

**Boston University
Journal of Science & Technology Law**

Article

**The Expanded Hypothetical Claim Test: A Better Test for Infringement for
Biotechnology Patents Under the Doctrine of Equivalents**

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The Expanded Hypothetical Claim Test: A Better Test for Infringement for Biotechnology Patents Under the Doctrine of Equivalents †

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I. INTRODUCTION

Although the doctrine of equivalents has existed for over a century,¹ how it applies to a particular case remains vague. This vagueness has generated unpredictable results, undermining the value of many patents. Thus, this unpredictability concerns all industries, especially the biotechnology industry where a company's primary assets are usually its intellectual property rights. Therefore, this Article proposes a new test for infringement under the doctrine of equivalents and uses a biotechnology example to illustrate this new test. [1]

Part II of this Article reviews *Graver Tank's*² tripartite and substantial differences tests, currently used to determine infringement under the doctrine of equivalents, and discusses their failings. Part III discusses the *Graver Tank* concept of interchangeability and its utility in determining equivalence. Part IV analyzes the similarities between obviousness, interchangeability, and the doctrine of equivalents. Part IV further distinguishes between obviousness and the doctrine of equivalents, illuminating the doctrine's lack of framework. Part V discusses *Wilson Sporting Goods*³ and its hypothetical claim test, which employs obviousness

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1 Winans v. Denmead, 56 U.S. (15 How.) 330 (1853).

2 Graver Tank & Mfg. Co., Inc. v. Linde Air Products Co., 339 U.S. 605 (1950).

3 Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677 (Fed. Cir. 1990).

analysis. Part VI explains the expanded hypothetical claim test in detail, including its use of the obviousness framework. Part VII then applies the expanded hypothetical claim test to *Genentech, Inc. v. Wellcome Foundation Ltd.*,⁴ a recent biotechnology case that illustrates the failings of the tripartite test—failings especially relevant to biotechnology patents. Part VIII discusses criticisms of the hypothetical claim test and applies these criticisms to the expanded hypothetical claim test. [2]

This Article concludes that the expanded hypothetical claim test is supported by precedent, and further, that it provides a better framework for determining equivalent infringement than do either the tripartite or substantial differences tests, especially for biotechnology patents. Consequently, this Article takes the position that the tripartite test and the substantial differences test should be abandoned in favor of a more workable test, especially for biotechnology patents. Abandoning the two tests in favor of an expanded hypothetical claim test does not necessitate abandoning *Graver Tank*. It merely calls for dispensing with the ritual invocation of the tripartite test or the substantial differences test to justify the fact finder's conclusion. [3]

II. THE TRIPARTITE TEST, THE SUBSTANTIAL DIFFERENCES TEST, AND THEIR PROBLEMS

In 1853, the Supreme Court in *Winans v. Denmead* first recognized the doctrine of equivalents.⁵ The benchmark Supreme Court opinion on the doctrine of equivalents, however, is *Graver Tank*.⁶ Guided by earlier patent cases,⁷ *Graver Tank* has long been considered to have established the tripartite test for infringement analysis under the doctrine of equivalents.⁸ The tripartite test compares the function, way, and result of an accused product or process with that of the asserted claim.⁹ The accused product or process infringes under the doctrine of

⁴ 29 F.3d 1555 (Fed. Cir. 1994).

⁵ 56 U.S. (15 How.) at 344. In articulating the doctrine of equivalents, the Supreme Court stated that the alleged infringing product “must be so near to a true circle as substantially to embody the patentee’s mode of operation, and thereby attain the same kind of result as was reached by his invention . . . [and that it] be the same in kind, and effected by the employment of [the patentee’s] mode of operation in substance.” *Id.*; see also DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW § 2F[2][b], at 2-253 to 2-254 (1992) [hereinafter CHISUM & JACOBS].

⁶ *Graver Tank*, 339 U.S. at 605.

⁷ See *Winans*, 56 U.S. (15 How.) at 343-44; *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 41-42 (1929).

⁸ See 4 DONALD S. CHISUM, PATENTS § 18.02[2], at 18-8 to 18-11 (Sept. 1995) [hereinafter 4 CHISUM]; CHISUM & JACOBS, *supra* note 5, § 2F[2][b], at 2-252 to 2-253.

⁹ *Graver Tank*, 339 U.S. at 608.

equivalents if it performs substantially the same function in substantially the same way to obtain substantially the same result as the patented claim.¹⁰ [4]

Unfortunately, the tripartite test is of little practical use to fact finders¹¹ because of its question-begging nature. Judge Learned Hand best expressed the test's deficiency with the following statement:

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.¹²

The tripartite test has been further criticized for its lack of control over the level of generality to be used in characterizing an invention's function, way, and result.¹³ To illustrate the lack of control over the level of generality to be used, one need not look further than to the prevalent litigation practice today. In an infringement action, the patentees tend to characterize an invention's function, way, and result broadly to show the similarities between the accused product or process and the patented invention.¹⁴ The accused infringers, on the other hand, tend to characterize the invention's function, way, and result narrowly to show the

¹⁰ *Id.* The Supreme Court in *Graver Tank* used confusing language concerning the "same result" prong of the tripartite test. The Court first spoke of "the same result," *id.* (quoting *Sanitary Refrigerator Co.*, 28 U.S. at 42), but in the very next sentence, the Court spoke of "substantially the same result." *Id.* at 339 U.S. at 608 (quoting *Union Paper-Bag Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877)). The Court of Appeals for the Federal Circuit has indicated, however, that it sees no difference in this language. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 901-02 (Fed. Cir. 1984) (stating that even though *Graver Tank* talks of the "same" and "substantially the same" result, the doctrine of equivalents is based on substantial identity, and not on exact identity).

¹¹ *See, e.g.*, *Mead Digital Systems, Inc. v. A.B. Dick Co.*, 723 F.2d 455, 463 (6th Cir. 1983) (stating that employing the function, way, and result test to determine infringement under the doctrine of equivalents necessarily suffers from a lack of precedential guidance as "[s]uch case is inevitably a matter of degree, . . . and [therefore,] other decisions have little or no value since a decision is bound to have an arbitrary color, as in all close cases of interpretation, and it is difficult to give it greater authority than an appeal to the sympathetic understanding of an impartial reader."); *Coal Processing Equip. Inc. v. Campbell*, 578 F. Supp. 445, 457 (S.D. Ohio 1981) (stating that under the general rubric of the doctrine of equivalence, the function, way, and result test "is not a particularly workable test"); *see also* 4 CHISUM, *supra* note 8, § 18.04[5], at 18-134 and the cases cited therein (the tripartite test "is too general to be of much assistance in the resolution of particular problems."). Professor Chisum has also noted that "[c]ourt decisions are of limited precedential value since they frequently turn on . . . specific factual circumstances." *Id.* at 18-135.

¹² *Claude Neon Lights, Inc. v. Marchlett's Sons*, 36 F.2d 574, 576 (2d Cir. 1929).

¹³ 4 CHISUM, *supra* note 8, § 18.04[5], at 18-134.

¹⁴ CHISUM & JACOBS, *supra* note 5, § 2F[2][b], at 2-255.

dissimilarities between the accused product or device and the patented invention.¹⁵ Therefore, a court's determination of infringement simply depends upon whose characterization it accepts.¹⁶ It is evident from the above illustration that the tripartite test's question-begging language does not aid the inquiry into infringement under the doctrine of equivalents. [5]

The concern with the tripartite test is especially evident in the case of biotechnology patents. Often, these patents involve subject matter that neither party fully understands.¹⁷ If the parties in interest themselves do not have a complete grasp of how the invention works, fact finders surely will be faced with an even greater challenge in attempting to understand the subject matter of the invention. Thus, it has been the case that the fact finders in biotechnology cases have often encountered difficulties in correctly applying the "way" element of the tripartite test.¹⁸ [6]

In recognizing the problems with the tripartite test, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") recently "restate[d] . . . the test for infringement under the doctrine of equivalents."¹⁹ The court held that the "application of the doctrine of equivalents rests on the *substantiality of the differences* between the claimed and accused products"²⁰ The substantial differences test, however, faces at least as many obstacles as the tripartite test, as it simply summarizes the tripartite test while discarding its framework. No longer are fact finders to determine whether the accused product or process performs *substantially* the same function in *substantially* the same way to achieve *substantially* the same result. Under this test, fact finders decide if there are *substantial* differences between the accused and claimed product or process. Therefore, even though the fact finders still decide the scope of the "substantial"

15 *Id.*

16 *Id.*

17 See Laura A. Handley, *Refining The Graver Tank Analysis With Hypothetical Claims: A Biotechnology Exemplar*, 5 HARV. J.L. & TECH. 31, 44-45 (1991) (often, the "way" a biotechnology invention works identifies the underlying patent as many recombinant protein inventions are new and efficient procedures for manufacturing known products); *Hilton Davis Chem. Co. v. Warner-Jenkinson Co., Inc.*, 62 F.3d 1512, 1546 (Fed. Cir. 1995) (*en banc*) (Archer, C.J., and Lourie, Nies, Plager, and Rich, J.J., dissenting), *cert. granted* 64 U.S.L.W. 3570 (U.S. Feb. 26, 1996) (No. 95-728). The court in *Hilton Davis* stated that "[n]ew chemical compounds differ structurally from old compounds (that is what makes them new) and yet they perform the same function (have the same use), provide the same result, and do so in the same way. The fact that they do so in the same way does not make them substantially the same way they are defined, i.e., by structure." *Hilton Davis*, 62 F.3d at 1546.

18 *Hilton Davis*, 62 F.3d at 1546.

19 *Id.*

20 *Id.* at 1518 (emphasis added).

prong, the substantial differences analysis is more holistic than the tripartite test's three-step analysis. That the juries have "a virtually uncontrolled and unreviewable license . . . to find infringement if they so choose"²¹ under the tripartite test inevitably expands under the substantial differences analysis. [7]

Unsurprisingly, many practitioners have already criticized the substantial differences test for this very lack of guidance regarding the meaning of "substantial differences."²² This test does not remedy the failings of the tripartite test. Rather, the substantial differences test may actually exacerbate these failings by discarding even the tripartite test's weak framework. The Federal Circuit recently stated in *Hilton Davis* that "the function-way-result test often suffices to assess equivalency because similarity of function, way, and result leaves little room for doubt that only insubstantial differences distinguish the accused product or process from the claims."²³ Thus, it seems that the Federal Circuit has endorsed fact finders' continuing use of the tripartite test to determine equivalent infringement. As long as the ultimate answer is phrased in terms of "substantial differences" and not the tripartite test, applying the tripartite test will meet the Federal Circuit's standard of equivalency analysis. The failings of both of these "substantial" tests, especially evident regarding biotechnology patents, will continue. This undoubtedly contributed to the five dissenting votes and three dissenting opinions in *Hilton Davis*. Tellingly, the two Federal Circuit judges with chemical backgrounds, Judges Rich and Lourie, dissented from *Hilton Davis*.²⁴ [8]

III. THE SYMMETRY OF OBVIOUSNESS, THE DOCTRINE OF EQUIVALENTS, AND INTERCHANGEABILITY

²¹ *Id.* at 1538 (Plager, J., dissenting).

²² See, e.g., J. Michael Jakes & Howard Kwon, *Infringers Beware: Federal Circuit Revisits the Doctrine of Equivalents* (on file with the Boston University Journal of Science & Technology Law; shorter version published in IP WORLDWIDE, JANUARY/FEBRUARY 1996, at 26) (stating that the Federal Circuit "neglected to consider the inherent problems of determining infringement based upon an imprecise standard" such as "insubstantiality"); Steven M. Anzalone, *Infringement Under the Doctrine of Equivalents*, 76 PATENT WORLD 16, 19 (Oct. 1995) at 1t ("Substantial vs. Insubstantial: What's the Difference?"); Teresa Riordan, *Patents: Substantial Questions Linger After a Ruling that Could Give Patent Holders More Power*, N.Y. TIMES, Aug. 21, 1995, at D2 ("[T]he court [in *Hilton Davis*] did not clarify what 'insubstantial' meant."); Dominic BenCivenga, *Patent Infringement: Federal Circuit Re-Examines the Role of Jurors*, N.Y.L.J., Sept. 14, 1995, at 5 (insubstantial element will give little predictability to the patentees in their defense of the patent validity) (paraphrasing Stanley L. Amberg, Partner, Davis, Hoxie, Faithful & Hapgood, L.L.P., New York, New York).

²³ *Hilton Davis*, 62 F.3d at 1518.

²⁴ *Id.* at 1536 (Plager, J., dissenting, joined by Archer, C.J., and Rich and Lourie, J.J.); *id.* at 1545 (Lourie, J., dissenting, joined by Rich and Plager, J.J.).

In *Graver Tank*, the Supreme Court stated that "[a]n important factor [in determining infringement under the doctrine of equivalents] is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was."²⁵ The Supreme Court further emphasized that through expert testimonies, and through the testimonies of those well versed in the technology at the time of infringement, one reasonably skilled in the art would have recognized the interchangeability of the allegedly equivalent elements.²⁶ [9]

The first Supreme Court opinion to recognize the doctrine of equivalents also used this interchangeability analysis.²⁷ *Winans v. Denmead* relied heavily on expert testimony on the lack of substantial differences between the allegedly equivalent element and the claimed element at the time of infringement.²⁸ Another Supreme Court case used interchangeability analysis to determine infringement under the doctrine of equivalents.²⁹ In addition, the Federal Circuit has also recognized the Supreme Court's interchangeability analysis as one standard for determining equivalents infringement.³⁰ Even in *Hilton Davis*, the Federal Circuit stated that known interchangeability is "potent evidence" of equivalent

²⁵ *Graver Tank*, 339 U.S. at 609.

²⁶ *Id.*

²⁷ *Winans*, 56 U.S. (15 How.) at 330.

²⁸ *Id.* at 340-44.

²⁹ See *Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 573 (1898) (suggesting that only nonobvious inventions will be deemed free of infringement).

³⁰ *Rite-Hite Corp. v. Kelley Co., Inc.*, 819 F.2d 1120, 1124 (Fed. Cir. 1987) (citing *Graver Tank*, 339 U.S. at 609); see also *Perkin-Elmer*, 822 F.2d at 1535; *Lockheed Aircraft Corp. v. United States*, 553 F.2d 69, 82 (Ct. Cl. 1977) (stating that interchangeability is a useful consideration when determining whether two specific structures are equivalents); *Extrel FTMS Inc. v. Bruker Instruments, Inc.*, 954 F.2d 734, 22 U.S.P.Q. 2d (BNA) 1945, 1948 (Fed. Cir. 1992) (using interchangeability analysis to determine equivalence under means plus function limitation per 35 U.S.C. § 112, ¶ 6).

In stating that "an interchangeable device is not necessarily an equivalent device[.]" the Federal Circuit in *Key Mfg. Group, Inc. v. Microdot, Inc.*, 925 F.2d 1444 (Fed. Cir. 1991), seemed to reject an interchangeability analysis. *Id.* at 1449. A closer analysis of *Key Mfg. Group*, however, reveals that the court rejected an interchangeability analysis that only considered anticipation, not obviousness. Thus, the court made a refinement to the *Graver Tank* interchangeability analysis: interchangeability can lead to a finding of infringement under the doctrine of equivalents as long as the interchange would not have been obvious in light of the prior art. See ROBERT P. MERGES, *PATENT LAW AND POLICY* 706 (1992). The Federal Circuit has further stated that "substitution of an ingredient known to be an equivalent to that required by the claim presents a *classic example* for a finding of infringement under the doctrine of equivalents." *Corning Glass Works v. Sumimoto Elec. U.S.A., Inc.*, 868 F.2d 1251, 1261 (Fed. Cir. 1989) (citing *Graver Tank*, 339 U.S. at 609) (emphasis added).

infringement.³¹ Thus, an interchangeability test seems as valid a test for infringement under the doctrine of equivalents as either the tripartite or the substantial differences test. Deciding equivalent infringement by determining interchangeability would avoid the problem posed by the tripartite and substantial differences tests.³² Furthermore, it seems that the best way to determine interchangeability is to use the well-developed framework of obviousness analysis.
[10]

Most patent law doctrines are adaptable and interconnected.³³ Courts have long recognized the conceptual relationship between literal infringement and novelty—and thus anticipation.³⁴ Indeed, literal infringement is often introduced to students by the maxim "that which infringes, if later, would anticipate, if earlier."³⁵ The courts have often recognized the relationship between obviousness and the doctrine of equivalents. In the companion case to *Graham v. John Deere Co.*,³⁶ the Supreme Court based its holding of nonobviousness primarily on the finding that a claimed limitation was not *equivalent* to elements in the prior art.³⁷ The Federal Circuit also has recognized the close nexus between the doctrine of equivalents and obviousness.³⁸ For example, the Federal Circuit modified the "classic" test for anticipation—that which infringes, if later in time, will anticipate, if earlier than the date of invention—to "[t]hat which would *literally* infringe if later

³¹ *Hilton Davis*, 62 F.3d at 1519. Patent systems in other countries have also recognized the usefulness of interchangeability analysis in determining infringement under the doctrine of equivalents. Under German patent law, for example, an embodiment infringes if one skilled in the art could identify equivalent means "as being *equally* effective in the solution of the problem underlying the invention," a test similar to the *Graver Tank* interchangeability analysis. *Handle Cord for Battery Case*, German Fed. Sup. Ct., Oct. 3, 1989 (emphasis added), reprinted in 22 INT'L REV. INDUS. PROP. & COPYRIGHT L. 104, No.1, 106-07 (1991).

³² See *supra* notes 12 to 23 and the accompanying text.

³³ See generally Donald S. Chisum, Comment: *Anticipation, Enablement, and Obviousness: An Eternal Golden Braid*, 15 AIPLA Q.J. 57 (1987) [hereinafter Chisum, Comment].

³⁴ See, e.g., *Knapp v. Morss*, 150 U.S. 221, 228-29 (1893); *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889).

³⁵ *Peters*, 129 U.S. at 537; see also 1 DONALD S. CHISUM, PATENTS § 3.20[1], at 3-12 to 3-15 (Sept 1995) [hereinafter 1 CHISUM].

³⁶ 383 U.S. 1 (1966) (*Graham* was the first case where the Supreme Court considered the new statutory concept of obviousness).

³⁷ *United States v. Adams*, 383 U.S. 39, 51 (1966) (stating that wholly unexpected advantages of an invention indicate neither equivalency nor nonobviousness).

³⁸ *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 748 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

in time anticipates if earlier than the date of invention."³⁹ Furthermore, patent law scholars have noted that "[t]he lack of novelty (anticipation) test is the same test as for literal infringement."⁴⁰ The interplay between the doctrine of equivalents and obviousness can be summarized by the maxim "that which infringes under the doctrine of equivalents, if later, would render obvious, if earlier." Even though the classic test is usually only recited for purposes of determining anticipation,⁴¹ the converse is equally true: that which renders obvious, if earlier than the patent, will infringe under the doctrine of equivalents, if later in time. [11]

Given this similarity between the doctrine of equivalents and obviousness,⁴² it is not surprising that the interchangeability aspect has been called perhaps the most important factor in determining infringement under the doctrine of equivalents.⁴³ Indeed, the Supreme Court in *Graver Tank* relied heavily on the concept of interchangeability.⁴⁴ *Graver Tank* was decided at the same time as the first significant revision of the United States Patent Code ("Patent Code").⁴⁵ Perhaps the most important change was the codification of the concept of obviousness.⁴⁶ Thus, when the Supreme Court relied heavily on the concept of interchangeability, it was most likely influenced by the contemporaneous formulation of the concept of obviousness. [12]

³⁹ *Id.* at 747 (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)) (for the rewording of the "classic" test). The court also noted that this modification of the classic test was not a change in the law; rather, it merely recognized the changed meaning of "anticipates" following the 1952 Patent Act's addition of the concept of obviousness. *Id.*; see also 35 U.S.C. §§ 1 - 376 (1994).

⁴⁰ CHISUM & JACOBS, *supra* note 5, § 2C[3][a], at 2-54 (emphasis added) (citing *Lewmar Marine*, 827 F.2d at 744).

⁴¹ See *Graham*, 383 U.S. at 12.

⁴² Although not identical, the standards of review for obviousness and equivalent infringement are similar. As Judge Rich noted in *Jurgens v. McKasy*, 927 F.2d 1552, 1561 (Fed. Cir.), *cert. denied*, 502 U.S. 902 (1991), "[i]n [a situation of infringement under the doctrine of equivalents], as for obviousness, we presume that the jury resolved the underlying factual dispute in favor of [the patentee] and . . . inquire only whether the legal conclusion embodied in the judgment—that the patent did not encompass the prior art—is correct in light of the presumed jury findings." *Id.* (emphasis added).

⁴³ Gregory B. Sephton, Note, *Biotechnology: The Doctrine of Equivalents and Infringement of Patented Proteins*, 25 SUFFOLK U. L. REV. 1035, 1045 (1991).

⁴⁴ *Graver Tank*, 38 U.S. at 609.

⁴⁵ Patent Act of July 8, 1870, ch. 230, 16 Stat. 198, replaced by Patent Act of July 19, 1952, ch. 950, 66 Stat. 792 (codified at 35 U.S.C. §§ 1-376 (1994)).

⁴⁶ 35 U.S.C. § 103.

Section 103 of the Patent Code ("section 103") improved upon the pre-existing standard for obviousness by providing a framework for analysis: "It supplies both a yardstick to compare the invention with—the whole of the prior art—and a fictional artisan—the person 'skilled in the art'—to apply that prior art to the problem addressed in the patent."⁴⁷ Thus, the statutory test for obviousness provides a workable framework for determining obviousness, defining both for what and from what perspective the judge or jury should be looking. Critics of the doctrine of equivalents focus on the unpredictability of decisions on infringement under the doctrine and their result-oriented nature.⁴⁸ [13]

The pre-section 103 standard of obviousness was criticized for the very same reasons.⁴⁹ Nevertheless, it seems evident that the analysis of infringement under the doctrine of equivalents would benefit from such a framework. This can be achieved by expanding the use of obviousness in the hypothetical claim analysis of *Wilson*⁵⁰ from a tool for determining the limiting effect of the prior art to the actual test for equivalence. [14]

IV. WILSON'S HYPOTHETICAL CLAIM ANALYSIS AND THE PROPOSED EXPANDED HYPOTHETICAL CLAIM TEST

The Wilson Sporting Goods Company, which manufactures golf balls, sued one of its competitors for infringement of patent claims for dimple configuration of golf ball covers.⁵¹ Writing for the majority, Judge Rich introduced a new way "[t]o simplify analysis [of the limiting effect of prior art] and bring the issue onto familiar turf."⁵² He stated that "it may be helpful to conceptualize the limitation on the scope of equivalents by visualizing a *hypothetical* patent claim, sufficient in scope to *literally* cover the accused product."⁵³ Having visualized such a hypothetical claim,

⁴⁷ MERGES, *supra* note 30, at 380.

⁴⁸ See *supra* notes 11-17, and the accompanying text.

⁴⁹ See, e.g., *Harries v. Air King Prods. Co.*, 183 F.2d 158, 162 (2d Cir. 1950) (L. Hand, C.J.) (stating that the notion of a patentable invention is "as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts"); *Kirsch Mfg. Co. v. Gould Mersereau Co.*, 6 F.2d 793, 794 (2d Cir. 1925) (L. Hand, J.) ("There comes a point when the question must be resolved by a subjective opinion as to what seems an easy step and what does not. We must try to correct our standard by such objective references as we can, but in the end the judgment will appear, and no doubt be, to a large extent personal, and in that sense arbitrary.").

⁵⁰ 904 F.2d at 677.

⁵¹ *Id.* at 678.

⁵² *Id.* at 684.

⁵³ *Id.*

the analysis then becomes whether the United States Patent and Trademark Office (“PTO”) would have allowed that hypothetical claim over the prior art.⁵⁴ If the PTO would not have allowed the claim, then the patentee could not obtain the patent claim scope under the doctrine of equivalents in an infringement suit.⁵⁵ If the PTO would have allowed the hypothetical claim, then the prior art would not limit the scope of equivalents.⁵⁶ Therefore, the prior art would not bar infringement under the doctrine of equivalents.⁵⁷ But even if the PTO would not have rejected the hypothetical claim as obvious in light of the prior art, the patentee would not have proved equivalent infringement.⁵⁸ Rather, the patentee would only have established that the prior art does not preclude the asserted equivalency.⁵⁹ Further, a finding of infringement under the doctrine of equivalents would be possible, but not necessarily proven. [15]

According to Judge Rich, three related advantages emerge from this new analysis. First, the hypothetical claim analysis “allows the use of traditional patentability rules”⁶⁰ Second, the hypothetical claim analysis “permits a more precise analysis than determining whether an *accused product* (which has no claim limitations on which to focus) would have been obvious in view of the prior art.”⁶¹ Finally, the hypothetical claim analysis reminds the court that the patentee “seek[s] patent coverage beyond the limits considered by the PTO examiner.”⁶² [16]

Unlike *Wilson’s* hypothetical claim test, the expanded hypothetical claim test proposed in this Article would decide definitively the issue of equivalent infringement. Under this expanded view, the judge first drafts a claim that literally covers the claimed invention. Once the judge has drafted such a claim, the fact finder then evaluates the claim as if she were a PTO examiner assessing its obviousness. If the fact finder determines that the PTO examiner would not have

54 *Id.*

55 *Id.*

56 *Id.*

57 *Id.*

58 *Id.* at 685; see also *In re Certain Doxorubicin and Preparations Containing Same*, 20 U.S.P.Q.2d (BNA) 1602, 1609 n.5 (ITC 1991) (“[e]ven if a finding of equivalency were not precluded by the prior art . . . this does not mean that equivalency has been established”).

59 *Wilson*, 904 F.2d at 684.

60 *Id.*

61 *Id.*

62 *Id.* at 685.

found the asserted claim to be obvious over the accused product or process in light of the prior art, the substitution will be found not equivalent. Thus, the accused product or process does not infringe, and the inquiry ends. [17]

If, however, the asserted claim renders the hypothetical claim obvious, the accused product or process will be found to be equivalent to the claimed invention. Thus, the accused product or process may infringe under the doctrine of equivalents. The fact finder then must decide whether to allow the patentee to capture this equivalency within the claim. If the PTO would not have allowed the hypothetical claim under section 112 or section 103 of the Patent Code,⁶³ or the patentee already had surrendered the scope of the asserted equivalency, the court will not allow the patentee to capture this equivalency. The accused product or process will be found to infringe under the doctrine of equivalents. [18]

The Federal Circuit has indicated that *Wilson's* hypothetical claim test "does not envision application of a full-blown patentability analysis."⁶⁴ *Wilson's* hypothetical claim analysis, however, concerns only one aspect of infringement: the limiting effect of the prior art on an asserted range of equivalence.⁶⁵ In contrast, the expanded hypothetical claim test determines not simply the scope of equivalence, but the actual infringement under the doctrine of equivalents. [19]

Patentability of a claim requires more than nonobviousness.⁶⁶ Similarly, infringement under the doctrine of equivalents requires more than a determination of the scope of the prior art. Therefore, the *expanded* hypothetical claim test proposes an evaluation of all the elements of the symmetrical process of patentability to determine equivalent infringement. Predicating a determination of equivalent infringement on nonobviousness alone could allow a patentee to obtain greater coverage than the PTO initially would allow. To avoid such results, the expanded hypothetical claim test considers other patentability factors such as enablement, prosecution history, and the relevant time frame. [20]

A. *Enablement*

⁶³ See 35 U.S.C. §§ 103, 112.

⁶⁴ *Key Mfg. Group*, 925 F.2d at 1449.

⁶⁵ *Wilson*, 904 F.2d at 684.

⁶⁶ *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979) (stating that sections 101, 102, and 103 of the Patent Code are "three doors" to be opened in order to obtain a patent).

In many ways, the enablement requirement of the Patent Code is the most important requirement for patentability.⁶⁷ The first paragraph of section 112 requires an inventor to provide "a written description of the invention, and of the manner and process of making and using it."⁶⁸ Upon the fact finder's obviousness determination of the hypothetical claim, the next step is to consider whether the PTO would have rejected the hypothetical claim under enablement analysis. If the hypothetical claim would have been considered nonenabled, then the accused product or process containing an equivalent limitation cannot infringe under the doctrine of equivalents. [21]

For biotechnology patents, section 112 represents one of the largest obstacles to the patentability of a claim.⁶⁹ Similarly, the "way" prong of the tripartite test, related to enablement, presents the largest problem for determining equivalent infringement of biotechnology patents.⁷⁰ Therefore, this Article's proposed expanded hypothetical claim test in the context of biotechnology patents would require a satisfactory analysis of the enablement standard of the alleged equivalent. [22]

Under the first paragraph of section 112, the patent disclosure must be sufficiently clear to enable any person skilled in the art to make and use the invention.⁷¹ This disclosure and enablement function of a patent is established as the *quid pro quo* of the patent grant.⁷² The policy behind the section 112, paragraph one requirement is predicated upon a contract theory of patents. The inventor provides disclosure and enablement to the federal government as consideration for the government's grant of a term of exclusivity.⁷³ [23]

⁶⁷ Section 112 requires an inventor's patent application to "particularly point[] out and distinctly claim[] his invention." 35 U.S.C. § 112, ¶ 1. This is also an important function of the patent system. The "particularly pointing out and distinctly claiming" function of a patent provides the definition of the inventor's property rights. Under a deed theory of patents, this function serves to define the metes and bounds of the inventor's claimed property, as do real property deeds. The judge's drafting of the hypothetical claim, however, would satisfy this requirement.

⁶⁸ 35 U.S.C. § 112, ¶ 1.

⁶⁹ *See id.*; *see also* Handley, *supra* note 17, at 55, 58.

⁷⁰ Handley, *supra* note 17, at 62; *see generally supra* notes 17-18, and the accompanying text.

⁷¹ *See* Handley, *supra* note 17, at 62.

⁷² *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1210 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

⁷³ Congress mandated the term of patent exclusivity as seventeen years from the issue date. 35 U.S.C. § 154. The Uruguay Round Agreements Act, however, amended section 154 to change patent exclusivity terms to twenty years from the original filing date. Pub. L. No. 103-405, 532 tit. V, subtit. C., sec. 532, 108 Stat. 4809, 4983-84 (1994).

Assessing the enablement standard would have the same advantages as the *Wilson* hypothetical claim by allowing the use of traditional patentability rules,⁷⁴ permitting a more precise analysis, and finally, reminding a court that the patentee “seek[s] patent coverage beyond the limits considered by the PTO examiner.”⁷⁵ [24]

B. *Prosecution History Estoppel*

Prosecution history estoppel may preclude a finding of infringement under the doctrine of equivalents.⁷⁶ Estoppel arises when a patentee attempts, through an infringement action, to obtain coverage greater than that allowed by the examiner. An examiner will not allow an applicant to assert that the language of a pending claim is broader than the applicant previously argued to avoid prior art.⁷⁷ Similarly, an examiner may reject a claim by relying upon admissions by an applicant “[a]s to any matter affecting patentability.”⁷⁸ Because the *Wilson* hypothetical claim analysis does not consider prosecution history estoppel, it is merely a tool, and not a test, to determine infringement.⁷⁹ [25]

When applying the expanded hypothetical claim test, the fact finder would consider the prosecution history of the asserted patent in the same manner as a PTO examiner with a pending application. The fact finder would not allow a claim to be broader when determining infringement than that which the patentee originally asserted to avoid the prior art during prosecution. Thus, under this analysis, the claim would be found not to infringe if the PTO would have rejected the hypothetical claim because of the applicant's surrender of the claim scope during prosecution. [26]

⁷⁴ *Wilson*, 904 F.2d at 684.

⁷⁵ *Id.* at 685.

⁷⁶ *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 870 (Fed. Cir. 1985).

⁷⁷ *See id.*

⁷⁸ 37 C.F.R. § 1.106(c) (1995).

⁷⁹ *International Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 772 (Fed. Cir. 1993) (“Hypothetical claim analysis is an optional way of evaluating whether prior art limits the application of the doctrine of equivalents.”); *Key Mfg. Group*, 925 F.2d at 1449 (stating that the hypothetical claim analysis is a nonobligatory tool that does not require complete patentability analysis); see also Brian E. Lewis, *Expanding The Use Of Hypothetical Analysis When Evaluating Patent Infringement Under the Doctrine of Equivalents*, 16 U. PUGET SOUND L. REV. 1409, 1415 (1993).

C. *Relevant Time Frame for Analysis*

There is an asymmetry between the relative time frames of equivalent infringement and obviousness. This asymmetry presents a potential problem with using the obviousness framework of the expanded hypothetical claim test to determine infringement under the doctrine of equivalents. Under the Patent Code, an applicant may not obtain a patent "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."⁸⁰ That a person of ordinary skill in the art would have known of the equivalency at the time of the invention is a "classic example" for finding infringement under the doctrine of equivalents.⁸¹ Determining equivalency, however, takes place at the time of the alleged infringement.⁸² Thus, "advances subsequent to [a] patent may still infringe."⁸³ [27]

Although *Wilson's* hypothetical claim test turns upon whether the PTO would have rejected the hypothetical claim over the prior art, it leaves unclear the appropriate time frame for equivalency analysis.⁸⁴ Since *Wilson's* hypothetical claim test seeks to prevent the patentee from obtaining coverage that would read on the prior art, a court would probably apply the *Wilson* hypothetical claim analysis from the time the invention was made, as courts do for most patent law issues. Considering post-invention art in a doctrine-of-equivalents determination represents an exception to the general symmetry between obviousness and the doctrine of equivalents.⁸⁵ The expanded hypothetical claim test, however, resolves this asymmetry easily. Rather than asking whether one of ordinary skill in the art would find the hypothetical claim obvious at the time of invention, the expanded hypothetical claim test asks whether one of ordinary skill in the art would have found the hypothetical claim obvious at the time of infringement. Thus, the

⁸⁰ 35 U.S.C. § 103 (emphasis added).

⁸¹ *Corning Glass Works*, 868 F.2d at 1261 (quoting *Graver Tank*, 339 U.S. at 609).

⁸² *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1581 (Fed. Cir. 1984).

⁸³ *Marsh-McBirney, Inc. v. Montedoro-Whitney Corp.*, 882 F.2d 498, 504 (Fed. Cir. 1989).

⁸⁴ See *Wilson*, 904 F.2d at 684 (the court falls short of prescribing a complete infringement framework that would take account of the appropriate time frame for equivalence analysis).

⁸⁵ See generally Roy H. Wepner, *The Patent Invalidity/Infringement Parallel: Symmetry of Symantics?*, 93 DICK. L. REV. 67 (1988) (arguing that the standards used to determine infringement should be parallel to those governing the decision to grant a patent).

expanded hypothetical claim test considers the prior art that exists at the time of infringement, thereby including the asserted patent itself.⁸⁶ [28]

It must be remembered that the expanded hypothetical claim test determines equivalence. In this context, the obviousness framework merely provides a tool for determining equivalence. Hence, rote adherence to obviousness rules is inappropriate where those rules differ from the rules for infringement. The expanded hypothetical claim test uses the obviousness framework as a tool, but properly determines equivalence at the time of the alleged infringement. [29]

D. “Element By Element” Or “As A Whole?”

Another asymmetry between obviousness and the doctrine of equivalents is whether an invention is viewed as a whole or element by element. This presents another potential problem with using the obviousness framework to determine equivalent infringement. A proper determination of obviousness depends upon consideration of the invention as a whole.⁸⁷ The current law regarding this aspect of the doctrine of equivalents, however, is somewhat unsettled. [30]

In *Pennwalt Corp. v. Durand-Wayland, Inc.*,⁸⁸ the Federal Circuit adopted an element-by-element rule.⁸⁹ The court found that there must be an equivalent for each claim limitation in the accused device.⁹⁰ In *Corning Glass*, however, a later panel explained that there was no rigid formula for equivalence, and that “[a]n equivalen[ce] must be found for every limitation of the claim somewhere in an accused device, but not necessarily in a corresponding component.”⁹¹ It is unclear whether the “invention as a whole” approach,⁹² which existed before *Pennwalt*,

⁸⁶ The asserted claim must necessarily be involved in the obviousness analysis to determine equivalence; otherwise, a hypothetical claim may be obvious in light of the prior art, and, thus, equivalent, but may be wholly unrelated to the asserted claim. Nonetheless, because obviousness determines equivalence under the expanded hypothetical claim test, the trier of fact would have to find equivalence. For example, a hypothetical claim to green cars may be obvious in light of prior art teaching blue and yellow cars. The asserted claim, however, may be wholly unrelated: for black bicycles. Nonetheless, if the asserted claim was not required to be part of the obviousness analysis, a trier of fact would have to find the accused green cars equivalent to black bicycles.

⁸⁷ 35 U.S.C. § 103.

⁸⁸ 833 F.2d 931 (Fed. Cir. 1987)(*en banc*), cert. denied, 485 U.S. 961 (1988).

⁸⁹ *Id.* at 935.

⁹⁰ *Id.*

⁹¹ *Corning Glass*, 868 F.2d at 1259.

⁹² See, e.g., *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1364 (Fed. Cir. 1983).

continues to be the proper approach for infringement under the doctrine of equivalents. Given, however, that the *Pennwalt* decision is the precedent for the Federal Circuit despite the retreat of *Corning Glass*, it appears that some form of an element-by-element rule is the proper analysis to use under the doctrine of equivalents. [31]

The expanded hypothetical claim test would utilize the obviousness framework to determine infringement under the doctrine of equivalents, with a slight modification. Under this test, the fact finder would determine the obviousness of the hypothetical claim in light of the prior art and the substitution made by the alleged infringer, rather than in light of the claim as a whole. This approach poses no substantial conflict since the goal of the expanded hypothetical claim test is to determine whether the changes made by the alleged infringer lie beyond a finding of infringement under the doctrine of equivalents. For this reason, the expanded hypothetical claim test is better than the tripartite and substantial differences tests for determining infringement under the doctrine of equivalents, especially for biotechnology patents. This Article illustrates below the superior workability of the expanded hypothetical test by applying the test to the facts of *Genentech, Inc. v. Wellcome Foundation, Ltd.*⁹³ [32]

V. APPLICATION OF THE EXPANDED HYPOTHETICAL CLAIM TEST TO *GENENTECH, INC. V. WELLCOME FOUNDATION, LTD.*

Genentech is the only protein patent case involving the doctrine of equivalents in which the Federal Circuit reversed a lower court's ruling. It is also the only protein patent case where the accused infringer did not win on equivalent infringement. Leuven, a co-plaintiff with Genentech, Inc., discovered a way to produce natural tissue plasminogen activator ("t-PA"), a protein involved in dissolving fibrin⁹⁴ clots in humans and obtained from human melanoma cells.⁹⁵ Leuven obtained a patent on this human tissue plasminogen activator.⁹⁶ Genentech was the exclusive licensee of the patent.⁹⁷ Subsequently, Genentech

⁹³ 29 F.3d at 1555 [hereinafter *Genentech III*].

⁹⁴ Fibrin is a protein that forms the structural backbone of blood clots. LUBERT STRYER, *BIOCHEMISTRY* 249-50 (3d ed. 1988). Fibrin monomers, which are fibrinogen molecules devoid of fibrinopeptides, spontaneously assemble into ordered fibrous arrays called fibrin. *Id.*

⁹⁵ *Genentech II*, 29 F.3d at 1557.

⁹⁶ *Id.* at 1558.

⁹⁷ *Id.* at 1559.

discovered a process for creating t-PA through recombinant DNA technology.⁹⁸ Genentech obtained a patent on this process of producing human t-PA as well as on the intermediates used to produce the protein, including the DNA sequence encoding the protein.⁹⁹ [33]

The Wellcome Foundation Ltd., Genetics Institute, Inc., and GI Manufacturing, Inc. were accused of making, using, and importing into the United States natural t-PA or variants of natural t-PA, produced by recombinant DNA technology.¹⁰⁰ The accused products were met-t-PA and FE1X.¹⁰¹ FE1X differs from natural t-PA in that it (1) has methionine substituted for valine at position 245;¹⁰² (2) is lacking one of the five domains of natural t-PA;¹⁰³ (3) is missing most of another domain;¹⁰⁴ and (4) has glutamine substituted for arginine at position 117.¹⁰⁵ This latter substitution alters the glycosylation of the protein.¹⁰⁶ [34]

The United States District Court for the District of Delaware, after a jury trial, found no literal infringement.¹⁰⁷ The court, however, found substantial evidence to support a jury finding that both of the defendants' products infringed the plaintiffs' patent under the doctrine of equivalents.¹⁰⁸ Therefore, the court denied defendants' motion for judgment notwithstanding the verdict.¹⁰⁹ The court

98 *Id.* at 1558.

99 *Id.*

100 *Id.* at 1559.

101 *Id.*

102 *Id.* n.4. Methionine and valine are amino acids. A series of amino acids can be combined to form a protein. The location of an amino acid in a protein is designated by its position in the series. The first amino acid in the protein is located at position 1, the second at position 2, etc. *Id.*

103 *Id.* A domain is a compact unit of a protein, and the missing domain in this case was called the Finger (F) region. *Id.*

104 *Id.* This domain is called the Epidermal Growth (E) region of the natural t-PA. *Id.*

105 *Id.* Glutamine and arginine are also amino acids, and the substitution in this case eliminated one of the carbohydrate chains by changing the gene at position 117 of the K1 region. *Id.*

106 *Id.* Glycosylation is the attachment of carbohydrate chains to a protein. *Id.*

107 *Genentech, Inc. v. Wellcome Found., Ltd.*, 798 F. Supp. 213, 214 (D. Del. 1992), *rev'd.*, 29 F.3d 1555 (Fed. Cir. 1994) [hereinafter *Genentech I*].

108 *Id.*

109 *Id.* at 219.

reasoned that substantial evidence supported a finding of equivalent infringement by the defendants' met-t-PA product because it performed substantially the same function to obtain substantially the same result, with the only dispute remaining in the analysis of the "way" prong.¹¹⁰ That only one of 527 amino acids¹¹¹ was substituted, and that the substitution was due to a mistaken cloning error, supported the jury's finding that the "way" prong of the analysis was also met.¹¹² Regarding the defendants' FE1X product, the court noted that plaintiff Genentech's patent specified retention of the functional regions, and that the two regions of the protein missing or largely missing from FE1X did not affect the function of the protein.¹¹³ [35]

The Federal Circuit reversed the district court with regard to defendants' FE1X product.¹¹⁴ In its opinion, the court stated that issues relating to the doctrine of equivalents depended upon the definition of t-PA, which the district court neglected to define for the jury.¹¹⁵ The court discarded the four possible definitions upon which the PTO could not have reasonably relied when it issued the patent.¹¹⁶ Rather, the court adopted the most narrow definition, by limiting the scope of t-PA to that which is produced through recombinant DNA technology, with the same structure as natural t-PA, and including natural allelic variants (natural variations between individual humans).¹¹⁷ Using this definition, the court found that the jury's conclusion that the defendants' FE1X product infringed on the plaintiffs' claim was not supported by substantial evidence.¹¹⁸ [36]

110 See *id.* at 215-16. This is a recurrent problem in biotechnology infringement cases, where the "way" prong is often difficult both for the parties and the lay fact finders to understand. See *Handley*, *supra* note 17, and the accompanying text.

111 *Genentech II*, 29 F.3d at 1570.

112 See *Genentech I*, 798 F. Supp. at 215.

113 *Id.* at 216.

114 *Genentech II*, 29 F.3d at 1569. The Wellcome Foundation did not appeal the finding of infringement by met-t-PA because it was no longer developing a t-PA product. *Id.* at 1560.

115 *Id.* at 1561.

116 *Id.* at 1563-64. The four possible definitions were (1) a narrow structural definition where the t-PA is produced through recombinant DNA technology but has the same structure as natural t-PA, (2) a broader structural definition where all the products contain the "essential" Kringle region, and the Serine Protease region, (3) an even broader structural definition where all products contain just the enzymatically active portions, that is, the Serine Protease portion, and finally (4) a functional definition where the t-PA is characterized as being capable of catalyzing the conversion of plasminogen to plasmin, binding to fibrin, and being classified as a t-PA based on immunological properties. *Id.*

117 *Id.*

118 *Id.* at 1568.

Interestingly, on several occasions the Federal Circuit in *Genentech II* mentioned the same problems with the tripartite test as those identified in this Article.¹¹⁹ The Federal Circuit indicated that determination of whether the "way" prong is satisfied is highly dependent on how broadly one defines the "function" of t-PA.¹²⁰ This aspect of the tripartite test again illustrates the difficulty in defining the "way" prong for biotechnology patents.¹²¹ Foreshadowing his dissent in *Hilton Davis*, Judge Lourie argued in his *Genentech II* concurrence that this case illustrated the problems with the tripartite test, especially for biotechnology inventions.¹²² He suggested that use of the other factors of *Graver Tank*, that is, equivalence, would have led the fact finder to a more sound result.¹²³ [37]

Genentech II appears to represent the panel's attempt to separate equivalent infringement analysis from the tripartite test—now the substantial differences test—especially with respect to biotechnology patents. Indeed, the logic used to determine the proper definition of t-PA in *Genentech II* is strikingly similar to that used in *Wilson*.¹²⁴ In *Genentech II*, the Federal Circuit discarded those definitions "upon which the PTO could not reasonably have relied . . . because it avoids the possibility of an applicant obtaining in court a scope of protection which encompasses subject matter that, through the conscious efforts of the applicant, the PTO did not examine."¹²⁵ Similarly, in *Wilson*, the Federal Circuit stated that one of the advantages of the hypothetical claim test is that it reminds a court that the patentee "is seeking patent coverage beyond the limits considered by the PTO examiner."¹²⁶ [38]

The use of the expanded hypothetical claim test at trial in *Genentech I* would have avoided this confusion and the need for an appeal to reach the correct result. First, the judge would have drafted a hypothetical claim reading literally on the defendants' accused FE1X product. Such a claim would necessarily have been limited to the FE1X sequence, excluding the regions it was missing and including the substitution. This would have avoided the primary reason for the appeal in

119 See *supra* Part II.

120 *Genentech II*, 29 F.3d at 1567.

121 See Handley, *supra* note 17, and the accompanying text.

122 *Genentech II*, 29 F.3d at 1570 (Lourie, J., concurring).

123 *Id.*

124 See *Wilson*, 904 F.2d at 684.

125 *Genentech II*, 29 F.3d at 1564.

126 *Wilson*, 904 F.2d at 685.

Genentech II, namely, that the judge did not construe the claim for the jury.¹²⁷ Requiring the judge to actually draft a claim would have avoided this problem altogether. The judge would then have presented this claim to the jury, which would have been charged with determining equivalence by deciding whether the judge-drafted hypothetical claim would have been obvious in light of the asserted claim at the time of infringement. The jury would have considered the later-filed British application, which disclosed the binding of fibrin as being critical to the function of t-PA.¹²⁸ Since fibrin binding is critical to the function of t-PA, it would not have been obvious to remove the fibrin-binding domain of t-PA at the time of infringement, as was done in FE1X. Consequently, the jury would have found no equivalence. Since the jury would have found no equivalence, it would not have had to address prosecution history estoppel or the limiting effect of the prior art. Therefore, by employing the expanded hypothetical claim test, the jury would have reached the correct result at trial, avoiding the necessity for an appeal. [39]

VI. POSSIBLE CRITICISMS OF THE EXPANDED HYPOTHETICAL CLAIM TEST

Wilson's hypothetical claim test originally faced much criticism from the patent law community.¹²⁹ The critics' main concern lay in the new test's potential to confuse rather than clarify the doctrine-of-equivalents analysis. After its initial negative reception, however, the test received more favorable treatment.¹³⁰ Indeed, several individuals have proposed both refinements and expansions of the hypothetical claim test.¹³¹ Nonetheless, since the expanded hypothetical claim test advocated in this Article builds upon *Wilson's* hypothetical claim test, criticisms of the *Wilson* test must be addressed. [40]

¹²⁷ *Genentech II*, 29 F.3d at 1561.

¹²⁸ *Id.* at 1567.

¹²⁹ See, e.g., Michael L. Keller & Kenneth J. Nunnenkamp, *Patent Law Developments in the United States Court of Appeals for the Federal Circuit During 1990*, 40 AM. U. L. REV. 1157, 1206 (1991) (arguing that the hypothetical claim analysis obfuscates rather than clarifies analysis under the doctrine of equivalents); Henrik D. Parker, *Doctrine of Equivalents Analysis After Wilson Sporting Goods: The Hypothetical Claim Hydra*, 18 AIPLA Q.J. 262, 274-75 (1990) (noting that the new test will confuse and complicate the presentation of evidence at trial).

¹³⁰ See generally Michael J. Bridges, Note, *Wilson Sporting Goods & the Hypothetical Patent Claim: A Sorely Needed Guideline that Should Be Applied with Discretion*, 39 WAYNE L. REV. 139 (1992) (addressing the recent adoption of the hypothetical claims test by other courts).

¹³¹ See, e.g., Handley, *supra* note 17, at 57 (proposing incorporation of section 112 into the hypothetical claim analysis); Lewis, *supra* note 79, at 1432 (suggesting expansion of the hypothetical claim analysis to contemplate each limitation of the patent claim, the prosecution history, and the pioneering nature of the patent).

Opponents of the *Wilson* test criticized it as being confusing, or even as shifting the burden of proof for infringement, particularly in jury trials.¹³² Usually the patentee bears the burden of proving infringement.¹³³ To prove infringement under the doctrine of equivalents, the patentee must prove, *inter alia*, that the prior art does not bar the asserted equivalency.¹³⁴ On the other hand, the *Wilson* hypothetical claim analysis imposes the burden on the patentee to prove the validity of the hypothetical claim.¹³⁵ [41]

Criticism of the *Wilson* test's alleged confusion and burden-shifting focuses on this requirement that the patentee prove the validity of the hypothetical claim in her case-in-chief. Under the statutory presumption of validity, however, the patentee need not prove the validity of the asserted claim.¹³⁶ Instead, an alleged infringer bears the burden of proving the affirmative defense of invalidity of the asserted claim.¹³⁷ Critics have asserted that the requirement of proving validity of a hypothetical claim may lead the jury to believe that the patentee must also prove the validity of the asserted claim.¹³⁸ Once the patentee meets the burden of proof regarding the validity of the hypothetical claim in her case-in-chief, the alleged infringer would then attempt to show the invalidity of the asserted claims. Thus, the patentee would only present evidence of the hypothetical claim's validity. The alleged infringer, however, would have to produce evidence of invalidity as to both the hypothetical claim and the asserted claim, leaving the jury to infer that the patentee had no evidence to prove the validity of the asserted claim.¹³⁹ The inference is of practical concern: a reasonable jury is likely to believe that the patentee would have presented evidence on the validity of the asserted claim when

¹³² Parker, *supra* note 129, at 278-84.

¹³³ Under Sea Indus. Inc. v. Dacor Corp., 833 F.2d 1551, 1557 (Fed. Cir. 1987) (citing *Environtech Corp. v. Al George Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984)).

¹³⁴ *Id.* at 1577-78.

¹³⁵ *Wilson*, 904 F.2d at 685.

¹³⁶ Parker, *supra* note 129, at 277-78. A patent, once issued, enjoys a presumption of validity. 35 U.S.C. § 282.

¹³⁷ See *Alco Standard Corp. v. Tennessee Valley Auth.*, 808 F.2d 1490, 1498 (Fed. Cir. 1986), *cert. denied*, 483 U.S. 1052 (1987).

¹³⁸ Parker, *supra* note 129, at 274-75.

¹³⁹ See *id.* at 276 (arguing that obligating the patentee to show validity of the hypothetical claim will necessarily compel the patentee to "emphasize any potential weaknesses in the actual asserted claims, since the expansion to the hypothetical claims will occur where the patentee thinks that he may have trouble proving literal correspondence, and will thus be detrimental to the patentee's case as a whole . . . , and he now [will be] compelled to point to the aspects of his asserted claims that he believes are the weakest").

proving the validity of the hypothetical claim.¹⁴⁰ Thus, to avoid this negative inference by the jury, the critics argue that the patentee would be forced to prove the validity of the asserted claim in her case-in-chief despite the claim's presumptive validity.¹⁴¹ [42]

In *Wilson*, however, the Federal Circuit anticipated and expressly addressed this concern. Immediately after enumerating the advantages of the hypothetical claim test, Judge Rich addressed the issue of the burden of proof.¹⁴² He noted that patent owners have always borne the burden of proving infringement and that this burden should not change simply because the inquiry involves a hypothetical claim.¹⁴³ Leaving the burden to prove equivalence on the patentee, however, "does not in any way undermine the presumed validity of [the patentee's] actual patent claims. [The patentee's] claims will remain valid whether or not [the patentee] persuades [the court] that it is entitled to the range of equivalents sought here."¹⁴⁴ Thus, the Federal Circuit specifically stated that the hypothetical claim test does not shift the burden of proving either infringement or validity. [43]

Further, although the *Wilson* court did not specifically address the issue of jury confusion, two considerations must be kept in mind. First, the Federal Circuit decided *Wilson* in a unanimous opinion joined by former Chief Judge Markey. Judge Markey, who was deeply concerned about the confusion of the burdens of proof in infringement suits, blamed patent litigators for this confusion.¹⁴⁵ He believed that the confusion resulted from patent litigators' desire to present evidence of validity in the patentee's case-in-chief, and, to prevent this confusion, he recommended the use of pretrial orders.¹⁴⁶ Indeed, so great was his concern with this issue that he even went so far as to propose bifurcation of all infringement trials.¹⁴⁷ Second, commentators view the Federal Circuit as an active court, one that

140 *Id.*

141 *Id.*

142 *Wilson*, 904 F.2d at 685.

143 *Id.*

144 *Id.*

145 *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570-71 (Fed. Cir. 1986).

146 *Id.*

147 Howard T. Markey, *On Simplifying Patent Trials*, 116 F.R.D. 369, 377 (1987). For further discussion of Judge Markey's proposal see *The 6th Annual Judicial Conference of the United States Court of Appeals for the Federal Circuit: Patent & Trademark Breakout Session*, 122 F.R.D. 281, 417 (1988) (statement by Mr. John E. Kidd, Partner, Rogers & Wells, New York, New York, advocating bifurcation to limit the plaintiff's argument solely to infringement); Rita Mankodich Irani, *The New Skirmish in Patent Cases: Who Goes First at Trial and With What Evidence*, 17 AIPLA Q.J. 364, 374-75 (1989) (comparing the order of proof in Judge Markey's proposal with traditional patent trials).

is skeptical about juries' abilities to decide complicated patent law issues such as the doctrine of equivalents.¹⁴⁸ Thus, it is unlikely that the Federal Circuit would author an opinion further confusing the burdens of proof. [44]

The *Wilson* panel was not oblivious to this possibility of confusion. Instead, it believed it could control confusion by continuing to exercise strict review of lower court decisions. The Federal Circuit has been doing just that, addressing the possibility of confusion over burdens of proof by closely monitoring lower courts' treatment of this issue.¹⁴⁹ Therefore, just as the alleged confusion over burdens of proof does not significantly interfere with the hypothetical claim test, it should not interfere with the expanded hypothetical claim test. [45]

VII. CONCLUSION

The expanded hypothetical claim test proposed in this Article provides a framework that simplifies and clarifies the issue of infringement before the fact finder. This simpler framework has advantages over the tripartite test as well as the substantial differences test. It also conforms with doctrine-of-equivalents precedents. By simplifying and clarifying the issues before the fact finder, use of the expanded hypothetical claim test will also simplify and clarify patent appeals, since the fact finder's logic will be easier to discern. These benefits of the expanded hypothetical claim test should serve particularly well in the context of biotechnology cases, where the tripartite test has proven confusing and inadequate. The expanded hypothetical claim test fills in the voids left by the tripartite and substantial differences tests, neither of which served well, especially for biotechnology patents. Because biotechnology, is one of the fastest growing fields in patent law, it needs a solid analytical foundation for infringement, and this Article has demonstrated the simplicity and flexibility of the expanded hypothetical claim test as applied to biotechnology patents. [46]

¹⁴⁸ Lewis, *supra* note 79, at 1431 (arguing that the Federal Circuit lacks confidence in juries and district courts with regard to infringement under the doctrine of equivalents).

¹⁴⁹ See *We Care, Inc. v. Ultra-mark Int'l Corp.*, 930 F.2d 1567, 1571 (Fed. Cir. 1991) (vacating preliminary injunction and remanding because district court did not consider obviousness of asserted equivalents in determining possible infringement). *But see Jurgens*, 927 F.2d at 1562 (holding that presumed fact findings upholding patent claims would apply equally to a hypothetical claim). Perhaps this would further confuse the issue of burdens of proof.