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A PROPOSED TEST FOR APPLYING THE DOCTRINE OF EQUIVALENTS TO BIOTECHNOLOGY INVENTIONS: THE NONOBVIOUSNESS TEST

Qing Lin, Ph.D.

Abstract: In patent law, the doctrine of equivalents allows courts to find infringement if one makes or uses a device or process without substantial change from a patented invention. A test that clearly defines the appropriate scope of patent protection is crucial to development in various industries, especially in biotechnology, an industry that requires significant long-term investment. However, the most commonly applied test for determining equivalents is vague and fails to provide practical guidance. The “all elements” limitation to the test causes additional confusion. A more appropriate test for defining the scope of patent protection would be the “nonobviousness test,” a test similar to the nonobviousness requirement when inventors first apply for patents. The proposed test would benefit from a rich body of case law on the nonobviousness requirement for obtaining patents, would evaluate inventions as a whole, and would provide appropriate protection to patent owners. This Comment examines the recent development of the doctrine of equivalents, analyzes the problems with the current test that courts use to apply the doctrine, and urges courts to adopt the nonobviousness test to resolve patent infringement cases.

Consider Company A, which spent years of effort and millions of dollars to develop and patent a recombinant protein (Recombinant Protein A) that can dissolve blood clots and prevent heart attacks. Consider Company B, which also invested significant effort and money to develop a recombinant protein (Recombinant Protein B) that is structurally similar to Recombinant Protein A. Recombinant Protein B has less ability to dissolve blood clots than Recombinant Protein A, but is less likely to cause uncontrolled bleeding. Does Recombinant Protein B infringe the patent of Recombinant Protein A? The answer depends on whether Recombinant Protein B is considered the “equivalent” of Recombinant Protein A under the doctrine of equivalents.¹ Thus, the determination of equivalency among different inventions is crucial to both patent holders and those inventors working in fields, in which there are already a myriad of existing patents. Therefore, the legal test courts adopt to apply the doctrine of equivalents must provide clearly defined and appropriate boundaries both to protect those with patented inventions

1. *See* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607–08 (1950) (stating that patent infringement is not limited to copying patented devices, but also includes making or using equivalent devices); *see also* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 25–28 (1997) (upholding doctrine of equivalents).

and to encourage others with genuinely new inventions to disclose their discoveries to the public.

The current test for the application of the doctrine of equivalents, however, fails to define clearly the patent protection scope. Under the doctrine, the accused device is equivalent to the patented device if there is no substantial difference between them.² To determine whether there is a substantial difference, courts often apply the function-way-result test, which examines whether the accused device performs substantially the same function in substantially the same way to obtain substantially the same result.³ However, the test provides little practical guidance because the word “substantially” is inherently vague.⁴ An additional factor for determining substantial difference is “known interchangeability,” which asks whether a person with ordinary skill in the pertinent technical area would have known of interchangeability between each element of the accused device and its corresponding element in the patented device.⁵ However, the factor’s usefulness is limited by the lack of an appropriate definition of the term “element” and the courts’ failure to examine inventions as a whole.

This Comment urges courts to adopt a test similar to the invention standard for obtaining a patent—the nonobviousness requirement—to define the scope of patent protection. Part I briefly introduces patent protection of biotechnology products. Part II describes the current test courts use in applying the doctrine of equivalents as well as the policy issues underlying the doctrine. Part III discusses the problems with this current test, especially in biotechnology. Part IV explores the nonobviousness requirement for patentability and proposes a similar test for determining equivalency in infringement cases. This Comment concludes that courts should adopt the nonobviousness test for the application of the doctrine of equivalents.

2. See *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517, 1519 (Fed. Cir. 1995) (en banc) (per curiam), *rev'd on other grounds*, 520 U.S. 17.

3. See *Graver Tank*, 339 U.S. at 608; *Hilton Davis*, 62 F.3d at 1522.

4. See *infra* Part III.A.

5. See *Warner-Jenkinson*, 520 U.S. at 36; *Hilton Davis*, 62 F.3d at 1519 (quoting *Graver Tank*, 339 U.S. at 609).

I. A PRIMER ON PATENT PROTECTION OF BIOTECHNOLOGY PRODUCTS

The U.S. patent system encourages inventors to disclose their inventions to the public by granting inventors rights to exclude others for a limited period of time from using, making, selling, or offering to sell their inventions.⁶ To be eligible for a patent, the invention must not be obvious to a person having ordinary skills in the pertinent technical area.⁷ Upon issuance of the patent, the patent owner can enforce his or her rights against others who use or make the patented device or its equivalents.⁸ Properly defining the scope of patent protection is imperative to technological development, especially in biotechnology, an industry that requires significant long-term investment.⁹

A. *An Overview of the Patent System*

1. *The U.S. Constitution*

The U.S. Constitution gives Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹⁰ Congress implemented this power by establishing the patent system.¹¹ Under this system, patentees disclose their inventions to the public¹² in exchange for the right to exclude others.¹³ The award of monopoly helps ensure that patentees will recoup their research costs and

6. See 35 U.S.C.A. § 154(a)(1) (West Supp. 1998). The statute provides that “[e]very patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.” 35 U.S.C.A. § 154(a)(1). The patentee’s rights to exclude others from profiting from the patented invention ends 20 years after the patent application filing date. See 35 U.S.C.A. § 154(a)(1).

7. See 35 U.S.C.A. § 103(a) (West Supp. 1998).

8. See 35 U.S.C.A. § 271(a) (West Supp. 1998) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

9. See *infra* Part I.B.

10. U.S. Const. art. I, § 8, cl. 8.

11. See Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.

12. See 35 U.S.C. § 112 (1994) (requiring patentee to disclose how to make and use invention and what is contemplated best mode of carrying out invention).

13. See 35 U.S.C.A. § 154(a)(1) (West Supp. 1998).

profit from their inventions, thereby encouraging inventors to disclose useful innovations to the public.¹⁴

2. Patent Prosecution

Patent prosecution is the process by which inventors obtain patents by applying with the U.S. Patent and Trademark Office.¹⁵ A patent application contains a specification and claims.¹⁶ The specification describes the invention and how to make and use the invention.¹⁷ Claims delineate the scope of an inventor's patent so that others may either license the invention or try to design around it.¹⁸

To be eligible for patent protection, an invention must be useful, novel, and nonobvious.¹⁹ An invention is useful if it benefits humanity.²⁰ It is novel if, as of the filing date of the patent application, the invention has not been published, publicly sold or used, previously invented, or abandoned.²¹ An invention is nonobvious if, at the time of invention, a person having ordinary skill in the pertinent technical area would not have found the invention obvious in light of prior art.²² The term "prior art" includes any relevant knowledge, art descriptions and patents that pertain to but predate the invention at issue.²³

14. See Jeffrey S. Dillen, Comment, *DNA Patentability—Anything But Obvious*, 1997 Wis. L. Rev. 1023, 1026.

15. See 35 U.S.C.A. § 111 (West Supp. 1998) (requiring inventor to file patent application); Martin J. Adelman et al., *Cases and Materials on Patent Law* 708 (1998) (defining patent prosecution as administrative process through which inventor acquires patent).

16. See 35 U.S.C.A. § 111; 35 U.S.C. § 112. Technically, a specification includes claims. See 35 U.S.C. § 112 ("The specification shall conclude with one or more claims . . ."). However, patent practitioners usually regard claims as an element separate from a specification.

17. See 35 U.S.C. § 112 ("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 person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.").

18. See 35 U.S.C. § 112 (requiring claims to particularly point out and distinctly claim subject matter of invention).

19. See 35 U.S.C. §§ 101–102 (1994); 35 U.S.C.A. § 103(a) (West Supp. 1998).

20. See 35 U.S.C. § 101; see also Donald S. Chisum & Michael A. Jacobs, *Understanding Intellectual Property Law* § 2C[2], at 2-50 (1996).

21. See 35 U.S.C. § 102.

22. See 35 U.S.C.A. § 103(a).

23. See *Mooney v. Brunswick Corp.*, 663 F.2d 724, 733 (7th Cir. 1981); see also Brian E. Lewis, Comment, *Expanding the Use of Hypothetical Analysis When Evaluating Patent Infringement Under*

3. *The Effect of Obtaining a Patent*

A patent provides an inventor the right to exclude others for a limited period of time from using, making, offering to sell, selling, or importing the patented inventions without authorization.²⁴ If a person makes or uses a device having every element in a patent claim, the device literally infringes the patent.²⁵ However, the scope of a patentee's protection under patent law is broader than mere literal infringement.²⁶ An accused device may infringe a patent under the doctrine of equivalents even though it does not duplicate every element in the claim.²⁷ The doctrine of equivalents protects a patentee's rights against others who make insubstantial changes to the patentee's claimed invention to escape the plain language of the patent.²⁸

B. *The Importance of Patent Protection in Biotechnology*

Biotechnology uses living organisms to make commercially and therapeutically valuable products and processes, including therapeutic compositions, agricultural products, and industrial products.²⁹ For instance, recombinant protein technique has allowed the production of a large quantity of growth factors and enzymes useful in the treatment of various diseases.³⁰ Transgenic plant technology has improved crops'

the Doctrine of Equivalents, 16 U. Puget Sound L. Rev. 1409, 1410 n.9 (1993) (stating that prior art can be understood to mean "existing technology").

24. See 35 U.S.C.A. §§ 154, 271(a) (West Supp. 1998).

25. See *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950) ("if accused matter falls clearly within the claim, infringement is made out . . ."); Ronald D. Hantman, *Patent Infringement*, 72 J. Pat & Trademark Off. Soc'y 454, 497 (1990) (stating that literal infringement occurs when accused product or process is within scope of wording of claim).

26. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 25–28 (1997); *Graver Tank*, 339 U.S. at 607–09.

27. *Graver Tank*, 339 U.S. at 609 (holding that flux composition that substituted silicates of calcium and manganese for silicates of calcium and magnesium in patented flux composition infringed patented flux composition).

28. See *id.*

29. See Rochelle K. Seide, *Landis on Mechanics of Patent Claim Drafting* IX-1 (Robert C. Faber ed., 4th ed. 1996).

30. See *Competitiveness of the U.S. Biotechnology Industry: Hearing Before the Subcomm. on Science, Tech., and Space of the Senate Comm. on Commerce, Science, & Transp.*, 103d Cong., 3 (1994) [hereinafter *Biotech Hearing*]. See, e.g., U.S. Patent No. 4,752,603, No. 4,766,075, No. 4,853,330 (claiming tissue plasminogen activator ("t-PA"), which can dissolve clots in blood vessels and is beneficial to heart-attack patients). For detailed description of t-PA, see *infra* Part III.A.2.

resistance to external stress.³¹ In addition, natural and genetically engineered microorganisms have been used to decontaminate soil and water.³²

Biotechnology is a fast-growing industry. Worldwide annual sales of biotechnology-derived products grew from zero in 1980 to seven billion dollars by 1993.³³ In 1997, the annual revenue of publicly traded biotechnology companies exceeded sixteen billion dollars.³⁴

Proper patent protection is especially important for the continued growth of the biotechnology industry. The development of commercial biotechnology products is time-consuming and expensive.³⁵ In 1997, it took an average of 15.3 years before a new drug could be put on the market: 6.1 years to discover, 6.9 years to clinically develop, and 2.3 years for FDA approval.³⁶ The average cost of developing a biotechnology-derived product and bringing it to the market was \$359 million dollars in 1993.³⁷ Because of the cutting-edge nature of the industry, it was estimated that only five out of 4000 compounds tested in preclinical trials were eventually tested on humans.³⁸ Even then the FDA approved only one of those five compounds tested on humans.³⁹ Thus, without appropriate patent protection, investors would be understandably reluctant to invest time and money in the biotechnology industry. Without that investment, the public ultimately suffers.⁴⁰

31. See *Biotech Hearing*, *supra* note 30, at 29 (1994).

32. See, e.g., U.S. Patent No. 5,814,514 (claiming method for degrading undesirable ether-based environmental contaminant with propane-oxidizing microorganism or isopropanol-oxidizing microorganism); U.S. Patent No. 5,567,304 (claiming method of biodegrading hydrophobic organic compounds with microorganism).

33. See *Biotech Hearing*, *supra* note 30, 18, 29.

34. See *Public Biotech: The Numbers*, 16 *Nature Biotechnology* 425 (1998).

35. See Alan Walton, *The Annual State of the Biotech Industry Address: Walton's Words of Wisdom*, 13 *BioVenture View* 1 (1998); *Biotech Hearing*, *supra* note 30, at 56 (testimony of Mark Skaletsky, CEO of GelTex Pharmaceuticals).

36. See Walton, *supra* note 35, at 1.

37. See *Biotech Hearing*, *supra* note 30, at 56 (testimony of Mark Skaletsky, CEO of GelTex Pharmaceuticals).

38. See *id.*

39. See *id.*

40. See Shaoyi Alex Liao, *Resolving the Dilemmas Between the Patent Law and Biotechnology: An Analysis of Three Recent Biotechnology Patent Cases*, 11 *Santa Clara Computer & High Tech. L.J.* 229, 231 (1995).

II. THE DOCTRINE OF EQUIVALENTS

The doctrine of equivalents delineates the scope of patent protection by determining whether an accused device is equivalent to the patented invention.⁴¹ Although the doctrine originated over a century ago,⁴² courts have failed to develop a clear test for determining how the doctrine applies.⁴³ Recently, recognizing the inadequacy of the most commonly used function-way-result test,⁴⁴ the Federal Circuit set forth the “insubstantial difference” test as the ultimate test for the doctrine.⁴⁵ It included “known interchangeability” as an additional factor for determining insubstantial differences between accused and patented devices.⁴⁶ Courts also have imposed limitations on the doctrine to prevent the undue expansion of the scope of the patent protection and to provide adequate public notice.⁴⁷

A. *Competing Policy Issues Underlying the Doctrine of Equivalents*

The doctrine of equivalents attempts to balance two competing policy concerns: (1) protecting patentees’ exclusive rights to inventions against others that make insignificant changes to the patented inventions, and (2) providing the public with notice about the limits of the patent monopoly.⁴⁸ On one hand, to limit the scope of the patent protection to the literal wording of the claims “would be to convert the protection of the patent grant into a hollow and useless thing.”⁴⁹ Such a limitation would encourage unscrupulous copyists to make insignificant changes to

41. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 25–28 (1997); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950).

42. See *Winans v. Denmead*, 56 U.S. (15 How.) 330, 339 (1853) (holding that pyramidal-shaped railroad car infringed patent relating to conical-shaped railroad car).

43. See *Warner-Jenkinson*, 520 U.S. at 39–40 (pointing out shortcomings of function-way-result test and insubstantial difference test).

44. See *id.*

45. See *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1516 (Fed. Cir. 1995) (en banc) (per curiam), *rev’d on other grounds*, 520 U.S. 17.

46. See *Warner-Jenkinson*, 520 U.S. at 36; *Hilton Davis*, 62 F.3d at 1519.

47. See *Warner-Jenkinson*, 520 U.S. at 29–30.

48. See *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991); Ronald E. Larson, *Balancing the Competing Policies Underlying the Doctrine of Equivalents in Patent Law*, 21 *AIPLA Q.J.* 1, 28 (1993); Werner Stemer, *The Doctrine of Equivalents After Hilton Davis and Markman and a Proposal for Further Clarification*, 22 *Nova L. Rev.* 783, 794 (1998).

49. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950).

the patented devices so they could enjoy the fruit of patentees' labor.⁵⁰ It would effectively deprive patentees of the benefit of their inventions and would foster concealment rather than disclosure of inventions.⁵¹ On the other hand, other inventors are entitled to notice of the boundaries of patents so that they can either license inventions from patentees or legally design around the inventions.⁵² Both policies promote innovation in technology.⁵³

B. The Evolving Test for the Doctrine of Equivalents

I. Graver Tank & Manufacturing Co. v. Linde Air Products Co.

In a landmark decision, *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*,⁵⁴ the U.S. Supreme Court held that a patentee may invoke the doctrine of equivalents to prohibit the production of a device if it performed substantially the same function in substantially the same way to obtain the same result as the patented device.⁵⁵ The issue in that case was whether a change in the chemical composition of an electric welding flux was insubstantial enough to invoke the doctrine of equivalents.⁵⁶ The Court reasoned that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape."⁵⁷ Based on the trial court's finding that the accused product was substantially identical to the patented device in both operation and result, the *Graver Tank* majority held that the defendant infringed the patent.⁵⁸

50. *See id.*

51. *See id.*

52. *See* *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.* 62 F.3d 1512, 1541 (Fed. Cir. 1995) (Plager, J., dissenting), *rev'd on other grounds*, 520 U.S. 17; *see also* *Warner-Jenkinson*, 520 U.S. at 29 (stating that broad application of doctrine of equivalents conflicts with definitional and public-notice functions of statutory claiming requirement).

53. *See* *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 945 (Fed. Cir. 1987) (Bennett, J., dissenting).

54. 339 U.S. 605.

55. *See id.* (citing *Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877)).

56. *See id.* at 606-07. The patent claims for the flux composition included essentially a combination of alkaline earth metal silicates (silicates of calcium and magnesium) and calcium fluoride. *See id.* at 610. The accused flux substituted silicates of calcium and manganese—the latter not an alkaline earth metal—for silicates of calcium and magnesium. *See id.* In all other respects, the two compositions were alike. *See id.*

57. *Id.* at 608 (quoting *Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877)).

58. *See id.* at 611-12.

In addition to the function-way-result test, the Court also required that equivalency be determined in consideration of the context of the patent, the prior art, and the particular circumstances of the case.⁵⁹ It further emphasized “known interchangeability”—whether persons reasonably skilled in the relevant technical area would have known of the interchangeability of an ingredient not contained in the patent with one that was—as an important factor to consider in applying the doctrine of equivalents.⁶⁰ Finally, the Court regarded the evidence of independent research or experiments by the accused infringer as relevant in determining equivalency.⁶¹

2. Hilton Davis Chemical Co. v. Warner-Jenkinson Co.

During the forty years following the *Graver Tank* decision, courts exclusively applied the function-way-result test.⁶² However, in *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*,⁶³ the Federal Circuit rejected the *Graver Tank* Court’s regard for the function-way-result test as the only test for the doctrine of equivalents.⁶⁴ The Federal Circuit held that the ultimate test for infringement analysis was the “insubstantial difference” test, which asks whether the accused device was substantially different from the patented device.⁶⁵ The court stated that the function-way-result test would often suffice to show the extent of the differences between the accused and patented devices.⁶⁶ The court, however, noted that other factors, such as evidence of the known interchangeability of the accused and patented elements, evidence of copying, and evidence of designing around a patented invention, might also be informative in some cases.⁶⁷ In addition, the court explained that evidence of independent research by the accused infringer was relevant to equivalency analysis because it was useful to refute a patent owner’s

59. *See id.* at 609.

60. *See id.*

61. *See id.* at 611–12.

62. *See* Adelman et al., *supra* note 15, at 900.

63. 62 F.3d 1512 (Fed. Cir. 1995) (en banc) (per curiam), *rev’d on other grounds*, 520 U.S. 17 (1997).

64. *See id.* at 1518.

65. *See id.* at 1517.

66. *See id.*

67. *See id.* at 1519–20.

contention that the accused infringer copied the substance of the patented invention.⁶⁸

3. Warner-Jenkinson Co. v. Hilton Davis Chemical Co.

The U.S. Supreme Court granted certiorari in *Hilton Davis*, but did not clarify which test—the function-way-result test or the “insubstantial difference” test—was appropriate in applying the doctrine of equivalents. The Court left that decision to the Federal Circuit’s discretion.⁶⁹ The Supreme Court regarded the particular linguistic framework for applying the doctrine as less important than whether courts directed their inquiries at the essential issue: did the accused device contain elements equivalent to the patented invention?⁷⁰ It held that different tests might be desirable in different situations.⁷¹

However, the U.S. Supreme Court rejected the Federal Circuit’s explanation about why evidence of independent research by an accused infringer was relevant to the equivalency determination.⁷² The Court held that the evidence of independent research was relevant not because it might disprove the contention that the accused infringer copied the patented invention, but instead because tend to prove whether a person skilled in the relevant technical area would have known of the interchangeability between elements in the accused and patented devices.⁷³ The Supreme Court criticized the Federal Circuit’s suggestion that an alleged infringer’s behavior, whether copying or designing around a patent, indirectly reflects the substantiality of the differences between the accused and patented devices.⁷⁴ The Court pointed out that it was nearly impossible to “distinguish between the intentional copyist making minor changes to lower the risk of legal action and the incremental innovator designing around the patented device, yet seeking to retain as much as is permissible of the patented advance.”⁷⁵

68. *See id.* at 1520.

69. *See Warner-Jenkinson*, 520 U.S. at 40.

70. *See id.*

71. *See id.* (“Different linguistic frameworks may be more suitable to different cases, depending on their particular facts.”).

72. *See id.* at 35–36.

73. *See id.* at 36.

74. *See id.* at 35.

75. *Id.* at 36.

In sum, because the U.S. Supreme Court in *Warner-Jenkinson* indicated that the Federal Circuit was responsible for the development of the test for applying the doctrine of equivalents, the current test seems to be the “insubstantial difference” test. To determine whether there is substantial differences between the accused and the patented devices, courts ask whether the accused device performs a substantially similar function in a substantially similar way to achieve a substantially similar result as the patented device. In addition, courts may consider other evidence such as the known interchangeability between the accused and the patented devices and the evidence of independent research by the accused infringer.

C. *Limitations to the Doctrine of Equivalents’ Application*

The application of the doctrine of equivalents is limited by three legal tenets that play important roles in infringement cases.⁷⁶ These limitations are intended to prevent undue expansion of the scope of patent protection and to provide adequate public notice.

1. *The All Elements Rule*

The all elements rule requires courts to apply the doctrine of equivalents to individual elements of a claim, not to the invention as a whole.⁷⁷ Accordingly, infringement occurs only if each element of a claim either literally or equivalently exists in the accused product.⁷⁸

However, the courts’ application of the all elements rule has become less stringent over the years. Initially, courts required a one-to-one correspondence of the individual elements between the accused and the patented devices.⁷⁹ Later, the Federal Circuit held that the all elements requirement was met if an equivalent element exists for every element of the claim somewhere in the accused device, but not necessarily in a corresponding component.⁸⁰ Even after the U.S. Supreme Court

76. See Adelman et al., *supra* note 15, at 934.

77. See *Warner-Jenkinson*, 520 U.S. at 29.

78. See *Pennwalt Corp. v. Durand-Wayland Inc.*, 833 F.2d 931, 935 (Fed. Cir. 1987) (citing *Lemelson v. United States*, 752 F.2d 1538, 1551 (Fed. Cir. 1985)).

79. See *id.* at 939 (holding that accused fruit sorter did not infringe patented sorter because memory components of accused sorter did not perform same or equivalent function of corresponding components of patented sorter).

80. See *Coming Glass Works v. Sumitomo Elec. U.S.A., Inc.* 868 F.2d 1251, 1259 (Fed. Cir. 1989) (holding that accused optical fiber with negatively doped cladding and core was equivalent to

emphasized the importance of the all elements rule,⁸¹ the Federal Circuit further relaxed the rule's application and found infringement even when the accused device did not have all the elements of the patented product.⁸² The Federal Circuit stated that the lack of an element should not change the analysis of infringement under the doctrine of equivalents if later-developed technology obfuscated the significance of the limitation.⁸³

2. *Prosecution History Estoppel*

Prosecution history estoppel precludes patentees from asserting equivalence to the subject matter they clearly gave up when the Patent and Trademark Office (PTO) rejected their patent applications.⁸⁴ Prosecution history includes all of the documents that record the communications between a patent applicant and the PTO during patent prosecution.⁸⁵ However, not every amendment or argument that a patentee made during patent prosecution automatically surrenders the subject matter that the amendment or argument concerns.⁸⁶ Prosecution history estoppel bars the doctrine of equivalents' application only to the subject matter of arguments or amendments that relate to patentability or that otherwise clearly indicate the abandonment of the subject matter.⁸⁷

patented fiber with cladding and positively doped core because limitation of appropriate refraction index differential between cladding and core was found in accused fiber).

81. See *Warner-Jenkinson*, 520 U.S. at 29.

82. See *Hughes Aircraft Co. v. United States*, 140 F.3d 1470, 1475 (Fed. Cir. 1998) (holding that although accused device did not have limitations relating to sending instantaneous spin angle position data to ground crew, it nevertheless infringed patented device).

83. See *id.*

84. See *Chisum & Jacobs*, *supra* note 20, § 2F[2][c], at 2-270. This doctrine is also referred to as "file-wrapper estoppel." *Id.*

85. See generally 4 Donald S. Chisum, *Patents* § 18.05, at 18-151 (1992).

86. See *Warner-Jenkinson*, 520 U.S. at 33 (stating that where reason for amendment was not related to avoiding prior art, introduction of new element by amendment does not necessarily preclude application of doctrine of equivalents).

87. The standard for determining whether prosecution history estoppel should apply to a subject matter is "whether one of ordinary skill in the art would objectively conclude from the prosecution history that an applicant surrendered it." *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1462 (Fed. Cir. 1998). The court listed three situations where the prosecution history estoppel applies: (1) the subject matter was deemed unpatentable in view of the prior art, (2) an applicant narrowed a claim element in the face of an examiner's rejection based on the prior art, and (3) an applicant's arguments clearly and unmistakably surrendered the subject matter. See *id.*

3. *The Prior Art*

The prior art itself imposes the third limitation on the application of the doctrine of equivalents.⁸⁸ The rationale underlying this limitation is that patentees should not be able to expand patent protection to cover subject matter on which they could not have obtained patents from the PTO in the first place.⁸⁹ Because the prior art limits what inventors could have claimed, it also limits the applicability of the doctrine of equivalents.⁹⁰

In *Wilson Sporting Goods Co. v. David Geoffrey & Associates*,⁹¹ the Federal Circuit established a method of determining whether the prior art prevented a patentee from invoking the doctrine of equivalents.⁹² The issue in that case was whether Dunlop's golf balls infringed Wilson's golf ball patents.⁹³ The court suggested that it might be helpful to first draft a hypothetical patent claim sufficient in scope to cover both the patented and the accused devices.⁹⁴ The inquiry then became whether the PTO would have allowed the hypothetical claim in light of the prior art.⁹⁵ If the PTO allowed the hypothetical claim, then prior art would not bar a finding of infringement under the doctrine of equivalents.⁹⁶ Finding that the hypothetical claim covering both Dunlop's and Wilson's golf balls would be obvious in light of the prior art, the Federal Circuit held that Dunlop did not infringe Wilson Sporting Goods' patent.⁹⁷

III. PROBLEMS WITH THE CURRENT TEST FOR THE DOCTRINE OF EQUIVALENTS

The current test for the application of the doctrine of equivalents creates problems in resolving infringement cases. The function-way-

88. See *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed. Cir. 1990). For the definition of the term "prior art," see *supra* note 23.

89. See *Wilson Sporting Goods*, 904 F.2d at 684.

90. See *id.*

91. 904 F.2d 677.

92. See *id.* at 684.

93. See *id.* at 678-81. David Geoffrey & Associates owns Dunlop.

94. See *id.* at 684.

95. See *id.*

96. See *id.*

97. See *id.* at 685. A person cannot get a patent for an obvious invention. See 35 U.S.C.A. § 103 (West Supp. 1998).

result test only describes the essential equivalence inquiry in a slightly different way and thus fails to provide any practical guidance. In addition, the test is not applicable to certain infringement disputes in biotechnology. Although the known interchangeability factor is helpful for courts to determine equivalency, it is only a factor rather than an independent test and it is not a mandatory consideration in all cases. Furthermore, the all elements rule adds another level of confusion to the current test because courts must first define what constitutes an element and then examine the equivalency for each element of a patent claim.

A. The Function-Way-Result Test Is Inappropriately Vague

The function-way-result test provides little guidance to the courts because it is essentially a different expression of the equivalency inquiry. Although the test directs the inquiry to three aspects of an invention,⁹⁸ it nevertheless fails to define what constitutes a significant difference in the function, way, and result of an accused device when the accused device is compared to the patented device.⁹⁹ The lack of clearly delineated underlying principles in determining the substantial differences between the accused and the patented devices renders courts' application of the test unhelpful in terms of precedential value.¹⁰⁰

Prevalent litigation practices also undermine the utility of the function-way-result test.¹⁰¹ Litigants generally characterize the inventions' function, way, and result differently. Patentees describe these terms broadly while the accused infringers define the terms narrowly.¹⁰²

98. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39–40 (1997).

99. See Michael T. Siekman, *The Expanded Hypothetical Claim Test: A Better Test for Infringement of Biotechnology Patents Under the Doctrine of Equivalents*, 2 B.U. J. Sci. & Tech. L. 6 at ¶ 5, Mar. 27, 1996, available in LEXIS, Mass. Library, BUJSTL file. (criticizing question-begging nature of function-way-result test).

100. See *Claude Neon Lights, Inc. v. Marchlett's Sons*, 36 F.2d 574, 576 (2d Cir. 1929). Judge Learned Hand commented on the test's deficiency: "Each case is inevitably a matter of degree, as so often happens, and other decisions have little or no value. The usual ritual [of invoking function, way, and result], which is so often repeated and which has so little meaning, . . . does not help much in application; it is no more than a way of stating the problem." *Id.*; see also Chisum, *supra* note 85, § 18.04[5], at 18-405 (stating that function-way-result test is too general to be of much assistance in resolution of particular problems).

101. See Adelman et al., *supra* note 15, at 900; Chisum, *supra* note 85, § 18.04[5], at 18-407.

102. See Chisum, *supra* note 85, § 18.03[2], at 18-111; Chisum & Jacobs, *supra* note 20, § 2F[2][b], at 2-255.

Often a court's determination of infringement simply depends upon whose characterization it accepts.¹⁰³

B. The Function-Way-Result Test Is Not Applicable in Certain Biotechnology Patent Infringement Disputes

In *Warner-Jenkinson*, the U.S. Supreme Court stated that although the function-way-result test might be suitable for analyzing mechanical devices, it provides a poor framework for analyzing other products or processes.¹⁰⁴ The Court's observation proves especially true as applied to biotechnological inventions.

The function, way, and result components are often indistinguishable from one another in the biotechnology context, as illustrated in *Genentech, Inc. v. Wellcome Foundation Ltd.*¹⁰⁵ This Federal Circuit case concerned a patented recombinant protein, tissue plasminogen activator (t-PA), which activates plasminogen and converts it to plasmin.¹⁰⁶ The accused product, FE1X, was a modified protein with the same activating function and was also produced by using recombinant technology.¹⁰⁷ The Federal Circuit defined the function of human t-PA for the purposes of equivalency analysis as being a catalyst for converting plasminogen to plasmin and binding plasmin to fibrin.¹⁰⁸ It noted that the affinity to fibrin, the mode of binding to fibrin, and the half-life of FE1X were different from the patented t-PA.¹⁰⁹ Thus, the court held that FE1X was not an equivalent of the patented t-PA.¹¹⁰

In his concurring opinion, Judge Lourie emphasized the limitation of the function-way-result test.¹¹¹ He criticized the test because it did not

103. See *Chisum & Jacobs*, *supra* note 20, § 2F[2][b], at 2-255.

104. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997).

105. 29 F.3d 1555 (Fed. Cir. 1994).

106. See *id.* at 1557. Plasmin is an enzyme that binds to fibrin and severs the bonds between the fibrin molecules, resulting in the dissolution of fibrin clots in the human body. See *id.* The t-PA consists of five separate domains: the Finger (F) region, the Epidermal Growth (E) region, the Kringle 1 (K1) region, the Kringle 2 (K2) region, and the Serine Protease (P) region. See *id.* at 1559 n.4.

107. See *id.* at 1557, 1559 n.4. FE1X lacked the F region and most of the E region of natural t-PA and had an amino acid substitution at position 117 of K1 region, which eliminated one of the carbohydrate chains. See *id.* at 1559 n.4.

108. See *id.* at 1567.

109. See *id.* at 1568-69.

110. See *id.* at 1569.

111. See *id.* at 1570.

fully elucidate the equivalency inquiry in infringement cases that involved chemical or biotechnological products.¹¹² He found it difficult to decide whether the half-life should be part of the “way” analysis or a different “result,” and whether the binding to fibrin constituted “function” or part of the “way” t-PA dissolves clots.¹¹³

Another reason for the difficulty in applying the function-way-result test to biotechnological inventions is that scientists often know little about how these inventions actually work and therefore can never fulfill the “way” requirement.¹¹⁴ In such situations, a judge or a jury may reduce the function-way-result test to a mere comparison of observable end results between the accused and the patented products.¹¹⁵ This is exactly what happened in *Genentech*. Supposing that the majority was correct in concluding that the binding of t-PA to fibrin was the “function” of t-PA, then the manner in which the t-PA binds to fibrin and the affinity of t-PA to fibrin became the “way” and the “result,” respectively. Because Genentech did not know the mechanism for the binding, the court relied heavily on the FE1X’s relatively low affinity to fibrin to reach its conclusion that FE1X was not equivalent to t-PA.¹¹⁶

C. *The Usefulness of the Known Interchangeability Factor Is Limited*

Unlike the inherently vague function-way-result test, the known interchangeability factor can be somewhat useful in resolving patent infringement disputes. However, its usefulness is limited. The known interchangeability is but one factor to be considered and does not by itself establish equivalence.¹¹⁷ In addition, courts do not have to consider this factor in every case. The Federal Circuit stated that the function-way-result test alone often suffices to determine equivalency if similarity of function, way, and result left little doubt that there were only

112. *See id.*

113. *See id.*

114. *See* Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection*, 102 Yale L.J. 777, 791 (1992).

115. *See id.*

116. *See Genentech*, 29 F.3d at 1568–69.

117. *See* Key Mfg. Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1449 (Fed. Cir. 1991) (stating that “an interchangeable device is not necessarily an equivalent device,” and holding that trial judge erroneously relied on interchangeability of patented and accused capped wheel nuts to support finding of infringement under doctrine of equivalents).

insubstantial differences between the accused and the patented devices.¹¹⁸ The court further indicated that whether trial courts should consider other factors would depend on the way the parties framed their arguments.¹¹⁹

D. The All Elements Rule Increases Current Confusion

The U.S. Supreme Court's recent emphasis on the all elements rule further complicates equivalency analysis. Unlike the other two limitations to the application of the doctrine of equivalents, the all elements rule is unsound in principle. Expanding one element into two or combining two elements into one should not change the application of the doctrine of equivalents.¹²⁰ Although the Federal Circuit recognized that a strict application of an all elements approach was little more than a literal infringement inquiry,¹²¹ the Federal Circuit failed to define how far beyond the literal scope of a claim the all elements rule should limit the application of the doctrine of equivalents.¹²² Even though the Federal Circuit recently relaxed the application of the rule,¹²³ different courts or panels may draw inconsistent conclusions in resolving infringement disputes due to their differing interpretations of the rule.

In addition, the all elements rule greatly frustrates patent law's public notice purpose. Given the countless variety of inventions, it is difficult to define the term "element." Courts must determine on a case-by-case basis what constitutes an element for the equivalency analysis. For instance, it is uncertain whether a claim directed to a DNA or protein sequence consists of only one element or whether each nucleotide, codon (three consecutive nucleotides encoding an amino acid), amino acid, or

118. See *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1518 (Fed. Cir. 1995) (en banc) (per curiam), *rev'd on other grounds*, 520 U.S. 17 (1997).

119. See *id.* at 1522.

120. See *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 968 (Fed. Cir. 1987) (Newman, J., commenting).

121. See *id.* at 939–40 (Bennett, J., dissenting); see also *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1317 (Fed. Cir. 1998) (“[A]ny analysis of infringement under the doctrine of equivalents necessarily deals with subject matter that is ‘beyond,’ ‘ignored’ by, and not included in the literal scope of a claim.”).

122. See *Ethicon Endo-Surgery, Inc.*, 149 F.3d at 1317 The court stated that “subject matter [that is beyond, ignored by, and not included in the literal scope of a claim] is not necessarily ‘specifically excluded’ from coverage under the doctrine [of equivalents] unless its inclusion is somehow inconsistent with the language of the claim.” The court’s statement is ambiguous because subject matter outside the literal scope of a claim, strictly speaking, is inconsistent with the language of the claim.

123. See *supra* Part II.C.1.

protein domain (such as the F region and the E region of t-PA) is a distinct element.¹²⁴ This uncertainty is likely to stunt the growth of the biotechnology industry because investors will be reluctant to sponsor a project without a reliable prediction about whether that project will infringe others' patents.

Furthermore, due to the vague definition of "element,"¹²⁵ the case law will have to evolve significantly before the application of the all elements rule is refined, if it can be refined at all.¹²⁶ So far, the Federal Circuit has declined to adopt any definitive formula to determine how equivalency to a required element in a patent claim is met.¹²⁷ The Federal Circuit, however, agreed with the use of the function-way-result test by a district court in determining whether elements of an accused device were equivalents to those of a patented device.¹²⁸ Given its inherent vagueness and limited applicability when used to examine an invention as a whole, it is doubtful that the test would be much help in the equivalency inquiry at the element level.

IV. THE NONOBVIOUSNESS TEST IS APPROPRIATE FOR THE DOCTRINE OF EQUIVALENTS IN BIOTECHNOLOGY

Courts should adopt a nonobviousness test for equivalency analysis in patent infringement disputes similar to the nonobviousness requirement for patentability. This proposed nonobviousness test would consist of a two-pronged analysis. The first prong would impose the prior art and the prosecution history estoppel limitations on the application of the doctrine of equivalents. The second prong would ask whether a person skilled in the relevant technical area would find an accused device obvious in light of a patented invention. The proposed test would eliminate the inherent vagueness of the function-way-result test. In addition, it would evaluate inventions as a whole and thus avoid the confusion associated with the

124. See Robert D. Bajefsky & Howard W. Levine, *Impact of 'Hilton Davis' on Biotech is Unclear: 'All-Elements Rule' Upheld by the High Court May Not Be Easy to Apply to a DNA Sequence*, Nat'l L.J., Jun. 16, 1997, at C9-C10.

125. See, e.g., Robert P. Merges, *Patent Law and Policy* 867-68 (2d ed. 1997).

126. See Jing James Li, *Doctrine of Equivalents* Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co., 13 Berkeley Tech. L.J. 199, 212 (1998).

127. See *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1325 (Fed. Cir. 1991) (stating that court has not set forth test as to how one proves that element in accused device is substantial equivalent of element in claims).

128. See *id.* at 1326.

all elements rule. To understand the proposed test, it is necessary to introduce the nonobviousness requirement for patentability.

A. *The Nonobviousness Requirement for Patentability*

While the doctrine of equivalents asks how different an accused device must be to avoid infringing a patented device, the nonobviousness requirement for patentability asks how different from the prior art inventions must be to be eligible to obtain patents.¹²⁹ The current test for the nonobviousness requirement is based on the Patent Act of 1952, which attempted to establish invention standards and clarify the confusion caused by earlier judicially created standards.¹³⁰ Because it uses the knowledge possessed by a typical skilled person in the pertinent technical area as the yardstick,¹³¹ the current nonobviousness test is applicable to inventions in all areas, including biotechnology.

1. *Early Development of the Nonobviousness Requirement*

Although early patent statutes required only that an invention be novel and useful to be patented,¹³² the U.S. Supreme Court, as early as the mid-nineteenth century, imposed a requirement similar to the current nonobviousness requirement.¹³³ The Court held that to be patentable, an invention must make an improvement that surpasses the knowledge and skills possessed by an ordinary person in the pertinent technical area.¹³⁴

However, subsequent U.S. Supreme Court decisions did not use an objective standard to determine patentability. Instead, the Court framed the invention standard in terms of various vague expressions and raised it far above the mere knowledge and skills that a typical person in the pertinent technical area would have.¹³⁵ The inventiveness requirement

129. See 35 U.S.C.A. § 103(a) (West Supp. 1998).

130. See P.J. Federico, *Origins of Section 103*, 5 Am. Pat. L. Ass'n Q.J. 87 (1977); L. James Harris, *Some Aspects of the Underlying Legislative Intent of the Patent Act of 1952*, 23 Geo. Wash. L. Rev. 658, 674 n.62 (1955).

131. See 35 U.S.C.A. § 103(a).

132. See *Edmund W. Kitch, Graham v. John Deere Co.: New Standards for Patents*, 1966 Sup. Ct. Rev. 293, 303.

133. See *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 267 (1851).

134. See *id.*

135. See *McClain v. Ortmayer*, 141 U.S. 419, 427 (1891) (describing invention as "that impalpable something"); *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59, 73 (1885) (describing invention standard as "the creative work of that inventive faculty"); *Altantic Works v.*

reached its height in *Cuno Engineering Corp. v. Automatic Devices Corp.*,¹³⁶ in which the Court announced that a patentable device must reveal a “flash of creative genius.”¹³⁷

2. *The Patent Act of 1952*

To clarify the standard of patentability and counteract the effects of earlier court decisions, Congress enacted section 103(a) of the Patent Act of 1952.¹³⁸ The statute provides that an invention is not patentable when “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 it pertains.”¹³⁹ Thus, section 103(a) clarified for the first time in patent law history that to be patentable, an invention must be nonobvious in addition to useful and novel.¹⁴⁰ This section also rejected the “flash of genius” requirement as reaching too far.¹⁴¹

3. *The Current Nonobviousness Test*

In 1966, the U.S. Supreme Court clarified the meaning of section 103 in the landmark case *Graham v. John Deere Co.*¹⁴² To determine whether an invention is obvious, courts should consider the scope and content of the prior art, differences between the prior art and the claims at issue, and

Brady, 107 U.S. 192, 200 (1882) (describing invention standard as “some substantial discovery or invention”); *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 497 (1876) (describing invention standard as “inventive effort”).

136. 314 U.S. 84 (1941).

137. *Id.* The U.S. Supreme Court elaborated on the invention standard as follows:

We may concede that the functions performed by Mead’s combination were new and useful. But that does not necessarily make the device patentable. Under the statute . . . the device must not only be “new and useful,” it must also be an “invention” or “discovery.” . . . [I]t has been recognized that if an improvement is to obtain the privileged position of a patent more ingenuity must be involved than the work of a mechanic skilled in the art. . . . That is to say the new device, however useful it may be, must reveal the flash of creative genius, not merely the skill of the calling. If it fails, it has not established its right to a private grant on the public domain.

Id. at 90–91.

138. See *supra* note 130 and accompanying text.

139. See 35 U.S.C.A. § 103(a) (West Supp. 1998).

140. See 35 U.S.C.A. § 103(a); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966).

141. See *Graham*, 383 U.S. at 15.

142. 383 U.S. 1.

the level of ordinary skill in the pertinent area.¹⁴³ The ultimate question is whether the prior art would suggest to those with ordinary skills in the art how to make the claimed invention.¹⁴⁴ In addition, courts may use secondary considerations such as commercial success, long-felt but unsolved needs, or the failure of others to shed light on the circumstances surrounding the origin of the invented subject matter.¹⁴⁵

The Federal Circuit further emphasized secondary considerations in determining the nonobviousness of an invention. It extended the list of secondary considerations to include unexpected results, evidence of copying, licensing, and laudatory statements by an infringer.¹⁴⁶ The Federal Circuit also held that courts should always consider such objective considerations.¹⁴⁷

In determining the nonobviousness of an invention, the Federal Circuit developed the procedural rule of “*prima facie* obviousness” as a burden-shifting tool.¹⁴⁸ According to this rule, either the PTO or a party challenging the validity of a patent during infringement litigation bears the initial burden of demonstrating that the claimed subject matter would be obvious to one of ordinary skill in the art.¹⁴⁹ After the *prima facie* establishment of obviousness, the burden then shifts to the patentee or prospective patentee to rebut the obviousness of the invention.¹⁵⁰ After the rebuttal, the ultimate burden of persuasion shifts back to the PTO or the party challenging the validity.¹⁵¹

143. *See id.* at 17.

144. *See id.*

145. *See id.* at 17–18.

146. *See Halliburton Co. v. Western Co. of N. Am.*, 10 U.S.P.Q.2d 1973, 1979 (W.D. Okla. 1988) (including copying, unexpected results, and licensing as secondary considerations in determining nonobviousness), *aff'd*, 12 U.S.P.Q.2d 1151 (Fed. Cir. 1989); *Libbey-Owens-Ford Co. v. BOC Group, Inc.*, 655 F. Supp. 897, 914 (D.N.J. 1987) (including laudatory statement by alleged infringer as secondary consideration in determining nonobviousness).

147. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) (“Objective evidence . . . is not merely icing on the cake.”); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (stating that courts must consider evidence of secondary considerations in determining obviousness).

148. *In re Spada*, 911 F.2d 705, 707 n.3 (Fed. Cir. 1990).

149. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

150. *See id.*

151. *See Avia Group Int’l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988).

4. *A Biotechnology Example*

In determining whether a biotechnological invention meets the nonobviousness requirement for patentability, courts consider the *Graham* factors as well as other factors. For instance, courts also inquire whether, using the techniques revealed in the prior art, those of ordinary skill would have a reasonable expectation of success.¹⁵² A prior art reference that makes it “obvious to try” an invention is not sufficient to show that the invention is obvious.¹⁵³ In addition, hindsight cannot be used in the determination of obviousness.¹⁵⁴

Hybritech, Inc. v. Monoclonal Antibodies, Inc.,¹⁵⁵ was the first nonobviousness case involving a biotechnological invention. The invention in dispute was a “sandwich” immunoassay using monoclonal antibodies.¹⁵⁶ The Federal Circuit found that all the references, including the method of producing monoclonal antibodies, the usefulness of monoclonal antibodies in the characterization, and localization of a peptide and sandwich immunoassays with polyclonal antibodies, did not suggest the claimed invention.¹⁵⁷ The court noted that these references at most were invitations to try monoclonal antibodies in immunoassays.¹⁵⁸ In reaching its conclusion that the immunoassay was nonobvious from the prior art, the court also took account of objective secondary considerations such as increase of market share, unexpected results, greater sensitivity, and greater reliability of the immunoassay than those of other assays.¹⁵⁹

B. *The Proposed Nonobviousness Test for the Doctrine of Equivalents*

The proposed nonobviousness test, as applied to the doctrine of equivalents, would consist of a two-pronged analysis.¹⁶⁰ The first prong

152. See *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

153. See *Jones v. Hardy*, 727 F.2d 1524, 1530 (Fed. Cir. 1984).

154. See *In re Gorman*, 933 F.2d 982, 987 (Fed. Cir. 1991) (“It is impermissible . . . simply to engage in a hindsight reconstruction of the claimed invention, using the applicant’s structure as a template and selecting elements from references to fill the gaps.”).

155. 802 F.2d 1367 (Fed. Cir. 1986).

156. See *id.* at 1368–69.

157. See *id.* at 1383.

158. See *id.* at 1380.

159. See *id.* at 1382–83.

160. Several commentators have proposed using nonobviousness tests for the application of the doctrine of equivalents. See Toshiko Takenaka, *Doctrine of Equivalents After Hilton Davis: A*

would focus on whether, in light of the prior art and subject matters that the patentee clearly gave up during patent prosecution, the accused product is obvious to a person of ordinary skills in the pertinent technical area. Both the prior art and the ordinary skills in the pertinent technical area would be defined as of the time of the patented device's invention. If the accused product is obvious in light of the prior art or subject matters that the patentee had clearly surrendered, the accused device does not infringe the patented invention. This conclusion is based on the reasoning that if the accused device can be derived exclusively from the prior art or subject matters that the patentee clearly gave up, the alleged infringer does not need to use the patented invention. In other words, the first prong of the analysis would reflect the prior art and prosecution history estoppel limitations to the application of the doctrine of equivalents.

If the accused product is not obvious from the prior art, then the trier of fact would have to conduct the second prong of the analysis to determine whether the accused product is modification of the patented technology obvious to a person of ordinary skills in the pertinent technical area at the time of the alleged infringement. If the accused product or process is obvious in light of the patent claims, it infringes the patented invention.

C. *Application of the Nonobviousness Test to Genentech, Inc. v. Wellcome Foundation Ltd.*

The facts underlying *Genentech, Inc. v. Wellcome Foundation Ltd.*¹⁶¹ exemplify how the application of the nonobviousness test would resolve an infringement dispute. Applying the proposed test, a court would first determine whether FE1X was obvious from the prior art to a person skilled in recombinant protein technique at the time of the recombinant t-PA invention. The answer would be “no” because the prior art did not

Comparative Law Analysis, 22 Rutgers Computer & Tech. L.J. 479, 516–19 (1996) (proposing that requirement for patent infringement should be same as that for patentability); Siekman, *supra* note 99, at ¶¶ 17–32 (proposing to use obviousness test not only for prior art limitation to application of doctrine of equivalents, but also for application of doctrine itself). Siekman's proposed test also includes the enablement requirement, which requires the specification in the allegedly infringed patent enable a person of ordinary skill in the relevant technical area to make and to use the accused device. *See id.* However, because the nonobviousness test contains the enablement requirement, *see* Part IV.A.4, the enablement requirement of Siekman's tests is redundant. This Comment instead proposes exclusively using the nonobviousness test.

161. 29 F.3d 1555 (Fed. Cir. 1994).

contain the t-PA DNA sequence essential for making further modifications of the t-PA protein.¹⁶² The court would then proceed to the second prong of the nonobviousness test to determine whether the modification of t-PA to produce FE1X was obvious to an ordinary skilled recombinant protein researcher at the time of alleged infringement. The answer to the second inquiry would also likely be “no” because even the patentee characterized the effects of both amino acid substitution at position 117 of the K1 region and the deletion of the F and E regions in the FE1X protein as unexpected.¹⁶³ Thus, FE1X is not an equivalent of the t-PA protein.

D. The Advantages of the Proposed Nonobviousness Test

1. The Nonobviousness Test Provides Appropriate Patent Protection

Appropriately defining patent protection boundaries is crucial to promoting technological innovation. For example, granting an extremely large range of equivalents to patents discourages competitors from improving the technology because the patentee retains the exclusive right to capitalize on that field of technology.¹⁶⁴ On the other hand, granting an inappropriately narrow range of equivalents to patents discourages prospective inventors from disclosing their inventions for fear that competitors will benefit from the inventors' efforts.¹⁶⁵

The nonobviousness test would provide adequate protection to patentees. By determining the equivalents at the time of infringement, the test protects patentees not only for the claimed invention but also for its equivalents obvious to one skilled in the pertinent technical area on the infringement date.¹⁶⁶ Inventors, therefore, would not have to face the somewhat impossible task of predicting technology's future development

162. Genentech's patent claims the t-PA sequence and is valid, so the prior art does not contain the t-PA sequence. *See id.* at 1558.

163. *See id.* at 1564 n.23.

164. *See Lewis, supra* note 23, at 1423.

165. *See id.*

166. *See Takenaka, supra* note 160, at 518 (proposing dynamic invention scope theory that views invention scope as consisting of claimed invention and its equivalents that are obvious to one skilled in art on invention date).

and drafting claims that cover hypothetical future competitors' variations.¹⁶⁷

The difficulty in drafting broad claims is especially pronounced for pioneering biotechnological inventions. Although pioneer inventors contribute more significantly to technological innovations than others, they often may not be able to obtain broad claims because they likely fail to disclose sufficiently all possible embodiments covered in the claims.¹⁶⁸ The stricter enablement requirement in biotechnology, due to its unpredictability, may further limit the scope of patent claims for pioneer biotechnology inventions.¹⁶⁹ Failure to provide protection covering the obvious deviations of claimed inventions under the doctrine of equivalents would allow competitors to take advantage of the literalism of claim drafting and consequently discourage prospective inventors, especially pioneer inventors, from disclosing their inventions for fear that competitors will benefit from the inventors' efforts.¹⁷⁰

In addition, the nonobviousness test would be especially advantageous in providing adequate protection to biotechnological inventions in light of the recently heightened written description requirement targeting biotechnological inventions. To fulfill the written description requirement, a patent specification must describe an invention in sufficient detail so that one of ordinary skill in the relevant technical area can clearly conclude that the inventor invented the claimed invention.¹⁷¹ This requirement is intended to prevent an inventor from later claiming something more than the inventor has actually invented as of the application filing date.¹⁷² Contrary to its precedent that adequate written

167. See generally Robert D. Katz & Steven E. Lee, *Advanced Claim Drafting and Amendment Writing for Chemical Inventions*, 426 PLI Patents, Copyrights, Trademarks & Literary Property Course Handbook Series 121, 125 (1995) (discussing difficulty of claim drafting).

168. See Takenaka, *supra* note 160, at 506; see also Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839, 854 (1990) (discussing pioneer inventions and doctrine of equivalents).

169. See *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (holding that in unpredictable technical areas, required level of disclosure would be greater than disclosure of an invention involving 'predictable' factor such as mechanical or electrical element); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) ("the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved"); see also Adelman et al., *supra* note 15, at 580 (regarding biotechnology and chemistry as unpredictable arts).

170. See Lewis, *supra* note 23, at 1421.

171. See *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.").

172. See *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967).

descriptions of chemical and biotechnological compounds were not restricted to disclosures of physical structure,¹⁷³ the Federal Circuit in *Regents of the University of California v. Eli Lilly & Co.*¹⁷⁴ invalidated claims directed to vertebrate and mammalian insulin cDNA because the patentee failed to disclose vertebrate or mammalian insulin cDNA sequences other than rat insulin cDNA.¹⁷⁵ The court emphasized that a functional definition of cDNA was insufficient because it indicated only "what the gene does, rather than what it is."¹⁷⁶ However, if it is obvious to one of ordinary biotechnological skill to make or use vertebrate or mammalian insulin cDNA in light of the patented rat insulin cDNA at the time of alleged infringement, a court applying the proposed nonobviousness test would find that the making or using of vertebrate or mammalian cDNA infringed the rat insulin cDNA claim under the doctrine of equivalents.

The nonobviousness test would not grant patentees overly broad patent protection.¹⁷⁷ When a competitor makes changes that are obvious to one skilled in the art at the time of the replacement, the resulting product really represents imitation rather than substantial innovation.¹⁷⁸ To prevent such imitation, a court should interpret a patent to cover obvious substitutions, whether or not the inventor anticipated these variations and drafted claims to cover the substitutions.¹⁷⁹ However, if a competitor's product is not obvious as compared to the patented invention, the inventive effort should be exempted from infringement

173. See *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1978) (holding that written description of patent application adequately supported applicant's later presented claim to water-insoluble polyol even though appellant described claimed compound by process of making it, not its physical structure); *In re Fisher*, 427 F.2d 833, 836 (C.C.P.A. 1970) (holding that structural description of claimed adrenocorticotrophic hormone (ACTH) extracts was not required to satisfy written description requirement of later submitted patent application claiming ACTH extract in terms of its amino acid structure).

174. 119 F.3d 1559 (Fed. Cir. 1997).

175. See *id.* at 1568-69.

176. See *id.* at 1568 (citing *Fiers v. Revel*, 984 F.2d 1164, 1169-71 (Fed. Cir. 1993)).

177. The standard for patent infringement implemented by the current test for equivalency analysis on an element-by-element basis is unreasonably high and uncertain, similar to the invention standard prior to the Patent Act of 1952. For comparison between obviousness and the doctrine of equivalents, see generally Stephen G. Kalinchak, Comment, *Obviousness and the Doctrine of Equivalents in Patent Law: Striving for Objective Criteria*, 43 Cath. U. L. Rev. 577, 599-606 (1994).

178. See Takenaka, *supra* note 160, at 517.

179. See *id.*

liability.¹⁸⁰ A competitor does not infringe a patent if the competitor's product is obvious from the prior art as of the invention date of the patented device.¹⁸¹

2. *The Nonobviousness Test Simplifies the Patent System*

The application of the nonobviousness test to the doctrine of equivalents would benefit the development of patent laws by simplifying the patent system. Because the test for novelty in patent prosecution is the same as that for literal infringement in patent infringement,¹⁸² the use of the nonobviousness test for determining infringement under the doctrine of equivalents would unify standards for patent prosecution and for patent infringement.¹⁸³ Rather than searching for and developing a new test for the equivalency analysis, courts could enjoy the benefit of a rich body of case law on nonobviousness.¹⁸⁴

3. *The Nonobviousness Test Provides Better Public Notice*

Another major advantage of the proposed nonobviousness test over the current test would be its lack of inherent vagueness. Using the well-established nonobviousness framework, the proposed test would increase the consistency and predictability of outcomes in infringement disputes, thus providing better public notice. It would help attract investment in the biotechnology industry as well. Inventors could decide to seek patent protection, to seek trade secret protection, to invent around the prior art, or to donate to the public domain.¹⁸⁵

V. CONCLUSION

The current test for determining whether a device is an equivalent of and thus infringes a patented invention suffers from inherent vagueness

180. *See id.* at 496 (suggesting that courts should use same threshold for granting patent and for escaping infringement charge).

181. *See Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed. Cir. 1990).

182. *See Chisum & Jacobs, supra* note 20, § 2c[3][a], at 2-54 (citing *Lewmar Marine v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987)).

183. *See Takenaka, supra* note 160, at 496-97.

184. *See id.* at 497.

185. *See Jeremy Cubert, U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. Pat. & Trademark Off. Soc'y 151, 152 (1995).

and provides little guidance in resolving infringement disputes. In addition, the all elements rule, a limitation to the test, causes further confusion. In contrast, the proposed nonobviousness test would clarify the equivalency analysis by evaluating inventions as a whole. The test would provide not only appropriate protection to patentees, but also better public notice. Founded on over forty years of case law development, the test would serve as a solid analytical framework for infringement, which is critical to the rapid growth of the biotechnology industry.