An Economic Analysis of Biotechnology Patent Protection

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The emergence of biotechnology, the science of creating new organisms with useful and commercially viable applications, has thrown traditional conceptions of patent law into turmoil. In *Diamond v. Chakrabarty*, the United States Supreme Court broadened the concept of patent protection to include inventions derived from biological advances, holding that genetically altered living microorganisms constituted patentable subject matter. This marriage of biotechnological inventions and patent law is not a happy one. Biotechnology distinguishes itself from the traditional mechanical and chemical arts that undergird patent law doctrines. Self-replicating biotechnological inventions pose unique problems, not only because the product duplicates itself for competitors as well as for consumers, but because the concept of patenting a living creature cuts against patent law's mechanically based norms. Moreover, the puzzle of distinguishing the man-made from the natural challenges the definitions that both patent doctrine and traditional science impose on the resulting organisms.

As more biotechnological inventions mature into marketable products,
commercial conflicts over the problem of defining such products in traditional terms have increased. Courts, however, have consistently applied traditional patent doctrines to resolve biotechnology infringement suits. The courts’ decisions in these cases have intensified the debate on whether patent law adequately protects biotechnology patents so as to encourage growth and research in the biotechnology industry.

The most important issue in this debate is determining the patent’s proper scope. Under U.S. law, a patent guarantees the holder a monopoly in the product for seventeen years. The economic power a patent confers depends on its scope. The broader the scope, the wider the market within which the patent holder can exercise monopoly power. Broader scope confers power to exclude a greater range of competing products and processes from the market. Since scope determines the extent to which the patent holder may exclusively exploit or improve products and processes, scope determination decisively impacts the progress of biotechnology.

Two recent cases, *Scripps Clinic & Research Foundation v. Genentech, Inc.* and *Genentech, Inc. v. Wellcome Foundation, Ltd.*, illustrate the conflicting interests involved in determining biotechnology patent scope. The
Scripps court found that a patent teaching how to isolate and extract a protein from natural products is infringed when other researchers construct the same protein using DNA recombinant techniques. The Wellcome court held that a second generation recombinant protein with many improvements over the first generation protein infringed the patent on the first generation protein. Both courts gave strong protection to the patented inventions. In so doing, however, they may have dampened incentives for others to create recombinant products and to make improvements on existing products.

Commentators disagree as to whether courts in such cases have given biotechnology inventions the proper degree of protection. However, much of the debate thus far has focused on whether courts either failed to apply or erroneously applied the traditional patent doctrines. This approach to the question of proper scope is incomplete, and perhaps misguided. Patent awards derive from the notion that patent monopoly promotes technological advancement. This Note explores that notion by examining the economic incentives created by different scope “sizes” through four economic theories about how patents promote technological advancement. Within this framework, the Note inquires whether traditional patent law should apply to the unique features of biotechnology. This Note does not argue for a blanket rule dictating the proper patent scope, because scope determination depends heavily on the facts of each case and the language of each patent. Nonetheless, the Note seeks to reveal important factors for scope determination, factors that create economic incentives aligned with promoting progress in biotechnology.

Part I of the Note defines patent scope and explains its significance for technological progress. Part II examines biotechnology’s unique features and then clarifies the interests at stake when courts determine the scope of a biotechnology patent. Finally, Part III introduces four economic theories and analyzes how courts’ decisions pursuant to these theories may promote progress in biotechnology.

I. THE ECONOMIC SIGNIFICANCE OF PATENT SCOPE

A. Defining Scope

The scope of a patent is the range of products or processes for which the patent holder has the right to “exclude others from making, using, or selling the invention.” Patent claims measure and define scope.15 Claim interpre-

12. “Teaching” is a term of art in patent law. A patent “teaches” the information or knowledge that it discloses.
tation is a question of law. To determine the proper scope of a claim, a court must consider the language of the claim not in isolation, but rather in the context of the patent reference as a whole. Courts must refer to the specification disclosures, both for the meaning of particular terms used by the claim and for an understanding of the invention actually patented. The Supreme Court outlined this relationship between the specification and the claim:

While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention.

The patent holder's exclusive right to exploit products or processes within the scope of his patent grants him economic power. If the patent holder believes others are exploiting products or processes within the scope of his patent, he may sue for infringement. Courts analyze infringement in three steps. First, courts examine the claims, as described above, to ascertain the scope of a patent. "Literal" infringement results if the alleged infringing matter falls within the scope of the claims as properly construed. Even if an accused product or process does not literally infringe the claim, it may still infringe under the "doctrine of equivalents." Under this judicially created doctrine, a product or process, though it does not fall within the literal language of the patent claims, may infringe if it "performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result

16. A patent has two required parts: specification and claims. The specification contains a discussion of the invention's background, a summary of the invention, and a detailed description of at least one embodiment of the invention. The embodiment must be described in sufficient detail "to enable any person skilled in the art to which [the invention] pertains . . . to make and use [the invention]." 35 U.S.C. § 112 (1988). Claims usually encompass much more than this, but they must describe only what is new, without including anything that is already in the public domain. Id.


18. A patent reference includes the specification, prosecution history, and other claims in the same patent. Moeller v. Ionetics, Inc., 794 F.2d 653, 656 (Fed. Cir. 1986). Prosecution history is the record kept by the Patent and Trademark Office which includes the initial patent application, all official actions mailed by the Patent Examiner, all responses made by the patent applicant, modifications of the initial patent application, and the final version of the patent allowed by the Examiner. IVER P. COOPER, 1 BIOTECHNOLOGY AND THE LAW § 5A.05, at 5A-19 (1991).


23. See, e.g., Hughes Aircraft Co. v. United States, 717 F.2d 1551, 1561 (Fed. Cir. 1983). Courts use this doctrine to try to make an equitable delineation of patent scope. In effect, courts will ignore the letter of a broad patent claim or read greater breadth into a narrowly drafted patent claim in order to achieve a just result. Ellen P. Winner, Enablement in Rapidly Developing Arts - Biotechnology, 70 J. PAT. & TRADEMARK OFF. SOC'Y 608, 631 (1988).
as the claimed invention." However, this doctrine cuts both ways. Under the "reverse" doctrine of equivalents, even if an accused product or process "falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement." This happens if the accused product or process is "so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way."

Patent scope defines the extent to which the patent holder can exclude other inventors from exploring and exploiting variations or improvements of the patented invention. While courts should not necessarily limit a claim to the embodiments disclosed by the specification, the degree to which the scope should extend beyond the disclosed embodiments is uncertain. For guidance on this question courts turn to a complex body of traditional patent doctrines concerning claim interpretation and infringement.

B. Economic Implications of Scope Determination

What defines proper patent scope depends on the goals of the patent system. The Constitution mandates "securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries," in order "[t]o promote the Progress of Science and useful Arts." Pursuant to this grant of power, Congress enacts patent legislation for the specific purpose of promoting scientific progress. To implement this goal, Congress and the courts award monopolies to inventors who, in return, must explain their inventions in their patent applications. Thus, in theory, a patent confers a monopoly for a limited time in exchange for an inventor's public disclosure that ensures—again, in theory—widespread diffusion of benefits once the patent expires.

Determining the scope of a patent's monopoly power is a special case of property rights allocation, a general problem that concerns the distribution of rights in property among parties in order to promote the most efficient use of that property. In the context of patents, the property in question is the opportunity to appropriate returns and make improvements on inventions within the scope

25. SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1123 (Fed. Cir. 1985) (en bane) ("The law also acknowledges that one may only appear to have appropriated the patented contribution, when a product precisely described in a patent claim is in fact 'so far changed in principle' that it performs in a 'substantially different way' and is not therefore an appropriation (reverse doctrine of equivalents).") (emphasis omitted).
27. Id. at 608.
28. And yet, "the legal principles and objective evidence often leave considerable room for discretion" to the courts. Merges & Nelson, supra note 9, at 841.
of the patent. Imagine dividing the entire field of biotechnology among a number of inventors. Each patent would allocate to each patentee a segment of the field within which to make, use, or sell improvements. The Coasian theory of property allocation suggests that parties will bargain to a Pareto-superior solution no matter how entitlements are initially assigned. Therefore, the "size" of the rights should affect only the individual parties’ personal gain, not the overall efficiency of the allocation in benefiting society.³⁰ In the patent context, the Coasian theory implies that the scope of patents has no impact upon technological and scientific progress.

However, empirical studies of the Coasian theory have shown that the initial distribution of property rights can alter the bargaining parties’ equilibrium level of output.³¹ A substantial literature documents the steep transaction costs of technology licensing.³² In addition, indirect evidence suggests that the transfer of major improvements increases these costs.³³ Such studies demonstrate that the size of patent scope affects development in biotechnology.

Economic literature has not focused on how patent scope affects technological advances, with the exception of an article by Robert P. Merges and Richard R. Nelson entitled On the Complex Economics of Patent Scope.³⁴ Through the use of historical studies, the authors contend that the courts’ grant of broad patent scope to important inventions has slowed progress in several industries.³⁵ The authors encourage the courts to exercise their discretion to narrow patent scope whenever the traditional patent doctrines so allow.³⁶ In addition, the authors find that patent scope affects progress in each industry differently depending upon the nature of the technology involved, the manner in which technical

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³¹ See ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 105 n.15 (1988); Mark Kelman, Consumption Theory, Production Theory, and Ideology in the Coase Theorem, 52 S. Cal. L. Rev. 669 (1979); Merges & Nelson, supra note 9, at 884-909 (tracing history of technological development in various industries and demonstrating effect of patent scope on the development of those industries).

³² See, e.g., FAROK J. CONTRACTOR, INTERNATIONAL TECHNOLOGY LICENSING: COMPENSATION, COSTS, AND NEGOTIATION 104-05 (1981) (calculating the transaction costs in licensing deals studied); DAVID J. TEECE, THE MULTINATIONAL CORPORATION AND THE RESOURCE COST OF INTERNATIONAL TECHNOLOGY TRANSFER 44 (1976) (indicating that transfer costs constitute over 19% of total project costs in international projects studied).

³³ Transaction costs such as possible opportunistic behavior are described in David Teece, Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy, 15 Res. Pol'y 285, 294 (1986).


³⁵ Merges & Nelson, supra note 9, at 897.

³⁶ Id. at 841, 843-44 ("[T]he legal principles and objective evidence often leave considerable room for discretion. . . . [T]he law should attempt at the margin to favor a competitive environment for improvements, rather than an environment dominated by the pioneer firm.").
advances in the industry relate to each other, and the extent to which firms license technologies to each other.37

II. THE STAKE IN DISPUTES OVER BIOTECHNOLOGY PATENT SCOPE

Two recent cases, Scripps Clinic & Research Foundation v. Genentech, Inc.38 and Genentech, Inc. v. Wellcome Foundation Ltd.,39 illustrate the conflicting interests involved when courts determine the scope of a patent in a biotechnology infringement suit. Because the unique nature of biotechnological science complicates legal determinations of biotechnology patent scope, this Part surveys the history and certain techniques of biotechnology before considering the interests at stake in biotechnology patent cases.

A. The History of Biotechnology

Biotechnology is the science of manipulating and modifying the genetic make-up of living matter. Although humans have employed microorganisms for thousands of years in brewing and baking, and have manipulated genetic material through selective breeding of plants and livestock, only in the last twenty-five years have humans managed to manipulate and alter biological matter at the cellular and molecular levels. In 1973, Professors Stanley N. Cohen and Herbert W. Boyer invented the basic technique for creating recombinant DNA.40 They demonstrated how to cut a gene from the DNA of one organism,42 recombine it in vitro with DNA of a host organism,43 and re-introduce44 the recombinant gene into the cells of the host organism to confer the gene’s characteristic trait on the host organism.45 Insulin, the earliest achievement of

37. Id. at 843.
40. See Stanley N. Cohen et al., Construction of Biologically Functional Bacterial Plasmids In Vitro, 70 PROC. NAT’L ACAD. SCI. USA 3240 (1973).
41. DNA guides cellular synthesis of proteins. See, e.g., JAMES D. WATSON ET AL., RECOMBINANT DNA: A SHORT COURSE 1 (1983). DNA is an enormous, long molecule comprised of subunits called nucleotides. Certain sections of DNA, called genes, contain the “blueprint” for proteins encoded in their nucleotide sequence. There is a correspondence between DNA nucleotide sequence and protein amino acid sequences: the order of nucleotides in each gene corresponds to the amino acid sequences of a particular protein. Id. at 32-33.
42. Special proteins called restriction enzymes that recognize certain sequences in DNA cut the DNA strand at appropriate points. Id. at 61.
43. Enzymes called ligase reconnect severed DNA strands. Id. at 65.
44. This process is accomplished by way of a vector, which is a DNA molecule that can be moved between cells and is functional in different cells. Common types of vectors are plasmids (circular pieces of DNA often exchanged by bacteria) and viruses.
recombinant DNA technology, derives naturally from human pancreas cells, cells that cannot be cultured. Until the advent of recombinant technology, diabetics received insulin extracted from the pancreas of a cow or a pig. Using recombinant DNA technology, a biotechnician cuts the insulin gene from human DNA, splices it into a plasmid and introduces the altered plasmid into a microbe to create a microbe capable of manufacturing insulin. Through this process, scientists can now culture insulin-producing microbes cheaply and efficiently on a large scale.

Other early successes of recombinant technology include several types of interferon for the treatment of cancer and leukemia, human growth hormones for the treatment of pituitary dwarfs, tissue plasminogen activators—natural proteolytic enzymes—used for the dissolution of blood clots, and hepatitis B sub-unit vaccine. Recombinant DNA technology can reduce the production cost and increase the supply of many materials now used in medicine, agriculture, and industry.

B. Inventing a Recombinant Protein

A research project typically begins with the discovery that a particular protein performs some desirable function. To understand how this protein functions, scientists must extract the desired protein from a natural source. Isolating the gene that expresses this protein and placing that gene in a suitable environment enables the production of the protein in large quantities. The process of extraction and purification can prove technically difficult, making the decision to research recombinant techniques contingent on the availability of large quantities of the protein from natural resources.

The process of recombinant DNA protein production involves a high degree of randomness at several stages. First, isolating the desired protein in sufficient quantities and purity from a mixture containing vast numbers of protein remains extremely complicated. Second, and more importantly, the search for the human gene that expresses the desired protein begins by using a complementary

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46. Insulin is a human hormone that coordinates the activities of individual cells and tissues in order to maintain the correct amount of sugar in the bloodstream. Some types of diabetes can be treated by supplying patients with extra insulin. See, e.g., Kent M. van de Graaff, Human Anatomy 426-27 (2d ed. 1988).

47. A plasmid is a circular DNA molecule that replicates in a host cell, independent of the host cell's genes.


50. Proteins are long, folded chains of chemical subunits called amino acids.

51. Office of Technology Assessment, supra note 49, at 119-36 (illustrating scientific and commercial developments of several protein products).
construct, chosen somewhat at random, to probe a DNA library. The probe may be a DNA fragment from another animal species or a synthetic construct from the amino acid sequence of the naturally-derived protein. The process becomes complex because a given amino acid may correspond to two or more different DNA codons. Synthetically constructing all of the possible gene variations that encode for a specified amino acid sequence can thus be a formidable job. Using a probe to isolate a specific gene compares unfavorably to searching for a needle in a haystack. Because of the variety and complexity of the DNA in living cells, isolating a single gene requires isolating a specific sequence of hundreds or thousands of nucleotides from among several billion.

With a gene isolated through this process, the researcher may explore ways to modify the codon sequence to produce a protein with one or more variations in its amino acid structure. These new proteins, known as "second generation," contain variations that may enhance potency, resistance to degradation, or other desirable qualities. Variations in the physical shape of each protein allow it to interact selectively with complementary surfaces of other molecules, meshing much like gears in a machine, to perform various cellular functions. This physical shape derives from the sequence of amino acids in the protein chain.

With present techniques, however, the physical configuration of a protein remains unpredictable even when the entire amino acid sequence of the protein is known. Nonetheless, one can analyze the probability that a protein's amino acid sequence forms a particular configuration. For example, homologous sequences function similarly more often than do unrelated sequences. However, a single amino acid change at a critical locus can dramatically alter the shape of the protein, nullifying the protein's original function or creating an entirely new function. Because this relationship between structure and function remains unpredictable, creating an improved second generation protein may be as daunting a task as producing the first generation recombinant protein.

52. A "DNA library" is a genomic library containing a complete set of human genes.
53. Each nucleotide contains a phosphate group linked to a sugar molecule, which in turn, is linked to one of the following chemicals called "nucleotide bases": adenine (A), thymine (T), guanine (G), or cytosine (C). A cell's protein synthesis machinery "reads" the sequence of nucleotide bases in groups of three, called "codons." Each codon corresponds to an amino acid, and more than one codon may correspond to the same amino acid.
54. JAMES WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE 86-88 (4th ed. 1987). The difficulty of identifying and isolating the gene for a desired protein results from the complexity of the natural environment in which genes and proteins are found; DNA in each human cell consists of a total of about 3 billion nucleotide base pairs, organized into 100,000 or more individual genes. See generally WATSON ET AL., supra note 41.
56. BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 97-100 (2d ed. 1989); Klaus Kaluza et al., Oligonucleotide-directed Mutagenesis of the Rhizobium japonicum nifH Promotor, 188 FED'N OF EUR. BIOCHEM. SOC'Y LETTERS 37, 41 (1985); Van Brunt, supra note 55, at 655.
57. Homologous sequences have identical mutations or genes in a genetic map and are identical in their visible structure.
58. See, e.g., Van Brunt, supra note 55, at 656-61.
Adding to the randomness and consequent risky nature of the biotechnological invention process, the basic research involved in isolating, characterizing, and expressing particular genes consumes huge amounts of time and money. Moreover, the industrial scale-up for manufacture of biotechnological products poses formidable obstacles to reproducing a laboratory's precisely controlled environment on a factory floor. Such technical obstacles have increased development times and costs for most biotechnological products. Technical and financial impediments combine with stringent regulatory requirements to demand an average of $240 million and more than ten years to bring a recombinant product to market.

C. Proteins Isolated from Natural Sources Versus Those Made with Recombinant Technology

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, Scripps charged Genentech with infringement of its patent on Factor VIII:C, a protein that activates the blood clotting mechanism. The lawsuit underscored the problems faced by an industry built around innovative and economical methods of producing naturally-occurring substances. Scripps purified Factor VIII:C using conventional chemical methods and obtained a patent for the products of, and a process for purifying and concentrating, Factor VIII:C from human and porcine blood plasma. The Scripps patent included both product and product-by-process claims.

60. *Id.*
61. *Id.*; see also *OFFICE OF TECHNOLOGY ASSESSMENT, supra* note 49, at 13-14, 323-24 (finding government funding of biotechnology insufficient to support rapid commercialization).
64. *Id.*
65. *Id.* at 1385.
66. The product claims alleged to have been infringed by Genentech were Claim 24: "A human VIII:C preparation having a potency in the range of 134 to 1172 units per ml. and being substantially free of VIII:RP"; and Claim 25: "A human VIII:C preparation of claim 24, wherein the VIII:C concentration is at least 160,000 fold purified relative to VIII:C in plasma." *Id.*
67. *Id.* A product-by-process claim is one in which a product is claimed by the process of making it, in contrast to a product claim, in which a product is claimed by its characteristics, such as its composition, purity, function or structure. The product-by-process claim asserted to be infringed by Genentech was Claim 13: "Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1." *Id.* Claim 1 as incorporated by reference in Claim 13 stated:

1. An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of
Although Genentech manufactured its Factor VIII:C by recombinant techniques, Genentech was accused of infringement on both the product and product-by-process claims. The recombinant process avoided using human plasma pools that may contain infectious agents such as HIV-1, the etiologic agent of AIDS. In addition, the recombinant process produced Factor VIII:C in higher purity and made large-scale production feasible. The issue was whether a patent claim obtained on the basis of isolating and purifying the natural protein was infringed when the same protein was produced by recombinant means.

Addressing the allegation of infringement of the product claims, Genentech argued that it had not infringed for two reasons: (1) the asserted product claims must be interpreted to apply solely to Factor VIII:C derived directly from human blood plasma, and (2) since the preferred embodiment described in the specification disclosed a process for filtering Factor VIII:C from human or porcine plasma, the court should read this limitation into the claims. The trial court refused to limit Scripps’ claims to VIII:C from human plasma and to the process Scripps taught in the patent. Instead, the trial court focused on the fact that recombinant Factor VIII:C is structurally and functionally the same as Scripps’ plasma-derived Factor VIII:C. The trial court granted summary judgment on the ground that the recombinant product infringed the product claims.

On appeal, the Federal Circuit likewise refused to construe the product claims to include the inherent process limitation. As a matter of literal construction, the recombinant product was not excluded from Scripps’ product claims. Genentech raised the defense that the recombinant product was so far changed in principle that it did not infringe Scripps’ product claims by virtue of

(a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,
(b) eluting the VIII:C,
(c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,
(d) eluting the adsorbed VIII:C, and
(e) recovering highly purified and concentrated VIII:C.

Id.

68. Genentech scientists sequenced the protein, cloned the Factor VIII:C gene, cloned the cDNA by encoding the actual coding sequence, expressed the DNA in a mammalian cell system, and devised a protein purification process. Id. at 1384.
69. The proceedings also involved several other issues including patent validity, infringement, inducement to infringe, and reissue law and practice. The present discussion focuses on the courts’ analysis relating to patent scope.
71. Id. at 1389.
72. Id. at 1389-94.
73. Id. at 1394.
74. Id. at 1395.
76. Id. at 1580.
of the "reverse doctrine of equivalents." The court found that Genentech's theory of reverse doctrine of equivalents raised contested issues of fact that precluded summary judgment. Explaining that the doctrine exists "to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention," the court reasoned that "[t]he principles of patent law must be applied in accordance with the statutory purpose, and the issues raised by new technologies require considered analysis." The court found the trial court's grant of summary judgment inappropriate because "Genentech ha[d] raised questions of scientific and evidentiary fact material to the issue of infringement."  

Some commentators criticized the Federal Circuit court's approach in Scripps. One argued that case law has established that a patent claim to an ordinary chemical compound is infringed even if the alleged infringer makes the chemical in a purity superior to that achieved using the process described in the patent. 80 This commentator found troubling the court's apparent attempt to put biotechnology inventions into a special category: "[I]t is questionable whether the same result would have been reached if the invention had been one of conventional chemistry and, if it would not, whether the decision reflects a sound distinction between those technologies." 81

With regard to the product-by-process claims, the trial court refused to grant summary judgment, reasoning that since Genentech did not practice the recited process, there could be no infringement. 82 The Federal Circuit disagreed with that analysis, finding that the scope of the product-by-process claims was not limited to products prepared by the process set forth in the claims. 83 No authority was cited for that proposition. The Federal Circuit made no comment on the applicability of the Supreme Court decision in Cochrane v. Badische Anilin & Soda Fabrik, 84 which the trial court cited in support of its conclusion that "[a] product-by-process claim is infringed only by a product produced by following the same process described in the claim." 85

The Scripps decision has a major impact on the scope of patent rights obtainable by inventors who isolate proteins from natural sources vis-à-vis those who make the same protein by recombinant technology. The decision reflects two antagonistic results, creating possible process-related exceptions to infringement of a product claim that, on its face, makes no reference to any

77. Id. For a discussion of the "reverse doctrine of equivalents," see supra notes 25-27 and accompanying text.
78. Id. at 1581.
79. Id.
80. Baechtold et. al, supra note 13, at 171.
81. Id.
84. 111 U.S. 293 (1884).
process parameters, while reading process limitations out of a claim that expressly recites them.

D. Genentech: First Generation Invention Versus Second Generation Invention

In *Genentech, Inc. v. Wellcome Foundation, Ltd.,* the court determined the scope of two Genentech patents. One patent described a method to isolate and purify tissue-type plasminogen activator (t-PA) from cultured human melanoma cells and included a claim to the resulting purified t-PA. The second patent described the use of genetic engineering techniques to produce recombinant t-PA. The t-PA holds the promise of dissolving blood clots in heart attack victims without causing widespread bleeding in the patient. Native human t-PA is a 527 amino acid glycosylated protein divided into five domains, each with a different function. Genentech charged that two Wellcome products infringed Genentech's patents: met-type t-PA, which differs from t-PA only in a substitution of a different amino acid at position 245 of the t-PA protein; and a variant of t-PA, known as FE1X, in which the amino acids in two of the five domains have been deleted. Because of the deletion of these two domains, FE1X has less affinity for fibrin than native t-PA. In contrast to t-PA, which has a half-life of four minutes in the blood stream, FE1X has a half-life of forty-two minutes. FE1X's longer half-life reduces the dosage required for effective treatment.

The critical issue for determining the scope of Genentech's patents was the meaning of "human plasminogen activator" in the patents. At one extreme, it could be deemed to refer to a protein having the exact same amino acid

87. U.S. Patent No. 4,752,603 (June 21, 1988). Claim 1 of the patent is as follows:
   Human plasminogen activator, having thrombolytic properties, immunologically distinct from
   urokinase and having a specific activity of about 500,000 IU/mg. using the WHO First
   International Reference Preparation of t-PA (tissue plasminogen activator) as assay standard or
   a specific activity of about 90,000 IU/mg. using the WHO First International Reference Preparation
   of urokinase as assay standard.
88. U.S. Patent No. 4,766,075 (Aug. 3, 1988) describes genetic engineering techniques to produce a
   recombinant t-PA product. The chief claims were 1, 3, and 8:
   1. A DNA isolate consisting essentially of DNA sequence encoding human tissue plasminogen
      activator; . . .
   3. A recombinant expression vector containing a DNA sequence encoding human tissue
      plasminogen activator, wherein the vector is capable of expressing human tissue plasminogen
      activator in a transformed microorganism or cell culture; and . . .
   8. A cell culture capable of expressing human tissue plasminogen activator, obtained by
      transforming a mammalian cell line with a vector according to claim 3.
89. Plasminogen activator, t-PA, works by converting plasminogen into its active form, plasmin. Plasmin
    then dissolves fibrin, which is the major component of blood clots. Unlike nonspecific plasminogen activators,
    t-PA binds to fibrin and hence avoids the problem that the nonspecific activators have in activating
    plasminogen throughout the blood stream, causing systemic degradation of blood proteins and internal
    bleeding. Arthur Klausner, Researchers Probe Second-Generation t-PA, 4 BIO/TECH. 706, 708 (1986); Mark
90. This yields a two-fold benefit of "possibly cutting manufacturing costs" as well as "reducing the
    potential for serious side-effects such as cranial bleeding." Ratner, supra note 89, at 385.
sequence, glycosylation, and conformation as native t-PA. On the other hand, it could be read to cover proteins having one or more biochemical activities characteristic of t-PA, with less regard for structural similarity.

The Delaware federal district court construed the term "human plasminogen activator" restrictively and concluded that "human plasminogen activator" could only refer to the defined human t-PA or a naturally occurring variant. The term obviously could be read more broadly. The court held that neither met-type t-PA nor the second generation variant, FE1X, was human t-PA or a naturally occurring variant and therefore there had been no literal infringement.

However, the court took a liberal interpretation of claim scope under the doctrine of equivalents analysis. Patent infringement "may be found (but not necessarily) if an accused device performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result as the claimed invention." Both variants of t-PA convert plasminogen into plasmin, the enzyme that breaks down fibrin clots formed in blood vessels. Wellcome argued that the single substitution of an amino acid in met-type t-PA altered the secondary and tertiary protein structure, resulting in greater vulnerability to proteolytic inactivation and a decrease in thermal stability. Wellcome also contended that FE1X could not be equivalent to the native t-PA since it does not work in the same way. FE1X had been designed by removing two domains and therefore bound only weakly to fibrin. In contrast, Genentech had promoted the strong fibrin-binding properties of its product. FE1X is also different in that it is administered as a one-time bolus injection, rather than the three-hour infusion required for t-PA. Despite these functional differences, the court decided that any distinction between the patented t-PA and the accused variant "hinges on the means of producing the cleavage of plasminogen to plasmin." The court labelled this distinction a material issue of fact to be decided by the jury, which returned a verdict against Wellcome on the issue of equivalents.

92. COOPER, supra note 18, § 5A.0616, at 5A-40.
94. A single amino acid change in a protein at a critical locus can nullify the function of the protein, or can result in creating a new function. Scientists do not yet know enough about biological activities to predict such changes. Margaret M. Wall & Justin Dituri, The En Banc Rehearing of In re Dillon: Policy Considerations and Implications For Patent Prosecution, 68 DENV. U. L. REV. 261, 272 (1991) ("[R]elative unpredictability in some aspects of biotechnology is due to the fact that small variations in structure may or may not result in significant changes in biological function.") (citation omitted).
95. Ratner, supra note 89, at 385.
96. Id.
98. t-PA Variants Are Equivalent to Genentech's Patented t-PA, 39 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 977, at 503 (April 19, 1990). This decision ended Wellcome's six-year research effort to improve t-PA. Ratner, supra note 89, at 387 ("The anti-competitive effect of such a verdict, therefore, is worrisome.").
In the equivalents analysis, the court's focus on the "means" by which the two products cleave plasminogen shows a lack of understanding of biotechnological science. The court's focus on "means" poses two problems. First, application of the doctrine of equivalents is straightforward when the relationship between structure and function is well defined, as in most mechanical devices, or when the chemical equivalents can be understood through well-accepted principles of reaction mechanism or physical properties. However, the structure-function relationships in biotechnology are not well understood. Second, it is very difficult to demonstrate to the trier of fact exactly how the biotechnological inventions function, because they occur within complex processes in living things and involve mechanisms about which we understand very little. In the face of these difficulties, the trier of fact may reduce the test of equivalents to a mere examination of observable end results produced by the accused embodiment. Here the court's decision reduced the comparison of the two products to the fact that "they both cleave plasminogen to plasmin."

III. ECONOMIC ANALYSIS OF INCENTIVES AND PATENT SCOPE

Having explored the nature of biotechnological science and the courts' analysis of disputes both between recombinant and natural protein manufacturers and between first and second generation recombinant technology producers in Part II, this Note now expands on Part I's discussion of the effect of patent scope on progress in biotechnology. This Part examines in detail four economic theories explaining how patents promote technological progress: the incentive-to-invent theory, the incentive-to-disclose theory, the incentive-to-innovate theory, and the prospect theory.

A. Incentive-to-Invent Theory

The incentive-to-invent theory recognizes that an inventor demands compensation for his investment in research and development. Absent government subsidies or awards, an inventor makes a profit on his invention in the market. However, these profits disappear if free-riders can quickly copy the invention. Competition drives prices down to marginal cost, at which point the inventor recovers manufacturing costs but receives no return for his original

99. See supra notes 56-58 and accompanying text.
investment in research and development.\textsuperscript{101} As a result, if competition prevents the inventor from recouping his investment, his incentive to invent vanishes.\textsuperscript{102} Lack of protection from such competition may significantly delay socially beneficial inventions, or prevent them entirely.

The incentive-to-invent theory holds that patent protection, by providing the inventor an exclusive right to make, use, and sell his invention,\textsuperscript{103} insulates the inventor from competition. The inventor can charge a monopoly price to recover his research and development investment. This price reflects the value to the invention’s users rather than the mere cost of production.\textsuperscript{104}

Several economists challenge the incentive-to-invent theory. First, the theory rests on the dubious assumption that the invention would not exist but for the efforts of the inventor who patented it. If another inventor might have produced the invention, a grant of monopoly power to the first inventor may be inappropriate.\textsuperscript{105}

Second, subjecting new inventions to monopoly control restricts their use and thereby reduces the social benefits they provide. Granting patent monopolies to restrict output or to raise prices may prove unnecessary for stimulating invention. Alternative incentives to invest in research, such as the first-mover advantage\textsuperscript{106} and competition with technological rivals, may be sufficient.\textsuperscript{107} Similarly, nonpatent barriers to market entry may deter competition sufficiently to make research and development profitable without patents.\textsuperscript{108}

Finally, some writers have argued that patents hinder progress because they may undermine the incentive of other researchers to make improvements in the patented technology.\textsuperscript{109} Once an invention is patented, only the patent holder and his licensees can profit from the research that refines the invention; the absence of patent protection would allow competitors the chance to profit as well and therefore stimulate them to research for improvements of the patented invention. Patents not only deter competitors from researching improvements

\textsuperscript{101} Research and development costs include the costs of inventing the product or process, of enabling commercialization by large scale manufacturing, of gaining FDA approval, and of modifying the product or process to satisfy consumer taste.


\textsuperscript{104} Baxter, supra note 102, at 270.

\textsuperscript{105} See, e.g., BOWMAN, supra note 100, at 17. Some commentators argue that inventions arise inevitably with or without patents when the state of basic knowledge and other social conditions become favorable. S. C. GILFILAN, THE SOCIOLOGY OF INVENTIONS 71-78 (1935).

\textsuperscript{106} SCHERER, supra note 102, at 444-45.

\textsuperscript{107} Id. at 445-46.

\textsuperscript{108} See, e.g., id. at 446-47. Examples of nonpatent barriers include production facilities, managerial experience, and distribution channels. Id. at 447.

\textsuperscript{109} See, e.g., id. at 452. For example, James Watt, owner of the steam engine patent, saw little value in high-pressure engines. Watts denied researchers who were interested in developing the high-pressure engine access to his steam engine technology, which was essential to the new research. This hindrance may have delayed the introduction of steam locomotives and steamboats. Id.
1. Implications for Patent Scope

Under the incentive-to-invent theory, patents permit inventors to reap returns on their inventions sufficient to recover investment in research and development. To reach this goal, patent scope must be broad enough to recompense the cost of invention. On the other hand, patent scope should not extend further than necessary to accomplish this objective, because patents restrict distribution of the invention and reduce incentives for others to make improvements. Broad patent scope therefore reduces the social benefits of patented inventions. If, as the critics assert, alternative incentives to invent remain despite the absence of patent rewards, or if nonpatent barriers provide sufficient protection to the inventor in the market, efficiency dictates narrower patent scopes.

2. Alternative Incentives to Invent in Biotechnology

One common alternative to patent protection, the race for scientific discovery, often motivates inventors. Government, special interest groups, and industry fund academics engaged in research. These financial supports free academics from the need to justify their inventions on a profit basis. However, the spheres of discovery for academic and industrial researchers rarely overlap. In contrast to industrial research, directed toward practicality and marketability, academic research typically seeks solely the expansion of human knowledge.

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110. Donald F. Turner, The Patent System and Competitive Policy, 44 N.Y.U. L. REV. 450, 455 (1969). However, judicial opinions often view the incentive to invent around patents as a positive benefit of the patent system because this incentive stimulates further research. See, e.g., Yarway Corp. v. Eur-Control USA, Inc., 775 F.2d 268, 277 (Fed. Cir. 1985). Some commentators likewise argue that inventing around patents is not necessarily socially wasteful if the research leads to the development of superior products or processes. Bowman, supra note 100, at 21-22.

111. Scope determination demands accommodating the desires of two parties: the inventor and society. The inventor will invent if the profits from his invention equal or exceed the costs. Society will grant patent protection to an invention equal to or less than the value society attributes to the invention. If the invention's value to society falls short of the cost of inventing, granting the patent makes no economic sense.


113. See Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1017-18 (1989) (discussing distinction between basic and applied research); see generally Eric Von Hippel, THE SOURCES OF INNOVATION 133-207 (1988) (providing comprehensive account of basic research and commercialization of inventions in different fields). For example, in 1975, publicly funded researchers invented the technology to fuse a cancer cell with antibody-producing cells to create a hybrid that conserves not only the capacity to secrete a particular type of antibody but also the immortal character of cancerous cells. See Michael MacKenzie et al., The Commercial Application of a Scientific Discovery: The Case of the Hybridoma Technique, 17 RES. POL’Y 155 (1988). Although the inventors noted the commercial and industrial potential of their discovery, they neither patented their invention nor polished it for commercial use. Id. at 155 n.1. Biotechnology companies did not explore commercial
Nonetheless, the distinction between results or products of basic and applied research is blurred in biotechnology. Modern techniques in biotechnology have "accelerated the commercial development of basic research discoveries and attracted commercial interest in academic biomedical research in its early stages." Biotechnology firms and academia have formed hundreds of strategic alliances. Although basic research conducted in universities can never completely substitute for industrial inventions, narrowing patent scope for biotechnology makes sense, because alternatives to financial reward may be sufficient to stimulate inventions.

3. Nonpatent Barriers to Ensure Recovery of Research and Development Cost

Critics of the incentive-to-invent theory also argue for narrowing patent scopes if inventors can otherwise capture sufficient market share to recoup their research and development costs. Typical nonpatent means of appropriation include head start, trade secrets, sales, and service efforts. Although these factors present strong nonpatent barriers to market entry in some industries, biotechnology cannot rely on these nonpatent barriers alone. Thus far, recombinant technology chiefly produces proteins with medical value. Trade secrets do not protect these products, because commercial exploitation necessarily discloses the product's composition. A competitor can easily discover the amino acid sequence of the protein since large quantities of the pure product are now available for detailed inspection and analysis. This accessibility eases competitors' effort to copy or improve the invention.

Likewise, head start and sales and service efforts are unreliable nonpatent barriers in the biotechnology industry. Typically, the inventor can secure a significant head start by preparing its production facilities, leading to early production and development of marketing channels. However, the head start advantage is not very significant in the biotechnology industry because biotechnology scale-up operations are relatively small, requiring little capital investment. The large number of small biotechnology firms demonstrates that

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development of the hybridoma technique until the early 1980's. See id. at 162-68.
114. Eisenberg, supra note 113, at 1018; see also MacKenzie, supra note 113, at 169.
117. Id.
118. See supra note 51 and accompanying text.
119. Trade secrets have proven effective only with regard to product innovation that incorporates various technological barriers to analysis or with regard to process innovations that can be hidden from public view. VON HIPPEL, supra note 113, at 54; see also Wall & Dituri, supra note 94, at 274 (1991) ("[M]any biotechnology inventions cannot be adequately protected as trade secrets.").
start-up costs do not pose a significant barrier to market entry. Advertising, sales and service efforts are often undertaken to develop consumer familiarity and goodwill, both of which increase producers’ market shares. However, consumer familiarity and goodwill hold less sway over the consumers of biotechnology, who are a few sophisticated research institutes and medical specialists who select products on the basis of technical knowledge rather than familiarity alone.

4. Summary

The incentive-to-invent theory suggests that in order both to stimulate inventive activities and to minimize the undesirable output-restricting effect of patents, patent scope should be just broad enough to allow the inventor to recover the cost of the inventions. Since nonprofit, academic research contributes significantly to inventions in the field, biotechnology patent scope can be further narrowed. However, biotechnology patents should not be narrowed simply on the assumption that inventors have nonpatent means to ensure their ability to appropriate a return.

While the incentive-to-invent theory illuminates the general discussion on biotechnology patent scope, it gives no guidance to the question of patent scope from an alleged infringer’s perspective. This theory has little to offer in resolving the issues that Scripps and Genentech present, that is, whether a patent on a protein isolated from natural sources should cover the same protein made by recombinant technology, and whether a patent on a recombinant protein should protect variations and improvements of that protein.

B. Incentive-to-Disclose Theory

The incentive-to-disclose theory holds that, without patent protection, inventors would conceal their inventions in order to prevent exploitation by competitors. Concealment deprives the public of a full range of benefits: wider distribution, alternative uses and price-cutting competition for the market. Secrecy can also lead to waste to the extent that competitors duplicate

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120. As of June 1990, there were more than 300 biotechnology companies. Of these, 185 were publicly traded, representing a market capital of $7 to 8 billion. Role of Patents in Biotechnology is the Focus of Two Conferences, 40 Pat. Trademark & Copyright J. (BNA) No. 987, at 211 (June 28, 1990).


123. SCHERER, supra note 102, at 440; BOWMAN, supra note 100, at 12-13.
research.\textsuperscript{124} This theory contains several potential flaws, because patents may not necessarily promote disclosure of inventions that would otherwise remain secret.\textsuperscript{125} First, secrecy may not be a viable option. Secrecy can prove impractical for protecting inventions,\textsuperscript{126} as competitors can eventually uncover secret technologies through reverse engineering.\textsuperscript{127} Moreover, were long-term secrecy possible, inventors would eschew the patent's limited, seventeen-year protection. Critics also question whether patent disclosures inform the public sufficiently to disperse this new knowledge.\textsuperscript{128} Such criticisms undermine the proposition that patents promote disclosure through rewards to inventors.

Despite these criticisms, patents create legal rights that permit disclosure, enabling sales negotiations or licensing of the patented product or technology.\textsuperscript{129} Secrecy complicates the sale or licensing of inventions for commercial development or marketing, because potential purchasers will not pay for an idea without first understanding the invention. Yet, after disclosure, without a legal right in the invention, the inventor has nothing left to sell. The patent system solves this problem by permitting inventors to disclose their patented inventions to potential users without losing their exclusive rights. The patent holder may sue unauthorized users for infringement.\textsuperscript{130} Patents thus discourage secrecy and wasteful duplicative research while increasing the public's access to valuable information.

1. Implications for Patent Scope

The incentive-to-disclose theory suggests that the scope of a patent should cover the range of products or processes the public could make relying on the information the patent discloses. That is, patent scope should cover not only the disclosed invention, but also variations one skilled in the art could make given the teaching. This interpretation finds direct and concrete support in statutes and doctrines of patent scope. To begin with, Congress requires patents to describe the embodiment in sufficient detail to enable any person skilled in the art to make and use the invention\textsuperscript{131} without undue experimentation.\textsuperscript{132}

\begin{thebibliography}{99}
\bibitem{125} See, e.g., Scherer, supra note 102, at 441.
\bibitem{126} Bowman, supra note 100, at 13.
\bibitem{127} Arnold Plant, \textit{The Economic Theory Concerning Patents for Inventions}, 1 ECONOMICA 30, 44 (1934). On a lower technology level, departing employees may simply steal the technology or sell their knowledge to competitors. Scherer, supra note 102, at 441.
\bibitem{128} William D. Nordhaus, \textit{Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change} 89 (1969) ("It is well known that a firm tries not to disclose key parts of the invention in order to reduce the chance of imitation, thereby reducing the effective diffusion of knowledge.").
\bibitem{129} Arrow, supra note 100, at 615.
\bibitem{131} 35 U.S.C. § 112 (1988) requires the patentee to provide an enabling disclosure: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any
\end{thebibliography}
In addition, courts must interpret the claims in the context of the "specification, the prosecution history, and the other claims." The specification, in particular, guides courts both as to the meaning of the particular terms the claims use and in understanding the invention itself. Furthermore, courts require the scope of enablement to match the scope of the claims. That is, courts ask whether "the scope of enablement provided to one of ordinary skill in the art by the disclosure [in the patent] is such as to be commensurate with the scope of protection sought by the claims."

For example, courts generally grant narrower scope to chemical patents than to mechanical patents. Adjustments to mechanical inventions produce predictable consequences. Conversely, a chemical patent’s specification teaches little about how varying the chemical’s structure or reactive conditions would alter its effects. To explain the less expansive protection they accord chemical arts, courts reason that the breadth of claims a patent’s disclosure supports "varies inversely with the degree of unpredictability of the factors involved."

2. Applying the Theory to Biotechnology

Many biotechnology patents have earned Patent and Trademark Office approval despite the limited disclosure supporting their broad claims. Examples include claims to any DNA sequence that codes for a certain protein when only one such sequence is disclosed, claims for certain proteins and analogs thereof with certain biological activity when only a few analogs are disclosed, person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...
and claims to DNA expression in all organisms when expression in a single host alone is disclosed.\textsuperscript{141}

Courts and scientists agree that variations on biotechnological inventions yield unpredictable results.\textsuperscript{142} Therefore, the enablement theory supports narrowing claims to only those products or processes discoverable within the limited circle of predictability that the state of biotechnological research permits.

3. Application of the Incentive-to-Disclose Theory to Scripps and Genentech

The incentive-to-disclose theory contradicts the holdings of both \textit{Scripps} and \textit{Genentech}. In \textit{Scripps}, the court found that Scripps' patent teaching extraction and isolation of the Factor VIII:C protein was infringed by Genentech's recombinant protein.\textsuperscript{143} First, the court refused to limit Scripps' patent for protein Factor VIII:C to proteins isolated from blood plasma, although the patent's products claim did not teach those skilled in the art how to make the same protein by recombinant methods. Second, the court refused to limit Scripps' product-by-process claims to proteins derived by the conventional isolation and extraction method.\textsuperscript{144} The \textit{Scripps} court's ruling contradicts the incentive-to-disclose theory's justification for patents. That theory holds that patent scope of a protein made with conventional methods should not be extended to include the recombinant protein, since the patent on the conventional protein in no way teaches one skilled in the art to make the recombinant protein.

The \textit{Genentech} court's approach also conflicts with the incentive-to-disclose theory. In \textit{Genentech}, the court invited the jury to examine whether the doctrine of equivalents protected claims of the t-PA protein against alleged infringement by an improved version of the protein, FE1X. However, the court focused on the means by which the two proteins cleave plasminogen into plasmin. This focus on the means through which the two proteins function is inconsistent with the incentive-to-disclose theory's emphasis on what the invention actually teaches and enables those skilled in the art to produce.

\textsuperscript{141} See Lentz, supra note 140, for examples of such claims as they appear in biotechnology patents.
\textsuperscript{142} See, e.g., \textit{Ex parte} Forman, 230 U.S.P.Q. (BNA) 546, 548 (Bd. Pat. App. & Int'l 1986) ("[E]xperiments in genetic engineering produce, at best, unpredictable results."); \textit{Ex parte} Old, 229 U.S.P.Q. 196, 200 (Bd. Pat. App. & Int'l 1985); see also supra notes 56-58 and accompanying text; C. T. Taylor & Z. A. Silverston, \textit{The Economic Impact of the Patent System: A Study of the British Experience} 252 (1973) ("[U]npredictability \[of the behavior of chemicals in the human body\] is of a much higher order than that found in non-biological areas of chemical research—and very much higher than that in engineering fields.").
\textsuperscript{143} See supra notes 70-81 and accompanying text.
\textsuperscript{144} See supra notes 82-85.
C. The Incentive-to-Innovate/Schumpeterian Theory

The incentive-to-innovate theory recognizes that inventions may require considerable further investment beyond mere discovery for commercial exploitation.\(^{145}\) Commercial feasibility may demand further research and development, and large-scale development may necessitate the construction of new plants and equipment. A new invention may require refinements to suit the tastes of consumers, as well as advertising to persuade consumers to buy it. "Innovation" denotes these necessary steps between inventing a product or process and bringing it to market.\(^{146}\)

Joseph Schumpeter was first to distinguish innovation from invention.\(^{147}\) Schumpeter noted that the invention itself produces "no economically relevant effect at all."\(^{148}\) Innovation, on the other hand, engenders revolutionary changes in the economic system through "a process of Creative Destruction."\(^{149}\) In this process, new firms continually arise to exploit new innovations, driving out old firms that provide obsolete goods and services. Schumpeter argued that in this dynamic model of the capitalist system, patent monopoly promotes innovation and growth more effectively than pure competition. Schumpeter based his view on the observation that economic advances are more frequently traced to big monopolistic businesses than to firms in atomistically competitive industries.\(^{150}\) He also reasoned that protection from competition allows firms time and space for further developments. More importantly, the prospect of extraordinary returns permits innovators to induce investment and to lure away productive resources from other uses.\(^{151}\) A monopoly secured through patent protection could thus increase, rather than restrict, the use of an invention by facilitating its commercial introduction by innovating firms. Schumpeter therefore maintained the necessity of patent monopolies to induce investment in "innovation."\(^{152}\)

\(^{145}\) See, e.g., SCHERER, supra note 102, at 441.


\(^{147}\) JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY 81-110 (3rd ed. 1950) [hereinafter SCHUMPETER, CAPITALISM]; JOSEPH A. SCHUMPETER, 1 BUSINESS CYCLES 84-192 (1939) [hereinafter SCHUMPETER, BUSINESS CYCLES].

\(^{148}\) SCHUMPETER, BUSINESS CYCLES, supra note 147, at 84.

\(^{149}\) SCHUMPETER, CAPITALISM, supra note 147, at 83.

\(^{150}\) Id. at 82.


\(^{152}\) Like the incentive-to-invent and incentive-to-disclose theories, the incentive-to-innovate theory holds that the patent system offers monopoly profits to promote desired behavior. But it differs from these other theories regarding the point at which the incentive operates. The incentive-to-invent and incentive-to-disclose theories assume that the patent monopoly has already served its social function of promoting invention and disclosure as soon as the patent issues, and that enforcement of the patent thereafter merely constitutes the social cost of fulfilling the bargain. Reducing the scope of existing patents would thus offer short-term social benefits by increasing the use of previously patented inventions, although in the long run it would reduce incentives to make and disclose new inventions. In contrast, the incentive-to-innovate theory gives existing patents an on-going role in preserving the incentives of patent holders to invest in development during the patent term.
Empirical studies testing Schumpeter’s assumption—that monopolistic conditions created by patents more readily induce innovation than do competitive conditions—have proved inconclusive.\footnote{FREDERICK M. SCHERER, INNOVATION AND GROWTH: SCHUMPETERIAN PERSPECTIVES 169-255 (1984); SCHERER, supra note 102, at 423-24.} One commentator, Eric von Hippel, attacked this assumption through a study on the sources of innovation.\footnote{VON HIPPEL, supra note 113, at 11-42.} According to von Hippel, the original inventors do not necessarily innovate. Whether users, suppliers, or others develop innovations varies with the different technological fields. Firms expecting the greatest return from the innovation are typically first to develop it. Therefore, granting a patent monopoly to the inventor would not necessarily motivate innovation based on that invention.

However, Schumpeter’s notion that monopoly surpasses competition in stimulating innovation finds support in biotechnology.\footnote{See Martin Kenney, Schumpeterian Innovation and Entrepreneurs in Capitalism: A Case Study of the U.S. Biotechnology Industry, 15 RES. POL’Y 21, 21 (1988) (“The role of small biotechnology firms in reducing these innovations to practice and in their ability to continue to grow demonstrates that the independent entrepreneur . . . has been very active in the biotechnology industry.”).} The ability of small biotechnology firms with patents that give them a monopoly over important products or processes to outstrip the large traditional pharmaceutical companies comports with Schumpeterian’s concept of “Creative Destruction.” The traditional pharmaceutical companies, despite their superior innovative resources, lag far behind the small start-up companies in contributing to biotechnological innovations.

The Schumpeterian argument offers little guidance in determining the proper scope of patent claims. This theory emphasizes that scope determination should take the difficulty and cost of innovation into account. However, like the incentive-to-invent theory, it offers little insight in deciding the scope of a patent vis-à-vis an alleged infringer’s interest.

D. The Prospect Theory

According to the prospect theory,\footnote{Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L. & ECON. 265, 267-71 (1977). Kitch created the term “prospect theory” to describe an analogy between functions of patent monopolies and awards of exclusive mineral claims in government-owned lands in the American West. This theory offers a justification for patents in keeping with broader theories of property rights elaborated by Harold Demsetz and Richard Posner. RICHARD POSNER, ECONOMIC ANALYSIS OF LAW at 27-31 (2d ed. 1977); Demsetz, supra note 30, at 347. Demsetz and Posner argue that in contrast with communal ownership, private property rights promote more efficient use of resources. Individuals tend to exploit communally owned resources too quickly in order to appropriate the resources for themselves, before the resources are depleted by other community members. The result is an exhaustion of resources by individuals in the present with the externalities born by the community as a whole in the future. Private ownership corrects this problem by placing property owners in a position to bear the full costs as well as the benefits of exploitation, thereby internalizing what would otherwise be external costs in a system of communal ownership. Kitch analogizes patents to the depletable property discussed by Demsetz and Posner. Kitch clarifies the analogy, noting that while information embodied in patents is not depletable by use, resources are needed to use the information and are scarce. Property rights in inventions ultimately improve the efficiency with} patents promote efficient development
of patented inventions by allowing patent owners to coordinate further research and development efforts. If the patent owner holds the exclusive right to exploit and to improve the technology defined in the patent claims, others will not invest in improving this technology without prior arrangements with the patent owner. Otherwise, an improvement infringing the patent will provoke legal sanctions.\footnote{Critics of the prospect theory believe that competitive rivalry for the patent offsets the efficiency gained through coordination. Patents do not eliminate the inefficiency of competition, but rather shift the competition back one stage, since there is no pre-patent right to a patent.\footnote{Moreover, critics question whether granting broad scope to an initial inventor induces more effective development and future invention. These critics argue that eliminating rivalry induces complacency since it also “diminishes the threatened costs of inaction.”\footnote{Moreover, firms’ limited “cognitive capacity” creates a “tendency to focus on past experience.”\footnote{Once a firm reaches competence in one part of a “prospect,” it may ignore other potential advances apparent to other firms.\footnote{However, these firms may still achieve the efficiency of coordination if the patent holder brings in talented individuals to develop selected areas using selective licensing, which does not increase real competition. However, tailoring licenses to particular licensees entails high transaction costs.\footnote{In order to eliminate inefficient competition and to achieve efficient coordinated research, the prospect theory opposes the limitation of patent scopes to the version of the invention as described in the patent. Rather, this theory proposes extending the patent to subsequent refinements as well. Even if others’ further research produces improved versions, the patent owner will still control all versions until the patent expires.}}}}}}\footnote{\textit{Implications for Patent Scope}}

1. \textit{Implications for Patent Scope}

In order to eliminate inefficient competition and to achieve efficient coordinated research, the prospect theory opposes the limitation of patent scopes to the version of the invention as described in the patent. Rather, this theory proposes extending the patent to subsequent refinements as well. Even if others’ further research produces improved versions, the patent owner will still control all versions until the patent expires.

\footnote{which these resources are managed. Kitch, \textit{supra}, at 275-76.}
\footnote{35 U.S.C. §§ 271(a), 281 (1988).}
\footnote{Kitch, \textit{supra} note 156, at 276-79.}
\footnote{Merges & Nelson, \textit{supra} note 9, at 872.}
\footnote{Id. at 873.}
\footnote{Id.}
\footnote{See Richard Caves, et al., \textit{The Imperfect Market for Technology Licenses}, 45 Oxford Bull. Econ. & Stat. 249, 260-62 (1983); Merges & Nelson, \textit{supra} note 9, at 875 (“[W]e have not found a single case where the holder of a broad patent used it effectively through tailored licensing to coordinate the R&D of others.”).}
Patent law doctrine supports this notion to some degree. Though the accused product or process does not literally infringe a claim, the “doctrine of equivalents” finds infringement when the device is essentially the same as the one patented.  

Consistent with the notion of facilitating coordination, courts determined the width of “equivalents” based on the patented invention’s advance beyond the prior art. When the patent is a “mere improvement” over the prior art, courts tend not to consider “equivalent” a product or process even if it is only marginally beyond the patent claims. After all, there is not much coordination to be gained if the patentee’s invention is a small improvement. On the other hand, a “pioneer” invention—which the Supreme Court has defined as “a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art”—is “entitled to a broad range of equivalents.” Nonetheless, this range of equivalents is limited in that infringement under the “doctrine of equivalents” requires substantial identity in the “function performed, means by which [that] function is performed, and [the] result achieved.” A pioneer patent is not infringed by a device if it achieves a different result, or achieves it in a different way. This doctrine has been applied to find infringement of patented inventions by subsequent improvements that are unforeseen at the time of the patent. Again, this application of the doctrine supports the...
prospect theory's notion that patent scope should be extended only so far as coordination will be gained. If a subsequent improvement is completely unforeseeable, then there is no coordination possible and patent scope should not be extended to that improvement.

2. *The Prospect Theory Applied to Biotechnology*

The prospect theory favors broad patent scope for inventions in order to allow coordination of subsequent research. If such coordination is not possible, the claim for broad scope fails. Even ignoring the twin dangers of inaction\(^{171}\) and the cognitive limitation of a firm coordinating research,\(^{172}\) the prospect theory applies poorly to biotechnology. Biotechnology's unpredictability\(^{173}\) confounds the prospect theory's central notion of coordination. As long as the subsequent research the patent holder monitors and controls remains routine trial and error, efficiency gains from coordination probably outweigh any loss in individual productivity that impediments to creativity and initiative in coordinate research impose. However, the ability to coordinate depends on the predictability of the science. Because no one can predict the next step in biotechnological development, the benefits from coordination may be nil.\(^{174}\)

3. *Application to Scripps and Genentech*

This brief analysis of the prospect theory suggests the drawbacks of broad protection for biotechnology patents. In particular, the prospect theory justifies a holding of patent infringement by an improvement which is a predictable "next step" from the original patented invention and which the original inventor could have coordinated. In *Scripps*, the court did not attempt to expand the patent scope with the doctrine of equivalents. The *Genentech* court, however, invoked the doctrine of equivalents after a finding that FE1X was outside the claims of the patent.\(^{175}\) The prospect theory analysis suggests that the court in *Genentech* should inquire whether FE1X was a predictable improvement of t-PA rather than merely focusing on how the two proteins achieve their functions, namely cleaving plasminogen to dissolve blood clots. Although whether FE1X was a predictable improvement of t-PA is not easily resolvable, this inquiry at the very

\(^{171}\) Even for easy improvements, coordinative efficiency may not exist because the original patent holder has little incentive to expedite improvements unless improvements would lead to higher sales volume.

\(^{172}\) See *supra* notes 161-62 and accompanying text.

\(^{173}\) See *supra* notes 52-54, 56-58, 142 and accompanying text.

\(^{174}\) The patent owner on a broad prospect "need not attempt to control the development of that prospect in any detail." Instead, the owner "could license widely and collect royalties. . . . But if used this way, the grant of a broad prospect cannot be justified on the grounds [of the prospect theory]." Owners of broad patents would not be operating as coordinators, "and the subsequent development of prospects would proceed in spite of, or at least in indifference to, the broad patent." Merges & Nelson, *supra* note 9, at 907.

least directs the debate in a direction consistent with the prospect theory's goal of coordinative efficiency.

IV. CONCLUSION

Biotechnology issues a new challenge to the courts and Congress to effect the constitutional mandate "to promote the Progress of Science and useful Arts."176 But courts, as well as commentators, seem to have lost sight of the ultimate purpose of patent awards—promoting technological progress. Courts have determined biotechnology patent scope by strictly applying patent doctrines developed for mechanical and chemical arts. Similarly, commentators have focused on whether traditional patent doctrines have been applied "correctly" or "incorrectly." Such a focus is misguided. Traditional patent doctrine, developed as it was for traditional industries, does not necessarily achieve its purpose—the promotion of technological progress—when applied to industries, such as biotechnology, in which research is characterized by unpredictability and randomness. Instead, traditional patent doctrine should be updated to accommodate the new economic and scientific realities of modern technological innovation. In particular, patent scope definitions, the aspect of patent law that essentially dictates economic incentives, should be fashioned to encourage private parties to invent new products and processes, to disseminate knowledge, to innovate, and to accelerate progress and avert duplicative effort by promoting coordination among researchers. "Correct" or "incorrect" application of traditional patent doctrines does not, as courts and commentators have suggested, dictate the proper scope of patent protection for biotechnological inventions. The proper scope is that which best promotes technological progress.