysis and the more useful focus on methods.

D. In re Vaeck (1991)\(^\text{143}\)

In this case, the district court had rejected a patent claim on grounds of obviousness. The Federal Circuit reversed this finding and held that the invention was not obvious as there was neither a suggestion from the prior art nor a "reasonable expectation of success" for the experiment.\(^\text{144}\) The case purports to hinge on the detail of the "suggestion" for an invention. Yet the analysis focuses on the methodology revealed by the prior art. A more explicit recognition of this analysis would better serve the opinion.

1. The Invention

The Bacillus bacteria produce a protein that is toxic to insects and useful for clearing insects from swampy areas. Unfortunately, Bacillus lives at the bottom of swamps where insects are not exposed to it. Cyanobacteria, a much less studied species, grow on the swamp surface where they can be consumed by insects.\(^\text{145}\)

The scientists in Vaeck took an isolated Bacillus insecticidal gene and combined it with a stretch of DNA from cyanobacteria to create a "chimeric gene."\(^\text{146}\) This stretch of DNA allowed expression of the foreign protein in cyanobacteria. Subsequently, scientists successfully transformed cyanobacteria with a plasmid containing the insecticidal chimeric gene. The difficulty with these experiments lay in the difference between cyanobacteria and Bacillus and the lack of knowledge

\(\text{142}\) Id.
\(\text{143}\) 947 F.2d 488 (Fed. Cir. 1991).
\(\text{144}\) Id. at 495.
\(\text{145}\) Id. at 499.
\(\text{146}\) Id. at 489-90. The name chimeric DNA comes "[f]rom chimera, a mythological creature with the head of a lion, the body of a goat, and the tail of a serpent." BIoCHEMISTRY, supra note 7, at 125.
about the cyanobacteria genus.147 Because of the difficulties in the experiments, the Court found the invention not to be obvious.148

2. The Analysis

The analysis in Vaeck focused on methods revealed by the prior art and the availability of chimeric genes. In addition, the opinion recognized both explicit and implicit suggestions. Unfortunately, the analysis confuses a suggestion that an experiment is “obvious to try” with the availability of methods and sequences to make that experiment possible. Although the holding rests on the availability of successful methods, the opinion blurs the distinction between this and the suggestion to try an experiment.

The Patent and Trademark Office determined that the invention would have been obvious in light of two sets of scientific work. The first was an article149 describing the successful expression of a chimeric gene in cyanobacteria. The chimeric gene comprised an antibiotic marker gene150 and a chloroplast promoter sequence.151 The second set was three articles that described expression of Bacillus insecticidal proteins in other bacterial hosts. The Patent Office reasoned that it would have been obvious to substitute the three described Bacillus genes for the marker gene in the chimeric plasmid described above.152 This would result in high level expression of Bacillus genes in transformed cyanobacteria.153

In an opinion by Judge Rich, the Federal Circuit reversed the finding of obviousness.154 The court initially declared that “a proper analysis . . . requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested . . . that they should make the [invention]; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.”155 By focusing on the

147 Vaeck, 947 F.2d at 494.
148 Id. at 494-95.
149 Id. at 490 n.6 (citing 12 Nucleic Acids Res. 8917 (1984)).
150 This confers resistance to a certain antibiotic that would normally inhibit bacteria. Antibiotic resistance genes can be used as markers to check for successful insertion of a foreign plasmid into a host bacteria. For instance, if the marker gene is put on the plasmid, only successfully transformed bacteria have that gene. Exposure of the bacterial sample to the antibiotic will kill off the non-transformed cells and leave only the bacteria with the plasmid. These then can be isolated and studied.
151 A promoter is a regulatory sequence that allows the expression of a certain gene. The promoter’s function is to provide a recognition and attachment site for the enzyme that initiates the process of “decoding” the gene sequence. See generally BIOCHEMISTRY, supra note 7, at 98 (generally describing transcription of DNA).
152 Vaeck, 947 F.2d at 492.
153 Id.
154 Id. at 496.
155 Id. at 493 (quoting In re Dow Chemical Co., 837 F.2d 469, 473 (Fed. Cir. 1988)).
methodology needed for chimeric gene expression, the court found that neither of these factors was present and therefore the invention was nonobvious.156

The court distinguished O'Farrell157 by noting that the invention at issue in that case involved an explicit suggestion and detailed enabling methodology, thus making the invention obvious.158 In contrast, "the prior art in this case offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art."159 Focusing on the scientific methods needed to successfully transform cyanobacteria with an insecticidal gene, the court found no implicit suggestion in the prior art.

Referring to the first article of prior art, the court declared that "the expression of [a marker gene] in cyanobacteria, without more, does not render obvious the expression of unrelated genes in cyanobacteria for unrelated purposes."160 This is because "it is only in recent years that the biology of cyanobacteria has been clarified."161 While the idea for a chimeric gene may be straightforward, the invention was not obvious because the scientific methods for manipulating cyanobacteria were unpredictable.162

If methods for manipulating cyanobacteria were interchangeable with those for other bacterial strains, then the conclusion would be different. The substitution of cyanobacteria for other bacteria to express the gene would have been implicitly obvious. Since the knowledge was poor and methods unpredictable, the court found that there was no implicit suggestion for the invention.

The court looked to those same unpredictable methods to find that there was no "reasonable expectation of success."163 This finding, however, was really only an afterthought. The court devotes the vast bulk of its analysis to explain why the prior art did not implicitly suggest the invention because of the uncertainty in manipulating cyanobacteria.

Unfortunately, this analysis confuses the distinction between a "suggestion for an invention" and a "reasonable chance for its success." Perhaps a better approach would have been to find that the

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156 Id. at 496.
157 853 F.2d 894 (Fed. Cir. 1988).
158 Vaeck, 947 F. 2d at 494-95.
159 Id. at 495.
160 Id. at 493.
161 Id. at 494.
162 "The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability regarding heterologous gene expression in this large, diverse, and relatively poorly studied group of procaryotes is high." Id. at 493 (quoting the patent examiner).
163 Id. at 495.
prior art had indeed implicitly suggested the substitution of an insecticidal gene for a marker gene in cyanobacteria. This would make the invention “obvious to try.” The court could then have examined whether available methods predicted a “reasonable expectation of success.”

This approach could utilize the “obvious to try/obvious” distinctions described in O'Farrell. It also could build on a framework, drawn from Amgen and Hybritech, that emphasizes the need to determine the availability of sequences and methods. While the result reached would be the same, the court could have explicitly recognized and described the method-based standard for DNA inventions. This would clarify future analysis and remedy the vagueness of the obviousness standard.

IV

THE FUTURE OF OBVIOUSNESS ANALYSIS

There is a need for a clear and practical standard with which to evaluate the obviousness of biotechnology inventions. Such a standard would both ease congestion at the Patent Office and create greater predictability for the biotechnology industry. With the large costs of modern science, research funds are far better spent on actual research than financing excessive litigation occasioned by vague patentability criteria. By formulating a clear standard of method and sequence availability, the Federal Circuit may be able to achieve these two goals.

A. The Need for a Clear Obviousness Standard

A clear obviousness standard would serve two important goals in biotechnology research. First, it would help ease the patent application process. Second, it would increase the predictability of success in patent applications. This would reduce litigation costs and encourage more industry investment in biotechnology research.

Faced with a backlog of cases, the Patent Office has applied overbroad, general rules to specific claims. While this may be an understandable reaction to a large backlog of claims, it has led to unduly expansive interpretations of the case law.

The Patent Office is indeed swamped with biotechnology applications. Michael Gough, manager of the Office of Technology’s Biological Applications Program, testified before the House Subcommittee on Intellectual Property and Judicial Administration that the backlog of cases is a continuing source of controversy and an impediment to U.S. biotechnology. Moreover, the backlog is continually growing

since the Patent Office is unable to train and retrain qualified examiners.\textsuperscript{165} In fact, one witness stated that "despite heroic efforts,"\textsuperscript{166} the Patent and Trademark Office today is desperately short of examining resources. As a result, the pendency of a biotechnology application may be up to five years, according to Reid Adler, the director of National Institute of Health's technology transfer department.\textsuperscript{167}

Faced with this volume of work, the Office needs a clear framework of precedent with which to analyze the obviousness of biotechnology applications. The Commissioner of the Patent Office, Harry Manbeck, has testified that he and the Patent Office support legislation that would clarify the evaluation of biotechnology patent claims. At a House subcommittee hearing, he stated that administrative costs are high and the case law in the biotechnology field is generally unclear.\textsuperscript{168}

As well as encouraging application efficiency, a clear obviousness standard is also important for the industries that fund highly expensive modern science. Funds for biotechnology research are limited, yet the legal costs of patenting are great.\textsuperscript{169} Funding now allocated to processing and litigating patents can be better directed to medical research and other scientific endeavors. For example, Amgen Co.'s legal costs in its battle with Genetics Institute over the erythropoietin (EPO) patent were at least $10 million.\textsuperscript{170} This represents 10\% of the costs for developing EPO. A system that fosters spending this much to cope with a legal morass is flawed.

\begin{thebibliography}{9}
\bibitem{165} Id.
\bibitem{168} Biotechnology Patent Protection Act Hearing, \textit{supra} note 166, at 17-19 (testimony of Harry F. Manbeck, Jr., Asst. Secretary and Commissioner of Patents and Trademarks, U.S. Dept. of Commerce). This reasoning was answered quite directly by Donald Banner, President of Intellectual Property Owners Inc., in the same hearing:
\begin{quote}
We heard also about the great advantage of reducing the workload of the Patent and Trademark Office and what a nice idea that would be. Well, you know, when you think about it, you could just allow all the patents. Wouldn't that be fun? They wouldn't have anything to do. We would save money in the Patent Office, but what chaos would that create in the real world?
\end{quote}
Id. at 89.
\end{thebibliography}
Minimizing legal costs will encourage more research and permit lower prices for the resulting products. Establishing clear guidelines for patentability will help achieve these goals. If the law is clear, companies and institutions will not have to fight legal battles to establish their rights. Additionally, this may encourage more industry investment in both private and university-based research. Thus, both the patent office and the biotechnology industry would benefit from a clear obviousness standard. However, the pace of scientific research exceeds that of judicial or Patent Office decisions. For this reason, some “bright line” rules may be inappropriate for emerging technologies. What is needed is a standard that is both clear and adaptable to new discoveries and research.

B. The Availability Doctrine—Clarity and Adaptability

This Note proposes a framework for obviousness analysis that is both clear and adaptable. Clarity can arise from a lucid explanation of the standard and its application in past decisions. This proposed standard is adaptable to future discoveries because of its focus on scientific methods.

At first, this focus on the methods and techniques may seem counter-intuitive. Why should one look at the process of creating an invention when the obviousness of the invention itself is being questioned? The answer lies in the nature of DNA sequences. DNA sequences exist wholly apart from scientific attempts to manipulate them. These inventions are in essence “discoveries” of existing DNA information. The inventive step is not the general conception of an invention that utilizes DNA, but the actual discovery and isolation of the specific DNA sequences.

To this point, the Federal Circuit has ignored the centrality of research procedures to biotechnology inventions. This has produced confusion and a tension within the opinions. This Note proposes to

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171 Landmark court decisions in patent law deal with the state of the art of 5 to 10 years earlier. Fundamentally, advances in patent law lag behind developments in science. . . . This is particularly significant for biotechnology, where new medical or industrial technologies emerge before basic questions of patentability are even framed clearly.


172 Pure discoveries of nature are not patentable. See supra note 36. However, isolated and purified DNA is deemed not to be in a natural state. For instance, eucaryotic genomic DNA contains stretches of introns that are not translated into protein. By obtaining the mRNA copy of a certain gene, scientists can use the enzyme reverse transcriptase to obtain the translated DNA sequence for that gene. This sequence without introns, called cDNA, does not exist in nature and so can be said to be an invention. Thus, any in vitro manipulation of DNA can be said to create a non-natural, human invention.
resolve this confusion by focusing explicitly on available scientific procedures.

The proposed framework can be divided into two sections. The initial inquiry searches for a suggestion for the claimed invention from the prior art. This suggestion can be either explicit, as in O’Farrell, or implicit, as in Vaeck. Once a suggestion has been found, the invention can be deemed “obvious to try.” This threshold analysis is not stringent because most biotechnology inventions can be characterized as obvious to try. The second stage of the analysis determines whether or not an “obvious to try” invention is also legally obvious.

The second stage of the analysis evaluates the reasonable expectation of success of the “obvious to try” invention. This is accomplished by evaluating the availability of the discovery. For patents claiming DNA sequences, standard, predictable techniques may make the specific gene sequence readily accessible. If a gene sequence is readily available, the invention stands a reasonable chance of success. Thus, by focusing on scientific techniques, the Court can analyze availability. A claimed discovery/invention that is readily available is obvious.

This stage of the analysis can be applied to Amgen, O’Farrell, and Monoclonal. In Monoclonal, the prior art did not provide sufficient methodology for making the sandwich assay readily available. In O’Farrell, the prior art provided explicit procedures for making the hybrid vector readily available to a skilled geneticist. In Amgen, the erythropoietin DNA sequence was not readily available by any known scientific methods. Although the Vaeck court found no suggestion in the prior art, the case might be better analyzed as an “obvious to try” invention that had no reasonable chance of success. This is so because the prior art made available neither the methods nor DNA sequences necessary to create a chimeric insecticidal gene in cyanobacteria.

Under this analysis, the decisions in all four of the Federal Circuit cases should turn on the reasonable chance of success of each inven-

173 For instance, cloning a medically useful gene is a straightforward general idea. This would be “obvious to try.” Successfully accomplishing this goal though may not be so “obvious.”

174 Of course, a biotechnology invention that was so unique that it could not be deemed “obvious to try” should not move to the second stage of inquiry. These inventions, however, would likely not reach this level of litigation over the obviousness issue.

175 “At most, these articles are invitations to try monoclonal antibodies in immunoassays but do not suggest how that end might be accomplished.” Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987).

176 See supra notes 112-17 and accompanying text.

177 See supra notes 140-42 and accompanying text.

178 See supra notes 154-56 and accompanying text.
The court should scrutinize the scientific methods revealed by the prior art. Only by careful evaluation of each method and procedure should the Court determine obviousness. Scientists do not discover useful inventions by hypothesis alone. Rather, biotechnology discoveries hinge on the careful development of successful and creative methods. By focusing explicitly on these methods, the court can determine whether the invention would have been obvious to a scientist in the relevant field.

This standard can adapt to emerging technologies because of its focus on methodology. New scientific procedures lie at the forefront of biotechnology discoveries. Inventions arise from new methods of discovering and manipulating genetic information. By analyzing scientific methods and not general ideas, the standard can remain applicable to emerging technologies. As scientific knowledge continues to grow and expand, the focus on methods can be applied to inventions from other fields of research.

CONCLUSION

Biotechnology and the exploration of genetic processes have created much exciting research. These discoveries can result in medical, agricultural, and other applications of tremendous importance. Patents have emerged as a method for protecting and owning some of this valuable knowledge. Of the various statutory requirements, obviousness has become the most contested.

An emerging pattern underlies the Federal Circuit's approach to the obviousness of biotechnology inventions. The court could significantly clarify this pattern by acknowledging the importance of scientific methods. This Note argues that for a finding of obviousness, an invention must meet a two part test. First, the invention must be either explicitly or implicitly suggested in the prior art. Second, there must be readily available methods to achieve the suggestion with a reasonable chance of success. To illustrate, in a claim for a DNA sequence, the invention would have been obvious if the sequence was accessible by readily available methods.

This standard of "available methods" has not been fully clarified by the Federal Circuit. By fully acknowledging the importance of scientific techniques, and not products, the court can create a doctrine that is both consistent and practical. This would alleviate Patent Of-

179 The genetic code holds far more information than just single gene to single protein structures. Research is beginning to uncover vast, complicated regulatory and structural systems and gene "families."
fice congestion, reduce litigation costs, and encourage more investment in biotechnology.

Brian C. Cannon†

† I would like to thank Professor Richard Beresford for his comments on my note.
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