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HYBRITECH, INC. v. MONOCLONAL ANTIBODIES, INC.: ARE COURTS PROMOTING PROGRESS IN RAPIDLY EXPANDING SCIENTIFIC FIELDS?

INTRODUCTION

Patent protection, which stems from the Constitution, exists to "promote the Progress of Science and useful Arts."¹ Today's technological world is an increasingly complex place that includes genetically altered animals and semiconductor chips. These scientific products, which were undreamed of when the Constitution was written, make it appropriate to ask whether the patent laws adequately address the needs of both the public and inventors when the invention occurs in a rapidly expanding scientific field.

Society now enjoys the fruits of the recent micro-electronic revolution, is in the midst of a biotechnology revolution, and faces, perhaps, an upcoming scientific revolution based on ceramic superconductors.² Innovations arising from these rapidly expanding scientific areas have raised unique problems concerning patentability. The United States Patent and Trademark Office (PTO), Congress, and courts have been called upon to resolve these issues. For instance, the Board of Patent Appeals and Interferences recently redefined patentable subject matter to include nonhuman multicellular organisms that do not occur naturally.³ This ruling led to the April 12, 1988 issuance of a

1. U.S. CONST. art. I, § 8, cl. 8.

2. See Dagani, *New Class of Superconductors Discovered*, CHEMICAL & ENGINEERING NEWS, Feb. 1, 1988, at 5. "The world of superconductivity research is sizzling again with the discovery of a new class of copper oxide ceramics that carry electric currents with zero resistance at liquid nitrogen temperatures (77 K and above)."

3. *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Int. 1987) (finding a man-made polyploid oyster patentable). Prior to the 1980 United States Supreme Court determination that patentable subject matter included man-made micro-organisms, "living things" were not considered patentable. See *Diamond v. Chakrabarty*, 447 U.S. 303, 306 (1980) (finding a genetically-engineered bacterium capable of digesting oil patentable). *Ex parte Allen* "reversed a long-standing PTO policy" and recognized that man-made live organisms, including animals, that are more complex than single-cell micro-organisms are patentable; this action prompted the Senate to amend the supplemental appropriations

patent on the Harvard mouse, a rodent whose susceptibility to cancer is genetically engineered.⁴ Previously, Congress passed the Semiconductor Chip Protection Act after finding patent and copyright laws inadequate to protect the rights of inventors of products which were developed in the wake of the micro-electronic revolution.⁵

A more fundamental issue, however, is whether the existing patent law structure is capable of addressing the intricacies necessary to resolve patentability issues in complex, highly technical scientific fields, which may themselves be in flux. This Comment will use a recent biotechnology patent dispute as a vehicle to discuss whether the patent laws adequately serve their constitutional purpose in rapidly expanding scientific fields.⁶ The patent dispute in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*⁷ required the district and appellate courts to address technologically complex issues. This Comment assesses the difficulties these courts had in analyzing these issues, difficulties that were compounded by confusion over which patentability standards were applicable, and presents a possible alternative to the present patenting process. A discussion of general patent principles and a summary of the district and appellate court opinions in *Hybritech* precedes this analysis.

bill (H.R. 1827) "to bar the PTO from expending funds during fiscal year 1987 for the purpose of granting patents on genetically altered or modified animals." News & Comment, 34 Pat. Trademark & Copyright J. (BNA) 124 (1987). After the PTO voluntarily agreed to refrain from issuing such patents during that period, the conference committee struck the amendment. 133 CONG. REC. H5654 (daily ed. June 27, 1987). Following many House hearings, various proposals to prohibit animal patents because of religious or moral beliefs were defeated. Furthermore, on September 13, 1988, the House passed HR 4970, which recognizes animal patents by exempting farmers "who reproduce, use, or sell patented animals" from infringement liability. HR 4970 also explicitly excludes human beings from patentable subject matter. News & Comment, 36 Pat. Trademark & Copyright J. (BNA) 485 (1988). As of March 1988, 3,600 applications for bioengineered organisms were pending before the PTO; of these, 22 sought patentability for animals created by gene splicing. Washington Whispers, U.S. NEWS & WORLD REPORT, Mar. 7, 1988 at 15.

4. See News & Comment, 35 Pat. Trademark & Copyright J. (BNA) 508 (1988).

5. 17 U.S.C. §§ 901-14 (Supp. V 1987).

6. This Comment is limited to a discussion of the patent system and does not address in depth other intellectual property rights, such as trade secret common law rights, that can affect the "Progress of Science and the useful Arts." A discussion of the interaction between intellectual property rights and the traditional scientific ideal of full sharing of scientific discoveries and its effect on scientific research can be found in Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987).

7. 623 F. Supp. 1344 (N.D. Cal. 1985), *rev'd*, 802 F.2d 1367 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987).

I. BACKGROUND

The government derives its authority to issue patents directly from the Constitution: "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."⁸ The current Patent Act, enacted in 1952, gives a patent owner the exclusive right to make, use, or sell inventions for a term of seventeen years.⁹ The overriding constitutional purpose—the advancement of science and the useful arts—has been interpreted by Congress to require that patent holders fully disclose to the public not only how their inventions work but also how to reproduce them.¹⁰ Thus, the development of technology is encouraged by giving the inventor an incentive to invent while providing the public, including other inventors, full disclosure of the latest inventions.

Any patent, whether it be a utility,¹¹ plant,¹² or design¹³ patent, is granted only for a concrete application that solves a real problem; abstract ideas or concepts are unpatentable.¹⁴ Furthermore, a naturally occurring substance is not patentable, but "anything under the sun that is made by man" is patentable subject matter.¹⁵

8. U.S. CONST. art. I, § 8, cl. 8.

9. 35 U.S.C.A. § 154 (West 1984 & Supp. 1989).

10. 35 U.S.C. § 112 (1982). Full disclosure takes place only when and if a patent issues; the PTO cannot reveal the contents of a patent application during the application's pendency. 35 U.S.C. § 122 (1982).

11. A utility patent is the "normal type of patent" and encompasses products and processes as "distinguished from design patent[s] and plant patents." 1 D. CHISUM, PATENTS G1-23 (1988). Thus, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (1982).

12. 35 U.S.C. § 161 (1982) (protects new and distinct varieties of asexually reproducing plants).

13. 35 U.S.C. § 171 (1982) (protects new and original ornamental design for articles of manufacture).

14. Ideas become patentable when a "reduction to practice" occurs. Reduction to practice is "either actual (the building and testing of an operative embodiment) or constructive (the filing of a patent application with an adequate enabling disclosure)." 1 D. CHISUM, *supra* note 11, at G1-20. *See also infra* text accompanying note 21.

15. S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952) (1952 Patent Act Committee reports). This language was quoted by the Supreme Court to support its finding that man-made micro-organisms are patentable. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). *See also supra* note 3 and accompanying text.

Three sections of the Patent Act enumerate the basic standards for patent protection. Section 101 limits patentable inventions to those that are "new and useful" and thus gives rise to the requirements of novelty and utility.¹⁶ Although the utility standard usually is met by stating that the invention solves a real world problem, the novelty standard, which is defined in section 102,¹⁷ is met only when no single prior device or reference discloses every element of the claimed invention.¹⁸ The third standard, which was adopted by Congress from an earlier judicially created requirement,¹⁹ is the nonobviousness requirement of section 103. Thus, if a "person having ordinary skill in the art" deems the invention to be obvious at the time of invention, the invention is not patentable.²⁰

Because a determination of novelty depends upon whether a prior art discloses every element of the invention, what constitutes prior art is a necessary determination. Although an invention comes into being when it is reduced to practice,²¹ the date of conception marks the time that the inventor can claim priority to an invention if she has been reasonably diligent in reducing her invention to practice.²² Thus, the time of conception marks

16. 35 U.S.C. § 101 (1982).

17. 35 U.S.C. § 102 (1982) (patent barred if prior art, such as previous patents or printed publications, enables a person skilled in the field to perform the process or produce the product that the inventor wishes to patent).

18. A "reference" is any prior publication or prior patent used by the PTO to determine whether the invention is novel and nonobvious. 1 D. CHISUM, *supra* note 11, at G1-20. "Disclosure" refers to facts that the PTO or courts deem published by a reference or patent application.

19. *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850) (clay cabinet knobs that have same design as previously known wood knobs not patentable).

20. Section 103 provides:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103 (1982 & Supp. V 1987). The hypothetical person defined in the Code section must have not only ordinary skill, but also an extraordinary memory because she knows all the relevant prior art regardless of when it was disclosed. *See Ebert, Superperson and the Prior Art*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 657 (1985).

21. *See supra* note 14 and accompanying text.

22. Section 102(g) states:

A person shall be entitled to a patent unless . . . before the applicant's invention thereof the invention was made in this country by another who

the point when potential rights vest in the inventor.²³ Presently, a court must determine both the conception and reduction to practice dates as a matter of law based on factual findings.²⁴

The patenting process is complicated and includes an *ex parte* examination before the PTO. Following issuance, a patent's status may be clarified by reexamination²⁵ or reissuance²⁶ hearings. PTO decisions denying patentability may be appealed to the Board of Patent Appeals and Interferences.²⁷ If a patent is not issued after an appeal to the Board, the patent applicant may appeal to the United States Court of Appeals for the Federal Circuit (CAFC).²⁸ Once a patent is obtained, its validity may be challenged only in a federal district court through either a declaratory judgment action seeking a declaration of invalidity or in a defense to a patent infringement action claiming that the patent is invalid and

had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102(g) (1982).

23. The existence of a potential right at the time of conception is unusual among the various patent laws in the world; only the United States, Canada, and the Philippine Islands recognize this right. Other countries use the filing date of the patent application to determine when rights attach. In practical terms, a patent applicant may find that another's undisclosed work predates and anticipates her work. See Kayton, *Novelty Requirement for Patentability and Loss of Right to Patent*, in 1 PATENT PRACTICE 2 (I. Kayton ed. 1985).

24. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987).

25. 35 U.S.C. § 302 (1982) (process whereby a third party can request the PTO to conduct another limited examination).

26. 35 U.S.C. § 251 (1982) (process to cure defects in original patent).

27. 35 U.S.C. § 134 (1982 & Supp. V 1987) (patent applicant whose claims have been twice rejected may appeal the decision upon paying a fee).

28. 28 U.S.C. §§ 1292, 1295 (1982); 35 U.S.C. §§ 141-44 (1982 & Supp. V 1987). The Court of Claims and the Court of Customs and Patent Appeals merged to create the CAFC on October 1, 1982. Prior to the creation of the CAFC, appeal could be made to the various numbered circuit courts of appeal or the now abolished Court of Customs and Patent Appeals. In its first published opinion, the CAFC declared that precedents for the Court of Claims and the Court of Customs and Patent Appeals decided before October 1, 1982, would serve as precedents for the CAFC; by implication, decisions of the numbered circuit courts would not serve as precedents. *South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982). Prior to the formation of the CAFC, there were significant differences concerning patent validity determinations among the numbered circuit courts; for example, the Eighth Circuit held invalid all patents that came to it from 1950 to 1970. Kayton, *Nonobviousness of the Novel Invention*, in 1 PATENT PRACTICE 19 (I. Kayton ed. 1985).

therefore cannot be infringed.²⁹ The CAFC has exclusive jurisdiction over appeals from district court decisions determining patent validity.³⁰ Final appeal from the CAFC is made to the United States Supreme Court by writ of certiorari.³¹

Because the Supreme Court rarely speaks to patent issues, the CAFC, for the vast majority of patent cases, has become the last avenue of appeal.³² However, in interpreting the Patent Act, it appears that the CAFC has modified some important standards first enunciated by the Supreme Court.

One key area of the CAFC's divergence from the Supreme Court's interpretation of the Patent Act concerns the determination of obviousness.³³ In *Graham v. John Deere Co.*,³⁴ the Court established this three-part test for obviousness: "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."³⁵ The results of these factual inquiries provide a framework to determine whether the invention is obvious. In addition, the Court focused on the commercial success of the innovation, a long-felt but unfulfilled need for the invention, and failure of others to succeed in producing the invention. The Court termed these factors "secondary considerations" that "may have relevancy" and "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."³⁶ These factors previously had been used by the Court to help resolve obviousness issues in close cases³⁷ but not when

29. Original and exclusive jurisdiction for infringement of a patent lies in the federal district courts. 28 U.S.C. § 1338 (1982); 35 U.S.C. § 281 (1982).

30. 28 U.S.C. § 1295(a)(4) (1982).

31. SUP. CT. R. 17.2.

32. *See, e.g.*, *Graham v. John Deere Co.*, 383 U.S. 1 (1965). "After a lapse of 15 years, the Court again focuses its attention on the patentability of inventions . . ." *Id.* at 3. This was the first patent case heard by the Court after the passage of the 1952 Patent Act.

33. *See supra* note 20 and accompanying text.

34. 383 U.S. 1 (1965).

35. *Id.* at 17.

36. *Id.* at 17-18. The CAFC has added to the list of secondary considerations whether competitors have copied the invention, whether other inventors simultaneously solved the problem, and whether other members of the industry were willing to license the invention. *See, e.g.*, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983); *Kayton, supra* note 28, at 17.

37. *See, e.g.*, *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944).

the assessment of the prior art led to a firm conviction of invalidity.³⁸

Instead of evaluating the obviousness of a patent via the *Graham* test, supplemented by the secondary considerations, the CAFC has elevated secondary considerations when they are present to an importance equal to that of the original three inquiries of the *Graham* test.³⁹ Secondary considerations, which the CAFC terms objective evidence, must be considered "as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art."⁴⁰ Also, secondary considerations are not to be used as a counterweight to a finding of obviousness or nonobviousness based on prior art; the prior art must be re-evaluated in light of the objective evidence whenever this evidence is presented.⁴¹

The CAFC emphasizes the critical importance of examining objective evidence in nonobviousness determinations. This approach follows Judge Learned Hand's rationale that a determination of nonobviousness without considering secondary considerations

directs us to surmise what was the range of ingenuity of a person "having ordinary skill" in an "art" with which we are totally unfamiliar; and we do not see how such a standard can be applied at all except by recourse to the earlier work in the art, and to the general history of the means available at the time. To judge on our own that this or that new

38. See, e.g., *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 567 (1949).

39. See e.g., *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 446—47 (Fed. Cir. 1986) (secondary considerations constitute one of the "four inquiries mandated by *Graham*").

40. *Stratoflex*, 713 F.2d at 1538—39.

41. *Ashland Oil, Inc. v. Delta Resins & Refractories*, 776 F.2d 281 (Fed. Cir. 1985), *cert. denied*, 106 S. Ct. 1201 (1986). As one commentator noted, the CAFC, in the interest of creating a rational system for patent law, "benignly neglect[s]" most Supreme Court obviousness analyses; however, the CAFC does apply "the tenets (not the holding) of *Graham* [because they] are a model of clarity with emphasis on the proper considerations for § 103 determinations." Kayton, *supra* note 28, at 16, 20. The commentator rationalizes this result because

it is clear for all to see that the *composite* holdings, dicta and language [concerning patent standards articulated by the Supreme Court] are an undecipherable nightmare. In view of the extraordinarily heavy caseload burden the Supreme Court has been under, pronouncements about which are now surfacing from the Justices themselves, there is little wonder that a small esoteric legal area such as patent law should have been in such judicial disarray.

Id. at 16.

assemblage of old factors was, or was not, "obvious" is to substitute our ignorance for the acquaintance with the subject of those who were familiar with it. There are indeed some sign posts: e.g. how long did the need exist; how many tried to find the way; how long did the surrounding and accessory arts disclose the means; how immediately was the invention recognized as an answer by those who used the new variant?⁴²

Thus, secondary considerations can be primary evidence of the nonobviousness of the claimed invention.⁴³

A difference of opinion also exists between the Supreme Court and the CAFC over the application of obviousness standards to combination inventions. Patent claims for inventions which combine elements, each of which is individually old in the art, receive a form of strict scrutiny from the Supreme Court; the combination must yield unusual, surprising, or synergistic effects to be considered nonobvious.⁴⁴

In contrast, rather than looking for synergism to validate a claim, the CAFC considers whether the prior art suggests the desirability of the combination to one of ordinary skill in the art and, therefore, invalidates a claim.⁴⁵ Explicitly rejecting the synergism test, the CAFC stated that

[t]he reference to a "combination patent" is . . . without support in the statute. There is no warrant for judicial classification of patents, whether into "combination" patents and some other unnamed and undefined class or otherwise. Nor is there warrant for differing treatment or consideration of patents based on a judicially devised label. Reference to "combination" patents is, moreover, meaningless. Virtually *all*

42. *Reiner v. I. Leon Co.*, 285 F.2d 501, 503-04 (2d Cir. 1960).

43. *But see Merges, Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 805 (1988) (arguing that heightened emphasis on secondary considerations unjustly rewards nontechnical achievements, including marketing decisions and distribution systems, instead of actual invention).

44. *See, e.g., Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976) (invalidating a patent for a water system to remove cow manure from dairy barn floors because the combination of elements could not "properly be characterized as synergistic"); *Anderson's Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 61 (1969) (invalidating a patent for machinery to lay blacktop pavement because the combination of elements did not "result in an effect greater than the sum of the several effects taken separately"); *A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 152 (1950) (invalidating a patent because of the absence of "any unusual or surprising consequences from the unification of the elements here concerned").

45. *See, e.g., Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563 (Fed. Cir. 1983).

patents are "combination patents," if by that label one intends to describe patents having claims to inventions formed of a combination of elements.⁴⁶

Thus, instead of focusing on whether a combination of old elements produces something unexpected, the CAFC examines the prior art to see if it suggests the claimed invention as a whole.⁴⁷ The CAFC's suggestion test is far more pro-patent than the synergism test of the Supreme Court.

The Supreme Court has not chosen to address the obviousness issue since the CAFC was formed. However, when it does, the CAFC analysis "may well turn out to be a house of cards under the scrutiny of the Supreme Court."⁴⁸ Because an obviousness determination "is the most frequently dispositive patentability issue,"⁴⁹ uncertainty in obviousness determinations has significant ramifications. Potential for confusion exists at the district court level over which patentability standards are applicable. Such confusion likely occurred in the case that is the focus of this Comment.

II. *HYBRITECH INC. V. MONOCLONAL ANTIBODIES, INC.*⁵⁰

Hybritech Inc. (Hybritech) and Monoclonal Antibodies, Inc. (MAB) are companies that were formed in the late seventies to take advantage of the recent discovery of a method to produce large quantities of monoclonal antibodies *in vitro*.⁵¹ Both companies

46. *Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983). *See also* *Fronson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985).

47. *See, e.g., Custom Accessories Inc. v. Jeffrey-Allan Ind.*, 807 F.2d 955 (Fed. Cir. 1986).

48. Harris, *Prospects for Supreme Court Review of the Federal Circuit Standards for Obviousness of Inventions Combining Old Elements*, 68 J. PAT. & TRADEMARK OFF. SOC'Y 66, 67 (1986).

49. *Id.* at 66.

50. 623 F. Supp. 1344 (N.D. Cal. 1985), *rev'd*, 802 F.2d 1367 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987).

51. *Hybritech*, 802 F.2d at 1370; *Hybritech*, 623 F. Supp. at 1345.

Monoclonal antibodies are the product of a complicated process. The immune system produces antibodies in response to the presence of foreign molecules (antigens). The molecular shape of the antibody is designed by the immune system to bind to the foreign molecule in its effort to render the antigen harmless. Each antibody is specific to a particular antigen; furthermore, an antibody can bind to only one place on the antigen, like a key fitting one of many locks. Not only are many different antibodies produced for each antigen, there are many different antigens in body fluids. Thus body fluids always contain a variety of different antibodies. This mixture of antibodies is termed polyclonal. A solution that contains only one kind of antibody is termed monoclonal. *See Hybritech*,

intended to use monoclonal antibodies to create fast, sensitive immunoassays for detecting antigens in body fluids.⁵² Because the identification and quantification of particular antigens allows diagnosis of various medical conditions including pregnancy, allergies, hepatitis, and colon cancer, both companies planned to market diagnostic kits using monoclonal antibodies.⁵³

By the time these two companies were formed, two general kinds of immunoassays using polyclonal antibodies were in use: "competitive" and "sandwich." The competitive immunoassay, in which the antigen to be measured competes with labeled antigen for a known quantity of antibody binding sites, takes considerably more time to produce results than a sandwich assay but requires only a small quantity of antibody.⁵⁴ Conversely, a sandwich assay, in which the antigen to be measured is bound to two antibody molecules in sandwich form, produces results more rapidly but requires much larger quantities of antibodies.⁵⁵ This quantity differential was important prior to 1975 because there was a limited supply of animal serum, which is the source of polyclonal antibodies.⁵⁶

Hybritech developed sandwich diagnostic kits and received a patent for its monoclonal antibody sandwich assays after its claims had been rejected twice by the Patent Examiner for being obvious.⁵⁷ In the meantime, MAB had independently developed its own commercial kits using monoclonal antibodies in sandwich

802 F.2d at 1368-69; *Hybritech*, 623 F. Supp. at 1346.

In 1975 Georges Kohler and Cesar Milstein published their paper describing how to make hybridomas (fused mouse spleen cells and malignant mouse cells) produce monoclonal antibodies in vitro. In short, a mouse is first injected with a particular antigen. The antigen activates the spleen cells to produce antibodies to the antigen. The spleen cells are removed and fused with cancer cells that are capable of growing in a test tube. The resulting hybridomas are separated one per test tube and allowed to reproduce. These cloned hybridomas all produce the same kind of antibody (monoclonal antibodies). Kohler and Milstein received a Nobel Prize for their work in 1984. See *Hybritech*, 802 F.2d at 1369; *Hybritech*, 623 F. Supp. at 1347; Fox, *Antibody Reagents Revolutionizing Immunology*, CHEMICAL & ENGINEERING NEWS, Jan. 1, 1979, at 15.

52. An antigen is either a substance foreign to the body, such as a virus, or a chemical produced by the body because of its condition. *Hybritech*, 802 F.2d at 1368; *Hybritech*, 623 F. Supp. at 1346. Immunoassays are "diagnostic methods for determining the presence or amount of antigen in body fluids . . . by employing the ability of an antibody to recognize and bind to an antigen." *Hybritech*, 802 F.2d at 1369.

53. *Hybritech*, 802 F.2d at 1370; *Hybritech*, 623 F. Supp. at 1349.

54. See *Hybritech*, 802 F.2d at 1369; *Hybritech*, 623 F. Supp. at 1347.

55. See *Hybritech*, 802 F.2d at 1369-70; *Hybritech*, 623 F. Supp. at 1347-48.

56. See *Hybritech*, 802 F.2d at 1369. See also *supra* note 51.

57. *Hybritech*, 623 F. Supp. at 1350.

assays.⁵⁸ Hybritech sued MAB claiming that MAB's monoclonal antibody diagnostic kits for detecting pregnancy and ovulation infringed Hybritech's patent. MAB's defense was that Hybritech's patent was invalid.⁵⁹

The District Court for the Northern District of California agreed with MAB and found all twenty-nine claims in Hybritech's patent invalid, principally for being anticipated by prior art and obviousness under 35 U.S.C. § 103.⁶⁰ On appeal, the CAFC sharply criticized the district court's decision. The CAFC found all twenty-nine claims new and nonobvious and held the patent valid, remanding the case for trial on the issue of infringement.⁶¹ On remand, the district court issued a preliminary injunction in favor of Hybritech and the two parties settled. MAB agreed to pay Hybritech two-and-a-quarter million dollars to settle the past infringement disputes and Hybritech agreed to grant MAB a one-year license at a royalty rate of fifteen percent for its pregnancy and ovulation tests.⁶² The outcome of this litigation turned upon the validity of Hybritech's patent. Validity, in turn, entailed a determination of whether the patent met the novelty and nonobvious criteria.⁶³

58. *Id.* at 1349.

59. *See Hybritech*, 802 F.2d at 1371.

60. *Hybritech*, 623 F. Supp. at 1356-57.

61. *Hybritech*, 802 F.2d at 1371.

62. News & Comment, 34 Pat. Trademark & Copyright J. (BNA) 277 (1987). Subsequently, Hybritech sued Abbott Laboratories alleging that Abbott's immunoassays infringed Hybritech's patent. The Federal Circuit upheld the district court's imposition of a preliminary injunction against Abbott partially based upon the MAB court's finding of patent validity. News & Comment, 36 Pat. Trademark & Copyright J. (BNA) 203 (1988). However, to protect public interests, the preliminary injunction was not extended to the use of Abbott's monoclonal assays by cancer patients who were currently using Abbott's product. In addition, the preliminary injunction did not prohibit Abbott's production of nonA/nonB hepatitis test kits because Hybritech currently did not market a hepatitis kit. News & Comment, 34 Pat. Trademark & Copyright J. (BNA) 349 (1987). Hybritech is currently involved in an interference proceeding over its patent. News & Comment, 36 Pat. Trademark & Copyright J. (BNA) 203 (1988).

63. The district court, in addition to finding that the patent was invalid because it was anticipated and obvious, also found that the patent did not meet the requirements of section 112 of Title 35. *Hybritech*, 623 F. Supp. at 1352. This section requires the patent to enable "any person skilled in the art . . . to make and use" the claimed invention and requires the patent to "set forth the best mode contemplated by the inventor." 35 U.S.C. § 112 (1982). Furthermore, the patent must "conclude with one or more claims particularly pointing out and distinctly claiming" the invention. *Id.* In reversing on all these grounds, the CAFC referred to the district court's findings regarding section 112 as "utterly baseless" and hypothesized that they were included because the district court, as it stated at trial, wished to see that "whoever wins wins all the way or whoever loses loses all the way." *Hybritech*, 802 F.2d at 1384.

The trial court originally found that two research groups had reduced the claimed invention to practice prior to either conception or reduction to practice by Hybritech, and thus their work anticipated Hybritech's invention.⁶⁴ Because the court found "no credible evidence of conception" prior to the arrival at Hybritech of a scientist/executive who had experience with patents, the court placed the conception date just a few months before Hybritech filed the patent application.⁶⁵ This finding, along with the determination that the work of two other research groups completely disclosed the claimed patent, led to the conclusion that the patent was invalid because it lacked novelty.⁶⁶

The CAFC, in reversing the district court's novelty determination, found the lower court clearly in error for failing to find credible evidence of an earlier conception date.⁶⁷ The appellate court's evaluation was based on numerous lab book entries, correspondence, and testimony introduced at trial that dated Hybritech's conception of the invention almost a year and a half earlier than the date determined by the district court.⁶⁸ This earlier conception date allowed the CAFC to determine as a matter of law that the work of one of the research groups cited by the district court did not predate Hybritech's work and thus was not prior art.⁶⁹

In addition, the CAFC distinguished Hybritech's claimed invention from that of the second anticipatory reference cited by the district court, finding "that a mistake was made because that work does not meet every element of the claimed invention."⁷⁰ No single prior art was found to "read on"⁷¹ Hybritech's invention literally, and thus the invention was deemed novel.⁷²

64. *Hybritech*, 623 F. Supp. at 1351-52. See *supra* notes 21-24 and accompanying text.

65. *Hybritech*, 623 F. Supp. at 1354.

66. *Id.* at 1356. "The said patent is invalid because it teaches nothing new in the art, the art alleged to be taught was obvious and logical to anyone skilled in the field." *Id.*

67. *Hybritech*, 804 F.2d at 1376.

68. *Id.* at 1376-78.

69. *Id.* at 1378.

70. *Id.* at 1379.

71. To have a § 102 anticipation,

it is not necessary that a prior art reference "teach" what the patent teaches.

Rather, it is only necessary that the claim under attack, as construed by the court, "read on" something disclosed in the reference, i.e., that all limitations of the claim are found in the reference, or are "fully met" by it.

1 P. ROSENBERG, PATENT LAW FUNDAMENTALS 7-15 (1988) (citing *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771-72 (Fed. Cir. 1983)).

72. *Hybritech*, 802 F.2d at 1397.

Although the district court and the CAFC differed on the novelty issue, both courts recognized that (1) two different types of immunological assays using antibodies, competitive and sandwich assays, were known in the field at the time Hybritech conceived the claimed invention;⁷³ (2) methods to produce both polyclonal and monoclonal antibodies were prior art;⁷⁴ (3) polyclonal antibodies had been used in both competitive and sandwich assays;⁷⁵ and (4) monoclonal antibodies had been used in competitive assays.⁷⁶ Thus, the only combination of the two kinds of assays using the two kinds of antibodies which had not been reduced to practice was the monoclonal antibody—sandwich assay combination found in Hybritech's patent.

The district court concluded that it would have been "obvious" and "logical" to use monoclonal antibodies in a sandwich assay combination.⁷⁷ Furthermore, the "alleged advantages [of monoclonal sandwich assays] were expected as naturally flowing from the well-known natural characteristics of monoclonal antibodies compared to polyclonal antibodies."⁷⁸ The court based its obviousness finding in part on eight scientific articles published prior to the patent application date that, according to the court, showed that the use of monoclonal antibodies in immunodiagnostic tests was "expected and predicted."⁷⁹

The CAFC, because it had determined an earlier date of invention, quickly dismissed four of the articles as not being prior art.⁸⁰ These articles could not invalidate the patent under section 102 because they neither described the invention prior to the time ascribed by the CAFC as Hybritech's invention date nor were published more than a year prior to Hybritech's filing date.⁸¹

73. *Id.* at 1369–70; *Hybritech*, 623 F. Supp. at 1347.

74. *Hybritech*, 802 F.2d at 1369, 1380; *Hybritech*, 623 F. Supp. at 1346–47, 1352.

75. *Hybritech*, 802 F.2d at 1381; *Hybritech*, 623 F.Supp. at 1349, 1354.

76. *Hybritech*, 802 F.2d at 1380–81; *Hybritech*, 623 F. Supp. at 1354.

77. *Hybritech*, 623 F. Supp. at 1351, 1356.

78. *Id.* at 1350.

79. *Id.* at 1354.

80. *Hybritech*, 802 F.2d at 1380.

81. *Id.* Section 102 describes unpatentability due to prior art as existing when: (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States

35 U.S.C. § 102(a)–(b) (1982).

The CAFC applied its own obviousness test⁸² to evaluate the remaining prior art, which included the other four articles, finding that all references “skirt[ed] all around but [did] not as a whole suggest the claimed invention.”⁸³ In explicitly rejecting the four articles classified as prior art, the CAFC characterized the articles as mere discussions of the “*production* of monoclonal antibodies” and declared that “at *most*, these articles are invitations to try monoclonal antibodies in immunoassays but do not suggest how that end might be accomplished.”⁸⁴

The courts also disagreed over the role of secondary considerations in the nonobviousness determination. The district court seemed to follow the Supreme Court’s two-level analysis.⁸⁵ Only after concluding that the patent was obvious based on the scope and content of the prior art did the court consider the effect of objective evidence, dismissing that evidence as “icing on the cake.”⁸⁶

The CAFC emphatically declared that a one-step analysis is the law;⁸⁷ that is, “[o]bjective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered *before* a conclusion on obviousness is reached.”⁸⁸ The CAFC found “undisputed evidence . . . that Hybritech’s diagnostic kits had a substantial market impact.”⁸⁹ Furthermore, the court found this impact resulted from the “merits of the claimed invention” rather than a benefit derived from either the availability of monoclonal antibodies or business acumen.⁹⁰ The CAFC also found that Hybritech’s kits “unexpectedly solved longstanding problems” because users testified that Hybritech’s kits were more accurate than other kits, solved a false detection

82. *See supra* text accompanying notes 45–47.

83. *Hybritech*, 802 F.2d at 1383.

84. *Id.* at 1380. This suggestion test, particularly as used in this case, is far more pro-patent than that articulated by the district court.

85. *See supra* notes 34–38 and accompanying text.

86. *Hybritech*, 802 F.2d at 1380. The district court used this phrase during the trial proceedings.

87. *See supra* notes 39–43 and accompanying text.

88. *Hybritech*, 802 F.2d at 1380.

89. *Id.* at 1382. Hybritech “became the market leader with roughly twenty-five percent of the market at the expense of market shares of the other companies” including “industry giants such as Abbott Labs, Hoffman LaRoche, Becton-Dickinson, and Baxter-Travenol.” *Id.* Apparently, the substantial market impact of Hybritech’s kits clearly indicated to the court the innovation’s commercial success and fulfillment of market needs.

90. *Id.* The CAFC held clearly erroneous the district court’s finding that the “sudden availability of monoclonals” caused the commercial success.

problem, and performed more rapidly without any loss in sensitivity.⁹¹ This evidence, considered simultaneously with an analysis of the scope and content of the prior art, the level of ordinary skill in the art, and the differences between the prior art and the claimed invention, led the CAFC to find that Hybritech's claimed invention was nonobvious as a matter of law.⁹²

III. DISCUSSION

The appropriateness of the patenting process in rapidly expanding scientific fields must be analyzed in light of the constitutional purpose of the Patent Act—the advancement of science and the useful arts. Standards and procedures that inhibit inventors from inventing, encourage inventors to keep their inventions secret, or allow the withdrawal of inventions from the public domain without any corollary new disclosure to the public should be suspect. The patenting process in general has developed with the constitutional purpose as its guiding principle. Therefore, the pivotal question is whether highly technical and rapidly changing fields present unique problems which cause the patenting scheme to fail in its essential purpose in those fields.

Hybritech illustrates some of the patenting problems inherent in inventions generated in a rapidly expanding scientific field. The complexity of the technical issues that a court must understand to decide the scope and content of the prior art and to distinguish the prior art from the invention is forbidding. The court's degree of familiarity with the scientific distinctions involved in the process may affect its approach to the problem. Confusion over the appropriate standards to determine patentability makes the court's job even more difficult.

As the issues become more complex and the guidelines become blurred, a court may be prompted to act instinctively rather than to apply a principled analysis. As the costs of developing useful technical solutions grow, inventors and investors may be more wary of gambling their resources on a project when patentability, and thus profitability or the ability to recoup expenses, are in doubt.⁹³ This result would hinder the constitutionally expressed policy of encouraging invention.

91. *Id.* at 1382–83.

92. *Id.* at 1383.

93. Alternatively, an inventor might choose to keep the invention secret to take advantage of trade secret laws or forego profit for the fame of scientific publication.

A. *Complexity of the Issues*

Although a court may not understand the technology described in a patent, the testimony of a person of "ordinary skill" should provide the court with the expertise needed to understand the technology. In practice, however, courts may not fully understand expert testimony when the subject matter is on the cutting edge of a new scientific field. It is possible that the concepts, the relationships between the concepts, and the vocabulary of the field may simply overwhelm the court when explained by an expert who has years of postgraduate training in a narrow, specialized field.

There is some indication that the district court in *Hybritech* faced this problem. Most of the court's opinion was a direct quotation of the pretrial brief, pretrial findings of fact, and conclusions of law presented by MAB.⁹⁴ The few paragraphs that the court did not quote displayed its unfamiliarity with the subject matter; in fact, its statement that "[m]onoclonal antibodies are genetically engineered cells called 'hybridomas'" is wrong.⁹⁵ Given the district court's failure to understand the basic terminology of the bioengineering field, it is not surprising that the court did not distinguish and recognize the significance of the evidence presented by Hybritech. The CAFC, however, evaluated the content of numerous Hybritech laboratory notebooks containing graphs and data and considered this information crucial in ascertaining the dates for conception and reduction to practice of the invention.⁹⁶ The lower court was found clearly in error for failing to recognize this evidence.⁹⁷

94. *Hybritech*, 802 F.2d at 1371. "With the exception of the first eight paragraphs, the first half of the district court's opinion here is Monoclonal's *pretrial* brief and the last three pages of the opinion are Monoclonal's *pretrial* findings of fact and conclusions of law." *Id.* at 1374.

95. *Hybritech*, 623 F. Supp. at 1345. Monoclonal antibodies are *produced* by hybridomas but are not hybridomas themselves. See Fox, *supra* note 51, at 15.

96. *Hybritech*, 802 F.2d at 1376-78. Frequently the interpretation of graphs and data is difficult. For instance, Dr. Uotila, a scientist who uses monoclonal antibodies in her research, was deposed in this case. After being shown a dose-response graph of an experiment that she had performed earlier and whose procedure was unknown and in dispute, she was unable to reconstruct the procedural method even after refreshing her memory with her laboratory notebook. *Hybritech*, 802 F.2d at 1372.

97. *Id.* at 1376. "[W]e hold clearly erroneous the district court's finding that there is no clear or corroborated evidence [regarding] when the *claimed invention* was conceived, and therefore reverse the court's holding, as a matter of law, that Hybritech's inventors did not conceive the claimed invention before May 1980." *Id.*

In *Hybritech*, the CAFC had the ability to correct the lower court's findings of fact because those findings were clearly erroneous. Had the district court found reasons to support its conclusion that the graphs and data in Hybritech's notebooks did not establish an early conception date, rather than summarily rejecting the evidence,⁹⁸ the outcome at the appellate level might have been different. An appellate court cannot overturn findings " 'simply because it is convinced that it would have decided the case differently. . . . [I]f the district court's account of the evidence is plausible in light of the record viewed in its entirety' or 'where there are two permissible views of the evidence' " then the findings are not clearly erroneous.⁹⁹ Thus, a trial's outcome is dependent upon a court's ability to understand scientific intricacies sufficiently to support its holding. As the issues become more complex, the trial results can become more erratic. Inconsistent rulings regarding inventors' intellectual property rights can decrease incentives to invent, which is contrary to the purpose of the Patent Act.

Even when a court has a good grasp of the scientific questions presented, it still must view the situation "through the eyes of the person of ordinary skill in the art."¹⁰⁰ Because the person of ordinary skill in advanced scientific fields is highly educated and comes to the courtroom with considerable background knowledge, the court must determine what this person knows to make either a novelty or nonobviousness determination.¹⁰¹ This determination can lead to courts giving legal meaning to subtle scientific distinctions.

For example, the *Hybritech* courts had to determine whether the person of ordinary skill would have known that appropriate monoclonal antibodies would have affinity constants greater than 10⁸ liters/mole. Hybritech's patent application for the monoclonal antibody—sandwich assay combination had been rejected twice by the Patent Examiner for being obvious.¹⁰² After Hybritech

98. *Hybritech*, 623 F. Supp. at 1349.

99. *Hybritech*, 802 F.2d at 1375 (quoting *Anderson v. City of Bessemer City*, 470 U.S. 564 (1985)).

100. Kayton, *supra* note 28, at 25.

101. *Id.* For instance, information relating to facts in a well-used chemistry textbook might be reasonably presumed known by the person of ordinary skill in the field of chemistry. *See id.*

102. *Hybritech*, 623 F. Supp. at 1350. In light of references that disclosed the use of monoclonal antibodies in a competitive immunoassay and the use of polyclonal antibodies

amended its application to limit its claims to the use of monoclonal antibodies with at least a 10^8 liters/mole binding affinity to the antigen,¹⁰³ the Examiner granted the patent.¹⁰⁴

Because none of the prior art references mentioned a 10^8 liter/mole baseline for an affinity constant, the CAFC found that the combination of all the references did not suggest the claimed invention as a whole.¹⁰⁵ Therefore, the CAFC found the claimed invention nonobvious.¹⁰⁶ However, the CAFC could have found just as readily that the person of ordinary skill in the art at the time of the invention would have recognized from background knowledge that high affinity antibodies would be necessary for a workable assay; the exact numerical baseline is fairly trivial.¹⁰⁷ This subtle difference may have cost MAB over two-and-a-quarter million dollars.

B. Secondary Considerations

Perhaps to avoid the pitfalls of trying to ascertain what background knowledge the person of ordinary skill in the field possesses, the CAFC uses secondary considerations as signposts

in sandwich assays, the Examiner stated that "it would be obvious to use the monoclonal antibody for the polyclonal antibodies in the conventional immunoassay protocols defined by the instant claims." *Id.*

103. As the affinity constant increases, the attraction between the antibody and the antigen increases and these species tend to bind more selectively to each other. Thus, the sensitivity of the antibody to the antigen increases. *Hybritech*, 802 F.2d at 1369.

104. *Hybritech*, 623 F. Supp. at 1350. Thus, the amended application read:

In an immunometric assay to determine the presence or concentration of an antigenic substance in a sample of a fluid comprising forming a ternary complex of a first labelled antibody, said antigenic substance, and a second antibody said second antibody being bound to a solid carrier insoluble in said fluid wherein the presence of the antigenic substance in the samples is determined by measuring either the amount of labelled antibody bound to the solid carrier or the amount of unreacted labelled antibody, the improvement comprising employing monoclonal antibodies having an affinity for the antigenic substance of at least about 10^8 liters/mole for each of said labelled antibody and said antibody bound to a solid carrier.

Hybritech, 802 F.2d at 1370 (emphasis added by the court).

105. *Hybritech*, 802 F.2d at 1380-81.

106. *Id.* at 1381.

107. "The affinity constant for the reaction is probably the single most important overall parameter of the reaction since it determines the sensitivity of detection of the antigen." Otterness & Darugh, *Principles of Antibody Reactions*, in ANTIBODY AS A TOOL 98 (J. Marchalonis & G. Warr ed. 1982). "The higher the value of [the affinity constant], the more suitable the antiserum [antibody] will be in terms of sensitivity and precision." J. RANSOM, PRACTICAL COMPETITIVE BINDING ASSAY METHODS 71 (1976). Suitable binding constants are in the range of 10^8 to 10^{10} moles/liter for radioimmunoassay tests. *Id.*

to denote when an invention is nonobvious.¹⁰⁸ However, in a rapidly expanding scientific field, there are very few signposts. When innovations occur rapidly, a later product's monetary success could be due to the underlying inventions rather than the claimed invention itself.¹⁰⁹ Secondary considerations such as long felt need and failure of others become meaningless when changes are rapid. However, unexpected or surprising results, failure of others to successfully develop the invention, simultaneous solutions by different inventors, and copying, when present, may be evidence of the nonobviousness of the invention even in rapidly expanding fields.¹¹⁰

In addressing secondary considerations, the CAFC in *Hybritech* attributed the kits' monetary success to Hybritech's patented invention rather than the underlying pioneer discovery of a method to produce large quantities of monoclonal antibodies. Noting a three-year span between the availability of monoclonal antibodies and the marketing of Hybritech's kit, the court concluded that three years time sufficiently separated these events in the "fast-moving biotechnology field" so that the success could be attributed to Hybritech's kits alone.¹¹¹ The CAFC ignored evidence that production of the appropriate monoclonal antibody and development of feasible ways to attach it to a solid surface were time consuming. As the district court explained:

While the idea was a simple one, putting it into practice was time consuming, and expensive, because of the steps necessary to produce the monoclonals for commercial diagnostic purposes. There are a number of complex steps to be gone through before such kit would be available. Suitable screening assays must be developed to select the best antibody-producing clones from perhaps hundreds of thousands of them. The sheer work and time involved in "cell forming" is also considerable.¹¹²

108. *See supra* text accompanying note 42.

109. Because the time between innovations is short, it is difficult to determine if the financial success of a succeeding innovation is due to the improvements claimed by the invention or due to previous inventions; the nexus between the financial success and the claimed invention may be difficult to prove. *See Merges, supra* note 43.

110. Although there was evidence of simultaneous development of similar kits during the time that Hybritech developed its kits, the CAFC chose not to address the probative value of this evidence, which would tend to negate nonobviousness, "because the other evidence of nonobviousness [was] adequate." *Hybritech*, 802 F.2d at 1380 n.4.

111. *Hybritech*, 802 F.2d at 1382.

112. *Hybritech*, 623 F. Supp. at 1348.

The CAFC also considered evidence that Hybritech's kits "unexpectedly solved longstanding problems."¹¹³ Citing testimony showing that Hybritech's immunoassay was more accurate, less prone to producing false positive results, and faster, the CAFC found that Hybritech's invention exhibited unexpected advantages.¹¹⁴ Although the evidence showed that Hybritech's kits performed better than some of its competitors, the greater specificity of monoclonal antibodies, and thus their accuracy, may not have been unexpected. Some of the references that the CAFC found not to be prior art might nonetheless indicate the general expectations prevalent in the field at the time that Hybritech was developing its kits.¹¹⁵ Prior to Hybritech's filing date, scientists predicted that because "large quantities of monospecific antibodies can be produced, the emergence of simple and reliable assay procedures far surpassing current [radioimmunoassay] techniques in sensitivity, precision, speed, specificity, convenience and overall reliability is within sight."¹¹⁶ Thus, it could be argued that Hybritech's assays, rather than "unexpectedly solv[ing] longstanding problems" as determined by the CAFC, performed as expected in the industry.

The problems discussed in this section, though not unique to this type of patent, are exacerbated in *Hybritech* because biotechnological methods in immunology comprise a complex and rapidly changing field. The unfamiliarity of the court with the technology complicates not only the determination of the level of ordinary knowledge and skill in the field but also the application of secondary considerations.

Because the complexity makes it difficult for a court to view the patent through the eyes of the person of ordinary skill in the art and to establish what meaning, if any, should attach to secondary considerations, the crucial determination of nonobviousness can become unprincipled. On one hand, if an invention really is "obvious" but a patent nonetheless is held valid, the public loses the ability to use information for seventeen years that was already in the public domain without any new

113. *Hybritech*, 802 F.2d at 1382.

114. *Id.* at 1382-83.

115. For instance, six months prior to Hybritech's filing for its patent, a medical journal predicted that "[t]he specificity and uniformity of monoclonal antibodies should markedly improve diagnostic accuracy." Baumgarten, *Viral Immunodiagnosis*, 53 YALE J. MED. 71 (1980).

116. Ekins, *More Sensitive Immunoassays*, 284 NATURE 14, 15 (1980).

compensating disclosure from the inventor. On the other hand, a court advantaged with hindsight could easily find an invention that was truly “nonobvious” to be “obvious.” This finding could have the effect of discouraging invention or encouraging inventors to keep their innovations secret. Neither of these effects is consistent with the constitutional purpose underlying the Patent Act.

C. *The Graham Inquiries*

Because secondary considerations are likely to become more unreliable when the invention springs from a rapidly expanding scientific field,¹¹⁷ the three *Graham* inquiries may become more important.¹¹⁸ Both the Supreme Court and the CAFC use these inquiries as the foundation of their nonobviousness determinations, but their paths diverge in the interpretation of these findings. In short, the Supreme Court looks for a synergistic or surprising result to find patentability.¹¹⁹ By contrast, the CAFC recognizes the sometimes slow and painful progress of science and demands only that the prior art not explicitly suggest the claimed invention.¹²⁰

The CAFC, in evaluating Hybritech’s claims, considered all the elements, including the 10^8 liters/mole affinity limitation and found that the combination of them was not suggested by the prior art.¹²¹ According to the CAFC, the district court impermissibly determined whether the “gist” or idea of the invention—sandwich assays using monoclonal antibodies—was

117. See *supra* notes 108–110 and accompanying text.

118. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1965). See *supra* text accompanying notes 34–35.

119. See *supra* note 44 and accompanying text.

120. See *supra* text accompanying notes 45–47. A guide to the CAFC’s interpretation of § 103 is found in *Hodosh v. Block Drug Co.*, 786 F.2d 1136 (1986):

[O]bviousness determination[s] generally include the following tenets of patent law that must be adhered to when applying § 103: (1) the claimed invention must be considered as a whole (though the difference between claimed invention and prior art may seem slight, it may also have been the key to advancement of the art); (2) the references must be considered as a whole and suggest the desirability and thus the obviousness of making the combination; (3) the references must be viewed without the benefit of hindsight vision afforded by the claimed invention; (4) “ought to be tried” is not the standard with which obviousness is determined; and (5) the presumption of validity remains constant and intact throughout litigation.

Id. at 1143 n.5.

121. *Hybritech*, 802 F.2d at 1380–81.

disclosed by the prior art.¹²² The district court's finding that the invention was "obvious and logical"¹²³ in light of prior teachings was, therefore, flawed because the court had failed to properly consider the 10^8 liters/mole affinity limitation.¹²⁴ Furthermore, the CAFC viewed as irrelevant references that "establish that it would have been *obvious to try* monoclonal antibodies of 10^8 liters/mole affinity in a sandwich immunoassay that detects the presence of or quantitates antigen."¹²⁵ The prior art, all references taken together, must explicitly suggest the entire invention.

The CAFC's adherence to the explicit suggestion test gives creative attorneys the leeway to search the relevant art to find a limitation to patent claims which, though "obvious" in the nonlegal sense to those skilled in the art, is not explicitly discussed in the literature. This limitation could then be used to render the invention nonobvious.

The 10^8 liters/mole affinity constant limitation could fit this category.¹²⁶ Although in a technical sense, the limitation to antibodies that have a binding strength to the antigen of greater than 10^8 liters/mole was not explicitly present in the prior art, it may have been in the mind of the ordinary person skilled in the art.¹²⁷

The result in *Hybritech* prohibits any other company from producing monoclonal sandwich assay kits using monoclonals that have an affinity greater than 10^8 liters/mole without paying a royalty to Hybritech; this prohibition includes, for all practicable purposes, all usable monoclonal antibodies.¹²⁸ If the affinity constant limitation was known, in a practical sense, to those working in the field, patent protection for Hybritech's invention would violate the goals of the Patent Act because information would be taken from the public domain without any corresponding new advancement to technology.

122. *Id.* at 1380.

123. *Hybritech*, 623 F. Supp. at 1353.

124. *Hybritech*, 802 F.2d at 1381.

125. *Id.* at 1380.

126. *See supra* notes 102-03 and accompanying text.

127. The ability of an antibody to bind selectively to a particular antigen correlates positively with the affinity constant. *See supra* note 107. There is an affinity limit, therefore, below which an antibody would not be expected to bind that antigen selectively; an antibody below this limit would not be effective in a diagnostic test for the presence of that antigen. Nonspecific associative reactions could occur leading to errors in analyses using these lower affinity monoclonal antibodies. *See J. RANSOM supra* note 107, at 44.

128. *See supra* note 62.

D. Possible Remedies

The technical complexity and rapid advances in a scientific field like biotechnology can promote arbitrary patenting decisions. The question arises whether other methods of protecting intellectual property more adequately fulfill the constitutional mandate of promoting science and the useful arts in rapidly expanding scientific fields.

In *Hybritech*, the general idea of using monoclonal antibodies in sandwich assays probably was recognized by many workers in the immunology field shortly after the technique of hybridomas was perfected.¹²⁹ However, a practical application of this idea required expertise and time, both of which can be translated into money.¹³⁰ The Patent Act fostered a horserace to “invent” and reduce to practice a sandwich assay; the winner earned a patent that entitled it to a seventeen-year limited monopoly on the resulting product.

This winner-take-all philosophy may be inappropriate for the production of biotechnological products.¹³¹ Because development and production of these products are expensive and possibly duplicitous, the potential for wasted resources is tremendous.

For instance, in *Hybritech*, at least five other research groups developed sandwich monoclonal assays; however, this concurrent research was not disclosed until after the filing date of Hybritech’s patent application.¹³² Thus, even though at least six groups invested time and money to “select the best antibody-producing clones from perhaps hundreds of thousands”¹³³ of potential clones, only one was eligible for patent protection.

There are similarities between the patenting problems found in bioengineered products and in semiconductor chip products. Transistors, resistors, and capacitors are expensive to design¹³⁴ and easy to copy.¹³⁵ However, most improvements to chips are

129. See *supra* notes 115–16 and accompanying text.

130. See *supra* text accompanying note 112.

131. The CAFC hypothesized that the district court in *Hybritech* adhered to this philosophy. See *supra* note 63.

132. *Hybritech*, 623 F. Supp. at 1354; *Hybritech*, 802 F.2d at 1380 n.4.

133. *Hybritech*, 623 F. Supp. at 1348.

134. The design of a chip can “take the innovating chip firm years, consume thousands of hours of engineer and technician time, and cost millions of dollars. The development costs for a single new chip can reach \$100 million.” H.R. Rep. No. 781, 98th Cong., 2d Sess. 2, reprinted in 1984 U.S. CODE CONG. & AD. NEWS 5750, 5751.

135. “In several months, for a cost of less than \$50,000, a pirate firm can duplicate the

obvious and thereby unpatentable;¹³⁶ furthermore, trade secret laws are of no value once the chip is sold.¹³⁷

The Semiconductor Chip Protection Act of 1984¹³⁸ was the legislative solution to the semiconductor chip dilemma. The Act creates a *sui generis* form of intellectual property; it combines both patent and copyright law with some new concepts. Following registration, the Act gives the owner of a design the exclusive right "to reproduce the mask work, to import or distribute a semiconductor chip product" embodying the mask work, and to license others to do the same.¹³⁹

The Congressional goal of the Act was to provide "particular protection for the costly and time-consuming process of designing the circuitry of semiconductor chips. By according such protection, Congress sought to provide a continuous economic incentive for research and improvement of chip technology through an orderly mode of constructive rivalry."¹⁴⁰ Thus, the inventor is given an incentive to risk time and capital on the invention of a new, but obvious, semiconductor chip. Furthermore, as long as a mask work is created independently, it does not infringe another's work.¹⁴¹

A similar system for registering an inventor's rights to bioengineered products might better promote scientific progress in the biotechnology field than the current patenting scheme.¹⁴²

mask work of an innovator." Samuelson, *Creating a New Kind of Intellectual Property: Applying the Lessons of the Chip Law to Computer Programs*, 70 MINN. L. REV. 471, 491 (1985).

136. See *id.* at 503.

137. Once the semiconductor chip is marketed, competitors can discover how to make the chip by reverse engineering.

138. 17 U.S.C. §§ 901-14 (Supp. V 1987).

139. 17 U.S.C. § 905 (Supp. V 1987). "[A] mask work fixed in a semiconductor chip product' . . . is . . . how the [Semiconductor Chip Protection Act] defines the set of sheets embodying the many individual layer images etched into the semiconductor chip." Rasking & Stern, *Introduction to the Symposium on the Semiconductor Chip Protection Act of 1984 and Its Lessons*, 70 MINN. L. REV. 263, 264 (1985) (quoting 17 U.S.C. § 902(a)(1) (Supp. II 1984)).

140. Rasking & Stern, *supra* note 139, at 264.

141. The standard of originality in copyright law "means only that the work owes its origin to the author, *i.e.*, is independently created, and not copied from other works." 1 M. NIMMER, NIMMER ON COPYRIGHT § 2.01[A], at 2-8 (1988). The Semiconductor Chip Protection Act intended its "originality" requirement to be similar to that of copyright law. See H.R. Rep. No. 781, 98th Cong., 2d Sess. 19, reprinted in 1984 U.S. CODE CONG. & AD. NEWS 5750, 5768.

142. Some also argue that a *sui generis* intellectual property right should also be created for computer programs. See Samuelson, *supra* note 135, at 507.

Because only registration of an independently created bioengineered product would be required, a court or the patent office would no longer have to determine the date of conception of an invention or whether the invention is obvious in light of prior art. Thus, judicial interpretation of complex scientific issues would be minimized. Furthermore, interpretation of conflicting judicial standards and ambiguities regarding secondary considerations would be moot. Following the Semiconductor Chip Act's example, independently created inventions that are similar could both be protected; however, pirated works would be disallowed.

Factors mitigating against the creation of a *sui generis* form of protection for bioengineered products or processes include difficulties in the administration and enforcement of intellectual property rights as the number and kind of rights increase. In particular, because the terms "bioengineered products" or "bioengineering process" are not as clearly defined as the term "semiconductor chips," courts would need to make the technically difficult decision whether an invention was protected. These difficulties would be magnified if the *sui generis* approach were followed for a variety of other inventions, such as superconduction materials, produced from advances in complex, rapidly changing scientific fields.

CONCLUSION

Inventions that are spawned in rapidly expanding scientific fields tend to be distinguished by their technical complexity and expense. Because these inventions incorporate ideas on the cutting edge of science, there is a real danger that courts presented with patent cases will misconstrue the scientific questions presented. A court is obligated to make findings of fact based on the *Graham* criteria; this process entails determining what the ordinary person skilled in a highly technical field knows and how that knowledge differs from the claimed patent. Furthermore, because innovations occur rapidly in a scientific revolution, a court's reliance on secondary considerations such as long-felt need, failure of others, or monetary success of the product may be misplaced. Time may be too brief to effectively evaluate long-felt need and failure of others, while monetary success could be due to other underlying innovations rather than the invention.

A court put in this difficult position must also grapple with conflicting patentability standards promulgated by the Supreme

Court and the CAFC. A district court must choose between following the standards of the Supreme Court or the CAFC; the choice to follow the standards of one will most likely lead to reversal by the other.

The conflict over the appropriate application of the patentability standards promotes a more subjective approach to patentability decisions. The uncertainty created by this subjective approach could result in unjustified monopolistic protection for "obvious" inventions. Also, a strict interpretation of the patentability hurdles could inhibit inventors from inventing or investors from underwriting the products. Both of these results violate the constitutional mandate of the Patent Act.

Although a possible solution for at least some of the inventions arising from scientific revolutions might lie with *sui generis* protection similar to that afforded by the Semiconductor Chip Protection Act, multiplicity of different kinds of intellectual property rights, with their own peculiar standards, could muddy the waters even further. There are no easy answers for the problems presented in this Comment. However, because scientists working in complex scientific fields will continue to invent, all involved with patent law should carefully consider and address the unique problems raised by these inventions.

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