The Calculus of Comparison: Obviousness and Equivalency Principles in Patent Law

By: Robert G. Oake, Jr., LL.M. (1997)

I. Introduction

At its core, patent law involves making two comparisons: comparing a claimed invention against the prior art[1] to determine whether a patent should be granted, and comparing the claimed invention against accused products or processes to determine whether patent infringement has occurred.[2] The first comparison requires asking whether the claimed invention involves enough of an advance over the prior art to deserve patent protection. The key issue in this comparison usually involves the concept of "obviousness": would the claimed invention have been obvious to a hypothetical person of ordinary skill in the art at the time the invention was made? If so, patent protection is denied. If not, patent protection may be granted.[3]

The second comparison involves asking whether the accused product or process is the same as, or very similar to, the claimed invention.[4] The key issue in this comparison usually involves the concept of "equivalency": are the differences in the patent claims and the accused product or process so insubstantial that the two should be considered, in law, as equivalent? If

---

[1] In general, the term "prior art" in legal theory means “knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art.” Kimberly-Clark Corporation v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984).

[2] In general, direct patent infringement occurs when “whoever without authority makes, uses, offers to sell or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor.” 35 U.S.C. § 271 (a). Liability for patent infringement may also be based on actively that induces or contributes to infringement. 35 U.S.C. §§ 271 (b)(c). A patentee has a remedy by civil action for infringement. 35 U.S.C. § 281.

[3] To receive a patent, subject matter must be patent eligible (35 U.S.C. §101), novel (§102), useful (§101), nonobvious (§103), adequately described (§112, para. 1), enabled (§112, para. 1), and the best mode must be disclosed (§112, para. 1). Of these requirements, nonobviousness is considered to be the “real battleground.” *See* Harold C. Wegner, ABRIDGED COMMENTARY ON THE PATENT LAW, §103(2) (1996) (Draft). Obviousness will be the only requirement addressed in depth in this paper.

[4] When the accused matter “falls clearly within the claim,” infringement is considered literal. Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607 (1950). Otherwise, infringement is analyzed under the doctrine of equivalents. *Id.* at 607, 608.

yes, patent infringement may exist.[5] If not, patent infringement does not exist.

Resolution of obviousness[6] and equivalency[7] issues in a patent case is often a complex and difficult task for two reasons. First, questions concerning these issues usually cannot be completely resolved by objective criteria. This is because obviousness and equivalency are ultimately subjective in nature and require the exercise of judgment.[8] Objective criteria can serve as a guide to the decision maker, but usually cannot reach completely to and dictate the point of decision. The final distance must be traversed by some amount of subjective judgment.

Second, the objective comparative analysis currently used by courts to resolve obviousness and equivalency issues is incomplete and often unpredictable.[9] It is based on a variety of seemingly nonunified factors and methods that are often selected and arranged differently in different cases.[10] The result is a body of case law that appears inconsistent and confusing, and that makes decisions regarding

---

5 Patent infringement depends on other factors as well, such as prior art limitations and prosecution history estoppel, discussed at length *infra.*

6 Although obviousness is not traditionally thought of as a "doctrine," it will sometimes be referred to as such for ease of expression with equivalency.

7 The term "equivalency" is used herein as a synonym for "doctrine of equivalents." It is not intended to refer to equivalency under 35 U.S.C. §112 para. 6, which is an issue discussed only briefly herein.

8 By use of the term "subjective," it is meant that informed judgment plays an important role in the decision making process, not that evidence of intent should be considered relevant to either obviousness or equivalency.

9 *See* Paul R. Michel, *The Challenge Ahead: Increasing Predictability In Federal Circuit Jurisprudence For The New Century*, 43 AM. U. L. REV. 1231 (1994).

10 *See generally* (all discussing uncertainty in the legal standards) Barrett, *Discretionary use of the doctrine of equivalents in patent law: Going beyond the triple identity test of Graver Tank*, 17 U. HAW. L. REV. 513 (Fall 1995); Rudolph P. Hofmann, Jr., *The Doctrine of Equivalents: Twelve Years of Federal Circuit Precedent Still Leaves Practitioners Wondering*, 20 WM. MITCHELL L. REV. 1033 (1994); Landry, *Certainty and discretion in patent law: The on sale bar, the doctrine of equivalents, and judicial power in the Federal Circuit*, 67 S. CAL. L. REV. 1151 (Sept. 1994); Kalinchak, *Obviousness and the doctrine of equivalents in patent law: Striving for objective criteria*,"43 CATH. U. L. REV. 577 (Winter, 1994); Adelman and Francione, *The doctrine of equivalents in patent law: Questions that Pennwalt did not answer*, 137 U. PA. L. REV. 673 (1989); Kalinchak, *Obviousness and the Doctrine of Equivalents in Patent Law: Striving for Objective Criteria*, 43 CATH. U. L. REV. 577 (1994); Varma and Abraham, *DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J. L. & TECH. 53 (1996).

obviousness and equivalency more difficult.[11]

The difficulty is unfortunate. The need to predict and determine the boundaries of patentability and patent protection within reasonable degrees of accuracy has never been more important - for several reasons. First, it is now generally accepted that long term national economic health depends in large part upon the rapid and successful development and commercialization of emerging technologies.[12] Such technologies in their infant stages usually require large sums of capital, but often can offer nothing more as security for investors than patent and other intellectual property rights. The ability of these intangible rights to serve as investment security is heavily dependent on the ability of the law to make such rights reliable and predictable.[13] When excessive uncertainty exists in the patent law, it decreases the ability of a patent to serve as collateral for investment[14] - which decreases the United States' ability to successfully compete in the international race to commercialize basic research and emerging technologies.

Second, the debate is continuing over the appropriate role of juries in a patent case. Although the right to a jury trial is guaranteed by the United States Constitution[15], this right has been eliminated from certain aspects of patent litigation,[16] and is being questioned in others.[17] The usual rationale for such transfer of decision making power is that a judge is better able to cope with the complexities of a patent case.[18] However, given the

---

11 *See, e.g.*, Hilton Davis Chemical Co v. Warner-Jenkinson Company, Inc., 62 F.2d 1512, 1535 (Fed. Cir. 1995) (Judge Newman concurring) (listing similar equivalency cases and noting dissimilar results).

12 *See generally*, National Science Board, The Competitive Strength of U.S. Industrial Science and Technology: Strategic Issues (1992)]; Helene Miale, *The National Competitiveness Act: Gauging The Federal Government's Role In Promoting Technology Policy To Enhance U.S. Economic Growth*, 18 SETON HALL LEGIS. J. 779 (1994); Roland W. Schmitt, *Beyond Competitiveness: Technology Policy For The 1990s*, 5 STAN. L. & POL'Y REV. 119 (Fall, 1993); Lewis D. Solomon and Suzanne E. Schoch, *Developing Critical Technologies: A Legal And Policy Analysis*, 9 SANTA CLARA COMPUTER & HIGH TECH. L.J. 153 (March 1993).

13 *See* Hilton Davis, 62 F.3d at 1531-1535 (and investment and economic articles cited therein) (Judge Newman concurring).

14 *Id.*

15 The Seventh Amendment states: "In suits at common law . . . the right to trial by jury shall be preserved, and no fact tried by a jury shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law." U.S. Const. amend. VII.

16 *See* Markman v. Westview Instruments, 116 S. Ct. 384 (1996) (holding that claim construction is matter of law for the court).

17 *See* Hilton Davis, 62 F.3d at 1543, 1549 (Judges Plager and Lourie dissenting separately).

18 *Id*; *See also* Markman, 116 S. Ct. at 1395-1396 (concluding that judges are better suited than juries to construe claims).

current state of the law regarding obviousness and equivalency, the alleged inability of juries to deal with patent cases may be due in no small measure to the failure of courts to provide clear jury instruction.[19] Our founding fathers included seventh amendment protection for good reasons.[20] The judiciary should therefore be reluctant to remove juries completely from the fact finding process, particularly since every effort has not yet been made to provide clear and consistent jury instruction.

Third, patent law is becoming increasingly international. Differing national patent systems gradually are being integrated by laws and treaties, and as a practical result of the emerging global economy.[21] In this context, proposals to harmonize U.S. patent laws with other patent systems are currently being debated.[22] Obviously, the potential effects of these proposed changes should be thoroughly understood before any changes are made. However, it is difficult to understand potential effects without a thorough understanding of the system as it now exists.[23] The current confusion and inconsistency in the doctrines of obvious and equivalency are the types of problems that prevent such a thorough understanding.

The thesis of this paper is that a more comprehensive and comprehensible set of principles and rules (a comparative calculus, if you will)[24] can and should be developed to

---

[19] *See* Hilton Davis, 62 F.3d at 1550 (Judge Nies dissenting).

[20] *See* Parklane Hosiery Co. v. Shore, 439 U.S. 322, 344 (1979) (Rehnquist, J., dissenting) (stating "The founders of our Nation considered the right of trial by jury in civil cases an important bulwark against tyranny and corruption, a safeguard too precious to be left to the whim of the sovereign, or, it might be added, to that of the judiciary. [noting that] Thomas Jefferson stated: 'I consider [trial by jury] as the only anchor yet imagined by man, by which a government can be held to the principles of its constitution.' 3 The Writings of Thomas Jefferson 71 (Washington ed. 1861)").

[21] *See* John R. Thomas, *Litigation Beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement*, 27 LAW & POL'Y INT'L BUS. 277, 351 (Winter 1996) (discussing problems and complexity of international patent enforcement and urging reconsideration of "self-imposed jurisdictional restriction of national courts to entertain foreign patent suits"); Soobert, *Analyzing Infringement by Equivalents: A Proposal to Focus the Scope of International Patent Protection*," 22 RUTGERS COMPUTER & TECH. L. J. 189 (1996); Hatter, *The Doctrine of Equivalents in Patent Legislation: An Analysis of the Epilady Controversy*, 5 IND. INT'L. & COMP. L. REV. 461 (Spring 1995) (discussing different formulations of the doctrine of equivalents and attempts at harmonization).

[22] *Id.*

[23] Given the current state of confusion over the doctrine of equivalents in U.S. law, it is difficult to comprehend how an international system would affect the U.S. competitive position.

[24] A fundamental problem in mathematical calculus is determining

make decisions regarding patent obviousness and equivalency more predictable and consistent. The goal of this paper will be to outline and explain such a set of principles and rules. This goal will be pursued by first describing in part II the problems presented. Parts III and IV will then discuss how such problems have been addressed by past and present statutory and case law, and will include an evolutionary history of obviousness (part III) and equivalency (part IV), a detailed description of the doctrines' current status,[25] and an explanation of the uncertainty remaining in each doctrine. In part V, an analysis will be undertaken of the similarities and differences in the two doctrines to aid in understanding the nature of the problems remaining and their potential solutions.

Following the above discussions and analysis, additional procedures and comparative factors will be proposed in part VI to further reduce the uncertainty remaining in obviousness and equivalency. A comparative calculus then will be constructed in part VII by combining presently effective portions of the doctrines with the proposed additional procedures and comparative factors. After the calculus is set forth, it will be evaluated in part VIII in light of current case law to authenticate its effectiveness. In part IX, the comparative calculus will be applied to the emerging technologies of genetic engineering and protein chemistry to determine whether it remains a useful and effective tool in new and rapidly developing technological fields. Finally, in part X, this paper concludes with a summary of the observations and proposals for increasing objectivity in the doctrines of obviousness and equivalency.

The general approach to understanding and resolving some of the confusion and uncertainty remaining in obviousness and

---

the slope of a line tangent to a curve. The problem is created because slope is defined by two points, and a tangent line intersects the curve at only a single point. The problem may be solved by drawing a secant line on the curve (intersecting the curve at the point of interest and at a second point - so a slope may be calculated) and developing a function that reduces the distance between the point of interest and the second point to a value that approaches, but never quite reaches, zero. *See* Douglas Downing, Calculus the Easy Way, Second Edition (1992).

Roughly speaking, if the "one perfect rule" for determining obviousness and equivalency in any given case is analogized to the unknowable slope of the line tangent to the point of interest on the curve, and objective legal rules and principles are analogized to the function that creates the second point and attempts to move it as close as possible to the point of interest, the analogy in this paper to the concept of calculus becomes useful beyond alliteration.

[25] An extensive discussion of the current status of obviousness is set forth as a background and basis for comparing it to the Doctrine of Equivalents. Readers already familiar with obviousness law may wish to skip this section and read only the explanation of the uncertainty remaining in obviousness set forth at the end of section III.

equivalency will be two-fold. First, a broad look at both topics with an integrated analysis to reveal some of their underlying, and perhaps unifying, concepts and principles. Second, a detailed and rigorous dissection of their complex inferential innerworkings. The consistent theme will be to increase objectivity - and to decrease subjectivity - whether it might be in standards, factors, or procedures.

II. The Problem Presented

To obtain a patent, an applicant must conclude the specification "with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[26] Particular and distinct claiming is required so the patent examiner may know precisely what is to be compared against the prior art, and so that others may know precisely what must be avoided to avoid infringing the patent.[27] However, after claim language is chosen, issues may be raised over the effective meaning and scope of the words used.

A simple example is the term "approximately 6," chosen as the numerical value for a distance, length, or degree of something in a patent claim. Does the term "approximately 6" include the values "5" and "7", or "4" and "8"? Does it include the values "5.9" and "6.1"? The values "5.999" and "6.001"? A second example might be the term "circular" used to define the shape of an opening or a component part. Does the term "circular" include "elliptical," oblong," or "octagonal"? Does it encompass an opening whose shape was substantially circular but that actually consisted of thirty straight, small sides?

The patentee[28] and alleged infringer[29] traditionally argue different sides of the issue. The patentee argues that a certain degree of flexibility must be afforded due to the inherent limitations of language, and so that infringers are not allowed to appropriate the substance of the invention by merely making small changes in form.[30] The alleged infringer argues, conversely, that the claim

---

[26] 35 U.S.C. § 112, para. 1 (1991).

[27] Infringement is determined by comparing the accused device with the patent claims. *See* SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (*in banc*) ("Infringement . . . is determined by comparing an accused device . . . with the properly and previously construed claims in suit.")

[28] The applicant, if during prosecution.

[29] The examiner or solicitor, if during prosecution.

[30] Judicial expressions of this position may be found in the majority opinions of Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607 (1950) (stating "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing"), and Winans v. Denmead, 56 U.S. 330, 343 (1853) (stating "the patentee, having described his invention, and shown its principles, and claimed it in that form which most perfectly embodies it, is, in contemplation of law, deemed to claim every form in which his invention may be copied, unless he manifests an intention to disclaim some of those forms.").

language should be interpreted literally in order to preserve the definitional and notice functions of the claims, particularly since it was the patentee (or their agent or attorney) that chose the language in question. Otherwise, goes the argument, the integrity of the patent system will be compromised because the reliability and predictability of patent claims will be lessened.[31] Since both sides of the argument have some merit in both policy and logic, the debate over interpretation of claim language has continued, always in search of a satisfactory resolution or workable compromise.

III. Obviousness

A. Origins and Development

Every patent system has to address the difficult conceptual issue of defining precisely when a given invention or discovery is patentable over the prior art.[32] The challenge is to develop an objective, principled approach that is based on something more than a general feeling by a judge or jury; something more than the subjective conclusion "yes, it's a patentable invention," or "no, it's not a patentable invention." The challenge is difficult, as previously mentioned, because it requires an objective approach to what is ultimately a subjective problem. No single definition or rule can possibly serve to establish the precise patentability point in all cases, particularly when novel facts or complex technologies are involved.[33] Therefore, even a principled and objective approach must retain, in the end, a certain degree of flexibility and subjectivity.

The approach U.S. patent law has taken to date on the issue of patentability is to gradually move toward principled objectivity through increasingly structured and objective processes. In other words, to guide the

---

[31] Judicial expressions of this position may be found in the dissenting opinions of Graver Tank, 339 U.S. at 860 (1950) ("The Court's ruling today sets the stage for more patent 'fraud' and 'piracy' against business than could be expected from faithful observance of the congressionally enacted plan to protect business against judicial expansion of precise patent claims."), and Winans, 56 U.S. at 347 (1853) ("The patentee is obliged, by law, to describe his invention, in such full, clear, and exact terms, that from the description, the invention may be constructed and used.... Nothing, in the administration of this law, will be more mischievous, more productive of oppressive and costly litigation, of exorbitant and unjust pretensions and vexatious demands, more injurious to labor, than a relaxation of these wise and salutary recognitions of the act of Congress.").

[32] *See* Graham v. John Deere Co., 383 U.S. 1, 9 (quoting Thomas Jefferson's difficulty in "drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.")

[33] *See, e.g.*, In re Lainson, 339 F.2d 252, 254 (C.C.P.A. 1964) ("The question of obviousness, however, is so closely tied to the facts of each particular case that prior decisions in cases involving different facts are ordinarily of little value in reaching a decision."); Graver Tank at 609 ("Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum.").

decision maker closer and closer to the decision point through the use of objective criteria, without sacrificing the flexibility needed to cover a wide range of technologies and fact patterns. The movement toward principled objectivity has taken place in several steps.

The first major step was taken by the United States Supreme Court in *Hotchkiss v. Greenwood*[34]. In *Hotchkiss*, the plaintiff was granted a patent for door knobs made out of clay pottery or porcelain.[35] The knobs contained a dovetail cavity, larger at the bottom, into which a metallic shank and spindle could be fastened by pouring fused metal.[36] The Court found nothing new about the invention except for the substitution of clay or porcelain knobs for the metal or wooden knobs then in common use.[37] The Court invalidated the patent and stated that an invention was not patentable unless it required more ingenuity and skill to invent than was possessed "by an ordinary mechanic acquainted with the business."[38] By so holding, the Court established an objective standard for patentability, i.e., according to the level of skill possessed by a person of ordinary skill in the relevant art, rather than a subjective standard, ie., by the level of skill of the particular inventor involved.[39]

The Supreme Court continued to develop and refine the concept of patentability in *Smith v. Nichols*.[40] In *Nichols*, the Court provided a negative definition[41] of patentability by describing just how much of an advance over the prior art was required. The patent in *Nichols* involved fabric that was formed by weaving threads through stretched elastic cords.[42] Upon completion of the weaving process, the stretched elastic would return to its original length, and tighten the weave of the fabric.[43] An accused infringer argued the patent was invalid because a similar fabric had been used previously in public.[44] The plaintiff countered that the prior fabric was of less quality in

---

34 52 U.S. 248 (1850).

35 *Id.* at 264.

36 *Id.*

37 *Id.* at 265.

38 *Id.* at 267.

39 An objective standard is based on something external to or independent of the mind. A subjective standard exists or originates within the observer's mind and is incapable of being verified externally. *See* WEBSTER'S NEW WORLD DICTIONARY OF THE ENGLISH LANGUAGE, pgs. 980, 1418 (2nd College Ed. 1970). The relevance of the distinction between objectivity and subjectivity to patent law was explained by the Federal Circuit in Ryko Manufacturing Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir. 1991): ("The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry. Instead of ascertaining what was subjectively obvious to the inventor at the time of invention, the court must ascertain what would have been objectively obvious to one of ordinary skill in the art at such time.").

40 88 U.S. 112 (1875).

41 A negative definition defines a term by describing what the term is not.

42 *Id.* at 116.

43 *Id.*

44 *Id.* at 117.

tightness and appearance.[45] Despite the improved quality, the Court held the patent invalid, stating that "a change only in form, proportions, or degree, the substitution of equivalents, doing substantially the same thing in the same way by substantially the same means with better results, is not such invention as will sustain a patent."[46]

An emphasis on the concept of "invention" was continued in *Smith v. Goodyear Dental Vulcanite Co.*[47] The patent in this case involved an improved denture plate made out of vulcanized rubber instead of gold.[48] The Court stated that improvements amounting to mere substitutions "for the same use, in substantially the same manner and with the same effect" would amount to "no invention."[49] The patent was upheld since the dentures could be set when the rubber was initially soft, resulting in dramatic improvements of fit, lighter weight, and strength.[50]

An affirmative definition[51] of patentability was attempted by the Supreme Court in *Cuno Engineering Corp. v. Automatic Devices Corp.*[52] The patent at issue in *Cuno Engineering* involved an improved automobile cigarette lighter design.[53] Previous lighters had to be manually held in and removed when they were thought to be hot enough for use.[54] The improved lighter employed a thermostatic control and spring mechanism to return the lighter to an off position when it was sufficiently hot.[55] The Court noted that thermostatic controls had been used previously in other electrical devices and invalidated the patent, declaring that a patentable invention must reveal "the flash of creative genius, not merely the skill of the calling."[56] The flash of creative genius expression was quite subjective and represented an unfortunate move away from principled objectivity.[57] Some courts interpreted the test as a focus on the process by which the invention was made, rather than on an invention's degree of advancement over the prior art.[58]

To eliminate the confusion and uncertainty created by the "invention" and "creative flash of genius" tests,[59] Congress in 1952 passed Section 103 of the Patent Act.[60] Section 103 retained

---

45 *Id.* at 118.

46 *Id.* at 119.

47 93 U.S. 486 (1877).

48 *Id.* at 490.

49 *Id.* at 492.

50 *Id.* at 494.

51 An affirmative definition attempts to describe what something is, rather than what it is not.

52 314 U. S. 84 (1941).

53 *Id.* at 85, 86.

54 *Id.* at 86.

55 *Id.* at 87.

56 *Id.* at 91.

57 *See* P.J. Federico, *Origins of Section 103*, 5 AM. PAT. L. ASS'N. Q. J. 87 (1977).

58 *See* Graham v. John Deere Co., 383 U.S. 1, 15 n. 7 (1966) ("Although some writers and lower courts found in the language connotations as to the frame of mind of the inventors....")

59 *See* Graham v. John Deere Company, 383 U.S. 1 (1966) (stating that use of the term "invention" as a label "brought about a large variety of opinions as to its meaning both in the Patent Office, in the courts, and at the bar." *Id.* at 11, 12.

60 35 U.S.C. § 103 provides: "A patent may not be obtained though the

the objective standard of *Hotchkiss v. Greenwood*, but replaced the negatively defined "invention" and affirmatively defined "creative flash of genius" tests with a more objective test: an invention was patentable unless it was obvious to a person of ordinary skill in the art at the time the invention was made.[61] The statute also shifted focus from the inventive process back to the invention itself by stating that "patentability shall not be negatived by the manner in which the invention was made."[62] Under Section 103, the objective concept of obviousness replaced the subjective concepts of "invention" and "flash of genius" as the ultimate test on the issue of patentability.[63]

Following the enactment of section 103, the task confronting the courts was how to define the concept of obviousness in an objective and consistent manner.[64] The first step occurred in *Graham v. John Deere Co.*[65] The patent in *Graham* involved an improved spring clamp for a chisel plow.[66] A spring clamp, in general, allows the shank of a plow to be pushed up over obstructions in the soil and then returned to normal position when the obstruction is passed over.[67] Prior art spring clamps located the shank between an upper plate frame member and a spring plate, resulting in wear to the upper plate when the shank was pushed up.[68] The claimed improvement relocated the shank to below the spring plate, which moved the area of wear from the upper plate frame member to the easily replaced spring plate.[69]

The Court rejected the claimed spring clamp as being obvious over the prior art, stating that a person of ordinary skill "would immediately see" that the wear to the frame could be eliminated by inverting the shank and the hinge plate.[70] The Court also described the analytical process that should be followed when determining obviousness: "Under s 103, the scope and content of the prior art are to be

---

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

61 *Id.*

62 *Id.*

63 *See* L. James Harris, *Some Aspects of the Underlying Legislative Intent of the Patent Act of 1952*, 23 GEO. WASH. L. REV. 658 (1955).

64 *See* P.J. Federico, *Commentary on the New Patent Act, 35 U.S.C.A. § 103* (West 1954), reprinted in 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 184 (1993).

65 383 U.S. 1 (1966). Graham resolved a split among lower courts as to whether the new obviousness standard merely codified the invention and flash of genius tests. *See generally* Beckett, *Judicial Construction of the Patent Act of 1952 - Codification v. Substantive Change*, 37 J. PAT. OFF. SOC'Y 467 (1955).

66 *Id.* at 19, 20.

67 *Id.*

68 *Id.* at 22.

69 *Id.* at 23.

70 *Id.* at 25.

determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined."[71] In addition, the Court stated that certain secondary considerations such as "commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."[72]

Although *Graham* affirmed the concept of obviousness as the ultimate test of patentability and set forth a framework for analysis consistent with section 103, the case did not provide definitions for the terms "obviousness" or "nonobviousness." Instead, the Court admitted the difficulties in applying the test, predicted there would not be "uniformity of thought in every given factual context,"[73] and suggested the difficulties of application should be "amenable to a case by case development."[74] The Court believed that strict adherence to the requirements in *Graham* would result ultimately in the "uniformity and definiteness which Congress called for in the 1952 Act."[75]

Following *Graham*, the lower federal courts continued to develop and define the concept of obviousness on a case by case basis. The case development resulted in the emergence of a defined test for obviousness and further refinement of both the new test and other aspects of the analytical framework set forth in *Graham*. The new test for obviousness became known as the "suggestion" test, a common statement of which is "whether the references, taken as a whole, would suggest the invention to one of ordinary skill in the art."[76] Coupled with the suggestion test were the requirements that the prior art provide a "motivation" to combine the references,[77] and a "reasonable likelihood of success" of achieving the invention.[78]

Although the suggestion test added a degree of analytical clarity to the obviousness inquiry, the new test required additional clarifications of its own. Further explanation was needed to identify the type of prior art references that might be eligible to

---

71 *Id.* at 17.

72 *Id.* at 17-18.

73 *Id.* at 18.

74 *Id.*

75 *Id.*

76 Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1582 (Fed. Cir. 1983).

77 *See* In re Dillon, 919 F.2d 688, 693 (Fed. Cir. 1990) (prima facie case of obviousness may be rebutted "when the prior art is so deficient that there is no motivation to make what might otherwise appear to be obvious changes"), citing In re Albrecht, 514 F.2d 1389, 1396 (C.C.P.A. 1975); In re Stemniski, 444 F.2d 581 (C.C.P.A. 1971); In re Ruschig, 343 F.2d 965 (C.C.P.A. 1965).

78 In re Dow Chemical Co., 837 F.2d 469, 472 (Fed. Cir. 1988) ("The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art.").

provide a suggestion, and to clarify the meaning of the phrases "suggest the invention,"[79] "motivation,"[80] and "reasonable likelihood of success."[81] Additionally, the courts needed to develop and describe the analytical process that should be followed when the suggestion test was applied.[82]

Cases from the Federal Circuit have addressed these issues, and have also further developed the concepts of "ordinary skill in the art"[83] and "secondary considerations"[84] contained within the original *Graham* section 103 analysis. Additionally, the Federal Circuit has provided guidance on the appropriate role and effect of the "prima facie case",[85] a burden shifting procedural device that has become interwoven with the obviousness inquiry in many cases. The Federal Circuit's efforts to clarify these issues are discussed below in the context of the current test for determining obviousness.

B. Current Test for Obviousness

The current test for obviousness is derived from section 103, the *Graham* analysis, and the suggestion test. It can be thought of as occurring in seven steps.[86] First, the level of ordinary skill in the pertinent art is resolved.[87]

---

[79] *See* notes 123-161 *infra* and accompanying text.

[80] *See* notes 162-172 *infra* and accompanying text.

[81] *See* notes 173-177 *infra* and accompanying text.

[82] *See* notes 178-184 *infra* and accompanying text.

[83] *See* notes 94-102 *infra* and accompanying text.

[84] *See* notes 208-260 *infra* and accompanying text.

[85] *See* notes 185-207 *infra* and accompanying text.

[86] The test for obviousness is traditionally thought of as a three step process, or four step if the secondary considerations are included. *See* In re Huang, 100 F.3d 135, 138 (Fed. Cir. 1996) (referring to the "four part analysis" of "1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." citing Graham, 383 U.S. at 17-18 (1966). The additional three steps included in the seven step process are (1) claim construction, (2) establishment of the prima facie case, and (3) rebuttal of the prima facie case.

[87] *See* notes 94-102 *infra* and accompanying text. Although this is not in the order set forth in Graham, *supra*, the resolution of ordinary skill in the art is the first logical step because it is needed to determine the content and scope of the prior art and to properly construe the claims. *See, e.g.*, Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc., 21 F.3d 1068, 1071 (Fed. Cir. 1994) (stating a prior art reference is reasonably pertinent "when a person of ordinary skill would reasonably have consulted those references and applied their teachings in seeking a solution to the problem that the inventor was attempting to solve"); Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995), *aff'd* 116 S.Ct. 1384 (1996) (stating that the focus in construing disputed terms in claim language is on what one of ordinary skill in the art at the time of the

Second, the content and scope of the prior art are determined.[88] Third, the claims are construed.[89] Fourth, the differences between the prior art and the claims at issue are ascertained.[90] Fifth, in the context of the foregoing, a determination is made whether the prior art, taken as a whole, contains prima facie evidence of a suggestion and motivation for the claimed combination, and provides a reasonable expectation for its success.[91] Sixth, the nature and extent of secondary considerations are reviewed to determine whether the prima facie case is rebutted.[92] Seventh, in the event the prima facie case is rebutted, evidence concerning the suggestion, motivation, and reasonable expectation is weighed with evidence concerning secondary considerations to determine the issue of obviousness.[93]

---

invention would have understood the term to mean).

[88] *See* notes 103-109 *infra* and accompanying text.

[89] *See* notes 110-119 *infra* and accompanying text.

[90] *See* notes 120-122 *infra* and accompanying text.

[91] *See* notes 123-184 *infra* and accompanying text. If a suggestion to combine is found, then a prima facie case of obviousness may be established. *See* In re Rinehart, 531 F.2d 1048, 1051 (C.C.P.A. 1976) ("A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.").

[92] *See* notes 208-260 *infra* and accompanying text.

[93] *See* notes 261-274 *infra* and accompanying text.

1. Level of Ordinary Skill in the Art

The Federal Circuit has listed the following factors to be considered when determining the level of ordinary skill in the art: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field."[94] Further, "[i]n a given case, every factor may not be present, and one or more factors may predominate."[95] The level of skill in the art is determined as of the time the invention was made.[96]

The level of the actual inventor's skill and experience is not determinative of the level of ordinary skill in the art.[97] The inquiry therefore is not what was subjectively obvious to the inventor at the time of invention, but rather what was "objectively obvious to one of ordinary skill in the art at such time."[98] The requirement that the prior art references suggest the invention to one of ordinary skill in the art maintains objectivity in the obviousness determination.[99] A person of ordinary skill is presumed to be aware of all the

---

[94] Environmental Designs, Ltd. v. Union Oil Co of California, 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

[95] Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc., 807 F.2d 955, 962 (Fed. Cir. 1986).

[96] *See* Ryko, 950 F.2d at 719; In re Epstein, 32 F.3d 1559, 1564 n. 4 (Fed. Cir. 1994) (citing Graham, 383 U.S. at 17).

[97] *Id.*

[98] Ryko, 950 F.2d at 718.

[99] *Id.*

pertinent prior art,[100] which includes references in the field of the invention and references in all analogous fields.[101] Further, such a person is presumed to have the ability to select and utilize knowledge from all such fields.[102]

2. Content and Scope of the Prior Art

The second step in the obviousness inquiry is determining the content and scope of the prior art. The Federal Circuit has instructed that only "analogous" prior art references are eligible for consideration.[103] A reference is analogous if it is within the inventor's field of endeavor or "reasonably pertinent" to the problem being solved by the inventor.[104] A reference is reasonably pertinent "when a person of ordinary skill would reasonably have consulted those references and applied their teachings in seeking a solution to the problem that the inventor was attempting to solve."[105]

The Federal Circuit has also stated that the issue of whether a person of ordinary skill would reasonably have consulted references in another field of art to solve a problem necessarily involves "subjective aspects,"[106] "common sense" [107] and a consideration of "the reality of the circumstances."[108] A reference that is neither within the inventor's field of endeavor, nor reasonably pertinent to the problem being solved by the inventor, is nonanalogous art and is not eligible to provide a suggestion.[109]

3. Claim Construction

The claims must be construed before the differences between the claims and the prior art can be ascertained. Claim construction is performed by the court solely as a matter of law and is reviewed de novo on appeal.[110] A complete analysis of the rules of claim construction is beyond the scope of this paper.

In general, when construing a claim, a court should look first to the intrinsic evidence, which consists of the claims, the specification, and the prosecution history.[111] The words of a claim are given their ordinary meaning unless a special definition for a word is clearly stated in the specification or prosecution history.[112] Statements by a

---

100 Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc., 807 F.2d 955, 962 (Fed. Cir. 1986).

101 In re Sernaker, 702 F.2d 989 (Fed. Cir. 1983).

102 Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015 (Fed. Cir. 1985).

103 In re Clay, 966 F.2d 656, 658 (Fed. Cir. 1992).

104 *Id.* at 658-59; In re Deminski, 796 F.2d 436 (Fed. Cir. 1986); In re Paulsen, 30 F.3d 1475 (Fed. Cir. 1994).

105 Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc., 21 F.3d 1068, 1071 (Fed. Cir. 1994).

106 In re Oetiker, 977 F.2d. 1443, 1447 (Fed. Cir. 1992).

107 *Id.*

108 In re Wood, 599 F.2d 1032, 1036 (C.C.P.A. 1979).

109 In re Clay, 966 F.2d at 658.

110 Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (*in banc*), *aff'd*, 116 S.Ct. 1384 (1996).

111 *Id.*

112 *See* Vitronics Corporation v. Conceptronic, Inc. 90 F.3d 1576, 1582, 39 U.S.P.Q.2d 1573 (Fed. Cir. 1996); *See also*

patentee concerning claim scope and prior art may be considered if the prosecution history is in evidence.[113] When analysis of intrinsic evidence resolves claim term ambiguity, reliance on extrinsic evidence is improper.[114]

If analysis of intrinsic evidence is insufficient to determine claim meaning, the court may rely on extrinsic evidence to understand, but not to vary or contradict, the claim language and specification.[115] Extrinsic evidence is external to the patent and file history and includes expert testimony, inventor testimony, dictionaries, and technical treatises and articles. Courts may consult technical treatises and dictionaries at any time to understand the underlying technology and may use dictionaries to construe claim terms as long as the definitions do not contradict definitions found in or ascertained by a reading of the patent documents.[116]

Courts in their discretion may also admit and rely upon prior art not cited in the specification or file history to understand, but not to vary or contradict, the meaning of claims.[117] Reliance on such prior art is improper when the disputed terms can be understood from the intrinsic evidence alone.[118] An issue that appears to be unresolved is whether claim construction by a district court involves fact finding that cannot be set aside on appeal absent clear error.[119]

4. Differences in Claims and Prior Art

After the content and scope of the prior art are determined and the claims are construed, the differences between them, if any, are ascertained.[120] The purpose of this step is to require the decision maker to identify the principal differences between the claim and the prior art "to place the obviousness analysis into proper perspective."[121] When making the comparison, both the prior art and the claimed invention are to be viewed as a whole.[122]

5. Suggestion, Motivation, and Reasonable Expectation of Success

a. Suggestion to Combine References

Once the above three background factual issues specified in the *Graham* analysis have been resolved (together with the necessary step of proper claim construction), a preliminary determination on the issue

---

Cole v. Kimberly-Clark Corporation, 102 F.3d 524, 531 (Fed. Cir. 1996).

113 *Id.* at 1582, 1583.

114 *Id.* at 1583.

115 *Id.* at 1584; *See also* Tanabe Seiyaku Co., Ltd. v. United States International Trade Commission, 109 F.3d 726, 732 (Fed. Cir. 1997).

116 *Id.*

117 *Id.*

118 *Id.*

119 *See Metaullics Systems Co. v. Cooper*, 100 F.3d 938, 939 (Fed. Cir. 1996) ("Where a district court makes findings of fact as a part of claim construction, we may not set them aside absent clear error.") *But see Id.* at 940. ("There is no basis, even in dictum, for us to state in this case that we should have to defer to the trial court on so-called issues of fact arising in claim construction.") (Judge Lourie, concurring in part).

120 Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

121 Ryko Manufacturing Co. v. Nu-Star, Inc., 950 F.2d 714, 717 (Fed. Cir. 1991).

122 *Id.*

of obviousness can be made. This determination depends on whether an appropriate suggestion to combine references can be found in the prior art.[123]

The Federal Circuit has developed a rather complex set of rules to determine when such a suggestion to combine references may exist in the context of various factual and technological settings. These rules break down roughly into the three categories of 1) general rules, 2) what can provide a suggestion, and 3) what cannot provide a suggestion. In addition, various rules exist concerning the requirements of a "motivation," "reasonable expectation of success," and the procedure for determining whether a suggestion to combine exists, including the prima facie case mechanism.

(1) General Rules

Perhaps the broadest general rule is that it is impermissible to reconstruct the invention by simply picking and choosing among separate references in the prior art.[124] Rather, a suggestion to combine must be present before prior art references may be combined.[125] This rule is, in effect, simply a restatement of the suggestion to combine test itself.

A second important general rule is that the claimed invention must be considered "as a whole."[126] This means that the comparative analysis cannot focus on separate substitutions or individual components, but must include the whole invention.[127] The concept of "whole invention" includes its entire structure, its properties, and the problem solved by the invention.[128]

Similarly, the prior art must be considered as a whole.[129] All prior art references must be analyzed and considered for what they fairly teach in combination with other references.[130] For example, prior art that teaches away

---

123 Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed. Cir. 1991); In re Merck & Co., Inc., 800 F.2d 1091, 1097 (Fed. Cir. 1986); Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1582 (Fed. Cir. 1983).

124 SmithKline Diagnostic, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 887 (Fed. Cir. 1988) (party asserting obviousness cannot simply "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention").

125 Northern Telecom, Inc. v. Datapoint Corp., 908 F2d 931 (Fed. Cir. 1990).

126 Para-Ordnance Manufacturing, Inc. v. Sgs Importers International, Inc., 73 F.3d 1085 (Fed. Cir. 1995); W. L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

127 Gillette Co. v. S. C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed. Cir. 1990).

128 In re Wright, 848 F.2d 1216 (Fed. Cir. 1988).

129 Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1462 (Fed. Cir. 1984); In re Lamberti, 545 F.2d 747, 750 (C.C.P.A. 1976) (all relevant prior art disclosures must be considered).

130 In re Merck & Co., Inc., 800 F.2d 1091 (Fed. Cir. 1986); Vandenberg v. Dairy Equipment Co., 740 F.2d 1560 (Fed. Cir. 1984).

from the invention cannot be ignored.[131] When prior art references apparently conflict, the suggestive power of each must be weighed, and the degree to which they discredit each other must be considered.[132] What a prior art reference suggests or teaches is a question of fact.[133]

Third, the prior art must be evaluated as of the time the invention was made, not at the time of the litigation.[134] A practical effect of this rule is to prevent the invention itself from serving as the suggestion to combine.[135] Fourth, the suggestion in the prior art to combine the references does not have to be identical to the suggestion followed by the inventor.[136] This rule is consistent with the objective nature of the test in that it prevents the analysis from focusing on the particular inventive process followed by the actual inventor.

(2) What can Provide a Suggestion

A suggestion to combine may come from a variety of sources. It may come from an express statement in a reference,[137] or it may come from an implied statement in a reference that suggests the combination indirectly, or by inference.[138] Suggestions to combine may also come from common knowledge possessed by one of ordinary skill in the art.[139] Such knowledge must be generally available and clearly present in the art to provide the suggestion.[140]

The nature of the problem to be solved may also provide the suggestion to combine.[141] If an inventor of ordinary skill in the art was attempting to solve the problem confronting the inventor and would have combined the references in search of a solution, a suggestion to combine may be found.[142] Conversely, if two references relate to

---

131 Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448 (Fed. Cir.1986).

132 In re Young, 927 F.2d 588, 591 (Fed. Cir. 1991).

133 *See* In re Bell, 991 F.2d 781, 784 (Fed. Cir. 1993) ("What a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact.").

134 35 U.S.C. s 103.

135 The patent may not serve as the suggestion to combine. *See* Orthopedic Eqpt. Co. v. United States, 702 F.2d 1005, 1012 (Fed. Cir. 1983) ("It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.")

136 In re Kemps, 97 F.3d 1427 (Fed. Cir. 1996); In re Dillon, 919 F.2d 688, 693 (Fed. Cir. 1990) (*in banc*).

137 In re Sernaker, 702 F.2d 989 (Fed. Cir. 1983).

138 In re Nilssen, 851 F.2d 1401, 1403 (Fed. Cir. 1988); Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1025 (Fed. Cir. 1985).

139 In re Bozek, 416 F.2d 1385 (C.C.P.A. 1969).

140 In re Sernaker, 702 F.2d 989 (Fed. Cir. 1983).

141 Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 103 F.3d 1538, 1546 (Fed. Cir. 1997) (the nature of a problem to be solved may lead inventors "to look to references relating to possible solutions to that problem.")

142 In re Wright, 848 F.2d 1216 (Fed. Cir. 1988).

different problems, or the problem to be solved has not been identified, a suggestion to combine may not be indicated.[143] Finally, a suggestion to combine may come from a convincing line of reasoning, logic, or motivation based on sound scientific principles,[144] as long as an impermissible hindsight analysis is not used.[145]

(3) What cannot Provide a Suggestion

The Federal Circuit has also explained what cannot provide a suggestion to combine. First and foremost, the patent at issue cannot provide the suggestion.[146] This is a natural consequence of the general rule that the prior art must be evaluated as of the time the invention was made. This rule prevents hindsight reconstruction and prevents the patent in suit from being used as a blueprint or guide to combine the prior art.[147] Additionally, as discussed previously, non-analogous art may not provide a suggestion to combine.[148]

Statements or knowledge that merely make a particular combination of references "obvious to try" cannot provide a suggestion to combine.[149] "Obvious to try" means that the references only provide general guidance or a general incentive that is not specific to the particular form of the claimed invention.[150] Two types of "obvious to try" are 1) general guidance to try a number of possible choices until success is achieved[151], and 2) general

---

143 *See* In re Zurko, 111 F.3d 887, 890 (Fed. Cir. 1997) (stating "to say that the missing step comes from the nature of the problem to be solved begs the question because the Board has failed to show that this problem had been previously identified anywhere in the prior art"); *see also* In re Sponnable, 405 F.2d 578, 585 (C.C.P.A. 1969) ("[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified."); In re Wright, 848 F.2d 1216 (Fed. Cir. 1988) (differences between the problem solved by the invention and those solved in the prior art may defeat the rejection); In re Shaffer, 229 F.2d 476 (C.C.P.A. 1956) (lack of identification of the problem facing the inventor is basis for finding that references could not have suggested a solution to the problem).

144 In re Oetiker, 977 F2d 1443 (Fed. Cir. 1992); Ex Parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985); In re Regel, 526 F.2d 1399 (C.C.P.A. 1975).

145 *See* In re Zurko, 111 F.3d 887 (Fed. Cir. 1997) (suggestion to combine not found even though inventor's solution may seem logical in retrospect).

146 Orthopedic Equipment Co. v. U.S., 702 F.2d 1005 (Fed. Cir. 1983).

147 *Id.* at 1012 (Fed. Cir. 1983).

148 In re Clay, 966 F.2d 656, 658 (Fed. Cir. 1992).

149 Jones v. Hardy, 727 F.2d 1524, 1530 (Fed. Cir. 1984); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); In re Goodwin, 576 F.2d 375 (C.C.P.A. 1978).

150 In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988).

151 *Id.*, citing In re Geiger, 815 F.2d at 688; Novo Industri A/S v. Travenol Laboratories, Inc., 677 F.2d 1202, 1208 (7th Cir. 1982); In re Yates, 663 F.2d 1054, 1057 (C.C.P.A. 1981); In re Antonie, 559 F.2d at 621.

guidance for further experimentation or investigation[152]. Additionally, inherent[153] qualities or characteristics may not provide a suggestion to combine, because something that may be inherent may not be necessarily known, and knowledge is required for a suggestion to combine.[154]

If a large number of references are required to establish a suggestion, evidence of non-obviousness may exist.[155] However, the ultimate criterion is "not the number of references, but what they would have meant to a person of ordinary skill in the field of the invention."[156] The inability to physically substitute the features of one reference into the structure of another usually is not relevant, although it may indicate non-obviousness.[157] What ultimately matters is "whether a person of ordinary skill in the art, having all of the teachings of the references before him, is able to produce the structure defined by the claim."[158] However, if references would be destroyed for their intended purposes after being combined, a suggestion to combine will not exist.[159] Finally, extensive efforts by the inventor to solve the problem indicate the absence of a suggestion to combine the prior art references.[160]

---

[152] *Id.*, citing In re Dow Chemical Co., 837 F.2d 469, 473 (Fed. Cir. 1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 1606 (1987); In re Tomlinson, 363 F.2d 928, 931 (C.C.P.A. 1966).

[153] The term "inherent" means "existing in something as a natural and inseparable quality, characteristic or right." WEBSTER'S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE, Second College Edition (1970).

[154] In re Newell, 891 F.2d 899, 901 (Fed. Cir. 1989).

[155] State Industries, Inc. v. A.O. Smith Corp., 221 USPQ 958, 973, 1983 WL 327 (M.D. Tenn. 1983), *aff'd in part, rev'd in part*, 751 F.2d 1226 (Fed. Cir. 1985).

[156] In re Gorman, 933 F.2d 982, 986 (Fed. Cir. 1991), citing Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987) (combination of about twenty references that "skirt[ed] all around" the claimed invention failed to show obviousness; In re Miller, 159 F.2d 756, 758-59 (C.C.P.A. 1947) (obviousness shown by eight references); Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1149 (Fed. Cir. 1983) (conclusion of obviousness strengthened by numerous repeated references); In re Troiel, 274 F.2d 944, 947 (C.C.P.A. 1960) (combining large number of references to show obviousness not "farfetched and illogical").

[157] Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005, 1013 (Fed. Cir. 1983); In Re Sneed, 710 F.2d 1544, 1550 (Fed. Cir. 1983); In re Andersen, 391 F.2d 953, 958 (C.C.P.A. 1968).

[158] *See* Orthopedic Equipment Co. at 1013 (Fed. Cir. 1983); *see also* In re Twomey, 218 F.2d 593 (C.C.P.A. 1955).

[159] Ex parte Westphalen, 159 USPQ 507 (Bd. App. 1967).

[160] Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 103 F.3d 1538, 1546 (Fed. Cir. 1997) (extensive efforts by inventor "tend to show that one skilled in the art would have had no reasonable expectation of success in

In the specific context of biotechnology, the Federal Circuit has stated that a general method of determining the proper sequence of a DNA or a cDNA molecule is "essentially irrelevant to the question of whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs."[161] In other words, the Federal Circuit has taken the position that a general method reference cannot be combined with a prior art amino acid reference to provide a suggestion for the DNA sequence.

b. Motivation

A suggestion to combine will not render an invention obvious unless the prior art also provides a motivation to make the combination.[162] Motivation in this sense means that the prior art provides a reason to make the combination. It is a different concept than both a suggestion to combine references and reasonable expectation of success. Motivation to combine is more analogous to the concept of patent utility.[163]

Perhaps the best way to distinguish and understand the additional requirement of motivation is through a case example. In *In re Stemninski*,[164] the claimed invention was similar in structure and function to a prior art compound. However, there was no known utility for the prior art compound at the time of the invention. The court held that since there was no known utility for the similar structure in the prior art, there was no motivation to make the claimed invention.[165] Since there was no motivation to make the combination, the claimed invention was not obvious. In short, when a similar prior art compound has no known use, the claimed invention cannot be obvious because there is no motivation to make it.

When the similar prior art compound does have a known use, the issue of motivation does not usually arise because similarity of structure gives rise to a presumption of both similarity of function and utility.[166] An exception to this rule is when the similar prior art compound is a chemical intermediate for producing other compounds.[167] The rule in this situation is that no presumption of similar utility exists.[168] This is true even when the prior art compounds are intermediates

---

combining the prior art machines in question"); In re Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988) ("five to six years of research that preceded the claimed invention" was entitled to fair evidentiary weight in determination of nonobviousness).

161 In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995).

162 In re Stemniski, 444 F.2d 581, 586 (C.C.P.A. 1971).

163 In re Ruschig, 343 F.2d 965, 977 (C.C.P.A. 1965) ("What is important is the fact that the utility discovered by the appellants is not disclosed in the prior art.").

164 In re Stemniski, 444 F.2d 581, 586 (C.C.P.A. 1971).

165 *Id.*

166 In re Gyurik, 596 F.2d 1012, 1017 (C.C.P.A. 1979).

167 *Id;* In re Lalu, 747 F.2d 703, 707 (Fed. Cir. 1984) (use of prior art compounds as intermediates is "not motivation sufficient to support the structural obviousness rejection")

168 *Id.*

of other prior art compounds having similar utility to the claimed invention.[169]

A motivation to combine references is also required in the mechanical arts. In such cases, motivation is variously described as the "desirability,"[170] "advantages,"[171] or "justification"[172] for a combination.

c. Reasonable Expectation of Success

A suggestion to combine references must also either contain or be accompanied by teachings in the prior art that provide one of ordinary skill a reasonable expectation of success of achieving the claimed invention.[173] Absent such teachings, a suggestion to combine cannot support a finding of obviousness,[174] and is conceptually similar to an inadequate "obvious to try." However, the teaching need only provide a reasonable expectation of success.[175] Absolute predictability is not required.[176] The requirement that a reasonable expectation of success accompany the suggestion to combine references is consistent with the requirement in section 112 that a patent be both "enabled" and "adequately described."[177] Since the "expectation of success" standard is one of reasonableness, the courts have not developed an extensive analysis to assist the decision maker on this issue. In particular, the courts have not specifically determined to what degree effort expended and experimentation are relevant to a reasonable expectation of success.

d. Suggestion Test Procedure

The Federal Circuit has not clearly defined any specific step by step analytical procedure to follow when determining whether the prior art suggests the claimed invention. Rather, the suggestion requirement is usually stated generally, without reference to any procedural discipline. For example, the court in *In re Geiger*[178] stated: "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination."[179] Perhaps the most detailed procedural statement to date on

---

169 *Id.*

170 In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984); In re Imperato, 486 F.2d 585, 587 (C.C.P.A. 1973).

171 In re Sernaker, 702 F.2d 989, 995-96 (Fed. Cir. 1983).

172 Carl Schenck, A.G. v. Nortron Corp., 713 F.2d 782, 787 (Fed. Cir. 1983).

173 In re Dow Chemical Co., 837 F.2d 469, 473 (Fed. Cir. 1988).

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

175 Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720 (Fed. Cir. 1990).

176 In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988).

177 35 U.S.C. § 112, para. 1 provides: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

178 815 F.2d 686 (Fed. Cir. 1987).

179 *Id.* at 688, citing ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577 (Fed. Cir. 1984).

the suggestion test was contained in *In re Sernaker*[180]:

> We may assume, for purposes of this decision, that all the prior art references in this case are sufficiently related to one another and to a related and common art, that the hypothetical person skilled in the art must be presumed to be familiar with all of them. That being so, the next questions are (a) whether a combination of the teachings of all or any of the references would have suggested (expressly or by implication) the possibility of achieving further improvement by combining such teachings along the line of the invention in suit, and (b) whether the claimed invention achieved more than a combination which any or all of the prior art references suggested, expressly or by reasonable implication.[181]

Some commentators argue that the suggestion test takes place in two steps.[182] The first step occurs when a suggestion to combine references is sought, and the second step occurs when a suggestion to arrive at the subject matter is sought from the combination.[183] However, the cases do not clearly set forth or recognize this two step formulation. The Federal Circuit has instead expressed the suggestion test procedure in general terms, without describing any specific analytical process for determining whether a suggestion to combine exists.[184]

e. Prima Facie Case

The so called "prima facie case" is a procedural device designed to allocate the evidentiary burdens of going forward and persuasion between the applicant and the examiner.[185] It was developed to place the burden of producing evidence on the party that is best able to produce it. Determinations of obviousness are made with the

---

180 702 F.2d 989 (Fed. Cir. 1983).

181 *Id.* at 994.

182 *See* Kenneth R. Adamo, *The Power of Suggestion (Teaching, Reason or Motivation) and Combined Reference Obviousness*, 76 J. Pat. & Trademark Off. Soc'y 177 (March, 1994); Irah H. Donner, *Obvious Rejections: Doing the "Tango" with the PTO*, 11 No. 8 Computer Law 15, 18 (August, 1994); Kenneth R. Adamo, *Letter to the Editor* 17 CRO, 76 JPTOS 178, 77 Pat. & Trademark Off. Soc'y 71 (January, 1995); Irah H. Donner, *Combating Obviousness Rejections Under 35 U.S.C. Section 103*, 6 Alb. L. J. Sci. & Tech. 159, 168 (1996).

183 *Id.*

184 *See, e.g.*, Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1582 (Fed. Cir. 1983) (stating the test to be "whether the references, taken as a whole, would suggest the invention to one of ordinary skill in the art").

185 In re Piasecki, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

assistance of the prima facie case procedure.[186]

In patent prosecution, all patent applications are initially presumed to be nonobvious, and therefore patentable.[187] The burden of proving otherwise falls on the examiner.[188] However, the examiner has limited resources with which to meet this burden.[189] The prima facie case procedure allows the examiner to satisfy his or her initial burden with a degree of proof that is appropriate to the examiner's limited resources. The result is that the burden of coming forward with evidence that is difficult and time consuming to produce is shifted to the applicant.

In general, a prima facie case is made when enough evidence is produced to permit the trier of fact to infer the fact at issue.[190] In the patent obviousness context, the degree of proof necessary to establish a prima facie case is satisfied by proof of a suggestion to combine references.[191] The rationale is that the suggestion to combine provides the requisite inference of obviousness.[192]

If the examiner is unable to produce enough evidence to establish a suggestion to combine, the invention should be considered nonobvious and the patent should issue.[193] However, if a sufficient suggestion to combine is found in the relevant prior art, a prima facie case of obviousness is established,

---

186 The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. In re Mayne, 104 F.3d 1339 (Fed. Cir. 1997), citing Graham v. John Deere Co., 383 U.S. at 17-18; Miles Labs., Inc. v. Shandon Inc., 997 F.2d 870, 877 (Fed. Cir. 1993).

187 In re Piasecki, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

188 In re Bell, 991 F.2d 781, 783 (Fed. Cir. 1993); In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

189 *See, e.g.*, In re Huang, 100 F.3d 135 (Fed. Cir. 1996) (stating that the PTO lacks the means or resources to gather evidence concerning commercial success); Ex parte Remark, 15 USPQ2d 1498, 1503 (1990) (examiner has no available means for adducing evidence).

190 *See* Texas Dept. of Community Affairs v. Burdine, 450 U.S. 248, 254 n. 7, (1981) (stating "[t]he phrase "prima facie case" ... may be used by courts to describe the plaintiff's burden of producing enough evidence to permit the trier of fact to infer the fact at issue") (citing 9 J. Wigmore, Evidence s 2494 (3d ed. 1940); E.W. Cleary, McCormick on Evidence s 342 (3rd ed. 1984) ("The judge, using ordinary reasoning, may determine that fact A might reasonably be inferred from fact B, and therefore that the party has satisfied his burden [of producing evidence], or as sometimes put by the courts, has made out a "prima facie" case.").

191 In re Mills, 281 F.2d 218 (C.C.P.A. 1960) (Prima facie case involves an "inference of fact").

192 *See* In re Rinehart, 531 F.2d 1048, 1051 (C.C.P.A. 1976) ("A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.").

193 In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

and the burden shifts to the applicant to come forward with rebuttal evidence.[194] If the applicant is then able to produce enough evidence for the trier of fact to reasonably infer *non*obviousness as an opposite conclusion, the prima facie case will stand rebutted.[195] The examiner must then reconsider all relevant evidence and make the decision regarding obviousness anew.[196]

The prima facie case procedure first appeared in U.S. patent law in cases involving chemical inventions.[197] Chemistry is one of the so called "unpredictable" arts, where the relationship between structure and function is not as completely understood as in the mechanical or electrical arts.[198] New chemical compounds that are structurally similar to prior art compounds may nonetheless have functional properties that are quite different and unexpected.[199] Proof of obviousness of chemical compounds therefore requires proof of both structural and functional similarity.[200] Unfortunately, proof of functional similarity can be time consuming and difficult due to the complexity of the chemical arts.

The prima facie case procedure was developed so examiners could avoid the difficult burden of proving the functional similarity of chemical compounds. The procedure provides that as long as structural similarity is demonstrated, functional similarity is presumed, and a case of prima facie obviousness is established.[201] The

---

194 Dillon, 919 F.2d at 692; In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995).

195 In re Heldt, 433 F.2d 808, 811 (C.C.P.A. 1970) (Rebuttal is "a showing of facts supporting the opposite conclusion").

196 In re Rinehart, 531 F.2d 1048 (C.C.P.A. 1976); In re Wright, 848 F.2d 1216 (Fed. Cir. 1988).

197 In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (history of the prima facie case includes mechanisms called "presumptions of unpatentability", as reflected in early chemical cases such as In re Henze, 181 F.2d 196, 201 (C.C.P.A. 1950).

198 *See* In re Soni, 54 F.3d 746 (Fed. Cir. 1995) (stating “The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results.”); *see also* Application of Carleton, 599 F.2d 1021 (C.C.P.A. 1979); 2 Peter D. Rosenberg, PATENT LAW FUNDAMENTALS § 9.04 [8] (2nd ed. 1995 rev.).

199 *See* Patricia E. Roberts, *Comment, Chemical Compounds Related as Genus and Species and the Patentability Requirements of Novelty*, 54 WASH. L. REV. 815 n. 1 (1979) (stating that chemical compounds with the same formula but different structures can have completely different properties).

200 2 Rosenberg, *supra* note 198, § 9.04 [8].

201 *See* In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990) (*in banc*) ("structural similarity between claimed and prior art subject matter, ... where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness"), *cert. denied*, 500 U.S. 904 (1991); *see also* In re Payne, 606 F.2d 303, 314 (C.C.P.A. 1979). Stated in terms of a suggestion to combine, the prior art similar structure combined with the common knowledge in

burden then shifts to the applicant to rebut the prima facie case, customarily with evidence of different and unexpected functional properties.[202] If the applicant is able to come forward with such evidence, the prima facie case is rebutted, and the examiner is required to consider all the evidence on obviousness anew.[203]

Unfortunately, the chemical prima facie procedure has not performed well in the field of biotechnology.[204] Specifically, the structural similarity test has proven not to be effective in the context of DNA and proteins.[205] This is because the relationship between a prior art amino acid sequence and DNA sequence is fundamentally different from the relationship between two structurally similar prior art chemical compounds.[206] Amino acid and DNA sequences relate to each other through the genetic code, not through structural similarity. The difference in relationship makes the presumption based on structural similarity inappropriate.[207]

6. Secondary Considerations

a. Factors

The United States Supreme Court in *Graham v. John Deere*[208] stated that secondary considerations "may have relevancy" on the issue of obviousness.[209] The Court explained that "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."[210] Since *Graham*, the Federal Circuit has increased the importance of secondary considerations in the obviousness inquiry and has approved additional secondary considerations for use.[211]

---

chemistry that similar structures usually result in similar properties, properly produces the prima facie case.

202 *See* In re Soni, 54 F.3d 746 (Fed. Cir. 1995) (stating "The basic principle behind this rule is straightforward--that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results.")

203 *See* In re Rinehardt, 531 F.2d 1048, 1052 (C.C.P.A. 1976).

204 *See* Anita Varman and David Abraham, *DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J. L. & TECH. 53, 68 (Winter 1996).

205 *Id.*

206 *Id.*

207 *Id.* This subject is taken up at length *infra* at notes 679-709 and accompanying text.

208 383 U.S. 1 (1966).

209 *Id.* at 17-18. The statement was followed by citation to Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169 (1964).

210 *Id.*

211 *See generally* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803 (1988); Note, *A Critique of the Use of Secondary Considerations in Applying the Section 103 Nonobvious Test for Patentability*, 28 B. C. L. REV 357 (1987); Jerome G. Lee, *The Role of Secondary Considerations, and*

The term "secondary considerations" is actually a misnomer. The Federal Circuit has made clear that evidence of "secondary" considerations is not to be considered secondary in importance to the primary three part *Graham* test.[212] Indeed, the Federal Circuit has declared that evidence of secondary considerations "may often be the most probative and cogent evidence in the record"[213] and "may often establish that an invention appearing to have been obvious in light of the prior art was not."[214]

Secondary considerations are always to be considered on the issue of obviousness, not just when the decisionmaker remains doubtful following a review of the prior art.[215] Such evidence may be especially useful when "differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field."[216] However, evidence of secondary considerations is not a requirement for patentability,[217] and the failure to prove them does not weigh against a finding of nonobviousness.[218]

Secondary considerations now expressly approved by the Federal Circuit include: commercial success[219]; long felt but unsatisfied need[220]; failure

---

Objective Evidence in Determining Obviousness Under 35 U.S.C. Section 103, 213 PLI / PAT 199 (1985).

212 *See* Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 719 (Fed. Cir. 1991) (stating "secondary considerations are not secondary in importance to primary considerations").

213 Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983). *see also* Address by D. Chisum, AIPLA Annual Meeting (October 26, 1984), reprinted in 1984 AIPLA Bull. 618, 620 ("secondary not because they are secondary in importance [but] ... because they are relevant through a process of inference to the ultimate technical issue of nonobviousness.")

214 *Id.*

215 *Id.* at 1539.

216 Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1273 (Fed. Cir. 1991).

217 *See* Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 960 (Fed. Cir. 1986).

218 *Id.*; *See also* Medtronic, Inc. v. Intermedics, Inc., 799 F.2d 734, 739 (Fed. Cir. 1986) (stating the absence of objective evidence "is a neutral factor").

219 *See* In re Mayne, 104 F.3d 1339, 1341 (Fed. Cir. 1997) (stating objective indicia such as commercial success is relevant to the determination of obviousness); Evidence of commercial success must include evidence of market share and evidence of a nexus between the commercial success and the unique characteristics of the claimed invention. *See* In re Huang, 100 F.3d 135, 140 (Fed. Cir. 1996) (affidavit only indicating number of units sold provided no indication of market share and was insufficient; inventor's conclusory statement in affidavit regarding nexus held insufficient); For a recent discussion concerning commercial success in the context of a factual setting *see* J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997).

220 *See* In re Piasecki, 745 F.2d 1468,1475 (Fed. Cir. 1984) (obviousness rejection reversed after evidence of unique design combining lighter-than-

of others[221]; copying by others[222]; contemporaneous reaction by the industry[223]; licensing of the patented invention[224]; skepticism of experts[225]; unexpected results[226]; simultaneous invention[227]; and departure from other

---

air ships with helicopters satisfied long felt need of lifting heavy loads).

[221] *See* Gambro Lundia AB v. Baxter Healthcare Corporation, 110 F.3d 1573, 1580 (Fed. Cir. 1997) (evidence that those skilled in the art tried numerous, ultimately unsuccessful, solutions was objective evidence that supported a conclusion of nonobviousness).

[222] *See* Vandenberg v. Dairy Equipment Co., 740 F.2d 1560, 1567 (Fed. Cir. 1984) (stating that "the copying of an invention may constitute evidence that the invention is not an obvious one") citing Troy Co. v. Products Research Co., 339 F.2d 364, 367 (9th Cir. 1964), cert. dismissed, 381 U.S. 930 (1965). The Vandenberg court further stated "this would be particularly true where the copyist had itself attempted for a substantial length of time to design a similar device, and had failed") *Id.*

[223] *See* Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985) (stating that "courts have long recognized the usefulness of evidence of the contemporaneous attitude toward the asserted invention"); *see also* W.L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540, 1545 (Fed. Cir. 1983) (expressions greeting the product such as "magical," "bewitching," and "a remarkable new material" constituted objective evidence of nonobviousness).

[224] *See* Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1539 (Fed. Cir. 1983) (stating that "[r]ecognition and acceptance of the patent by competitors who take licenses under it to avail themselves of the merits of the invention is evidence of nonobviousness")

[225] *See* In re Dow Chemical Co., 837 F.2d 469, 473 (Fed. Cir. 1988) (stating that the "skepticism of an expert, expressed before [an inventor] proved him wrong, is entitled to fair evidentiary weight.") citing In re Piasecki, 745 F.2d 1468, 1475 (Fed. Cir. 1984); In re Zeidler, 682 F.2d 961, 966 (C.C.P.A. 1982).

[226] *See* In re Dillon, 919 F.2d 688, 692, 693 (Fed. Cir. 1990) (*in banc*) (stating that unexpectedly improved properties or properties can establish rebut a prima facie case of obviousness); In re Wright, 848 F.2d 1216, 1219 (Fed. Cir. 1988) (stating "[f]actors including unexpected results, new features, solution of a different problem, novel properties, are all considerations in the determination of obviousness in terms of 35 U.S.C. s 103."); *see also* In re Mayne, 104 F.3d 1339, 1343 (Fed. Cir. 1997) (stating "[t]he basic principle behind this rule is straight forward--that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.").

[227] *See* International Glass Co. v. U. S., 408 F.2d 395, 405 (Ct. Cl. 1969) (stating that "[t]he fact of near-simultaneous invention, though not determinative of statutory obviousness, is strong evidence of what constitutes the level of ordinary skill in the art"); However, this factor may or may not be probative depending on the circumstances since 35 U.S.C. s 135, (establishing and governing interference practice) recognizes the possibility of

principles in the art.[228] The list is not exclusive. Secondary considerations may also include "other events proved to have actually happened in the real world."[229]

The Federal Circuit gives substantial weight to secondary considerations for several reasons. First, such considerations "provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product."[230] Second, they "illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made."[231] Third, secondary considerations "give light to the circumstances surrounding the origin of the subject matter sought to be patented."[232]

The increased emphasis on secondary considerations may also be due to a fundamental shift in thinking with regard to the economic theories underlying the patent system. In the last decade, economic theories that recognize the importance of the commercial aspects of the patent grant have been developed and studied.[233] One such theory is the "prospect" theory of patent law, which emphasizes the importance of future economic returns as the primary function of the patent grant.[234] It stands in contrast to the reward theory of patent law, which emphasizes the reward function of patents as the primary purpose of patent law.[235] Secondary considerations such as commercial success are thought

---

near simultaneous invention by two or more inventors working independently. *See* E.I. DuPont de Nemours & Co. v. Berkley & Co., 620 F.2d 1247 (8th Cir. 1980).

[228] Perkin-Elmer Corp. v. Computervision Corp. 732 F.2d 888, 895 (Fed. Cir.), *cert. denied*, 105 S.Ct. 187 (1984) (stating evidence that invention had numerous advantages over previous products, became the industry standard, revolutionized the industry, and constituted a radical departure from traditional approaches to lens design constituted highly probative evidence of nonobviousness).

[229] *See* Panduit Corporation v. Dennison Manufacturing Co., 810 F.2d 1561, 1569 (Fed. Cir. 1987).

[230] Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1391 (Fed. Cir. 1988).

[231] Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1273 (Fed. Cir. 1991).

[232] *See* Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1564 (Fed. Cir. 1987) quoting from Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

[233] *See* A. Samuel Oddi, *Ununified Economic Theories of Patents -The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267, 269 (1996) (stating that "the modern era in patent economic theory may be seen as beginning in 1977 with Kitch's publication of an article describing the "prospect" theory of the patent system -- analogizing from the U.S. mineral claims system").

[234] *See* Kitch, *The Nature and Function of the Patent System*, 20 J. L. ECON. 265 (1977).

[235] *See* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation* 78 VA. L. REV. 305, 310 (1992).

to be consistent with the "prospect" theory of patent law.[236]

In actual practice, secondary considerations have proven to be an effective barometer of obviousness. This may be because they are easier for courts to understand and use than the *Graham* three part technical analysis. In the words of the Supreme Court, secondary considerations "focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation."[237] Secondary considerations are also helpful because they "often prevent a court from slipping into an impermissible hindsight analysis."[238] It is reversible error not to consider secondary considerations when determining obviousness.[239]

b. Requirement of a Nexus

If the secondary evidence is to be given substantial weight in the obviousness determination, a nexus must be established between the merits of the claimed invention and the secondary consideration.[240] The burden to prove this connection or nexus rests on the applicant / patentee.[241]

The burdens of proof differ in inter partes and ex parte practice. In the context of civil litigation, the patentee must only come forward with enough evidence to constitute a prima facie case of the requisite nexus.[242] Such a case is established when the patentee provides enough evidence to support a reasonable inference of a nexus.[243] A

---

236 Edmund Kitch shifted his position on the relevance of commercial success - which he had earlier found to be a poor indicator of patentability - following his development of the prospect theory. *See* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 838 (1988).

237 *See* Graham v. John Deere Co., 383 U.S. 1, 35-36 (1966); *See also* Safety Car Heating & Lighting Co. v. General Electric Co., 155 F.2d 937, 939 (2d. Cir. 1946) (L. Hand, J: "Courts, made up of laymen as they must be, are likely either to underrate, or to overrate, the difficulties in making new and profitable discoveries in fields with which they cannot be familiar; and, so far as it is available,they had best appraise the originality involved by the circumstances which preceded, attended and succeeded the appearance of the invention.").

238 Vandenberg v. Dairy Equipment Co., 740 F.2d 1560, 1567 (Fed. Cir. 1984).

239 *See* Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986).

240 *See* Stratoflex, Inc. v. Aeroquip Corp. 713 F.2d 1530 (Fed. Cir. 1983) (stating "a nexus is required between the merits of the claimed invention and the evidence offered, if that evidence is to be given substantial weight enroute to [a] conclusion on the obviousness issue.") *Id.* at 1539.

241 *See, e.g.*, Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1027, 226 USPQ 881, 888 (Fed. Cir. 1985).

242 *See* Texas Dept. of Community Affairs v. Burdine, 450 U.S. 248, 254 n. 7, 101 S.Ct. 1089, 1094 n. 7, 67 L.Ed.2d 207 (1981).

243 *Id.*

reasonable inference will be supported by proof that the commercial success was due to the patented invention itself.[244] The patentee is not initially required to prove that factors other than the patented invention did *not* cause the commercial success of the product.[245] However, the asserted commercial success of the product must be shown to result from advantages of the claimed invention beyond what was already available in the prior art.[246]

When a patented device is coextensive with a commercial product, there is an inference that its commercial success is due to the patented device itself, absent a showing to the contrary.[247] However, if the patented device is only a component of a commercially successful product, then the patentee must show prima facie a legally sufficient relationship between the patented component and the commercial product.[248] Such a prima facie showing may be made by demonstrating continuous use of the patented feature while other features of the commercial product were changed,[249] or through testimony as to the advantages of the patented feature.[250]

If the patentee can establish a prima facie case of nexus, the burden then shifts to the accused infringer to come forward with rebuttal evidence.[251] Such evidence must consist of proof that the secondary factor was due to factors other than the patented invention. For example, that the secondary

---

[244] Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387 (Fed. Cir. 1988).

[245] Demaco at 1394 (stating "a requirement for proof of the negative of all imaginable contributing factors would be unfairly burdensome, and contrary to the ordinary rules of evidence." *See also* Hybritech 802 F.2d 1367, 1382.

[246] *See* J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997) (citing Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1580 (Fed. Cir. 1983) (claims held obvious despite alleged commercial success for failure to show that "such commercial success as its marketed system enjoyed was due to anything disclosed in the patent in suit which was not readily available in the prior art").

[247] Demaco at 1392.

[248] Demaco at 1392.

[249] *See* Hughes Tool Co.v. Dresser Industries, Inc., 816 F.2d 1549, 1556 (Fed. Cir.), *cert. denied*, 108 S. Ct. 261 (1987).

[250] *See* Railroad Dynamics, Inc. v. A. Stucki Co., 579 F.Supp. 353, 366-67, 218 USPQ 618, 628 (E.D.Pa. 1983) *aff'd*, 727 F.2d 1506 (Fed. Cir.), *cert. denied*, 469 U.S. 871 (1984).

[251] *See* Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387 (Fed. Cir. 1988) (citing Hazelwood School District v. United States, 433 U.S. 299, 314 (1977) (Stevens, J., dissenting) ("The basic framework [in a title VII action] is the same as that in any other lawsuit. The plaintiff has the burden of proving a prima facie case; if he does so, the burden of rebutting that case shifts to the defendant"); see also McCormick s 336: "The burden of producing evidence on an issue ... is usually cast first upon the party who has pleaded the existence of the fact, but as we shall see, the burden may shift to the adversary when the pleader has discharged his initial duty.")

consideration of commercial success was due to such non-technical factors as advertising[252], better distribution, or superior workmanship.[253] There must be actual proof of extraneous factors. Mere "argument" and "conjecture" are not sufficient.[254] If the accused infringer cannot produce evidence that completely rebuts the inference of nexus, the evidence of secondary factors must be considered in the obviousness determination.[255] The secondary considerations need not solely result from the patented features to be given appropriate weight along with the other evidence.[256]

The prima facie case procedure is not available to prove secondary considerations such as commercial success in ex parte patent prosecution.[257] This is because the examiner, unlike a private litigant, does not have the resources with which to rebut a prima facie case of commercial success.[258] In ex parte patent prosecution, the applicant must initially produce evidence that directly connects the commercial success to the patented invention.[259] Absent such proof, the examiner need not consider evidence of commercial success when making the obviousness determination.[260]

---

252 Prominence of the patented technology in the advertising, however, creates an inference that links the commercial success to the invention. *See* Gambro Lundia Ab v. Baxter Healthcare Corporation, 110 F.3d 1573, 1579 (Fed. Cir. 1997).

253 Demaco at 1393.

254 Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546 (Fed. Cir. 1984)

255 *See* W. L. Gore & Associates, 721 F.2d at 1555.

256 *See generally* Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392-94, (Fed. Cir.), *cert. denied*, 488 U.S. 956, 109 S.Ct. 395, 102 L.Ed.2d 383 (1988); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546 (Fed. Cir. 1984). [Continental Can Company USA, Inc. v. Monsanto Company, 948 F.2d 1264 (Fed. Cir. 1991)].

257 *See* In re Huang, 100 F.3d 135, 139 (Fed. Cir. 1996); Ex parte Remark, 15 U.S.P.Q.2d 1498, 1503 (1990).

258 *See* Huang at 139 (stating "In the ex parte process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion that the sales constitute commercial success.") see also Remark at 1503 (stating "the examiner in ex parte proceedings has no available means for adducing evidence to show that the commercial success was due to extraneous factors. For this reason, we are of the opinion that the evidentiary routine pertaining to the shifting of the burden upon presenting a prima facie case of nexus is inapplicable to ex parte proceedings in the Patent and Trademark Office")

259 Huang at 139 (stating "the PTO must rely upon the applicant to provide hard evidence of commercial success").

260 *See* In re Huang, 100 F.3d 135, 140 (Fed. Cir. 1996) (stating "[commercial] success is relevant in the obviousness context only if there is proof that the sales were a direct result of the unique characteristics of the claimed invention--as opposed to other

7. Weighing Suggestion Evidence and Secondary Considerations

The Federal Circuit has not attempted to express any comprehensive analytical framework to assist the decision maker in comparing and weighing the primary and secondary considerations. However, some general guidelines can be found in the case law. The general rule is that the decision maker should carefully weigh all the evidence, both primary and secondary, and render a decision based on the relative strengths of all factors.[261] Neither secondary considerations nor primary technical suggestions should control the outcome.[262] Depending on the facts of the particular case, primary considerations may overcome secondary considerations, and vice versa.[263]

For example, evidence of secondary considerations can support a conclusion of nonobvious, even when the prior art references prima facie suggest the invention to one of ordinary skill in the art.[264] Conversely, when the secondary considerations "weigh in favor" of the applicant/patentee, the evidence may still not carry sufficient weight to overcome a finding of obviousness based on a suggestion.[265] The relative quantums of proof are always important. When the differences are "minor" between the claimed invention and the prior art (indicating obviousness), the secondary considerations must be "sufficiently compelling" to support a finding of nonobviousness.[266] In some cases, the evidence of secondary considerations

---

economic and commercial factors unrelated to the quality of the patented subject matter.")

[261] *See* Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1539 (Fed. Cir. 1983) (stating "[e]nroute to a conclusion on obviousness, a court must not stop until all pieces of evidence on that issue have been fully considered and each has been given its appropriate weight").

[262] *See* Newell Cos. v. Kenney Mfg. Co., 864 F.2d 757, 768 (Fed. Cir. 1988) (secondary considerations of obviousness must be considered, but do not control the question of obviousness), *cert. denied*, 493 U.S. 814 (1989).

[263] *See* Ryko Manufacturing Co. v. Nu-Star, Inc., 950 F.2d 714, 719 (Fed. Cir. 1991) (court upheld ruling that "secondary considerations did not carry sufficient weight to override a determination of obviousness based on primary considerations"); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306 (Fed. Cir. 1985) (stating that "under certain circumstances, the evidence of secondary considerations may be particularly strong and entitled to such weight that it may be decisive").

[264] Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538-39 (Fed. Cir. 1983 (secondary considerations "often establish that an invention appearing to have been obvious in light of the prior art was not").

[265] *See* Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 719 (Fed. Cir. 1991) (court found that the secondary considerations weighed in favor of appellant but did not carry sufficient weight to override a determination of obviousness based on primary considerations).

[266] *See* Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 291-92 (Fed. Cir. 1985).

may be "particularly strong and entitled to such weight that it may be decisive."[267] As long as all relevant factors are contemplated, a decision will be upheld unless clear error has been committed.[268]

Beyond these general principles, the Federal Circuit has also offered some comments on the weight to be given certain secondary considerations. The Federal Circuit typically considers the failure of others to solve the problem to be strong evidence of nonobvious.[269] More variable is evidence of commercial success. In some cases, such evidence may be "extremely strong" and entitled to "great weight."[270] In other cases, evidence of commercial success may be entitled to less weight.[271] "Copying by others" is generally considered to be a weak secondary consideration.[272] This is because copying may be due to many reasons other than the technical advance of the invention.[273] The weight to be given a secondary factor also depends on the relative strength of the nexus existing between the secondary factor and the patented invention.[274] In sum, unless completely rebutted, all secondary factors must be considered and given more or less weight, depending on the nature of the evidence and the strength of the nexus.

8. Additional Procedural Considerations

a. As a Whole or Element by Element

In an obviousness determination, both the prior art and the claimed invention are to be considered "as a whole."[275] It is necessary to consider the

---

267 *Id.* at 291.

268 *See* Ryko Manufacturing Co. v. Nu-Star, Inc., 950 F.2d 714, 719 (Fed. Cir. 1991)

269 *See, e.g.*, In re Piasecki, 745 F.2d 1468 (Fed. Cir. 1984).

270 *See* Simmons Fastener Corp. v. Illinois Tool Works, Inc., 739 F.2d 1573, 1575 (Fed. Cir. 1984).

271 *See* Para-Ordnance Mfg., Inc. v. SGS Importers Intern., Inc., 73 F.3d 1085, 1090 (Fed. Cir. 1995).

272 *See* Cable Elec. Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1028 (Fed. Cir. 1985) (stating that "more than the mere fact of copying by an accused infringer is needed to make that action significant to a determination of the obviousness issue".

273 *Id.* (copying could have occurred out of general lack of concern for patent property or for financial reasons)

274 *See* Ashland Oil, Inc. v. Delta Resins & Refractories, 776 F.2d 281, 306 (Fed. Cir. 1985) (stating "[t]he objective evidence of secondary considerations may in any given case be entitled to more or less weight, depending upon its nature and its relationship to the merits of the invention"), *cert. denied*, 475 U.S. 1017 (1986).

275 *See* Gillette Co. v. S. C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed. Cir. 1990) (stating that "[f]ocusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness."); Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448 (Fed. Cir. 1986) (stating that "focusing on portions of prior art references that are relevant to the claimed invention while ignoring other

claimed invention as a whole because most inventions consist of combinations of previously known elements. It is the unique combination that is considered patentable. If the obviousness inquiry were allowed to focus on individual elements, many otherwise patentable inventions would be considered obvious because their elements were already individually known or suggested in the prior art. Therefore, it is the entire combination, or the claimed invention as a whole, that is tested for obviousness.

With regard to the prior art, it is important to note that it is only the pertinent prior art that is being considered as a whole, and not all the prior art.[276] The objective mechanism that determines the appropriate subset of prior art to be considered "as a whole" is the hypothetical person of ordinary skill in the art.[277]

b. Submission to a Jury

Obviousness is considered to be an ultimate issue of law based on underlying factual considerations.[278] This legal hybrid is often referred to as a mixed question of law and fact.[279] The ultimate question of obviousness may be decided by either a judge or a jury.[280] When decided by a jury, the issue may be submitted either generally or specially.[281] If the issue is submitted generally, it may be submitted with or without interrogatories directed to the *Graham* factual inquiries.[282]

The trial judge becomes involved in a jury-submitted obviousness issue when reviewing a JNOV motion.[283] The standard of review is substantial evidence,[284] and the judge will presume that the jury found any material facts necessary to support its verdict.[285] If the trial court expressly finds the jury's verdict to be supported by substantial evidence, the trial court need not make additional findings.[286] On appeal, the Federal Circuit will also apply the substantial evidence test and presume facts necessary to support the jury verdict.[287] The Federal Circuit has not

---

portions that teach away from the claimed invention is also improper").

276 *See* In re Clay, 966 F.2d 656, 658 (Fed. Cir. 1992).

277 *See* Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc., 21 F.3d 1068, 1071 (Fed. Cir. 1994) (stating that a reference is reasonably pertinent "when a person of ordinary skill would reasonably have consulted those references and applied their teachings in seeking a solution to the problem that the inventor was attempting to solve").

278 *See* Connell v. Sears, Roebuck & Co., 722 F.2d 1542 (Fed. Cir. 1983).

279 *Id.*

280 *Id.*

281 *Id.*

282 *See* Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp., 739 F.2d 604 (Fed. Cir.), *cert. denied*, 469 U.S. 1038 (1985).

283 *See* Connell v. Sears, Roebuck & Co., 722 F.2d 1542 (Fed. Cir. 1983).

284 *See* Weinar v. Rollform Inc., 744 F.2d 797, 805 (Fed. Cir. 1984), *cert. denied,* 470 U.S. 1084 (1985).

285 *See* Perkin-Elmer Corp. v. Computervision Corp. 732 F.2d 888, 893 (Fed. Cir.), *cert. denied* 469 U.S. 857 (1984).

286 *See* Glaros v. Robertson, 797 F.2d 1564 (Fed. Cir. 1986).

287 *See* Perkin-Elmer Corp. v. Computervision Corp. 732 F.2d 888, 893

been unanimous over whether and how patent obviousness should be submitted to a jury.[288]

C. Obviousness - Summary

In summary, a patent application is initially presumed to be nonobvious. The examiner looks for a suggestion to combine references in the prior art to establish a prima facie case of obviousness. The suggestion to combine must meet various requirements. If a suggestion to combine is found, the prima facie case of obviousness is established. The applicant then attempts to rebut the prima facie case with additional evidence of nonobviousness. The additional evidence usually consists of secondary considerations, such as commercial success, long felt need, failure of others, unexpected results, etc. The secondary considerations must also meet various requirements, including that of a nexus. If adequate evidence of secondary considerations is found, the prima facie case of obviousness is rebutted and the examiner must consider all evidence on obvious anew. When making the consideration anew, the examiner must compare and weigh the technically based suggestion evidence with the market based secondary considerations. This comparison must follow certain principles and rules. A final decision is then made as to whether the invention is obvious.

D. Obviousness - Remaining Uncertainty

The Federal Circuit has continued to develop an increasingly principled and objective framework for analyzing obviousness issues. However, some old areas of uncertainty remain, and some new areas of uncertainty are arising as courts attempt to apply rules developed in the chemical arts to certain aspects of biotechnology. In particular, the Federal Circuit's attempt to apply the structural similarity test to the protein-DNA relationship, and the court's position that a general method reference cannot provide a suggestion for a DNA sequence has raised uncertainty in three areas.

First, uncertainty now exists about the very nature of the suggestion to combine test, i.e., whether it is different for different technologies and whether it is different when the references to be combined are of a different nature, e.g., one structural reference and one method reference. Second, uncertainty now exists about the requirement of a reasonable expectation of success. In particular, how strict the test should be, what types of references may satisfy the requirement, and whether evidence of the amount of effort required should be relevant to the inquiry. Third, uncertainty now exists over the nature of a prima facie case and how it may be

---

(Fed. Cir.), *cert. denied* 469 U.S. 857 (1984).

[288] *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc., 62 F.3d 1512, 1555 (Fed. Cir. 1995) (Nies, J. dissenting). *See also* In re Lockwood, 50 F.3d 966 (Fed. Cir. 1994), *vacated, reh'g granted, and reh'g in banc denied*, 50 F.3d 966 (1995), 50 F.3d 966 (Fed. Cir. 1995) (Nies, J., dissenting from denial of rehearing in banc, joined by Archer, C.J., and Plager, J.), *cert. granted sub nom.*, American Airlines, Inc. v. Lockwood, 115 S.Ct. 2274 (1995), *judgment vacated* 116 S.Ct. 29 (1995).

established in the field of biotechnology. Specifically, the chemically oriented prima facie case procedure based on structural similarity appears ineffective when applied to the DNA-protein relationship in biotechnology.

Old areas of uncertainty also remain. There is no comprehensive analytical framework for comparing the "secondary considerations" against the suggestion analysis in a consistent and predictable manner. Some general principles and rules do exist, but a more comprehensive guide would make the results more predictable. Further, the procedure for submitting the issue of obviousness to the jury is unsettled. Finally, confusion still exists over the precise meanings of some terminology used in obviousness, such as suggestion to combine and motivation. This confusion unnecessarily complicates the obviousness issue.

IV. The Doctrine of Equivalents

A. Origins and Development

1. Purpose

Article 8, clause 8 of the United States Constitution grants Congress the power to promote progress in Science and the Useful Arts by granting to inventors for limited times the exclusive rights to their inventions.[289] Congress has implemented this power through the patent statute. On a broad scale, the patent statute represents a bargain between the public and the inventor.[290] In exchange for disclosing, fully describing, and enabling the invention,[291] the inventor is given the right to exclude others from making, using, offering to sell, selling, or importing into the United States the invention[292] for a period of twenty years, in general, from the date of the earliest patent application relied upon.[293]

The right to exclude provides the inventor with incentive to invest time, effort, and money into the creative process. The description and enablement requirements permit the public to have both knowledge about and notice of the invention. Knowledge about the invention allows the public to learn from and build upon the inventor's contribution. Notice of the invention allows the public to be informed of the patent's boundaries to avoid infringement, and to know what must be achieved to obtain additional patents in the particular field of invention. In that regard, the notice function also provides a valuable incentive to invent, because a patent boundary that is precise encourages more design around activity than a patent boundary that is elusive.

The doctrine of equivalents maintains the incentive function of patent law by giving the patentee a meaningful benefit from the inventive effort. It accomplishes this by broadening a patent's exclusionary boundaries beyond the easily avoided literal language of a claim. In words often quoted from the United States Supreme Court, the doctrine of equivalents prevents "the unscrupulous

289 U.S. Const. art. I, § 8, cl. 8. ("To promote the progress of science and useful arts, by securing for limited times to ... inventors the exclusive right to their ... discoveries."

290 *See generally* Peter D. Rosenberg, Patent Law Fundamentals § 1.02 (1995).

291 *See* 35 U.S.C. § 112 par. 1, 2.

292 *See* 35 U.S.C. § 271 (a).

293 *See* 35 U.S.C. § 154 (a) (2).

copyist [from making] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of the law."[294]

Unfortunately, the broadening performed by the doctrine of equivalents also makes the patent's exclusionary boundaries less precise. It therefore decreases the ability of the patent claims to provide meaningful notice to the public. Consequently, the doctrine simultaneously increases the incentive function of patent law and decreases the notice function (with its attendant incentives). Due to this inherent conflict, rules making up the doctrine of equivalents must be carefully balanced to maximize the combined positive effects of incentive and notice, in order that "progress of science and the useful arts" may be effectively promoted.

2. Origin and Development

Descriptions of a procedure to compare a patented device with a device accused of infringement first appeared in United States case law in the early 1800s.[295] These descriptions focused on whether there was substantial similarity in the structure, mode of operation, and result achieved by mechanical devices.[296] In the words of Justice Washington: "But we think it may safely be laid down as a general rule, that where the machines are substantially the same, and operate in the same manner, to produce the same result, they must in principle be the same."[297]

The early focus on structure, mode of operation and result achieved was a natural consequence of the mechanical nature of most patents.[298] A patented machine usually operated on a new principle or mode of operation and achieved a certain result.[299] An infringer might build another machine and achieve substantially the same result using the same principle, but would attempt to avoid infringement by changing the structure or form of the machine.[300] By focusing on the differences and similarities in structure, mode of operation and result, the courts were able to determine, with reasonable consistency, whether changes made by the accused infringer were substantial or insubstantial, and therefore whether infringement had occurred.[301]

The first U. S. Supreme Court opinion to use the structure, mode of operation, and result achieved analysis

---

294 Graver Tank, 339 U.S. at 607.

295 *See* Gray v. James, 10 Fed. Cas. 1015, 1016 (No. 5,718) (C. C. D. Pa. 1817, April Term).

296 *Id.*

297 *Id.*

298 *See* Graver Tank at 608 ("In its early development, the doctrine was usually applied in cases involving devices where there was equivalence in mechanical components.").

299 *See* Winans v. Denmead, 56 U.S. 330, 342 (1853) (stating that "patentable improvements in machinery are almost always made by changing some one or more forms of one or more parts, and thereby introducing some mechanical principle or mode of action not previously existing in the machine, and so securing a new and improved result").

300 *Id.*

301 *Id.* at 338.

was *Winans v. Denmead*.[302] In *Winans*, the patentee received a patent on an improved design for railroad cars. Old railroad cars were rectangular in shape and had to be constructed from thick, heavy steel to support the cargo. The new car design was shaped like the frustrum of a cone. The new shape decreased the center of gravity of the car and spread the pressure of the load more evenly throughout the body. The result of the new structure and its load spreading principle of operation was a dramatic increase in the durability and load carrying capacity of railroad cars.

The accused infringer changed the form of the body from a circular cone to an octagonal cone, but retained the car's principle of operation and its beneficial results. The trial judge ruled that infringement had not occurred as a matter of law, holding that the patent claim was limited to the conical form described in the specification. Since the accused infringer's design was octagonal, rather than circular, the judge found that infringement had not occurred.[303]

The Supreme Court reversed, stating that the analysis should focus on four inquiries: structure of device, mode of operation, result attained, and whether the claim covered the described mode of operation by which the result was attained.[304] As to the fourth inquiry, the Court stated the general rule was that a patentee was not limited to the specific forms of the invention described in the specification and claims.[305] Rather, the patentee was in law understood to claim and cover all other forms that embodied the principle or mode of operation of the invention.[306] This was due to the presumption that the patentee intended to claim everything he had a right to claim, and that the specification was to be construed liberally in accordance with the Constitutional and congressional mandate to promote progress of the useful arts.[307] Since evidence existed that the defendant's octagonal design substantially embodied the mode of operation and result achieved by the patentee's design, the Court held that the ultimate question of infringement was for a jury.[308]

Winans kept the focus of the doctrine of equivalents on structure, mode of operation and result attained. Additionally, the case added the principle that a change in form of structure of the device would still be an infringement if a) the mode of operation and result attained by the accused device remained substantially similar to that of the patented invention, and b) the patentee had not expressly limited the patent claims to the structural forms described in the specification.

The Supreme Court changed the form of expression of the doctrine of equivalents in *Union Paper-Bag Machine Company v. Murphy*.[309] In this case, the patentee obtained a patent on an improved cutter for a machine that made paper bags.[310] The cutter's improved design made all the necessary cuts to the paper stock in a single

302 56 U.S. 330 (1853).
303 *Id.* at 336.
304 *Id.* at 338, 339.
305 *Id.* at 341.
306 *Id.*
307 *Id.*
308 *Id.* at 344.
309 97 U.S. 120 (October Term, 1877).
310 *Id.* at 121.

movement. The cutter was lifted by means of a rotating cam, and cut the paper after falling by force of gravity. The defendant's cutter also made all necessary cuts in a single movement, but consisted of a stationary knife located below the paper stock. The defendant's paper was cut when a striker descended upon the paper and forced the paper against the knife.[311]

The Supreme Court considered the defendant's cutter an infringement, stating that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape."[312] The Court also set forth the now familiar "function, way, result" formulation of the doctrine of equivalents: "... one thing is substantially the same as another, if it performs substantially the same function in substantially the same way to obtain the same result...."[313]

The *Union Paper-Bag Machine Company* formulation of the doctrine of equivalents dropped any reference to structure. The change occurred because in the typical mechanical infringement case, the infringer modifies the machine's structure, but retains the overall function, mode of operation (way), and result achieved by the patented machine. Since the structure is usually changed, a comparison of structure is generally not as useful to the infringement analysis.[314]

Following *Union Paper-Bag*, the function-way-result test was used to determine patent infringement without a great deal of difficulty, even in mechanical cases of some complexity. For example, in *Sanitary Refrigerator Co. v. Winters*,[315] the patentee held a patent on an improved refrigerator door latch.[316] The improved design allowed the door to latch tight when shut regardless of whether the latch handle was in a vertical or horizontal position. The design employed a cam on the surface of an arm which caused the latch lever to be automatically swung toward horizontal and under a keeper head as the door was being shut. The improvement resulted in less injury to the latch and door, and insured that the door would latch tight when shut.[317] The defendant's design also operated on the cam principle, but substituted a lug on the keeper head to contact a small curved cam on the latch lever.[318] The Court applied the *Union Paper Bag* function-way-result test, and found infringement: "Despite the changes in the Dent latch from the Winters and Crampton structure we find that the

---

311 *Id.* at 123.

312 *Id.* at 125 (citing Curtis, Patents (4th ed.), sect. 310).

313 *Id.*

314 *Id.* ("Except where form [i.e., structure] is the essence of the invention, it has but little weight in the decision of such an issue, the correct rule being that, in determining the question of infringement, the court or jury, as the case may be, are not to judge about similarities or differences by the names of things, but are to look at the machines or their several devices or elements in the light of what they do, or what office or function they perform, and how they perform it....")

315 280 U.S. 30 (1929).

316 *Id.* at 36.

317 *Id.* at 36, 37.

318 *Id.* at 40, 41.

two devices are substantially identical, operating upon the same principle, and accomplishing the same result in substantially the same way...."[319]

Even though the structures, mechanical principles and modes of operation of the devices in *Sanitary Refrigerator* were somewhat complex, the court was able to determine infringement in a predictable way and to clearly explain its analysis by using the function-way-result test.[320] This could be done because the court could understand, compare, and explain the operating principles and results achieved by the two different structures, and determine whether a substantial or insubstantial change had been made. Since the focus on understandable operating principles and results achieved made the decision both reasonable and predictable, the incentive and notice functions of the patent law were maximized, and progress in the useful arts was promoted.

The relative stability of the equivalency doctrine and its ability to effect a maximized balance of the incentive and notice functions of patent law through the function-way-result analysis was upset when it was applied to chemical technology. In *Graver Tank & Mfg. Co. v. Linde Air Products* Co.,[321] the patent at issue claimed a combination of calcium fluoride and an alkaline earth metal silicate to be used as an electric welding flux.[322] The flux actually consisted of a combination of calcium fluoride and the alkaline earth metal silicates of calcium and magnesium. The advantage of the patented flux was that, unlike any prior art flux, it became an electrical conductor when molten. This property allowed it to immediately shield the arc zone, which prevented ionized air particles from participating in the welding process and weakening the weld. The molten flux also eliminated the splatter and blinding glare of the open arc, and permitted single pass welding of thicker plates at a faster rate than any flux known previously in the art.[323]

The defendant's flux was similar to the patented flux, but substituted the non-alkaline earth metal silicate of manganese for the silicate of magnesium.[324] Since the silicate of manganese is not an alkaline earth metal, it fell outside the literal scope of the patent claims. The question in the case was whether the defendant's use of the silicate of manganese still constituted an infringement under the doctrine of equivalents.[325]

The court began the equivalency analysis by citing earlier mechanical cases and repeating the function-way-result test.[326] However, the Court did not apply the test in classic fashion. The nature of the chemical technology apparently prevented the court from performing a mechanical-type analysis of whether the silicate of manganese possessed the same mode of operation or operating principles as the silicate of

---

319 *Id.* at 42.

320 *Id.* at 41.

321 339 U.S. 605 (1950).

322 *Id.* at 610.

323 Linde Air Products Co. v. Graver Tank & Mfg. Co., 86 F. Supp. 191, 195 (N.D. Ind. 1947)

324 339 U.S. at 610.

325 *Id.* at 610.

326 *Id.* at 608.

magnesium. For example, the opinion did not contain any detailed scientific explanation or comparison of the ionic or covalent bonding occurring between the ingredients of the two fluxes, or the chemical bonding and chemical reactions that occurred when the fluxes were acted upon by the electric arc. Rather, the Court focused on and compared empirical-type evidence obtained by experiment to determine equivalence between ingredients in the chemical compositions:

> Consideration 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.[327]

The "way," or "mode of operation," inquiry had been dropped from the equivalency analysis, presumably to avoid the difficult task of comparing the operating principles of chemical bonds and reactions in detail.[328] "Function-way-result" had thus been modified to "purpose for use, qualities when combined, function to be performed, and interchangeability," all empirical-type[329] inquiries focusing primarily on the ultimate result achieved rather than specific mode of operation. The analytical test starting out as "structure, mode of operation and result" in *Winans v. Denmead*, and reduced to "mode of operation and result" in *Union Paper-Bag Machine Company*, had now for all practical purposes been reduced to simply "results" in *Graver Tank*.[330]

As "mode of operation" disappeared, the Court introduced two other empirical factors to supplement the analysis. First, the Court considered it relevant whether specialists in the art knew that silicates of manganese could be substituted for silicates of magnesium in the patented flux.[331] If interchangeability was known, equivalency and infringement were more likely.[332] Second, the Court considered it relevant whether the

---

[327] *Id.* at 609.

[328] The need to prove equivalency of chemicals through empirical evidence was recognized early in chemical patent law. *See* Tyler v. Boston, 74 U.S. 327, 330 (December Term, 1868) ("This term 'equivalent' when speaking of machines, has a certain definite meaning; but when used with regard to the chemical action of such fluids as can be discovered only by experiment, it only means equally good.").

[329] By empirical evidence, it is meant that the source of evidence is from the "real world," and can be observed.

[330] But as will be seen *infra*, empirical evidence of "results" allowed an inference to be made on the "way" prong of the test. See notes 794-796 *infra* and accompanying text.

[331] *Id.* at 610-612.

[332] *Id.*

accused flux had been developed through independent experimentation.[333] If experimentation was not independent, the trial court "could properly infer that the accused flux is the result of imitation rather than experimentation or invention."[334] The factors of known interchangeability and independent experimentation or invention thus became part of the equivalency analysis at the Supreme Court level.

Perhaps because in *Graver Tank* the doctrine of equivalents was in a transition state, or the case was considered close, the majority and dissent each bolstered their respective positions with eloquent descriptions of the competing policies underlying the doctrine of equivalents. The majority emphasized the incentive function of patent law, stating: "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing"[335] and "[t]he essence of the doctrine is that one may not practice a fraud on a patent."[336] The dissent emphasized the notice function of patent law, warning: "The Court's ruling today sets the stage for more patent "fraud and "piracy" against business than could be expected from faithful observance of the congressionally enacted plan to protect business against judicial expansion of precise patent claims. Hereafter a manufacturer cannot rely on what the language of a patent claims."[337]

Following *Graver Tank*, the lower federal courts continued the attempt to balance the policy interests described by the majority and dissent, and continued to develop and refine the doctrine of equivalents. A variety of splits developed on various issues. For example, splits of opinion developed on such issues as whether the doctrine required an equitable threshold, whether it should be decided by the court as a matter of law, whether its application was discretionary with the court, and whether other evidence might be relevant to equivalency in addition to function-way-result. Continuing uncertainty over these issues finally culminated in the Federal Circuit accepting *Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc.*[338] for an *in banc* review of the doctrine of equivalents.

3. *Hilton Davis*

a. Facts

The patent claims at issue in *Hilton Davis* covered an ultrafiltration process for filtering impurities from commercial food dyes.[339] The process used osmosis to draw dye through a membrane with pore diameters small enough to block impurities, but large enough to allow the dye molecules to pass through. The process operated most effectively at certain pH levels and pressures. Claim 1 of the patent specified membrane pore diameters of 5-15 Angstroms, a hydrostatic pressure of approximately 200 to 400 p.s.i.g., and a pH of approximately 6.0 to 9.0. The pH limitation was added during prosecution to distinguish a prior art

333 *Id.*

334 *Id.*

335 *Id.* at 607.

336 *Id.* at 608.

337 *Id.* at 617.

338 62 F.3d 1512 (Fed. Cir. 1995) (per curiam) (en banc).

339 *Id.* at 1515.

patent on an ultrafiltration process that operated at a pH above 9.[340] The defendant's dye filtration process, which had been developed independently, specified membrane pore diameters and pressures similar to the patentees', but operated at a pH of 5.[341]

A jury found that the defendant's process infringed plaintiff's patent under the function-way-result test of the doctrine of equivalents.[342] The defendant appealed, arguing that the doctrine of equivalents was an equitable doctrine and should have been decided by the court as a matter of law. The Federal Circuit, sitting *in banc*, requested the parties to brief the questions of whether the doctrine of equivalents (1) required proof of facts beyond function-way-result, (2) was an equitable doctrine to be decided by the court only, and (3) was discretionary with the court when literal infringement was not shown.[343]

b. Majority Opinion

The majority began its opinion by stating that the case presented "an opportunity to restate - not to revise - the test for infringement under the doctrine of equivalents."[344] Citing the Supreme Court's decision in *Graver Tank*, the court held that proof of "insubstantial differences" was the ultimate test for infringement under the doctrine of equivalents.[345] The court explained that the function-way-result analysis was often enough to determine whether a difference was substantial or insubstantial, but that other evidence might inform the fact finder as well.[346] Specifically mentioned was proof of known interchangeability, designing around, and copying.[347] Although proof of independent development was not considered relevant to showing substantial differences, the court stated it might be relevant to rebut allegations of copying.[348]

The court also held that infringement was an issue of fact to be decided by the jury, or a judge in a bench trial.[349] Finally, the court held that a trial judge did not have the discretion to decide whether to apply the doctrine of equivalents when literal infringement was not shown.[350]

c. Concurrences and Dissents[351]

The complexity and controversial nature of the issues in *Hilton Davis* resulted in a number of concurrences and dissents. The concurrence of Justice Pauline Newman focused on the

340 *Id.* at 1515, 1516.

341 *Id.* at 1516.

342 *Id.*

343 *Id.*

344 *Id.*

345 *Id.* at 1517-1518.

346 *Id.* at 1518. The court explained that the function-way-result test, which arose "in an era of relatively simple mechanical technology," was not "the" test for equivalency, and might not always be sufficient to demonstrate substantiality of the differences in cases involving more complex technology. *Id.*

347 *Id.* 1518-1520.

348 *Id.* at 1520.

349 *Id.* at 1520-1522.

350 *Id.* at 1522.

351 Although the United States Supreme Court has issued an opinion on Warner-Jenkinson, the Court left several important issues for the Federal Circuit to develop. The concurrences and dissents at the Federal Circuit level will therefore be discussed.

practical economic effects of the doctrine of equivalents in the context of technological innovation and the national interest.[352] Following her brief review of the literature on the relationship between patent law, technological innovation and economics, she concluded that "the doctrine of equivalents, on balance, serves the interest of justice and the public interest in the advancement of technology, by supporting the creativity of originators while requiring appropriators to adopt more than insubstantial technologic change."[353]

Justice Newman stated her belief that the "major contribution" of the doctrine of equivalents is "to the idea of a fairer, less technocratic, more practical patent system; one that is oriented toward encouraging technologic innovation and discouraging free riding...."[354] She stated further, however, that the doctrine of equivalents could not effectively serve this function until it became predictable enough to be relied upon for investment decisions.[355] Justice Newman criticized the majority decision because it provided "no more certainty than did the 1950 decision in Graver Tank, leaving in place the problems of application of the doctrine that have concerned this court."[356] Justice Newman invited creative thinking on new statutory procedures to "protect the continuing work"[357] of patentees as a possible alternative to the doctrine of equivalents.

Judge Plager's dissent[358] echoed the concerns of Judge Newman that the doctrine of equivalents is too unpredictable.[359] Judge Plager believes the statutory requirement that the patent specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention"[360] deserves greater attention in the equivalency analysis. He believes the current doctrine allows a judge or jury too much discretion to broaden the claims.[361] Judge Plager also believes the source of the doctrine is equity and that judges should make the decision regarding equivalency.[362]

Judge Lourie dissented[363] because he believes the trial judge erroneously charged the jury in terms of function-way-result when they should have been charged in terms of substantiality of the differences.[364] Judge Lourie believes the function-way-result test can be inadequate and confusing.[365] For example, in chemical technology, sometimes compounds that perform the same function to achieve the same result in the same way have remarkably different structure and should not be

352 62 F.2d at 1529.
353 *Id.* at 1533, 1534.
354 *Id.* at 1534.
355 *Id.*
356 *Id.*
357 *Id.* at 1536.
358 Chief Judge Archer, Judge Rich and Judge Lourie joined in Judge Plager's dissent. *Id.* at 1536.
359 *Id.* at 1537.
360 *Id.* at 1539.
361 *Id.* at 1538.
362 *Id.* at 1543.
363 Judge Rich and Judge Plager joined in Judge Lourie's dissent. *Id.* at 1545.
364 *Id.*
365 *Id.* at 1546.

considered equivalent.[366] Judge Lourie offered two examples. First, certain proteins may possess the same function-way-result, but have large differences in their numbers of amino acids.[367] Second, the well known analgesics aspirin and ibuprofen have similar function-way-result, but much different structures.[368] Further, Judge Lourie pointed out that the function-way-result analysis was often difficult to apply to chemical compounds under the *Pennwalt* all-elements rule because it is often not known how a particular element of the chemical composition works in isolation.[369] Rather, often one knows only of the function-way-result achieved by the entire compound.[370]

Judge Lourie also disagreed with the way the majority characterized the substantiality of differences test as being the ultimate test with all others subsumed within it.[371] Rather, he believes that substantiality of differences should be considered as only one factor, albeit perhaps the major factor.[372] Other factors to be considered according to Judge Lourie are whether independent development and copying have occurred, whether elements are known to be interchangeable, the pioneer status of the invention, whether the patentee has impaired the ability of the public to know what has been claimed (e.g., by disclosing but not claiming an embodiment), and failure of the patentee to seek reissue of the patent to cover a potentially infringing embodiment during the statutory time period permitted for reissue.[373] These factors were not intended to be exclusive.[374]

Judge Lourie believes that copying, designing around, and independent development are relevant on the issue of intent, and that intent should be considered as a factor in the doctrine of equivalents analysis independent of the substantiality of the differences.[375] Likewise, he believes that the pioneer status of the invention should be considered as a factor independent of substantiality of the differences.[376] Finally, Judge Lourie believes that the doctrine of equivalents is an equitable doctrine that should be applied by the judge only.[377]

Judge Nies dissented[378] because she believed that a finding of infringement under the doctrine of equivalents is a mixed question of law and fact.[379] The meaning and scope of the claim is a question of law for the court, and determination of equivalency is a question of fact that may be given to a jury with proper instructions.[380] Judge Nies believed that the instruction given the jury was overly simplistic and removed important safeguards on the doctrine.[381] She believed the doctrine of

366 *Id.*
367 *Id.*
368 *Id.*
369 *Id.* at 1547.
370 *Id.*
371 *Id.*
372 *Id.*
373 *Id.* at 1547-1549.
374 *Id.* at 1547, n. 2.
375 *Id.* at 1548.
376 *Id.* at 1549.
377 *Id.* at 1549, 1550.
378 The late Judge Nies was joined in dissent by Chief Judge Archer in Part IV, Sections C2-4, D, and E. *Id.* at 1550.
379 *Id.*
380 *Id.*
381 *Id.* at 1551.

equivalents is limited by several factors including (1) that the alleged equivalent be known in the art at the time of the invention, (2) prosecution history estoppel, (3) prior art limitations, and (4) that the invention not be enlarged beyond what is claimed.[382] She believed a distinction should be drawn between substituting an equivalent for an element of the claim on the one hand, and enlarging the metes and bounds of the claim on the other hand.[383]

Judge Nies further believed that the question of infringement in *Hilton Davis* should have been decided as a matter of law because there were no fact issues on equivalency to be decided by a jury.[384] According to Judge Nies, the claims were clear and specific, and nothing in the specification indicated that the invention extended beyond the ranges claimed.[385] Therefore, no fact issue was raised concerning equivalency, and the case should have been decided as a matter of law.[386]

d. Supreme Court Opinion

The Supreme Court granted *certiorari* to review the viability of the doctrine of equivalents.[387] The specific question presented for review was "[w]hether patent infringement exists whenever the accused product or process is 'equivalent' to the invention claimed in the patent, in that the differences are not 'substantial' as determined by a jury even though the accused product or process is outside the literal scope of the patent claims."[388] Justice Thomas, writing for a unanimous Court, declined the invitation "to speak the death of [the] doctrine."[389] Instead, the Court acknowledged the disagreement and confusion about the doctrine at the Federal Circuit, and stated it would "endeavor to clarify the proper scope of the doctrine."[390]

The Court began its analysis by addressing the petitioner's general argument that the doctrine of equivalents did not survive the 1952 revision of the patent act.[391] The four specific arguments made by the petitioner were that (1) the doctrine of equivalents was inconsistent with the requirement in section 112 that a patentee claim the invention with specificity, (2) the doctrine circumvents the express limitations on the patent reissue process, (3) the doctrine is inconsistent with the primary authority of the patent office to define the scope of a patent in patent prosecution, and (4) a general doctrine of equivalents was "implicitly rejected" when Congress included a specific and limited concept of equivalency in the "means" claiming permitted by section 112, paragraph 6.[392]

The Court easily brushed aside the first three arguments, noting that each had already been raised and

---

382 *Id.* at 1570-1574.

383 *Id.* at 1573, 1574.

384 *Id.* at 1581.

385 *Id.*

386 *Id.* at 1582.

387 116 S.Ct. 1014 (1996).

388 Warner-Jenkinson Co., 65 U.S.L.W. at 4162.

389 Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co., 117 S.Ct. 1040, 1045 (1997) (The Supreme Court opinion will be referred to throughout as "Warner-Jenkinson").

390 *Id.*

391 *Id.* at 1047.

392 *Id.*

rejected in *Graver Tank*. The Court reasoned that since the 1952 Patent Act contained only minor changes from the 1870 Act, and because such changes had "no bearing on the result reached in *Graver Tank*," there was "no reason to reach a different result [in *Warner-Jenkinson*]."[393]

The fourth argument concerning section 112, paragraph 6 was also rejected. The Court explained that section 112, paragraph 6 was enacted in response to the holding in *Halliburton Oil Well Cementing Co. v. Walker*, which rejected claims that used "conveniently functional language at the exact point of novelty."[394] The Court further explained that "[b]ecause s 112, P 6 was enacted as a targeted cure to a specific problem, and because the reference in that provision to 'equivalents' appears to be no more than a prophylactic against potential side effects of that cure, such limited congressional action should not be overread for negative implications."[395] Since there was nothing more compelling than the "dubious negative inference offered by Petitioner,"[396] the Court concluded that the doctrine of equivalents did not conflict with s 112, P 6.

Although the Court affirmed the viability of the doctrine of equivalents, the Court also acknowledged that when broadly applied, the doctrine conflicted with the "definitional and public-notice functions of the statutory claiming requirement."[397] The Court found that the way to avoid this conflict was to apply the doctrine of equivalents to the individual elements of the claim, and not to the invention as a whole.[398] In so holding, the Court concurred with the reasoning of Judge Nies that "[t]he 'scope' is not enlarged if courts do not go beyond the substitution of equivalent elements."[399] The Court further stated that it was important, even when the doctrine was being applied to each element, not to allow the doctrine to "effectively eliminate" any element in its entirety.[400] This was because "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention."[401] The Court concluded that as long as the doctrine of equivalents was applied to individual elements (and did not exceed related limits discussed later in the opinion), the Court was "confident that the doctrine [would] not vitiate the central functions of the patent claims themselves."[402]

The next issue addressed was prosecution history estoppel. The Court agreed with Petitioner that prosecution history estoppel is a limitation on the doctrine of equivalents, but declined to adopt petitioner's reasoning that all amendments should act as an estoppel to restrict equivalents.[403] Instead, the Court held that the reason for the claim language change was relevant to whether the range of equivalents would be affected.[404] Claim language changes made to avoid the prior art or to otherwise establish patentability would

393 *Id.* at 1047, 1048.
394 *Id.* at 1048.
395 *Id.*
396 *Id.*
397 *Id.* at 1049.
398 *Id.*
399 *Id.*
400 *Id.*
401 *Id.*
402 *Id.*
403 *Id.*
404 *Id.* at 1050.

act as an estoppel to limit equivalents. However, changes made for other reasons would not.[405] The Court also established a rule that when the reason for the change was not revealed by the record, a presumption would exist that the change was related to patentability.[406] In that event, prosecution history estoppel would prevent application of the doctrine of equivalents as to the changed element only.[407]

The Court next addressed the issue of whether equity or intent played a role in the doctrine of equivalents.[408] The Court reviewed the language of *Graver Tank* and conceded that it "certainly leaves room" for the inclusion of intent based elements.[409] However, the Court concluded that "[t]he better view, and the one consistent with Graver Tank's predecessors and the objective approach to infringement, is that intent plays no role in the application of the doctrine of equivalents."[410]

In reaching this conclusion, the Court relied on language found in two of its precedents, *Winans v. Denmead* and *Machine Co. v. Murphy*.[411] In *Winans*, the Court stated that "the claim extends to the thing patented, however its form or proportions may be varied,"[412] Under that view, the *Warner-Jenkinson* Court concluded, a "claim takes the form - half express, half implied - of 'X and its equivalents'."[413] In *Machine Co. v. Murphy*, the Court stated that "the substantial equivalent of a thing, in the sense of the patent law, is the same as the thing itself...."[414] The *Warner-Jenkinson* Court reasoned that under such interpretations, there was "no basis for treating an infringing equivalent any differently than a device that infringes the express terms of the patent," and since literal infringement did not require intent, neither should infringement under the doctrine of equivalents.[415]

The Court also addressed petitioner's argument that an equitable aspect of the doctrine of equivalents was suggested by two references in *Graver Tank* to an absence of independent research or experimentation (allowing an inference of "imitation").[416] The Federal Circuit had explained earlier that these references should be understood to mean that evidence of copying could support an inference of insubstantial differences (rebuttable by evidence of independent development), and that evidence of "designing around" could support an inference of substantial differences.[417] The Supreme Court stated that the Federal Circuit's explanation left "much to be desired," because "[a]t a minimum, one wonders how ever to distinguish between the intentional copyist making minor changes to lower the risk of legal action, and the incremental innovator designing around the claims, yet

405 *Id.*
406 *Id.* at 1051.
407 *Id.*
408 *Id.*
409 *Id.* at 1052.
410 *Id.*
411 *Id.* at 1051, 1052.
412 *Id.* at 1051.
413 *Id.* at 1052.
414 *Id.*
415 *Id.*
416 *Id.*
417 62 F.3d at 1519, 1520.

seeking to capture as much as is permissible of the patented advance."[418]

The Supreme Court offered an alternate explanation that was consistent with "generally objective principles of patent infringement."[419] Rather than supporting or rebutting potentially indistinguishable inferences of substantial or insubstantial differences, evidence of independent experimentation "could reflect knowledge - or lack thereof - of interchangeability possessed by one presumably skilled in the art."[420] The logic of the Court was apparently that if independent experimentation occurred, an inference might arise that the interchangeability of the accused equivalent was not known. According to the Court, such evidence would be helpful to the equivalency determination because "known interchangeability of substitutes for an element of a patent is one of the express objective factors noted by Graver Tank as bearing upon whether the accused device is substantially the same as the patented invention."[421]

The Court then discussed whether the range of equivalents could include those arising after the patent had issued, or had to be limited to those either disclosed within the patent itself, or known at the time of issue.[422] The Court held that it was proper to include equivalents arising after the patent has issued.[423] The reasoning was that since the proper time for determining equivalency is at the time of infringement, the proper time period for evaluating known interchangeable substitutes is the time of infringement as well.[424] Further, it was not the "knowledge" of interchangeability per se that was relevant, but rather what that knowledge indicated about the substantiality of the differences.[425]

The next issue to be addressed was whether the doctrine of equivalents was to be applied by the judge or jury.[426] The Federal Circuit had previously held that it could be applied by a jury.[427] The Supreme Court declined to take the issue up, stating that its resolution was not necessary to answer the question presented.[428] The Court did state, however, that there was "ample support" in Supreme Court case law for the Federal Circuit's holding, and that "[n]othing in [the] recent Markman decision necessitates a different result than that reached by the Federal Circuit."[429] In a footnote, the Court offered guidance over how submission to the jury should be managed.[430]

The final issue addressed by the Supreme Court was the appropriate test for determining equivalency. The Court observed that both the "function-way-result" test and the "insubstantial differences" test had their strong points and weak points.[431] The Court noted substantial agreement that function-

418 117 S.Ct. at 1052.
419 *Id.*
420 *Id.*
421 *Id.*
422 *Id.*
423 *Id.* at 1053.
424 *Id.*
425 *Id.*
426 *Id.*
427 62 F.3d at 1522.
428 117 S.Ct. at 1053.
429 *Id.*
430 *Id.*, n. 8.
431 *Id.* at 1054.

way-result "may be suitable for analyzing mechanical devices, [but] often provides a poor framework for analyzing other products or processes."[432] The Court continued that "[o]n the other hand, the insubstantial differences test offers little additional guidance as to what might render any given difference 'insubstantial',",[433]

Rather than choose between function-way-result and insubstantial differences, the Court offered the view that "the particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?"[434] The Court continued:

> Different linguistic frameworks may be more suitable to different cases, depending on their particular facts. A focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements should reduce considerably the imprecision of whatever language is used. An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.[435]

Other than making these general observations, the Supreme Court saw "no purpose in going further and micro-managing the Federal Circuit's particular word-choice for analyzing equivalence."[436] The Court left it to the Federal Circuit with its "special expertise" and "sound judgment" to "refine the formulation of the test for equivalence in the orderly course of case by case determinations."[437] In the end, the case was reversed and remanded, so the Federal Circuit could consider the potential impact of prosecution history estoppel, and the requirement that "some meaning for each element in a claim" be preserved.[438]

e. Federal Circuit Opinion on Remand

The Federal Circuit on remand in turn remanded the case to the district court to determine whether *Hilton Davis* could rebut the presumption by showing the reason for the lower pH amendment, and whether such reason was sufficient to overcome the prosecution history estoppel bar.[439] The court also reconsidered the pH equivalence issue in light of the

---

432 *Id.*

433 *Id.*

434 *Id.*

435 *Id.*

436 *Id.*

437 *Id.*

438 *Id.*

439 Hilton Davis Chemical Co. v. Warner-Jenkinson Company, 114 F.3d 1161, 1163 (Fed. Cir. 1997).

Supreme Court's instruction that "some meaning" must be preserved for each element of the claim. The court reviewed the record and held that there was substantial evidence to support the jury's verdict of equivalence.[440] Specifically, the court found substantial record evidence that "one of ordinary skill in the art would know that performing ultrafiltration at a pH of 5.0 will allow the membrane to perform substantially the same function in substantially the same way to reach substantially the same result as performing ultrafiltration at 6.0."[441]

B. Current Test for the Doctrine of Equivalents

The Supreme Court declined to formulate a specific test for the doctrine of equivalents in *Warner-Jenkinson*. Rather, the Court deferred this task to the Federal Circuit with the stipulation that the test be probative of whether "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention."[442] In particular, the Supreme Court stated that the test should (a) "focus on individual elements," and (b) possess a "special vigilance against allowing the concept of equivalence to eliminate completely any such elements."[443] Further, according to the Supreme Court, the inquiry as to whether a substitute element matches the "function-way-result" of a claimed element, or plays a role "substantially different" from a claimed element, should be informed by an "analysis of the role played by each element in the context of the specific patent claim."[444]

The Federal Circuit in *Hilton Davis* stated that "a finding of infringement under the doctrine of equivalents requires proof of insubstantial differences between the claimed and accused products or processes."[445] The majority further stated that "[n]either the Supreme Court nor this court limits the types of evidence that either party may proffer in support of a factor it considers probative of infringement under the doctrine."[446] The only limitation stated was that the evidence be relevant.[447] The following sections discuss the factors and evidence deemed relevant to date by the Federal Circuit, how the doctrine of equivalents is presently applied by the Federal Circuit, and whether such factors, evidence, and application are consistent with the Supreme Court opinion in *Warner-Jenkinson*.

1. Factors Deemed Relevant

a. Function / Way / Result

The traditional approach to proving equivalency under the doctrine of equivalents has been to show that the patented and accused devices perform substantially the same function in substantially the same way to achieve substantially the same result.[448] This so called "tripartite test" has a long history and is popular because it is often suffices to show that the two devices are equivalent.[449] The test is effective,

440 *Id.* at 1164.
441 *Id.*
442 *Id.*
443 *Id.*
444 *Id.*
445 62 F.3d at 1518.
446 *Id.* at 1522.
447 *Id.*
448 Hilton Davis, 62 F.3d at 1518.
449 *Id.*

particularly in the mechanical field, because it compares an invention's underlying operating principles and results achieved, and exposes insubstantial structural changes for what they are. Some courts, however, have realized that the function-way-result analysis has its shortcomings, particularly when applied to chemical inventions.[450] Following *Graver Tank*, and prior to *Hilton Davis*, the function-way-result analysis was used by many courts to describe the doctrine of equivalents.[451]

The Federal Circuit in *Hilton Davis* affirmed the function-way-result test as an effective analysis for equivalency, but pointed out that it was not "the" test under the doctrine of equivalents.[452] Rather, the ultimate test for equivalency was whether the two devices had insubstantial differences.[453] The Federal Circuit explained that proof of function-way-result often would suffice to prove the insubstantiality of the differences, but other evidence could be relevant as well, such as proof of interchangeability, copying, and designing around.[454]

The Federal Circuit has established a number of rules that must be followed when applying the function-way-result analysis. First, each prong of the test must be satisfied or there can be no equivalency.[455] Second, the test is applied on a limitation by limitation basis, rather than by comparing the function-way-result of the claimed invention and the accused product as a whole.[456] This approach is consistent with the approach approved by the Supreme Court.[457] Third, there must be particularized testimony that is linked to each prong of the function-way-result test to uphold a verdict.[458]

---

450 *Id.* at 1546. (Judge Lourie concurring).

451 *Id.*

452 *Id.*

453 *Id.*

454 *Id.*

455 *See* Genentech, Inc. v. Wellcome Foundation Ltd., 29 F.3d 1555, 1567 (Fed. Cir. 1994) (stating that "[i]f any one of the prongs is unsupported, the finding of equivalency cannot stand").

456 *See* Tanabe Seiyaku Co., Ltd., Marion Merrell Dow, Inc. v. U.S. International Trade Commission, 109 F.3d 726, 731 (Fed. Cir. 1997) (stating that "[t]he patent owner must show that every limitation of the patent claim asserted is found in the accused process or product, either literally or under the doctrine of equivalents").

457 *See* Warner-Jenkinson, 117 S.Ct. at 1049.

458 *See* Lear Siegler, Inc. v. Sealy Mattress Co., 873 F.2d 1422, 1425 (Fed. Cir. 1989) (stating that "[a]bsent the proper Graver Tank context, i.e., a showing of how plaintiff compares the function, means, and result of its claimed invention with those of the accused device, a jury is more or less put to sea without guiding charts when called upon to determine infringement under the doctrine") The Lear Siegler opinion cited as authority Nestier Corp. v. Menasha Corp.-Lewisystems Division, 739 F.2d 1576 (Fed. Cir. 1984), *cert. denied*, 470 U.S. 1053 (1985); *see also* Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320 (Fed. Cir. 1991), *cert. denied*, 504 U.S. 974 (1992).

The status of this last rule is unclear after *Hilton Davis*.[459]

b. Structure

Comparison of structure is considered relevant by the Federal Circuit in an equivalency analysis. Similarity in structure is considered to be evidence of equivalency,[460] and lack of similarity in structure is considered to be evidence of non-equivalency. Structural evidence can be particularly useful in the chemical arts, where it can be unclear how chemical compounds function to achieve their results.[461] Structural analysis can also effect the function-way-result test. An accused structure performing the same function may be so dramatically different in structure that it makes a finding of similar "way" much less likely.[462] Further, if the structure of the accused device is described in the prior art,[463] or is specifically excluded from the claims,[464] it cannot infringe under the doctrine of equivalents.

---

459 The Federal Circuit has recently held that this rule was not affected by Hilton Davis. *See* Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1566 (Fed. Cir. 1996) (since Hilton Davis restated and did not revise doctrine of equivalents, requirement for particularized testimony and linking argument was not overruled). However, the court in Texas Instruments was careful to say that the particularized evidence could relate to either insubstantial differences or function way result, as long as it was presented on a limitation by limitation basis. *Id.* at 1567. An earlier panel decision, National Presto Industries Inc. v. West Bend Co., 76 F.3d 1185, 1191 (Fed. Cir. 1996) stated that "[t]he court's en banc decision in Hilton Davis made clear that no specific formulation of evidence and argument is required.... [I]ndeed, neither Lear-Siegler nor Malta requires any particular formulation."). The conflict between these cases can probably be resolved by a careful application of the substantial evidence rule. *See* Genentech, 29 F.3d 1555, 1565 (application of substantial evidence rule). Indeed, as a practical matter, insubstantial differences will be hard to prove without some evidence on the function, way, and result of an element or limitation, whether such evidence comes directly or through inference, as for example, by proof of interchangeability. *See* note 732 *infra* and text following thereafter.

460 *See* Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1220 (Fed. Cir. 1995) (close similarity in chemical structure and identity of function, way, and result supported infringement finding by trial court).

461 *Id.*

462 Genentech, Inc. v. Wellcome Foundation Ltd., 29 F.3d 1555, 1568 (Fed. Cir. 1994) (finding of substantially same way and results less likely due to overwhelming and undisputed evidence of dramatically different properties and structure)

463 *See* Black & Decker, Inc. v. Hoover Service Center, 886 F.2d 1285, 1294 (Fed. Cir. 1989); Stewart-Warner Corp. v. Pontiac, Michigan, 767 F.2d 1563, 1572 (Fed. Cir. 1985).

464 *See* Wiener v. NEC Electronics, Inc., 102 F.3d 534, 541 (Fed. Cir. 1996) (stating that "protection of a patent may not 'embrace a structure that is specifically excluded from the scope of the claims.' citing Dolly, Inc. v.

Although structure is not mentioned in the function-way-result test, structural analysis remains an important part of the equivalency inquiry. An accused product must contain specific structure that meets all the limitations of a structural claim, or their equivalents, to infringe under the doctrine.[465] If a limitation (including its equivalent) is missing from the accused device, then the accused device cannot, as a matter of law, work in substantially the same way as the claimed invention.[466] However, a one-to-one correspondence between components of the accused device and the claimed invention is not required.[467] A combination of elements in the accused device can perform a function performed by a single element in the patented invention, and vice versa.[468]

c. Interchangeability

The known interchangeability of elements between an accused and patented structure is considered relevant to the issue of equivalency.[469] The Federal Circuit has stated that known interchangeability is "potent evidence that one of ordinary skill in the relevant art would have considered the change insubstantial."[470] However, interchangeability of elements does not necessarily mean the structures are equivalent.[471] It is therefore only one factor to be considered in a doctrine of equivalents analysis. Even with known interchangeability, the accused device must still perform substantially the same function in substantially the same way to obtain the same result.[472]

d. Copying

In *Hilton Davis*, the Federal Circuit stated that evidence of copying is relevant to infringement under the doctrine of equivalents.[473] According to the Court, the relevance arises not because copying is evidence of bad faith

---

Spalding & Evenflo Cos., 16 F.3d 394, 400 (Fed. Cir. 1994)).

465 *See* Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995)

466 This rule is consistent with the Supreme Court analysis in Warner-Jenkinson.

467 *See* Dolly, Inc. v. Spalding & Evenflo Companies, Inc., 16 F.3d 394, 399 (Fed. Cir. 1994) citing Sun Studs, Inc. v. ATA Equipment Leasing, Inc., 872 F.2d 978, 989 (Fed. Cir. 1989) (stating that "[o]ne-to-one correspondence of components is not required, and elements or steps may be combined without ipso facto loss of equivalency").

468 These rules address a complexity in the individual element approach to the doctrine of equivalents not acknowledged or addressed by the Supreme Court in Warner-Jenkinson. *See* notes 543-601 *infra*.

469 *See* Warner-Jenkinson, 117 S. Ct. at 1052.

470 Hilton Davis, 62 F.3d 1512 at 1519.

471 *See* Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1535 (Fed. Cir. 1987) (although known interchangeability of claimed with unclaimed elements is a factor in considering equivalence, the accused devices must still perform substantially the same function, in substantially the same way, to obtain the same result).

472 *Id.*

473 62 F.3d at 1519.

or a subjective awareness by the infringer, but because copying provides an inference that the differences in the accused and patented devices are insubstantial.[474] The inference is that a person who has copied has not likely made substantial changes to the patented device.[475]

The court in *Hilton Davis* also pointed out that the inference derived from copying "would not dominate the doctrine of equivalents analysis."[476] Rather, it was just a factor to be "weighed together with the other evidence relevant to the substantiality of the differences."[477] The continued viability of copying as a relevant factor in equivalence analysis has been called into question by comments of the Supreme Court in *Warner-Jenkinson*.[478]

e. Designing Around

Evidence the alleged infringer attempted to design around the patent claims may also be relevant to equivalency.[479] The inference arising from evidence of designing around is that the competitor has designed substantial changes into the competing device to avoid infringement.[480] Presumably evidence of designing around consists of evidence that the competitor invested time, money, and effort into studying the patented product and then designed around it. The inference of substantial differences created by evidence of designing around also is just one factor to be weighed in the overall equivalency analysis.[481] The relevance of designing around has also been called into question by the Supreme Court in *Warner-Jenkinson*.[482]

f. Independent Development

The Federal Circuit does not consider independent development directly relevant to the equivalency analysis.[483] This is because no inference may arise concerning the substantiality of the differences if the accused infringer is unaware of the patent claims.[484] However, the Federal Circuit believes that independent development may become relevant to rebut a charge of copying.[485]

g. Independent Experimentation [486]

474 *Id.*

475 *Id.*

476 *Id.*

477 *Id.*

478 *See* Warner-Jenkinson, 117 S. Ct. at 1052.

479 62 F.3d at 1520.

480 *Id.*

481 *Id.*

482 *See* Warner-Jenkinson, 117 S. Ct. at 1052.

483 62 F.3d at 1520.

484 *Id.*

485 *Id.*

486 Independent experimentation is technically different from independent development. Independent development occurs when the accused product has been developed without any knowledge of the patent claims. Independent experimentation occurs when the accused infringer has performed additional experimentation to develop the product regardless of whether the claims have been reviewed.

Independent development is based on an absence of knowledge of the patent claims, but does not require any level of independent experimentation per se. Independent experimentation requires that experimentation and further

The Supreme Court believes that independent experimentation or research may be relevant on the objective issue of whether a person of ordinary skill in the art would have knowledge of the interchangeability between two elements.[487]

2. Limitations

The doctrine of equivalents has a variety of limitations that have been recognized by the Supreme Court and the Federal Circuit. These limitations include prosecution history estoppel, disclosed but unclaimed subject matter, the prior art, and a prohibition against expanding the scope of the claims.

a. Prosecution History Estoppel

Prosecution history estoppel is a limitation to the doctrine of equivalents.[488] It may arise when a patentee attempts to recapture through equivalency claim scope surrendered during the prosecution process to overcome an examiner's rejection based on the prior art.[489] The rationale underlying prosecution history estoppel is that once a patentee has given notice to the examiner, the courts, and the public that certain subject matter is being surrendered, the patentee is estopped from recapturing the surrendered material.[490] Estoppel may arise when claims are amended or canceled during prosecution, when the patent application is refiled with changed claims, or when statements are made by the applicant.[491]

A finding of prosecution history estoppel precludes application of the doctrine of equivalents even when the differences between the accused device and patent claims are insubstantial or the function-way-result test has been met.[492] It is therefore an affirmative defense to infringement rather than a factor to be weighed in the equivalency analysis.

---

development be performed, regardless of whether the accused infringer is aware of the patent claims. From independent development, lack of copying may be inferred. From independent experimentation, lack of knowledge of interchangeability may be inferred (because if the substitute element was known to be interchangeable, independent experimentation presumably would not be required).

487 Warner-Jenkinson Co., 117 S.Ct. at 1052.

488 *See* Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1285 (Fed. Cir. 1986).

489 *See* Mark I Mktg. Corp. v. R.R. Donnelley & Sons, 66 F.3d 285, 291 (Fed. Cir. 1995), *cert. denied*, 116 S.Ct. 917 (1996).

490 *See* Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994) ("An applicant should not be able deliberately to narrow the scope of examination to avoid during prosecution scrutiny by the PTO of subject matter ... and then, obtain in court, either literally or under the doctrine of equivalents, a scope of protection which encompasses that subject matter.")

491 *See* Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211 (Fed. Cir. 1995).

492 *See* Modine Mfg. Co. v. U.S. Intern. Trade Com'n, 75 F.3d 1545, 1555 (Fed. Cir. 1996).

The standard for determining whether particular subject matter has been surrendered is objective in nature and is decided as a matter of law.[493] It is based on what a person of ordinary skill in the art, after having read the entire prosecution history, would reasonably conclude was surrendered by the applicant to obtain the patent.[494] The subject matter surrendered must also have been material to the patentability of the claims to create an estoppel.[495] In other words, the court must not only determine what was changed, but must determine why the changes were made as well.[496]

The test for materiality requires the court to examine the relevant prior art, statements made by the applicant concerning the reasons for the change, and the purpose of the change as it relates to the patentability of the claims.[497] In general, when the purpose of a claim change or statement is to overcome a rejection based on the prior art, estoppel is raised.[498] However, when the change or statement is made to more particularly point out the applicant's invention (for example to overcome a section 112 specificity rejection), estoppel usually is not raised.[499] When the purpose for a claim change is not clear from the record, a rebuttable presumption exists that the change is related to patentability and estoppel is raised.[500]

The presumption may be rebutted by the patentee through a two-step process. First, by establishing that the reason for an amendment was not related to patentability.[501] Second, by convincing the court that the reason for an amendment is sufficient to overcome prosecution history estoppel.[502] When determining sufficiency, the court is required to balance the need for public notice and reliance on the prosecution

---

493 *See* LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 867 F.2d 1572, 1576 (Fed. Cir. 1989).

494 *See* Haynes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1578 (Fed. Cir. 1993) ("The legal standard for determining what subjective matter was relinquished is an objective one, measured from the vantage point of what a competitor was reasonably entitled to conclude, from the prosecution history, that the applicant gave up to procure issuance of the patent.")

495 *See* LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 867 F.2d 1572, 1576 (Fed. Cir. 1989).

496 *See* Mannesmann Demag Corp. v. Engineered Metal Products Co., 793 F.2d 1279, 1285 (Fed. Cir. 1986).

497 *See* Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1284-85 (Fed. Cir. 1986).

498 *See* Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1219 (Fed. Cir. 1995).

499 *See* Caterpillar Tractor Co. v. Berco, S.p.A., 714 F.2d 1110, 1115 (Fed. Cir. 1983) (prosecution history estoppel not found where rejection based on indefiniteness under s 112, since prior art did not dictate the limitation at issue)

500 Warner-Jenkinson Co., 117 S.Ct. at 1051.

501 Hilton Davis Chemical Co. v. Warner-Jenkinson Company, 114 F.3d 1161, 1163 (Fed. Cir. 1997)

502 *Id.*

history with the need for fairness to the patentee.[503] The Federal Circuit expects that the rebuttable presumption rule will result in the PTO and applicants usually including in the prosecution history express statements concerning the reasons for claim changes and arguments.[504]

b. Disclosed but Unclaimed Subject Matter

Subject matter disclosed in the specification but unclaimed is deemed to be dedicated to the public and cannot be recovered under the doctrine of equivalents.[505] The rationale behind this rule is that a patentee should not be able to narrowly claim the invention during prosecution, but then capture through equivalency subject matter broadly disclosed in the specification.[506] However, subject matter may still be recaptured through equivalency if the disclosed subject matter was originally claimed, but such claims were subsequently rendered invalid.[507] The disclosed but unclaimed subject matter may also be recaptured through a broadening reissue procedure if done within two years from the grant of the original patent.[508]

It is important to note that subject matter need not be described and enabled in the patent specification to be considered for equivalency.[509] In other words, the applicant is not required to foresee and describe all potential equivalents at the time the patent application is filed.[510]

c. Prior Art

The relevant prior art is also a limitation to the doctrine of equivalents.[511] Specifically, the range of permissible equivalents may not embrace subject matter disclosed in or rendered obvious by the prior art.[512]

---

503 *Id.*

504 *Id.* For a discussion of the possible impact of *Warner-Jenkinson* on other issues related to prosecution history estoppel, *e.g.*, amendments related to enablement, limitations from other claims, amendments and arguments in the parent file, and recapture after estoppel, *see* Harold C. Wegner, *The Future of the Doctrine of Equivalents*, section VII, Paper prepared for the Pacific Rim Workshop of the Center for Advanced Studies and Research in Intellectual Property (CASRIP), University of Washington, July 25-26, 1997.

505 *See* Environmental Instruments, Inc. v. Sutron Corp., 877 F.2d 1561, 1564 (Fed. Cir. 1989).

506 Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994) ("An applicant should not be able deliberately to narrow the scope of examination to avoid during prosecution scrutiny by the PTO of subject matter ... and then, obtain in court, either literally or under the doctrine of equivalents, a scope of protection which encompasses that subject matter.").

507 *See* Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1107, 1108 (Fed. Cir. 1996).

508 *See* 35 U.S.C. s 251 (1994).

509 *See* Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1220 (Fed. Cir. 1995).

510 *Id.*

511 *See* Key Mfg. Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1449 (Fed. Cir. 1991) ("A range of equivalents may not embrace inventions already disclosed by the prior art.").

512 *Id.*

The rule exists to prevent a patentee from obtaining coverage under the doctrine of equivalents that could not have been obtained from the PTO through literal claims.[513] The burden is on the accused infringer to show that the prior art prevents equivalency once the patentee makes a prima facie showing of infringement under the doctrine of equivalents.[514]

A mechanism that may be used by the court to determine the extent to which the prior art restricts application of the doctrine of equivalents is the hypothetical claim analysis described in *Wilson Sporting Goods Co. v. David Geoffrey & Assoc*.[515] This approach requires the court to visualize a hypothetical patent claim sufficient in scope to literally cover the accused device.[516] The court then determines whether the hypothetical claim, as a whole, would be patentable over the prior art.[517] If the claim would have been patentable, the prior art does not limit application of the doctrine of equivalents.[518] If the claim would not have been patentable, then the prior art prevents the doctrine of equivalents from covering the accused device.[519] The hypothetical claim approach is thought to be helpful because it increases the precision of the equivalency analysis through the use of traditional patentability rules.[520]

Several rules are important when applying the hypothetical claim analysis. First, the limitations in the accused device must always be compared as a whole against the prior art.[521] It is improper to select out individual claim limitations of the accused device for comparison.[522] Individual limitations may be disclosed by the prior art, and such disclosure does not effect the range of permissible equivalents.[523] Second, it is not necessary that the limitations of the hypothetical claim be disclosed in any single prior art reference to be considered unpatentable.[524] It is enough that the prior art render the hypothetical claim obvious, and therefore outside the range of equivalents.[525] Third, the hypothetical claim analysis must be based on properly construed claims.[526] If the claim construction is held to be erroneous on appeal, the case should be remanded for a new equivalency

---

513 *See* Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677 (Fed. Cir.), *cert. denied*, 498 U.S. 992 (1990).

514 *See* National Presto Industries, Inc. v. West Bend Co., 76 F.3d 1185, 1192 (Fed. Cir. 1996)

515 904 F.2d 677 (Fed. Cir. 1990).

516 *Id.* at 683-85.

517 *Id.*

518 *Id.*

519 *Id.*

520 *Id.* at 684.

521 *See* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

522 *Id.*

523 *See* Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546 (Fed. Cir. 1984).

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

525 *Id.*

526 *See* International Visual Corp. v. Crown Metal Mfg. Co., Inc., 991 F.2d 768, 772 (Fed. Cir. 1993).

analysis.[527] Fourth, the analysis does not "envision application of a full-blown patentability analysis to a hypothetical claim."[528] Finally, the hypothetical claim analysis is not mandatory.[529] It is simply an optional way for a court to conduct an equivalency analysis.[530]

d. Scope of Claims

The potential of the doctrine of equivalents to impermissibly enlarge the scope of the claims was one of the Supreme Court's primary concerns in *Warner-Jenkinson*.[531] According to the Court, a broad application of the doctrine of equivalents conflicted with the definitional and notice functions of the patent claims.[532] The Court sought to address this concern by requiring that the doctrine be applied only to individual elements, and not to the invention as a whole.[533]

In the opinion of the Federal Circuit, the view that the doctrine of equivalents may enlarge claim scope is conceptually inaccurate.[534] In their view, the doctrine of equivalents does not expand claim scope.[535] Rather, it only expands the right to exclude to the "equivalents" of what has been claimed.[536] The legal scope of the claims remains the same.[537] The Federal Circuit agrees with the Supreme Court, however, that the doctrine of equivalents does not allow the court to ignore claim limitations.[538] The Federal Circuit also believes that it is correct to say that the scope of the claims cannot be expanded impermissibly during claim construction.[539]

Although the distinction between broadening claim scope and broadening the right to exclude may seem overly technical and largely a matter of semantics, it serves the practical and necessary purpose of separating matters

---

527 *Id.*

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

529 *See* International Visual, 991 F.2d at 772 (the hypothetical claim analysis is "an optional way of evaluating whether prior art limits the application of the doctrine of equivalents.").

530 *Id.*

531 117 S.Ct. at 1049.

532 *Id.*

533 *Id.*

534 *See* Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 684 (Fed. Cir.) ("To say that the doctrine of equivalents extends or enlarges the claims is a contradiction in terms."), *cert. denied*, 498 U.S. 992 (1990).

535 *Id.*

536 *Id.*

537 *Id.*

538 *See* Genentech, Inc. v. Wellcome Found., Ltd., 29 F.3d 1555, 1568 n. 41 (Fed. Cir. 1994) ("[I]t is impermissible to erase under the doctrine of equivalents 'meaningful limitations of the claim on which the public is entitled to rely in avoiding infringement.'" (citation omitted)); Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 935 (Fed. Cir. 1987) (*in banc*), *cert. denied*, 485 U.S. 961 (1988) ("It is well settled that each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device.")

539 *See* Markman v. Westview Instruments, 116 S. Ct. 1384 (1996).

of law from matters of fact. Claim scope is determined from the patent specification, claims and prosecution history, and is decided by the court solely as a matter of law.[540] Once determined, the scope of a claim remains the same.[541] The equivalency or non-equivalency of an accused device, however, is determined by a number of specific factual variables, and is decided by the judge or jury as a matter of fact.[542] In any event, regardless of the analysis used to describe the interplay between expanded claim scope and expanded equivalency, the doctrine of equivalents should not be used to, in effect, expand the scope of the underlying patented principle.

3. Procedure

a. As a Whole or Element by Element

In *Warner-Jenkinson*, the Supreme Court declared that the doctrine of equivalents should be applied to individual claim elements, and not to the claimed invention as a whole.[543] Additionally, the Court stated that every claim element is considered to be important, so no individual claim element may not be ignored when the analysis is performed.[544] The Court believed that this approach would prevent the doctrine of equivalents from broadening the scope of the patent claims.[545] This, in turn, was thought to prevent the doctrine from conflicting with the definitional and public notice functions of the claiming requirement.[546] The approach mandated by the Supreme Court is generally consistent with the approach that has been developed by the Federal Circuit.[547]

The case by case development in the Federal Circuit, however, has revealed complexities and problems not addressed or acknowledged by the Supreme Court in *Warner-Jenkinson*. To understand the nature of the difficulty that has been encountered, it is first necessary to understand the different outcomes that may result from using the different approaches, and to understand how the Federal Circuit's approach to the problem has evolved.

The equivalency of a claimed invention and accused device can be compared either element by element or by considering each as a whole. The different approaches often lead to different results. For example, a claimed invention that operates to produce a given result may consist of three elements. An accused device may produce substantially the same overall result in substantially the same overall way, but consist of just two elements, or have a third element that operates in a different way than claimed element three. If the comparison is performed "as a whole," then infringement under the doctrine of equivalents will probably be found to exist. However, if the court performs the analysis element by element, and requires a substantial equivalent for claimed element three in the accused device, then infringement

---

540 *Id.*

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

542 *See* Warner-Jenkinson Co., 117 S.Ct. at 1053.

543 *Id.* at 1049.

544 *Id.*

545 *Id.*

546 *Id.*

547 *See* Pennwalt Corp., 833 F.2d at 935.

under the doctrine of equivalents is unlikely.

The approach taken by the Federal Circuit has gradually evolved. In *Hughes Aircraft v. United States*,[548] the court stressed that it was necessary to "apply the doctrine of equivalents to the claimed invention as a whole."[549] The patent at issue in *Hughes* claimed a control system capable of keeping a spin stabilized space satellite at a desired attitude in relationship with the earth.[550] The satellite's attitude was adjusted by firing jets located on the periphery of the satellite.[551] The timing of the jet firings was calculated by using positional information that had been gathered from sun sensors on the satellite and radioed back to earth.[552] The overall system used by the accused satellites was substantially similar, but advances in computer technology allowed the necessary jet firing calculations to be performed on the satellite by an on board computer.[553]

The district court, using a strict element by element approach, concluded that no infringement existed because the accused satellites did not possess an element that radioed information back to earth for calculations.[554] The Federal Circuit reversed, stating that when the claimed and accused satellites were compared as a whole, each performed substantially the same function in substantially the same way to achieve substantially the same result.[555] The court felt that the function of processing the sun sensor information had simply been relocated (from the ground to the satellite), with "no change in the function performed, or in the basic manner of operation, or in the result obtained."[556] The Court emphasized that "an embellishment made possible by post-[invention] technology does not avoid infringement."[557]

An element by element approach was emphasized by the Federal Circuit in *Lemelson v. United States*.[558] In *Lemelson*, the Court stated that "[i]t is ... well settled that each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device."[559] In *Texas Instruments v. International Trade Commission*, the Federal Circuit once again stressed the "as a whole" approach: "In the case of infringement under the doctrine of equivalents, the accused structure, composition, or process is compared with the claimed invention as a whole."[560]

In *Perkin-Elmer Corp. v. Westinghouse Electric Corp.*,[561] the Federal Circuit sought to place the "as a whole" approach in perspective while emphasizing the element by element approach. The court stated the "as a whole" approach of *Hughes* "was a recognition that, in applying the

548 717 F.2d 1351 (Fed. Cir. 1983).
549 *Id.* at 1363.
550 *Id.* at 1353.
551 *Id.*
552 *Id.*
553 *Id.* at 1360, 1361.
554 *Id.* at 1357.
555 *Id.* at 1363.
556 *Id.* at 1366.
557 *Id.* at 1365.
558 752 F.2d 1538 (Fed. Cir. 1985)
559 *Id.* at 1551.
560 *Id.* at 1571.
561 822 F.2d 1528 (Fed. Cir. 1987)

doctrine of equivalents, each limitation must be viewed in the context of the entire claim. The statement should not be interpreted as sanctioning the treatment of claim limitations as insignificant or immaterial in determining infringement."[562] A dissent by Judge Newman argued that the majority had departed from the court's "consistent requirement that the invention as a whole be considered."[563]

The inconsistency in approach to the doctrine of equivalents was addressed by the Federal Circuit sitting *en banc* in *Pennwalt Corp. v. Durand-Wayland, Inc.*[564] The claims in *Pennwalt* covered a machine that sorted fruit based on color and weight.[565] One of the claims in the patent recited a "position indicating means" that continuously tracked the location of the fruit to be sorted.[566] Although the accused device also sorted fruit based on color and weight, it did not contain any means for tracking the location of the fruit.[567] The Federal Circuit found no infringement under the doctrine of equivalents, citing the rule from *Perkin-Elmer* that claim limitations may not be ignored and the rule from *Lemelson* that "each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device."[568] Fours judges dissented, arguing that the court was ignoring the rule that the equivalency analysis should be performed on an "as a whole" basis.[569]

Another perspective on the "element by element" and "as a whole" approaches was discussed in *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*[570] In *Sumitomo*, the patent claims covered an optical waveguide fiber consisting of a core and a cladding layer surrounding the core.[571] A positive dopant in the core created a certain refractive index differential between the core and cladding layer necessary for the preselection of particular modes of light waves.[572] The accused device performed the same function and achieved the same result as the claimed fiber, but produced the required refractive index by using a pure core and a negative dopant in the cladding layer.[573]

The district court held that infringement existed, finding that the substitution of a dopant that negatively altered the index of refraction in the cladding equivalently met the limitation that required the addition of a positive dopant to the core.[574] The defendant argued on appeal that infringement under the doctrine of equivalents did not exist because the *Pennwalt* "all elements" rule was not satisfied.[575] Specifically, the defendant argued that

---

562 *Id.* at 1533.

563 *Id.* at 1542.

564 833 F.2d 931 (Fed. Cir. 1987) (*in banc*), *cert. denied*, 485 U.S. 961 (1988).

565 *Id.* at 933.

566 *Id.*

567 *Id.* at 935.

568 *Id.* at 935.

569 *Id.* at 948.

570 868 F.2d 1251 (Fed. Cir. 1989).

571 *Id.* at 1254, 1255.

572 *Id.*

573 *Id.* at 1258.

574 *Id.* at 1259.

575 *Id.*

the element of a positively doped core was absent in the accused optic fiber.[576]

The Federal Circuit rejected the defendant's argument and affirmed.[577] The court reasoned that the term "element" in the *Pennwalt* all elements rule referred to a limitation, or a series of limitations of a claim, and not to a specific component of a claim.[578] It was therefore not necessary for there to be a one to one equivalency between components in the claimed and accused devices. Rather, the court held that the question of equivalency depended on whether the substitution of a negative dopant in the cladding was the equivalent to the limitation of a positive dopant in the core.[579] The court stated that it had not set forth any definitive formula "for determining equivalency between a required limitation or combination of limitations and what has been allegedly substituted therefor in the accused device,"[580] and did not propose to adopt one in the opinion. Rather, the court approved the approach taken by the district court which resolved the question "by comparison of the function / way / result of the substitution with the function / way / result of the limitation in the context of the invention."[581]

Another example of equivalency without a one-to-one correspondence of structure is *Sun Studs, Inc. v. ATA Equipment Leasing, Inc.*,[582] In this case the patents at issue concerned saw mill processes and apparatus for obtaining the maximum amount of usable wood products from a log.[583] The jury found, *inter alia*, that the defendants infringed claim 2 of one of the patents.[584] The infringed claim included limitations of an "aligning means for receiving and holding a log at a reference location,"[585] and a "charger means for releasably gripping said log at said reference location and transporting the log past [a scanning means]."[586] At trial, the plaintiff patentee presented testimony that the accused mills' aligning means were combined with the charger means.[587] The defendants contended that the accused mills apparatus did not perform the alignment function at all.[588] The trial court found that claim 2 required a separate aligning means as a matter of law.[589] Since a separate aligning means was absent in the accused mills' apparatus, the court held that no literal or equivalent infringement existed and granted defendant's motion for JMOL.[590]

On appeal, the Federal Circuit reversed and held it was legal error to require the aligning and charging steps to be performed by separate elements in the apparatus.[591] The court stated:

> One-to-one correspondence of components is not

576 *Id.*
577 *Id.* at 1261.
578 *Id.*
579 *Id.* at 1260.
580 *Id.*
581 *Id.*
582 872 F.2d 978 (Fed. Cir. 1989).
583 *Id.* at 980.
584 *Id.* at 988.
585 *Id.*
586 *Id.*
587 *Id.* at 989.
588 *Id.*
589 *Id.*
590 *Id.*
591 *Id.*

> required, and elements or steps may be combined without ipso facto loss of equivalency. Each case must be decided in light of the nature and extent of the differences between the accused device and the claimed invention, on the equitable principles of the doctrine of equivalents. [cites omitted].
>
> An apparatus claim describing a combination of components does not require that the function of each be performed by a separate structure in the apparatus. The claimed and accused devices must be viewed and evaluated as a whole. [cite omitted].[592]

The Federal Circuit therefore effectively compared the function performed by the structure, rather than compare the individual structural embodiments themselves. The breadth of the function compared was selected (1) by viewing and evaluating the claimed and accused devices "as a whole,"[593] (2) "in light of the nature and extent of the differences between the accused device and the claimed invention,"[594] (3) "on the equitable principles of the doctrine of equivalents,"[595] and "in the context of the entire claim."[596]

The approach to equivalency taken by the Federal Circuit in *Sumitomo* and *Sun Studs* is similar to the approach approved by the Supreme Court in *Warner-Jenkinson*. Each applies the equivalency analysis to individual claim elements or limitations in the context of the patent claim or invention. The phrase "in the context of the invention" generally means that when analyzing the characteristics, e.g., the function-way-result of a particular claim element for comparison, the element must be viewed not in isolation, but rather in light of how it relates and contributes to the invention as a whole.[597] The contextual requirement recognizes the reality that comparisons performed without acknowledging how elements function within the entire claimed invention can be misleading and often inaccurate. In the words of the Supreme Court in *Graver Tank*:

> Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be

592 *Id.*
593 *Id.*
594 *Id.*
595 *Id.*
596 *Id.*
597 *Id.* at 1259.

equivalents.

> Consideration 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.[598]

The Supreme Court approach additionally requires that individual claim elements not be ignored when performing the equivalency analysis.[599] This requirement, as a practical matter, prevents the doctrine of equivalents from broadening the legal scope of the claims. Each approach therefore helps preserve the function of the claims and moves the decision maker objectively closer to the equivalency decision point with a refined analytical framework.

Unfortunately, however, each approach still lacks an objective procedure whereby the decision maker can consistently select the element or limitation in the claimed invention that is to undergo the comparative analysis, and that is not to be ignored or eliminated. Under current law, the selection of the appropriate elements or limitations is subjective. Since different minds may attach different meanings to the terms “element,” “limitation,” and “series of limitations,” the outcome of the analysis in current use is inconsistent and unpredictable.[600]

For example, in *Sumitomo,* even after the court properly recognizing how the core and cladding elements worked in the context of the entire optical fiber invention, if the court had determined that the proper element or limitation for comparison (that could not be ignored) was the core only, the court would likely have reached the opposite conclusion of no infringement. The limitation chosen by the Court - that of the refractive relationship between the core and cladding layer, rather than that of the positively doped core itself - was selected without the aid of any express, objective procedure.

The limitation chosen by the court was easy to justify even under the rule that no claim limitation may be ignored. The court simply absorbed the positive core limitation into the broader functional limitation of the claimed refractive differential between the core

---

[598] Graver Tank, 339 U.S. at 609.

[599] *See* Warner-Jenkinson Co., 117 S.Ct. at 1049.

[600] Adding still more to the confusion is the imprecise way these terms are sometimes used. The Federal Circuit has commented on the problem in Sumitomo, 868 F2d at 1259. (“confusion [is] sometimes encountered because of misunderstanding or misleading uses of the term "element" in discussing claims. "Element" may be used to mean a single limitation, but it has also been used to mean a series of limitations which, taken together, make up a component of the claimed invention. [noting] Perkin-Elmer Corp. v. Westinghouse Electric Corp.: References to "elements" can be misleading.... [C]larity is advanced when sufficient wording is employed to indicate when "elements" is intended to mean a component ... of an embodiment of an invention and when it is intended to mean a feature set forth in or as a limitation in a claim. 822 F.2d at 1533 n. 9.”)

and cladding layer. Through this technique, the court was able to give the positive core limitation "some meaning," while effectively ignoring it on an individual basis. The court was able to determine the outcome of the case by subjectively deciding at what level of breadth the functionality of the elements, limitations, or series of limitations would be compared.

The court noted that the district court resolved the issue by comparison of the function-way-result of the substitution with the function-way-result of the limitation "in the context of the invention," [601] but offered no further insight into its selection process. The meaning of this phrase, beyond that which has already been described, is not precisely known with regard to the selection of claim elements or limitations. The phrase perhaps hints at an objective approach for element selection, but remains far too vague and subjective to be useful. Therefore, a procedure is still needed that is capable of consistently selecting the appropriate element, limitation, or series of limitations to be used for comparison and preservation. Absent such a consistent procedure, equivalency analysis will remain too subjective and unpredictable.

b. Submission to the Jury

Determination of equivalency under the doctrine of equivalents has been held to be a question of fact.[602] The issue is complicated, however, because other factors closely related to equivalency are considered to be questions of law reviewable de novo on appeal. For example, whether a given range of equivalents is precluded by the prior art is considered to be a question of law.[603] Similarly, prosecution history estoppel is considered to be a question of law for the court.[604] The related issue of claim interpretation has also been held to be solely a question of law.[605]

The fact/law distinction is a complicated legal issue, particularly in the context of mixed issues of law and fact. The issue is particularly troublesome when a fact finder is requested to apply facts to rules of law, as in a doctrine of equivalents question. The Federal Circuit, however, has not attempted to separate the legal issues from the factual issues in the equivalency analysis before the question is submitted to the fact finder. Issues such as prior art preclusion and prosecution history estoppel are only treated as matters of law after verdict or on appeal when appropriate standards of review must be determined. The practical result is that the fact finder is first asked to make an overall determination of equivalency as a matter of fact (with appropriate instructions if to a jury). The factual finding is then reviewed for factual and legal sufficiency by the court, with the legal issues of prior art preclusion and prosecution history estoppel reviewed de novo as matters of law.

The Supreme Court in *Warner-Jenkinson* offered guidance on how to deal with intermingled questions of fact and law at the trial court level,

---

601 *Id.* at 1260.

602 *See* Hilton Davis, 62 F.3d 1522.

603 *See* Wilson Sporting Goods, 904 F.2d at 683.

604 *See* Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1173 (Fed. Cir. 1993).

605 *See* Markman, 52 F.3d at 970-71.

particularly in view of the concerns over "black-box" jury verdicts.[606] The Court first noted that summary judgment is appropriate when "no reasonable jury could determine two elements to be equivalent."[607] The Court then advised that legal limitations on the doctrine of equivalents are to be determined by the court on summary judgment or JMOL.[608] The legal limitations specifically mentioned were prosecution history estoppel, and complete vitiation of a particular claim element.[609] Presumably prior art limitations could be determined as well. On cases submitted to the jury, the Court specifically stated that "special verdict and/or special interrogatories on each claim element could be very useful in facilitating review, uniformity, and possibly postverdict judgments as a matter of law."[610] Ultimately, however, the Supreme Court left the implementation of procedural improvements up to the Federal Circuit.[611]

4. Related Considerations

a. Pioneer Status

One factor that has been used to determine the permissible range of equivalents of a patent is its status as either a "pioneer" patent or an "improvement" patent. Pioneer patents typically are afforded a very broad range of equivalents, and improvement patents are granted a much narrower range.[612] The Supreme Court has defined a pioneer patent as "a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what has gone before."[613] The status of a patent is determined by comparing it with the prior art.[614]

The observation that a pioneer patent should be entitled to a broader range of equivalents than an improvement patent was made early in the context of mechanical inventions.[615] When an invention was claimed that performed a new function or operated on a new principle, the inventor could exclude all other forms of the invention that operated on the same principle and performed the same function. However, when a patent was obtained on an improvement to the principle, the inventor could only exclude other forms of the narrow improvement, and not other forms of the original broad principle. It was therefore said that a pioneer patent was afforded a broader range of equivalents than an improvement patent.

A different view of pioneering patents has been expressed in some cases from the Federal Circuit. These

606 117 S.Ct. at 1053., n. 8.

607 *Id.*

608 *Id.*

609 *Id.*

610 *Id.*

611 *Id.*

612 *See* Thomas & Betts Corp. v. Litton Systems, Inc., 720 F.2d 1572, 1580 (Fed. Cir. 1983).

613 Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 561-62 (1898).

614 *See* Tate Engineering, Inc. v. United States, 477 F.2d 1336, 1340-41 (Ct. Cl. 1973).

615 *See* Morley Machine Co. v. Lancaster, 129 U.S. 263 (1889).

cases state that pioneer status is not a separate rule of analysis, but rather a conclusion or effect that naturally flows from an absence of prior art and the prosecution history.[616] In other words, the broader range of equivalents afforded a pioneer patent is not due to its status as a "pioneer," but rather due to the absence of blocking prior art and limiting prosecution history estoppel.[617] These cases further state that a "pioneer" patent is not "a separate class of invention, carrying a unique body of law.[618] Rather, there is a "wide range of technological advance between pioneering breakthrough and modest improvement [that] accommodates gradations in scope of equivalency."[619] Where a particular invention falls on this spectrum "depends on all the circumstances, and is decided as a factual matter."[620] In each case the trier of fact must "balance the competing public policies of avoiding 'a fraud on the patent', and the need for reasonable certainty by the public as to the scope of the patent grant."[621]

b. Means Plus Function

The concept of equivalency under the doctrine of equivalents must be distinguished from the concept of equivalency under section 112 (6) of the patent code. Section 112(6) provides:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.[622]

Although equivalency under s 112, para. 6, and equivalency under the doctrine of equivalents are both determined by insubstantial changes, the Federal Circuit has stated that each has "a separate origin, purpose and application."[623] Under section 112, 6, the sole question is "whether the accused device, which performs the claimed function, has the same or an equivalent structure as the structure described in the specification corresponding to the claim's means."[624] The question under the doctrine of equivalents, on the other hand, is "whether the accused device is only insubstantially different than the claimed device."[625] This question involves making the entire analysis of substantiality, including the function-way-result test and other relevant factors.[626]

---

616 *See* Texas Instruments, Inc. v. United States International Trade Commission 846 F.2d at 1370.

617 *Id.*

618 *See* Sun Studs, Inc., 872 F.2d at 987.

619 *Id.*

620 *Id.*

621 *Id.*

622 35 U.S.C. § 112 (6).

623 Alpex Computer Corp. v. Nintendo Co. Ltd., 102 F.3d 1214, 1222 (Fed. Cir. 1996).

624 *Id.*

625 *Id.*

626 *Id.*

C. The Doctrine of Equivalents - Summary

In sum, the Supreme Court has recently stated that the essential inquiry in equivalency analysis is whether "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention[.]"[627] As presently interpreted by the Federal Circuit, equivalency under the doctrine of equivalents depends on the substantiality of the differences between the claimed invention and the accused device. Factors relevant to substantiality are function-way-result, structure, interchangeability, copying, and designing around. Independent development is relevant to rebut a charge of copying under Federal Circuit analysis, and independent experimentation is relevant to the issue of known interchangeability under Supreme Court analysis. Equivalency is limited by prosecution history estoppel, the specification (disclosed but unclaimed subject matter), and the prior art.

Under certain Federal Circuit analysis, the doctrine of equivalents does not broaden claim scope. Rather, it expands the patent's exclusionary boundaries to cover the "equivalents" of what has been claimed. However, the Supreme Court has stated that the doctrine of equivalents should not have the practical effect of either impermissibly expanding claim scope or eliminating the elements of a claim.

It is generally thought that "pioneer" patents have a broader range of equivalents than improvement patents in a crowded field of art. However, the Federal Circuit does not consider pioneer patents to be a separate class of invention. The concept of equivalency under the doctrine of equivalents is to be distinguished from equivalency under section 112, paragraph six. The later concerns structural equivalents only.

Equivalency is determined by comparing individual claim elements and limitations with the accused device, rather than by comparing the claimed and accused devices "as a whole." Each element is important and may not be ignored in the equivalency analysis. However, the term "element" may be defined as a single limitation, or as a series of limitations in a claim. There need not be a one to one correspondence between the specific components of the claim and the accused device.

Equivalency is determined as a matter of fact by the trier of fact. However, the factual issue of equivalency is mixed with questions of law such as prosecution history estoppel and prior art limitations. These questions of law are reviewed de novo on appeal.

D. The Doctrine of Equivalents - Remaining Uncertainty

Although the Federal Circuit has explained that "substantiality of the differences" is the ultimate test of equivalency, uncertainty remains in several areas.

First, uncertainty exists as to the precise relationship between "insubstantial differences," "function-way-result," and "interchangeability". The Supreme Court believes the choice between insubstantial differences and function-way-result is a matter of linguistics and "word choice," but the Federal Circuit

627 Warner-Jenkinson Co., 117 S.Ct. at 1054.

sees real differences. Second, the issue of how equivalency is to be analyzed on an individual element basis remains stubbornly problematic. Although *Pennwalt* and the Supreme Court's opinion in *Warner-Jenkinson* attempt to settle the issue by requiring analysis on an individual element basis, uncertainty will continue due to the difficulty of defining the term "element" in a precise and consistent manner. The courts have yet to develop a principled approach to the issue that will yield predictable results.

Third, no explanation or insight has been offered into the potential list of factors that might be considered relevant to the issue of substantiality of the differences. The factors currently considered relevant by the courts are function-way-result, structure, interchangeability, copying, designing around, independent development and independent experimentation. The Federal Circuit has expressly stated that analysis is not limited to these factors, but has failed to indicate what other types of factors may be applicable. The only guidance offered by the court is that the factors be "relevant." The current explanations of both the Federal Circuit and the Supreme Court on the relevance of copying, designing around, independent development, and independent experimentation appear incomplete and confusing.

Fourth, no consistent and comprehensive guide has been set forth for how to weigh the relative importance of the various factors, particularly when the factors are in conflict. Fifth, the procedure for submitting the equivalency issue to the jury is unsettled. Sixth, the issue of whether a pioneer patent should be afforded special treatment is unresolved and confusing. And seventh, some of the substantive definitional terms in equivalency are in need of clarification.

V. Obviousness and Equivalency

The development, current status, and uncertainty in the doctrines of obviousness and equivalency have been reviewed. Before an attempt is made to further reduce uncertainty, the doctrines of obviousness and equivalency will be compared, contrasted, and analyzed. This process should provide a greater understanding of the problems still plaguing these doctrines and reveal potential areas and approaches for increasing objectivity. Additionally, the difficulty that the concept of obviousness has encountered with biotechnology will be discussed. This discussion will provide a specific factual setting to illustrate problems remaining in obviousness, much as *Warner-Jenkinson* has served to illustrate problems remaining in equivalency.

A. Common Origins

The concept of obviousness was developed to determine when a claimed invention would be patentable over the prior art. The doctrine of equivalents was developed to determine when an accused device would infringe upon patent claims when the infringement was not literal. Although obviousness and equivalency in their current forms are conceptually distinct, the origins of the two doctrines are conceptually similar.

The early test for patentability was quite similar to the current test for equivalency.[628] Much like the doctrine

---

628 This historical fact was mentioned by the late Judge Nies dissenting in Hilton Davis, 62 F.2d at

of equivalents, early patentability requirements focused, in general, on the substantiality of the differences between the claimed invention and the prior art.[629] Section 2 of the Patent Act of 1793 provided that an invention would not be patentable if it consisted of a change in form only.[630] Further, two bills proposed in 1789 and 1790, respectively, provided that priority of invention must be determined when the two inventions "shall appear to be substantially the same, both in principle and execution."[631]

Similarly, the earliest case concerning patent validity, *Odiorne v. Winkley*,[632] focused on the substantiality of differences between competing patented inventions. In *Odiorne*, the plaintiff was the assignee of a patent covering a machine that could cut and head nails in one operation.[633] The plaintiff accused the defendant of infringing the patent by using a machine that operated "substantially upon the same principles, and by the same mode of operation"[634] as the plaintiff's machine. The defendant claimed that the plaintiff's patent was invalid because the machine used by the defendant had been invented and patented by another person before plaintiff's patent had been granted.[635] Justice Story charged the jury that the patent upon which plaintiff claimed was void if the two machines were "constructed substantially upon the same principles, and upon the same mode of operation."[636]

The earliest reported patent infringement case, *Gray v. Jam*es,[637] also involved a patent for cutting and heading nails. In *Gray*, Justice Washington laid down the general rule that "where the machines are substantially the same, and operate in the same manner, to produce the same result, they must in principle be the same."[638] This language was similar to language that had been used earlier to describe patentability requirements, and is similar to language now used in the doctrine of equivalents.[639]

The focus on the "substantiality of the differences" continued as the test for equivalency[640], but began to be

---

1564 ("Indeed, the doctrine of equivalents originated as a test for patentability").

629 *Id.*

630 *See* Edward C. Walterscheid, *Letter to the Editor* 76 J. PAT. & TRADEMARK OFF. SOC'Y 547, 548 (July, 1994) ("Section 2 of the Patent Act of 1793 expressly provided that a change in form or substance would not result in patentable invention.")

631 *Id.* at 549, 550. Although neither of these bills became part of the Patent Act of 1790, the language used reflects the understanding of patentability at the time. *Id.*

632 18 Fed. Cas. 581 (No. 10,432) (C.C.D.Mass. 1814).

633 *Id.*

634 *Id.*

635 *Id.*

636 *Id.* at 582.

637 10 Fed. Cas. 1015 (No. 5,718) (C.C.D.Pa. 1817).

638 *Id.* at 1016.

639 *See* Walterscheid at 548, 549.

640 *See* Winans v. Denmead, 56 U.S. at 343 ("Where form and substance are inseparable, it is enough to look at the form only. Where they are separable; where the whole substance of the invention may be copied in a different

replaced by other principles in patentability. The first divergence between patentability and the "substantiality of the differences" test occurred when the Supreme Court declared in *Hotchkiss v. Greenwood*[641] that the concept of invention required more than the work of an ordinary mechanic. This statement signaled the beginning of a shift in focus from comparing the claimed and prior art devices for "substantial differences" to analyzing the capabilities of the hypothetical inventor possessing ordinary skill in the art.

Following this early partial split, however, patentability and equivalency managed to retain a degree of similarity for some time. In cases such as *Smith v. Nichols*,[642] the Supreme Court stated that "a change only in form, proportions, or degree, the substitution of equivalents, doing substantially the same thing in the same way by substantially the same means with better results, is not such invention as will sustain a patent."[643] Similarly, in *Smith v. Goodyear Dental Vulcanite Co.*,[644] the Court stated that improvements amounting to mere substitutions "for the same use, in substantially the same manner and with the same effect" would amount to "no invention."[645]

The conceptual split between patentability and equivalency widened, however, when the Supreme Court began to define patentability simply in terms of "discovery," "invention," and "flash of creative genius."[646] Under this formulation, patentability no longer depended upon the substantiality of the differences between the claimed invention and the prior art.[647] The conceptual split continued when Congress enacted section 103 of the patent act and defined patentability in terms of whether the invention would be obvious to a person of ordinary skill in the art.[648] The split has continued to the present, with patentability now being determined by the concept of "obviousness," as defined by whether a suggestion to combine exists, and infringement being determined by the concept of equivalency, as defined by whether insubstantial differences exist between the claimed invention and the accused device.

The common origins and conceptual split of obviousness and the doctrine of equivalents raise three important questions. First, why did the doctrines begin with the same conceptual underpinnings? Second, why did the doctrines conceptually split? And third, can any of the problems now facing the two doctrines be solved by analyzing their common past and understanding their present divergent paths?

B. Questions Addressed

1. Common Past

---

form, it is the duty of courts and juries to look through the form for the substance of the invention - for that which entitled the inventor to his patent, and which the patent was designed to secure.").

641 52 U.S. at 267.

642 88 U.S. 112 (1875).

643 *Id.* at 119.

644 93 U.S. 486 (1877).

645 *Id.* at 492.

646 *See* Cuno Engineering at 90, 91.

647 Substantiality of the differences was no where mentioned in Cuno Engineering. *Id.*

648 35 U.S.C. § 103.

Both obviousness and equivalency were first expressed in terms of the substantiality of the differences between the claimed invention and either the prior art or the accused device. This commonality of origin existed probably because both doctrines are, in general, conceptually similar. Each seeks to analyze and determine the amount of differences existing between the claimed device and some external subject matter. Obviousness compares the claimed invention against subject matter that has come before the claimed invention (the prior art), and equivalency compares the claimed invention against matter that has come after (the accused device).

When U.S. patent law was first codified and some form of the doctrines of obviousness and equivalency became necessary, the context for comparison was quite different than it is today. Inventions were usually mechanical in nature, and the "prior art" consisted primarily of a limited number of prior similar machines.[649] There was no vast body of technology or extensive written prior art references to overcome. Due to the limited prior art, the comparative analysis for patentability and infringement tended to be the same. Each would compare the invention against a single (or small number) of similar machines, and the comparison could easily and effectively be based on the substantiality of the differences between the competing machines.

2. Conceptual Split

As the amount of prior art grew, the analytical challenges for patentability grew as well. The invention now had to be compared against a multitude of prior art devices in the same and different fields of art, multiple improvements thereto, an extensive body of literature, and a rapidly growing body of general technological knowledge. It was no longer practical to determine patentability based simply upon the substantiality of the differences between the invention and the prior art. Rather, a more sophisticated analysis had to be employed to compare the invention against the prior art as a whole. These same growing challenges did not confront infringement analysis because infringement still only compared the invention against a single accused device. Substantiality of the differences therefore remained an effective test for patent infringement.

The primary problem facing the patentability analysis was how to effectively compare a single device against a multitude of different prior art devices and references. Any new analysis would necessarily require a method for determining when a *combination* of prior art references would render the invention unpatentable. Further, the new method would have to be flexible enough to compare a widely varied mix of prior devices and improvements thereto, written references, and common knowledge. Finally, the new method would have to be discriminating enough to select some appropriate subset from the body of all prior knowledge.

The solution developed by the courts was to base patentability on whether the invention required more

649 *See* Graver Tank, 339 U.S. at 609 ("In its early development, the doctrine was usually applied in cases involving devices where there was equivalence in mechanical components.").

ingenuity and skill to invent than was possessed "by an ordinary mechanic acquainted with the business."[650] This analysis shifted the focus away from a narrow comparison of the "substantiality of the differences" to the analytical processes occurring in the mind of the inventor of ordinary skill when the invention and the prior art were compared as a whole. The focus on the mind possessed by an inventor of ordinary skill in the art made the standard objective. This objective concept accomplished the dual purposes of providing a method of comparing all forms of prior art at once (because that is, in effect, what an inventor's mind does), and distinguishing which prior art should be compared (because focus on the knowledge expected of an inventor of ordinary skill in the particular art provides an appropriate subset of prior art knowledge).[651]

Although the new test solved certain problems, it also created a new one. The shift in focus to the processes occurring in the mind of the inventor of ordinary skill led some courts to believe the test for patentability was somewhat metaphysical in nature. Courts began to determine patentability based on whether a "flash of creative genius," "invention," or the like had occurred.[652] These tests were quite subjective and the results achieved from them were unpredictable.[653]

This unfortunate turn toward creative metaphysics occurred primarily because the patentability analysis was simply underdeveloped. Although the standard for selecting and comparing prior art references had been objectively defined to be the mind of the inventor of ordinary skill, the process of comparison had yet to be defined in a similar objective manner. The "invention" and "flash of creative genius" tests temporarily filled this procedural gap with unprincipled subjectivity. The problem was remedied, however, when the objective concept of obviousness was introduced in the 1952 patent act. The new standard provided an objective framework for the patentability analysis by replacing "invention" and "flash of creative genius" with an objective standard. The objective analysis for patentability was further clarified when obviousness was defined to require a suggestion to combine prior art references.

In sum, since obviousness must compare the claimed invention against the entirety of the relevant prior art, its analytical framework has evolved to effectively compare patent claims against an enormous body of technical information. The requirement that the prior art references suggest the claimed invention to an inventor of ordinary

650 *See* Winans at 267.

651 The ability of an objective legal construct such as the hypothetical "person of ordinary skill" to provide meaning and limits on legal concepts such as obviousness and equivalence was recognized by the U. S. Supreme Court in Warner-Jenkinson, 117 S.Ct. at 1053 (1997) ("Much as the perspective of the hypothetical 'reasonable person' gives content to concepts such as 'negligent' behavior, the perspective of a skilled practitioner provides content to, and limits on, the concept of 'equivalence.'")

652 *See* Cuno Engineering at 91.

653 *See* Graver Tank at 12.

skill in the art allows such a comparison to occur. Equivalency, on the other hand, compares the patent claims against only a single accused device, so its analytical framework can more narrowly focus on the substantiality of the differences between the two.

3. Comparison of Problems

A more thorough understanding of the problems still facing obviousness and equivalency can be gained by comparing and contrasting the uncertainty remaining in the two doctrines. Four problems are similar. First, uncertainty remains in the theoretical tests for each doctrine. The application of traditional obviousness tests to biotechnology has raised uncertainty in both the obviousness suggestion to combine test and the reasonable expectation of success requirement. Equivalency faces uncertainty over the proper relationship between the insubstantiality of differences, function-way-result, and interchangeability tests. Second, uncertainty remains in both doctrines when comparative factors that conflict are weighed. Third, uncertainty remains in the procedure for submitting obviousness and equivalency to a jury. And fourth, both doctrines have some uncertainty in substantive terminology.

The two doctrines also face different problems. Equivalency alone faces an uncertain list of comparative factors, uncertainty in the individual claim element analysis, and some uncertainty as to the necessity and role of the "pioneer patent." Obviousness alone has uncertainty in the prima facie case procedure during prosecution.

These differences result from a variety of reasons. First, equivalency is less developed as a doctrine than is obviousness. The test for equivalency has recently been reclarified to be the "substantiality of the differences," whereas the concept of obviousness has been evolving since the 1952 Patent Act was passed. Second, obviousness would appear to have more analytical complexity than equivalency, at least with regard to its inference sources. Obviousness compares patent claims to a wide variety of prior art devices and references, and equivalency compares patent claims to only one device. Third, the two doctrines cover different time and procedural periods. Obviousness is primarily concerned with events and procedures occurring before the patent grant, whereas equivalency is primarily concerned with events and procedures occurring after the patent grant.

The similarities and distinctions in the doctrines can be used as a constructive analytical tool. Since obviousness is more mature as a doctrine than equivalency, some of the law developed in obviousness might be helpful to reduce the uncertainty remaining in equivalency. Similarly, problems unique to obviousness might be solved by studying why they do not exist in equivalency. Either a solution may be found, or it may be discovered that the concept is unnecessary. Additionally, problems the two doctrines have in common might be solved by using similar approaches and applying similar solutions.

4. Analysis and Comments

a. Theoretical Test Procedures and Comparative Procedures

Both obviousness and equivalency have uncertainty in their basic theoretical inference tests and in their methods for comparing the

theoretical conclusions with the empirical evidence. Each of the tests and methods involves a process whereby certain facts are inferred from evidentiary facts. The uncertainty therefore necessarily exists either in the selection of the evidentiary facts that support the inferences, or in the interpretation of the inferences to be drawn from the evidentiary facts, or both. The analysis of the uncertainty remaining - and the search for solutions - in all tests and methods can therefore be approached on this common basis.

b. Prima Facie Case

Obviousness alone lacks an incomplete prima facie case procedure. It is not needed for equivalency because the equivalency determination occurs in the context of an *inter partes* proceeding. However, it should be noted that inferences similar to the prima facie case procedure operate in both obviousness and equivalency to manage the burden of coming forward with, and the effect of, empirical evidence. In obviousness, the inference usually occurs in connection with establishing a nexus for commercial success.[654] In equivalency, the inference occurs in connection with evidence of copying and designing around.[655] These inferences operate on the same basis as the typical burden-shifting evidentiary presumptions commonly found in the law of evidence.[656]

c. Individual Element Comparison

As previously discussed, the doctrine of equivalents continues to be plagued by problems with the individual element approach. The primary problem is the lack of a consistent procedure for selecting the appropriate elements or limitations to be compared and that cannot be ignored or eliminated in the analysis.[657] Obviousness appears not to share these problems. Can the solution in obviousness be applied to equivalency?

(1) Source of the Problem

Both the United States Supreme Court and the Federal Circuit have held that the doctrine of equivalents is to be applied to individual claim elements, and not to the claimed invention "as a whole."[658] This is because an "as a whole" application often vitiates the limiting effect of claim elements, and impermissible broadens the exclusionary effect of the patent.[659] Unfortunately, when the equivalency analysis is conducted on any portion of the claimed invention that is less than the whole of the invention, any lesser amount selected is quite subjective and easy to manipulate under current procedural rules.[660] As has been discussed, this is because the terms "element" and "limitation" do not presently have fixed meanings. The problem which thus presents itself is how to objectively select an appropriate portion of the claimed invention for comparison and preservation that is less

---

654 *See* Texas Dept. of Community Affairs v. Burdine, 450 U.S. 248, 254 n. 7 (1981).

655 *See* Hilton Davis 62 F.3d at 1519, 1520.

656 *See* Demaco, 851 F.2d 1387.

657 *See* notes 543-601 *supra* and accompanying text.

658 *See* Warner-Jenkinson, 117 S.Ct. at 1049.

659 *Id.*

660 *See* notes 600-601 *supra* and accompanying text.

than the invention as a whole, but is not limited to the literal language of the claims.

(2) Obviousness Solution

The obviousness inquiry has not experienced problems selecting between the "individual element" and "as a whole" comparative approaches. A quick explanation for this fact might be that since in obviousness both the claimed invention and prior art are compared "as a whole," there is no need to devise an objective method for selecting an amount for comparison that is less than the "whole." However, such an explanation would be technically incorrect. Although it is often said that in the obviousness inquiry the prior art is to be considered as a whole, it is actually the *pertinent* prior art that is being considered as a whole. And the *pertinent* prior art is defined by what should have been known by an inventor of ordinary skill in the art facing the type of problem that the patentee faced.[661]

Can the same objective solution be applied to the equivalency analysis? Unfortunately, although equivalency is also determined according to the standard of an inventor of ordinary skill, this objective standard cannot help select the appropriate individual claim elements or limitations to be compared and preserved. This is because the equivalency analysis has never focused upon, or been defined by, the abilities and limitations of the inventor of ordinary skill in the art. Rather, in equivalency, the focus is on the substantiality of the differences between the claimed and accused devices.

However, the objective nature of the solution achieved in obviousness broadly suggests that such an objective solution may also exist for selecting elements and limitations in the doctrine of equivalents. The approach suggested is to objectively select some portion of the invention and then analyze the selected portion "as a whole." Fortunately, the basis for such an approach already exists. It was used early in the development of the doctrine of equivalents and is similar, in effect, to the intuitive procedure now being used by the Federal Circuit to select appropriate elements, limitations, and series of limitations for equivalency analysis. The approach is to select the element for comparison based on the distinguishing principle of the invention in light of the prior art.[662]

d. Underdeveloped List of Comparative Factors

In the doctrine of equivalents, uncertainty exists in the list of comparative factors because the test has recently been restated. Although *Graver Tank* mentioned insubstantial changes,[663] prior to *Hilton Davis* the test for equivalency was generally assumed to be primarily function-way-result, interchangeability, copying, and designing around. The list of comparative factors for obviousness is more complete because it has had more time to develop. Since both doctrines compare the patent claims against outside subject matter, factors considered relevant for obviousness should also be considered for potential

---

661 *See* notes 103-105 *supra* and accompanying text.

662 This approach is discussed in notes 733-762 *infra* and accompanying text.

663 339 U.S. at 610.

relevancy in equivalency analysis. An even more comprehensive approach would be to analyze the process that has produced the comparative factors in obviousness to determine whether additional comparative factors might be found for both obviousness and the doctrine of equivalents. Such an approach will be undertaken in the next section.

e. Matter of Law/Fact and Submission to the Jury

Obviousness is considered to be a question of law, and equivalency is considered to be a question of fact.[664] These different conclusions may seem curious given that obviousness and equivalency are conceptually similar, have common origins, and both involve mixed questions of law and fact. Indeed, both involve applying underlying factual issues to an ultimate standard of law. One explanation for considering validity to be an issue of law is that patents are public rights and cancellation of a patent for invalidity was considered historically to be an equitable remedy.[665]

Although obviousness is considered to be a question of law and equivalency a question of fact, the two issues have been treated the same procedurally in the trial court.[666] The Supreme Court has now offered the additional guidance that "special verdits and/or interrogatories on each claim element" might be helpful to avoid the black-box jury verdict problem in equivalency.[667] A similar solution might be considered when submitting the issue of obviousness to a jury.[668]

f. Pioneer Patent

The search for predictable comparative procedures in equivalency has tempted some courts and commentators to establish a separate classification for "pioneer patents," and to afford such patents a broader range of equivalents.[669] The Federal Circuit has explained that a separate rule of law is inappropriate because patents and patent scope exist on a continuum.[670] In obviousness, there has been no need or effort to artificially classify patents according to how much of an advance they represent over the prior art. This would suggest that the concept of a

---

664 *See* Graham v. John Deere Co., 383 U.S. 1, 17 (1965) ("the ultimate question of patent validity is one of law"); Hilton Davis, 62 F.2d at 1520. ("Infringement, whether literal or under the doctrine of equivalents, is a question of fact.").

665 *See* Hilton Davis, 62 F.2d 1512 at 1555. (Judge Nies dissenting) ("Essentially, validity is an issue of law because patent rights are public rights, not private rights, and historically cancellation of a patent for invalidity was an equitable remedy.")

666 *See* notes 278-288 and 602-611 *supra* and accompanying text.

667 Warner-Jenkinson Co., 117 S.Ct. at 1053, n. 8.

668 The issue of obviousness can currently be submitted to a jury without separating the interrogatories into the specific factual Graham inquiries. The guidance offered by the Supreme Court in Warner-Jenkinson suggests that submitting obviousness on separate interrogatories may be helpful.

669 *See* notes 612-621 *supra* and accompanying text.

670 *See* notes 616-621 *supra* and accompanying text.

pioneer patent is unneeded in equivalency as well.

C. Obviousness and Biotechnology

It has been discussed that the application of chemically-oriented obviousness rules to certain aspects of biotechnology has caused uncertainty in the suggestion to combine test, the reasonable expectation of success test, and the prima facie case mechanism. This uncertainty will be explained in the context of the technology following a brief primer on genetic engineering.

1. Genetic Engineering

Genetic engineering, in general, involves a process whereby DNA produces proteins.[671] Proteins consist of a chain of amino acids that can be from twenty to several hundred amino acids long. Each position on the molecular chain is occupied by one of twenty different types of amino acids. Each type of amino acid has different structural and chemical properties. These different properties determine how the amino acid chain will fold and react at each amino acid site. The unique structure and function of each protein is therefore determined by the unique overall sequence of amino acids found in each protein.

The unique sequence of amino acids in a protein is determined by the code on a template molecule called messenger RNA. The protein chain is built one amino acid at a time as the particular type of amino acid is transported to the template attachment site by its own transport RNA. The transport RNA for each amino acid has a unique molecular code that adheres to a corresponding molecular code on the messenger RNA. Each attachment site has three symbols, called a codon. The messenger RNA receives the code from the DNA in a process called transcription. The genetic code is redundant, meaning that each amino acid can be coded for by up to six different codons.[672] Therefore, simply because the amino acid sequence is known, it does not necessarily mean the DNA code is known. For example, the amino acids leucine, serine, and arginine are each encoded by six codons[673], and the amino acids valine and proline are each encoded by four amino acids.[674] A polypeptide chain containing just these

---

671 For a more extended discussion on this topic *see* In re O'Farrell, 853 F.2d at 896.

672 AUG encodes methionine, which initiates most amino acid chains. UGG encodes tryptophan. All other amino acids are represented by two to six triplets. The triplets UAA, UAG, and UGA are termination signals and do not encode amino acids. *See* William S. Klug and Michael R. Cummings, CONCEPTS OF GENETICS, 453 (4th ed. 1994).

673 Leucine is encoded by the triplets UUA, UUG, CUU, CUC, CUA, and CUG. Serine is encoded by the triplets UCU, UCC, UCA, UCG, AGU, and AGC. Arginine is encoded by the triplets CGU, CGC, CGA, CGG, AGA, and AGG. CONCEPTS OF GENETICS at 453.

674 Valine is encoded by the triplets GUU, GUC, GUA, and GUG. Prolein is encoded by the triplets CCU, CCC, CCA, and CCG. CONCEPTS OF GENETICS at 453.

six amino acids would have 3,456 possible DNA sequences.[675]

2. Patenting of DNA Sequences

Patent protection may be sought for a particular DNA sequence to exclude others from using it to produce a given protein.[676] When seeking such protection, an issue that typically arises is whether the DNA sequence will be rendered obvious, and therefore unpatentable, if the protein's sequence of amino acids is already known.[677] The obviousness issue arises because a DNA sequence may be determined from a known amino acid sequence through application of the genetic code.[678] However, since the genetic code is redundant, the DNA sequence cannot be derived without first using laboratory techniques. The amount of laboratory time and effort required to derive the sequence may vary according to the particular protein and DNA sequence chosen.

As previously discussed, the obviousness of DNA sequences has been approached from a traditional chemical perspective because DNA is considered to be a chemical compound.[679] In particular, the Federal Circuit has used the structural similarity test to determine whether claimed DNA is prima facie obvious.[680] In the chemical arts, this test is normally useful because compounds similar in structure are usually similar in function as well.

The structural similarity test has proven not to be a useful test for DNA and proteins.[681] This is because the relationship between a prior art amino acid sequence and a DNA sequence is different than the relationship between two structurally similar prior art chemical compounds.[682] In the DNA-amino acid relationship, the amino acid sequence is determined by the genetic code contained within the DNA sequence. No such relationship exists between structurally similar chemical compounds because one chemical compound is not determined by the other.

In addition, the degree of functional similarity between chemical compounds, while unpredictable, is usually determined by the degree of structural similarity between the compounds. This is not true for the DNA-protein relationship, where a single codon change usually leads to an entirely different amino acid being inserted into the protein.[683] Finally, the

---

675 (6x6x6x4x4=3,456). However, as a practical matter, certain codons are preferred for each amino acid, and these combinations are usually tested first.

676 Another reason for patenting DNA is that the sequence may be important as a binding site for particular protein.

677 *See* In re Bell, 991 F.2d 781 (Fed. Cir. 1993); In re Deuel, 51 F.2d 1552 (Fed. Cir. 1995)

678 *Id.*

679 *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (stating DNA is "a chemical compound, albeit a complex one."), *cert. denied*, 502 U.S. 856 (1991).

680 *Id.*

681 *See generally* Anita Varma and David Abraham, *DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, HARV. J. L. & TECH. 53 (Winter, 1996).

682 *Id.* at 68, 69.

683 *Id.* at 68.

exact causes of functional similarities and dissimilarities between chemical compounds is usually difficult to determine, and such proof is usually established only through empirical evidence of results achieved.[684] This is not true for the DNA-amino acid relationship, where the effect a DNA codon change has on the particular amino acid added to the chain is precisely understood.

3. Case Study - *In re Deuel*

The case of *In re Duel*[685] illustrates the problems that arise when current chemically-oriented obviousness principles are applied to the DNA-amino acid relationship. In *Deule*, the patent office rejected a claimed DNA sequence as being obvious in light of two prior art references.[686] The first reference was a partial amino acid sequence of a protein closely related to the protein encoded by the claimed DNA. The second reference taught a general method for determining a DNA sequence from an amino acid sequence.[687] On appeal, the patentee argued that the claimed DNA sequence was nonobvious because it was not structurally similar to the prior art amino acid.[688] The patentee argued further that the general method reference did not render the DNA sequence obvious due to the redundancy of the genetic code.[689]

The Federal Circuit agreed with the patentee and reversed the rejection.[690] The court stated that normally a prima facie case of obviousness is based on the structural similarity between a prior art compound and the claimed compound.[691] Since the prior art did not disclose any DNA molecules similar in structure to the claimed DNA, the PTO had not established a prima facie case of obviousness.[692] The court further stated that the PTO's reliance on a general method for determining a DNA sequence from an amino acid sequence was misplaced for two reasons. First, even with such a method, the redundancy of the genetic code would result in an "enormous number" of possible DNA sequences coding for the protein.[693] Any particular sequence therefore would be only "obvious to try."[694] Second, since the patentee's claims were directed to compounds and not to methods, the PTO could not focus on the methods by which the compounds were made.[695]

The Court justified its "redundancy" reasoning by drawing an analogy to the facts in *In re Baird*,[696] a chemical case which held that disclosure of a broad genus does not necessarily render obvious each species within it.[697] In *Baird*, the disclosed generic formula contained a "broad range" of variables encompassing what the court estimated to be more than "100 million" different species, one of which was the claimed

---

684 *See* Tyler v. Boston, 74 U.S. at 330.

685 51 F.2d 1552 (Fed. Cir. 1995).

686 *Id.* at 155, 1556.

687 *Id.* at 1556.

688 *Id.* at 1557.

689 *Id.* at 1557, 1558.

690 *Id.* at 1557.

691 *Id.* at 1558.

692 *Id.*

693 *Id.*

694 *Id.* at 1559.

695 *Id.*

696 16 F.3d 380 (Fed. Cir. 1994)

697 In re Deuel, 51 F.3d at 1559.

species.[698] The Federal Circuit found the claimed species to be nonobvious in light of the "vast number" of species covered by the generic disclosure, and because the generic disclosure listed preferred species that taught away from the claimed species.[699] The Court justified its rejection of the general method disclosure by quoting language from *In re Bell*, an earlier case involving DNA where consideration of method evidence was also refused.[700]

4. Analysis of *Deuel* and Future Issues

The practical effect of the court's holding in *In re Deule* is that a DNA sequence is nonobvious even when the amino acid sequence it encodes is known, and a routine method for obtaining the DNA sequence from the amino acid sequence is also known. Although this result may seem inconsistent with the very notion of obviousness, it is a natural consequence of not allowing the method evidence to provide a basis for a suggestion to combine or a reasonable expectation of success.

Commentators have been critical of the holding and rationale of *In re Deule*.[701] The general basis for the criticism is that the Federal Circuit departed from accepted principles of obviousness law to reach a result of non-obviousness for the DNA sequence. Specifically, the court's rulings that a method reference cannot be used to establish a suggestion to combine, and that any amount of redundancy eliminates a reasonable expectation of success, are contrary to traditional obviousness principles. In the end, *In re Deule* is perhaps best understood as a policy decision based on the patent protection needs of the emerging biotechnology industry, rather than as a decision based on established obviousness law.[702]

The authoritativeness of *Deule* probably will not survive for two reasons. First, the precedent it is based on is questionable.[703] Second, the

---

698 Baird at 381.

699 *Id.*

700 In re Deuel, 51 F.3d at 1559.

701 *See, e.g.*, Philippe Ducor, *The Federal Circuit and In re Deule: Does § 103 Apply to Naturally Occurring DNA?* 77 J. PAT. & TRADEMARK OFF. SOC'Y 871 (Nov., 1995) (arguing that the Federal Circuit chose to protect DNA at the expense of the patent law); Anita Varma and David Abraham, *DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH 53 (Winter, 1996) (arguing that the Federal Circuit has upset the "delicate balance" between biotech patentees and the market).

702 *See* Philippe Ducor, *supra* at 898. (stating that the court may have decided the case "from a policy concern, fearing that unprotected, these products never be developed, or that the biotechnology industry be damaged.")

703 The reasoning of the court can be criticized for at least four reasons. First, the chemical case cited, In re Baird, concerns the genus-species problem in chemistry. The inference that arises from the genus-species relationship is based on structural similarity, and is rebutted primarily through a showing of structural differences or unexpected results. The genus-species relationship is therefore not analogous to a relationship based on the genetic code. Second, the court stated that

technology of genetic engineering has advanced rapidly and its methods have become more routine. In light of legal precedent and the advancing state of the technology, it will be difficult for the Federal Circuit in future cases not to allow application of the traditional suggestion to combine test coupled with a reasonable expectation of success.[704]

---

obviousness might be found if no redundancy existed between the DNA and protein, 51 F.3d at 1559, which in effect established a requirement of absolute predictability. However, absolute predictability is not required for a prima facie showing of obviousness, only a reasonable expectation of success. *See* In re O'Farrell, 853 F.2d at 903.

Third, the rejection of the method evidence was based on language from In re Bell, which cites as authority In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985). In re Thorpe simply states that "[t]he patentability of a product does not depend on its method of production." In re Thorpe, in turn, cites for authority In re Pilkington, 411 F.2d 1345, 1348 (C.C.P.A. 1969), a case which states that a "product is not patentable [merely] because the process by which it is made is patentable." The relevance of these cases to the issue in Deule is therefore tenuous at best.

Fourth, the Federal Circuit allows method references to establish prime facie obviousness in other factual contexts. *See, e.g.*, In re Mayne, 104 F.2d 1339 (Fed. Cir. 1997) (two claimed compounds rendered obvious by two method references and one structural reference).

[704] *See* notes 720-726 *infra* and accompanying text.

This approach is more appropriate since the suggestion for a given DNA sequence arises not due to its structural similarity with the amino acid chain, but rather due to the genetic code and the reliability of the methods from which a DNA sequence can be derived from a known amino acid sequence.[705]

In the event the Federal Circuit does allow evidence of method to provide a suggestion to combine and then applies the traditional reasonable expectation of success requirement, two additional issues will arise. The first is an issue that the Federal Circuit has thus far successfully avoided. It is whether evidence of a general method to determine DNA sequences from amino acid sequences can establish a reasonable expectation of success even in light of the redundancy of the genetic code. The second issue is the form that the prima facie case of obviousness will take.

The first issue is important because procedures for determining the DNA sequence from a known amino acid sequence have become quite reliable and predictable.[706] Indeed, it is now not only "reasonable" to expect that the correct DNA sequence will be discovered from a known amino acid sequence, it is often a virtual certainty, given enough time and effort. If the prohibition against using method evidence to establish a reasonable expectation of success is dropped, then

---

[705] *See* DNA is Different *supra* at note 10.

[706] *See* DNA is Different at 65 (describing the current computerized state of the technology and the ease with which proteins may be sequenced and probable cDNA sequences obtained).

DNA sequences may go from being virtually *per se* non-obvious to being *per se* obvious. This problem has been noticed in the literature, and at least one legislative solution has been proposed.[707]

In the absence of *sui generis* legislation, one approach that may be effective to deal with this problem is to allow evidence of effort expended to rebut a prima facie case of a reasonable expectation of success. If such evidence is not allowed, the biotech applicant may have a difficult time proving nonobviousness[708] even when considerable effort is expended determining the DNA sequence of a complex protein. The issue of whether effort expended and undue experimentation should be considered relevant to rebut a prima facie case of obviousness appears not to be completely resolved.[709] The argument for allowing this type of evidence to be relevant as a primary factor is made in the next major section of this paper.

The second issue that may arise is the form the prima facie case should take. As previously described, the purpose of a prima facie case mechanism is to allow the examiner to meet the initial burden of proving obviousness without having to produce evidence that would be difficult or time consuming to obtain.[710] In the chemical arts, a special prima facie case mechanism was needed to help the examiner carry the initial burden of proving a claimed compound was functionally similar to a prior art compound. The structural similarity test provided the needed inference of functional similarity.

A special prima facie test should not be needed in the DNA context because a prior art amino acid sequence and methods for obtaining the DNA sequence should be able to establish a prima facie suggestion to combine and a reasonable expectation of success.[711] Once the prima facie case is established, the burden will shift to the applicant to come forward with rebuttal evidence such as unreliable procedures or considerable effort expended and undue experimentation. It will be important to remember, however, that the examiner need only raise an *inference* of reasonable expectation of success to establish the prima facie case. Evidence concerning such reasonable expectation may often consist of experimental data in the sole possession of the applicant,

---

[707] *See* Philippe Ducor, *supra* at 898. (suggesting possible alternative legislative or regulatory solutions).

[708] Empirical evidence may be unavailable to weigh against the suggestion to combine references. This is because genetic engineering is a rapidly developing technical field with perhaps no provable long felt need or failure of others on the specific DNA sequence in question. Further, commercial success may not be provable until years later, and unexpected results may not occur because the genetic code is known. However, unexpected results may be considered relevant if the DNA sequence is lengthy and the codons do not follow the normal preference patterns.

[709] *See* note 722 *infra* and accompanying text.

[710] *See* notes 185-203 *supra* and accompanying text.

[711] *See* note 727 *infra* and accompanying text.

and depend on a time consuming reliability analysis of complex techniques in the specific area of inquiry. Should the examiner be required to evaluate this type of proof in the first instance, a prima facie case of obviousness may be difficult to establish given the examiner's limited resources.

Likewise, the applicant's burden of rebuttal should also require only an *inference* that no reasonable expectation existed. Such an inference, if established, must be considered to completely destroy the initial inference that a reasonable expectation existed.[712] Otherwise, as a practical matter, ultimate success on the issue may be difficult for the applicant to achieve given the subjective nature of the reasonableness inquiry.[713] Should the applicant rebut the examiner's prima facie case of obviousness with a contrary inference, the examiner must then consider all evidence on the suggestion to combine and the reasonable expectation of success anew.

VI. The Comparative Calculus - Preparation

A. Introduction

As the doctrines of obviousness and equivalency have developed, the uncertainty remaining within them has, for the most part, been gradually reduced by increasing the objectivity in the comparative processes. It logically follows that additional reductions of uncertainty can be achieved through additional increases in objectivity. In general, such increases can be achieved in three ways. First, by thoroughly understanding and then refining the overall framework and objective procedures for comparison. Second, by examining all potential objective factors and selecting the appropriate ones for comparison. And third, by standardizing the terminology used in the comparative process.

Most of the uncertainty remaining in obviousness and equivalency exists because the comparative analyses are incomplete. In some cases an additional method or procedure is needed to further reduce the inherent subjectivity. In other cases an additional comparative factor is needed. To understand where and why the addition procedures and factors are needed, and to determine which procedures and factors should be selected, it is first necessary to rigorously analyze the comparative processes occurring in the doctrines of obviousness and equivalency.

B. Current Comparative Framework

---

712 *See* In re Piasecki, 742 F.2d at 1473.

713 The difficulty would arise because even the most precise definition of a "reasonable expectation" is still subjective. If the initial presumption did not completely disappear, the examiner's subjective conclusion concerning reasonableness would need to be rebutted by the applicant's subjective conclusion concerning reasonableness. The applicant would be in the unfortunate position of having to prove that, even with the suggestion to do what was done, it was not reasonable to expect the applicant to achieve what they did. Absent compelling evidence from the applicant, at best a condition of equipoise would likely result. And since the prima facie case mechanism places the burden of proof on the applicant, a condition of equipoise would result in a loss for the applicant.

1. Introduction

As previously discussed, both obviousness and equivalency compare the patent claims against other subject matter - the prior art in the case of obviousness, and an accused device in the case of equivalency. Although portions of the doctrines have diverged into the two different standards of "suggestion to combine references" and "substantiality of the differences," the underlying inquiry in both doctrines can be thought of as remaining substantially the same. At their respective cores, each doctrine seeks to determine whether the technical advance claimed in the patent also exists in the prior art or in the accused device.

By definition, the claimed technical advance does not exist in a single prior art reference, and does not exist in the accused device in the exact same form as in the patent. Otherwise, the claimed invention would be unpatentable due to lack of novelty, and the accused device would infringe literally. Rather, the doctrines of obviousness and equivalency detect whether the technical advance exists by analyzing inferences derived from various sources. These inferences may exist in the relevant prior art, may arise from a comparison between the claimed and accused devices, and may arise from empirical evidence.

2. Inferences

Before examining how inferences are used to determine whether a claimed invention is obvious, or whether an accused device is an equivalent, it may be helpful to describe what an inference is. The term "inference" has been defined as "the deriving of a conclusion in logic by either induction or deduction."[714] The term "induction," in the discipline of logic, means "reasoning from particular facts or individual cases to a general conclusion."[715] The term "deduction," in logic, means "reasoning from a known principle to an unknown, from the general to the specific, or from a premise to a logical conclusion."[716] An inference is therefore a logical conclusion derived either by inductively reasoning from specific facts to a general conclusion, or by deductively reasoning from a general principle to a specific conclusion.

It is important to understand that when determining whether a given inference exists, both the deductive and inductive reasoning processes may be used if appropriate sources are available. If a general testing principle is available, it can be applied to the specific situation to determine, through deduction, whether an inference exists. If specific facts are also available in the given situation, they too can be analyzed to determine, through induction, whether the same inference exists.

3. Deductive and Inductive Reasoning in Obviousness and Equivalency

The doctrines of obviousness and equivalency use both deductive and inductive reasoning to determine whether the necessary inference exists. The test for obviousness requires the factfinder to determine whether

---

714 WEBSTER'S NEW WORLD DICTIONARY, p. 721 (2nd College Ed. 1970).

715 *Id.* at 718.

716 *Id.* at 368.

inferences exist from two sources. First, whether the prior art supports inferences of a suggestion to combine references, reasonable expectation of success, and motivation. Second, whether various empirical "secondary considerations" support an inference of obviousness.

The suggestion to combine, reasonable expectation, and motivation portion of the test is in the nature of a deductive test. It is based on the general principle or theory that if the prior art references suggest the claimed invention to one of ordinary skill in the art, and provide motivation and a reasonable expectation of success, then a conclusion of obviousness can be inferred. The test is based on a conclusion derived from a general principle, so the reasoning is deductive. The second portion of the test inquires whether a variety of empirical evidence, such as commercial success, long felt need, etc., supports an inference of obviousness. It is based on specific evidence being evaluated to determine whether the general conclusion of obviousness can be inferred, so the reasoning is inductive.

Equivalency also contains a test with both deductive and inductive portions. The substantiality of the differences, function-way-result, and interchangeability portion is in the nature of a deductive test. It is based on the general principle or theory that if an accused device contains insubstantial differences from a claimed invention, performs the same function-way-result, or is interchangeable, a conclusion of equivalency may be inferred. The test is based on a conclusion derived from a general principle, so the reasoning is deductive. The second portion of the test inquires whether various empirical factors such as interchangeability, copying, designing around, independent development, and independent experimentation support an inference of equivalency. It is based on specific empirical evidence being evaluated to determine whether the general conclusion of equivalency can be inferred, so the reasoning is inductive.

4. Theoretical and Empirical Sources

The source materials for the deductive and inductive tests can also be divided into two categories. Evidence analyzed by the deductive or theoretical tests can be thought of as being theoretical evidence.[717] In obviousness, the theoretical evidence primarily consists of the claimed invention, the problem solved, and all relevant prior art references. In equivalency, the theoretical evidence is the structure and function of the claimed and accused devices. Evidence analyzed by the inductive or specific evidence test can be thought of as empirical evidence. In obviousness, the empirical evidence currently is commercial success, long felt need, failure of others, etc. In equivalency, the empirical evidence currently is interchangeability, copying, designing around, independent development and independent experimentation.

5. Suggestion Theoretical Procedure

[717] The term "theoretical" is preferable to other terms used in the case law such as "objective" or "technical," because the empirical evidence is also objective and can be technical in nature.

The suggestion test in obviousness requires additional discussion due to the uncertainty over whether it is a one or two step process. As previously discussed, some commentators believe that the test takes place in two steps, but the cases do not clearly set forth or recognize a two step formulation.[718] A brief analysis of the factors working within the suggestion test reveals that the process can be thought of as occurring in one step in some cases, and in two steps in other cases.

In general, the suggestion test seeks to determine whether the prior art references, taken as a whole, would suggest the invention to one of ordinary skill in the art. Prior art references may exist as specific references, or may exist as common knowledge in the art[719]. Specific prior art references can exist within the inventor's art, or in an analogous art reasonably pertinent to the inventor's problem.

Suggestions to combine references can be express or implied. An express suggestion will generally be found in a specific reference. Implied suggestions can be found within specific references, within the common knowledge, or arise due to a common problem in an analogous art. When a combination is properly suggested, the resulting combination may be the claimed subject matter itself, or it may be a lesser intermediate that itself may suggest the subject matter when combined with common knowledge and common sense.

When the combination of references produces the claimed subject matter itself, the suggestion test may be thought of as occurring in one step. This is because the suggestion that permits the combination of references also produces the claimed subject matter. When the combination of references does not produce the claimed subject matter, but rather produces some lesser intermediate, then the suggestion test might be thought of as occurring in two steps. This is because the lesser intermediate must be analyzed in a second step (usually in light of common knowledge in the art) to determine whether it suggests the claimed subject matter. Of course, if one considers the "common knowledge" found in the second step analysis to simply be one of the prior art references to be combined, then the whole process can once again be thought of as occurring in one step. When an inference is found through use of the theoretical test procedure, a prima facie case of obviousness has been established.

C. The Remaining Uncertainty

The purpose of the theoretical tests, their subtests, and the empirical tests is to provide a procedure for determining whether sufficient inferences exist to support findings of obviousness and equivalency. When the inferences derived from the theoretical and empirical tests are strong, clear, and consistent, the analysis can be relatively easy and straightforward. However, when the inferences are weak and/or in conflict, current analysis sometimes proves incapable of providing consistent

---

[718] *See* notes 182-184 *supra* and accompanying text.

[719] For authority on the rules of law in this section *see* notes 86-274 *supra* and accompanying text.

and predictable results. As previously stated, the usual reason that the analysis falls short is that the analytical procedures or comparative factors are incomplete. The general solution to this problem is to develop additional objective comparative procedures and factors, and to clarify and standardize the terminology.

Ten major remaining areas of uncertainty have been identified in obviousness and equivalency. Of these, seven are caused primarily by inadequate procedures. They are (1) the suggestion to combine references test as it has been recently interpreted in certain areas of biotechnology, (2) the reasonable expectation of success test in biotechnology and whether evidence of effort expended should be considered relevant, (3) the prima facie procedure in obviousness, (4) the precise relationship between the theoretical tests of insubstantial differences, function-way-result, and interchangeability, (5) the procedure for selecting the individual claim elements to be compared in equivalency, (6) the procedure for comparing the theoretical and empirical evidence in both obviousness and equivalency, and (7) the proper procedure for submitting the case to the jury in both obviousness and equivalency. The eighth area is the underdeveloped comparative factors in equivalency. The ninth area is the definitional confusion in obvious and equivalency. Finally, the tenth area of uncertainty is the appropriate role and status of the so-called "pioneer patent" in equivalency.

The analysis of the remaining areas of uncertainty will proceed as follows: First, the first five inadequate procedural areas will be addressed. Second, a comprehensive list of comparative factors will be developed. Third, the procedure for comparing the theoretical and empirical factors will be addressed. Fourth, the procedure for properly submitting obviousness and equivalency issues to a jury will be addressed. Finally, the issue of standard definitions will be discussed, and comments will be made on the necessity of retaining the status of "pioneer" patents.

D. Suggestion to Combine References Test

The general test for determining whether a claimed invention is obvious is whether the prior art, taken as a whole, suggests the claimed invention to one of ordinary skill in the relevant art. The Federal Circuit in *In re Deule* "reaffirmed" the rule that a general method reference could not be combined with an amino acid structural reference to render a DNA sequence prima facie obvious. This rule is inconsistent with traditional obviousness law, and raises the important issue of whether a court can construct different suggestion tests in different technologies to justify a given result, i.e., arbitrarily decide to ignore a given type of prior art reference to guarantee a particular outcome. If so, then additional uncertainty has been injected into the obviousness determination.

The Court in *In re Deule* was faced with a dilemma. If the court had applied the traditional suggestion and reasonable expectation tests, it would have rendered virtually all DNA sequences obvious once a partial amino acid sequence was known. This would have eliminated all patent based incentives for determining DNA

sequences. The court instead preserved patent incentives by ignoring the broad traditional tests and applying only the chemically-oriented structural similarity test. This had the effect of rendering virtually all DNA sequences prima facie non-obvious and, unfortunately, increasing the uncertainty about the nature and stability of the suggestion to combine test in new technologies.

The court also could have tried a third approach. The traditional suggestion to combine and reasonable expectation tests could have been used to establish a prima facie case of obviousness, and then the applicant could have been allowed to rebut the prima facie reasonable expectation of success with evidence of efforts expended, if applicable. This approach would have left the traditional suggestion to combine and reasonable expectation tests fundamentally intact, and would have focused the test on the very issue the Federal Circuit is concerned about - preserving patent incentives to determine DNA sequences when incentives are needed to recoup resources expended on difficult to determine DNA sequences. This approach is the subject of the next section.

E. Reasonable Expectation of Success

It previously has been suggested that the determinative issue concerning DNA-amino obviousness should be whether the applicant had a reasonable expectation of successfully discovering the correct sequence given the amino acid sequence and the disclosed method. Indeed, this will be the issue raised when method references are considered. In the early days of biotechnology, the reasonable expectation test, as it is traditionally understood, likely would have sufficed to adequately define when a known amino acid sequence and known lab methods provided an adequate suggestion for DNA sequence obviousness. The test was relevant and helpful because uncertainty did remain in the testing techniques, and a scientist may not have had a reasonable expectation of successfully finding the correct DNA sequence.

Under current technology, however, this is no longer true. Laboratory techniques are now so highly developed and refined that the process of deriving even the most complex DNA sequence from a known amino acid sequence is usually simply a matter of time and effort. Therefore, a test that simply asks whether there is a reasonable expectation of success of finding a given DNA sequence may no longer be useful - because there is virtually always a reasonable expectation of success. The only significant factor left to distinguish success from failure is the effort required to test all possible sequences until the correct one is found.

This reality leaves a court with four options. First, a court can decline to consider the method evidence, which is the option currently chosen by the Federal Circuit. Second, a court can consider all DNA sequences to be obvious in light of the high expectation of success. Third, a court can adopt an approach that focuses on the number of DNA sequences that must be tested. Fourth, a court can adopt a totality of the circumstances approach that includes consideration of the amount of effort required to determine the sequence.

The first option is inconsistent with generally accepted notions of the suggestion to combine test and recent authority.[720] The second option eliminates any patent based incentive to expend resources to find and then disclose DNA sequences. The third option is susceptible to being quite arbitrary in the midranges, and is too different from the "selection invention" chemical situation to rely on its principles. The fourth option relies primarily on empirical evidence traditionally not considered to be relevant as sole rebuttal evidence in a suggestion to combine or reasonable expectation of success analysis.

The fourth option should be considered the most appropriate option for several reasons. First, it avoids many of the problems created by or inherent in the first three options. It provides a compromise between what are, in effect, per se rules of obviousness and nonobviousness, and preserves the incentive for investment into DNA research. Second, a continuing theme in obviousness and equivalency law is that empirical evidence is allowed to supplement and often supersede the theoretical tests. Commercial success, long felt need, etc. are allowed to inform the suggestion to combine test, and interchangeability is allowed to inform the insubstantial differences and function-way-result tests. Similarly, evidence of efforts expended in the experimentation process should be allowed to inform the reasonable expectation of success test.[721]

Third, the relevance of efforts expended is at least conceptually supported by the case law. Although the specific issue of whether efforts expended can serve as the primary basis of nonobviousness appears unresolved,[722] evidence of extensive efforts and research have been held to constitute evidence that no reasonable expectation of success existed, and of nonobviousness.[723] Cases that consider evidence of efforts expended to be relevant when not used as the sole basis for lack of reasonable expectation should be supportive, as an applicant

---

[720] *See* In re Mayne, 104 F.3d 1339 (Fed. Cir. 1997).

[721] Of course, other evidence relevant to a reasonable expectation of success, if available, also should be allowed on the issue. Such evidence might consist of an incomplete amino acid sequence, an amino acid sequence to a different, but related protein, or the presence of many non-preferred codons.

[722] *See* In re deC. Kratz, 592 F.2d 1169, 1173 (C.C.P.A. 1979) (Board unaware of any holdings in obviousness cases evaluating degree of difficulty encountered); In re Mancy, Florent, and Prue d'Homme, 182 U.S.P.Q. (BNA) 303, 304 (C.C.P.A. 1974) (Board stated that long, tedious, and expensive process by itself does not confer patentability) Both case were decided on other grounds.

[723] *See* Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 103 F.3d 1538, 1546 (Fed. Cir. 1997) (extensive efforts by inventor "tend to show that one skilled in the art would have had no reasonable expectation of success in combining the prior art machines in question"); In re Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988) ("five to six years of research that preceded the claimed invention" was entitled to fair evidentiary weight in determination of nonobviousness).

should be able to prove difficulties in addition to effort needed. For example, that post-translational changes modified the protein sequence from its original DNA code.

Fourth, efforts expended is conceptually similar to undue experimentation in the law of enablement. A rule that allows evidence of efforts expended to rebut a prima facie reasonable expectation of success could draw from the factors that have been considered relevant on undue experimentation.[724] This framework of factors would allow the court flexibility to make policy decisions in emerging technologies without ignoring the traditional tests for a suggestion to combine references and a reasonable expectation of success.

An additional reason why empirical evidence should be considered is that it would allow the "reasonable expectation of success" test to remain consistent with the interchangeability test in the doctrine of equivalents.[725] Interchangeability serves as both a theoretical test and an empirical test in equivalency. It is the concept that links the theoretical tests of insubstantial differences and function-way-result to what actually occurs in the real world. The reasonable expectation test should be allowed to serve the same function in obviousness by linking the suggestion test to evidence of what reasonably would be required to successfully achieve the invention or discovery.

The argument against using evidence of efforts expended to rebut a prima facie case of reasonable expectation of success is that it decreases the threshold for patentability and changes the patentability question into a matter of effort rather then ingenuity. In a sense, this is true. However, section 103 of the patent statute states that the manner of making shall not negative the

---

[724] Factors relevant in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In re Wands, 858 F.2d 731 (Fed. Cir. 1988). An additional factor the court could consider is the need of the emerging technology for patent protection to provide incentives.

[725] The "reasonable expectation of success" and "interchangeability" tests are at the same conceptual level in equivalency and obviousness. Other terms in the two doctrines are at the same conceptual level as well. "Patentability" is at the same level as "infringement," and "obviousness" is at the same level as "equivalency," The theoretical analysis for obviousness (suggestion to combine references), is at the same level as the theoretical analysis for equivalency (insubstantial differences). Other subtests for "suggestion to combine references" are at the same level as the other subtests for "insubstantial differences" (structure, function-way-result). Finally, the empirical tests for obviousness are at the same conceptual level as the empirical tests for equivalency.

ability to get a patent.[726] Further, if an expensive and time consuming process of experimentation probably would not have been pursued but for the incentive of a patent grant, then absent such incentive, the DNA sequence determination can be conceptually thought of as not having a reasonable expectation of success.

The courts should be able to limit the use of efforts expended as the primary rebuttal evidence to facts where (1) a patent incentive must be retained to provide encouragement for investment of resources, and (2) other indicia of non- obviousness are not helpful, as in the case of determining DNA sequences from amino acid sequences. Such an approach would prevent evidence of efforts expended from becoming an easy and inappropriate method of rebutting a prima facie reasonable expectation of success in all areas of technology. Further, when a particular DNA sequence, or DNA sequences in general, become so easy to obtain that patent incentives are no longer needed as encouragement for experimentation, then the reasonable expectation of success should no longer considered to be rebutted. The courts should be able to decide the issue on a reasonably consistent basis by using the flexible framework discussed above, and by generally monitoring the progress of the technology and the need for patent incentives.

Although consideration of efforts expended is not a perfect solution, it is perhaps the best solution in the absence of *sui generis* legislation. It is appropriate because it bases non-obviousness on the very policy issue that the court should be concerned about - retaining patent incentives when patent incentives are needed to develop an area of technology. The approach is objective in the sense that it is based on empirical evidence of efforts expended, and the general state of the particular technology involved. It is also far more flexible than *sui generis* legislation, and should be adaptable to all new technologies as the need for patent protection arises, and as the need for patent protection disappears.

F. Prima Facie Case Procedure

The prima facie case procedure is sometimes needed to assist an examiner in meeting the initial burden of proving the claimed invention is obvious. This is particularly true when the required evidence is difficult or time consuming to obtain. The prima facie procedure achieved early success in the chemical arts where proof of functional similarity was often complex, but could be inferred from easily proven structural similarity.

The structural similarity test has proven to be ineffective in some areas of biotechnology. This is because the suggestion for a given DNA sequence does not result from its structural similarity to an amino acid sequence, but rather from the genetic code and lab procedures for discovering the correct sequence from a list of limited possibilities. An effective prima facie mechanism for biotechnology must take these differences into account.

The prima facie test for biotechnology discussed earlier focuses on the reasonable expectation of discovering a particular DNA sequence. Under this test, an examiner establishes

[726] 35 U.S.C. § 103.

a prima facie case by citing the amino acid sequence and the laboratory techniques for finding the DNA sequence. Rebuttal requires the applicant to raise an inference of lack of reasonable expectation of success. Ultimate victory on the issue requires the applicant to produce sufficient evidence that laboratory techniques were unreliable, the amino acid sequence insufficient, or that substantial efforts were expended to achieve the discovery.

The principles followed in formulating the prima facie test for biotechnology should be transferrable to other new technologies as well. Some form of a prima facie case will always be appropriate so the examiner can meet the initial burden of proof without obtaining and reviewing empirical evidence of non-obviousness. Whether a prima facie mechanism is needed on the suggestion test itself will depend on whether evidence that is difficult to obtain is required to prove the suggestion. For example, a prima facie procedure was not needed on the suggestion test in the mechanical arts because both structure and function could be determined by looking at the patent claims and the accused device. However, such a procedure was needed in the chemical arts since proof of similar function between different chemicals was often difficult for the examiner to obtain.

To determine whether a prima facie mechanism is needed on the suggestion test, a seven step process may be employed. The first step is to identify the type of prior art that may provide the suggestion for the claimed invention or discovery. In chemistry, the prior art consists of known chemical compounds. In the area of biotechnology that has been discussed, the prior art consists of the known amino acid sequence and known laboratory techniques for deriving the DNA sequence.[727] The second step is to determine the relationship between the prior art and claimed invention that may give rise to the suggestion to combine. In chemistry, the relationship is between the structure and function of the prior art chemicals and the structure and function of the claimed chemical. In biotechnology, the relationship is between the amino acid sequence and DNA sequence as determined by the genetic code, and the ability of laboratory techniques to identify the correct sequence from a limited list existing due to the redundancy of the code.

The third step is to identify the nature of the suggestion to combine. In chemistry, the suggestion exists because structure and function of known compounds suggests similar claimed compounds. In biotechnology, the suggestion exists because an amino acid sequence coupled with reliable laboratory techniques suggests the DNA sequence. The fourth step is to identify the proof necessary to establish the suggestion to combine. In chemistry, the proof is structural and functional similarity. In biotechnology, the proof is the amino acid sequence and a reasonable expectation of success with the known laboratory techniques.

The fifth step is to identify if any of the proof is difficult for the examiner to produce. In chemistry, functional

---

[727] The factual settings of chemistry and biotechnology are included to add context to the process.

similarity is difficult to produce. In biotechnology, proof of a reasonable expectation of success with the laboratory techniques may be difficult to produce. The fifth step is to determine whether these areas of proof can be supplied through inferences. In chemistry, functional similarity can be inferred from structural similarity. In biotechnology, a reasonable expectation of success can be inferred from known and reliable laboratory techniques. The sixth step is to determine whether the evidence upon which the inference is based can be obtained with relative ease by the examiner. The structure of a chemical is easily obtained. Whether a known laboratory technique is generally considered reliable should be relatively easy to obtain.

The seventh step is to determine whether the applicant has a reasonable chance of rebutting the inference through other evidence. In chemistry the evidence of functional similarity can be rebutted by proof that the claimed chemical functions differently or produces unexpected results. In biotechnology, the inference of a reasonable expectation of success can be rebutted through proof that the techniques were generally unreliable, unreliable in the specific application, or that substantial effort was required to achieve success. Since all seven steps can be determined and satisfied in both chemistry and biotechnology, the prima facie mechanisms described are appropriate and useful. By following the procedure outlined above, the necessity and proper form of prima facie mechanisms should be capable of being determined in other new fields of technology as well.

G. Relationship Between the Theoretical Tests in Equivalency

The three theoretical tests in equivalency are insubstantial differences, function-way-result, and interchangeability. Statements by the Federal Circuit and Supreme Court concerning the relationship between these three tests have left their status in a state of uncertainty. The Federal Circuit has explicitly held that "the application of the doctrine of equivalents rests on the substantiality of the differences between the claimed and accused products or processes, assessed according to an objective standard,"[728] and that "[o]ften the function-way-result test will suffice to show the extent of the differences."[729]

The Supreme Court has stated that the "essential inquiry" is whether "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention"[730], and that "different linguistic frameworks may be more suitable to different cases, depending on their particular facts."[731] The Supreme Court has further stated that "[a]n analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element,"[732]

---

728 Hilton Davis, 62 F.2d at 1519.

729 *Id.* at 1522.

730 Warner-Jenkinson Co., 117 S.Ct. at 1054.

731 *Id.*

732 *Id.*

One of the keys to understanding how the three tests relate to each other is to return to *Graver Tank*, where equivalency was expressed in terms of insubstantial differences, rather than function-way-result. In this case, the Supreme Court was prevented from explicitly comparing the "way" the claimed and accused chemicals in the fluxes performed due to their chemical nature. Rather, the court approved an empirical analysis that focused on the interchangeability of the chemical ingredients. Since the analysis had not been performed in the classic function-way-result manner, it was natural for the Court not to define the test in those strict terms. The Court instead expressed the test generally, in terms of insubstantial differences, which did not highlight the difficulty of analyzing "way."

However, from a conceptual standpoint, the Court had indeed performed a function-way-result test, but had used evidence of interchangeability to infer that the chemicals operated in substantially the same "way." The Court could therefore have stated that the function-way-result test was still appropriate and that evidence of interchangeability could be used to infer "way" when a mechanical type analysis of "way" could not be performed. Instead, the Court expressed the test in terms of the conclusion that the function-way-result test is designed to determine - the substantiality of the differences between the claimed and accused elements.

All of which leads to the following observations: Function-way-result is the method by which the substantiality of the differences is determined. Insubstantial differences is a conclusion drawn from application of the function-way-result test. When the "way" portion of function-way-result is difficult to determine, as in the chemical arts, the test should not be abandoned in favor of "insubstantial differences." Rather, proof of interchangeability and structural similarity should be considered to raise inferences that the accused element operates in substantially the same "way" as the claimed element.

In sum, equivalency is the ultimate issue to be determined. Substantiality of the differences is the factual standard by which equivalency is judged. Function-way result is the method by which substantiality of the differences is determined. And interchangeability can provide supporting inferences when any portion of function-way-result is difficult to directly determine.

H. Individual Element

As previously discussed, both the Supreme Court and the Federal Circuit have held that the equivalency analysis must be applied to individual claim elements, and not to the claimed invention as a whole. Further, the individual claim elements are to be considered in the context of the entire claim. Finally, since every claim element is considered important, it is impermissible to ignore or eliminate any claim element when performing the equivalency analysis.

The problem remaining with the doctrine of equivalents is how to objectively select an appropriate portion of the claimed invention for comparison that is less than the whole invention, but is not limited to the literal language of the claims. In other words, how to

appropriately and objectively select the elements, limitations, or series of limitations for comparison and preservation in the equivalency analysis. The solution in obviousness has suggested that an objective method should be used to select a predictable portion of the elements and limitations.

Early patent infringement case law used the distinguishing "principle" of the invention to define the portion of the invention that should be compared in an infringement analysis.[733] This approach might also be the appropriate way to select the elements and limitations to be used for doctrine of equivalents analysis, for two reasons. First, the distinguishing principle is the part of the invention that *should* be selected for protection because it is what the inventor has invented.[734] Second, the elements and limitations that claim the distinguishing principle can be objectively determined by analyzing the claimed invention in light of the prior art.[735] This objective determination should provide the consistency and predictability that is needed in the equivalency analysis. To determine whether the distinguishing principle of the invention should be the proper objective test to select elements and limitations for comparison and preservation, it is necessary to briefly retrace the development of patent infringement analysis and the doctrine of equivalents.

1. Early Reliance on the Principle of the Invention

---

733 *See* Winans 56 U.S. at 342.

734 The principle in Winans v. Denmead that the equivalents of a patented invention are just as much the invention as the invention itself was recently reaffirmed by the Supreme Court in Warner-Jenkinson. The legal principle was used to sweep away the notion that the doctrine of equivalents required proof of intent. ("If the essential predicate of the doctrine of equivalents is the notion of identity between a patented invention and its equivalent, there is no basis for treating an infringing equivalent any differently than a device that infringes the express terms of the patent." *Id.* at 11.

735 Nonspecific dicta exists in the case law that supports this approach in a general way. *See* Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d 1528, 1533 (Fed. Cir. 1987) (court aware of dicta stating that consideration of the "essence", "gist", or "heart" of the invention may be helpful in determining infringement under doctrine of equivalents, citing Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861 (Fed. Cir. 1985); Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1582 (Fed. Cir. 1984) (both citing Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567 (Fed. Cir. 1983)). Court further stated: "That dicta may not be read as implying that specific claim limitations can be ignored as insignificant or immaterial in determining infringement. It must be read as shorthand for the considerations set forth in Graver Tank, i.e., that the infringer should not appropriate the invention by making substitutions for those limitations, when the substitutions do not substantially change the function performed, or the way it is performed, by the invention.") *Id.*

The distinguishing "principle of the invention" approach was used early in patent infringement analysis. In *Winans v. Denmead*, discussed previously, an octagonal railcar frustrum design was compared against a patented conical railcar frustrum design. When determining whether the octagonal shape was infringing, the court inquired whether such shape had copied the distinguishing principle, or mode of operation, of the invention:

> It is generally true, when a patentee describes a machine, and then claims it as described, that he is understood to intend to claim, and does by law actually cover, not only the precise forms he has described, but all other forms which embody his invention; it being a familiar rule that, to copy the principle or mode of operation described, is an infringement, although such copy should be totally unlike the original in form or proportions.[736]
>
> ....
>
> And, therefore, the patentee, having described his invention, and shown its principles, and claimed it in that form which most perfectly embodies it, is, in contemplation of law, deemed to claim every form in which his invention may be copied, unless he manifests an intention to disclaim some of those forms.[737]

The court found that the distinguishing principle of the invention was not the precise conical shape of the frustrum, but rather the general frustrum shape that distributed the payload weight evenly and lowered the center of gravity of the railcar.[738] Finding that the octagonal frustrum copied this principle, the Court found infringement.[739]

2. Distinct Claiming Limits the Distinguishing Principle Approach

The ability of a court to use the principle of the invention to determine whether infringement existed became more difficult following an amendment included in the Patent Act of 1870.[740] This amendment required the applicant to "distinctly claim" what the applicant considered to be the invention.[741] The purpose of the amendment was to force the applicant to define and provide notice of the outer boundaries of the invention.[742] Following the 1870 amendment, courts began to shift the

---

736 56 U.S. at 342.

737 *Id.* at 343.

738 *Id.* at 344.

739 *Id.*

740 *See* Hilton Davis at 1566 (Judge Nies dissenting).

741 Act of July 8, 1870, Ch. 230, 16 Stat. 198, provided that the inventor "shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery."

742 *See* Hilton Davis at 1566 (Judge Nies dissenting). This change in focus has been described as a shift from central claiming to peripheral claiming. *Id.* at 1566.

infringement focus away from the principle of the invention, and toward the particular language used by the patentee to distinctly claim the invention.[743]

3. The Need for a Doctrine of Equivalents

Following the 1870 amendment, courts did not apply the distinct claiming requirement in a uniform manner.[744] Some courts applied the claiming requirement strictly, and refused to find infringement unless the accused device fell within the literal language of the claims.[745] The majority of courts, however, recognized that a patentee's rights could not be adequately protected unless some degree of flexibility was used when interpreting the claim language.[746] This was primarily because even precise and thorough claim language was unable to describe the outer boundaries of an inventive principle in all its possible forms. It was this need for flexibility in the face of a distinct claiming requirement that led to the creation of the doctrine of equivalents in its modern form.

4. Problems Created by the Doctrine of Equivalents

The flexibility of the doctrine of equivalents relieved the harshness of the distinct claiming requirement. However, it also created problems of ambiguity and uncertainty in the infringement analysis. Courts were faced with the following dilemma: How to consistently and predictably construe the range of equivalents to a patented invention when the analysis could not be based either completely on the distinguishing principle of the invention, or completely on the literal language of the claims. The courts were, in effect, left to subjectively slide between two opposing standards, neither one of which could be relied on completely for guidance.

The difficulties in the doctrine caused by the lack of a consistent, objective standard were compounded by patentees who argued for equivalency in a variety of circumstances. Patentees not only wanted the doctrine to cover different equivalent forms of a principle that had been properly claimed, but also to cover forms that would have, in effect, broadened claims that had been drafted too narrowly.

Use of the doctrine to determine the equivalents of a principle that had been properly claimed was appropriate. When the principle had been properly claimed, the analysis was relatively straightforward since the search for substantial equivalents could be based on the claim elements and limitations as drafted. However, when the claims were drafted too narrowly, i.e., when elements and limitations were included in the claims that were not necessary to distinguish the principle of the invention over the prior art, then a complex problem arose. Should the doctrine of equivalents be used to ignore unnecessary elements and limitations in order to protect the true distinguishing principle of the invention?

In that circumstance the patentee typically argued that the unnecessary elements and limitations should be

---

743 *Id.* at 1566, 1577.

744 *Id.* at 1567 (and cases cited therein).

745 *Id.*

746 *Id.* at 1568.

ignored. The argument was that since the patentee should receive the full benefit of the invention, only the elements and limitations that accurately described the distinguishing principle of the invention should be selected for comparison. The accused infringer, on the other hand, typically argued that no elements or limitations should be ignored because to do so would eliminate the definitional and notice function of the claims. The accused infringer also argued that since the patentee chose the claim language in question, the patentee should be bound by it. The inability of the courts to be completely persuaded by either argument caused continuing confusion and debate over the proper function of the patent claims and the doctrine of equivalents. However, eventually a consensus developed that the doctrine was too often being used to impermissibly broaden the patent claims, and was simply too unpredictable in its application and result.

5. Addressing the Problems

The Supreme Court and Federal Circuit have attempted to address the continuing problems in the doctrine of equivalents by reemphasizing the importance of the patent claims. Specifically, the courts have mandated that in the equivalency analysis, all claim elements are to be considered important, each should be examined individually, and none should be ignored.[747] This approach has done much to refine the equivalency analysis. However, as previously pointed out, the approach remains defectively incomplete because the term "element" has been left undefined and open to subjective interpretation.[748]

All of which brings us back to the question at hand: Is there an objective way to consistently determine what the term "element" means, and which elements and limitations should be selected and preserved in the equivalency analysis? The doctrine of equivalents has developed through the process of oscillating back and forth between an emphasis on the claiming requirement, and an emphasis on the principle of the invention. For example, the problem of impermissibly broadening the "principle of the invention" has been addressed by

[747] *See* notes 398-402 *supra* and accompanying text.

[748] It has been proposed that the different comparative methods used by the Federal Circuit can be harmonized if the approaches are seen to compare functionality of elements, rather then the elements themselves. *See* Ronald E. Larson, *Balancing the Competing Policies Underlying the Doctrine of Equivalents in Patent Law*, 21 AIPLA Q. J. 1 (1993) (discussing concept of "functional cooperation analysis"). While this observation seems valid, it does not solve the underlying problem: What breadth of functionality is to be chosen for comparison?

As previously discussed, individual claim elements, or their individual functions, can be given "some meaning" in the analysis - while still being effectively ignored on an individual basis - if they are absorbed into a broader function for comparison. Therefore, even under a functional approach, the choice of the functional breadth for comparison remains subjective and unpredictable.

reemphasizing the importance of the patent claim elements. Therefore, the problem of defining a patent claim "element," and selecting the proper elements and limitations for comparison and preservation, should logically be addressed by reemphasizing the distinguishing "principle of the invention." As it turns out, this is precisely what the Federal Circuit has been doing on an intuitive basis.

6. Defining Elements Based on the Principle of the Invention

The three cases of *Hughes Aircraft*, *Pennwalt*, and *Sumitomo* illustrate the point. In *Hughes Aircraft*,[749] the patent claims included an element or limitation that sent information concerning the position of the sun back to the earth for processing. The accused device did not contain this element because a post-patent grant advance in technology allowed the information to be processed by an on board computer. However, the court still found infringement because it determined that the distinguishing principle of the invention was the ability of the navigation system to receive information from the sun and to fire the jets appropriately. Since an element concerning the specific way this information was processed was not necessary to distinguish this principle from the prior art, the earth transmitting claim limitation could be ignored.

In *Pennwalt*,[750] the patent claims included an element that continuously tracked the location of the fruit. The accused device did not include this element. The Court found no infringement, however, because it determined that the distinguishing principle of the patented invention actually was the invention's ability to continuously track the fruit.[751] Therefore, this element could not be ignored without affecting the validity of the patent.

In *Sumitomo*,[752] the patent claims contained the element of a core with a positive dopant. The accused device did not contain this element. Rather, the accused device contained a cladding layer with a negative dopant. The court found no infringement because the distinguishing principle of the invention was the relationship between the core and cladding layers, not simply the characteristics of the core. The core could be individually ignored (and combined with another limitation) because it was not necessary to distinguish the principle of the invention (the refractive index) over the prior art.

The court in *Sumitomo* approved the district court's method of selecting the limitations for comparison and preservation in "the context of the invention."[753] This phrase is traditionally understood to mean that the elements must be interpreted in light of how they functioned with and

---

749 *See* notes 548-557 *supra* and accompanying text.

750 *See* notes 564-569 *supra* and accompanying text.

751 Pennwalt, *supra* at 937. (stating that "[o]riginally, the claims contained no position indicating means element with its associated functional limitations" and that "[t]he addition of that element was crucial to patentability").

752 *See* notes 570-581 *supra* and accompanying text.

753 *See* note 581 *supra* and accompanying text.

contributed to other elements of the invention. This meaning is not particularly helpful in selecting appropriate elements and limitations for comparison and preservation on a consistent and objective basis. What would have been more helpful, and accurate, for the *Sumitomo* court to explain is that elements and limitations chosen for equivalency analysis also should be determined based on the "distinguishing principle of the invention." This was, in fact, one of the factors that influenced the court's selection of limitations for comparison and preservation. It is the most accurate and complete way to express the concept of what is, and should be occurring in equivalency analysis, and is the most consistent and predictable way to select elements and claims for comparison and preservation.

Despite the apparent appropriateness of the principle of the invention as the objective method for selecting elements for comparison and preservation, legitimate concerns remain over preserving the definitional and notice function of the claims. If certain claim elements can be ignored or combined, even to legitimately protect the distinguishing principle of the invention, the definitional and notice functions of claims will be weakened. Further, if some claim elements simply can be ignored, then the whole purpose of the claim drafting requirement and the PTO is called into question. Finally, the United States Supreme Court has just declared that every element in a claim is important in the equivalency analysis, and no element is to be ignored.[754] An issue is therefore properly raised as to whether this statement is to be applied literally to the equivalency analysis.

There are several compelling reasons why certain claim language elements should be ignored in the equivalency analysis, and why the Supreme Court statement should not be applied literally. First, as recognized by the Supreme Court in *Warner-Jenkinson Co.*, sometimes language is included in the claims that is not intended to be limiting for patentability purposes.[755] Examples are terms included for adequate description and enablement under section 112.[756] If these terms are not ignored in an equivalency analysis, they might be unfairly converted into claim limiting elements.[757] Second, some substitutions are invented after the patent issues and are not contemplated by the claim drafter.[758]

---

754 *See* note 400 *supra* and accompanying text.

755 *See* Warner-Jenkinson Co., 117 S.Ct. at 1050.

756 This problem is virtually identical to the problem encountered with prosecution history estoppel.

757 If the applicant inserts these words into the claims initially to avoid examiner objections based on section 112, then a document would never be generated explaining the purpose of the language. In that event, the new presumption rule created by the Supreme Court in Warner-Jenkinson would be inappropriate because no reasonable opportunity would have arisen to explain the reason for the language.

758 *See, e.g.*, Hughes Aircraft, *supra* note 557.

The later developed technology may eliminate the need for various claim elements that were originally considered essential to the invention's distinguishing principle, but were later rendered nonessential.[759] It would be inappropriate to require the patent applicant to predict all future technological advances when drafting the patent claims. Third, although courts must compare claim elements individually, they also must compare them in the context of the entire claim or invention. A rule requiring an inflexible comparison of individual claim elements in a vacuum would seem to violate the spirit, if not the actual letter of the context rule.

But perhaps the most compelling reason not to apply the Supreme Court mandate literally is because the Supreme Court did not apply it literally themselves. The Court did not hold that the claim term "pH of approximately 6" was an element that could not be ignored. If the Court had, the Court would have concluded that since that element was not in the accused device, infringement did not occur as a matter of law. Instead, the Supreme Court remanded the case for further findings "related to prosecution history estoppel and the preservation of some meaning for each element in [the claims]."[760] The Supreme Court requested the Federal Circuit to determine whether the term "pH of approximately 6" should be considered a claim "element" whose meaning should not be completely eliminated from the equivalency analysis.[761] As discussed above, the only objective way to make such a determination is based on the *distinguishing principle of the invention in light of the prior art*, together with the "context of the particular claim."

7. The Final Test

Based on the above analysis, it is reasonable to conclude that some claim language may be ignored on an individual basis when applying the doctrine of equivalents, and that the "distinguishing principle of the invention" approach should be used to make the determination. The question then becomes what precise form the test should take. The challenge is to find an approach that is consistent with Supreme Court and Federal Circuit authority, and that appropriately balances the distinguishing principle of the invention in light of the prior art with the definitional and notice functions of the claims.

Fortunately, the test has formulated itself. It is simply that the term, element, or limitation may be ignored individually if (a) it is not necessary individually to distinguish the principle of the invention from the prior art, and (b) the comparison that occurs, be it functional or otherwise, preserves some meaning for the term, element, or limitation.[762] This expression of the test

---

759 *Id.*

760 Warner-Jenkinson Co., 117 S.Ct. at 1054.

761 *Id.*

762 The patentee will usually want to select a broad functional comparison that captures the accused product as an potential equivalent. This will be allowed as long as such comparison is based on the distinguishing principle of the invention. For a specific application of this principle to the *Hilton Davis* case,

is appropriate because it uses the distinguishing principle of the invention approach to protect the inventor's interest, yet gives meaning to the distinct claiming requirement by requiring that the comparative process preserve some meaning for the claim language.[763]

I. Comprehensive List of Factors

The test for equivalency recently has been restated to be whether the differences between the claimed invention and the accused device are insubstantial.[764] The Federal Circuit has not limited the type of evidence that may be considered probative of this issue, other than to say the evidence must be "relevant."[765] The Federal Circuit concurrence and dissent in *Hilton Davis* points out that such vague direction does not cure any uncertainty remaining in the doctrine of equivalents.[766]

A prior section of this paper has suggested that a way to reduce the uncertainty in this area is to review all potential comparative factors and select those that might be relevant.[767] By this process, both patentees and accused infringers alike would at least be aware of the general areas and factors that should be considered in the equivalency and infringement analysis. The most comprehensive way to identify all potential factors for comparison is to review the general patenting process itself.

1. General Patenting Process

The usual first step in the general process of patent prosecution and patent protection is that something is invented or discovered that solves a problem or satisfies a need.[768] Next, an application for patent is made that includes specific claims and an enabling disclosure.[769] A dialogue then occurs between examiner and attorney in which the examiner compares the claims against the prior art.[770] Usually this dialogue generates documentation concerning the patenting process that may narrow the claims or further define the invention.[771] Following completion of the dialogue, a patent may be granted. If a patent is granted, a product or process may be developed by another that is accused of infringing the patent.[772] The patented embodiment and the accused product might or might not be commercially successful.

---

see notes 836-839 *infra* and accompanying text.

763 The requirement to preserve some meaning for each claim element honors the Supreme Court mandate in Warner-Jenkinson and prevents a court from having to "sift through the entirety of the patent description to determine what [are] the material elements embodying the "principle" of the invention for ... infringement purposes." Hilton Davis, 62 F.2d at 1565 (Judge Nies dissenting).

764 Hilton Davis, 62 F.3d at 1519.

765 *Id.* at 1522.

766 *Id.* at 1534, 1563.

767 *See* note 663 *supra* and accompanying text.

768 *See generally* Adelman, Radar, Thomas, Wegner, PATENT LAW (1997); Kayton, PATENT PRACTICE (1-5) (Sixth Ed. 1995).

769 *Id.*

770 *Id.*

771 *Id.*

772 *Id.*

This process may be thought of as involving ten different elements that can be considered as comparative factors. The first element is the actual claiming language that defines the patented invention, both in terms of structure and function. The second element is the prior art, existing as tangible embodiments, documents, and common knowledge. The third element is the enabling disclosure contained within the patent application. The fourth is the developmental history of the invention, including efforts of the inventor and attempts by others. The fifth is the patent prosecution history. The sixth is the problem solved or need satisfied by the patented invention. The seventh is the degree of commercial success achieved by the patented invention. The eighth is the structure and function of the accused product or process. The ninth element is the developmental history of the accused product or process. And the tenth is the commercial success of the accused product.

2. Potential Comparative Factors

a. The Claims

The patent claims are presently a relevant comparative factor in equivalency. This is appropriate because the patent claims describe the structural and functional elements and limitations that are compared against the accused device in an equivalency analysis. The patent claims may also serve as a limitation to equivalency because they may contain amendments giving rise to prosecution history estoppel.[773]

b. The Prior Art

The prior art is not a direct comparative factor in equivalency because equivalency compares the patent claims with the accused device, and not with the prior art. However, the prior art is a limitation on equivalency.[774] If the accused device with its substituted element is disclosed in or rendered obvious by the prior art, the substituted element cannot be an equivalent. It is important to remember that it is the accused device as a whole that must be disclosed in or rendered obvious by the prior art, and not the individual accused element. Individual elements and limitations may exist in the prior art and still be considered equivalents. This rule will be particularly important to remember now that the Supreme Court has confirmed that the equivalency analysis is to be done on an individual element basis. The prior art exists as tangible embodiments, documents, and common knowledge, all of which may contribute to limitations on equivalency.

c. Patent Application Disclosure

The patent application enabling disclosure is relevant to equivalency in that it can be used to interpret the patent claims, which are then compared against the accused device.[775] The disclosure can also serve as a limitation to equivalency because it may contain language giving rise to prosecution history estoppel, and may contain disclosed but unclaimed subject matter

[773] *See* notes 488-504 *supra* and accompanying text.

[774] *See* notes 511-514 *supra* and accompanying text.

[775] *See* note 540 *supra* and accompanying text.

that cannot be recovered through equivalency.[776]

d. Developmental History of the Invention

The developmental history of the invention encompasses activity by the inventor, attempts by others, and the length of time the invention was needed and sought. The developmental history of the invention is not considered relevant to the substantiality of the differences between the accused device and patent claims. This is because the developmental history of the invention cannot measure the substantiality of the differences in any way. The invention's developmental history may possibly serve as a limitation to equivalency to the extent that it produces prior art that creates limitations to the range of equivalents.[777]

e. Patent Prosecution History

The patent prosecution history is relevant to equivalency for the same reasons that the claims, the disclosure, and the prior art are relevant. It is through the process of patent prosecution that claim meaning is refined, and that changes are made to the claims and disclosure that may give rise to an estoppel on equivalency.[778]

f. The Problem Solved

The problem solved is relevant to equivalency because an accused device that solves a different problem than the claimed device is not likely an equivalent. This is because it performs a substantially different function than the claimed device. This issue is not usually a significant comparative factor in equivalency because a device that solves a different problem is not usually accused of infringement.

g. Commercial Success of Claimed Invention

The commercial success of the claimed invention has been mentioned, at least tangentially, in connection with the concept of equivalency.[779] The argument apparently is that the commercial success of the invention indicates the invention is a pioneer, or at least important, and therefore should be afforded a broad range of equivalents.[780] This paper argues that an inquiry into pioneer status is not useful and should be abandoned in the equivalency analysis.[781] Commercial success therefore should not be considered relevant to equivalency because pioneer status is not to be considered in the equivalency analysis, and because commercial success is not relevant to the substantiality of the differences between

---

776 *See* notes 491-510 *supra* and accompanying text.

777 *See* note 511 *supra* and accompanying text.

778 *See* notes 488-504 *supra* and accompanying text.

779 *See* Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 39, 40 (1929).

780 In Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, (Fed. Cir. 1987), the patentee argued that the commercial success of the invention indicated that the invention was a pioneer and should be afforded a broad range of equivalents. *Id.* at 1532. In response, the court stated "[t]hat an improvement enjoys commercial success and has some industry impact, as many do, cannot compel a finding that an improvement falls within the pioneer category." *Id.*

781 *See* note 832 *infra* and accompanying text.

the claimed product and the accused device.

h. Accused Product

The accused product is highly relevant to equivalency. Indeed, it is the elements and limitations of the accused product that are compared with the patent claims to determine whether their structures and functions are equivalent.

i. Developmental History of Infringing Product or Process.

The developmental history of the accused product is currently considered relevant to equivalency. The developmental history refers to the manner in which the accused product was made. Specifically, whether the accused infringer copied the patent claims, designed around the patent claims, developed the accused product independently, or performed independent experimentation.[782]

The developmental history of the accused device is currently considered relevant to the issue of equivalency for four reasons. First, evidence of "copying" is thought to create an inference that the differences between the claimed and accused devices are insubstantial. Second, evidence of "designing around" is thought to create an inference that the differences are substantial. Third, evidence of independent development is allowed to rebut an allegation of copying. And fourth, according to the Supreme Court, evidence of independent experimentation may support or refute an inference of "known interchangeability," which is an objective factor relevant to equivalency.

To be effective in the equivalency analysis, the preceding inference framework may require some clarification. First, although insubstantial differences are to be inferred from "copying," and substantial differences are to be inferred from "designing around," the Federal Circuit has failed to explain how, or if, a distinction is to be drawn between the "intentional copyist" and "incremental innovator" who produce the exact same product after reviewing the patent claims. Indeed, a person who intentionally attempts to "design around" patent claims may ultimately achieve less in objective substantial differences than one who intentionally "copies," but makes minor changes to avoid literal infringement. In the words of Justice Thomas writing in *Warner-Jenkinson Co.*, the present explanation of the relevance of copying and designing around "leaves much to be desired."[783]

There are at least two significant problems created by using the terms "copying" and "designing around" in an objective determination of equivalency. First, these terms are subjective conclusions that, probably to most generalist judges and lay jurors, are heavily dependent on evidence of intent. Copying is likely seen as an intentional (and bad) act of piracy, and designing around is likely seen as an intentional (and honorable) act of invention. Although judges and jurors will want to instinctively search for evidence of intent when evaluating evidence of copying and designing around, they will be instructed that intent should play no part in their decision.

---

[782] *See* notes 473-487 *supra* and accompanying text.

[783] 117 S.Ct. at 1052.

The second problem is that "copying" and "designing around" are not evidence at all. Rather, they are conclusions drawn from various underlying facts. And since evidence of intent can play no part in the equivalency analysis, evidence of copying and designing around must be drawn from other objective facts. These objective facts consist primarily of the substantiality of the differences between the claimed and accused devices, and the amount of resources expended by the accused infringer after a review of the claims. These are, after all, the objective facts from which one typically infers whether something has been "copied" or "designed around." The obvious problem which arises is that it is circuitous to reason that the substantiality of the differences may be inferred from evidence of copying and designing around, when copying and designing around are in large measure inferred from the substantiality of the differences.

The end result of using evidence of "copying" and "designing around" in the equivalency analysis is that the fact finder is predisposed to considering evidence of intent, but can't, and is told to determine the substantiality of the differences by considering evidence that, in turn, is determined in large part by the substantiality of the differences. This unfortunate and confusing result suggests that the terms "copying" and "designing around" are unnecessary and misleading, and should perhaps be dropped from the equivalency analysis altogether.

The other objective evidence potentially capable of supporting an inference of substantiality of the differences is the amount of resources expended on the accused product after the patent claims have been reviewed. The reasoning might be that substantial resources expended on an accused product following a review of the patent claims infers substantial differences from the claims, and insubstantial resources expended infers insubstantial differences. Are such inferences valid, useful, and relevant?

The relationship of the amount of resources expended to the substantiality of the differences is complex. It is probably true that, in general, it takes more time, effort, and money to produce a substantial change from a patent claim after it is reviewed than it does to produce an insubstantial change. However, it is also true that a substantial amount of resources may be expended to produce only an insubstantial change (or no improvement),[784] and an insignificant amount of resources may be expended to produce substantial changes. This is because the test for substantiality of the differences depends on the differences themselves, and not in the amount of effort and money expended to achieve them.

However, given the complexity of modern technology, it is difficult in some fields of art to achieve a substantial difference from the patent claims without a substantial investment in resources. In fields where a substantial investment is virtually required to achieve a substantial

---

784 *See, e.g.*, Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1352 (Fed. Cir. 1983) (stating that "[d]espite huge expenditures, the government never solved the technical problem of attitude control.").

difference from the patent claims, evidence of an insubstantial investment would seem to at least create a useful inference of an insubstantial difference.

Resources expended might also be relevant if the term "substantiality" in the phrase "substantiality of the differences" were considered to include the amount of resources reasonably required to achieve the difference. For example, in the field of biotechnology, assume two proteins contain active sites for catalyzing reactions or cleaving other proteins. The first protein's active site is well understood both in terms of structure and function. Following a relatively insignificant amount of time, money, and effort expended, two amino acid substitutions are made that increase the reaction rate of the protein by fifteen percent.

The structure and function of the second protein's active site are poorly understood. Following a substantial amount of difficult, time consuming, and expensive experimentation involving numerous failures of many amino acid substitutions, ultimately two amino acid substitutions are made that improve the efficiency of the protein by fifteen percent. Assuming all other things are equal, should the differences achieved by the second protein be considered more substantial than the first based solely on additional resources expended?[785]

If the focus of the substantiality of the differences test is solely on function, way, and result, then the answer is no. However, if the concept of "substantiality" is considered to include the relative difficulty of achieving the given difference in light of the prior art and the circumstances of the case, then the answer may be different. Traditionally, however, the amount of experimentation required to achieve a given result has been only relevant to the question of enablement, and a substitute need not be enabled to be an equivalent.[786]

Evidence that the accused product was independently developed currently can rebut allegations of copying. In the event copying is dropped from the equivalency analysis, this rebuttal would no longer be necessary. Evidence of independent development could also rebut an inference of insubstantial differences based on insubstantial resources expended in the event this factor is deemed relevant by a court. Of course, evidence of substantial independent development should avoid the initial inference altogether.

The second concern with the preceding inference framework concerns the relevancy of independent experimentation to known interchangeability. In *Warner-Jenkinson*, Justice Thomas offered an alternate explanation for why evidence of

---

[785] The policy arguments on the issue cut both ways. On one hand, if amount of resources expended was considered relevant to substantiality of the differences, research and design around efforts would be encouraged. On the other hand, such a rule may encourage waste, reward inefficiency, and turn the infringement question into one of dollars rather than ideas, which would favor large corporations over individual inventors.

[786] *See* Pall v. Micron, 66 F.3d 1211, 1220 (Fed. Cir. 1995).

independent experimentation might be relevant to an equivalency analysis:

> But another explanation is available that does not require a divergence from generally objective principles of patent infringement. In both instances in Graver Tank where we referred to independent research or experiments, we were discussing the known interchangeability between the chemical compound claimed in the patent and the compound substituted by the alleged infringer. The need for independent experimentation thus could reflect knowledge - or lack thereof - of interchangeability possessed by one presumably skilled in the art. The known interchangeability of substitutes for an element of a patent is one of the express objective factors noted by Graver Tank as bearing upon whether the accused device is substantially the same as the patented invention. Independent experimentation by the alleged infringer would not always reflect upon the objective question whether a person skilled in the art would have known of the interchangeability between the two elements, but in many cases it would likely be probative of such knowledge.[787]

This is probably a more accurate interpretation of *Graver Tank's* reference to the absence of independent experimentation leading to an inference of "imitation." However, further clarification may be needed concerning the differences between the inferences created by the *absence* of independent experimentation, and the inferences created by the *presence* of independent experimentation. The above language in *Warner-Jenkinson* does not clearly distinguish between the two. This could lead to confusion because there does appear to be a difference, and *Graver Tank* did not address the issue of what inferences should be drawn from the *presence* of independent experimentation.

As intimated in *Graver Tank*, the absence of independent experimentation should be considered relevant to the issue of substantiality of the differences. This is because an absence of independent experimentation infers imitation by the accused infringer, and such imitation infers that the accused element was already known to be interchangeable with the claimed element. Prior knowledge of interchangeability, in turn, is evidence that those of ordinary skill in the art would consider the elements interchangeable at time of infringement. Knowledge of interchangeability at the time of infringement by those of ordinary skill in the art is considered by

[787] 117 S.Ct. at 1052.

the Supreme Court to be relevant to substantiality of the differences.[788]

However, evidence of the *presence* of independent experimentation does not support an inference that the accused element is *not* interchangeable with the claimed element.[789] This is because independent experimentation only infers lack of knowledge of interchangeable before the independent experimentation occurred. It does not infer lack of knowledge of interchangeability at the time of infringement, which is when evaluation of interchangeability occurs. Indeed, the Supreme Court stated in *Warner-Jenkinson* that "a skilled practitioner's knowledge of the interchangeability between claimed and accused elements is not relevant for its own sake, but rather for what it tells the fact-finder about the similarities or differences between those elements."[790] Simply because one of ordinary skill would not have possessed *knowledge* of interchangeability before independent experimentation occurs, does not mean that such person would not consider the two elements to be interchangeable at the time of infringement (necessarily after the experimentation occurs).

Evidence of the *presence* of independent experimentation becomes relevant in the event the patentee attempts to prove interchangeability at the time of the infringement by offering evidence that persons skilled in the art had previously considered the accused and claimed elements to be interchangeable. Such proof was offered in *Graver Tank*. In that event, evidence that the interchangeability of the accused element was discovered through independent experimentation would tend to refute proof that others knew of the interchangeability before the infringement (and experimentation) occurred.

However, the independent experimentation evidence only tends to refute the evidence of prior knowledge of interchangeability (which is being used by the patentee to establish an inference of interchangeability at the time of infringement). It is not directly relevant on the issue of whether those of ordinary skill in the art would consider the accused and patented elements to be interchangeable at the time of the infringement. Interchangeability at the time of infringement depends on the qualities of the accused element itself, not on the way it was discovered or developed.

j. Commercial Success of Accused Product

Although the commercial success of the accused product is relevant to the

---

788 This is because a substituted element that performs the same function and achieves the same result as a claimed element in the context of the claim is presumed to operate in the same way as the claimed element as well.

789 However, if *the results* of independent experimentation revealed a lack of interchangeability, this evidence would obviously be probative of a lack of interchangeability. *See, e.g.*, Tanabe Seiyaku Co., Ltd. v. U.S. Intern. Trade Com'n, 109 F.3d 726, 733 (Fed. Cir. 1997) (stating that applicant's "unsuccessful experiments with butanone indicate that the inventors did not consider butanone to be interchangeable with acetone for use in the claimed N-alkylation process.").

790 *Id.*

nonobviousness of the claimed invention,[791] it traditionally has not been considered relevant to the equivalency analysis. However, in the appropriate circumstances, it should be considered relevant.[792] In the event the patented and accused products are priced and marketed substantially the same, and the accused product is commercially successful while the claimed invention is not, an argument could be made that the difference in commercial success establishes an inference of substantial differences between the claimed and accused products. The reasoning would be similar to the rationale for allowing evidence of commercial success on the issue of nonobviousness. The inference of substantial differences would be rebuttable by proof of different price and marketing conditions.

3. Summary of Relevant Factors

In sum, the factors that should be considered relevant in equivalency are 1) the claimed and accused structure, 2) the claimed and accused function, 3) the way the claimed and accused function is performed, 4) the results achieved by the claimed and accused devices, 5) the interchangeability of the claimed and accused elements, 6) when appropriate, the amount of resources expended by the accused after reviewing the patent claims,[793] 7) whether the accused performed independent experimentation or research when developing the accused product, and 8) the commercial success of the accused product. The factors of intent, copying, designing around, pioneer status of the claimed invention, and commercial success of the claimed invention should not be considered.

J. Comparing the Factors

Obviousness and equivalency seek to compare the claimed invention against other subject matter according to a number of factors. The conclusion suggested by each factor may either corroborate or conflict with conclusions reached by other factors. There is currently no comprehensive analytical framework or guide for weighing the competing factors on a reasonably consistent basis. Until such a guide is developed, conclusions drawn from the comparative analysis will tend to be unpredictable. A comparative guide might be developed through the process of identifying and analyzing the various factors, noting their relative weights,

---

791 *See* Truswal Systems Corp. v. Hydro-Air Engineering, Inc., 813 F.2d 1207, 1212 (Fed. Cir. 1987); Willemijn Houdstermaatschaapij BV v. Apollo Computer, Inc., 707 F. Supp. 1429, 1434 (D. Del. 1989) (stating that "evidence of defendant's 'commercial success' is a relevant secondary consideration in a determination of obviousness under 35 U.S.C. section 103.")

792 *See, e.g., Baxter Diagnostics, Inc. v. AVL Scientific Corp.*, 924 F.Supp. 994, 1020 (C.D.Cal., Apr. 25, 1996) (commercial benefits deemed relevant). This case also deemed relevant to the issue of substantial differences the contemporaneous expressions of opinion by experts. *Id.*

793 In the event evidence of substantial resources expended is considered relevant and permitted to establish an inference of insubstantial differences, evidence of independent development should be allowed to rebut the inference.

and describing predictable patterns of result.

1. Equivalency

The Federal Circuit allows consideration of evidence beyond function-way-result on the issue of substantiality of the differences. Specifically, in *Hilton Davis*, the court considered evidence of interchangeability, copying, designing around, and indirectly, independent development. These additional factors have been refined by previous analysis in this paper to interchangeability, resources expended (under appropriate circumstances), independent experimentation, and independent development. The complete list of potential comparative factors for equivalency is therefore structure, function, way, result, interchangeability, resources expended, independent development, independent experimentation, and when appropriate, the commercial success of the accused product.

With the comparative factors identified, the challenge is to develop a method for comparison that will yield predictable results over a broad range of facts and technologies. To do that, it is necessary to understand how everything fits together. We begin with structure. The structure of a claimed and accused product in an equivalency analysis are always different. This is because if the structures were exactly the same, infringement would be literal. The point of the equivalency analysis is to determine whether a given change in structure should still be considered, in law, as an equivalent, and therefore as an infringement.

To make this determination, all other characteristics of the claimed and accused products are compared. A comparison is made between the functions performed by the claimed and accused products, the ways the functions are performed, and the results achieved. As long as all these characteristics can be determined and compared, the equivalency analysis can be performed.

Sometimes, however, function-way-result cannot be easily determined. For example, in the chemical arts it is often difficult to determine the precise way in which a chemical ingredient performs a given function, or accomplishes a certain result. In that event, other evidence must be found from which one can infer the "way" of a chemical ingredient. One method of inferring "way" is to determine whether the accused element is interchangeable with the element it was substituted for in the claimed product. This method is effective because the accused element is placed in the exact same environment previously occupied by the claimed element to determine whether it performs substantially the same function and achieves substantially the same result as the claimed element.

If the accused element does prove interchangeable in terms of function and result, then a rebuttable presumption is established that it also operates in substantially the same way as the claimed element. This presumption may be rebutted by evidence that the accused element operates in a substantially different way than the claimed element. One common way of proving that a person of ordinary skill in the art would consider an accused element to be interchangeable with a claimed element is to offer evidence that the two elements were considered

interchangeable in the past. In the event such evidence is offered, it may be rebutted by evidence that the interchangeability of the accused element was sought through independent experimentation, and could not have been previously known.

Examination of structure is an additional way of establishing an inference concerning "way." If the structure is substantially similar, an inference exists that the way the structure produces a given result is substantially similar.[794] Conversely, if the structure is substantially different, an inference exists that the "way" is substantially different.[795] However, when inferences drawn from structure and interchangeability conflict, the inference drawn from interchangeability should govern unless the change in structure is so different that the accused element cannot possibly operate in the same way as the claimed element.

An additional factor that might be considered relevant to the analysis in the appropriate circumstances is the amount of resources expended. Insubstantial expenditures may provide an inference of insubstantial differences in a situation where substantial expenditures are usually required to achieve substantial differences. Of course, the inference is rebuttable by credible evidence of serendipity or independent development. Evidence of resources expended will usually be a weak inference only useful for corroboration.

In sum, the ultimate test for proving equivalency is substantiality of the differences between the claimed and accused products on an individual element basis. Substantiality of the differences is determined primarily by comparing function-way-result.[796] When evidence of "way" is unavailable or inconclusive, inferences on this point may be supplied by evidence of interchangeability and structural similarity. Evidence of actual past interchangeability can be rebutted by evidence of independent experimentation. In this analysis, evidence of interchangeability typically does not compete with evidence of function-way-result, but rather supplies a portion by inference when it is unknown or inconclusive. To the extent that evidence concerning interchangeability and structural similarity lead to opposite inferences, the interchangeable inference should govern unless the structural proof is particularly compelling. Evidence of resources expended on the claimed invention and the commercial success of the accused product is relevant in the appropriate circumstances.

2. Obviousness

A claimed invention is obvious when the prior art 1) suggests the claimed invention to one of ordinary skill in the art, 2) motivates such person to make the claimed invention, and 3) provides such person a reasonable expectation of success in achieving the claimed invention.[797] A claimed invention may also be considered to be obvious or nonobvious based on

---

794 *See* notes 460-468 *supra* and accompanying text.

795 *Id.*

796 The difference in structure may be so great that function-way-result is not useful.

797 *See* notes 123-177 *supra* and accompanying text.

empirical evidence.[798] The factors relevant to this analysis are the prior art, the claimed invention, and the empirical factors of commercial success, long felt but unsatisfied need, failure of others, copying by others, contemporaneous reaction by the industry, licensing of the patented invention, skepticism of experts, unexpected results, departure from other principles in the art, simultaneous invention, and any other relevant real world evidence.[799]

Suggestion, motivation, reasonable expectation of success and the ultimate conclusion of obviousness or non-obviousness can be determined through two different methods. First, by the theoretical method of analyzing prior art references according to the appropriate definitional standard. Second, through the empirical method of analyzing real world evidence. The results of these tests usually will be consistent and will complement each other. Sometimes, however, the results of the theoretical and empirical methods may conflict. For example, a suggestion to combine references in the prior art may be found, but the need for the invention may have been long standing, the prior efforts of others to solve the problem intense, and the commercial success of the product great. Additionally, the empirical factors may conflict with each other. For example, long felt need and failure of others may not be accompanied by commercial success, and vice versa.

When the comparative factors conflict, the determination of obviousness becomes somewhat uncertain. The challenge in this area is to try to develop a predictable, yet flexible framework or guide that can add consistency to the obviousness analysis even when the factors conflict. The place to begin is with the one bright line rule concerning the general relationship between the theoretical and empirical factors.

The cardinal rule in obviousness is that there must be a suggestion to combine references found in the prior art, or obviousness cannot be established. Therefore, the only conflict that can occur between the theoretical and empirical evidence is when a suggestion is found in the prior art, and the empirical evidence conflicts with it. The suggestion will lead to a conclusion of obviousness, and the empirical evidence will lead to a conclusion of non-obviousness. Any ultimate conclusion must necessarily depend on the relative strengths of the various factors, which will vary from case to case. However, the purpose of both the suggestion test and the empirical factors is to determine whether obviousness can be inferred from the relevant evidence. Therefore, the appropriate way to determine the relative strength of each comparative factor is to determine the strength of its inference.

The relative strength of the suggestion to combine references[800] is influenced by many factors. These include: the clarity and source of the references; whether the suggestion is express or implied; whether the references all come from the same field of art, or whether an analogous field of

---

798 *See* notes 208-229 *supra* and accompanying text.

799 *See* notes 219-229 *supra* and accompanying text.

800 The suggestion to combine references is itself an inference.

art has been consulted; how related such analogous field is; whether some prior art references teach away from the suggestion; whether resort must be had to common knowledge or logic; how many references are needed to construct the suggestion; and whether the reference comes from a solution to a different problem, and how similar the problem is. Additionally, the strength of the suggestion is influenced by how strong the reasonable expectation of success is, i.e., when references suggest a range of possible solutions, how difficult and extensive the effort and experimentation must be.[801]

With regard to the empirical factors, the relative strength of each will necessarily depend on the quality and quantity of evidence in each case and the strength of its nexus to the claimed elements. However, the strength of an empirical factor can also be determined by analyzing the strength of its inferences, which in turn depend on at least five factors. First, the number of inferences that must be linked to reach the inferred fact. Second, the quality and quantity of evidence supporting each inference link. Third, the number and probability of other possible inferences for the factor. Fourth, the ease with which these alternative inferences may be disproved. Fifth, whether the factor is accompanied by other corroborating factors.

In general, the greater number of inferences that must be linked together to establish a finding of obviousness, the weaker the finding of obviousness will be.[802] Although there is no prohibition in the federal courts against linking inferences to establish a fact,[803] the greater the number of inferences that are required, the more speculative the conclusion will be. This is because an inference based upon another inference not only suffers from its own weaknesses, but from the weaknesses of its supporting inferences as well. Therefore, the strength of any particular factor will in large part depend upon how many inferences it must be link together, how strong the evidence is on each linked inference, and how many alternative inferences there are for each fact.

In general, an empirical factor should be given less weight when it requires more than one inference link to establish the ultimate fact, the quality and quantity of evidence on each inference is low, there are many alternative explanations for each inference link that are difficult to disprove, and the factor is not corroborated by other factors. Conversely, a comparative factor should

---

801 *See* notes 720-726 *supra* and accompanying text.

802 *See generally* W. E. Shipley, Modern Status of the Rules against basing an Inference upon an Inference or a Presumption upon a Presumption, 5 A.L.R. 3d 100 (1966) (August, 1996 Supplement).

803 *See* Fenner v. General Motors Corp., 657 F.2d 647, 650-51 (5th Cir. 1981), *cert. denied*, 455 U.S. 942 (1982) (under federal law there is no prohibition against pyramiding inferences; instead all inferences are permissible so long as they are reasonable); *see also* Cora Pub, Inc. v. Continental Casualty Co., 619 F.2d 482, 486 (5th Cir. 1980).

be given more weight when only one inference is required, the quality and quantity of evidence supporting the inference is high, few or no alternate explanations for the inferred fact are possible, and other corroborating factors are present.

The strengths of the various empirical factors vary considerably when they are evaluated according to this criteria. For example, the failure of others is a relatively strong inference of nonobviousness. Evidence that others actually attempted and failed to invent the claimed invention provides a single direct inference that one of ordinary skill in the art would not have considered the claimed invention obvious. The evidence on this inference will necessarily be strong because it will always consist of proof that no one else invented the claimed invention. Further, if others were attempting to solve the same problem facing the inventor and failed, there is no alternative explanation for the failure other than the solution was nonobvious.

Conversely, evidence of licensing is a relatively weak inference of nonobviousness. It requires the first inference that the licensing was due to the need for the claimed invention, the second inference that the licensor attempted to fulfill this need through inventive efforts and failed, and the third inference that such failure was due to the nonobviousness of the invention to a person of ordinary skill in the art. An alternative inference exists that the licensor made a business decision to license the product rather than pay development or litigation costs. This alternative inference is hard to disprove.

The strengths of some factors will vary considerably according to the evidence in the individual case. For example, commercial success may be considered either strong or weak. This factor is based on four inferences. First, that the commercial success was due to the patented feature. Second, that the commercial success of the patented feature was due to a long felt or unrecognized need. Third, that the long felt or unrecognized need was due to failed attempts by others to invent the patented feature. And fourth, that the failed attempts by others were due to the nonobviousness of the patented feature to one of ordinary skill in the art.[804] Several alternative inferences exist for evidence of commercial success. The success could be due to greater market power of the retailer or wholesaler, superior distribution channels, intense marketing and advertising efforts, or the very fact that a patent was granted. These alternative inferences can be difficult to disprove. Commercial success is considered a more reliable indicator of nonobviousness when it is accompanied by evidence of long felt need and failure

---

[804] Kitch identified four slightly different inferences a judge must make to conclude nonobviousness from market success: "First, that the commercial success is due to the innovation. Second, that ... potential commercial success was perceived before its development. Third, the potential commercial success having been perceived, it is likely that efforts were made to develop the improvement. Fourth, the efforts having been made by men of skill in the art, they failed because the patentee was the first to reduce his development to practice. Kitch, *supra* note 234 at 332.

of others to achieve the patented product. Such evidence, in effect, supplies direct evidence of the second and third inferences in the commercial success inference chain.

It is also helpful to consider that the empirical factors represent events that fall generally into one of three time periods: the period before the invention, the period contemporaneous with the invention, and the period after the invention. Occurring generally before the invention are the empirical factors of long felt but unsatisfied need, failure of others, belief the invention could not be done, and departure from other principles in the art. Occurring contemporaneous with the invention are unexpected results, contemporaneous reaction by the industry, and skepticism of experts. Occurring after the invention are copying by others, licensing of the patented invention, and commercial success.

In general, it is thought that events occurring before and during the invention are the more reliable indicators of nonobviousness. This is because factors occurring after the invention are more easily influenced by matters not related to the obviousness or nonobviousness of the patented claims. Such a time period analysis is consistent with the inference analysis discussed above. This is because all inference chains leading from events occurring after the invention are longer, and necessarily weaker, than inference chains leading from events occurring before and during the invention.[805]

With regard to the relative weight between the theoretical and empirical factors, the Federal Circuit has stated that empirical evidence "may be the most probative and cogent evidence in the record"[806] and "may often establish that an invention appearing to have been obvious in light of the prior art was not."[807] Such evidence may be especially useful when "differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field."[808] Further, empirical type evidence "may often prevent a court from slipping into an impermissible hindsight analysis."[809] Such statements by the court suggest that certain empirical factors should be given more weight than the suggestion test. Indeed, in some instances,

---

[805] To reach their ultimate destination of nonobviousness, all inference chains, with the exception of contemporaneous expressions of disbelief by experts, eventually relate back through "long felt need" and "failure of others," which are events occurring before the invention occurred. *See, e.g.,* the second and third inference link for commercial success above, and the first and second inference link for licensing above. Therefore, all inference chains which begin with events occurring after the invention occurred will necessarily be longer than inference chains leading from events occurring before and during the invention occurred. The contemporaneous expressions of disbelief by experts are direct evidence that one of ordinary skill in the art would not have considered the invention to be obvious.

[806] *See* Stratoflex, 713 F.2d at 1538.

[807] *Id.*

[808] *See* Continental Can Co., 948 F.2d at 1273.

[809] *See* Vandenberg, 740 F.2d at 1567.

empirical factors may directly refute the suggestion to combine. For example, if the suggestion to combine of a chemical is based on structural similarity to the prior art, evidence of unexpected results will refute the suggestion and lead to a conclusion of non-obviousness.

However, in light of the wide variety of evidentiary factors that might arise in any particular case, it is inadvisable to develop any rigid comparative framework, or even to suggest hard rules for comparison. Rather, it is best to develop a flexible guide that at most describes rebuttable presumptions. In such a guide, the empirical factors can first be classified as being generally strong or weak according to the five criteria listed above. The suggestion might then also be classified as being either generally strong or weak. Following such a classification, the factors can be compared in light of various presumptions, each of which may be rebutted upon an effective showing of contrary proof.

In general, strong empirical evidence of nonobviousness that arises before or during the invention and requires a single inference should be presumed to prevail over a suggestion to combine references. This is because actual evidence of nonobviousness should be considered more probative than theoretical evidence of obviousness. However, a suggestion to combine references should be presumed to prevail over empirical evidence that arises after the invention and requires multiple inferences, unless the empirical evidence is particularly compelling and preferably corroborated. This is because if no empirical evidence exists that arose before or during the invention and a suggestion to combine is present, the presumption should be that the empirical evidence arising after the invention did so due to factors other than the nonobviousness of the invention, such as marketing or advertising. Of course, each of these presumptions depends highly on the strength of the factor and nexus in the particular case, and each presumption may be rebutted.

K. Matter of Law/Fact and Submission to the Jury

Obviousness is considered to be a question of law and equivalency is considered to be a question of fact.[810] Although there is a conceptual distinction between questions of law and fact, in practice the dividing line is blurry and rather easily manipulated. It is probably more important that both obviousness and equivalency are considered to be mixed questions of law and fact, and that both can be submitted to a jury for resolution.[811] As a practical matter, the distinction between law and fact only becomes important when an appropriate standard of review must be chosen on motion for JMOL or on appeal.

In the event issues of obviousness and equivalency are submitted to a jury, the submission may be made in one of three different ways. First, on a general verdict with accompanying instructions. Second, on special verdicts with accompanying instructions.[812] And third, on a general verdict with interrogatories and accompanying

---

[810] *See* notes 278, 602 *supra* and accompanying text.

[811] *See* notes 278-288, 602-611 *supra* and accompanying text.

[812] *See* FED. R. CIV. P. 49(a).

instructions.[813] The method of submission is within the discretion of the trial court, and will not be reversed on appeal unless an abuse of discretion is shown.[814]

The benefits and limitations of the three methods of submission have been debated by courts, practitioners, and scholars.[815] Special verdicts and general verdicts with interrogatories are beneficial in patent cases because they identify the disputed issues for the jury, and make the verdict easier to review on JMOL and on appeal.[816] Without such guidance, a jury may be overwhelmed by the amount of law and disputed fact it must absorb and resolve.[817] On the other hand, general verdicts are more widely used in general litigation, are easier to submit, and are thought to contain less traps for the unwary.[818]

In *Warner-Jenkinson*, the United States Supreme Court stated that "a special verdict and/or interrogatories on each claim element could be very useful in facilitating review, uniformity, and possible postverdict judgments as a matter of law."[819] However, the Court left it to the Federal Circuit to implement any procedural improvements. Although the Federal Circuit has expressed a strong preference for special verdicts and interrogatories in patent cases,[820] it has not mandated such a submission.[821] Indeed, it is presently unclear whether the Federal Circuit even has the general supervisory authority to direct that special issues/interrogatories be used by district courts in patent cases.[822]

The pressure to mandate any particular form of jury submission may have been reduced by recent case holdings of the Supreme Court. In *Markman*, the Court held that claim interpretation was a matter of law exclusively for the court, and thereby removed complex issues of disputed claim language from the jury. In *Warner-Jenkinson*, the Court directed that equivalency must focus on individual claim elements, and identified legal issues that might be appropriate for resolution by the court on summary judgment and JMOL. These holdings should reduce the amount of law and disputed fact that a jury must attempt to understand and decide. Although special issues and interrogatories make patent jury trials more reliable, predictable, and consistent, the case to

---

813 *See* FED. R. CIV. P. 49(b).

814 *See* Structural Rubber Prods., 749 F.2d at 720.

815 *See, e.g.*, Paul R. Michel & Dr. Michelle Rhyu, *Improving Patent Jury Trials*, 6 FED. CIRCUIT B. J. 89 (1996); Charles W. Bradley, *The Changing Role of Juries in Patent Litigation*, 416 PLI/Pat 113 (1995); Tramontine & Johnston, *Patent Law Developments 1985: The Case for General Verdicts in Jury Trials*, 213 PLI/Pat 97 (1985).

816 *Id.*

817 *Id.*

818 *See* Tramontine, *supra.* (It should be noted that the authors of this article were making the arguments therein primarily *arguendo.)*

819 Warner-Jenkinson Co., 117 S.Ct. at 1053, n. 8.

820 *See. e.g.*, Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1516 (Fed. Cir.), *cert. denied*, 469 U.S. 871 (1984); Connell, 722 F.2d at 1547.

821 *See Improving Patent Jury Trials*, *supra* at 95, n. 23.

822 *Id.* at 102-104.

specifically mandate their use in patent cases may not be as strong following *Markman* and *Warner-Jenkinson*.

Proper instructions to the jury concerning contested issues of fact will continue to be important. The courts should strive to make such instructions clear, simple, and thorough, using plain language whenever possible. The complex inference analysis explained in the previous section has the potential for confusing a jury. However, such complexity should be manageable if appropriate general jury instructions are given on the nature of rebuttable single and multiple inferences, and the remaining complexity, if any, can be handled on jury argument. The complete inference analysis can be employed by trial courts when reviewing motions for summary judgment, motions for JMOL, and when the court is sitting as the finder of fact. Appellate courts may employ it when reviewing jury verdicts and rulings of the trial court.

L. Definitions

The meanings of certain terms used to describe important concepts in obviousness and equivalency are sometimes less than clear. The confusion may be caused by different terms being used to describe the same concept, or the same term being used to describe two different concepts. For example, a suggestion is sometimes described as a "suggestion," an "inference," a "motivation,"or a "teaching."[823] The term "motivation" is used variously to describe 1) a reason to combine references,[824] 2) a reason to explore an analogous field of art,[825] and 3) a reason to invent something.[826] The "secondary considerations," which are not secondary, are sometimes described as the "objective considerations,"[827] although all factors in obviousness are objective.

Independent development may be described as independent experimentation, and vice versa, although the terms should be thought of as being distinct.[828] The difference between an element, a limitation, and a series of limitations in a claim continues to cause uncertainty, although the Federal Circuit has attempted to provide guidance on this issue.[829] The

---

[823] *See, e.g.*, In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987) ("teaching, suggestion, or incentive"); In re Nilssen, 851 F2d 1401, 1404 (Fed. Cir. 1988) (motivation).

[824] In re Nilssen, 851 F2d at 1404.

[825] *See* In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

[826] *See* In re Stemniski, 444 F.2d at 586.

[827] *See, e.g.*, W.L. Gore & Assocs., Inc. 721 F.2d at 1553 ("objective considerations")

[828] *See* note 486 *supra* and accompanying text. *See also* Hilton Davis 62 F.3d at 1548 (Judge Lourie dissenting) ("Independent development is not, as the majority states, dependent upon lack of knowledge of the patented invention.")

[829] *See* Sumitomo at 1259 ("Element" may be used to mean a single limitation, but it has also been used to mean a series of limitations which, taken together, make up a component of the claimed invention.... In the All Elements rule, 'element' is used in the sense of a limitation of a claim."); Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d at 1533 n. 9 ("References to

uncertainty in this area will become more problematic in the wake of the Supreme Court's statement that some meaning must be preserved for each "element" in a claim. The very phrase "function-way-result" has caused confusion in the past,[830] and will likely in the future in light of the Supreme Court's "linguistic framework" and "word choice" descriptions.[831] The poor case reader is sometimes bewildered and left wondering if various terms are legal synonyms, or have significant distinctions in meaning.

Although some concepts are difficult to describe or define, and language is by its very nature imprecise, the Federal Circuit should continue its attempts to eliminate linguistic confusion in obviousness and equivalency by defining and using terms, to the extent it is possible, in standard and precise ways. The bar and lower courts should reciprocate in opinions, motions, and briefs. Good lexicography should help reduce some of the confusion in obviousness and equivalency, or at least keep it better defined.

M. Pioneer Status

The term "pioneer status" is a convenient way of expressing the notion that a claimed invention represents a "distinct step in the progress of the art," and should be afforded a broad range of equivalents.[832] However, the reason a broad range of equivalents is allowed is not because the invention is pioneering, but rather because there is very little prior art to limit the range of equivalents.[833] It is therefore the amount of prior art that determines the range of equivalents, and it is the range of equivalents that leads to the conclusion of whether a patent is pioneering.

There is no precise point when the evolving amount of prior art in a certain field will change the status of an invention from pioneering to non-pioneering. Rather, the amount of prior art exists on a smooth continuum. Any attempt to divide this continuum into pioneering inventions on the one hand, and non-pioneering inventions on the other hand, is subjective in the midranges. Therefore, the conclusory term "pioneer patent" is subjectively determined, and has no useful function in an objective analysis. The range of equivalents should be determined directly by the prior art, and not by a subjective conclusion drawn from the prior art. The concept of a pioneer patent does not increase objectivity, precision, or consistency in the equivalency analysis and therefore should be abandoned.

"elements" can be misleading.... [C]larity is advanced when sufficient wording is employed to indicate when "elements" is intended to mean a component ... of an embodiment of an invention and when it is intended to mean a feature set forth in or as a limitation in a claim.").

[830] *See* Genentech, Inc., 29 F3d at 1570 (Judge Lourie concurring)

[831] Warner-Jenkinson Co., 117 S.Ct. at 1054.

[832] The term "pioneer" patents was used by the Supreme Court in Warner-Jenkinson to suggest "that the abandonment of "central" claiming may be overstated." Warner-Jenkinson Co., 117 S.Ct. at 1048, n. 4.

[833] *See* notes 616-621 *supra* and accompanying text.

VII. Construction of the Calculus

With the foregoing analysis as a predicate, a comparative calculus may be constructed for obviousness and equivalency.

A. Obviousness

In the context of patent prosecution, a patent application is initially presumed to be nonobvious. The examiner looks for a suggestion to combine references in the relevant prior art as a whole to establish a prima facie case of obviousness. The prima facie case in the particular area of technology is derived from the source of the suggestion to combine, the relationship between the prior art references, the difficulty of obtaining evidence, and the ease to which the inferences can be established and rebutted.

Adequacy of the suggestion to combine is determined by the strength of the inferences after weighing all relevant prior art references. The suggestion to combine must be accompanied by motivation and a reasonable expectation of success. In the appropriate circumstances, the reasonable expectation of success may be determined by the amount of effort required to achieve the claimed discovery or invention.

If a suggestion to combine is found, a prima facie case of obviousness is established. The applicant then attempts to rebut the prima facie case with empirical evidence of nonobviousness such as commercial success, long felt but unsatisfied need, failure of others, copying by others, contemporaneous reaction by the industry, licensing of the patented invention, skepticism of experts, unexpected results, departure from other principles in the art, simultaneous invention, and any other relevant real world evidence.

If the empirical evidence raises an inference of nonobviousness, the prima facie case is rebutted with the initial inference being completely destroyed, and the evidence is examined anew. When making the consideration anew, the examiner must compare and weigh the theoretical suggestion evidence with the empirical evidence. The weight to be given an empirical factor depends on the number of inferences it requires, the quality and quantity of evidence supporting each inference, the number of alternate explanations for the inferred fact, the strength of the evidence on the alternative inferences, and whether other corroborating factors are present.

In general, strong empirical evidence of nonobviousness that arises before or during the invention and requires a single inference should be presumed to prevail over a suggestion to combine references.[834] However, a suggestion to combine references should be presumed to prevail over empirical evidence that arises after the invention and requires multiple inferences, unless the empirical evidence is particularly compelling and preferably corroborated. Each of these presumptions depends highly on the strength of the factor and nexus in the particular case, and each presumption may be rebutted. A final decision is then made as to whether the invention is obvious.

The issue of obviousness may be submitted to the jury either upon a general verdict with or without

[834] Empirical evidence of this type would include failure of others, comments by experts, and unexpected results.

interrogatories, or upon a special verdict. Accompanying interrogatories or a special verdict are preferred. The trial court should make the decision based upon the facts of the particular case.

B. Equivalency

Equivalency is determined by whether insubstantial differences exist between the accused and claimed devices on an individual element basis. Insubstantial differences, in turn, are determined by the two tests of function-way-result and interchangeability at time of infringement, as supplemented by empirical evidence of interchangeability, structure, independent experimentation, and independent development. Evidence of interchangeability at time of infringement may provide an inference that the accused and claimed elements function in substantially the same "way".

Evidence of interchangeable in the past is relevant to whether a person of ordinary skill would consider the accused and claimed elements interchangeable at time of infringement. Past knowledge of interchangeability can be rebutted by evidence of independent experimentation. Lack of independent experimentation may also establish an inference that the differences were insubstantial if significant experimentation is usually required to achieve substantial differences in the particular field of art. Evidence of independent development may rebut this inference.

Evidence of structural similarity between the accused and claimed elements may also provide an inference that the two operated in substantially the same "way". In the appropriate circumstances, evidence of the commercial success of the accused device and lack thereof by the claimed invention may provide an inference of substantial differences. Evidence of intent, copying, designing around, and the commercial success of the claimed invention is not to be considered in the insubstantial difference analysis. Further, the status of the claimed invention as a "pioneer" or "non-pioneer" is not to be considered.

The first step in the equivalency analysis is claim construction. The second step is selection of the elements to be compared according to the distinguishing principle of the invention in light of the prior art. The third step is application of potential limitations on equivalents such as prior art, prosecution history estoppel, and disclosed but unclaimed subject matter. Assuming any questions of fact remain, the appropriate method of submission to the jury is chosen and appropriate instructions are drafted based upon the evidence in the particular case.

VIII. The Comparative Calculus Evaluated

A. Introduction

The comparative calculus will now be evaluated by using two cases of current interest that reveal weaknesses and uncertainty in the doctrines of obvious and uncertainty as they currently exist. Aspects of the obviousness calculus will be tested by *In re Deule*, and aspects of the equivalency calculus will be tested by *Hilton Davis*.

B. Obviousness

1. Case Study - *In re Deule*

The case of *In re Deule*[835] involves patent claims covering isolated and purified DNA and cDNA molecules encoding human and bovine heparin-binding growth factors ("HBGFs"). HBGFs are proteins that help repair or replace damaged tissue by stimulating cell division. Deuel obtained the DNA and cDNA sequences for bovine HBGF by (1) isolating and purifying the protein from a bovine uterus, (2) determining the first 25 amino acids of its N-terminus, (3) constructing a oligonucleotide probe from such sequence and screening a cDNA library to isolate the correct cDNA with the probe, and (4) purifying and sequencing the cDNA. Deuel discovered the bovine cDNA had a sequence of 1196 nucleotide base pairs. From this, Deuel predicted the entire amino acid sequence of bovine HBGF.

Deuel then screened a human cDNA library with the bovine probe, isolated the correct cDNA, and purified and sequenced the human cDNA. Deuel found the human cDNA had a sequence of 961 nucleotide base pairs. From this sequence, Deuel predicted the complete amino acid sequence of human HBGF. The predicted sequences of both human and bovine HBGF had 168 amino acids, 163 of which were identical.

Deuel filed patent claims covering the DNA sequence encoding the 168 amino acid sequence for human HBGF (Claim 4), the cDNA of the disclosed sequence of human HBGF (claim 5), the DNA sequence encoding the 168 amino acid sequence for bovine HBGF (Claim 6), and the cDNA of the disclosed sequence of bovine HBGF (claim 7). The claims were rejected by the examiner and the board as being obvious over two prior art references.

The first reference disclosed the first 19 amino acids in the N-terminal sequence of human and bovine heparin binding brain mitogens ("HBBMs"). HBBMs are proteins useful in treating burns and repairing tissue (particularly brain tissue). The 19 disclosed N-terminal amino acids in HBBM were identical to the first 19 amino acids in the N-terminal of HBGF. The second reference disclosed a general method of isolating DNAs or cDNAs by screening a DNA or cDNA library with a gene probe.

On appeal, the Federal Circuit held the claims were nonobvious over the prior art and reversed. The court accepted Deuel's argument that normally the test for prima facie obviousness of structural claims is structural similarity, and that no prior art reference contained structure that suggested the claimed DNA and cDNA structures. The court further held that the disclosed HBBM 19 amino acid sequence and general method for screening DNA and cDNA libraries using gene probes did not render Deuel's claims obvious since the genetic code is redundant and the method reference was not relevant.

2. Application of Comparative Calculus

The comparative calculus does not restrict the prima facie case to structural similarity. Rather, in the DNA-amino acid context, the appropriate prima facie case consists of finding references in the prior art that suggest the correct DNA sequence and

[835] 52 F.3d 1552 (Fed. Cir. 1995). (the case will be described without footnotes)

that provide a reasonable expectation of successfully determining such sequence. The reasonable expectation of success can depend on how much time, effort, and money is required to determine the particular DNA sequence.

The prior art in *Deuel* consisted of a partial amino acid sequence to the protein HBBM that had a similar function to the claimed protein, but which came from the brain instead of the uterus. The prior art also described a general cloning technique for screening cDNA and DNA libraries with oligonucleotide probes. The prior art reference containing the partial amino acid sequence of HBBM suggested the protein was brain tissue specific, but was highly homologous between species. These references may be sufficient to establish a prima facie suggestion for the claimed cDNA and DNA sequences along with an inference that a reasonable expectation of success exists. Although the prior art reference taught that the HBBM protein was tissue specific, in the absence of any other prior art references suggesting homology between tissue types, the examiner may be able to rely on the "analogous art" or "analogous problem" principle to establish an initial inference. Of course, the reference teaching away from the claimed discovery would affect the strength of the reference. In any event, for the purposes of this paper evaluation, a prima facie case will be assumed.

The burden then shifts to the applicant to rebut the prima facie case. In addition to the lack of a reference suggesting amino acid sequence homology between tissue types, the applicant could produce evidence that (1) only a partial amino acid sequence was revealed in the prior art, (2) due to the amino acid sequence and the redundancy of the genetic code, a large number of different DNA sequences were possible, and (3) a significant amount of resources would need to be spent on isolating the proper sequence. In addition, to the extent that the isolated DNA sequence contained codons that did not follow the preferred codon pattern, the applicant could produce evidence of unexpected results that increased the amount of effort required. This evidence would likely rebut the prima facie case and the examiner would have to review all the evidence anew.

In making the final determination on obviousness, the examiner should review the evidence in light of the reliability of the procedures when the discovery was made and how much time, effort, and money was required to discover the correct sequence. The pivotal issue will be whether such evidence establishes that the applicant did not have a reasonable expectation of success of determining the DNA sequence. If a reasonable expectation is not found, the DNA sequence will be nonobvious and patentable. The evidence necessary to make this determination is not contained in the opinion.

C. Equivalency

1. Case Study - *Hilton Davis*

The facts in *Hilton Davis*[836] have been set forth earlier. The Supreme Court remanded the case to the Federal Circuit to determine the effect that prosecution history estoppel and the requirement that some meaning be

[836] The case will be described substantially without footnotes.

preserved for each element in a claim might have on the claim language "at a pH from approximately 6.0 to 9.0". The Federal Circuit in turn remanded the case to the district court. The pH limitation was apparently included during patent prosecution to distinguish a prior art patent that disclosed an ultrafiltration process operating at a pH above 9.0. The reason for the lower limit pH of 6.0 was in dispute. The accused infringers claimed the lower limit was added due to foaming problems and because the process was shown not to work below that level. The plaintiffs claimed the process was shown to work without problems to a pH as low as 2.2, but offered no reason why the 6.0 lower limit was included. The accused process operates at pressures of 200 to nearly 500 p.s.i.g., and at a pH of 5.0. The specific issue is therefore whether a pH of 5.0 is equivalent to a pH of 6.0.

2. Application of Comparative Calculus

The first issue at this point in the equivalency analysis is whether any legal limitations exist to prevent the range of equivalents from extending to a pH of 5.0. The Supreme Court in *Warner-Jenkinson* established a presumption that unless the reason for the amendment was clear, it would be presumed to relate to patentability and prosecution history estoppel would apply.[837] The reason for the amendment is unclear. However, the concurrence in *Warner-Jenkinson* states that this rule should not be applied woodenly to cases in which the patentee had no notice during prosecution that the new presumption would apply,[838] and the case was indeed remanded to the district court to afford the plaintiff an opportunity to explain the reason for the amendment.

In the event the purpose for the amendment is explained to be something other than to avoid the prior art, then prosecution history estoppel should not apply. The prior art would then have to be checked to determine whether any references existed that would render the accused infringer's process either anticipated or obvious. If such prior art existed, the 5.0 pH could not be an equivalent as a matter of law. It is important to note that the entire accused process must be considered in this prior art analysis, and not merely the pH of 5.0.

On remand, the Federal Circuit reconsidered the equivalency issue and determined that substantial evidence existed to support the jury's verdict that the accused process contained "insubstantial differences" from the claimed process. This determination was performed by the court with a "function-way-result" and "interchangeability" analysis. The specific evidence relied upon by the Federal Circuit was that one of ordinary skill in the art considered a pH of 5.0 to be interchangeable with a pH of 6.0 at the time of infringement. Since the ultrafiltration process worked equally well at pH's of 6.0 and 5.0, the equivalency analysis was straightforward and relatively easy to resolve.

A more complex issue would have been presented if the evidence had indicated that foaming had occurred at a

[837] Warner-Jenkinson Co., 117 S.Ct. at 1051.

[838] *Id.* at 1054, 1055.

pH of 5.0, or that the process did not otherwise work at a pH of 5.0, and such differences in function, way, or result were considered substantial. In that event, should plaintiff automatically lose? The answer depends on how the court chooses to preserve "some meaning" for each element in the claim." In *Sumitomo*, discussed earlier, the court did not require the accused device to have a positively doped core because the function-way-result compared was the core's functional relationship with the cladding layer, and not the core by itself. In *Hughes*, discussed earlier, the court did not need to find an element in the accused device that radioed information back to earth for calculations because the function-way-result compared was the processing of information received from the sun and transmitted to the jets, and not the particular location of the processing devices. Each of these determinations, as previously discussed, was made based on the distinguishing principle of the invention in light of the prior art.

Under the reasoning of *Sumitomo* and *Hughes*, a court might find in *Hilton Davis* that the function-way-result to be compared is not the pH levels by themselves, but rather the functional relationship existing between the pH levels, the pressure levels, and the membrane pore sizes. In that event, if a pH of 5.0 caused substantial differences to occur in function-way-result, the membrane pore sizes and pressure levels (and perhaps other variables such as temperature) could be adjusted to reduce the differences. These other adjustments could be changed to any value as long as the relationship between the variables remained within the parameters of the invention's principle and did not read on the prior art. In the event a permitted change of variables (for example a pressure increase up to 500 p.s.i.g.) reduced the differences in function-way-result to insubstantial when the pH was lowered to 5.0, then insubstantial differences could once again be shown by the plaintiff.

Would such a comparison still preserve "some meaning" for a pH value of approximately 6.0? If the court determined that the meaning of the pH value did not arise independently, but rather as a result of its functional relationship with the other variables, then some meaning would be preserved as long as the original functional relationship with the other variables was retained as the pH dropped to 5.0 (the other variables would have to be adjusted in some manner to retain the relationship as the pH dropped). The determination of whether such a comparison would be proper depends on the breadth of the distinguishing principle of the invention in light of the prior art. If the necessary functional relationship between the variables was already known in the relevant prior art and the plaintiff's invention was only a narrow improvement of the broader principle, then any functional comparison should be limited accordingly.[839] However, if the

[839] It appears that the functional relationship between the variables was not disclosed in the prior art. *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc., 64 F.3d 675 (Fed. Cir. 1995) (unpublished) ("The Bulletin does not suggest the particular combination of membrane pore sizes,

distinguishing principle of the plaintiff's invention was the broad functional relationship between variables that accomplishes the desired function-way-result, then any functional comparison up to and including the distinguishing functional relationship should preserve "some meaning" to all the variables involved.

IX. The Comparative Calculus Tested

A. Introduction

Protein Chemistry is the latest technology to challenge and expose the weaknesses in obviousness and equivalency doctrine. Two cases that illustrate the applications are *In re Mayne*[840] (obviousness), and *Genentech v. Wellcome Foundation Limited*[841] (equivalency). In this section, these two cases are described in detail, and the problems in obviousness and equivalency within them are explained. The comparative calculus is then applied to determine if the problems can be effectively addressed. The case on equivalency is discussed first so its facts might also be used to test obviousness. As an aid to understanding the science involved, this section will begin with an introduction to protein chemistry.

B. Protein Chemistry

1. Introduction - Proteins

Proteins serve many diverse and important functions in living organisms. For example, proteins may function as structural building blocks in cells, as enzymes to catalyze reactions, as carrier molecules and membrane channels to transport other important biochemicals, as regulators and polymerases in the DNA replication process, and as communication signals within cells and across cell membranes.[842] The function of a protein depends on its structure, and the overall structure of a protein, in turn, depends primarily on the protein's amino acid sequence[843].

The amino acid sequence of a protein consists of a series of amino acid residues connected by peptide bonds.[844] There are twenty different naturally occurring amino acids,[845] each of which contains a side chain that is unique in molecular shape and electrical charge.[846]

---

pHs, and pressures for purifying food dyes as claimed in the "746 patent.").

840 104 F.3d 1339 (Fed. Cir. 1997).

841 29 F.3d 1555 (Fed. Cir. 1994).

842 *See* Alberts, et al, MOLECULAR BIOLOGY OF THE CELL, Third Edition, 111-135 (1994); *See also generally* Branden & Tooze, INTRODUCTION TO PROTEIN STRUCTURE (1991) (hereinafter "PROTEIN STRUCTURE").

843 *See* PROTEIN STRUCTURE at 3, 4.

844 *Id.*

845 The eight nonpolar (hydrophobic) amino acids are Alanine (ala), Valine (val), Leucine (leu), Isoleucine (ile), Proline (pro), Methionine (met), Phenylalanine (phe), and Tryptophan (trp). The seven polar (hydrophilic) amino acids are Glycine (gly), Serine (ser), Threonine (thr), Cysteine (cys), Tyrosine (tyr), Asparagine (asn), and Glutamine (gln). The two negatively charged (acidic) amino acids are Aspartic acid (asp) and Glutamic acid (glu). The three positively charged (basic) amino acids are Lysine (lys), Arginine (arg), and Histidine (his). CONCEPTS OF GENETICS, *supra* at 500, 501.

846 Kyte, STRUCTURE IN PROTEIN CHEMISTRY, at 58-69 (hereinafter "PROTEIN CHEMISTRY").

The specific sequence of amino acids (called the primary structure), determines both the shape of the substructures consisting of alpha helices, beta sheets, and loops (the secondary structure), and the overall shape of the protein (the tertiary structure, and if more than one polypeptide is involved, the quaternary structure).[847] Since polypeptide chains are typically fifty to five thousand amino acids long[848] and each position along the chain can be filled by one of twenty amino acids, an almost infinite number of diverse primary and tertiary protein structures are possible.

Many different forces affect how the primary structure of amino acids will ultimately fold into the protein's unique secondary and tertiary structures. The alpha helix, beta sheet, and loop secondary structures in a protein are determined primarily by (1) steric interactions between amino acid side chains that allow the protein backbone to adopt only a limited number of conformations[849], and (2) hydrogen bonds that form between the backbone atoms, backbone and side-chain atoms, and between the amino acid residues and the surrounding water.[850] An important consideration is whether an amino acid residue is hydrophobic, with a tendency to avoid hydrogen bonding with water and reside in the protein interior, or hydrophilic, with a tendency to form hydrogen bonds with water and reside on the protein exterior.[851] These hydrogen bonding patterns are sensitive to changes in the aqueous environment of the protein, such as changes in pH, temperature, and ionic strength.[852]

The tertiary structure of a protein is also determined, in large part, by the hydrogen bonds that occur between the various secondary structures, their side chains, and the water solvent.[853] Additionally, tertiary structure can be affected by covalent bonds that occur between side chains, such as disulfide bonds that can occur between two cysteine amino acid residues.[854] Finally, tertiary structure may be affected by external, non-environmental factors such as metal ion cofactors that serve to stabilize the protein structure, post-translational modifications to the polypeptide chain such as the covalent attachment of sugar residues, and chaperon molecules that help the polypeptide chain fold into its proper conformation.[855]

2. Amino Acid Changes - Structural

Targeted amino acids changes in polypeptide chains are now routinely

---

847 PROTEIN STRUCTURE at 11-19; PROTEIN CHEMISTRY, at 197-210.

848 PROTEIN CHEMISTRY, at 58.

849 *See* PROTEIN CHEMISTRY, at 197-209.

850 *See* Stickle, et al, *Hydrogen Bonding in Globular Proteins*, 226 J. Mol. Biol. 1143 (1992) (hereinafter *Hydrogen Bonding*).

851 *See* PROTEIN CHEMISTRY, at 179-188.

852 *Id.* at 164-168.

853 *See* PROTEIN STRUCTURE, Chapter 2.

854 *Id* at 5.

855 *See* Moran, et al, BIOCHEMISTRY 5-31, 5-32, Second Edition (1994) (chaperons); MOLECULAR BIOLOGY OF THE CELL, at 606-609 (glycosylation); *see also* Lewin, GENES V, at 21-27 (1994).

performed in the laboratory through site specific mutagenesis procedures.[856] It has previously been stated that the structure and function of a protein are derived almost exclusively from the protein's primary amino acid sequence. However, experiments have shown that many amino acid changes made to a polypeptide chain have little to no effect on the structure or function of the protein. To understand why this is so, it is necessary to understand the overall structural organization of a protein molecule.

The amino acid residues in a protein fall into two broad functional categories: an underlying structural, or scaffolding function, from which the overall shape of the protein molecule is built up[857]; and an active site function that can perform such diverse duties as catalyzing reactions, binding to DNA, forming bonds with other molecules, and in general, forming highly specific binding and reactive sites that possess unique electrical charge and structural characteristics.[858] Most of the amino acids in a protein serve as structural support for the relatively small active sites. A rough analogy might be made to the surface of the human body, where the vast majority supports the small active sites consisting of fingers for binding, eyes and ears for recognition, and mouth and nose for catalyzing reactions.

In addition to making up a majority of the protein, the structural elements of the polypeptide chain are redundant, or over determined. By this it is meant that the amino acids that form the secondary structure, or scaffolding of the protein, collectively contain more than enough internal information or instructions to fold to and retain the appropriate structural form.[859] This phenomenon results from a variety of factors.

First, the overall shape of the protein is built up from secondary structures that, due to steric interactions and hydrogen bonding patterns, usually assume only two forms: a helical spring type structure known as an alpha helix, and a roughly planar type structure known as a beta pleated sheet.[860] Additionally, the links, or loops, that form between the secondary structures all tend to be right handed and do not form kinks or knots. Therefore, the fundamental building blocks of proteins are limited in number and generally are regular in pattern and shape.

Second, the change of a single or a few amino acids in an alpha helix or beta pleated sheet usually will not alter the shape of the secondary structure. This is because most of the hydrogen bonds that form in the secondary structure are between backbone atoms that are common to all amino acids.[861]

---

856 *See* Mendel, et al, *Site-Directed Mutagenesis with an Expanded Genetic Code*, 24 Annu. Rev. Biophys. Biomol. Struct., 435 (1995).

857 *See* PROTEIN STRUCTURE, at 249.

858 *Id.* at 18.

859 *See* DeGrado, et al, *Protein Design, a Minimalist Approach*, 243 Science 622 (1989).

860 *See* PROTEIN STRUCTURE, at 12.

861 *See Hydrogen Bonding, supra* note 850 at 1156 (most of the protein [on average 82%] is involved in regular, hydrogen bonded, secondary structure,

Additionally, the bonding forces and hydrophobic or hydrophilic characteristics of a given stretch of amino acids tend to be cumulative in nature and are defined more accurately on a moving average basis than by the characteristics of any single amino acid.[862] This cumulative effect can also be understood in terms of the marginal stability of proteins and the changes in free energy that occur in the folding process.[863] Further, many amino acids share approximately the same polar, nonpolar, positive or negative charge identities and roughly the same physical geometry and packing characteristics[864]. All these qualities result in secondary structural building blocks that can successfully tolerate and absorb many individual amino acid changes without losing their fundamental identities as helices, sheets, or loops.

Third, there are a limited number of *combinations* of secondary structure that tend to form, remain stable, and ultimately constitute proteins. It has been previously mentioned that since any one of twenty amino acids may reside at a given position in the long polypeptide chain, an almost unlimited number of different polypeptides can form. However, due to energy considerations and stereochemical constraints in the folding process, only a small number of the possible polypeptide sequences actually form structures that remain stable at physiological pH levels. These are the structures that, due to their energetic stability, are potentially useful to the organism and are replicated through selective evolutionary pressures.[865]

The four main classes of secondary structural combinations that exist are: all alpha helix; all beta sheet; alternating alpha helix and beta sheet; and alpha helix plus beta sheet, in different arrangements.[866] These four main categories can then be subdivided into sequence families and single fold families. Due to stereochemical constraints in the packing together of helices and strands, it has been estimated that there is less than one thousand ways a sequence may fold.[867] Further, it has been determined that protein domains having more than 30% of their sequence in common adopt the same fold structures[868].

---

with slightly more than 2/3 [68%] of all hydrogen bonds situated between backbone polar groups).

862 *See* Bryson, et al, *Protein Design: A Hierarchic Approach*, 270 Science 935 (1995). *see also* PROTEIN STRUCTURE, at 210-211.

863 Typically, the free energy change that occurs from start to finish of folding is approximately 5-15 kcal/mol per protein molecule, with each individual amino acid only contributing to a small fraction of the energy change. PROTEIN STRUCTURE, at 256.

864 *See* PROTEIN CHEMISTRY, at 58-69.

865 *See generally*, PROTEIN CHEMISTRY, Chapter 7.

866 *Id.*

867 *See* PROTEIN STRUCTURE, at 248.

868 One study of 2,511 polypeptide chains, determined by X-ray crystallography to less than three angstroms, found that the polypeptides clustered into 212 sequence families and 80 single domain fold families. *See* Orengo, et. al., *Protein super families and domain superfolds*, 372 Nature 631 (1994).

3. Amino Acid Changes - Active Sites

The second broad functional category of amino acids in a protein is known as the active site, which may serve as a binding or catalytic site. The change of a single or a few amino acids at this location is often an exception to the rule that a small change in amino acid sequence will not affect the structure or function of a protein. Indeed, the change of a single amino acid at an active site may dramatically decrease, increase, or alter the binding, catalytic, or other specific functions of a protein. A number of specific examples found in proteins will help explain why this is so.

Perhaps the best known example of a single amino acid change, or mutation, causing a dramatic effect on protein structure and function is the genetic disease known as sickle cell anemia. This condition is caused by a single change from glutamine to valine in residue six of the beta chain of hemoglobin[869]. Residue six is on the surface of the beta chain A alpha helix and also on the surface of the hemoglobin tetramer[870]. When the mutation occurs, a charged residue (glutamine) is changed to a hydrophobic residue (valine), and a small hydrophobic knob appears on the surface of the alpha helix[871]. This hydrophobic knob fits into and can bind the hydrophobic pocket of an adjacent deoxygenated hemoglobin molecule. After the hemoglobin delivers its oxygen, many of these hydrophobic interactions occur and deform the red blood cells into a characteristic sickle shape[872]. An organism that is homozygous for the sickle cell condition will not survive[873].

The conversion of trypsin to chymotrypsin offers a second example that demonstrates the effects of a single or a few amino acid changes in the catalytic sites of proteins. Trypsin and chymotrypsin both belong to the trypsin family of serine proteases[874]. Trypsin hydrolyses peptides with arginine or lysine at the P1 position, while chymotrypsin attracts and hydrolyses large hydrophobic peptide residues at the P1 position[875]. The different substrate specificities of these two proteases result from different residues in their S1 binding pockets: Asp 189 in trypsin binds to positively charged residues; and serine in chymotrypsin binds to hydrophobic residues[876].

When Asp189 in trypsin is mutated to serine, trypsin does not acquire chymotrypsin specificity, but rather becomes a poor, nonspecific protease[877]. The conversion to chymotrypsin-like specificity requires further substitutions in the S1 binding pocket[878] and the conversion of two

869 *See* PROTEIN STRUCTURE, at 39, 40.

870 *Id.*

871 *Id.*

872 *Id.*

873 *Id.*

874 *See* Hedstrom, et al, *Converting Trypsin to Chymotrypsin: Residue 172 is a Substrate Specificity Determinant*, 33 Biochemistry 8757 (1994).

875 *Id.*

876 *Id.*

877 *Id.*

878 (Gln192 to Met, Ile138 to Thr, and insert Thr219).

adjacent surface loops[879] to the loops found in chymotrypsin[880]. The resulting mutant[881] exists in equilibrium in two different conformations: a predominant inactive species and an active minor species. The two different conformations lead to impaired substrate binding relative to that of chymotrypsin, but equal catalytic properties once the substrate is bound[882].

An additional mutational change in a single amino acid[883] stabilizes the active conformation and results in a 20-50 fold increase in enzyme activity[884]. The increased stability and enzyme activity is thought to result from three structural changes[885]. First, the Ser217 side chain rotates by 100% about the X^1 rotamer angle and adopts an identical conformation to that found in chymotrypsin[886]. Second, the sterically larger indole group of Trp172 causes adjacent water molecules to rearrange into a pattern similar to that of the base S1 site in chymotrypsin, which then reorients the position of Ser217[887]. Third, the degree of order in loop 1 is improved by a presently unknown propagation mechanism that increases the stability of residues across the entire width of the S1 binding pocket[888].

A third example of the effect a single amino acid change can have on function is provided by DNA binding proteins. DNA is a long, double helical molecule consisting of two, antiparallel phosphate sugar backbones connected by rungs of hydrogen-bonded, nucleotide base pairs[889]. The particular sequence of the four nucleotide bases, adenine, thymine, cytosine, and guanine, provides both information for the genetic code and specificity for DNA binding proteins[890]. For example, the guanine-cytosine pair in the major groove contains a pattern of hydrogen bond (h-bond) acceptor, h-bond acceptor, h-bond donor and hydrogen atom[891]. The adenine-thymine pair contains a pattern of h-bond acceptor, h-bond donor, h-bond acceptor and a methyl group[892]. These different patterns, contained in unique sequences in the major (and to some extent minor) grooves of DNA can be recognized by unique side chain sequences in proteins containing complementary h-bond patterns[893].

DNA binding proteins are extremely sensitive to even minor alterations in the h-bonding patterns between their side chains and the DNA nucleotide sequence. A common example of this sensitivity is provided by DNA restriction enzymes. A

---

879 (residues 185-188 and residues 221-225).

880 *Id.*

881 (Tr–>Ch[S1+L1+L2]).

882 *Id.*

883 (Tyr172 to Trp).

884 *Id* at 8758.

885 *See* Perona, et al, *Structural Origins of Substrate Discrimination in Trypsin and Chymotrypsin*, 34 Biochemistry 1489 at 1494 (1994).

886 *Id.*

887 *Id.*

888 *Id.*

889 *See* GENES, Chapter 4.

890 *Id.*

891 *See* PROTEIN STRUCTURE, at 82.

892 *See* PROTEIN STRUCTURE, at 83.

893 *Id.*

restriction enzyme is a protein that cuts DNA at specific sites. The match between an amino acid side chain in the protein binding domain and the binding domain of DNA is highly specific, and even small mismatches will result in a failure of the restriction enzyme to bind and cut DNA[894].

In addition to the three preceding examples, many other instances exist where either a single or a few amino acid changes result in a dramatic change in the function of a protein. For example, replacement of Glu43 by Asp and Gln in the enzyme staphylococcal nuclease results in a significant decrease in the enzyme's ability to hydrolyze phosphodiester bonds in nucleic acids[895]. A mutation from Glu165 to Asp in triose phosphate isomerase dramatically decreases the catalytic efficiency of that enzyme[896]. A mutation in Gln61 or Gly12 of the cellular signal-transduction protein ras p21 leads to impaired GTPase activity and an inability to properly cycle between active and inactive phosphorylation states[897]. The decreased GTPase activity, in turn, often leads to oncogenic activity in the cell[898]. Additionally, any amino acid that becomes phosphorylated, acetylated, methylated, or otherwise chemically altered in a biochemical pathway or cascade will have a tendency to change the function of a protein when it is mutated[899].

From the foregoing examples and discussion, a set of principles relating protein structure to protein function begins to emerge. It is clear that the function of a particular amino acid is closely related to its position in the overall structure of the protein. Amino acids not located in or near protein active sites primarily serve structural roles and usually do not alter the protein's function when mutated. However, amino acids located in protein active sites may serve critical roles in the binding, catalytic, or other biochemical functions of a protein. Often when these amino acids are mutated, the particular function of the protein will be dramatically altered due to the unique stereochemical and electrical charge characteristics of the relevant amino acid side chains. Additionally, even when an amino acid side chain is not

---

894 *See* Klug & Cummings, CONCEPTS OF GENETICS, at 384 (4th Edition, 1994).

895 *See* Hibler, et al, *Site-directed mutants of staphylococcal nuclease. Detection and localization by ^1H NMR spectroscopy of conformational changes accompanying substitutions for glutamic acid 43,* 26 Biochemistry 6278-86 at 6280 (1987).

896 *See* Knowles, *Tinkering with enzymes: what are we learning?* 236 Science 1252-58 at 1257 (1987).

897 *See Site-Directed Mutagenesis with an Expanded Genetic Code* at 452, 453.

898 *Id.*

899 Phosphorylation is the addition of a phosphate group to (usually) the hydroxyl group of serine or tyrosine, and sometimes threonine. The phosphate group contains negative charges and significantly alters the electrical characteristics of the side chain. Acetylation and methylation are the addition of acetyl and methyl groups, respectively, usually to lysine, which prevents positive charges from forming on the amino groups. *See* GENES V at 11, 12.

directly involved in binding or catalysis, it may indirectly effect function by, for example, providing needed stability to a protein binding site, or by influencing substrate binding specificity through the propagated or distributed effects of the protein fold[900]. The mutation of these amino acids that fulfill a hybrid structural and active site role also will likely alter the function of a protein[901].

Changes in structure and function of a protein caused by a single or a few amino acid changes may result from a variety of causes, including alteration of hydrogen bonds, vandervaals forces and covalent bonds, steric interactions and hindrances, and rearrangement of water molecules surrounding the amino acid side chains[902]. Effects of the changes may be direct and local, or may indirectly propagate across the breadth of binding and catalytic domains[903]. Due to the complexity and variety of the forces and interactions involved, a given amino acid change in or near an active site may produce structural and functional changes that were predicted, or that were not predicted and were, in fact, quite surprising[904]. Unknown structural interdependence between amino acids may result in a favorable mutation at one location resulting in "catastrophic" consequences elsewhere[905].

C. Equivalency

1. Case Study

The patent claims in *Genentech v. Wellcome Foundation Ltd.*[906] involve the protein known as human tissue plasminogen activator (human t-PA). Human t-PA plays an important role in the dissolution of fibrin clots in the human body. Such clots are formed typically by the body to repair ruptured blood vessels. After fibrin clots have fulfilled their function, they are dissolved by plasmin, an enzyme that binds to fibrin and breaks the bonds between the fibrin molecules. Plasmin usually circulates in the blood in an inactive state called plasminogen. When plasmin is needed for repair, human t-PA activates the plasminogen and converts it to plasmin. When large fibrin clots form and cause circulatory problems, additional dosages of substances that activate the plasminogen are needed to supplement the body's natural supply of t-PA.

Before plaintiff's discoveries, adequate sources of supplemental activator did not exist. Natural t-PA could not be extracted from the body in adequate amounts of sufficient quality to be a useful supplement. The other known plasminogen activator supplements, streptokinase and urokinase, were considered inadequate due to low binding affinity to fibrin and harmful side effects. Plaintiffs solved the supply problem when they discovered that human t-PA of sufficient volume and purity could be produced from human melanoma cell cultures and through recombinant DNA technology.

---

900 *See Structural Origins of Substrate Discrimination in Trypsin and Chymotrypsin* at 1497.

901 *Id.*

902 *Id.* at 1494.

903 *Id.*

904 *See, e.g., Protein Design: A Hierarchic Approach* at 938.

905 *See Tinkering with enzymes* at 1256.

906 The case will be described substantially without footnotes.

Plaintiffs obtained three patents related to the human t-PA protein. The '603 patent claimed the protein itself, the '330 patent claimed the process for producing the protein by recombinant DNA technology, and the '075 patent claimed the intermediates used in the process. The protein was defined in the '603 patent as "human plasminogen activator" and in the '330 and '075 patents as "human tissue plasminogen activator." A claim limitation of a "specific activity level of about 500,000 IU / mg." was included in the '603 patent claim to distinguish it from a prior art human t-PA isolate with a specific activity of 266,000 IU / mg.[907]

The accused protein, FE1X, which also converts plasminogen to plasmin, was developed independently through experimentation by the defendants. It is different than natural t-PA in four respects. First it has a different structure. Natural t-PA has 527 amino acids and five separate functional domains, consisting of the Finger region, Epidermal Growth region, Kringle 1 region, Kringle 2 region, and the Serine Protease region. FE1X has 446 amino acids, and lacks the Finger region and most of the Epidermal Growth region of natural t-PA. Further, FE1X substitutes a methionine for a valine at position 245 of the Kringle 2 region. Finally, FE1X eliminates one of the carbohydrate chains by substituting a glutamine for arginine at position 117 of the Kringle 1 region, which changes the pattern of glycosylation. Second, FE1X has a different binding affinity to fibrin than natural t-PA. Third, FE1X has a different half life in the human body than natural t-PA. And fourth, FE1X has a decreased affinity for binding to the endothelial cells of blood vessels as compared to natural t-PA.

On cross motions for summary judgment concerning infringement of the '603 and '075 patents, the trial court focused on the claim limitations "human plasminogen activator" in the 603 claim, "human tissue plasminogen activator" in the '705 claim, and "specific activity of about 500,000 IU / mg." contained in the '603 claim. As a matter of claim interpretation, the court ruled that the descriptive activator phrases meant the entire amino acid sequence of human t-PA plus any "naturally occurring allelic variant thereof." The court further held that the specific activity limitation was implicit in the '705 claim. The court granted summary judgment in favor of defendants on the issue of literal infringement since FE1X did not contain the amino acid sequence of natural t-PA or any natural variant thereof, and no proof was offered concerning the specific activity of FE1X.

The issue of infringement under the doctrine of equivalents was submitted to a jury on special verdicts. The court refused to instruct the jury concerning the claim interpretations the court had used on the literal infringement question, but did issue general instructions on claim construction, the doctrine of equivalents, and prosecution history estoppel. The jury found that FE1X infringed all three patents concerning

---

907 Specific activity is a measure of the enrichment of the subject protein relative to the other proteins in the sample. It measures the progress of protein purification. *See* Jack Kyte, STRUCTURE IN PROTEIN CHEMISTRY, page 17 (1995).

human t-PA under the doctrine of equivalents. On appeal, the defendants complained there was a lack of substantial evidence that FE1X met either the specific activity limitation, or the "human tissue plasminogen activator" limitation.

Before reaching the substantial evidence points, the Federal Circuit first interpreted the claims. The court found that the specific limitation existed only in the '603 patent and meant 500,000 IU/mg. in the context of the "bovine fibrin plate assay." The court further found that the phrase "human tissue plasminogen activator" meant "natural t-PA." Based on these claim constructions, the court held 1) the jury's implied conclusion that the specific activity limitation in the '603 patent was met equivalently by FE1X was not supported by substantial evidence, and 2) the jury's implied conclusion that the "human tissue plasminogen activator" limitation in the '075 and '330 patents was met equivalently by FE1X was not supported by substantial evidence.

The court's first holding was based on the lack of evidence connecting the 500,000 IU/mg. value to the bovine fibrin plate assay. All evidence of values close to this range for FE1X were performed using different assays or were unreliable. The only evidence concerning the specific activity values for FE1X in the context of the bovine fibrin plate assay was a range from 208,116 to 299,484. Since this number was significantly closer to the prior art specific activity number of 266,000 than to the claimed 500,000, the court held that FE1X was outside the range of equivalents as a matter of law due to prosecution history estoppel.

The court's second holding was based on whether particularized evidence existed that FE1X met the "human tissue plasminogen activator" limitation on each of the function, way, and result prongs of the equivalency test. Before performing this analysis, the court stated that it was confronted with the problem of how broadly to interpret the "function" of human t-PA. If the function were interpreted broadly to be "the dissolution of fibrin clots through the cleavage of plasminogen to plasmin," then the court considered a finding of infringement likely. However, if the function were interpreted more narrowly to include binding to fibrin, then the question of equivalency became " a much closer one."

The court found that the function of human t-PA included fibrin binding - for several reasons. First, fibrin binding was defined to be a critical function of human t-PA in the specification. Second, evidence existed that fibrin binding is critical in a therapeutic sense to human t-PA in that it reduces the risk of hemorrhaging. Third, a functional definition of t-PA that ignored fibrin binding would fail to distinguish it over two prior plasminogen activators, urokinase and streptokinase, therefore making its range of equivalents impermissible read on the prior art.

The court then found that no substantial evidence existed that "FE1X functions in substantially the same way as human t-PA or achieves substantially the same results." This finding was based on the speculative and conclusory evidence from the plaintiffs concerning if and how FE1X binds to fibrin, and the "overwhelming and undisputed evidence" that FE1X and human t-PA

"possess dramatically different properties and structure." Specifically, evidence existed that (1) the fibrin binding affinity of FE1X was only forty percent that of human t-PA due to the deletion of the Finger and Epidermal Growth regions of FE1X, (2) without an amino acid substitution at position 117 of the Kringle 1 region that eliminated a glycosylation site[908], the deletion of the Finger and Epidermal Growth regions of FE1X would have resulted in FE1X being completely incapable of binding to fibrin, (3) FE1X has a half life approximately ten times that of human t-PA, and (4) FE1X has a significantly reduced binding affinity to endothelial cells as compared to human t-PA. The court concluded that the trial judge should have granted defendant's motion for JMOL because the jury's verdict was not supported by substantial evidence that FE1X contained equivalents to the specific activity limitation and the "human tissue plasminogen activator" of human t-PA.

Judge Lourie wrote a concurring opinion in which he expressed a different method of interpreting the phrase "human tissue plasminogen activator," and explained an additional reason why FE1X should not be considered to infringe human t-PA under the doctrine of equivalents. According to Judge Lourie, the phrase "human tissue plasminogen activator" has a definite meaning in that it describes a specific compound consisting of 527 amino acids in a specific sequence. If the phrase did not have a definite meaning, and sought to describe the claimed substance only by its function (that of activating human tissue plasminogen), then it would encompass all substances performing that function, similar to a single means claim, and might fail for indefiniteness. However, since human t-PA does have a definite meaning, all claims including t-PA are to be limited to its specific meaning.

The additional reason Judge Lourie believes FE1X should not be considered to infringe human t-PA under the doctrine of equivalents is that it contains substantial differences from human t-PA. Specifically, Judge Lourie noted that FE1X contains fifteen percent fewer amino acids than human t-PA, a difference he described as "not an insubstantial change, but a substantial one," and has a half-life ten times longer than human t-PA. Judge Lourie also believed it was relevant that the developers of FE1X did not copy human t-PA. The lack of copying was supported by evidence that "FE1X is a very different material, independently invented and developed, requiring an estimated 130 man-years, and costing $20 million." Judge Lourie ended his concurrence by pointing out problems with the doctrine of equivalents:

> Thus, this case illustrates the problem that results not only when a court fails to construe the claims for the jury, but also when the fact-finder unduly focuses only on the function, way, result analysis of Graver Tank [citation omitted].

---

[908] The elimination of the glycosylation site prevented "a carbohydrate side chain from being attached to the protein during post-translational modifications."

> These limited means of analysis fail to fully elucidate the issue, especially when the patented material is a chemical, as it is here. Is the increased half-life part of the "way" analysis or is it a different "result"? Is the binding to fibrin "function," as stated by the majority, or is it part of the "way" t-PA dissolves clots? These questions illustrate the shortcomings of the function, way, result tests which relate to "how" a substance works, i.e., what it does, rather than what it is, which claims purport to define. The other aspects of Graver Tank, if properly considered by the fact finder, would have led to a sounder result. The substantiality of the differences between the accused and claimed compounds, the fact of independent development, and the lack of copying, all lead to a conclusion of lack of infringement.[909]

2. Application of Comparative Calculus

The issue to be resolved is whether the FE1X has insubstantial differences from human t-PA. Insubstantial differences are determined by the two tests of function-way-result and interchangeability. The factors to be compared by the constructed calculus are structure, function, way, result, interchangeability, independent experimentation, independent development, and if appropriate, resources expended. Not to be considered are intent, copying, or designing around. The first step in the equivalency analysis is claim construction. The second step is selection of the limitations to be preserved and compared according to the principle of the invention in light of the prior art. The third step is application of potential limitations on equivalents such as prior art, prosecution history estoppel, and disclosed but unclaimed subject matter. Assuming any questions of fact remain, the appropriate method of submission to the jury is chosen and appropriate instructions are drafted.

a. Claim Construction and Limitation Selection

The claim construction performed by the Federal Circuit on "specific activity" and "human tissue plasminogen activator" will be adopted. It should be pointed out that it was probably unnecessary for Judge Plager to decide whether human t-PA included the function of "fibrin binding," because as pointed out by Judge Lourie (joined by Judge Cowen), the meaning of human t-PA is definite, and is known to include fibrin binding. However, assuming arguendo that the issue was fairly raised, the question should not have concerned the functional definition of t-PA, but rather what limitations of t-PA needed to be preserved and compared to FE1X.

The comparative calculus would have asked what limitations were necessary to distinguish t-PA over the

---

909 29 F.3d at 1570.

prior art. If they were needed to distinguish human t-PA over the prior art, then they needed to be preserved and compared.[910] As pointed out by the Federal Circuit, fibrin binding was "critical" to distinguish human t-PA over the prior art plasminogen activators urokinase and streptokinase. Therefore, according to the comparative calculus, the fibrin binding limitation cannot be eliminated, and the limitations to be preserved and compared are the 500,000 IU/mg specific activity value according to the bovine fibrin assay, and human t-PA, including its fibrin binding affinity.

b. Application of Limitations

The first limitation in the human t-PA patent claim is the 500,000 IU/mg. specific activity value according to the bovine fibrin assay. The only credible evidence indicates that FE1X has a value in the range from 208,116 to 299,484 IU/mg. in the context of the bovine fibrin plate assay. This number is significantly closer to the prior art specific activity number of 266,000 than to the claimed value of 500,000. Since the 500,000 value was included in the claim to avoid prior art, prosecution history estoppel prevents FE1X from having an equivalent specific activity value to t-PA as a matter of law. Because the specific activity value of t-PA is a necessary limitation in the t-PA claim and it cannot be met equivalently by the specific activity value of FE1X as a matter of law, infringement under the doctrine of equivalents does not exist as a matter of law.

The second limitation in the human t-PA patent claim is "human plasminogen activator" construed to mean "human t-PA." No legal limitations exist to prevent this limitation from being considered for equivalency.

c. Comparing Limitations

To prevail on an infringement claim under the doctrine of equivalents, it is plaintiff's burden to prove that the accused FE1X contains insubstantial differences from the claimed human t-PA. Insubstantial differences are proven through the tests of function-way-result, interchangeability, structure, and perhaps independent experimentation, resources expended, and independent development. The function of human t-PA is to convert plasminogen to plasmin. The way it performs this function is to bind to fibrin and sever its molecular bonds over the period of time determined by its half-life in the human bloodstream. The result of the human t-PA function is that fibrin clots are dissolved.

The function of t-PA and FE1X are the same - to convert plasminogen to plasmin. However, it is unknown how FE1X performs this function. The comparative calculus allows the "way" portion of the test to be either substituted or inferred by evidence of interchangeability and structural

---

[910] The Federal Circuit included fibrin binding in part because "a functional definition of t-PA which ignores this distinction would result in a range of equivalents which impermissibly reads on the prior art." This analysis may be inappropriate because it must rely on conclusions from an equivalency analysis that has yet to be performed and that is a question of fact. The better inquiry is whether the limitation (fibrin binding) was necessary to distinguish the t-PA patent from the prior art.

similarity. The evidence is that FE1X has a half-life ten times that of t-PA and a significantly decreased affinity for binding to endothelial cells. Therefore, FE1X is not interchangeable with t-PA in the same claimed environment, and it is not appropriate to infer that FE1X functions in "substantially the same way" as human t-PA. Further, the structure of FE1X is dramatically different from that of t-PA both in terms of number of amino acids, domains, and gross structure. No inference of "substantially the same way" is therefore raised by structural similarity. Since plaintiffs cannot prove directly or by inference that FE1X operates in substantially the same way as, or is interchangeable with, the claimed human t-PA, they are unable to prove insubstantial differences.[911] Additionally, to the extent that evidence of independent development and resources expended are considered relevant to the issue of substantiality of the differences, this evidence also is consistent with a finding of substantial differences.

3. Function-Way-Result and Insubstantial Differences

The concurrence of Judge Lourie raises concerns with the function-way-result approach to equivalency, particularly in the context of chemical compounds. Specifically, Judge Lourie suggests that a test which relates to how a substance works may be inappropriate to analyze what a substance is. This concern, however, may be misplaced given the developmental history and nature of the doctrine of equivalents.

The primary reason the equivalency test evolved into function-way-result is that these factors are considered to be more relevant than structure to the infringement analysis. This was because in a potential infringement involving the doctrine of equivalents, the structure of the accused device is always different than that of the claimed device. A focus on function-way-result, however, does not mean that structure should be completely dropped from the analysis. To the contrary, a structural comparison can provide an important inference of the "way" a device or chemical works when other evidence of "way" is unavailable or inconclusive. Further, the structure of the accused device can be so different from the claimed device that equivalency cannot exist as a matter of law. But a comparison of structure should rarely be conclusive, for good reason.

For example, Judge Lourie would conclude that because the accused protein contains 15% less amino acids than the claimed protein, the difference is substantial. But a difference in the number of amino acids does not necessarily reflect a substantial difference between proteins. The foregoing primer on protein chemistry indicates that most proteins can tolerate significant changes in there scaffolding and still retain the same active site functions. Further, through various quirks of evolution, a protein may possess domains that are unnecessary to their function. Eliminating these domains would significantly change the number of amino acids making up the protein, but would not effect the

[911] If plaintiffs would have brought forward any credible evidence on interchangeability or structural similarity, a fact issue may have been raised concerning these issues.

function of the protein, or the results the protein achieves in any significant way.

Additionally, with current techniques in protein engineering, new amino acids easily can be added to the end or to the middle of the polypeptide chain. These additions change the number of amino acids in the protein and could substantially alter the protein's gross structure, but may result in no other substantial changes in function or result. For these reasons, the function-way-result test is better left as the primary test in equivalency. To the extent the "way" portion of the test may be difficult to determine in some technologies such as chemistry, inferences of "way" can be supplied by evidence of interchangeability and structural similarity.

The concurrence also indicates that lack of evidence of "copying" supports a finding of substantial differences. However, the only support for the conclusion of lack of copying is that the accused protein consisted of "a very different material" and was "independently invented and developed, requiring an estimated 130 man-years, and costing $20 million." To conclude that the accused protein was not copied because it consisted of a "very different material" is to engage in the type of circuitous argument that was criticized earlier. If the "difference" in the material is the conclusion sought from a conclusion of lack of copying, it should not also be the basis for the conclusion of lack of copying.

Further, although independent invention and development would rule out intentional copying, intent is not an element in equivalency analysis. Independent development also does not directly support insubstantial differences. For example, two scientists, each attempting to design the same function into a protein and working independently, may achieve substantially similar results. The fact of their independence does not affect the substantiality of the differences in their final results. Indeed, to the extent each scientist was working independently to discover a natural protein or DNA sequence with the same function, the probability is that each would independently discover the same result.

The relevance of the amount of time and money spent is also problematical. Although significant expenditures tend to rule out intentional copying, intent is not relevant to equivalency. Further, although substantial expenditures of time and money are certainly consistent with substantial differences being achieved, they are not proof of it. Tremendous resources may be expended to achieve insubstantial differences. The proof of the difference is the difference itself and not the amount of time and money spent on it. However, a different situation might present itself if the accused infringer was claiming substantial differences and no resources had been expended to achieve it. At least in the field of protein chemistry, lack of experimentation and expenditure may well lead to an inference that would corroborate the plaintiff's claim of insubstantial differences. This inference could of course be rebutted by credible proof of serendipity.

A further basis for Judge Lourie's criticism is confusion over whether the "increased half life" and "fibrin binding" should be classified as a "function" or "way" in the function-

way-result test. This criticism raises interesting semantic issues over the function-way-result division[912], but in the end is not relevant to the outcome of a case. Since each prong of the function-way-result test must be satisfied for equivalency to be established, it should not matter in which category the comparative analysis takes place. Finally, the concerns raised in the concurrence over the difficulties a jury may encounter when the court fails to construe the claims have been recognized and remedied in *Markman*.

D. Obviousness

1. Case Study - *In re Mayne*

The patent claims in *In re Mayne*,[913] involve fusion proteins comprised of the amino acid Methionine (Met), an enterokinase cleavage site, and either human or bovine growth hormone (HGH or BGH). All newly translated proteins have Met as their initial amino acid. This is because the mRNA codon that signals initiation of translation is AUG, which codes for Met. Often the Met is not required for the protein's final function, and it is cleaved by an enzyme in a post-translation modification to the polypeptide chain. The enzyme determines precisely where to cleave the nascent polypeptide chain by recognizing a specific sequence of amino acids. The particular enzyme in this case is enterokinase, which recognizes a cleavage site with the amino acid sequence Asp-Asp-Asp-Asp-Lys ((Asp)4-Lys). The enterokinase cleaves the amino acid chain between the Lys and the initial amino acid of HGH or BGH.

The applicant in this case claimed two fusion proteins with the cleavage sites Met-Phe-Pro-Leu-(Asp)4-Lys-HGH, and Met-Phe-Pro-Leu-(Asp)4-Lys-BGH. The Board affirmed the rejection of these claims as being obvious in light of three primary prior art references. The first reference cited taught recombinant DNA technology to fuse an enzyme cleavage site to a protein. The second reference cited taught two naturally occurring enterokinase cleavage sequences beginning with Phe-Pro-Ile or Leu-Pro-Leu and followed by a sequence of acidic amino acids (either Glu or Asp), and the use of enterokinase to recognize the cleavage sites. The third reference disclosed the nucleotide and amino acid sequences of HGH and BGH.

On appeal, the applicants argued that their compounds were not prima facie obvious because the prior art lacked a sufficient suggestion to combine references. Alternatively, applicants argued that unexpected results rebutted the prima facie case. The Federal Circuit affirmed the rejection, holding that structural

---

912 The division of the properties of a device or chemical compound into function, way, and result is indeed confusing. The two broad categories of the characteristics of a device or compound are generally considered to be structure and function, with the term "function" tending to include what the function is, how the function occurs, and the results achieved by the function. However, in the phrase function-way-result, the term "function" is only taken to mean what the function is. The term "way" describes how the function occurs, and the term "result" describes the results achieved by the function.

913 The case will be described substantially without footnotes.

similarity between the claimed and prior art cleavage sites supported the finding of prima facie obviousness, and that the results of the amino acid substitutions were not unexpected.

Specifically, the Federal Circuit compared the claimed cleavage sequence Phe-Pro-Leu with the prior art sequence Phe-Pro-Ile and found the only difference to be a substitution of Leu for Ile in the third position. The court found that Leu and Ile have similar structures in that they (1) are isomers (possess identical chemical formulas with differences only in bonding between atoms), (2) have the same number of carbon and hydrogen atoms in their side chains, and (3) each have nonpolar, hydrophobic chemical properties. The court also found that the structural similarity inferred functional similarity and provided a suggestion to substitute the Leu for Ile - which rendered the claimed compound prima facie obvious.

The applicants attempted to rebut the prima facie case with evidence of two allegedly unexpected results. First, a low immune response when the claimed proteins were administered by injection. Second, biological activity of the claimed proteins before cleavage of the leader peptide sequence. The court reviewed the applicants' evidence of alleged low immune response and found it to be speculative and based on impermissible inferences. The court also considered applicants' evidence of pre-cleavage biological activity not unexpected because no evidence was presented that BGH and HGH were inactive when fused to other known enterokinase cleavage sites.[914]

2. Application of Comparative Calculus

This case presents no great challenge for the comparative calculus because it involves the established rule that structural similarity can constitute a suggestion to combine references and can establish a prima facie case of obviousness. Further, no competent evidence of unexpected results or other empirical proof was available to weigh against the suggestion to combine references. The case does illustrate that the structural similarity rule is useful in protein chemistry because the function of an amino acid can be predicted from its structure. As long as the comparison of structural similarity remains on an individual amino acid basis, the analysis is not too complex.

However, different challenges may be presented to obviousness doctrine when a claimed protein based on a natural or other prior art protein is fundamentally re-engineered through the addition, deletion, or rearrangement of domains and active sites. These potential challenges can be explored by reconsidering the *Genentech* case, discussed above, and altering it slightly to include the issue of obviousness.

3. Second Case Study - *Genentech*

For the purposes of this case study, it will be assumed that the FE1X compound is the claimed compound

---

914 The court stated that even if such biological inactivity were obvious to a practitioner in the art, the applicants still had the burden of producing such evidence to the PTO. 104 F.3d 1339, 1344.

and the human t-PA is the prior art compound. It will be further assumed that the obviousness inquiry is being made during prosecution rather than litigation. The question presented is whether the FE1X compound, taken as a whole, would have been obvious to a person of reasonable skill in the art. This question raises the issue of whether the prior art contains sufficient references to establish a prima facie case of obviousness, and if so, whether any empirical evidence of nonobviousness can overcome the prima facie case and compel a conclusion of nonobviousness.

The patent application for the FE1X accused protein is initially presumed to be obvious. The examiner must rebut this presumption by establishing a prima facie case of obviousness. The prior art references available to the examiner will include: (1) the natural human t-PA protein with a specific activity of 500,000 IU / ml; (2) its less purified predecessor protein with a specific activity of 266,000 IU / ml; (3) urokinase; (4) streptokinase; (5) the general literature on fibrin clot dissolution; (6) the specific literature on how the human t-PA protein dissolves fibrin clots by transforming plasminogen to plasmin, binding to fibrin, then breaking the fibrin's molecular bonds; (7) the specific literature that attempts to describe how the human t-PA binds to fibrin; (8) the specific literature that attempts to describe how the FE1X binds to fibrin; and (7) the general literature on laboratory techniques for engineering proteins.

The differences in the claimed and accused devices are that (1) natural t-PA has 527 amino acids and five separate functional domains, consisting of the Finger region, Epidermal Growth region, Kringle 1 region, Kringle 2 region, and the Serine Protease region, while FE1X has 446 amino acids, lacks the Finger region, and lacks most of the Epidermal Growth region of natural t-PA; (2) FE1X substitutes a methionine for a valine at position 245 of the Kringle 2 region; (3) FE1X eliminates one of the carbohydrate chains by substituting a glutamine for arginine at position 117 of the Kringle 1 region, which changes the pattern of glycosylation; (4) FE1X has a different binding affinity to fibrin than natural t-PA; (5) FE1X has a different half life in the human body than natural t-PA; and (6) FE1X has a decreased affinity for binding to the endothelial cells of blood vessels as compared to natural t-PA.

To establish the prima facie case, the examiner must find references that suggest the FE1X protein to a person of ordinary skill in the art and that provide a reasonable chance of successfully creating the protein. The examiner might cite the prior art human t-PA protein, the literature indicating that the Kringle 2 region is involved in binding fibrin in both proteins, and the literature teaching how to add and remove amino acids to and from proteins. Although this would be a weak suggestion without more, it would likely provide inferences to establish a prima facie case and shift the burden of producing additional evidence to the applicant.

The applicant could then come forward with evidence of the difference in structure, the substituted amino acids in the Kringle 1 and Kringle 2 regions, the effect of such substitutions on the glycosylation patterns, and the unexpected results of increased half life and decreased affinity for binding to

endothelial cells. This evidence should rebut and completely destroy the initial presumption. The examiner would then have all evidence available for review and consideration and could make a final decision concerning obviousness.

The final decision would require the examiner to determine the relative weight of the suggestion to combine references, the relative weight of the empirical evidence of nonobviousness, and then weigh the two in relation to each other. The suggestion to make the FE1X protein in this case is weak. The primary references are the human t-PA protein and the literature describing the involvement of the Kringle 2 region to fibrin binding. The suggestion would be that a protein containing the Kringle 2 region, which FE1X does, may be able to bind to and dissolve fibrin. Other prior art references teach how amino acids may be eliminated or modified in the t-PA protein to produce the FE1X two with Kringle 2 intact.

However, the literature cited does not contain a clear explanation of the Kringle 2 role in fibrin binding. Further, there apparently is a reference which teaches that elimination of the F and E regions from the t-PA protein results in no fibrin binding at all. This suggests that these regions are involved along with Kringle 2 in the fibrin binding mechanism. The FE1X protein lacks all of the F and most of the E domains. It is unknown whether the portion of the E region that is retained by FE1X is the necessary functional portion of the F and E complex. There is no reference which suggests how much of the E and F regions may be eliminated without losing the fibrin binding ability of the protein.

The FE1X protein apparently substitutes some of the function of the F and E domains by making an amino acid substitution at position 117 of the K1 region, which eliminates a glycosylation site and prevents a carbohydrate side chain from attaching to the site. There is no apparently no reference available which teaches how the eliminated carbohydrate chain allows the FE1X to bind fibrin in the absence of most of the E domain and all of the F domain.

In sum, when the prior art is viewed as a whole, as it must be, the suggestion to make the FE1X protein is weak. This is primarily because the prior art references teach that elimination of the E and F regions of t-PA result in no fibrin binding at all, and the FE1X protein lacks all of the F and most of the E regions. Further, there is no reference teaching how to regain fibrin binding affinity in the absence of the E and F regions, and in particular, how the elimination of a carbohydrate side chain attachment site might accomplish this result. Indeed, but for the retention of a small part of the E region in the FE1X protein, there would likely be no suggestion to make the FE1X protein at all. The suggestion which may remain is extremely weak. Additionally, the lack of any teachings on how much of the E and F regions may be eliminated without affecting fibrin binding suggests that no reasonable expectation of success to make the FE1X exists absent extensive effort and experimentation.

The empirical factors of nonobviousness, on the other hand, are strong. The FE1X protein has a half life of about ten times that of human t-PA and a significantly decreased affinity for

binding to endothelial cells. Each of these findings represents evidence of unexpected results, which is a strong single inference empirical factor suggesting nonobviousness. Each represents a significant increase in an important characteristic of fibrin clot dissolving proteins, and therefore represents a particularly strong empirical factor. The comparison of a strong single inference empirical factor with a weak suggestion raises a strong presumption of nonobviousness. Given the above suggestion and empirical evidence, the examiner should consider the FE1X protein to be nonobvious and allow the patent to issue.

E. The Future of Protein Chemistry

Protein Chemistry should continue to be a challenge to both obviousness and equivalency. Proteins combine many of the principles found in both the mechanical and chemical arts. Their scaffolding and domains can be analogized to mechanical structure, but they fold and function based on principles of chemistry. An added complexity is that the weak hydrogen bonds existing between a protein's amino acid side chains tend to increase the unpredictability of protein behavior even beyond that of other unpredictable chemical compounds.

As the field of protein engineering develops, some of the patenting problems will diminish, and others will increase. An increase in the prior art literature and the overall predictability of the art likely will make some legal principles easier to apply. However, progress in the art will also boost the creativity and abilities of the protein engineer. Domains will be added, removed, rearranged, and combined. Portions of proteins from different tissues and different species will be integrated. Some proteins will contain incremental improvements in function obtained by methodical mutations, and others will contain dramatic and unexpected results following a few amino acid substitutions. In some cases the nature of the relationship between structure and function will be known more or less, and in others the relationship will remain a complete mystery. The principles of obviousness and equivalency must be able to provide guidance and consistent conclusions over this broad range of possibilities.[915]

Although the task of determining obviousness and equivalency in a consistent manner may seem daunting, the difficulty is manageable when certain principles are kept in mind. First, the focus must remain on the principle of the invention in light of the prior art to determine what claim elements should be compared, by functional relationship or otherwise. Second, the relationships between insubstantial differences, function-way-result, and interchangeability must be observed. Evidence concerning interchangeability, structural similarity, and results achieved will be particularly important to support and refute inferences of "way" in protein function. Third, the legal limitations on equivalency, including the prior art and prosecution history estoppel, must be

---

915 For insight into protein claiming strategies, *see* Stephen G. Whiteside, Ph.D., *Patents Claiming Genetically Engineered Inventions: A Few Thoughts on Obtaining Broad Property Rights*, 30 NEW. ENG. L. REV. 1019 (1996).

used to narrow the issues for the finder of fact.

There will be many close and complicated issues to resolve in protein chemistry and protein engineering. Subtle differences will arise concerning the structure, function, way, and result of both natural and engineered proteins. But as long as certain principles are followed, and adequate instructions are given to a jury if empaneled, the uncertainty in this interesting and complex field should be reduced to a manageable, if not healthy, level.

X. Conclusion

The goal of this paper has been to construct an objective comparative analysis capable of increasing the consistency and predictability of decisions regarding patent obviousness and equivalency. An objective analysis is particularly appropriate in the area of equivalency since the Supreme Court has recently instructed that intent and other subjective equitable principles have no place in the doctrine of equivalents. The analysis, or comparative calculus, was constructed in a three step process. First, a study was done of how the doctrines of obviousness and equivalency developed, how they currently operate, and what areas of uncertainty remain within each doctrine. Second, an analysis was performed of how the doctrines relate to each other and what fundamental underlying forces and principles are at play within obviousness and equivalency. Third, based on the foregoing study and analysis, new objective procedures and factors were proposed, and old ones were discarded.

The fundamental principles of obviousness were observed to be (1) the theoretical tests of suggestion to combine references, motivation, and a reasonable expectation of success, and (2) the empirical factors of long felt need, failure of others, commercial success, unexpected results, etc. The appropriate method of comparison between the theoretical tests and the empirical factors was concluded to be a thorough analysis of the strengths and weaknesses of the inferences created by this comparative evidence. Except for a change in terminology and a more thorough analysis of the inference process, these conclusions are fully consistent with obviousness law as it is presently understood. The one additional objective factor proposed for obviousness in the context of DNA discoveries was an examination of effort expended to determine whether a reasonable expectation of success existed. A process was also proposed for determining whether a particular technology required a special prima facie mechanism for the suggestion to combine references test and the reasonable expectation of success requirement.

The fundamental comparative principle in the doctrine of equivalents was observed to be the substantiality of the differences test as determined by an analysis of the function-way-result of the claimed and accused products. Interchangeability was identified as a method of inferring “way” in function-way-result, and as an empirical factor as well. The additional factors proposed for the equivalency analysis, to be applied in the appropriate circumstances, were resources expended and the commercial success of the accused product. A proposal was also made to eliminate from the analysis the

concepts of copying, designing around, and "pioneer" patents. These three concepts were all determined to be misleading intermediate conclusions that did not add useful objectivity to the equivalency analysis. Further, the distinction between independent development and experimentation, and their relevancy to the equivalency analysis was described. Finally, a method was proposed to identify the appropriate elements and limitations for equivalent comparison. The proposed method was to determine the appropriate comparison by identifying the distinguishing principle of the invention in light of the prior art.

The three step construction process revealed the degree to which the uncertainty caused by new technologies can be identified and eliminated by understanding the fundamental comparative principles operating in obviousness and equivalency. When the fundamental principles are understood, the subtests developed for certain technologies are identified as such, and are not automatically applicable to new technologies. The better approach is to first apply the fundamental principles of comparison. If they are found to be inadequate, then new appropriate subtests can be developed.

For example, when the fundamental comparative principles identified in the mechanical arts were applied to chemical compounds, new subtests were developed to smooth the transition. The structural similarity prima facie test was developed for obviousness, and a greater emphasis was placed on interchangeability in equivalency. When it was understood that these subtests were appropriate for the chemical arts but did not alter the fundamental tests of (1) suggestion to combine and reasonable expectation of success in obviousness, and (2) insubstantial differences as determined by function-way-result in equivalency, then confusion was significantly reduced. The subtest of structural similarity was not automatically applied to biotechnology, but rather the new subtest of efforts expended was developed when the fundamental reasonable expectation of success test proved inadequate. Further, the tests of insubstantial differences and function-way-result were found not to be in conflict or mutually exclusive, but rather to be consistent and complementary, i.e., substantiality of the differences was determined by function-way-result. Finally, interchangeability was observed to be a method of inferring "way" when direct evidence of "way" was difficult or impossible to obtain.

The insights gained from observing the transition of obviousness and equivalency law from the mechanical arts to the chemical arts to biotechnology have produced a number of valuable lessons that should be kept in mind and applied to new technologies as they arise. First, as just discussed, new technologies should be analyzed based on the fundamental principles of obviousness and equivalency, and subtests developed due to the special needs of previous technologies should not be applied automatically. Second, if the fundamental principles and rules prove inadequate, new factors and tests should be developed if possible and appropriate. Third, the process of comparison should focus on the

inference analysis, and conclusions should be reached based on the relative strengths of the various inferences.

Fourth, as new methods and comparative factors are being considered, objectivity should be increased when possible, and subjectivity decreased wherever possible. Fifth, terminology should be based on accurate characteristics of the concept being labeled and should be clear and consistent. Sixth, methods and tests should be designed to strike a proper balance between underlying competing forces. For example, the division of decision making between a judge and jury should retain the jury as a check on concentrated power, but should not overwhelm and render the jury ineffective as a decision making body. And seventh, subjective intermediate labels and conclusions such as “copying,” “designing around,” and “pioneer” patent should be eliminated from the comparative analysis. When these general lessons are kept in mind, the law of obviousness and equivalency should be able to flexibly and predictably adapt to emerging technologies at a pace fast enough to effectively serve the business and technological communities.

The business of patent law is important. It is not an overstatement to say that the future prosperity of the United States in large part depends on the development and proper protection of new technologies. The patent law must be designed to cope with these new technologies - predictable enough to provide incentive and notice, but flexible enough to cover a bewildering assortment of new ideas. When patent law is consistent and predictable, it serves as a partner to the inventor, and helps them along their way. But when patent law is inconsistent and confusing, it hinders the process of invention, and prevents creative progress from achieving its full potential. Obviousness and equivalency have thus far had a rather uncertain relationship with inventors and their inventions. It is hoped that the principles described and discussed in this paper will help strengthen the partnership and contribute to a process of greater understanding.