ARTICLE

NONOBVIOUSNESS AND THE BIOTECHNOLOGY INDUSTRY: A PROPOSAL FOR A DOCTRINE OF ECONOMIC NONOBVIOUSNESS

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I. INTRODUCTION
In the 23 years since the groundbreaking scientific discovery that made biotechnology possible, the biotechnology industry has grown to a 4 billion dollar per year industry that employs almost 100,000 people in 700 firms.\(^1\) Conservative predictions estimate the industry will have 30 billion dollars in sales by the year 2000. American biotechnology is clearly a global leader in both biomedical and agricultural inventions, and the United States enjoys a significant trade surplus in biotechnological products.

In the words of Dr. Bernadine Healy, director of the National Institutes of Health, "[t]o maintain our world leadership in biotechnology, the United States must see the support of progress in biomedical research as one of its highest Federal priorities."\(^2\) This support, however, need not come from monetary subsidies or regulatory relief (which seem unlikely in the current political climate). Rather, the U.S. Patent and Trademark Office, in conjunction with the Court of Appeals for the Federal Circuit, stands in a unique position to give needed support to the industry through a change in patent policy. Virtually cost-free to the public fisc, making patents slightly easier to get will satisfy the policy needs of the biotechnology industry and will be logically defensible.

Part II argues for the need to encourage the biotechnology industry. It considers arguments that focus on specific cultural and economic needs of the biotechnology industry, as well as why our society should give this particular industry special treatment. Part III suggests that patent law is


the best vehicle to implement a biotechnology industrial policy. Part IV provides an overview of the patent system, discussing both the law and the administrative scheme. Part IV concludes that modifying the nonobviousness requirement, in particular, would benefit the biotechnology industry. Part V discusses the current nonobviousness doctrine. After a discussion of the general doctrine, it gives a brief and non-technical explanation of molecular biology and biotechnology, thereby laying the groundwork for the ensuing discussion of the nonobviousness requirement as it applies to biotechnological inventions.

Part VI proposes a modification of the nonobviousness requirement for biotechnological inventions. It suggests the nonobviousness inquiry should take into consideration not only technical nonobviousness, but also economic nonobviousness. Finally, the nonobviousness standard proposed herein explains certain outcomes in recent biotechnology case law better than the doctrine on which those cases purport to stand.

II. WHY SHOULD BIOTECHNOLOGY RECEIVE SPECIAL TREATMENT?

In order to support the conclusion reached in this article—that biotechnological inventions should be given patents more easily in order to foster the industry's growth—two underlying assumptions must be stated. First, the industry needs special treatment to become fully developed; that is, something is wrong with allowing the market to determine how much investment biotechnology receives. Second, society should encourage biotechnology for equitable and economic reasons. The first assumption is supported by an analysis of the culture and economy of the industry, the second by an analysis of the potential benefits industry brings to society.

A. Cultural Aspects of the Biotechnology Industry

The biotechnology industry is characterized by several interrelated properties. Perhaps the most obvious of these is that the industry is primarily made up of small, single-product start-up companies. This paper argues that this important characteristic is related to, and mandated by, two other properties of the industry: its highly educated workforce and the close relationship between basic and applied science in the field.

This interrelationship is illustrated by the evolution of the first biotechnology company: Genentech. The basic scientific discovery which makes the industry possible is a method of making functional chimeric DNA (recombinant DNA) discovered by Stanley Cohen at Stanford University and Herbert Boyer at the University of California, San Francisco in 1973, for which a patent was filed in 1974 and granted in
Genentech was founded by Robert Swanson, a venture capitalist, and Hebert Boyer and successfully produced genetically engineered insulin by 1977. What is important to note is that the potential commercial value of the academic research was immediately apparent and continues to be so. For example, BRCA1, the gene responsible for most breast cancers, was discovered through collaboration between scientists at Vanderbilt University School of Medicine and the University of Washington, the gene responsible for early onset Alzheimer's Disease was discovered at the University of Toronto; the gene for neurofibromatosis (Elephant Man Disease) was discovered at the University of Michigan; the gene for Duchenne Muscular Dystrophy was discovered at Baylor College of Medicine; the gene for Huntington's Disease was discovered at Johns Hopkins University.

Because of the close association between academic laboratories and industrial laboratories, biotechnology companies developed a culture that borrows several features of the university setting. The academic culture in which scientists train produces men and women who are accustomed to working in highly focused, small, independent laboratories. Although the university itself is a large institution, the laboratories are highly autonomous, self-funded functional units. Most laboratory research funding is from outside the university (through government grants and private endowments).

As a result of the influence of academic research on the biotechnology industry, the "research ethos" is encouraged, with publication and sharing of results encouraged. Additionally, companies are relatively small and focused, not unlike some academic research laboratories.

An interdisciplinary team at the University of California, Los Angeles has done empirical research that bears out at least part of this

9. See id.
intuitive description. Lynne Zucker, Marilynn Brewer, and Michael Darby asked whether the relationship among scientists, universities, venture capital, and other economic factors influenced the founding of biotechnology companies. They examined what they termed "intellectual capital" and found that this intellectual capital is critical to the birth of a biotechnology company. A person has intellectual capital if "she embodies a specialized body of knowledge which enables the individual to earn supranormal returns on the cost of obtaining that knowledge." The authors say that biotechnology is intellectual capital intensive because radically new laboratory techniques need to be learned first hand, thus making the initial discoverers of the techniques and their apprentices extremely valuable. Because intellectual capital dissipates as a technique becomes more widely understood and applied, it is "by its nature a transient property of disequilibria." Despite this transience, intellectual capital is critical to the birth of biotechnology companies because these companies come into existence before new technological knowledge is diffused. Using the metric of publications of gene sequences, the authors found that intellectual capital is geographically concentrated. Understandably, these centers of concentration are frequently universities. The researchers found that the concentration of intellectual capital, in time and place, is an accurate predictor of the birth of biotechnology companies.

By following the academic model, biotechnology loses some of the economic advantages of large industries, such as economies of scale. However, it retains a feature critical to successful innovation in high-tech industries: an atmosphere of creativity and intellectual freedom. The need for this atmosphere argues for an economic policy for biotechnology that will compensate for the economic losses that accompany this academic atmosphere.

Because biotechnology requires a very highly skilled work force, there is a need for the industry to continue to lure academic scientists to industry. To do this, the industry must create an environment similar to that in a university, and as a result, must be provided with viable economic incentives to maintain a high level of innovation.

11. Id. at 5.
12. Id.
13. Id. at 6.
14. See id.
15. Id. at 7.
16. See id. at 11-12.
17. Id. at 11.
B. Economic Aspects of the Biotechnology Industry

In addition to having cultural attributes (and the concomitant economic problems) that need to be protected in order to remain innovative, the biotechnology industry has purely economic considerations that suggest the need for special policies. For instance, venture capital is an important source of funding for biotechnology start-ups. One commentator has gone so far as to say that “[b]iotechnology has emerged as an industry largely because of one economic institution: venture capital.”\(^{18}\) Others have been more cautious, merely noting that “the existence of the venture capital industry in America has had a significant effect on the development of the biotech industry.”\(^{19}\)

Regardless of the exact quanta of importance that venture capital has had in the development of the biotechnology industry, as realities such as technical difficulties and limited markets have become apparent, venture capitalists have become much less willing to invest. The increased competition in the venture capital market has necessitated the development of a metric for differentiating between biotechnology firms. Because venture capitalists are typically not experts with respect to the technology, intellectual property rights have become the proxy for technological value. It is therefore important that the patent system award patents to deserving inventions so that the companies developing those inventions can attract venture capital, thereby supporting the biotechnology industry.

Related to this argument is the suggestion made by Professor Robert Merges that very expensive and very risky inventions tend to be pursued at less than socially desirable levels.\(^{20}\) Biotechnology inventions are frequently both risky and expensive. Professor Merges takes a statistically rigorous approach, through economic modeling, to show how this risk will result in less than optimal investment. Nonetheless, a less mathematical approach is also instructive.\(^{21}\) Any given invention will have a certain likelihood of success and a certain expected market payoff. The market payoff must be discounted by the probability of success in order to decide whether it is economically wise to pursue an invention. However, these are not the only factors in the equation. Inventors and, perhaps more importantly, investors, are more or less risk averse. For instance, given two investments, one with a 100% chance of a $1 million payoff, and the other with a 50% chance of a $50,000 loss and

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21. This intuitive approach is based on Prof. Merges' discussion, id. at 43-55.
a 50% chance of a $2,100,000 payoff, it is not surprising that some
investors will prefer the former. \(^2\) They will invest in the former despite
the fact that it has a lower absolute payoff ($1 million vs. \((0.5)(-$50,000) + (0.5)($2,100,000)\), or $1,025,000). The preference will stem instead
from the first investment’s lower risk. This risk aversion can be overcome
only by offering a greater return. In other words, investors will more
heavily discount a high risk investment than a low risk one.

This very basic risk analysis is complicated when there are a number
of different possible outcomes, each with a certain probability of
occurring. For instance, two investments, one with a 50% chance of
winning $20 and a 50% chance of losing $10, and the other with a 1% chance
of winning $1000, a 1% chance of winning $100, a 1% chance of
losing $500 and a 96% chance of breaking even, both have a predicted
return of $5. \(^3\) Intuitively, one can understand the greater appeal of the
first investment, again because of its lower risk. This intuition can be
articulated with a statistical measure called variance. \(^4\) In this context,
variance, as its name implies, describes how widely varying a set of
possible outcomes is. The higher the variance, the higher the risk. \(^5\)
Biotechnology inventions, because they have many hurdles to clear before
commercial success, can be described as high variance. There must be
positive in vitro results, animal tests, and three or four stages of clinical
trials before ever even entering the market. Also, biotechnology products
must compete with traditional, often less expensive, alternatives. Finally,
there is always the possibility of a high payoff when a biotechnology
product is found to be useful in a multitude of contexts. \(^6\)

Furthermore, risk aversion also results in heavier discounting of
extremely expensive inventions. To understand this, one need only
imagine oneself going into a gambling casino. Although the odds of
winning a hand of blackjack are exactly the same whether you bet $5 or
$500, the more risk averse gambler will intuitively discount the chance of
winning the $500 hand and be less likely to wager that amount of
money. \(^7\)

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23. See Merges, supra note 20, at 143.
24. Variance describes how closely a collection of values is clustered around the mean
value. It is defined as the average squared deviation of the observations from the mean. See
25. Merges, supra note 20, at 43.
26. For example, Epo, a product of Amgen, was initially intended to be used for patients
undergoing dialysis. It has since been shown to be useful in treating cancer.
27. The gambling analogy breaks down somewhat since it does not take into account
the adrenaline rush that people who bet $500 a hand are seeking.
The implication of this analysis is clear. Because biotechnology inventions are high cost and risky, they will be pursued at less than optimal levels because their perceived payoff is discounted disproportionately to their actual probability of success. This should be compensated for by giving an added incentive (that is, increasing the total payoff) to pursue these expensive, risky inventions.

C. Biotechnology: An Industry That Should Be Developed

The economic needs of the biotechnology industry due to expense, risk, and cultural needs, however, do not answer the more fundamental question of whether biotechnology is an industry that should be encouraged. This argument is two pronged: technological and economic.

The field of biotechnology offers society extremely important technological advances. Medically, biotechnology promises treatment and prevention of previously incurable and inevitable disease. Biotechnology also makes possible early detection and genetic screening. Moreover, even in areas where traditional medicine has made great advances, biotechnology shows great promise. For instance, while the advent of antibiotics made a tremendous difference in society’s health, now antibiotic resistant bacteria are threatening this medical mainstay. Biotechnology is attacking this problem in ways impossible with traditional techniques.\(^{28}\) Agriculturally, biotechnology has the potential of increasing food production, limiting the need for fertilizers and pesticides that harm the environment, and increasing the quality of products that reach the market.

Economically, biotechnology also offers important advantages to the United States. In the words of one commentator: “the spectacular innovations in recombinant DNA technology introduced in the early 1970s, and subsequently refined beyond all expectations, have transformed molecular biology into one of the ‘high-tech’ fields that supposedly presage the future economic and professional base of Western society.”\(^{29}\) Biotechnology offers high wage jobs and, currently, American biotechnology enjoys a distinct advantage in the worldwide market because virtually all the major discoveries have been made here, and the American post-graduate educational system is regarded as producing some of the finest molecular biologists. In order to retain this economic advantage, the United States should give extra incentives to the industry in order to keep up with the policies in other parts of the world that support biotechnology.

\(^{28}\) See Lawrence M. Fisher, Biotech Counterattack on Resistant Bacteria; Small Companies Leading in Research, N.Y. TIMES, Apr. 26, 1996, at C1.

\(^{29}\) NATALIE ANGIER, NATURAL OBSESSIONS 28-29 (1988).
In conclusion, our system should be revised to give biotechnology companies an extra push. The necessary culture of the industry, combined with risk averse, investment strategies have led to less than optimal innovation. This innovation is socially desirable for both equitable and economic reasons.

III. PATENT POLICY SHOULD BE CHANGED TO ENCOURAGE THE BIOTECHNOLOGY INDUSTRY

The standard industrial policy mechanisms are direct subsidization and regulatory relief. Direct subsidization of the biotechnology industry, while perhaps appealing as a transparent, controllable method for supporting the industry, is not the best choice. First, it is indiscriminate. Direct subsidies are to industries, rather than to individual inventions that would otherwise not be pursued at the desired levels. Second, in today’s fiscal climate, direct subsidization is politically unlikely. Third, direct subsidization of other industries has not worked well in the past. In fact, there is no reliable model in American politics for how to make subsidization work.

Regulatory relief is equally problematic. Part III of this article will review the agencies that currently regulate the biotechnology industry in the public health and safety arena. It will then discuss how a modification of the patent system, rather than regulatory relief in the classic sense of the term, would best meet the needs of the industry.

A. Possible Sources for a Biotechnology Policy: Current Regulation of the Industry

The biotechnology industry is currently regulated by at least eight administrative agencies with overlapping and sometimes conflicting authority. The Biotechnology Research Subcommittee (BRS) of the interagency Committee of Health and Life Sciences, established in 1990, coordinates the regulation of biotechnology by the Food and Drug Administration (FDA), National Institutes of Health (NIH), United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), National Science Foundation (NSF), and Occupational Safety and Health Administration (OSHA). The BRS replaced the Biotechnology Science Coordinating Committee (BSCC), established in 1986, and has similar responsibilities to the BSCC. This paper refers to both committees collectively as the BRS.


31. See Karen Goldman Herman, Issues in the Regulation of Bioengineered Food, 7 HIGH TECH. L.J. 107, 120 (1992). The BRS replaced the Biotechnology Science Coordinating Committee (BSCC), established in 1986, and has similar responsibilities to the BSCC. Id. This paper refers to both committees collectively as the BRS.
Safety and Health Administration (OSHA). Any regulatory relief for the biotechnology industry would have to be coordinated and approved by the BRS. The U.S. Patent and Trademark Office (PTO) also regulates the biotechnology industry, but is not coordinated by the BRS.

The BRS is responsible for effecting the "Coordinated Framework for the Regulation of Biotechnology" (coordinated framework), which was a statement of federal biotechnology regulation policy promulgated by the Office of Science and Technology Policy in 1986. Under the coordinated framework, existing agencies regulate biotechnological products. Products are regulated according to type, and if a product has aspects that bring it under the regulatory umbrella of more than one agency, the BRS designates a lead agency. For instance, a tomato plant genetically engineered to create its own pesticide could be regulated as a pesticide by the EPA, a plant by the USDA, or a food product by the FDA.

The FDA's regulatory purpose is to ensure the safety and efficacy of drugs and the safety of foods. As an agency, the FDA is a potential candidate for the implementation of regulatory relief because certain types of drugs receive special treatment under the Food, Drug and Cosmetic Act. For instance, under intense pressure by the AIDS lobby, the FDA has devised special, expedited examination procedures and special experimental use provisions for drugs for the treatment of AIDS. These procedures apply to a lesser extent to drugs for the treatment of other immediately life-threatening diseases. Also, so called "orphan drugs" that treat diseases affecting fewer than 20,000 people have special protections.

These types of regulatory relief, however, are unlikely to be extended to biotechnological drugs as a general class. The policies behind the expedited procedures for AIDS drugs do not apply to drugs that treat diseases from which people are not dying in the pre-approval interim. Furthermore, diseases that affect larger numbers of people do not need extra incentives to induce the development of treatments. Finally, given the FDA's administrative purpose of ensuring that drugs are safe and

32. See Cuttler, supra note 30, at 204. OSHA's regulatory power over biotechnology is only incident to its regulatory power over all industry, so it will not be discussed in this paper.
33. See Herman, supra note 31, at 119.
34. See id.
35. See id.
36. See id. at 121. This is a hypothetical example, so the BRS has not designated a lead agency.
effective, it is unlikely that biotechnological products will be given any special regulatory relief.38

Likewise, the other agencies regulating the biotechnology industry are not in a viable position to grant the industry regulatory relief. OSHA's goals are too tangential to the purposes of the industry; the USDA and EPA have regulatory purposes too important to compromise through regulatory relief (safety of the food supply and protection of the environment, respectively); the NIH and NSF are primarily research and research funding agencies that already support most of the academic molecular biology research underpinning the entire industry. For these, and other reasons, an extended discussion of which are beyond the scope of this paper, standard regulatory relief for the industry is not advisable. Instead, this paper advocates the use of patent policy to give an additional incentive to biotechnology research and investment.

B. An Argument for the Use of Patent Law

Patent law is unique among the administrative schemes regulating biotechnology in that it has a constitutional basis. The Constitution states that Congress shall have the 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." 39 It is also unique because, as the constitutional language reflects, the regulatory system is designed to promote the progress of science, rather than protect public health and safety. This underlying purpose makes patent law an ideal forum for the institution of a policy to give incentives to the biotechnology industry. Rather than subsidizing the industry or giving regulatory relief, a "fine tuning" of the patent scheme for the industry is squarely within political grasp.

Patents are granted for two reasons: to give an incentive to innovators to invent, and to get innovators to disclose their technological findings.40 The disclosure goal has been characterized as a contract

38. One exception to this may be user fees. The FDA has recently restructured their fee system so that the agency can depend on user fees to fund itself to a greater extent. This has resulted in much higher user fees. Biotechnology companies, generally small and with limited funding, may be able to lobby for reduced user fees for companies below a particular size. This type of relief would not, however, be limited to biotechnology companies.


between the inventor and society. Society grants a 20-year monopoly to the inventor in exchange for the inventor's disclosure of how to practice the invention. This information is included in the patent application, which becomes publicly available as soon as the patent is granted. Thus, when the patent expires, others can use the information in the patent for society's benefit. Background information, the use of which does not infringe the patent, can be used to society's benefit even during the patent term. The incentive goal has as its premise that certain socially desirable inventions will not be pursued unless the inventor is given an extra economic incentive. The patent monopoly is this incentive. According to then Chairman of the House of Representatives Subcommittee on Intellectual Property, William J. Hughes, "[p]atent law is a powerful economic incentive that can actually determine the amount of capital investment and research activity that occurs within a particular area."

Patent law is a particularly appropriate vehicle for a biotechnology policy because patents are extremely important to the industry. Like other pharmaceutical industries, the real risk in biotechnology is that what appears to be a promising product will not actually work well enough to be approved by the FDA and become commercially successful. This result occurs because pharmaceuticals deal with complex biological systems that are not completely understood. Also like other pharmaceuticals, biotechnological products, once perfected and shown to be commercially viable, are easy to copy. Thus, there is a real danger that without patent protection an inventor's return on her investment in a risky endeavor will be siphoned off by copyists. Because of this, the pharmaceutical industry, including biotechnology, is one of the few industries that literally could not survive without patent protection.

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42. Actually, patent rights are not quite a monopoly. A patent gives the patent-holder the right to prevent others from making, using, selling or importing the patented invention. It does not give the patent holder an affirmative right to practice the invention. Thus, although a drug may be patented, it must still be licensed by the FDA before it can be marketed. A patent also does not obligate the patentee to make, use, or sell the invention, nor does it obligate the patentee to license the invention. See Miller & Davis, supra note 40, at 12-14.
43. See Merges, supra note 41, at 513.
44. Hearing, supra note 2 (opening statement of William J. Hughes).
46. See id. at 244-45.
47. See Levin et al., Appropriating the Returns from Industrial Research and Development, 1987 Brookings Papers Econ. Activity 783.
Patent policy changes are the proper strategy for encouraging the biotechnology industry for three main reasons. First, the goals of the patent system (to encourage innovation and disclosure) are not undermined by supplying additional incentive to the biotechnology industry. Second, the patent system is set up as an economic incentive, which means it can easily address the economic needs of the industry. Third, because patents are demonstrably critical to the industry as it now stands, a change in patent law will readily be recognized as good for the industry and thus elicit quick and positive responses.

IV. THE NONOBVIOUSNESS REQUIREMENT SHOULD BE USED TO CHANGE PATENT POLICY

The administrative scheme for granting patent rights requires that an invention be new, useful, and nonobvious patentable subject matter. Part IV introduces this scheme and argues that the nonobviousness requirement should be changed in order to increase biotechnology innovation.

A. Basic Patent Law

The basic requirement for patenting an invention that falls within patentable subject matter is that the invention be new, useful, and nonobvious. Patentable subject matter includes processes, machines, manufactures, compositions of matter, and improvements of any of these.48 These categories have been judicially interpreted so that laws of nature, mental processes, intellectual concepts, ideas, natural phenomena, mathematical formulae, methods of calculation, fundamental truths, original causes, and motives are not patentable subject matter.49 The novelty requirement provides that any invention known, used, published, or patented domestically, or patented or published abroad is unpatentable.50 The utility criterion, set out in 35 U.S.C. § 101, requires only that an invention be "useful." This requirement has been interpreted to mean that an invention must actually do something that the inventor has shown, not that he or she merely suspects, and that the invention actually does what it purports to do.51 The first utility requirement would render unpatentable, for instance, a machine with moving parts that merely spins around without serving any purpose (although to amuse or to entertain is considered a valid purpose for patentability inquiries).52

49. See In re Bergy, 596 F.2d 952 (C.C.P.A. 1979).
51. See Merges, supra note 41, at 147.
52. See id.
The second utility requirement would render unpatentable, for instance, a perpetual motion machine (which, under commonly accepted laws of physics, cannot do what it purports to do). The utility requirement is not typically a particularly onerous hurdle for a patentee to overcome. The non-obviousness requirement states that "if the differences between the [invention] and the prior art are such that the [invention] as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art" the invention is unpatentable. The non-obviousness requirement is typically thought to be the greatest hurdle to patentability and has been called "the ultimate condition of patentability."

B. The Administrative Scheme

The administrative scheme for patents follows a slightly different model from the typical regulatory agency. The Patent and Trademark Office grants patents. Agency employees called examiners examine patent applications and determine whether or not to grant patents based on the law briefly outlined above. Through a procedure called prosecution, the examiner and patent applicant carry on a written and sometimes oral discourse, arguing about patentability and amending the patent application. Ultimately, the examiner either grants the patent or issues a final rejection. However, there is little final, about a "final" rejection.

The applicant can appeal the examiner's decision to the Board of Patent Appeals and Interferences, which reviews the rejection. If the Board affirms the rejection, the applicant can appeal the rejection to the Court of Appeals for the Federal Circuit. The Federal Circuit is an Article III court, which was established in 1982. While its jurisdiction is not completely patent related, the main

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53. See id. at 148.
54. See id. at 147.
55. "[Prior art] ... includes any relevant knowledge, acts, descriptions and patents which pertain to, but predate, [the] invention in question." BLACK'S LAW DICTIONARY 828 (Abridged 6th ed. 1991).
57. See NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY (J. Witherspoon ed. 1980).
58. See MERGES, supra note 41, at 30-31.
59. See id. at 31.
60. See id. at 32.
61. See id.
62. See id. at 9.
reason for the creation of the court was to bring all patent questions to
the same appellate court. Previously patent decisions were appealed to
whatever circuit was geographically appropriate. Because patent law is
highly technical, both legally and scientifically, and because the Supreme
Court rarely hears patent questions, prior to the formation of the Federal
Circuit, there were many circuit splits in patent law and the doctrine was
muddled. Generally, the Federal Circuit is perceived to have
accomplished its mission of bringing coherence and consistency to patent
law. The court is also perceived to be quite pro-patent, in that it
generally upholds the patentability of the invention and the validity of
patents.

The Federal Circuit reviews the decision of the Board de novo for
questions of law, while factual findings are reviewed for clear error. If
the Federal Circuit upholds the Board’s decision to affirm the examiner’s
final rejection, the applicant does have recourse in the Supreme Court.
Because the Supreme Court so rarely grants certiorari to patent issues,
though, the Federal Circuit is generally regarded as the court of last resort
for patent questions.

If the examiner grants the patent and the patent issues, there is still
an opportunity for the validity of the patent to be challenged. The most
common forum for this is in an infringement action. Invalidity is an
absolute defense to patent infringement. While a patent carries a
presumption of validity, this presumption is rebuttable under a clear and
convincing evidence standard. Patent infringement actions can be brought
in any Federal District Court (there is exclusive federal jurisdiction for
patent law). Any appeals are to the Federal Circuit.

63. See id.
64. See id.
65. See id.
66. See id.
67. See In re Vacek, 947 F.2d 488, 493 (Fed. Cir. 1991); In re Woodruff, 919 F.2d 1575,
1577 (Fed. Cir. 1990).
68. Less common, but not rare, is a re-examination proceeding where a third party
challenges the validity of an issued patent outside of an infringement action. This is an
administrative proceeding that essentially seeks a declaratory judgment of invalidity. See
MERGES, supra note 41, at 32.
69. See id.
70. See id. at 9.
C. The Nonobviousness Requirement Should Be Used to Effect a Biotechnology Industrial Policy

1. NOVELTY AND PATENTABLE SUBJECT MATTER

A quick analysis of the requirements for patentability shows that the nonobviousness requirement has the greatest opportunity for changes to effect a policy to benefit the biotechnology industry. Despite continuing controversy over the ethics of patenting living things, it is clear that biotechnological inventions, including living subject matter, are patentable subject matter. Save for the remote possibility of congressional action prohibiting patents on biotechnological inventions, this is not likely to change. Likewise, because novelty is such a low threshold requirement, it too presents no real challenge to biotechnology inventions.

2. UTILITY

Utility is an area that has seen some interesting developments in biotechnology patents. The National Institutes of Health (NIH) attempted to patent a collection of gene sequences. The patent application was originally rejected for lack of utility. The subject matter of the application requires some explanation. Craig Venter, a scientist at NIH involved with the Human Genome Project, made a cDNA library of all the genes expressed in the human brain. In lay terms, he collected the information that codes for every cellular function in the brain. He then sequenced parts of each of these cDNAs. The utility rejection was based mostly on the fact that Venter did not know what any of the sequences did in the brain, and therefore the sequences lacked utility. Because of the nature of the experiment, though, he had parts of sequences for every gene used in brain function. Some, if not all, of the genes will eventually be found to be important for understanding the way the brain functions. Thus there is a definite argument that there is at least latent utility in the sequences.

71. Jeremy Rifkin of the Foundation on Economic Trends, along with others such as Dr. Michael W. Fox, have consistently opposed both the patenting of genetically engineered organisms, and the underlying genetic engineering itself. These oppositions are on ethical grounds, and focus on the profanation of all life when genes are manipulated. Rifkin’s views have been almost universally dismissed by the scientific community. See DR. MICHAEL W. FOX, SUPERPIGS AND WONDERCORN: THE BRAVE NEW WORLD OF BIOTECHNOLOGY ... AND WHERE IT ALL MAY LEAD 22-26 (1992).


73. The scope of patentable subject matter has always been a one-way ratchet. Once a subject matter is declared patentable, courts have not revisited the issue.
This utility question has not been judicially resolved. NIH has since withdrawn the patent applications on policy grounds. This does not mean, however, that the issue is a dead letter. Dr. Venter has left NIH and is continuing his work, including attempts at patenting gene sequences of unknown function, at an independent lab. Other inventors are also attempting to attain similar patents. Because PTO proceedings are closed, the resolution of this very interesting question about utility will have to wait until the issue finishes winding its way through the administrative process.

Aside from the fascinating open question regarding the utility of gene sequences of unknown function, most biotechnology inventions routinely clear the utility hurdle. According to the recent Federal Circuit opinion in *In re Brana*,74 and the Patent and Trademark Office's interpretive Utility Examination Guidelines,75 utility for a biotechnology invention can be shown by proof of clinical utility in humans or animals, or by *in vitro* testing. *In vitro* testing is the first step in determining whether a given drug has any biological activity. The court in *Brana* focused on the fact that it is the FDA's responsibility to determine safety and efficacy in humans; usefulness for patent purposes can be shown with much less rigorous data.76

The policies behind the utility requirement, and the economic implications of where the requirement is set, are quite interesting. The basic premise of the requirement is that society should not suffer the "embarrassment" of a monopoly unless society gets something in return. Unless an invention has some measure of usefulness, society has received nothing for its grant of patent rights. Pulling against this force for increasing the quantum of utility required for patentability is the patent policy of giving an incentive for innovation. The earlier in the research process patent rights are granted, the more of that process is protected, and the more likely it is that people will be enticed to innovate. There is a lower limit, however, to this incentive-driven pull for lower utility requirements. At some point, competitors will begin to engage in inefficient "racing" behaviors, where the goal becomes patent rights rather than quality inventions. This lower limit has arguably been reached in the biotechnology context. There is no lesser way to demonstrate biological activity than to do *in vitro* testing. Utility is a low hurdle for biotechnological inventions to overcome, and probably should not be further reduced for biotechnology inventions.

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74. 51 F.3d 1560 (Fed. Cir. 1995).
75. 60 Fed. Reg. 36263 (July 14, 1995).
76. 51 F.3d at 1568.
V. THE NONOBVIOUSNESS REQUIREMENT

A. The General Requirement of Nonobviousness

The basic nonobviousness inquiry was set out in *Graham v. John Deere Co.*77 The Court held that § 103 obviousness is a factual inquiry under which "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."78 Nonobviousness is then to be determined given these considerations.79 The test is focused on the unpredictability of the patentee's invention. The standard is whether a person of ordinary skill in the art, knowing all of the prior art, would have a reasonable expectation that the invention would work.80 If that person would have expected the invention to work, the invention is obvious and non-patentable.81

An invention can be deemed obvious if an inventor merely pieced together aspects from separate prior art references—there need not be a single reference that makes the invention obvious. However, there must have been a "suggestion" in the prior art to combine the prior art elements in the way in which they are combined in the patentee's invention.82 Furthermore, an invention will not be found obvious if it was merely obvious to try.83 Again, the standard is a reasonable expectation of success. If an invention is both obvious to try and a person skilled in the art would reasonably expect it to succeed at some level, the invention can nonetheless be found nonobvious if the invention works much better than expected.84 If the prior art suggests the combination of a number of variables, and parameters are given for each variable, a specific combination of variables can be found nonobvious.85 For this type of invention to be nonobvious, there cannot be a reasonable expectation of success for all possible combinations nor can there be a suggestion in the prior art to combine the variables in the way that the invention combines

78. Id. at 694.
79. See id.
80. See Loctite Corp. v. Ultraseal, 781 F.2d 861, 874 (Fed. Cir. 1985).
81. See id.
83. See, e.g., In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988); Merck & Co. v. Biocraft Labs., 874 F.2d 804, 807 (Fed. Cir. 1989).
84. See Novo Industri A/S v. Travenol Labs., 677 F.2d 1202, 1208 (7th Cir. 1982).
85. See In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988).
them. Instead, the test is again a reasonable expectation of success. As a whole, the "obvious to try" doctrine seems to be a particular application of the reasonable expectation of success standard.

This paper will next turn to the application of the nonobviousness requirement to biotechnological inventions. To give this discussion some context, a brief description of the technology, and the underlying molecular biology, is in order. This introduction is not meant to be comprehensive. Because of this simplicity, many of the exceptions to and nuances of general principles have been omitted from this discussion. Where it is scientifically and intellectually irresponsible to do this, the exceptions or nuances have been noted in footnotes.

**B. Overview of Molecular Biology and Biotechnology**

Biotechnology is used in three main ways. First, a biologically active molecule, such as an antibody or a peptide hormone, made naturally in small amounts in a given organism, can be produced in large quantities using bacteria. Second, an individual organism that is malfunctioning can be corrected by adding a correct copy of a malfunctioning gene (somatic gene therapy). Third, an entire line of organisms with a unique or corrected characteristic can be made by altering genes in reproductive cells (transgenic animals).

1. **BASICS**

There are three main classes of molecules important to biotechnology, each intimately related to the others: DNA, RNA, and proteins. DNA has been described as the "genetic blueprint" and every cell in an organism contains a complete copy of all the DNA that defines the organism. This complete copy of DNA is called the genome. Thus, each cell has a complete copy of the instructions necessary for the development, maintenance, and reproduction of the organism.

However, not all genes function in all cells. Those parts of the DNA that a nerve cell, for example, needs to function as a specialized cell, are "transcribed" into messenger RNA (mRNA) for subsequent translation by

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86. See Merck & Co. v. Biocraft Labs., 874 F.2d 804 (Fed. Cir. 1989).
90. See Wills, supra note 87, at 83.
cellular machinery into a protein. Thus, the mRNA present in a cell is a direct reflection of the genes that are functioning in that particular cell type. Because different genes function in different cell types, the spectrum of mRNA will vary from cell type to cell type. The proteins translated from mRNA are the workhorses of the cell. Although some protein, indeed the protein with which we are perhaps most familiar, is merely structural (for instance, the protein in hair or cartilage), by far the most important role for proteins is enzymatic. Enzymes are required for catalyzing every biochemical reaction that happens in every cell, in every organism. For instance, the protein DNA polymerase helps the cell to copy its DNA so the cell can divide.

2. WHAT CAN BIOTECHNOLOGY DO?

Lest this all seem hopelessly circular (DNA begot RNA; RNA begot protein; protein begot DNA ...), one must remember the myriad other tasks for cells that proteinaceous enzymes must catalyze: building the cellular machinery, respiring, metabolizing, breaking down of waste products, producing cellular secretions, and communicating with other cells. Biotechnology is the technology that uses the understanding of molecular biology to manipulate living organisms in any of these, or countless other functions.

For instance, biotechnology can be used to treat diseases that are caused by malfunction in any one of these cellular tasks. If DNA is damaged, the RNA does not carry the right information. The protein that is then made does not function properly. Malfunctioning proteins result in disease. Cancer is a breakdown in the regulation of cellular division. Cells, instead of dividing at just the rate required to replace dead cells, begin to divide uncontrollably into cancer cells. Lactose intolerance is due to a deficiency in lactase, which breaks down milk sugar. Some

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91. See id. at 20.
92. See ANGER, supra note 29, at 41
93. See id.
94. See GONICK AND WHEELIS, supra note 88, at 113.
95. See DAVID FREIFELDER, MOLECULAR BIOLOGY 224 (2d. ed. 1987).
96. See GONICK AND WHEELIS, supra note 88, at 113-14.
97. See ANGER, supra note 29, at 71.
98. See id.
99. See SUZUKI ET AL., supra note 24, at 595. Cancer cells are "dedifferentiated" cells, which are generic. They contrast with differentiated cells, such as lung cells, liver cells, skin cells, muscle cells. Cells differentiate very early in embryonic development. Dedifferentiation is a hallmark of cancer. Id.
genetic diseases, like SCIDs or lactose intolerance, are wholly inherited; others, like cancer, are often partly due to environmental factors damaging otherwise healthy DNA.

3. **HOW DOES BIOTECHNOLOGY DO IT?**

Biotechnology attacks these problems in several ways. The most straightforward way is to use another organism, usually bacteria, to make lots of whatever proteins people need. For instance, the first biotechnology company, Genentech, set out to treat diabetes. It was known that diabetics lacked the enzyme insulin and were therefore unable to metabolize sugar properly. The traditional treatment involved isolating insulin from bovine and porcine pancreases (available in large quantities from slaughterhouses), and injecting it into diabetics. Although this worked, and still works, reasonably well for most diabetics, because bovine and porcine insulin are slightly different from human insulin, some diabetics have allergic reactions. Clearly, the administration of human insulin would be superior. Just as clearly, for ethical reasons, you couldn’t isolate human insulin from human pancreases.

Genentech approached the problem via recombinant DNA technology. First, scientists isolated the gene (DNA) that codes for insulin. Then they took that gene and put it into a bacteria’s genome. By using special inducers of transcription, they were able to induce the bacteria to transcribe the insulin gene and translate it into insulin. The insulin could then be isolated and administered to diabetics. Given the

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100. Genetic diseases, like SCIDs or Tay-Sachs, can appear in children even when the parents are unaffected because every cell actually contains two complete copies of the genome, one inherited from each parent. Usually, one copy of a gene can make enough of a protein for the child to be healthy. It is only when a child in unlucky enough to inherit a bad gene from both parents that the disease will result. There are, however, some genetic diseases where only one bad copy is enough to result in disease. Huntington’s disease is a particularly insidious example of this. It is insidious because the disease does not manifest itself until a victim is in their 40s or 50s. People can therefore pass this debilitating disease onto their children without realizing it.


103. See id. at 90.

104. See id.

105. See id. at 91.

106. See id.

107. See id.
state of the knowledge and technology at the time, each of these steps was an amazing technical breakthrough.

4. CURRENT TECHNOLOGICAL CAPABILITIES OF BIOTECHNOLOGY

Given the great strides of the technology in the last few years, Genentech's amazing feat of the early 80s would now be almost trivial. Indeed, once certain scientific principles had been discovered, and technical problems solved, application of those technical solutions to new scientific problems was made theoretically obvious (although a certain amount, sometimes a great amount, of trial and error is required for any given problem to be solved). To understand what biotechnology is currently capable of, a few more facts about the interrelationships of DNA, mRNA, and protein are needed.

DNA is a double stranded molecule which looks like a ladder with each rung split in half. Each half-rung is "complementary" to its matching half-rung. Only one vertical half of the ladder carries protein coding information. RNA is a single stranded molecule complementary to the coding strand of DNA. Because of the relationship between DNA and mRNA, if you know the sequence of the DNA of a gene, the sequence of the mRNA can be deduced exactly. Conversely, knowing the sequence of the RNA allows you to deduce the sequence of the DNA exactly.

The relationship between mRNA (and, since it is informationally equivalent, DNA) and protein is more complicated. The ladder half-rungs of RNA are four different types of chemical bases. Protein is made from sequences of 20 different kinds of amino acids. Three consecutive DNA bases code for each amino acid in the sequence, providing 64 different possible codons for 20 amino acids. As a result of this "degeneracy" of the code (that is, that a given amino acid may have been coded for by one of several possible mRNA/DNA sequences of three bases), while one can deduce the protein amino acid sequence exactly from a given RNA or DNA sequence, for a given the protein sequence, there are many possible mRNA/DNA sequences. For instance, bovine insulin has 51 amino acids. Given an average of three possible base sequences for each amino acid, there are billions of possible DNA sequences.

This does not mean, however, that if only the protein sequence is known, the DNA/RNA sequence cannot be found. As little as a

108. See id. at 135.
109. See id. at 146.
110. See SUZUKI ET AL., supra note 24, at 286.
111. Specifically, $3^{51}$, or $2.2 \times 10^{24}$. 
sequence of DNA encoding a sequence of 6 amino acids will only be found once in the entire human genome. Using straightforward technology, every possible DNA combination that will code for that 6 amino acid sequence can be chemically synthesized. This is about 700 different 18-base DNA sequences. You can then use this collection of small pieces of DNA sequence as a kind of very specific molecular magnet to retrieve the rest of the gene. Only the one sequence that matches the actual genetic sequence in the organism will retrieve the full length gene, but all 700 sequences can be tried together in one experiment.

Thus, if one were trying to produce recombinant insulin, one could sequence a piece of the naturally-occurring insulin, synthesize a collection of all the possible DNA sequences of that piece, and use the collection of DNA sequences to retrieve the rest of the gene. You could even start with bovine insulin and use that to retrieve the human insulin gene because bovine and human insulin are very close to identical. You could then insert the human insulin gene into a bacteria and allow the bacteria to divide and make buckets of human insulin. Diabetics could inject this insulin with no fears of allergic reaction. This type of protein-production biotechnology is also used in non-medical applications. For instance, bovine somatotropin is produced by genetically engineered bacteria to be injected into cows to increase their milk production.112

Biotechnology is not limited to this type of protein manufacture. It can also be used in so-called "gene therapy." There are two types of gene therapy. For example, a diabetic’s problem is that his or her pancreas does not make insulin because the gene for insulin is partially missing or mutated. One type of gene therapy would attack the problem by changing the pancreas of the diabetic. A few pancreas cells could be removed and the correct insulin gene could be inserted into the cells. The cells could then be placed back into the patient’s pancreas, where they could divide and produce insulin.

While not being pursued currently in the medical context, a second type of gene therapy, "germ-line gene therapy," is being pursued in agricultural and environmental contexts. For instance, certain tomatoes on the market have themselves been genetically engineered to retard spoilage.113 Rather than genetically engineering each individual tomato, the gametes of a tomato were altered thereby, creating an entirely new line of genetically engineered plants. Research is being done to create plants that make their own pesticides: pesticides that cannot wash off and contaminate the environment, are resistant to plant viruses, and have increased nutritional value.114

112. See Herman, supra note 31, at 112.
113. The “Flavr-Savr” tomato, developed by Calgene in Davis, California.
114. See Herman, supra note 31, at 109-11.
C. The Current Nonobviousness Doctrine Applied to Biotechnology Inventions

In Part VI of this paper, a modification of the nonobviousness requirement for biotechnological inventions is proposed. As a backdrop to this proposal, a discussion of the current biotechnology nonobviousness doctrine is in order. This will give a basic doctrine upon which the modification will overlay, and which will serve as an example to demonstrate the superiority of the proposed modification over the current doctrine.

In re Deuel115 is the most recent pronouncement of the Federal Circuit with regard to the nonobviousness requirement for biotechnology inventions. The patent applicants (referred to here collectively as "Deuel") appealed to the Federal Circuit from a decision of the Board of Patent and Trademark Appeals and Interferences upholding a final rejection based on the examiner's finding of obviousness.116

The invention in Deuel is much like the description of the finding of the insulin gene discussed above. Deuel had purified a protein called heparin-binding growth factor from bovine uterine tissue.117 He was interested in this protein because it stimulates cell division and, thus, may be useful in facilitating the repair and replacement of damaged or diseased tissue.118 He figured out the sequence of amino acids for a small piece of the protein and then synthesized a collection of DNA fragments that represented all the possible DNA sequences for the heparin-binding growth factor.119 He then used this collection of DNA sequences to pull out the complete gene from a collection of all the genes transcribed in the bovine uterus.120 He also used the collection of short DNA sequences to isolate the human heparin-binding growth factor gene from a collection of genes transcribed in human placentas (recall that human and bovine genes are generally quite similar).121 He then sequenced both genes and deduced from the sequences what the complete protein amino acid sequences are.122 This last step may seem odd since he could have simply found the entire protein sequence from the isolated protein that he started

115. 51 F.3d 1552 (Fed. Cir. 1995).
116. Id. at 1552.
117. Id. at 1555.
118. Id. at 1554. Note that this activity is exactly the opposite of what one would be looking for to treat cancer, where there is uncontrolled cell division. Heparin-binding growth factor may thus also be interesting to cancer researchers.
119. Id. at 1555.
120. Id.
121. Id.
122. Id.
with. However, determining exact amino acid sequences is technically difficult and time consuming. In contrast, sequencing DNA is relatively straightforward. Also, recall that once a DNA sequence is known, deducing the protein sequence is trivial. Since Deuel was going to find the gene and sequence it anyway, it made much more sense to wait to find out the entire protein sequence.

Deuel claimed in his patent application the human and bovine DNA sequences, as well as the deduced amino acid sequences. The examiner issued a final rejection based on a finding that the invention was obvious. The rejection was based on the fact that a partial amino acid sequence for heparin-binding growth factor had previously been published. The examiner reasoned, and the Board agreed, that this published sequence, combined with the routine nature of finding the gene and complete protein sequence, rendered the invention obvious.

The issue confronted by the Federal Circuit 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, may render DNA ... molecules encoding the protein prima facie obvious under Section 103.” The focus of the inquiry was whether a holding of obviousness could only be supported by the actual physical structure of the DNA and protein being made obvious by the prior art or whether obvious methods of finding that structure are sufficient to support the holding of obviousness.

The court held that the claimed DNA and protein sequences were nonobvious. The reasoning was based primarily on analogizing molecular biological inventions to chemical inventions. In chemical cases, the teaching of a particular compound, combined with a suggestion to make a specific kind of change to that compound, renders the new compound obvious. The court noted that because the prior art partial

123. 51 F.3d at 1555. There was actually some dispute as to whether the published partial amino acid sequence was for heparin-binding growth factor or not. The published sequence was of a protein found in bovine brain (not uterus, as Deuel found here) and exhibiting similar properties to heparin-binding growth factor. The Federal Circuit assumed the proteins were the same for purposes of their discussion.

124. Id.

125. Id.

126. Id.

127. Id. at 1560.

128. See, e.g., In re Jones, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc) (“[s]tructural similarity between claimed and prior art subject matter, ... where the prior art gives reason or motivation to make the claimed compositions creates a prima facie case of obviousness”), cert. denied, 500 U.S. 904 (1991); In re Grabiak, 769 F.2d 727, 731-32 (Fed. Cir. 1985) (“[T]here
amino acid sequence was not a DNA sequence, it could not render the DNA sequence structure obvious. Furthermore, the court reasoned, because there were so many possible DNA sequences that could potentially code for the protein, a person of ordinary skill in the art could not have determined the DNA sequence without actually doing the experiment that Deuel did. The court stated, "[w]hat cannot be contemplated or conceived cannot be obvious."

The court rejected the argument that the genetic code relationship between DNA and proteins rendered the claimed compounds obvious. Citing In re Baird, the court stated that the disclosure of a "broad genus of compounds does not necessarily render obvious each [species] compound within its scope." In other words, the disclosure of the protein sequence, which could be used to deduce the billions of possible DNA sequences, does not render the particular DNA sequence actually found in the organism obvious. Importantly, the court did not reach the question whether the prior art disclosure of a small protein with a very limited number of possible DNA sequences would make each sequence obvious.

The court also rejected the argument that a person with ordinary skill in the art would, given the prior art, know how to make the claimed compounds. The court stated that, because it was compounds, and not the methods to make the compounds, that were being claimed, the fact that the methods were known was irrelevant. This was based on the decision in In re Bell.

must be adequate support in the prior art for the ester/thioester change in structure, in order to complete the PTO's prima facie case [of obviousness]."

129. Deuel, 51 F.3d at 1559.
130. Id.
131. Id.
132. Id.
133. 16 F.3d 380 (Fed. Cir. 1994). Baird dealt with a prior art reference that disclosed a general chemical formula with many variables in it. The applicant claimed a compound that was one of the more than 100 million different possible chemicals under the prior art reference. The court held that the applicant's compound was nonobvious because it worked well and the prior art reference made no suggestion that this particular compound would work well, or even at all.
134. Id.
135. Id. The court cited In re Petering, 301 F.2d 676 (C.C.P.A. 1962), where a prior art reference disclosing a genus with 20 species was held to render obvious each of the 20 species.
136. Deuel, 51 F.3d at 1559.
137. 991 F.2d 781, 785 (Fed. Cir. 1993).
In *Bell*, the court held that the prior art disclosure of the complete amino acid sequence of insulin-like growth factors I and II (IGF I and II), in combination with a prior art patent entitled “Method for Cloning Genes,” did not make the cloning of the IGF I and II genes obvious. The fact situation, however, was not entirely analogous to that in *Deuel*. The court discussed the vast numbers of possible DNA sequences and the lack of suggestion of the structure of the particular DNA sequence in the prior art. However, the court based its holding, at least in part, on the fact that the “Method for Cloning Genes” patent counseled the use of a short string of amino acids with unique DNA codes, thereby limiting the amount of degeneracy that needed to be addressed. In *Bell*, the actual amino acids used to construct the DNA probes did not have unique DNA sequences. The court stated that “we cannot say that [the patent] fairly suggests that its teachings should be combined with those of [the amino acid sequences], since it nowhere suggests how to apply its teachings to amino acid sequences without unique codons.”

Because the cloning method relied on by the PTO in *Deuel* did not depend on the use of the unique DNA sequences for amino acids, this reasoning from *Bell* does not apply to *Deuel*.

VI. A PROPOSED MODIFICATION OF THE NONOBVIOUSNESS REQUIREMENT WHICH WILL GIVE AN INCENTIVE TO THE BIOTECHNOLOGY INDUSTRY

A. The Proposal

The current test for nonobviousness is a test for technical nonobviousness. This paper proposes an additional test for economic nonobviousness. Under this test, an invention need only be technically or economically nonobvious to be patentable. To understand this distinction, imagine a proposed invention that has a 1% chance of becoming commercially successful (recall that under the traditional test for nonobviousness, the invention need only be technically successful, not commercially successful). Imagine further that it will take $5 million to research and develop this invention to the point where commercial viability is apparent. If the expected payoff is $501 million, the invention is efficient to pursue because expected payoff, discounted by the probability of success is less than the investment risked. However, because of additional discounting of the expected payoff due to the natural, rational risk aversion of a rational economic actor, this socially desirable invention will not be pursued. Thus, although it might be

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138. *Id.* at 783.

139. *Id.* at 784 (internal quotation marks omitted).
conceded that an invention is "obvious" in the sense that it is technically possible, an invention may be economically, or relatively, nonobvious because a rational economic actor would not pursue it.

Recognizing this type of economic nonobviousness does two things. First, it reflects the fact that inventions are not made in an economic vacuum. Technical nonobviousness gives inventors an incentive to go out on a technological limb; economic nonobviousness gives investors an incentive to go out on an economic limb. Given two possible inventions with the same expected return (projected return discounted by the chance of failure), investors are more likely to invest in the less risky invention. If the riskier invention is a socially desirable one, however, giving the extra incentive of greater ease in patent acquisition will shift investment toward that socially desirable invention. Second, assuming that expected payoff takes into account the normal chances of getting a patent on the invention, making the patent easier to get would increase the expected payoff. This increase results both because of the patent monopoly rights granted and because a patent can be an early property right that will discourage competition even before the invention is developed. Thus, the recognition of economic nonobviousness creates the needed additional incentive so that socially desirable inventions will be pursued.

Of course, this example assumes that the patent office can determine ex ante both the probability of commercial success and the potential commercial payoff. This assumption is patently false. What the example serves to illuminate is the existence of a class of inventions that would not be granted patents under the current doctrine of nonobviousness, but which should nonetheless be granted patents in a perfectly rational system. What is needed, then, is a proxy for determining which inventions are likely to fall into this class.

Because biotechnological inventions are expensive to pursue and have a high risk of ultimate commercial failure, the classification of an invention as biotechnological can serve as this proxy. While this will not address the issue of which inventions will ultimately prove to be commercially successful it will pick out those inventions which are likely to be under-pursued due to risk aversion.

In addition to specifying which inventions will receive special treatment, the type of special treatment needs to be defined. One alternative might be to determine nonobviousness based on actual, individual expense. For instance, an invention might be classified as economically nonobvious if it actually cost more than 150% of the average cost for the industry. This type of system is administratively intractable and fraught with opportunity for deception or manipulation.

140. See MERGES, supra note 41, at 418.
141. See Merges, supra note 20, at 1.
It would encourage inefficient spending to increase the possibility of patent protection and the “average” cost for the industry would spiral upward. Although this system may appear theoretically sound, practical considerations must prevail. Furthermore, this alternative does nothing to address the issue of an entire industry which is expensive and risky to pursue. A test based on actual numbers needs a baseline for comparison; the baseline in the biotechnology industry is too high to make this alternative workable.

Instead, I propose a definition of economic nonobviousness which is much closer in spirit to the current definition of technical nonobviousness. The test should be whether one skilled in the art, considering the cost and likelihood of commercial success, would have regarded the invention as an obvious one to pursue. This is a highly subjective test. Nonetheless, because it is modeled on the test for technical nonobviousness, judges, patent practitioners, inventors, and investors already have the requisite experience. Indeed, it would actually be easier to prove economic nonobviousness, because it lends itself to hard evidence much more easily than technical nonobviousness.

Precise definitions of economic nonobviousness aside, the mere existence of a label of economic nonobviousness will be helpful. Currently, it appears that when the PTO or Federal Circuit is faced with a technically obvious invention that the judges or examiners intuitively recognize should have patent protection (that is, they intuitively respond to the economic nonobviousness of the invention), they are forced to bend the technical nonobviousness doctrine to fit what they perceive to be the only just outcome. By giving the agency and the court a label for what they are doing, the practice can be legitimized and brought out so that it can be discussed without subterfuge.


The economic nonobviousness standard gives an extra incentive to biotechnological inventions. By acknowledging that there are types of inventions that deserve special patent treatment because they are particularly expensive or risky, it gives the needed incentive to overcome the risk aversion that is otherwise problematic in the industry. In doing so, it gives economic support to the industry as whole. The economic advantage of finding some inventions economically nonobvious will spill over to other inventions in the intellectual property portfolio.

Because this modification will support the industry as a whole, it is more likely that the biotechnology industry will be able to raise the funds it needs to maintain its academic laboratory model. Without this change, it is more likely that the current spate of mergers and acquisitions of
biotechnology companies will continue, thus undermining the otherwise preferable research model. As discussed above, the model of the financially and economically independent, focused, academic lab must be seen as vitally important to the continued successes in biotechnology. By granting patent rights to economically risky inventions, the economic nonobviousness doctrine allows small biotechnology companies to remain independent. Without this type of patent protection, it is more likely that this type of research would be forced into large conglomerates, where economic risk could be spread, but at the expense of the culture which has been responsible for so many successes.

The addition of the proposed doctrine of economic nonobviousness reflects the economic realities that are so important to the business of innovation. It also reflects the fact a person of ordinary skill in the art would take into account economic realities when deciding if a given invention had a reasonable expectation of success. The purpose of patents is to encourage innovation, and the recognition of the economics of innovation will facilitate this purpose. Ignoring economics is illogical and not mandated by the statute.

Also, the concept of economic nonobviousness is not inconsistent with the current doctrine of nonobviousness. For instance, section 103 states that an invention's nonobviousness “shall not be negatived by the manner in which the invention was made.”142 This sentence was included in order to abolish the “flash of genius” test previously used in judicial determinations of nonobviousness.143 That is, “brute force” or trial and error inventions can be nonobvious. This language tacitly allows economic factors to be considered. Currently this language is used only to support inventions which could have been made through a flash of genius, but happened to have been made through hard work. Nonetheless, it is not inconsistent to say that trial and error invention that one of ordinary skill in the art would not have done (for technical or economic reasons), is not “negatived by the manner in which [it] was made.”144 The secondary considerations of commercial success, failure of others, and long-felt need also import some economic considerations to the traditional nonobviousness test.

The economic nonobviousness doctrine also compensates for some unfairness to biotechnology inherent in the traditional nonobviousness test. The “ordinary skill in the art” of biotechnology is very high because of the high degree of education required even to be a technician in the field. Because the nonobviousness of an invention is determined with

reference to the technical skill of "one of ordinary skill in the art," this makes a legitimate finding of nonobviousness quite difficult. By incorporating the real-life economic concerns of "one of ordinary skill in the art," the doctrine of economic nonobviousness compensates for the difficulty in finding technical nonobviousness in a field of high ordinary skill.

Another major advantage of the proposed economic nonobviousness requirement is that the implementation is politically feasible. Such a policy theoretically could be implemented in one of three ways: through examiner guidelines issued by the PTO after notice and comment, through judicial interpretation, or through congressional action. Because the proposed modification would constitute a real change in the law, and because the PTO issued examiner guidelines are not technically rulemaking and thus do not have the force of law, it is probably inappropriate for this modification to be implemented by the PTO. However, either of the other two possible methods of implementation is not only proper, but possible.

The Federal Circuit is a patent policy making body. As discussed earlier, there is generally little oversight by the Supreme Court. Consequently, any doctrinal changes made by the Federal Circuit are unlikely to be overruled. Since the use of economic nonobviousness is justifiable logically and legally, it is entirely possible that the Federal Circuit could choose to implement it. Moreover, the Federal Circuit has shown a willingness to make doctrinal changes in the nonobviousness area. For instance, the Supreme Court, in Graham v. John Deere Co., mentioned that "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others" might have "relevancy" to the question of nonobviousness. The Federal Circuit has drastically increased the importance of secondary considerations or objective indicia. In Hybritech, Inc. v. Monoclonal Antibodies, Inc., the court stated that secondary considerations "must be considered before a conclusion on obviousness is reached." Congressional action in this area is also possible. Congress' willingness to carve out special considerations for particular industries is evidenced by the recent amendments to the nonobviousness statute with regard to biotechnology inventions. Under the amendment, signed into law in November, 1995, an otherwise obvious biotechnological process

146. Id. at 17-18.
148. Id. at 1379.
will be considered nonobvious if it uses or results in a product that is nonobvious. 149

Between these two implementation strategies, judicial implementation is preferable. There are several arguments for this type of implementation. First, the Federal Circuit knows more about patent law and is therefore likely to make better decisions about it than Congress. Second, a judicially created doctrine can more easily change over time because it does not need to worry about political majorities. Consequently, the doctrine can evolve with the needs of the industry. Third, the Federal Circuit's current approach to nonobviousness is actually quite similar to the modification proposed here. Economic considerations are being made sub rosa; they should be made explicitly.

By any honest interpretation of the nonobviousness statute, the decisions in Deuel 150 and Bell 151 are wrong. Given the sequence, or partial sequence of a protein, along with known molecular cloning techniques, any person of ordinary skill in the art would reasonably expect to have success in cloning the gene that encodes the protein. Granted, there may be technical difficulties, but given infinite time and financial resources, which the traditional technical nonobviousness test appears to give, one would expect eventually to find the gene.

The court's focus on the fact that a particular structural product is claimed is misplaced. While comparing structures of simple organic compounds in chemical cases makes some sense scientifically, it makes no sense to draw this distinction in biotechnological cases, because DNA and proteins are informationally related. The court's focus on the different chemical structure of the two molecules is akin to saying an English translation of a French book is nonobvious.

The method/product distinction is also insupportable. It ignores the scientific reality that method and product are intimately related. It is disingenuous to say that a person of ordinary skill in the art could not take a known starting product, and apply a known method to create a new product. The distinction drawn by the court very much raises form over function. Furthermore, it encourages manipulative claiming in order to avoid a finding of obviousness. Because methods and products are functionally related, virtually any product can be claimed as a method and vice versa. The court's distinction gives a perverse incentive for inventions to be claimed in non-straightforward ways.

It is also possible that, after the economic nonobviousness doctrine has been developed judicially, it could be legislatively ratified. This is what happened with the current doctrine of nonobviousness. The Patent

150. 51 F.3d 1552 (Fed. Cir. 1995).
151. 991 F.2d 781 (Fed. Cir. 1993).
Act prior to 1952 required only that an invention be novel and useful. The requirement of nonobviousness was judicially created. The doctrine was tied to the statutory language by the argument that if obvious, there was no true “invention.” After over a century of judicial evolution, the requirement of nonobviousness was added in the Patent Act of 1952.

VI. SUMMARY

Biotechnology offers great promise to the health and welfare of the American people, as well as great promise to the American economy. It creates high wage jobs and enjoys a huge trade surplus. Perhaps more importantly, it offers tangible, non-economic advantages. Disease treatment and prevention, and more efficient production of more nutritious food with limited environmental impact are made possible by biotechnology.

However, as the realities of technical difficulties and economic limitations have become apparent, the promise of biotechnology has moved further from our reach. In response to the needs of the industry for a culture that encourages innovation and research and development funds for expensive and risky invention, the patent law should be changed to give certain biotechnology inventions an easier time of getting a patent.

By creating a judicial doctrine of economic nonobviousness for biotechnological inventions, the needs of the industry can be met without sacrificing health and safety regulation or burdening the public fisc. The proposed doctrine is logically sound, consistent with patent policy, and implementation is feasible.
