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REFINING THE *GRAVER TANK* ANALYSIS WITH HYPOTHETICAL CLAIMS: A BIOTECHNOLOGY EXEMPLAR

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INTRODUCTION

The Constitution empowers Congress to "promote the Progress of Science and useful Arts . . . ."[1] Congress has exercised this power by creating patents, which are issued through the Patent and Trademark Office ("PTO"). Patents grant inventors exclusive rights to their inventions for a limited time. A primary goal of the patent system is to promote disclosure of new information that will benefit society and that might otherwise go undisclosed absent the patent right.[2] A useful analogy can be drawn from contract law: One can view a patent as a bargained-for exchange between the inventor and society, where the novelty[3] and nonobviousness[4] of the inventor's claims, as well as the enablement[5] of his disclosure, are the required "consideration" for the statutory grant of "rights to exclude."[6]

Through patent infringement litigation, courts have granted patent holders broad exclusionary rights which are often broader than the original language of the patent, and which often cannot be justified by the

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1. U.S. CONST. art. I, § 8, cl. 8.

2. *See* PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS § 1.07 (2d Ed. 1980 & Supp. 1990).

3. *See* 35 U.S.C. § 102 (1988). This section requires that the invention be novel, i.e. it cannot be wholly described by any pre-existing reference. This description by a previous reference is also referred to as "anticipation," and the reference is referred to as the "anticipating reference." This reference must be "fully enabling," i.e., it must teach how to practice the invention.

4. *See id.* § 103. This section is similar to 35 U.S.C. § 102, but the description of the invention may be judged against any combination of prior art references, in light of the knowledge possessed by those skilled in the art in the field of the invention.

5. *See id.* § 112. This section imposes several related requirements on the patent applicant; the application must teach how to "make and use" the invention, must clearly claim the invention in definite terms, and must disclose the applicant's "best mode" for practicing the invention. The object of this section is to insure that the public will gain useful information on how to use the invention in exchange for the patent.

6. *See* Marcyan v. Nissen Corp., 578 F. Supp. 485, 498 (N.D. Ind. 1982), *aff'd*, 725 F.2d 687 (7th Cir. 1983); ROSENBERG, *supra* note 2, § 1.02.

contributions made by the inventions. This broadening of patent scope has resulted from the courts' application of the doctrine of equivalents as expounded in *Graver Tank & Manufacturing Co., Inc. v. Linde Air Products Co.*[7] In response, some courts have sought to limit the over-inclusiveness of the equivalents doctrine by employing the hypothetical claims test introduced in *Wilson Sporting Goods v. David Geoffrey & Associates*,[8] which considers the prior art in an analysis under section 103 of the Patent Act.[9] That this analysis still fails to achieve equitable results is illustrated by recent cases involving patents in biotechnology. This Article proposes further refining the *Graver Tank* analysis by limiting the hypothetical claims with an enablement analysis under section 112 of the Act.[10]

This Introduction provides a brief overview of the patent application process and of the framework that courts use to determine whether a product has infringed a patent. Section I discusses the development of the doctrine of equivalents and its use in infringement analysis, highlighting those aspects most relevant to a discussion of the *Wilson* hypothetical claims test. Section II briefly describes the reverse doctrine of equivalents, and Section III shows how the hypothetical claims test is used to restrict the coverage of the doctrine of equivalents. Section IV discusses how the doctrine of equivalents has been used in representative biotechnology cases, and demonstrates how a hypothetical claims test could have been used in these cases. Section V proposes that the hypothetical claims test, generally used in conjunction with a section 103 analysis, be extended into the section 112 enablement realm to provide a better analytical framework for later-developed products that use technology discovered after the initial patent was sought.

To procure a patent the inventor submits to the PTO an application containing a specification and claims. The specification describes how to make and use the invention, and must indicate the inventor's "best mode" of doing so. The claims delineate the material falling within the applicant's patent monopoly, so that others may either license that material or attempt to design around it. The application is reviewed by a patent examiner. Frequently, the examiner will force the applicant to provide a narrower, more precise definition of the invention, so that the claims are commensurate with the disclosure in the specification.

In cases where patent infringements are alleged, the courts have employed a two-step analysis. Initially, the court must determine the

7. 339 U.S. 605 (1950).
8. 904 F.2d 677 (Fed. Cir.), *cert. denied*, 111 S.Ct. 537 (1990).
9. 35 U.S.C. § 103 (1988). *See supra* note 4.
10. 35 U.S.C. § 112 (1988). *See supra* note 5.

scope of the claims,[11] whereby the court reads the claims in light of the specification. Although the patentee is not limited to only those examples described in the specification, the specification helps the court to define the exact nature of the invention that was envisioned by the examiner and the inventor during their negotiation. Once the claims are properly construed, the court determines whether any claim encompasses the allegedly infringing product.[12] If this product encroaches upon claims delineated in the patent application then it literally infringes.[13] If the accused product does not literally infringe, but performs "substantially the same function in substantially the same way to obtain the same result," then it infringes under the doctrine of equivalents as expounded in *Graver Tank*.[14]

The language of patents may imperfectly express the author's intent.[15] When this results in a narrower claim than appears to have been intended, the courts often interpret the patent's language broadly in order to obtain an equitable result. Sometimes, however, courts exceed the limits of reasonable interpretation.[16] In this process, courts depart from the literal language of the patent, and instead look to the heart of the invention, making an equitable judgment as to whether it has been misappropriated.[17] The court may then find infringement, even though the infringer has successfully evaded the precise claim language. The equitable principle involved here is known as the "doctrine of equivalents."[18] The doctrine of equivalents "casts around a claim a penumbra which also must be avoided if there is to be no infringement."[19]

In essence, the doctrine of equivalents departs from the language of the patent, and thus works against a primary goal of the patent system—

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11. Although the scope of claims is a question of law, this determination may also require the court to interpret the meaning of specific terms used in the claims. *See* Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985).

12. *See* Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1562 (Fed. Cir. 1986), *reh'g denied*, 846 F.2d 1369 (Fed. Cir. 1988).

13. Literal infringement is subject to the defense of the "reverse doctrine of equivalents." *See* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608–09 (1950). *See also infra* Section II.

14. 339 U.S. at 608–09.

15. *See* Claude Neon Lights, Inc. v. E. Machett & Son, 36 F.2d 574, 576 (2d Cir. 1929).

16. *See* Royal Typewriter Co. v. Remington Rand, Inc., 168 F.2d 691, 692 (2d. Cir.), *cert. denied*, 335 U.S. 825 (1948).

17. *See Graver Tank*, 339 U.S. at 608; Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1533 n.8 (Fed. Cir. 1987); *Claude Neon Lights*, 36 F.2d at 576.

18. *See infra* Section I.

19. Autogiro Co. of Am. v. United States, 384 F.2d 391, 400 (Ct. Cl. 1967).

clear notice to others regarding the scope of the patent.[20] When inventions are complex or technologically sophisticated, or when courts are not disposed to rigorous technological inquiries, the doctrine of equivalents can become a loose cannon. Courts that overextend a patentee's scope of permissible exclusion do injury to the patent system, and as a consequence may deter the work of later inventors.

Equity provides a counterpart to the doctrine of equivalents for the benefit of accused infringers—the reverse doctrine of equivalents.[21] Under the reverse doctrine, an alleged infringer whose product falls within the literal language of the claims may escape liability for infringement if he can show that his product works by a principle different from that of the patented invention. This doctrine similarly stems from equity's recognition that language may imperfectly describe the invention. For example, later-developed technology may give a breadth to the claim language which did not exist at the time of the initial bargain between the patent applicant and the examiner.

Recent Federal Circuit opinions have begun to limit the doctrine of equivalents to rough parity with that scope initially conceptualized in the bargaining between examiner and applicant. The court has used the hypothetical claim approach set forth in *Wilson Sporting Goods v. David Geoffrey Associates*[22] to provide a means for judicial definition of the intent of the parties during their negotiation of the patent contract. Although the hypothetical claims analysis has been used primarily to limit the patent monopoly by reference to prior public knowledge, this approach should be used to limit patent coverage of future developments to those enabled by the patent.[23] Such a forward-reaching approach would apply equally to defining the scope of an equivalent under the doctrine of equivalents and to narrowing the scope of claims under the reverse doctrine of equivalents.

Biotechnology has recently blossomed into a multi-million dollar business, and the PTO has been flooded with patent applications in this

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20. *See Claude Neon Lights*, 36 F.2d at 575 (holding that "it is plain that such latitude violates in theory the underlying and necessary principle that the disclosure is open to the public save as the claim forbids, and that it is the claim and that alone which measures the monopoly"). It is "a deviation from the need of the public to know the precise legal limits of patent protection without recourse to judicial ruling." Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1572 (Fed. Cir. 1986), *reh'g denied*, 846 F.2d 1369 (Fed. Cir. 1988).

21. *See infra* Section II.

22. 904 F.2d 677 (Fed. Cir.), *cert. denied*, 111 S.Ct. 537 (1990).

23. *See* Key Mfg. Group, Inc. v. Microdot Inc., 925 F.2d 1444, 1449 (Fed. Cir. 1991).

field.[24] Not unexpectedly, these patents have precipitated a secondary wave of infringement litigation, one which poses complex and immediate challenges for the judiciary. The recent decisions of *Ex parte Kranz*,[25] *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[26] and *Scripps Clinic & Research v. Genentech, Inc.*[27] will heighten the importance of litigating infringement issues, since the net effect of these decisions is to shift the emphasis away from gaining claim breadth during patent prosecution and towards acquiring increased protection under the doctrine of equivalents. The *Wilson* hypothetical claim approach may systematize biotechnology infringement inquiries under both the doctrine of equivalents and the reverse doctrine of equivalents.

I. THE DOCTRINE OF EQUIVALENTS

A. *Development of the Doctrine of Equivalents*

The doctrine of equivalents is generally cited as originating in *Winans v. Denmead*.[28] In *Winans*, a pyramidal-shaped railroad car was deemed to violate a patent whose claim language described a conical-shaped railroad car. The infringer had made full use of the patent disclosure, but had attempted to escape the literal language of the claims by making minor alterations. Clearly, the pyramidal shape did not represent an independent invention.

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24. *See* Bradford J. Duft, *Patent Infringement and Biotechnology*, 16 A.I.P.L.A. Q.J. 340, 341 (1988).

25. 19 U.S.P.Q.2d (BNA) 1216 (B.P.A.I. 1991). In this case, the inventor sought to patent a diagnostic antibody for an envisioned *in vivo* use, even though he had not yet actually made an embodiment of that antibody which would be suitable for such use. The claims were drafted so as to cover both an *in vitro* use, which was enabled, and an *in vivo* use, which was not. The Board of Patent Appeals and Interferences reversed the examiner's § 103 rejections, but instead *sua sponte* entered a § 112 rejection.

This case demonstrates a position of increased scrutiny by the PTO, which may in turn cause patent applicants to draft patents more precisely, with claims much more commensurate with their disclosure. Any expanded patent protection will then reside in clever advocacy of the doctrine of equivalents.

26. 927 F.2d 1200 (Fed. Cir. 1991).

27. 927 F.2d 1565 (Fed. Cir. 1991).

28. 56 U.S. (15 How.) 330, 339 (1853); Claude Neon Lights, Inc. v. E. Machett & Son, 36 F.2d 574, 576 (2d Cir. 1929). *Cf.* H. C. Wegner, *Equitable Equivalents: Weighing the Equities to Determine Patent Infringement in Biotechnology and Other Emerging Technologies* (International Intellectual Property Foundation, Inc., Working Paper, 1991) (available from Robert P. Merges, Assoc. Prof. of Law, Boston University, School of Law) (tracing the equitable doctrine to cases predating *Winans* and criticizing the *Graver Tank* reformulation of the doctrine).

The modern statement of the doctrine of equivalents appears in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*,[29] in which the Supreme Court enunciated the benchmark test for infringing equivalents—substantial similarity of function, way, and result.[30] As part of this test, the Court addressed the issue of whether a patent is infringed when different but corresponding elements are substituted for elements of the patented invention:

> In determining equivalents, . . . [c]onsideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform. An important factor 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.[31]

Although it may appear to provide a clear framework, the Court's "function/way/result" test provides courts with only general guidance for their infringement analyses.

The Federal Circuit has elaborated on the *Graver Tank* "function/way/result" test in several cases.[32] In practice, the second prong of the test—"substantially the same way"—is often emphasized, since most infringement suits result from competition for a given market niche which dictates the "function" and "result" prongs.[33]

The Federal Circuit has emphasized that a court's equity powers may not remove limitations purposefully written into the claims by the patentee. In *Pennwalt Corp. v. Durand-Weyland, Inc.*, the court reaffirmed the "all elements" rule;[34] namely, that each and every element of a claim must be present for the product to be infringing, either literally or by equivalence. Although the *Pennwalt* decision occasioned much commentary,[35] it does little to answer the basic question which has plagued

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29. 339 U.S. 605 (1950).

30. *See id.* at 608.

31. *Id.* at 609.

32. *See, e.g.*, Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 761 (Fed. Cir. 1984); Raytheon Co. v. Roper Corp., 724 F.2d 951, (Fed. Cir. 1983).

33. *See* Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1531 (Fed. Cir. 1987).

34. 833 F.2d 931, 935 (Fed. Cir. 1987).

35. *See, e.g.*, Martin J. Adelman & Gary L. Francione, *The Doctrine of Equivalents in Patent Law: Questions that Pennwalt Did Not Answer*, 137 U. PA. L. REV. 673 (1989); William E. Player, *Elemental Equivalence: Interpreting "Substantially the Same Way" Under Pennwalt and Corning Glass*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 546 (1989).

doctrine of equivalents decisions since *Graver Tank*—what is an equivalent?

A trial court's use of the doctrine of equivalents, even prior to *Pennwalt*, was not unbounded. Indeed, the scope of infringing equivalents has been limited by the prior art[36] and the prosecution history as well.[37] Both of these limitations reflect the basic premise that an inventor should not be able to receive broader protection from the courts than he would have been entitled to from the PTO.

B. The Doctrine of Equivalents and Later-Developed Technology

Products which allegedly infringe under the doctrine of equivalents may utilize new knowledge or materials. Normally the patentee whose application predates these advances cannot specifically claim the later-developed product. Yet the doctrine of equivalents extends to these products under the *Graver Tank* "function/way/result" test.[38]

Later-developed technology can play varied roles in the allegedly infringing product. The technology may provide a new component which allows the invention as a whole to operate more efficiently.[39] The technological advance may provide a new and more sophisticated method for producing the same product.[40] Finally, the technology may be used to circumvent the literal language of the claims and thus embodies little or no independent contribution by the inventor.[41]

Products employing later-developed technology receive variable treatment under the doctrine of equivalents, though the courts generally invoke some variant of the notion that later-developed technology may

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36. "Prior art" is information existing in the public domain; its range is defined by 35 U.S.C. §§ 102–103. In order for a patent to issue, the examiner must be satisfied that the claimed invention is neither anticipated nor obvious in light of the prior art. The examiner thereby assures that the public is receiving new and nonobvious information in exchange for the patent rights it confers. *See* Ryco, Inc. v. Ag-Bag Corp., 857 F.2d 1418, 1423 (Fed. Cir. 1988).

37. Prosecution history estoppel, also referred to as file wrapper estoppel, upholds the outcome of the bargaining process which occurs between examiner and patent applicant. If a patentee has surrendered claim breadth in order to receive a patent from the examiner, then a court cannot resurrect the surrendered material. *See* Kitzenbaw v. Deere & Co., 741 F.2d 383, 389 (Fed. Cir.), *cert. denied*, 470 U.S. 1004 (1984).

38. *See* Datascope Corp. v. SMEC, Inc., 776 F.2d 320, 326 (Fed. Cir. 1985); Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1361 (Fed. Cir. 1983).

39. *See Datascope*, 776 F.2d at 327.

40. *See* Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379 (N.D. Cal. 1987) (Recombinant technology provides for production of Factor VIII:C, which Scripps had previously purified from existing natural sources).

41. *See* Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co., 339 U.S. 605 (1950).

not escape the "web of infringement."[42] A finding of infringement will often turn on the court's perception of how significantly the later-developed technology has altered the "way" prong of *Graver Tank*. Courts may phrase this analysis in terms of "mere substitutions" or "embellishments" versus "substantially different ways of achieving a result."

1. An Infringing Product Employing Later-Developed Technology

In *Hughes Aircraft Co. v. United States*,[43] the initial patentee's claims for a satellite capable of "attitude control" included means for receiving and executing control signals from a large mainframe computer on the ground. The development of microprocessors small enough to be placed within the satellite obviated the need for ground communication. The Federal Circuit held that "a partial variation in technique, an embellishment made possible by subsequent technology, does not allow the accused spacecraft to escape the 'web of infringement.'"[44] The subsequent product, like that in *Graver Tank*, retained the gist of the patentee's invention. Had microprocessors been available to engineers of the early 1960s, the success of substituting these microprocessors for a ground-based computer would have been predictable.[45]

2. Non-Infringing Products Employing Later-Developed Technology

Although the "way" prong of the *Graver Tank* test has been characterized as being merely an unhelpful restatement of the problem,[46] it still limits the scope of infringing equivalents. Courts may employ this test at varying levels of abstraction, and "way" may refer to the underlying principle,[47] or to the means employed.[48] In *American Hospital Supply Corp. v. Travenol Laboratories, Inc.*, for example, the court held that the challenged amino acid nutritional formulation, which differed from the

42. *See Hughes*, 717 F.2d at 1365 (holding that greater commercialization due to efficiency does not exclude the innovation from the scope of the claim).

43. *See id.* at 1360–61.

44. *Id.* at 1365. *But see* Peter U.D. Wilde, *Modern Technology and the Law of Permissible Claim Scope*, J. PAT. & TRADEMARK OFF. SOC'Y 799, 806–07 (1990) (criticizing the holding and strength of the cited precedent).

45. *See Hughes*, 717 F.2d at 1365. *See also* Adelman & Francione, *supra* note 35, at 713 (explaining the application of the doctrine of equivalents in the *Hughes* decision).

46. *See* Claude Neon Lights, Inc. v. E. Machett & Son, 36 F.2d 574, 576 (2d Cir. 1929).

47. *See* American Hosp. Supply Corp. v. Travenol Labs., 745 F.2d 1 (Fed. Cir. 1984).

48. *See* Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1562 (Fed. Cir. 1986), *reh'g denied*, 846 F.2d 1369 (Fed. Cir. 1988).

claimed formulation in five of the nineteen amino acid ratios, was not an infringing equivalent.[49] The court distinguished between the means employed and the underlying principle for altering the means. The court cited *Hughes* in holding that "the Commission erred in determining equivalence at the time of invention without regard to subsequent developments in the art,"[50] but concluded that the formulation was not an infringing equivalent because it had been developed in accordance with "a competing theory for treating [the medical condition]."[51]

Moreover, seemingly minor substitutions or improvements in the individual components of the invention may cumulatively result in a product so different as to be noninfringing. In *Texas Instruments, Inc. v. U.S. International Trade Commission Co.*,[52] the Federal Circuit held that technologically advanced models of the hand-held calculator were not infringing equivalents of the pioneer patent in the field. The court stated:

> While the prior art and prosecution history are necessary considerations in applying the doctrine of equivalents, they do not of themselves control the breadth of equivalents available under the doctrine. In this case, the determination turns on the totality of change in the accused devices from that described in the specification.... [T]he extensive technological advances in all of the claimed functions support the ALJ's finding that the accused devices are not equivalent ....[53]

The court cautioned that the "determination of equivalency by its nature is inimical to the basic precept of patent law that the claims are the measure of the grant."[54]

Texas Instruments demonstrates the willingness of courts to limit the patentee's right to exclude those using later-developed technology. Unfortunately, the court provided no concrete grounds for its holding; the language of the decision implies an equity-based "I'll know it when I see it" approach.[55]

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49. *See* 745 F.2d at 10.

50. *Id.* at 8.

51. *Id.*

52. 805 F.2d 1558 (Fed. Cir. 1986), *reh'g denied*, 846 F.2d 1369 (Fed. Cir. 1988).

53. *Id.* at 1572. The claims at issue were "means plus function" claims, drawn in accordance with § 112, para. six.

54. *Id. Accord* Mead Digital Sys. v. A.B. Dick Co., 723 F.2d 455, 464 (6th Cir. 1983) (later-developed ink jet printer "quite simply, is a more sophisticated device, embodying inventive insights not part of [the earlier patent]").

55. *Cf. Texas Instruments*, 805 F.2d at 1572 (generally citing *Graver Tank*).

3. Pioneer Patents

Decisions regarding the scope of infringing equivalents using later-developed technology are particularly difficult for so-called "pioneer" patents. The Supreme Court has defined a pioneering invention as "a distinct step in the progress of the art, distinguished from a mere improvement or perfection of what had gone before."[56] Since pioneer patents by definition have little or no relevant prior art, the "backward-looking" limitations of prosecution history estoppel and the prior art will not limit the scope of infringing equivalents.[57] Thus, when the trial court must analyze the pioneer patent's scope of infringing equivalents, it is left with nothing more than its equitable judgment and the highly generalized *Graver Tank* test. This is unfortunate, since the dangers of over-reward of initial inventors and deterrence of subsequent inventors are especially acute with pioneer patents.[58]

II. THE REVERSE DOCTRINE OF EQUIVALENTS

The Supreme Court set forth the reverse doctrine of equivalents in *Westinghouse v. Boyden Power Brake Co.*:

> The patentee may bring the defendant within the letter of his claims, but if the latter has so far changed the principle of the device that the claims of the patent, literally construed, have ceased to represent his actual invention, he is as little subject to be adjudged an infringer as one who has violated the letter of a statute has to be convicted, when he had done nothing in conflict with its spirit and intent.[59]

In this case, although the defendant's product literally fell within plaintiff's broad patent claim for a type of train brake, the Court was persuaded that the defendant's brake was an improvement of such magnitude as to be beyond any equitable interpretation of the claim:

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56. Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 562 (1898).

57. *See Texas Instruments*, 805 F.2d at 1572.

58. *See* Studiengesellschaft Kohle v. Eastman Kodak Co., 616 F.2d 1315, 1324 (5th Cir.) ("A patent does not give an individual unlimited protection against every conceivable item which may employ some elements of the teaching of the patent."), *cert. denied*, 449 U.S. 1014 (1980).

59. 170 U.S. at 568.

> [A]lthough Mr. Boyden may have intended to accomplish the same results, the Westinghouse patent, if he had it before him, would scarcely have suggested the method he adopted to accomplish these results. Under such circumstances, the law entitles him to the results of an independent inventor.[60]

The reverse doctrine of equivalents was again enunciated by the Supreme Court in *Graver Tank*, as a counterpart to the doctrine of equivalents:

> The wholesome realism of this doctrine is not always applied in favor of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.[61]

Although the reverse doctrine has been validated by the Federal Circuit,[62] it has been set forth with some skepticism.[63] Further, the Federal Circuit has made it clear that the reverse doctrine is not to be used by defendants whose products differ merely by being superior versions of the claimed invention.[64] When the reverse doctrine is applied to composition of matter claims in which the final products are the same, such as in the biotechnology cases discussed herein, the "way" prong of the *Graver Tank* test is rearticulated as the "principle" of the inventor's contribution.[65]

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60. *Id.*

61. Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950).

62. *See* SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107 (Fed. Cir. 1985).

63. *See id.* at 1123 n.19. "Because products on which patent claims are readable word for word often are in fact the same, perform the same function in the same way, and achieve the same result, as the claimed invention, a defense based on the reverse doctrine of equivalents is rarely offered." *Id.* at 1123.

64. *See* Studiengesellschaft Kohle v. Dart Indus. Inc., 726 F.2d 724, 728 (Fed. Cir. 1984) (Holding that Dart's catalysts may be superior to those actually invented, disclosed, and contemplated by the patentee would not by itself remove Dart's catalysts from the scope of claims one and four.).

65. *See, e.g.*, U.S. Steel Corp. v. Phillips Petroleum, 865 F.2d 1247, 1253 n.9 (Fed. Cir. 1989); American Standard Inc. v. Pfizer, Inc., 722 F. Supp. 86, 104 (D. Del. 1989).

III. *WILSON*: LIMITING THE DOCTRINE OF EQUIVALENTS WITH HYPOTHETICAL CLAIMS

In *Wilson Sporting Goods v. David Geoffrey & Associates*, the Federal Circuit reaffirmed that the range of equivalents cannot be expanded to encompass the prior art.[66] As with its earlier attempt in *Pennwalt* to bring a semblance of order to the doctrine of equivalents, the Federal Circuit again failed to answer the truly difficult question which precedes the inquiry into the prior art: Namely, what is an equivalent?

The patent at issue in *Wilson* featured a golf ball design which increased flight distance. Since ball design is constrained by U.S. Golf Association rules, golf ball manufacturers have focused their inventive energies on optimizing the dimple designs on the ball's surface.[67] The Wilson patent partitioned the golf ball surface into an imaginary icosahedron. The twenty resultant equilateral triangles were again subdivided with six "great circles." The patent claimed a restrictive dimple distribution, where no dimple could intersect any "great circle" or the side of any "central triangle" of the repeating pattern.[68]

Although Wilson's patent application was allowed on the first action without comment by the examiner, the prior art contained golf balls with strikingly similar designs.[69] One prior art patent described division of a golf ball surface into an icosahedron with great circles, but further divided the triangles and used triangular rather than circular dimples. The prior art also included a golf ball sold in the 1970s by Uniroyal, which was icosahedral and had six "great circles," but differed in that thirty or more dimples intersected the "great circles" by twelve to fifteen thousandths of an inch. Defendant Dunlop's balls had the familiar icosahedral arrangement but had sixty dimples which intersected the great circles by 4.0 to 8.7 thousandths of an inch. At trial, a jury had entered a verdict of patent "validity [sic]"[70] and willful infringement.[71]

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66. *See* 904 F.2d 677, 683 (Fed. Cir.), *cert. denied*, 111 S.Ct. 537 (1990) (citing Senmed, Inc. v. Richard-Allan Medical Indus., 888 F.2d 815, 821 (Fed. Cir. 1989)), *appeal pending*.

67. *See id.* at 678–79.

68. *See id.* at 679.

69. *See id.* at 680.

70. A trial court should not hold a patent to be "valid"; the proper holding is that the patent is "not invalid."

71. *See id.* at 678.

The Federal Circuit reversed in part on the infringement issue and vacated in part on the validity issue.[72]

Judge Rich's opinion introduced a new tool for infringement analysis—the hypothetical claim. This analytical device focuses a trial court's attention on the essential limitation of the range of possible equivalents by requiring it to determine the maximum coverage that the patentee could have demanded.[73] First, the court constructs a hypothetical claim that is "sufficient in scope to literally cover the accused product."[74] If the PTO would have allowed that claim in light of the prior art, then a court may grant the patentee a coextensive range of equivalents. Thus, hypothetical claims assure that courts exclude others only from the inventor's contribution, not from the prior art.

In this case, the hypothetical claim that would cover Dunlop's product read: "an icosahedral ball having six great circles intersected by 60 dimples in amounts up to 9 thousandths of an inch."[75] Any differences between the hypothetically claimed ball and the prior art Uniroyal ball were summarily dismissed by the court:

> We hold that these differences are so slight and relatively minor that the hypothetical claim which permits twice as many intersecting dimples, but with slightly smaller intersections—viewed as a whole would have been obvious in view of the Uniroyal ball.[76]

Therefore, Wilson's claims did not cover Dunlop's product.

One panel of judges from the Federal Circuit has recently stated that the hypothetical claim analysis should be limited to the section 103 realm. In *Key Manufacturing Group, Inc. v. Microdot Inc.*,[77] this panel stated:

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72. *See id.*

73. *See id.* at 684. Although the facts of *Wilson* require a § 103/prior art analysis, Judge Rich's overarching emphasis on limiting the courts to claim breadth allowable by the PTO applies equally well to § 112/enablement of future development analyses. *See infra* Section V for a proposed § 112 analysis of the hypothetical claim to limit the patentee's right to exclude future developments.

74. 904 F.2d at 684. This language does not clarify whether the hypothetical claim should include the full range of the defendant's contribution, or only those elements sufficient to distinguish plaintiff's patent claims.

75. *Id.* at 685.

76. *Id.*

77. 925 F.2d 1444 (Fed. Cir 1991).

> The *Wilson* hypothetical claim analysis does not envision application of a full-blown patentability analysis to a hypothetical claim. *Wilson* simply acknowledges that prior art limits the coverage available under the doctrine of equivalents. A range of equivalents may not embrace inventions already disclosed by prior art.[78]

Such a limitation regretfully reduces the overall effectiveness of the hypothetical claim tool. Nevertheless, even a limited section 103 hypothetical claim analysis may prove useful in limiting the scope of future biotechnology claims, since scientific advances have traditionally been published extensively in this field.

IV. BIOTECHNOLOGY INFRINGEMENT SUITS

The difficulties of defining the proper scope of infringing equivalents and noninfringing reverse equivalents are highlighted in patent infringement cases involving biotechnological claims. A few representative biotechnology cases are discussed herein, and hypothetical claims will be proposed and tested in each.[79] The different legal issues present in these cases may best be understood by first highlighting the underlying differences in fact patterns.[80]

Recombinant protein[81] inventions in particular raise difficult infringement issues because many of these products are essentially new and efficient procedures for manufacturing previously identified proteins. Thus, a protein which can be manufactured in large quantities by cultured cells bearing the genetically-engineered DNA may be the same

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78. *Id.* at 1449.

79. The hypothetical claims are drawn only from the prior art discussed in the reported decisions; no independent search of the prior art or examination of the prosecution history has been conducted.

80. For an excellent synopsis of recombinant DNA technology, see Dan L. Burk, *Copyrightability of Recombinant DNA Sequences*, 29 JURIMETRICS J. 469, 472–84 (1989).

81. Scientists generally make these proteins by inserting the appropriate gene into a cell. The gene consists of DNA, and it is the genetic blueprint for constructing the desired protein product. This blueprint is inserted into a longer piece of DNA, and this instruction package is then inserted into a cell. This cell will then begin to produce the desired protein, according to the foreign gene blueprint. The scientist will then culture this cell. The end result is a population of descendant cells, all producing the desired protein. These cells are grown in a controlled liquid environment which provides the necessary nutrients, minerals, growth factors, gases, etc; this is termed "cell culture." This description is an oversimplification which does no justice to the difficulties encountered in initially identifying the desired gene, and in successfully coaxing the cell to make the protein. *See id.* for a particularly clear description of potential pitfalls.

protein which has been patented by scientists who earlier provided a patentable advance in its purification.[82] A trial court must determine whether the isolated, purified protein and recombinant protein are literally the same product. For example, to what degree has the amino acid sequence[83] or the biological activity or purity been altered? If they are not, do they perform their allotted biological task in "the same way"?

A. Purified Natural Products vs. Recombinant Products

In two major cases of this type the trial courts held that the patent for the purified natural product was infringed by the recombinant product. The Federal Circuit has recently reversed key holdings of the trial court in both cases.[84] In *Amgen, Inc. v. Chugai Pharmaceutical Co.*, the Federal Circuit strictly limited the scope of claims to which the inventor of the purified natural product was entitled;[85] in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, the Federal Circuit reversed the summary judgment verdict on infringement, and strongly intimated that the trial court should apply the reverse doctrine of equivalents on remand.[86] Taken together, these decisions indicate that both the doctrine of equivalents and the reverse doctrine of equivalents will hereafter play an expanded role in determining the scope of protection for biotechnology inventions.

1. Amgen v. Chugai

Erythropoietin ("EPO") is a glycoprotein which stimulates red blood cell formation in the bone marrow.[87] Those skilled in the art in the late 1970s believed that the accepted protocol for EPO preparation produced

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82. One who changes or purifies a known natural product may obtain a patent for its altered state. *See* Parke-Davis & Co. v. Mulford Co., 189 F. 95 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

83. Amino acids are the building blocks of proteins. The cell assembles the amino acids in a linear fashion (like stringing beads of a necklace). The linear chain (a polypeptide) will then fold into the final three-dimensional protein. Some amino acids of the chain may be altered without significantly affecting the three-dimensional structure. Other changes in the sequence may alter the three-dimensional structure enough to reduce or even eliminate the biological activity of the protein.

84. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991).

85. *See* 927 F.2d at 1217.

86. *See* 927 F.2d at 1581.

87. *See Amgen*, 927 F.2d at 1203. A glycoprotein is a protein with attached carbohydrates.

homogeneous EPO.[88] Scientists at Genetics Institute, however, succeeded in further purifying EPO and were granted U.S. Patent No. 4,677,195 ("the '195 patent"), which contained claims for both the purification method and the purified product itself.[89] Later, Amgen patented the genetically engineered components necessary for making recombinant EPO, obtaining U.S. Patent No. 4,703,008 ("the '008 patent").[90] The trial court granted summary judgment on the issue of infringement of the '195 patent, holding that the recombinant product did not escape infringement despite its different method of manufacture.[91] The trial court subsequently held both patentees' claims to be valid and infringed.[92]

The Federal Circuit affirmed all holdings of the trial court with one exception; the product claims of the '195 patent were held invalid under section 112,[93] and therefore the trial court's holding of infringement was vacated. The Federal Circuit's treatment of the '008 patent emphasized enablement issues. With regard to the section 102(g) challenge to validity, the court announced the "first to clone" rule, holding that biotechnology cases were analogous to chemistry cases in that conception required both an idea of the structure of the gene and a procedure for making it.[94] With the knowledge existing at the time of invention, this

88. *See* Amgen Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 96 (D. Mass. 1989).

89. *See* 927 F.2d at 1203.

90. *See id.* at 1203–04. Claim two of the patent covered the "purified and isolated DNA sequence" for human EPO; claims four and six covered the cell containing the DNA of claim two. *See id.*

91. *See* 706 F. Supp. at 101–03.

92. *See* 927 F.2d at 1205.

93. Specifically, the Federal Circuit held that the claim limitation to 160,000 IU, which the trial court had found to refer to *in vivo* specific activity, was not enabled, since the figure had been arrived at by calculation rather than testing. *See id.* at 1216–17. In fact, this specific activity was not duplicable by others, and Genetics Institute later reported a specific activity of only 109,000 IU to the Food and Drug Administration. *See id.* at 1216. The Federal Circuit appeared to take such a strict approach to enablement because the prior art contained preparations of 120,000 IU, *see id.* at 1217; thus, the § 112 invalidation appeared to be a back-handed way of invalidating the patent on grounds of obviousness, or insufficient advance over the prior art. This § 103/§ 112 interplay is precisely what the proposed expansion of the hypothetical claim test is intended to highlight.

94. *See id.* at 1206. Section 102(g) provides another defense to infringement: that the patentee was not the first to invent the claimed invention. This defense involves two components: "conception," or first envisioning the invention, and "reduction to practice," which refers to the work involved in converting the idea to either a concrete embodiment or a patent application. Here, Genetics Institute claimed that its scientists had conceived of the invention first, in that they had envisioned the gene and the method of isolating it. They had, however, lost the race to the patent office. The Federal Circuit rejected this argument by holding that the conception and reduction to practice were simultaneous for an invention of this sort. *See id.* However, the genetic engineering techniques used in isolating the EPO gene were relatively new and uncertain at the time of the invention. As techniques become more predictable, this holding may no longer be applicable. *See In re* Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988).

conception could only have occurred after the gene had been successfully cloned, since its structure was not sufficiently defined, nor was the success of the cloning process sufficiently certain.[95] The court indicated that the "structure" in biotechnology cases was the DNA sequence itself, although the court also acknowledged that some other characteristic sufficient to distinguish the gene from other genes might suffice.[96]

The Federal Circuit treated claim seven, a generic claim which attempted to cover all variants of the original EPO DNA sequence that are functionally equivalent (analogs), in a correspondingly strict manner. Although the specification had referred to methods for preparing analogs and contained a limited number of examples, the court held that the broad scope of the generic claim was not sufficiently enabled:

> This "disclosure" might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.[97]

Taken together with the emphasis on precise gene characterization—by sequence or otherwise—this holding suggests that future applicants may have a difficult time convincing PTO examiners that their disclosure of a DNA sequence broadly enables other analogs, without actually preparing, sequencing, and testing the analogs before applying for the patent. Consequently, the inventor who wishes to file a patent application as soon as possible may be left with the doctrine of equivalents to protect against competitors who attempt to market analogs of the claimed invention.

Wilson suggests that hypothetical claims be used to insure that the patentee not ensnare scientific or technical aspects that were known to the art prior to the applicant's invention. In *Amgen*, the court cited Miyake et al.,[98] which disclosed a chromatographic method for purification of EPO, as a major reference in the prior art.[99] Until the

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95. *See Amgen*, 927 F.2d at 1206.

96. *See id.*

97. *See id.* at 1213–14.

98. T. Miyake et al., *Purification of Human Erythropoietin*, 252 J. BIOL. CHEM. 5558 (1977).

99. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 96 (D. Mass. 1989).

Genetics Institute scientists further purified EPO with the technique of high performance liquid chromatography ("HPLC"),[100] scientists had believed the Miyake preparation to be pure.[101] Although other prior art references had described chromatography techniques similar to HPLC, the trial court held that there was no motivation to seek to further purify EPO because the Miyake EPO was thought to be pure.

The court could have used hypothetical claims in the following ways. First, it could hold that the recombinant EPO literally infringes Genetics Institute's claim, and then could use the hypothetical claim to analyze Amgen's reverse doctrine of equivalents arguments.[102] Second, absent literal infringement, the court could draft the hypothetical claim to mirror the patentee's claim format, so as to read "[h]omogenous EPO characterized by [slightly different physical properties]."[103] This claim format restricts the inquiry to plaintiff's inventive contribution. Third, the hypothetical claim could be drafted to include the defendant's independent contribution, which in this case was the DNA sequence coding for EPO.

The second and third hypothetical claims would yield identical outcomes under a section 103 analysis using the prior art, since the distinguishing elements were added by later art (the protein sequence) rather than the prior art.[104] As with pioneer inventions,[105] some other analytical tool is needed to precisely identify the equitable bounds of Genetics Institute's invention. Whereas pioneer inventions are typically granted wide latitude on the theory that their contribution to the art has been substantial, here the patentee contributed only the application of a known

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100. "HPLC" is a method of separating a desired compound from contaminants that is superior to regular chromatographic techniques.

101. *See id.*

102. *See* Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991).

103. The trial court did consider the slight differences in granting summary judgment on infringement. *See Amgen*, 706 F. Supp. at 108–10.

104. The second hypothetical claim format discussed in the preceding paragraph could conceivably be used to restrict the patent right if a court felt that the initial composition of matter claim was unjustified in light of the prior existence of purified EPO. The court may deem it to be inequitable for what was in essence an improvement patent to dominate later and superior improvements which utilized the substantially different recombinant DNA technology. A trial court might achieve the desired "equitable" result by analyzing the "obviousness" of the hypothetical claim *de novo*, instead of in light of the previously-granted '195 claim. Thus, in the EPO example, a trial court might hold the hypothetical claim invalid in light of Miyake et al., while simultaneously finding the '195 claim "not invalid." This odd dichotomy may be justifiable in light of the *Wilson* language that distinguishes expansion of the right to exclude from expansion of the claim.

105. *See supra* Section I.B.3.

purification method to a known protein, and thus such equitable generosity was not justifiable.

2. *Scripps v. Genentech*

The scope of the patent for Factor VIII:C, a protein essential for normal blood clotting, was at issue in *Scripps*. Scripps had obtained U.S. Patent No. 4,361,509 ("the '509 patent"), on a method for purifying natural Factor VIII:C,[106] while Genentech had subsequently sequenced the protein and had made genetically-engineered cells that produced the recombinant product.[107] The trial court granted summary judgment on the issue of infringement.[108] In holding that the recombinant product met the *Graver Tank* "function/way/result" test, the court placed great emphasis on Genentech's own representations of commercial equivalence. The court held that "Scripps is entitled to claim purified Factor VIII:C having the characteristics of human Factor VIII:C, whether derived through its disclosed process or any other process achieving the same result."[109]

The Federal Circuit reversed the trial court's grant of summary judgment on all grounds. Judge Newman issued an open invitation for the trial court to apply the reverse doctrine of equivalents on remand:[110]

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106. The '509 patent was later reissued as U.S. Reissue Patent No. 32,011. *See Scripps*, 927 F.2d at 1574. The Factor VIII:C was purified from blood using monoclonal antibodies to Factor VIII:RP. Since Factor VIII:RP is attached to Factor VIII:C, the separation process yields substantially pure VIII:C/VIII:RP complexes from which Factor VIII:C can easily be obtained. *See id.* at 1569.

107. *See id.* at 1580 n.9.

108. The court found both literal infringement and equivalence. Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1389–90 (N.D. Cal. 1987). In doing so, the court initially found that the Genentech Factor VIII:C was "human VIII:C," even though it was produced in non-human cell cultures. *Id.* The court later held the claims at issue invalid due to Scripps' inequitable conduct before the PTO during the reissue proceedings, invalid for concealing the "best mode", 35 U.S.C. § 112, and anticipated by a newly-discovered PhD. dissertation. The reissue claims were also held invalid, due to an inadequate showing of "error" required under 35 U.S.C. § 251. *See* Scripps Clinic & Research Found. v. Genentech, Inc., 707 F. Supp. 1547 (N.D. Cal. 1989).

109. 666 F. Supp. at 1390. This language, along with the emphasis on marketplace representations, indicates that the district court truncated the *Graver Tank* analysis and failed to fully consider the "way" prong. The proposed extension of the hypothetical claim test to enablement analysis would prevent such an oversight.

110. The court upheld the trial court's determination that the recombinant Factor VIII:C was "human" and therefore literally infringed the Scripps patent. Judge Newman stated that Genentech's interpretation of the word "human" was an inherent process limitation (limiting the claims to Factor VIII:C extracted from plasma) which was legally inconsistent with Genentech's failure to challenge the "propriety" of the product claims. *See Scripps*, 927 F.2d at 1580–81. Therefore, the Federal Circuit may be inviting future litigants to challenge product claims more forthrightly, either as obvious in light of the art, or as invalid under § 112 as "indefinite." *See also* Amgen, Inc. v. Chugai Pharmaceutical Co.,

> The reverse doctrine of equivalents flows from the Supreme Court's statement in *Graver Tank* that an accused article may avoid infringement, even if it is within the literal words of the claim, if it is "so far changed in principle from a patented article that it performs the same or similar function in a substantially different way." Application of the doctrine requires that facts specific to the accused device be determined and *weighed against the equitable scope of the claims, which in turn is determined in light of the specification*, the prosecution history, and the prior art.
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> . . .
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> *The principles of patent law must be applied in accordance with the statutory purpose, and the issues raised by new technologies require considered analysis.*[111]

Both the reverse doctrine of equivalents and the hypothetical claim enablement analysis proposed in Section V focus on the "way" prong of the *Graver Tank* test of equivalence. The approach suggested herein mirrors Judge Newman's suggested approach for the reverse doctrine of equivalents.[112]

Factor VIII:C, like EPO, was known prior to Scripps' '509 patent, which was granted in light of the novel purification procedure that Scripps disclosed. During later reissuance proceedings, product claims were added for the purity levels Scripps allegedly achieved.[113] As with the case of EPO in *Amgen*, these product claims were held to be literally infringed.[114] However, had the term "human" been limited to include VIII:C purified from human plasma but not VIII:C synthesized in a cell expressing the human gene, the analysis would have been one of equivalents. The hypothetical claims, if modelled closely upon patentee's claims, would be virtually indistinguishable from the product

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927 F.2d 1200, 1207 n.3 (Fed. Cir. 1991).

111. *Scripps*, 927 F.2d at 1581 (emphasis added) (citations omitted).

112. A variety of older, non-precedential cases which to some extent limit the patentee to the invention envisioned in the specification, and thus hold improvements to be non-infringing, are discussed in Charles F. Pigott, Jr., *Equivalents in Reverse*, 48 J. PAT. OFF. SOC'Y. 291, 291–308 (1966). Typically, the courts cited therein used some form of an enablement analysis in reaching the decision of noninfringement.

113. *See Scripps*, 927 F.2d at 1570–71.

114. Claim 24 reads "a human VIII:C preparation having a potency in the range of 134 to 1172 units per ml, and being substantially free of VIII:RP." *Id.* at 1570. The issue was mooted at a later stage of the suit, when defendants brought forth both a dissertation which allegedly anticipated many of the claims and proof of significant inequitable conduct. The court then held all the claims at issue invalid. *See id.* at 1572.

claims in the reissue. The prior art of the Scripps patent would naturally be devoid of limiting references, since the recombinant process was developed after the '509 patent was filed.

B. Synthetic Peptides vs. Recombinant Peptides

Recombinant DNA technology is not the only alternative to purification for producing a desired biological product. For example, when a protein's amino acid sequence is known, a scientist may sequentially attach individual amino acids to create a synthetic protein. In *Hormone Research Foundation v. Genentech, Inc.*,[115] a dispute involving recombinant and synthesized versions of the peptide human growth hormone ("HGH") arose when Genentech succeeded in making recombinant HGH.[116] The legal issues were complicated by the fact that the first scientist, in obtaining a patent for his synthetic HGH, initially misidentified several amino acids in the protein sequence.[117] The trial court granted Genentech's motion for summary judgment, holding that the initial patentee was estopped from claiming literal infringement or equivalence by statements before the PTO which seemingly limited his claims to the erroneous sequence.[118] The Federal Circuit upheld the trial court with regard to literal infringement, but remanded for factual development of the scope of the estoppel with regard to the infringement by equivalents.[119] Finally, the Federal Circuit indicated that the district court should apply the *Wilson* hypothetical claim analysis to determine infringement.[120]

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115. 708 F. Supp. 1096 (N.D. Cal. 1988) (summary judgment on file wrapper estoppel), *aff'd in part, vacated in part and remanded*, 904 F.2d 1558 (Fed. Cir. 1990).

116. *See id.* at 1098–99.

117. His claims were drawn to a figure which disclosed this erroneous sequence. *See id.* at 1098.

118. The trial court limited the claim term "corresponding" to the exact sequence disclosed, and later stated "in chemical structures as sensitive as these the literal infringement showing must be exacting." *Id.* at 1102.

119. The Federal Circuit upheld the holding, but based it more clearly on file wrapper estoppel. *Hormone Research Found. v. Genentech, Inc.*, 904 F.2d at 1558, 1564–65 (Fed. Cir. 1990). It is not clear what effect broadening claim language will have in future cases which lack the file wrapper estoppel limitation. The Federal Circuit in *Amgen* placed great emphasis on the precise DNA sequence, suggesting that trial courts in the future may limit literal infringement to the exact DNA sequence, or perhaps to a sequence with only conservative substitutions which do not alter the resultant amino acid sequence. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).

120. *See Hormone Research Found.*, 904 F.2d at 1567 n.14. ("If the court determines that estoppel does not apply, it should then determine whether Genentech's products are within a legally permissible range of equivalents.") (citing Wilson Sporting Goods v. David Geoffrey & Assocs., 904 F.2d 677 (Fed. Cir. 1990)).

As with the two preceding cases, HGH was known to the art at the time of the initial patent. This case differs from the "purified vs. recombinant" case in that the initial patent disclosed an amino acid sequence for the desired product.[121] Setting aside the issue of prosecution history estoppel,[122] a hypothetical claim drawn to a figure depicting the slight amino acid changes of Genentech's product is arguably no more obvious in light of the prior art than was the sequence originally disclosed. Thus, the prior art probably provides no meaningful limitation on the patentee's right to exclude recombinant products.[123]

C. First vs. Second Generation Recombinant DNA Products

Finally, infringement disputes arise between an initially patented recombinant product and subsequent recombinant products which are made with similar recombinant techniques. These situations conceptually are much closer to the *Graver Tank* "substitutions" than are the prior fact patterns discussed. The DNA sequence coding for the protein is known, and the first inventor's patent sets forth the fundamental recombinant techniques as applied to that specific protein. The second inventor may then use known techniques to add, delete, or substitute amino acids in the original recombinant sequence. The second inventor's product may have substantially similar biological activity, or it may display greater potency or additional characteristics. The new development here results from the alteration in the amino acid sequence and so can be conceptually thought to rest on the structure-function relationship.

In *Genentech, Inc. v. The Wellcome Foundation Ltd.*,[124] the court cited just such distinctions in denying both parties' motions for summary judgment. Genentech was the assignee for three patents: One contained

121. Although the disclosed amino acid sequence contained some errors, it probably provided sufficient information with which to construct probes for the isolation of the DNA coding for HGH.

122. The prior art (Bewley et al.) describes the alteration of natural HGH. The inventor responded by stressing the difference between natural and synthetic HGH, and later disclaiming "HGH and its derivatives." *See Hormone Research Found.*, 708 F. Supp. at 1105.

123. Of the four cases discussed herein, *Hormone Research Found.* provides the only meaningful opportunity for hypothetical claims analysis of the prior art. The HGH claims did not contain any purity limitations. Therefore an expansion of these claims to encompass Genentech's Protropin II, which was identical to the natural product long known to the art, ensnares the natural product. Without some element in the claim to distinguish that natural product, the claim is invalid. However, the patentee may try to argue the difference between "natural" HGH (as extracted from tissues) and "man-made" HGH (whether from peptide synthesis or genetic engineering).

124. 14 U.S.P.Q.2d (BNA) 1363 (D. Del. 1990).

product claims for human tissue plasminogen activator ("tPA")[125] of a given specific activity (U.S. Patent No. 4,752,603); another claimed a process for making recombinant tPA (U.S. Patent No. 4,853,330); and the third claimed the recombinant DNA sequence that codes for tPA (U.S. Patent No. 4,766,075).[126] Wellcome's second generation protein substituted one amino acid, thereby changing the glycosylation.[127] Another variant ("FE1X") deleted eighty-one of tPA's 527 amino acids. These changes resulted in FE1X having a longer half-life in the bloodstream than tPA.[128]

The court held that the sequence changes and variations in specific activity precluded a finding of literal infringement.[129] As for equivalent infringement, the court considered the unpredictable effect of sequence alterations on protein function, and wrote:

> [T]he trier of fact will have to determine whether the substitution of the methionine altered the interaction of the protein with plasminogen in addition to the reduction of specific activity. This will require experts to identify the importance of the alterations ... [all of the proteins] have the same intended result and function, [but] it is not clear at this time if they achieve it by the same means.[130]

First vs. second generation recombinant DNA products cases are at once simpler and more difficult than the prior two categories. Since both proteins are made by recombinant techniques, the complicating "apples and oranges" aspect of the previous analyses is not present. However, these cases involve alterations in the protein sequence, requiring the court to make difficult inquiries regarding structure-function relationships. Since there is little certainty in these analyses, the court will find itself directly confronted with section 112-type issues of enablement of screening methodologies and notions of "undue experimentation."[131] In

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125. The peptide tPA converts plasminogen to plasmin, which is a proteolytic enzyme involved in the dissolution of a blood clot. *See id.* at 1365.

126. *See id.*

127. *See id.* at 1368. "Glycosylated" proteins have certain sugar groups attached to them at specific locations; glycosylation frequently is required for biological activity.

128. The half-life of FE1X was 42 minutes, compared to a half-life of four minutes for Genentech's tPA. *See id.* at 1369.

129. *See id.* at 1370.

130. *Id.* at 1371.

131. *In re* Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988). The Federal Circuit has recently indicated the necessity of this inquiry in determining the breadth of the initial claim. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212–13 (Fed. Cir. 1991).

other words, did the initial patent provide sufficient guidance to produce the second-generation product, or were numerous trials and undue experimentation necessary to discover the second product?

The peptide tPA had been known for many years before Genentech's patents.[132] Through its research, however, Genentech acquired patents both for purification of naturally occurring tPA and for recombinant tPA. Wellcome subsequently modified the protein.

In *Genentech*, the patentee's hypothetical claim could be broadened to encompass Wellcome's product by adding the phrase "a glycoprotein essentially similar to [human tPA]," and disclosing the altered genetic sequence. Such a claim would have been patentable, since the prior art would not have provided any restrictions under section 103. Alternatively, the hypothetical claim could be drawn to encompass Wellcome's inventive contribution. The hypothetical claim could include limitations regarding the number of glycosylation sites, plasma half-life, or fibrin binding, all characteristics that distinguish Wellcome's product from Genentech's. Again, the prior art would not differentiate between the two claim formats—the new elements would be contributed by later-developed knowledge.

D. Limitations of the Wilson *Hypothetical Claim Approach*

These biotechnology cases pose the difficult questions of defining an infringing "equivalent" or a non-infringing "reverse equivalent". Whereas hypothetical claims are a useful tool for insuring that the patentee does not misappropriate prior art,[133] *Wilson* shares *Pennwalt*'s weakness in that it fails to provide guidance for the inquiry which necessarily precedes consideration of the prior art, namely, is the accused product an equivalent under the *Graver Tank* test? The issue reduces to defining when an allegedly infringing product works in a "way" that is substantially similar enough to warrant a court's including it in the range of potentially infringing equivalents, or a "way" that is so different as to justify a finding of noninfringement despite literal correspondence with the claim language. The above biotechnology examples highlight the need for a complementary equitable limitation which considers the art developed *after* the application is filed.

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132. *See Genentech*, 14 U.S.P.Q.2d (BNA) at 1365.

133. *But see* Henrik D. Parker, *Doctrine of Equivalents Analysis After Wilson Sporting Goods: The Hypothetical Claim Hydra*, 18 AIPLA Q.J. 262 (1990) (criticizing practical aspects of litigating hypothetical claims).

V. DEFINING INFRINGING EQUIVALENTS AND NONINFRINGING REVERSE EQUIVALENTS WITH A SECTION 112 ANALYSIS OF HYPOTHETICAL CLAIMS

An invention's scope of enablement as of the time of filing should be used to limit the scope of infringing equivalents. Indeed, that scope of enablement is vital to properly understanding and applying the second prong of the *Graver* test—the "way" prong. As with the *Wilson* approach to prior art under section 103, "[a]ny other approach would ignore the realities of what happens in the PTO and violate established patent law."[134] The PTO's analysis rests on two foundations: the prior art and compliance with section 112's enablement requirements. The doctrine of equivalents jurisprudence has placed a disproportionate emphasis on the prior art aspect, leaving the enablement aspect subsumed in the *Graver Tank* "substantially same way" analysis.

Extending the hypothetical claim analysis into the section 112 enablement realm provides an analytical framework for trial courts' equitable instincts. Section 112 prevents a patentee from extending his exclusionary right to all subsequent developments of the art.[135] Paragraph one of section 112 requires a "written description" disclosing how to "make and use" the invention, and paragraph two requires the inventor to "distinctly claim" his invention so that others may freely conduct their own research and add their subsequent contributions to the art.

Section 112 presupposes that the invention has been defined in accordance with the notion that the protected invention embody sufficient value to constitute a quid pro quo for the valuable rights received in return.[136] The doctrine of equivalents expands these rights—courts should insure that the scope is commensurate with the knowledge bestowed upon society by the invention. Thus a broad reading of a claim which is not enabled by the specification violates this quid pro quo. Similarly, an overly deferential approach to the literal claim language with no recourse to the reverse doctrine of equivalents violates the quid

134. Wilson Sporting Goods v. David Geoffrey & Assocs., 904 F.2d 677, 685 (Fed. Cir.), *cert. denied*, 111 S.Ct. 537 (1990).

135. Although Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1572 (Fed. Cir. 1986), did not clearly enunciate this principle, its holding is consistent with the § 112 analysis discussed herein.

136. *See* U.S. Plywood Corp. v. General Plywood Corp., 370 F.2d 500, 506 (6th Cir. 1966) (stating that the constitutional standard of invention includes "[i]nnovation, advancement, and things which add to the sum of useful knowledge") (quoting Graham v. John Deere Co., 383 U.S. 1, 6 (1966)), *cert. denied*, 389 U.S. 820 (1967).

pro quo. Courts, therefore, must keep this interplay of description and statutory reward firmly in mind when later determining infringement.

A. Inequities May Result from Judicial Noncognizance of the Section 112 Limitations on Infringing Equivalents

Consider these hypothetical inventor-examiner interactions during the prosecution of a claim for biological species X, which is a member of genus Y. Assume Inventor A claims genus Y, and the specification describes only species X. The examiner's section 112 rejection cites well-established precedent[137] for the proposition that biologicals are an unpredictable art, and therefore Inventor A has not enabled the claim for genus Y. Inventor A capitulates, and narrows his claim to species X. He may be precluded by prosecution history estoppel from later claiming that his specification enabled species Z (another species of genus Y), which Alleged Infringer has successfully brought into the market. Now assume that Inventor B, rather than attempting to claim genus Y, merely claims species X′ and that the examiner allows this narrow claim without comment. Under the doctrine of equivalents, Inventor B may successfully sue Alleged Infringer, claiming that Z is an infringing equivalent to X′.

Although the specifications of Inventor A and Inventor B contribute equivalent amounts of information to society, Inventor B has obtained more protection from the courts than Inventor A obtained from the PTO. *Wilson* makes it clear that this result is to be avoided.[138] Courts must therefore take care that the initial scope of the claims and definition of the invention incorporate a stringent enablement analysis.

Courts frequently have acknowledged that proper claim interpretation draws both on the specification and the prosecution history,[139] and section 112 is instrumental in shaping both. The specification and claims of a patent application are drafted with section 112 in mind, and the PTO frequently will reject the initial claims on the grounds that they are not enabled by the specification. Thus, the claims as finally allowed consti-

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137. *See, e.g., Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 548 (B.P.A.I. 1981).

138. *See* 904 F.2d at 684.

139. *See, e.g.*, SRI Int'l v. Matsushita Elec. Co. of Am., 775 F.2d 1107, 1118 (Fed. Cir. 1985); Autogiro Co. of Am. v. United States, 384 F.2d 391, 397 (Ct. Cl. 1967) ("The Alice-in-Wonderland view that something means whatever one chooses it to mean makes for enjoyable reading, but bad law. Claims are best construed in connection with the other parts of the patent instrument and with the circumstances surrounding the inception of the patent application.").

tute an agreement between the patentee and the examiner regarding the scope of enablement, and thereby the scope of invention.[140]

B. Proposed Incorporation of Section 112 into the Hypothetical Claim Test of Infringement

A properly construed claim which includes section 112-based limitations is analyzed under the general *Graver Tank* "function/way/result" rubric. For example, frequently the only significant distinction between two competing products is the "way" in which they work. Previous ad hoc determinations of this issue may be systematized by comparing the properly construed claim of the patent with the hypothetical claim describing the allegedly infringing product. A court may then determine whether the hypothetical claim is enabled by the properly-construed subject matter of the initial patent.[141] If it is, then the subject matter of the second claim is within the infringing realm of equivalents and improvements. If it is not, then a court may hold that the two products function in substantially different ways, therefore holding the second product to be non-infringing.[142]

The proposed test does not preclude "dominant" or "blocking" patents[143] because it is limited to products that have the same overall "function" and "result." Thus it is proposed only as a clarification of the "way" prong of the *Graver Tank* test for infringing equivalents. Later products which incorporate an element that functions or exists in a manner unchanged from its earlier-patented form would not be subjected

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140. *See, e.g.*, SSIH Equip., S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365 (Fed. Cir. 1983); Lemelson v. United States, 223 U.S.P.Q. (BNA) 1183, 1187–88 (Cl. Ct. 1983).

141. In accordance with the rule that equivalents are determined at the time of infringement and not at filing, the skill of the art should be measured at the initiation of defendant's work. *See* Atlas Powder Co. v. E. I. DuPont de Nemours & Co., 750 F.2d 1569, 1581 (Fed. Cir. 1984).

142. A dichotomy exists between the claimed invention, and expansion of the right to exclude others from the claimed invention. *See Wilson*, 904 F.2d at 684. Hypothetical claims deal solely with the right to exclude—they do not alter the underlying patent claims. Thus, the criticism voiced by the Federal Circuit in *Hormone Research Found.* regarding use of later-developed technology to invalidate a prior patent for lack of enablement is inapposite. *See In re* Hogan, 559 F.2d 595, 605 (C.C.P.A. 1977).

143. Dominant patents are basic patents, granted earlier in time, which subsequent improvement patents incorporate. *See Atlas Powder Co.*, 750 F.2d at 1581. Although the later invention may itself be patentable, it still infringes the earlier patent. For example, a patent for "a chair" will dominate the subsequent improvement patent for "a chair that rocks back and forth."

to this modified *Graver Tank* analysis and would still clearly infringe the earlier patent.

C. The Special Problem of Biotechnology Product Claims

The fundamental problem with all the above infringement inquiries arguably lies with the nature of claims granted by the examiner. When broad claims are unduly granted, the courts must turn to the complicated doctrines of equivalents and reverse equivalents. Nonetheless, an even more fundamental error arises in applying the *Graver Tank* test to biotechnology product claims where a *product* patent is granted for what is essentially an advance in the *process* of making a known protein. In all four of the representative cases discussed herein, the product and its therapeutic benefits were known in the prior art. In each of these cases, however, a product patent was granted under one of two theories.

Under the first theory, a party who achieves purity levels of a natural product exceeding that provided by Mother Nature is entitled to a product patent.[144] Such a patent will have claim language indicating threshold purity, and may in some situations also require some indication of a purity "ceiling" in the range of what the patentee actually achieved;[145] *Scripps* is an example of this. Under the second theory, the product's composition and its method of manufacture are both valid elements of the "invention"; the obviousness of the composition may be overcome, and a patent on the compound itself may issue, if the method of making is novel and nonobvious.[146] In *Amgen*, for example, broad product claims covering the identity of EPO were granted, even though EPO was known to exist prior to the '195 patent, and the inventive aspect arose only in the method of manufacture. Under both theories, the PTO's generous treatment of the initial applicant leads to equitable challenges in the trial court by subsequent inventors.

A forthright challenge to the initial claims would eliminate the need for doctrinally complicated secondary measures. Such a forthright attack was levelled by Judge Learned Hand in the wise but unfortunately

144. *See* Parke-Davis & Co. v. Mulford Co., 189 F. 95 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

145. *See In re* Fisher, 166 U.S.P.Q. (BNA) 18, 24 (C.C.P.A. 1970).

146. This line of reasoning stems from chemical compound cases such as *In re* Hoeksema, 158 U.S.P.Q. (BNA) 596 (C.C.P.A. 1968). The court there held that, although the structure of the amino acid was so similar to known amino acids as to be "obvious," the fact that the applicants had devised a patentable method of manufacture entitled them to a patent on the compound itself—that both the structure and the manufacturing process must be considered together, as they contributed to the "invention as a whole." *See id.* at 600.

non-precedential case of *Buono v. Yankee Maid Dress Corp.*[147] There, the patentee held a product patent for a "blind stitch." The stitch had been known to the art, but prior to the patentee's invention of a particular machine, could only be handmade. After pointing out that "the patent is not for the product of the machine," Judge Hand noted that the product patent (the stitch) "must lie exclusively in the conception of the product, and regardless of any method of its production, though of course the patent must disclose one way by which it can be made."[148] After noting that this imposed a "severe standard," Judge Hand justified his holding by noting:

> Unless conception alone is the test, and if the inventor may eke out his right by recourse to the ingenuity involved in any process or the machine, he gains an unfair advantage; for the claims cover the product produced by other machines and processes, to which by hypothesis he has contributed nothing. [Another case avoided this result] on the ground that the claims were too broad; but really the difficulty is deeper. At times indeed a process may leave traces in the product and the difficulty is avoided, but that is seldom or never true of the product of a machine . . . .[149]

Judge Hand then did what the patent examiner should have done—he invalidated the patent. In his view, the question of infringement simply never became an issue.

At some point, the scope of enablement must be examined closely, either by the examiner during a prima facie patentability inquiry, or by the trial court under an infringement analysis. While many difficulties might be avoided if the "expert agency," the PTO, fulfilled this function, current case law places the burden squarely upon the courts. In *In re Hogan*,[150] the subject matter was a polymer known as crystalline polypropylene, which was developed nearly simultaneously by several groups. A protracted interference ensued. Phillips Petroleum, the assignee of the victorious patent, also owned many continuations and

147. 26 U.S.P.Q. (BNA) 57 (2d Cir. 1935).

148. *Id.* at 61.

149. *Id.* at 61–62.

150. 559 F.2d 595 (C.C.P.A. 1977). The subject matter at issue, crystalline polypropylene, eventually reached litigation in Phillips Petroleum Co. v. U.S. Steel Corp., 673 F. Supp. 1278 (D. Del. 1987), *aff'd*, 865 F.2d 1247 (Fed. Cir. 1989). Here, defendant's reverse equivalents argument was rejected, and the patentee's undisputedly pioneer invention was finally allowed the claim breadth gained during patent prosecution.

divisional applications that were based on the parent application. By the time the PTO finally considered one of these applications, the post-invention art had contributed an amorphous form of polypropylene which nonetheless fell within the claim language aimed at claiming crystalline polypropylene. The examiner used this post-1953 advance in the art[151] to reject Hogan's application under section 112 as "non-enabling for other species of the claimed polymer."[152] The Court of Customs and Patent Appeals ("CCPA") sharply rebuked the PTO for using the "later state of the art" to reject Hogan's claims:

> Rejections under § 112, first paragraph, on the ground that the scope of enablement is not commensurate with the scope of the claims, orbits about the more fundamental question: To what scope of protection is this applicant's particular contribution entitled? . . . If later states of the art could be employed as a basis for rejection under 35 U.S.C. § 112, the opportunity for obtaining a basic patent upon early disclosure of pioneer inventions would be abolished.[153]

In responding to the PTO's policy concerns that later inventors would be discouraged by overbreadth of the initial patent, the CCPA responded:

> The business of the PTO is patentability, not infringement. Like the judicially-developed doctrine of equivalents, designed to protect the patentee with respect to later-developed variations of the claimed invention, the judicially-developed "reverse doctrine of equivalents," requiring interpretation of claims in light of the specification, may be safely relied upon to provide *improper* enforcement against later developers.[154]

Trial courts' reluctance either to limit the doctrine of equivalents in a meaningful way, or to implement the reverse doctrine of equivalents, however, suggests that the balance now inequitably protects the initial patentee. Judge Miller voiced just such concerns in his dissent:

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151. The 1971 application was entitled to the 1953 priority date of the parent application, since it pertained to the same subject matter. *See* 35 U.S.C. § 120 (1988).

152. *In re* Hogan, 559 F.2d at 604.

153. *Id.* at 605–06.

154. *Id.* at 607.

> Contrary to the majority opinion, to permit the outer boundaries of a claim to be construed in light of later art, rather than in light of art at the time the patent application was filed, could well *impede* progress in the useful arts. For example, it would relegate a later species of invention to a subservient position vis-a-vis an earlier species invention, even though the earlier inventor did not contemplate, much less enable, a generic invention, merely because the patent application for the earlier invention used a *broad* term which, at the time, had a meaning to one skilled in the art that was co-extensive with the species.[155]

When a trial court does not invalidate the patent, it must then shift to the more complex infringement analysis. The line between literal infringement and infringement by equivalents in biotechnology cases is sometimes imprecise.[156] A difference in one amino acid may suffice to preclude literal infringement, as may the trial court's interpretation of one word in the claim. Also, the trial court's doctrinal analysis will be dictated by the claim breadth granted by the particular examiner. Thus if an examiner bargains hard, the trial court will be applying the doctrine of equivalents, whereas if the examiner does not restrict the applicant during the patent procural procedure, the trial court will need to think in terms of the reverse doctrine of equivalents. Consequently, it seems illogical to treat the two types of cases in radically different manners. Just as there is a continuum of infringement, there should be a continuum of legal doctrine. As Judge Davis pointed out, the *Texas Instruments* opinions "reflect principles comparable to (though distinct from) the reverse doctrine of equivalents."[157]

Under the *Graver Tank* formulation of reverse equivalents, a prima

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155. *Id.* at 610 (Miller, J., dissenting).

156. *See supra* Section III. Doctrinally, composition of matter claims do read on all ways of making the product. The findings of literal infringement for Factor VIII:C and EPO indicate that the trial courts failed to restrict the breadth of the claims in light of the specification and the recognition of these proteins in prior art. The courts also construed the claims narrowly, as if they were product-by-process claims. This narrow construction would properly limit the patentee to his inventive contribution. *See* Robert E. Hillman & Paul T. Clark, *Fundamentally "Ancient" Statutes Take on Space-Age Biotechnology*, NAT'L L.J., Oct. 20, 1986, at 20–21. *But see* Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991) (product by process claims not limited to claimed process in infringement analyses).

157. Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 846 F.2d 1369, 1372 (Fed. Cir. 1988) (denying petition for rehearing). However, the claims were § 112, para. 6 "means plus function" claims; Judge Davis' opinion may turn on this fact, rather than on a recognition of any "continuum" of facts.

facie case of literal infringement may be refuted with proof that the subsequent product performs in a substantially different way.[158] As noted above, this prong of the "way" test underlies the proposed section 112 comparison with hypothetical claims, and thus the comparison is as appropriate for proving literal non-infringement as it is for proving non-infringing equivalents.

D. Probable Results Under a Section 112 Analysis of Hypothetical Claims

Two prerequisites are needed for the production of recombinant proteins: The actual recombinant methodology and the protein's amino acid sequence must be known.[159] With this information, scientists can synthesize DNA probes and isolate the gene coding for the protein.[160]

In the purified natural product vs. recombinant product cases, the scope of the patentee's enablement of future work is narrow. The patentee contributed neither the sequence nor the recombinant techniques used in making the later recombinant product. The inquiry then shifts to the hypothetical claim—is it enabled by the skill of the art at the time of defendant's protein production in combination with the teaching of the initial patent? If the answer is "yes," then the hypothetical claim has sprung from the "gist" of the initial patent, and is only a "partial variation in technique, an embellishment made possible by [later-developed] technology."[161] If the answer is "no," then the missing information—which is a vital element to the defendant's product—was contributed by the defendant. A court could then conclude that the two products perform the same function and achieve the same result in substantially different ways, and therefore that there is no infringement of the initial patent.

As an example of the second case, the production of recombinant Factor VIII:C required Genentech to break new ground because the

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158. *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 860–68 (1990).

159. The actual recombinant methodology must either have been known at the time of the initial patent, or be possessed by those of average skill at the time of infringement. This element will necessitate a factual inquiry into whether the genetic engineering carried out by the defendant was "routine" at that time. *See supra* notes 94–96 and accompanying text.

160. The need for the amino acid sequence was clear several years ago, when the gene encoding EPO was cloned. Today, however, new cloning tools such as polymerase chain reaction (PCR), automated DNA probe synthesis, and monoclonal antibody techniques have obviated the necessity of the amino acid sequence. If the prior art discloses the amino acid sequence, these tools facilitate the rapid cloning of the gene.

161. Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1364 (Fed. Cir. 1983).

protein consisted of 2,332 amino acids, a much larger protein than any previously produced by recombinant technology.[162] In addition, Genentech did not have the sequence available at the time it began work on the recombinant protein. Although Genentech's VIII:C was an improvement on the Scripps purified natural product in that it was cheaper and easier to produce, it cannot be said that Scripps provided enabling information for the hypothetical claim covering the recombinant Factor VIII:C.

In the synthetic vs. recombinant case (HGH), the initial patentee disclosed the amino acid sequence. Although that sequence contained errors, it would have been sufficient for the construction of the requisite DNA probes. One having average skill in the art at the time of Genentech's initiation of research probably would have been enabled by the prior patent. Accordingly, Genentech should be found to infringe.

The first vs. second generation recombinant case (tPA) comes closest to familiar section 112 ground. There, Genentech provided both the sequence and the technology necessary for making other recombinant products. Further, Genentech's patent attempted to enable later proteins such as that claimed by the hypothetical claim. The specification of the '075 patent referred to variations in the amino acid sequence and described how derivatives could be produced with recombinant DNA technology.[163] Thus, the enablement issue reduces to one familiar to the courts: Would it have required undue experimentation for Wellcome to produce the protein of the hypothetical claim in light of Genentech's patent?

CONCLUSION

Hypothetical claims are a useful method for redirecting the trial court's attention to the heart of the equitable *Graver Tank* inquiry—is the allegedly infringing device within the scope of the invention as initially conceived by the inventor and the PTO? Unfortunately, the hypothetical claim inquiry into prior art only fine-tunes the infringement analysis while leaving the necessary predicate—the "function/way/result" definition of equivalence—unrefined.

The line between defining the initial invention and delimiting infringing "improvements" on that invention is a fine one, necessarily fact-

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162. *See* Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1381 (N.D. Cal. 1987).

163. *See* Genentech, Inc. v. Wellcome Foundation., 14 U.S.P.Q.2d (BNA) 1363, 1367-68 (D. Del. 1990).

bound and unique. Hypothetical claims may help courts draw this line equitably, and in accordance with *Graver Tank*. They would do so most efficaciously by complementing the *Wilson* prior art inquiry with an enablement inquiry. Both these analyses will fulfill the same goal—to define accurately the terms of the contract between inventor and society, and ensure that the terms of that contract are not subject to a post-hoc attempt to redefine its claims during litigation.