
ECHOES OF SCIENTIFIC TRUTH IN THE HALLS OF JUSTICE: THE STANDARDS OF REVIEW APPLIED BY THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT IN PATENT-RELATED MATTERS

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INTRODUCTION

The interplay between science and the law finds its reflection in many aspects of legal practice.¹ Testing the limits of our scientific understanding is not an effort unique to patent law.² Yet, perhaps no other area besides patent law involves the consideration of the legal rights to which science itself may be entitled. In this sense, patent law stands alone in governing science. This result, however, is neither the intended focus of patent law, nor the mission of the United States Court of Appeals for the Federal Circuit (“Federal Circuit”).³

The goal of the U.S. patent system is to promote innovation to foster the continued global competitiveness of domestic industries.⁴

1. See Bert Black et al., *Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 716-53 (1994) (parsing certain ideological underpinnings of scientific evidence and commenting on the difficulties in bringing scientific knowledge in accordance with the law).

2. See, e.g., Jessie J. Barr, *The Use of DNA Typing in Criminal Prosecutions: A Flawless Partnership of Law and Science?*, 34 N.Y.L. SCH. L. REV. 485, 491-92 (1989) (commenting on the difficulty courts face in relying upon illegal evidentiary admissibility standards to incorporate scientific information in a principled manner); Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 645 (1992) (describing scientific methodology and its use in tort litigation); William J. Madia, *A Call for More Science in EPA Regulations*, 282 SCI. 45, 45 (Oct. 2, 1998) (expressing the concern over the perceived lack of credible scientific basis for environmental regulations).

3. See Steven R. Trybus, Note, *Federal Circuit Jurisdiction: This Court, That Law*, 61 CHI.-KENT L. REV. 731, 737-39 (1985) (reviewing the legislative mandates for the creation of the Federal Circuit and exploring efforts to ensure that the Federal Circuit did not become an overly specialized court focusing solely on scientific patent issues); see also *Paulik v. Rizkalla*, 760 F.2d 1270, 1276, 226 U.S.P.Q. 226, 230 (Fed. Cir. 1985) (observing that the purpose of the patent system was to advance technological innovation and its economic fruits).

4. See Jens H. Hillen, Note, *The Court of Appeals for the Federal Circuit: Independent Review of*

That science may be called into question during the application of the patent laws is a natural by-product of the determination whether a technology event rises to the level of innovation that merits government protection. Innocent victim or not, science often captures the spotlight in such patent considerations.

Reasonable minds may differ as to the best method to ensure that the patent system remains focused on encouraging innovation, rather than merely protecting science. Few, however, would argue against the proposition that clarity and consistency in patent law jurisprudence are necessary steps along this path.⁵ The Federal Circuit has been an instrumental force in bringing patent law practice closer to this ideal.⁶

Since its inception in 1982, the Federal Circuit has sought to operate in a manner mindful of its legislative purpose, to establish nationwide uniformity and to improve the administration of the patent laws.⁷ Of course, sufficient support exists in the decisions of the Federal Circuit to allow advocates and critics alike to debate the court's success with these goals.⁸ Nevertheless, most likely would

Patent Decisions and the Constitutional Facts Doctrine, 67 S. CAL. L. REV. 187, 189 (1993) ("The importance of serving the goal of technical innovation is especially important in a time of disappearing borders and increasing global competition.")

5. See Howard T. Markey, *The Federal Circuit and Congressional Intent*, 41 AM. U. L. REV. 577, 579 (1992). The author writes:

To best serve its critical role in a free society, the law must be understandable, uniform, reliable, and consistent with the intent of the people's representatives who enacted it. To the maximum extent achievable by human beings, it can fairly be said that the law entrusted to the Court of Appeals for the Federal Circuit fully meets those criteria.

Id.

6. See *id.* at 577 (discussing the Federal Circuit's success in fulfilling Congress's desire to create uniformity in patent law). Perhaps one of the most misunderstood aspects of Federal Circuit practice by the patent bar is the frequency of dissenting opinions among the judges. Such division likely reflects more deliberation than divisiveness on the court. See Helen Wilson Nies, *Dissents at the Federal Circuit and Supreme Court Review*, 45 AM. U. L. REV. 1519, 1527 (1996) ("[E]specially here at the Federal Circuit . . . dissents are virtually the sole means by which contradicting positions on the law are presented fully and without personal bias to the Supreme Court.")

7. See S. REP. NO. 275, at 2 (1981), reprinted in 1982 U.S.C.C.A.N. 11, 12 (describing legislative rationale behind the establishment of the Federal Circuit with enactment of Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25, 37 (codified as amended at 28 U.S.C. § 1295)); Daniel J. Meador, *The Origin of the Federal Circuit: A Personal Account*, 41 AM. U. L. REV. 581, 581 (1992) (discussing national scope of the Federal Circuit in relation to its establishment); Trybus, *supra* note 3, at 737-39 (reviewing the legislative mandates for the creation of the Federal Circuit and exploring the court's jurisdictional interface with non-patent matters); see also Howard T. Markey, *The State of the Court*, 38 AM. U. L. REV. 1093, 1094 (1989) (describing the mission of the Federal Circuit as "[t]he Best Possible Decisions in the Shortest Possible Time at the Least Possible Cost").

8. See Victoria Slind-Flor, *Federal Circuit Judged Flawed*, NAT'L L.J., Aug. 3, 1998, at A1 (discussing criticisms that the courts' decisions are too ambiguous); see also Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805, 806-11 (1988) (evaluating the economic effects on actual technological innovation attributable

agree with the appraisal that the renewed, if not unprecedented, prominence of patent rights in the United States owes much to the Federal Circuit's intensive efforts during the past seventeen years.⁹

The ability of commercial enterprise to embrace U.S. patents as important assets in worldwide market competition depends greatly upon the value of these legal instruments, which, in turn, depends upon the court's reliable patent enforcement.¹⁰ If judicial decisions in patent cases fail to comport with either public appreciation of technology or established legal paradigms, confidence in the patent system can erode.¹¹ The duality of these concerns creates a tension that the legal framework charged with the predictable enforcement of patents may find itself incapable of resolving with satisfaction.¹²

In an attempt to enhance clarity and consistency in patent law jurisprudence, the Federal Circuit adheres to specific standards of review over the decisions of its lower tribunals.¹³ In so doing, the Federal Circuit establishes an internal control mechanism in its operation.¹⁴ Moreover, the Federal Circuit provides a set of guiding principles to encourage more effective advocacy of patent-related cases well in advance of appeal.¹⁵

to the rewards for invention disclosures offered by the U.S. patent system).

9. See Markey, *supra* note 7, at 1094 (discussing the internal measures employed by the Federal Circuit to achieve uniformity in patent law).

10. See Pauline Newman, *The Federal Circuit - A Reminiscence*, 14 GEO. MASON L. REV. 513, 519 (1992) ("The predictability that patents improvidently granted will be held invalid is of no less interest to us as manufacturers and purveyors of goods than the predictability that patents will be held valid if they represent proper protection of a valuable investment in innovative technology.").

11. See Paul R. Michel, *The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1245 (1994) ("Greater dissonance, however, may occur between some of our decisions and technological, economic, or industrial reality. That reality, which is a means for measuring the practical effects of a given ruling, is usually missing from our records and, therefore, from our minds."); Pauline Newman, On Global Patent Cooperation, Address Before the Fifth Annual Conference on Intellectual Property Law and Policy (Apr. 3, 1997), in 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 3, 9 (1997). In her address, Pauline Newman notes that:

As more and more industry of all nations moves into the international marketplace, the economic consequences of international patent disputes will become more pervasive. . . . Ideally a commercial law would be sufficiently comprehensive that its application raises no uncertainty. . . . However, the areas in which these uncertainties arise are—it seems to me—matters not of national policy, but of technologic understanding.

Id.

12. See Michel, *supra* note 11, at 1243 (discussing how shifting paradigms in patent law may paralyze the business community and impede progress).

13. See *infra* Part II.B (discussing the standards of review followed by the Federal Circuit).

14. See Glenn L. Archer, Jr., *Conflicts and the Federal Circuit*, 29 J. MARSHALL L. REV. 835, 836-37 (1996) (reviewing procedural mechanisms employed by the Federal Circuit to ensure consistency and clarity in the law).

15. See Paul R. Michel & Dr. Michelle Rhyu, *Improving Patent Jury Trials*, 6 FED. CIR. B.J. 89, 93-102 (1996) (proposing improvements to the administration of patent jury trials, including

On the other hand, the standards of review followed by the Federal Circuit appear to have vested the court with increasing authority to conduct plenary reviews of lower tribunal decisions.¹⁶ Some of these new standards arose in the context of determining the proper roles of the judge and jury at trial.¹⁷ Of course, in considering certain inquiries as pure questions of law, the Federal Circuit gained greater latitude to step back from rulings made by the U.S. district courts and the U.S. Patent and Trademark Office ("USPTO").

In addition, the Federal Circuit recently upheld its historical standard of review of USPTO factual findings.¹⁸ Setting aside other concerns about judicial activism by the appellate court, such an expanding scope of review arguably creates a greater opportunity for the Federal Circuit to engage in substantive analysis of the science underlying patent-related cases.¹⁹ The potential consequences of these forays into science by the federal judiciary, and specifically by the Federal Circuit, is the crux of recent controversies involving the interface between science and patent law.²⁰

This Article addresses the difficulty at times in finding justice in the patent law decisions of the Federal Circuit in the face of apparent misapplications, or seemingly intentional ignorance, of otherwise accepted scientific or engineering principles. Part I discusses the confusion the casual observer might encounter when studying such decisions without an appreciation of the standards of review that dictate the Federal Circuit's resolution of an appeal.²¹ In Part II, the

comprehensible jury instructions, special verdicts, and interrogatories).

16. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996) (holding that interpretation of the meaning and scope of a patent claim is a legal question which the Federal Circuit reviews without deference to the determination of the district court); *infra* notes 149-83 and accompanying text (discussing *Markman* in greater detail).

17. See *Markman*, 52 F.3d at 979, 34 U.S.P.Q.2d (BNA) at 1329 (discussing the relative duties of jury and judge in patent cases).

18. See *In re Zurko*, 142 F.3d 1447, 46 U.S.P.Q.2d (BNA) 1691 (Fed. Cir. 1997) (en banc), *rev'd*, 119 S. Ct. 1816 (1999) (finding clearly erroneous a decision of the Board of Patent Appeals and Interferences, which held that the claims in the patent application were obvious); see also *infra* Part II.B.

19. Whether one perceives an individual or collective effort by the Federal Circuit to engage in technological adjudication, the fact remains that panels are assigned randomly, irrespective of the technical subject matter of the appeal. See Helen W. Nies, *Celebrating the Tenth Anniversary of the United States Court of Appeals for the Federal Circuit*, 14 GEO. MASON L. REV. 505, 505-06 (1992) (embracing the practice of assignment of cases at the Federal Circuit blindly rather than on the basis of individual judge's prior professional and judicial experience).

20. See Pauline Newman, *The Sixth Abraham L. Pomerantz Lecture: Commentary on the Paper by Professor Dreyfuss*, 61 BROOK. L. REV. 53, 62 (1995) (indicating that the Federal Circuit rarely has reviewed the technologic substance of patent cases, and stating that "[a] concerned public is the best guardian of not only the accuracy of the law, but of whether the court adequately understands and implements the social policy underlying the law").

21. See *infra* Part I (discussing the sources of conflict between scientific and legal

Article considers several significant cases, including *Dickinson v. Zurko*, in which the Federal Circuit struggles with questions about the appropriate standard of review.²² The Article concludes in Part III with a survey of the applicable standards of review by the Federal Circuit on various specific patent law issues. Through this review, the Article seeks to facilitate a more balanced consideration of the patent law decisions of the Federal Circuit in hopes of reaching a better understanding of otherwise suspect holdings from a scientific validity perspective.

I. THE PATENT (TECHNOLOGY) COURT MISNOMER

The historical relationship between science and the law generally has been less than cooperative at times.²³ In the patent law arena, the perceived dissociation of scientific truth and physical laws from justice in the courts can leave the parties to the litigation, and interested spectators alike, with an incredulity usually reserved for seemingly ill-founded criminal acquittals.

Indeed, the significance of the doctrinal rift between science and the law has not been lost on the jurists charged with the efficient administration of the patent laws.²⁴ For example, Judge Newman of the Federal Circuit commented:

The shaping of the patent law is to an exceptional degree in the hands of the judiciary, for in patent cases a relatively simple statutory law is applied to an extraordinary complexity of factual circumstances. These encompass the entire range of mechanical, electronic, biological, and chemical subject matter. The entrepreneurial and creative vigor of the nation's technology is metered by the system of laws governing patents. Review of the history of patent law over the economic cycles of the nation, indeed over the nation's evolution from an agricultural to an industrial economy, shows the judiciary reflecting in its patent decisions a variety of perceptions of the place of patents in the nation's

principles).

22. See *infra* Part II (reviewing relevant case law and recent decisions of the Federal Circuit).

23. See Black, *supra* note 1, at 716 (stating that "[j]udges and lawyers usually react to science with all the enthusiasm of a child about to get a tetanus shot"). Indeed, the issues of legal proof and accepted scientific tenets have whipped up dramatic tempests in criminal courtrooms. See generally PETER W. HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM* (1991).

24. See Howard T. Markey, *Jurisprudence or "Juriscience"?*, 25 WM. & MARY L. REV. 525, 526 (1984) (opining that "[s]cience and the law are inherently and irreconcilably different"); Pauline Newman, *The Federal Circuit: Judicial Stability or Judicial Activism?*, 42 AM. U. L. REV. 683, 688 (1993) (recommending a simplified approach to science and the law and asserting that undue complexity is often reflective of insufficient understanding).

economy. Although there was often manifest prescience and great wisdom, increasingly, mirroring society, there appears to have been a failure of the "two cultures" of law and science to understand each other. Today we cannot afford this gap, for scientific knowledge and technologic issues underlie large segments of modern jurisprudence, as well as of our economy.²⁵

Where the Federal Circuit is concerned, the potential outcry in this respect may be heightened for reasons beyond its control. Even before its creation, the Federal Circuit seemed burdened with the label of specialization as either the Patent Court or the Technology Court, a notion the court has taken great efforts to dispel.²⁶

To be certain, public perception easily could find support in the apparent operation of the Federal Circuit. With exclusive jurisdiction of patent appeals from federal courts nationwide and a judicial staff heavily loaded with individuals trained in various technical disciplines, the Federal Circuit seems outfitted for such a role, whether or not formally tasked with this responsibility. Despite the handling of cases of arguably equivalent legal and technical complexity, the regional circuit courts of appeals typically cannot lay claim to such workload or staff compositions.²⁷

In any event, a public perception of the mission of the Federal Circuit with respect to patent-related cases apparently includes the advancement of social policy involving the encouragement of continued private investment in research and development to ensure global competitiveness of U.S. companies.²⁸ In an era of relative economic prosperity, the patent system risks increased public scrutiny over the ease of patent procurement in conjunction with overly broad patent enforcement.²⁹ Simply stated, in good times, doubts usually

25. Newman, *supra* note 24, at 685-86.

26. See Randall R. Rader, *Specialized Courts: The Legislative Response*, 40 AM. U. L. REV. 1003, 1004-06 (1991) (reviewing the concerns voiced by legislators during the development of the Federal Circuit against the creation of a specialized court).

27. See Hillen, *supra* note 4, at 215-18 (noting the fundamental legal goals of consistency and coherence in implementing social policy and the difficulties faced by an arguably specialized court in achieving these goals).

28. See Lawrence G. Kastriner, *The Revival of Confidence in the Patent System*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 5, 5 (1991) (commenting that the patent system "has always been an integral part of the social and economic fabric of this nation"); Gerald Sobel, *The Court of Appeals for the Federal Circuit: A Fifth Anniversary Look at Its Impact on Patent Law and Litigation*, 37 AM. U. L. REV. 1087, 1092 (1988) (noting that heightened patent protection by the Federal Circuit reflects a broad judicial movement toward greater protection of technological development and innovation).

29. See Teresa Riordan, *A Growing Fear That Internet Patents Threaten to Undermine the Very Nature of the On-Line World*, N.Y. TIMES, Feb. 22, 1999, at C11 ("The United States Patent and Trademark Office has begun to issue a spate of patents that were applied for several years ago when the Internet was just becoming commercially viable. Some fear that these patents threaten the very architecture underlying the on-line world.").

recur over the conventional wisdom that aggressive patent protection is a necessary incentive to continue the strive for innovation.³⁰ Moreover, such concerns typically arise in connection with assertions that a strong patent system may actually inhibit innovation.³¹

When popular sentiment begins to sway against patent protection, one target of criticism is often an alleged disconnect between government action and the needs of commercial enterprise.³² With the USPTO arguably issuing patents with seemingly overbroad generic claims and the federal courts enforcing such claims, public dissatisfaction can arise over their respective failures to appreciate whether the particular technology events qualify as true innovation.³³ Furthermore, such charges may be based solely upon an asserted lack of ability of the legal arbiter to determine scientific truth or merit.

In the context of patent validity, enforceability, and infringement determinations, the purely technical aspects of an invention often come into play. In particular, comparative evidence regarding the technology typically drives the ultimate resolution of patent issues such as novelty, inventorship (including priority), and infringement.

30. Cf. Thomas H. Case & Scott R. Miller, *An Appraisal of the Court of Appeals for the Federal Circuit*, 57 S. CAL. L. REV. 301, 325 (1984) (assessing the specialization of the Federal Circuit and discounting the court's impact on increasing American industrial innovation in light of its ability to stabilize patent law).

31. Indeed, such a sentiment has been a longstanding criticism of the patent system and the Federal Circuit's role in its administration, an image the court has consistently rebuffed. Compare Thomas G. Field, Jr., *'Zurko' Raises Issue of Patentability Standards*, NAT'L L.J., Feb. 8, 1999, at C2 ("Because the invalidity rate is now lower than it was between the 1930s and the 1960s, some suspect federal circuit judges, even those not formerly on the CCPA, of being unduly 'pro-patent.' Former corporate patent counsel seem to be particularly suspect."), with Markey, *supra* note 5, at 579 ("[T]he uninformed, unsupported, and unsupportable assertion that the Federal Circuit might somehow become biased in favor of patents has apparently by now foundered on the facts."). See also John Greenwood, *Fields of Broken Dreams: Agricultural Biotechnology Holds the Promise of Modern Miracles in Food Production or Pharmaceuticals*, NAT'L POST, Oct. 29, 1998, at C12 ("In the wild-west world of agricultural biotech, it's called patent chill—the fear that the product you are developing infringes on someone else's patent. . . . Over the past few years, virtually every company in the sector, large and small, has had a brush with it. . . . And, observers say, because of patent chill, many [small, development companies] are in danger of losing momentum.").

32. See Joan E. Schaffner, *Patent Preemption Unlocked*, 1995 WIS. L. REV. 1081, 1089-91, 1127 (analyzing Lockean property principles as theoretical underpinnings of the United States patent system and considering the potential impairment to innovative progress posed by an improper balance of the property domain and the common).

33. See Allan N. Littman, *Federal Circuit Rulings Damage Patent Law*, NAT'L L.J., Jan. 18, 1999, at A26. The author states that:

The U.S. Court of Appeals for the Federal Circuit has drastically weakened judicial safeguards against invalid patents. A significant number of the more than 100,000 U.S. patents issued every year are invalid. They have not met the statutory standards for patents. They deter true invention, and, unless invalidated by judicial decisions, they subvert the patent system.

Id.; see also Newman, *supra* note 10, at 519 ("Industry is concerned not only with patent rights on its own products, but also with the opportunity to 'invent around,' to improve upon, and compete with, the patented products of others.").

In contrast, other inquiries like nonobviousness³⁴ and patent damages usually involve marketplace considerations beyond the true scientific merit of the subject matter.³⁵ As such, the first set of issues arguably speaks only to the invention, whereas the second set actually addresses the innovation attributable to that invention. In this sense, patent law treats science apart from innovation, but embraces both as important concerns to implement the social policy of fostering technological progress.

Despite the Federal Circuit's view that it should not adjudicate scientific principles, the public may have a different perception.³⁶ In more established technical fields, such as the engineering arts, the underlying physical precepts often have not demanded rigorous explanation by the Federal Circuit. In newer or rapidly developing technologies, such as biotechnology and computer software, the Federal Circuit has taken great pains to provide detailed primers on the relevant technical matters.³⁷ Such descriptions in precedential opinions, however, may give rise to controversies where the state of the art is unsettled or quickly rendered obsolete.³⁸

A. Schendel v. Curtis

The Federal Circuit itself is not immune to internal conflict about the degree to which its decisions may be driven improperly by the

34. See *infra* notes 393-402 and accompanying text (stating that patent protection is afforded to nonobvious inventions only).

35. One commentator has noted that:

[T]he increasing importance given to these nontechnical indicia of nonobviousness can be interpreted as an effort by the CAFC to move the trial courts away from a consideration of the technical merits of an invention, which they may be unqualified or underqualified to consider, toward an analog of specialized jury interrogatories, which the CAFC may more easily review and reinterpret. The secondary characteristics are meant to provide a trial court with nontechnical means by which to assess nonobviousness.

Hillen, *supra* note 4, at 199-200.

36. See Markey, *supra* note 24, at 540 (proposing rules for technological adjudication, which include "Rule IV: The Parties Shall Not Present Unanswerable Scientific Questions for Decisions" and "Rule V: The Court Shall Not Attempt to Decide 'Scientific Truth'").

37. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1203, 18 U.S.P.Q.2d (BNA) 1016, 1017 (Fed. Cir.) (providing detailed technical background on a method for producing erythropoietin, the subject of the patent litigation), *cert. denied*, 502 U.S. 856 (1991); see also *In re O'Farrell*, 853 F.2d 894, 895-99, 7 U.S.P.Q.2d (BNA) 1673, 1674-79 (Fed. Cir. 1988) (providing technical explanation of a genetic engineering invention).

38. See Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 12 COMP. & HIGH TECH. L.J. 1, 67 (1997) (indicating that the patent law rationales underlying established technologies, such as traditional chemistry, may not extend validly to more recent developments, like recombinant DNA inventions); see also *Dow Chem. Co. v. American Cyanamid Co.*, 816 F.2d 617, 623, 2 U.S.P.Q.2d (BNA) 1350, 1355-56 (Fed. Cir. 1987) (Davis, J., dissenting) (disagreeing with the conclusion reached by the majority because the chemical process at issue was substantially the same as that in a previous unrelated case on a different patent).

court's own view of the scientific merit of the subject matter. Perhaps one of the more revealing examples is the *Schendel v. Curtis* decision,³⁹ where a Federal Circuit panel disagreed on the impact that certain scientific tests should have had on the outcome of the case.⁴⁰

The *Schendel* case involved an appeal from the decision of the USPTO Board of Patent Appeals and Interferences, which granted summary judgment in favor of Curtis in a patent interference proceeding.⁴¹ The subject matter of the interference count related to a fusion protein of interleukin-3 (IL-3) and a hematopoietin, which could be granulocyte colony stimulating factor (G-CSF) or granulocyte-macrophage colony stimulating factor (GM-CSF).⁴² Schendel alleged priority of invention based on his alleged actual reduction to practice of an IL-3/G-CSF fusion protein before Curtis' effective patent application filing date.⁴³

The Federal Circuit, in a split decision, upheld the Board's ruling that Schendel's evidence failed to show that he had obtained an IL-3/G-CSF fusion protein.⁴⁴ Although the scientific evidence and declarations apparently indicated that Schendel had isolated material having the respective biological activities of IL-3 and G-CSF, there was no showing that this material constituted an actual fusion protein.⁴⁵ In particular, the absence of any chemical composition or structural data, such as a relatively simple molecular weight determination, appeared significant to the ultimate resolution of the case.⁴⁶

39. 83 F.3d 1399, 38 U.S.P.Q.2d (BNA) 1743 (Fed. Cir. 1996).

40. *See id.* at 1406, 38 U.S.P.Q.2d (BNA) at 1750 (Newman, J., dissenting) (contending that the majority acted improperly in deciding that the scientific record was insufficient, especially when the scientists themselves deemed the evidence sufficient). The judges of the Federal Circuit have often embraced panel conflicts as a vital component of effective decision making. *See, e.g.,* Newman, *supra* note 24, at 683 ("In meeting the court's responsibilities in each area of the law assigned to it, the occasional 'percolation' of divergent views illustrates the vigor of the judicial search for truth, the sometimes indirect progress toward the justice and fairness that animate the law."); Nies, *supra* note 6, at 1527 (noting the importance of dissenting opinions by the Federal Circuit to the development of the law).

41. *See Schendel*, 83 F.3d at 1400-01, 38 U.S.P.Q.2d (BNA) at 1744 (discussing the Board's decision to grant summary judgment in favor of Curtis because Schendel did not adequately establish that he had been able to reduce his claimed fusion protein to practice before Curtis filed its patent application).

42. *See id.* at 1400 & n.3, 38 U.S.P.Q.2d (BNA) at 1744 & n.3 (explaining the creation of fusion protein as part of recombinant DNA technology).

43. *See id.* at 1401, 38 U.S.P.Q.2d (BNA) at 1744 (outlining Schendel's claims before the Board of Patent Appeals and Interferences).

44. *See id.* at 1404, 38 U.S.P.Q.2d (BNA) at 1747.

45. *See id.*, 38 U.S.P.Q.2d (BNA) at 1747.

46. *See id.*, 38 U.S.P.Q.2d (BNA) at 1747 ("[W]ithout any molecular weight or other probative data relevant to the composition or structure of the molecule he allegedly prepared, there is insufficient evidentiary support for Schendel's conclusory assertion that he made a . . . fusion protein.") (citations omitted).

Judge Newman disagreed with the majority decision.⁴⁷ In her dissent, she stated:

Determination of whether the evidence is sufficient to make a *prima facie* showing that Schendel produced what he said he produced must be based on objective scientific standards, from the viewpoint of the scientists in the field of the invention. It is thus relevant whether the fusion reaction was scientifically routine and reliable, or exotic and unreliable; whether the bioassays were scientifically routine and professionally performed, or whether they were unusual or performed by amateurs. All of the procedures and data together present a *prima facie* case that Dr. Schendel had produced the molecule of the count. There was no contrary evidence. Although our standard of review of the Board's grant of summary judgment is plenary, at this stage of the proceedings neither the Board nor we can weigh evidence; to the contrary, reasonable factual inferences must be drawn in favor of the party Schendel. It is not our appellate role to devise experiments that the inventor did not deem it necessary to conduct, and then to hold that the judges' choice of experiments is dispositive of the issue.⁴⁸

The panel majority, however, noted that the decision turned not on the merits of the scientific evidence, but on the rulings of the lower tribunal as upheld by the Federal Circuit under the proper standard of review.⁴⁹ In particular, the majority indicated:

The dissent runs through all the data presented by Schendel and ends up concluding that "the analytical data confirmed that the expected linked product was obtained." That there were no analytical data is the nub of this case. The import of the dissent's extensive analysis of the facts is that the identity of the claimed product was proved and that the court has improperly assumed an "appellate role to devise experiments that the inventor did not deem it necessary to conduct."

As an appellate court, we are affirming the judgment of the expert agency because the agency did not apply an incorrect standard and did not make clear error in its evaluation of facts. Rather than weighing evidence and devising further experiments, we are affirming the board's determination that Schendel did not establish the structure or identity of the product of the count.

47. See *id.* at 1406, 38 U.S.P.Q.2d (BNA) at 1749 (Newman, J., dissenting) (concluding that the evidence was "prima facie probative of conception and reduction to practice of the subject matter of the count").

48. *Id.*, 38 U.S.P.Q.2d (BNA) at 1751-52.

49. See *id.* at 1404 n.8, 38 U.S.P.Q.2d (BNA) at 1749 n.8 (affirming that the expert agency applied the correct standard of review).

Whether we might agree, as nonexperts, that Schendel may have obtained the product is not the point. Even a *prima facie* case requires some real proof, not just vague inference, based on surrounding circumstances that tangentially support the inventor's goal. The question here is whether Schendel proved, irrespective of whether that proof was corroborated, that use of his starting gene fragments resulted in the synthesis of the fusion protein. We conclude that the PTO did not err in holding that he did not.⁵⁰

B. In re *Soni*

In *In re Soni*,⁵¹ the Federal Circuit reversed the decision of the USPTO Board of Patent Appeals and Interferences, which upheld the patent examiner's final rejection of the claims as obvious.⁵² The subject matter of the application involved conductive polymer compositions.⁵³ In rebuttal to the patent examiner's rejection of the claims as *prima facie* obvious, Soni argued that the claimed compositions exhibited unexpectedly improved physical and electrical properties compared to lower-weight prior art compositions.⁵⁴ Soni's contention failed to persuade the patent examiner or the Board.⁵⁵

The Board specifically noted that Soni's position was unsupported by any data.⁵⁶ The Federal Circuit disagreed, relying on specific data in Soni's specification showing improved properties.⁵⁷ The Federal Circuit held that absent evidence to the contrary, an applicant's assertion of surprise supported with a showing of substantially improved results suffices to establish unexpected results.⁵⁸ Given Soni's duty of candor, and the absence of a sound basis to question Soni's assertion, the Federal Circuit held that the Board clearly erred in finding that Soni did not establish unexpected results.⁵⁹

50. *Id.*, 38 U.S.P.Q.2d (BNA) at 1748 n.8.

51. 54 F.3d 746, 34 U.S.P.Q.2d (BNA) 1684 (Fed. Cir. 1995).

52. *See id.* at 748-49, 34 U.S.P.Q.2d (BNA) at 1685-86.

53. *See id.* at 747-48, 34 U.S.P.Q.2d (BNA) at 1685. The application at issue was U.S. Patent Application Serial No. 07/462,893. *See id.*, 34 U.S.P.Q.2d (BNA) at 1685.

54. *See id.* at 748, 34 U.S.P.Q.2d (BNA) at 1685 (noting distinctions between appellant's patent claims and other polymer compositions).

55. *See id.* at 748, 34 U.S.P.Q.2d (BNA) at 1685 (reviewing examiner's rejection of claims 1-6, 8-12, and 21 under 35 U.S.C. §§ 102-103).

56. *See id.* at 749, 34 U.S.P.Q.2d (BNA) at 1686 ("That which appellants characterize as 'evidence' consists of conclusory statements . . . which . . . are *unsupported by any factual data.*") (citations omitted).

57. *See id.* at 750, 34 U.S.P.Q.2d (BNA) at 1687 (concluding that the Board erred in deciding that appellant's evidence were merely conclusory statements).

58. *See id.* at 749-51, 34 U.S.P.Q.2d (BNA) at 1687-88 (noting that a showing of "unexpected results" allows a patent applicant to rebut a presumption of obviousness that exists between similar compositions).

59. *See id.* at 751, 34 U.S.P.Q.2d (BNA) at 1688 (concluding that the USPTO established a

One member of the *Soni* panel expressed concern that the failure of the court to articulate patentability standards with specificity might result in the otherwise unnecessary adjudication of the scientific merits.⁶⁰ In his dissent, Judge Michel stated:

[P]erhaps the majority means to say, more generally, that examiners, Board members, and Federal Circuit judges will know “substantial” improvements when they see them. Disagreements among these evaluators are, of course, inevitable, and will likely be frequent. This reading, though less perplexing, would have far broader implications: unhindered by any objectively established baseline of expected improvement in the relevant art, the assessment of an applicant’s unsupported assertion that the observed degree of improvement was unexpected can flex to suit the taste of the assessor, thus destabilizing the obviousness inquiry and virtually ensuring litigation through final appeal to us in most every case of allegedly unexpected improvement. The resulting loss of objectivity and predictability bodes ill for patentability determinations.⁶¹

The *Schendel* and *Soni* cases illustrate the problematic nature of deciding patent-related issues where the ultimate conclusion rests on a critique of the underlying science.⁶² On the other hand, these cases also show the arguable amelioration of any disjuncture facilitated by the faithful application by the Federal Circuit of the appropriate standard of review.⁶³

Recent changes in the patent law paradigm would appear to represent the initial evolution toward minimizing the frequency that the federal courts would need to engage in debates about the underlying scientific principles.⁶⁴ In this regard, the Federal Circuit has increasingly admonished the patent bar regarding its duty to notify the public about patent claims.⁶⁵ Echoing this sentiment, the

prima facie case, the applicant responded, and the USPTO failed to adequately challenge the applicant’s response).

60. *See id.* at 755, 34 U.S.P.Q.2d (BNA) at 1692 (Michel, J., dissenting) (“[T]he majority’s new rule may be inherently unworkable. For example, one may well ask how large improvements in results must be before the Board must consider them to be ‘substantially improved results’ such that they amount to an effective rebuttal of a *prima facie* case of obviousness. The majority provides no guidance on the question”) (citations omitted).

61. *Id.* at 755, 34 U.S.P.Q.2d (BNA) at 1692 (Michel, J., dissenting).

62. *See supra* note 60 and accompanying text (discussing the difficulty judges will have in adjudicating patent disputes without clear standards).

63. *See Schendel v. Curtis*, 83 F.3d 1399, 1406 n. 8, 38 U.S.P.Q.2d 1734, 1748 n.8 (Fed. Cir. 1996) (noting that the appellate court’s responsibility is to determine whether the agency applied the correct standard of review, not to evaluate the scientific evidence itself).

64. *See infra* note 65 and accompanying text (discussing the policy trend to inform the public about recently filed technology patents).

65. *See Litton Sys., Inc. v. Honeywell, Inc.*, 145 F.3d 1472, 1474, 47 U.S.P.Q.2d (BNA) 1106, 1108 (Fed. Cir. 1998). In *Litton*, the Federal Circuit set forth the social policy rationale for the

Supreme Court has set out new law in two substantive patent law issues, which essentially place a greater burden on those seeking patent protection to explain the technology and its potential significance to patentability.⁶⁶

C. Vitronics Corp. v. Conceptoronic Inc.

In *Vitronics Corp. v. Conceptoronic Inc.*,⁶⁷ the Federal Circuit provided specific guidance concerning the practical application of claim construction principles set forth by the Federal Circuit *en banc*, in *Markman v. Westview Instruments, Inc.*,⁶⁸ and affirmed by the Supreme Court.⁶⁹ The patented technology related to methods for the reflow soldering of surface mounted devices to a printed circuit board in which a conveyer moves the circuit board through a multizone oven.⁷⁰

patent system and the underlying public notice requirements:

Patents provide inventors with a legal right, for a limited time, to exclude others from using, selling, offering to sell, or manufacturing the invention. In essence, patents give their owners significant power over the development of technology and markets by giving patentees the right to exclude others from using their inventions. For this privilege, the government extracts a public disclosure of the invention in the hope that, among other things, the disclosure of all inventions will add to the sum total of knowledge available to the general public. Competitors and the markets, as well as the courts, must be able to ascertain what subject matter is covered by this right to exclude. Public notice of the scope of the right to exclude, as provided by the patent claims, specification and prosecution history, is a critical function of the entire scheme of patent law. The notice function is critical because it provides competitors with the necessary information upon which they can rely to shape their behavior in the marketplace.

Id., 47 U.S.P.Q.2d (BNA) at 1108; *see also* Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1424, 44 U.S.P.Q.2d (BNA) 1103, 1107 (Fed. Cir. 1997) (discussing the public notice function of claims in the context of a doctrine of equivalents analysis) (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997)); *In re* Clement, 131 F.3d 1464, 1468, 45 U.S.P.Q.2d (BNA) 1161, 1164 (Fed. Cir. 1997) (holding that the "recapture rule . . . prevents a patentee from regaining through reissue subject matter . . . surrendered" during prosecution, thus ensuring the ability of the public to rely on a patent's public record) (citations omitted); *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583, 39 U.S.P.Q.2d (BNA) 1573, 1577 (Fed. Cir. 1996) (holding that the public is entitled to rely upon the public record of a patent in determining the scope of the patent's claims).

66. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, (1998) (recognizing that the patent laws seek to protect the public's right to keep certain information in the public domain and the inventor's right to control whether and when to patent his invention), *aff'g*, 124 F.3d 1429, 43 U.S.P.Q.2d (BNA) 1928 (Fed. Cir. 1997); Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29-30 (1997), *rev'g on other grounds*, 62 F.3d 1512, 1516, 35 U.S.P.Q.2d (BNA) 1641, 1644 (Fed. Cir. 1995) (reconciling conflict between the notice requirement of patent claims and the doctrine of equivalents).

67. 90 F.3d 1576, 39 U.S.P.Q.2d (BNA) 1573 (Fed. Cir. 1996).

68. 52 F.3d 967, 979, 34 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (establishing that the claims, specification, and prosecution history, but not expert testimony, may be used to determine the meaning of claims).

69. *See Vitronics*, 517 U.S. at 370.

70. *See Vitronics*, 90 F.3d at 1578-79, 39 U.S.P.Q.2d (BNA) at 1573-74 (describing the patented invention assigned to Vitronics as directed to soldering applications). The patent-in-suit was U.S. Patent No. 4,654,502. *See id.* at 1578, 39 U.S.P.Q.2d (BNA) at 1573. To attach certain devices to a printed circuit board, solder paste between the device connectors and

The crux of the infringement controversy was the meaning of the claim terms “solder reflow temperature.”⁷¹ Vitronics contended that solder reflow temperature meant a temperature of approximately 20°C above the temperature at which the solder is completely melted and moves freely.⁷² In contrast, Conceptronic asserted that solder reflow temperature meant 183°C, the temperature at which a particular type of solder known as 63/37 (Sn/Pb) solder is completely melted and moves freely.⁷³ In support of its position, Conceptronic relied heavily on expert testimony.⁷⁴

At the outset, the Federal Circuit referred to the intrinsic evidence of the record, including the patent claims themselves and the patent’s specification and prosecution history, as the most significant source of the legally operative meaning of the disputed language.⁷⁵ On the other hand, the court held that extrinsic evidence external to the patent and file history, including expert testimony, inventor testimony, dictionaries, and technical treatises and articles, may be used only to the extent it facilitates a proper understanding of the state of the art.⁷⁶ Extrinsic evidence may not be used to vary or contradict the claim language or other parts of the specification and should not be afforded any weight where the patent documents are unambiguous.⁷⁷

Accordingly, the Federal Circuit held that the district court committed reversible error when it relied on expert testimony and other extrinsic evidence in the face of a clear and unambiguous definition in the specification of the disputed claim term.⁷⁸ In reaching this conclusion, the Federal Circuit commented on the

board is heated to melting as the board passes on a conveyer belt through an oven with different heating zones. *See id.* at 1579, 39 U.S.P.Q.2d (BNA) at 1574. This temperature differential allows the solder paste to melt and reflow while the circuit board stays below the solder reflow temperature. *See id.*, 39 U.S.P.Q.2d (BNA) at 1574. The solder reflow forms a solid connection between the device and the circuit board. *See id.*, 39 U.S.P.Q.2d (BNA) at 1574.

71. *See id.* at 1579-80, 39 U.S.P.Q.2d (BNA) at 1574.

72. *See id.* at 1580, 39 U.S.P.Q.2d (BNA) at 1574 (describing Vitronic’s proposed jury instruction defining the claim term, solder reflow temperature).

73. *See id.*, 39 U.S.P.Q.2d (BNA) at 1574.

74. *See id.* at 1581, 39 U.S.P.Q.2d (BNA) at 1575-76 (reporting Conceptronic’s reliance on testimony and documentary evidence from those skilled in the art that peak reflow temperature relates to the liquidus temperature at which the solder completely melts and moves freely).

75. *See id.* at 1582-83, 39 U.S.P.Q.2d (BNA) at 1573, 1576-77 (discussing the three proper sources for determining the meaning of disputed terms).

76. *See id.* at 1583, 39 U.S.P.Q.2d (BNA) at 1577 (noting that in most situations analysis of intrinsic evidence alone will resolve any ambiguity in a disputed claim term, thus prohibiting the use of extrinsic evidence).

77. *See id.*, 39 U.S.P.Q.2d (BNA) at 1577 (stating that use of extrinsic evidence is improper where the public record is clear).

78. *See id.* at 1585, 39 U.S.P.Q.2d (BNA) at 1579.

public notice rationale underlying its ruling.⁷⁹

In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence. In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention. Allowing the public record to be altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make this right meaningless. The same holds true whether it is the patentee or the alleged infringer who seeks to alter the scope of the claims.⁸⁰

The public notice responsibility sanctioned by the Federal Circuit heightens the demand on those seeking government protection of their inventions to set forth in their applications sufficient explanations of the technology to facilitate public (including judicial) understanding.⁸¹ From a social policy perspective, such burden shifting is beneficial because those persons best equipped to explain the patent's underlying science are required to do so.⁸²

D. *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*

In *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*,⁸³ the Federal Circuit clarified the law regarding infringement under the doctrine of equivalents.⁸⁴ This case presented the Federal Circuit with another opportunity to consider the respective roles of the judge and jury in

79. *See id.* at 1583, 39 U.S.P.Q.2d (BNA) at 1577 (discussing the importance of public reliance on the claims and other information disclosed in the patent).

80. *Id.*, 39 U.S.P.Q.2d (BNA) at 1577.

81. *See id.*, 39 U.S.P.Q.2d (BNA) at 1577 ("The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it.").

82. *See id.* at 1584, 39 U.S.P.Q.2d (BNA) at 1578 (explaining that an inventor's intent, as it relates to the scope of a claim, can be stated clearly in patent documents that constitute intrinsic evidence used to resolve ambiguous claim terms).

83. 62 F.3d 1512, 35 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 1995), *rev'd on other grounds*, 520 U.S. 17 (1997).

84. *See id.* at 1516, 35 U.S.P.Q.2d (BNA) at 1644 ("Courts have applied the doctrine of equivalents to protect the substance of the patentee's right to exclude since the first few decades after the enactment of the Patent Act of 1790, ch. 7, 1 stat. 109."). The Supreme Court has consistently recognized the doctrine of equivalents as a protection for patent owners. *See id.* at 1516-17, 35 U.S.P.Q.2d (BNA) at 1644-45.

patent cases.⁸⁵ The Federal Circuit *en banc* held unequivocally that infringement under the doctrine of equivalents is a factual issue for the jury to resolve after the court's instructions on the proper claim interpretation.⁸⁶ The Federal Circuit stated that a district court judge in a patent infringement jury trial may not withhold from the jury consideration of infringement under the doctrine of equivalents.⁸⁷ In so ruling, the appellate court rejected the argument that infringement under the doctrine of equivalents is a matter of equity to be applied at the discretion of the judge.⁸⁸ The Federal Circuit affirmed the district court's entry of judgment on the jury verdict of infringement.⁸⁹

Hilton Davis had sued Warner-Jenkinson alleging infringement of its patent to the ultrafiltration-mediated purification of commercial dyes for food and drug use.⁹⁰ The claims of the patent recited, *inter alia*, parameters for ultrafiltration through a membrane at "a hydrostatic pressure of approximately 200 to 400 p.s.i.g., at a pH from approximately 6.0 to 9.0, . . ."⁹¹ At trial, Hilton Davis presented evidence that the accused Warner-Jenkinson ultrafiltration process operated at a pressure between 200 to nearly 500 p.s.i.g., and sometimes at a pH of 5.0.⁹² The jury found that Warner-Jenkinson had infringed Hilton Davis' patent under the doctrine of equivalents.⁹³

On appeal to the Federal Circuit, Warner-Jenkinson argued that the doctrine of equivalents is an equitable remedy available only upon a suitable threshold showing of the equities by the patent holder, such as copying or piracy by the accused infringer.⁹⁴

85. See *infra* note 243 and accompanying text (discussing Federal Circuit's holdings regarding roles of judge and jury in patent cases).

86. See *Hilton Davis*, 62 F.3d at 1520-21, 35 U.S.P.Q.2d (BNA) at 1647 (citing *Graver Tank & Mfg. v. Linde Air Prods. Co.*, 339 U.S. 605, 609-10 (1949)).

87. See *id.* at 1522, 35 U.S.P.Q.2d (BNA) at 1648 ("The trial judge does not have discretion to choose whether to apply the doctrine of equivalents when the record shows no literal infringement.").

88. See *id.* at 1521, 35 U.S.P.Q.2d (BNA) at 1648 ("[T]he Supreme Court's cases on the doctrine of equivalents foreclose a holding that the doctrine is a matter of equity to be applied at the court's discretion.").

89. See *id.* at 1528-29, 35 U.S.P.Q.2d (BNA) at 1654 (concluding that the evidence supports the jury's verdict of infringement according to the doctrine of equivalents).

90. See *id.* at 1515-16, 35 U.S.P.Q.2d (BNA) at 1643. The patent-in-suit was U.S. Patent No. 4,560,746. See *id.* at 1515, 35 U.S.P.Q.2d (BNA) at 1642.

91. *Id.*, 35 U.S.P.Q.2d (BNA) at 1643.

92. See *id.* at 1524, 35 U.S.P.Q.2d (BNA) at 1650 (providing evidence to establish a finding of infringement).

93. See *id.* at 1516, 35 U.S.P.Q.2d (BNA) at 1643.

94. See *id.* at 1522-23, 35 U.S.P.Q.2d (BNA) at 1649 (indicating that Warner-Jenkinson's independent development of the process, without the knowledge of the plaintiff's patent, suggests the absence of conduct justifying application of the doctrine of equivalents).

Furthermore, Warner-Jenkinson asserted that, as a matter of equity, infringement under the doctrine of equivalents was a question for the court and not the jury to decide.⁹⁵ The Federal Circuit *en banc*, however, rejected Warner-Jenkinson's contentions.⁹⁶ The court held that a showing of culpable conduct is not necessary for, much less a prerequisite to, a finding of infringement under the doctrine of equivalents.⁹⁷ The Federal Circuit thus affirmed the jury verdict of infringement, despite the literal pressure and pH differences from the claimed invention.⁹⁸ The court relied on substantial evidence demonstrating that the Warner-Jenkinson ultrafiltration process performed the same function, in an equivalent way, to achieve the same result as the patented invention.⁹⁹

The Federal Circuit clearly set forth that infringement under the doctrine of equivalents exists where the differences between the claimed invention and the accused product or process are objectively insubstantial.¹⁰⁰ The court noted that often it may be adequate to rely solely on the function-way-result test¹⁰¹ to establish insubstantiality, and thus equivalency.¹⁰² In newer technologies, however, the court recognized the possibility that the function-way-result test would not suffice to illuminate the substantiality of the differences.¹⁰³ The Federal Circuit noted that important factors not considered in the function-way-result test included: evidence of known interchangeability of the accused and claimed elements; copying; designing around; and independent development.¹⁰⁴ Furthermore,

95. *See id.* at 1523, 35 U.S.P.Q.2d (BNA) at 1649 (stating that as a question of law, an equitable remedy must be considered by the court).

96. *See id.*, 35 U.S.P.Q.2d (BNA) at 1649 (upholding the trial court's instructions to the jury and rejecting Warner-Jenkinson's objection to sending the doctrine of equivalents question to the jury).

97. *See id.* at 1519, 35 U.S.P.Q.2d (BNA) at 1646 (asserting that the doctrine of equivalents does not rely on subjective awareness or intent of the accused infringer).

98. *See id.* at 1528-29, 35 U.S.P.Q.2d (BNA) at 1654 (noting that although the plaintiff's claim "recited 'a pH from approximately 6.0 to 9.0'" and defendant's process sometimes was below 6.0, this difference did not bar plaintiff's cause of action).

99. *See id.* at 1524-25, 35 U.S.P.Q.2d (BNA) at 1650-51 (reviewing the jury's substantial evidence finding on the pH variation and membrane pressure measurement).

100. *See id.* at 1517-18, 35 U.S.P.Q.2d (BNA) at 1644-45 (noting that insubstantial differences exist when the claimed and accused products perform the same function in the same manner, and produce the same result).

101. *See infra* note 301 (reviewing the tripartite test set forth in *Graver Tank*).

102. *See Hilton Davis*, 62 F.3d at 1518, 35 U.S.P.Q.2d (BNA) at 1645 (stating that a showing of a substantial sameness in function, way, and result between the claimed and accused process is sufficient for the doctrine of equivalency).

103. *See id.*, 35 U.S.P.Q.2d (BNA) at 1645 (noting that new technologies are more sophisticated than those in existence when the function-way-result test arose).

104. *See id.* at 1519-20, 35 U.S.P.Q.2d (BNA) at 1646-47. The Federal Circuit left open the question whether evidence of interchangeability, copying, or designing around would be sufficient, in the absence of a function-way-result analysis, to support a finding of equivalency.

the court stated that the proper objective standard for assessing the substantiality of differences is the perspective of a person of ordinary skill in the relevant art.¹⁰⁵

The Supreme Court reversed the Federal Circuit and remanded the case.¹⁰⁶ The Court stated:

Today we adhere to the doctrine of equivalents. The determination of equivalence should be applied as an objective inquiry on an element-by-element basis. Prosecution history estoppel continues to be available as a defense to infringement, but if the patent holder demonstrates that an amendment required during prosecution had a purpose unrelated to patentability, a court must consider that purpose in order to decide whether an estoppel is precluded. Where the patent-holder is unable to establish such a purpose, a court should presume that the purpose behind the required amendment is such that prosecution history estoppel would apply.¹⁰⁷

In creating new law essentially amounting to prosecution history estoppel by silence, the Court ostensibly set out a legal framework whereby the patent applicant bears the burden of explaining the scientific principles underlying the invention and their relationship to patentability.¹⁰⁸

Mindful that claims do indeed serve both a definitional and a notice function, we think the better rule is to place the burden on the patent holder to establish the reason for an amendment required during patent prosecution. The court then would decide whether that reason is sufficient to overcome prosecution history estoppel as a bar to application of the doctrine of equivalents to the element added by that amendment. Where no explanation is established, however, the court should presume that the patent application had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine equivalents as to that element. The presumption we have described, one subject to rebuttal if an appropriate reason for a required amendment is established, gives

See id. at 1518, 35 U.S.P.Q.2d (BNA) at 1645 (noting that analysis of function-way-result alone would suffice in many cases but acknowledging that test does not necessarily end the inquiry in certain instances).

105. *See id.* at 1519, 35 U.S.P.Q.2d (BNA) at 1646 (asserting that the objective test relies on objective evidence, not subjective conclusions offered by a person such as an expert witness).

106. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997) (rejecting the Federal Circuit's interpretation of the doctrine of equivalents).

107. *Id.* at 40-41.

108. *See id.* at 33-34 (discussing the Court's approach to the doctrine of equivalents and its requirement that patent holders explain any amendments).

proper deference to the role of claims in defining an invention and providing public notice, and to the primacy of the PTO in ensuring that the claims allowed cover only subject matter that is properly patentable in a proffered patent application.¹⁰⁹

Accordingly, with respect to infringement under the doctrine of equivalents, the federal courts need to engage less frequently in the evaluation of the science.¹¹⁰

E. Pfaff v. Wells Electronics Inc.

In *Pfaff v. Wells Electronics Inc.*,¹¹¹ the Supreme Court established new law with respect to the on-sale bar to patentability under 35 U.S.C. § 102(b).¹¹² In so doing, the Supreme Court overturned established Federal Circuit authority that stated the on-sale inquiry must take into account all of the circumstances surrounding the sale or offer to sell, including the stage of development and nature of the invention.¹¹³

On April 19, 1982, Pfaff filed a patent application relating to semiconductor sockets for testing leadless chip carriers that eventually issued on January 1, 1985, as U.S. Patent No. 4,491,377.¹¹⁴ Pfaff sued Wells for infringement of this patent, and Wells filed a counterclaim of patent invalidity.¹¹⁵ Wells alleged that Pfaff commercialized his invention before April 19, 1981, the critical date prior to which any legally sufficient sale of the invention would result in a bar to obtaining the patent.¹¹⁶

The evidence revealed that Texas Instruments ("TI") had

109. *Id.*

110. *See id.* (stating that the rebuttable presumption of prosecution history estoppel places the burden on the patent applicant to explain the reasons for the amendment).

111. 525 U.S. 55 (1998), *aff'g* 124 F.3d 1429, 43 U.S.P.Q.2d (BNA) 1928 (Fed. Cir. 1997).

112. *See id.* at 67 (articulating the two conditions required in order for the on-sale bar to apply). The Court stated: "First, the product must be the subject of a commercial offer for sale," and "[s]econd, the invention must be ready for patenting." *Id.*

113. *See* *Envirotech Corp. v. Westech Eng'g, Inc.*, 904 F.2d 1571, 1574, 15 U.S.P.Q.2d (BNA) 1230, 1232 (Fed. Cir. 1990) (stating that the court must consider the "totality of the circumstances" when determining whether a new invention was on sale); *UMC Elecs. Co. v. United States*, 816 F.2d 647, 656, 2 U.S.P.Q.2d (BNA) 1465, 1471-72 (Fed. Cir. 1987) (holding that the on-sale bar does not turn on a single factor regarding the reduction to practice but all circumstances relating to the sale of the invention); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860, 226 U.S.P.Q. (BNA) 402, 406 (Fed. Cir. 1985) (identifying the two factors which courts may use as evidence of being "on sale"). The first factor was "a sale or offer of sale of the invention," and the second factor was "an existing reduction to practice of the invention by the time of the offer." *Id.*, 226 U.S.P.Q. (BNA) at 406.

114. *See* *Pfaff v. Wells Elecs. Inc.*, 9 U.S.P.Q.2d (BNA) 1366, 1368-69 (N.D. Ind. 1988) (describing the development, in response to the need for high-density packaging for integrated circuit devices, of leadless chip carriers).

115. *See id.* at 1366.

116. *See id.* at 1375 (arguing that plaintiff's claim was invalid because the invention was on-sale beyond the statutorily permitted time period).

contacted Pfaff in November 1980 to develop a semiconductor chip socket for its carriers.¹¹⁷ Pfaff made detailed engineering drawings of the socket and sent them to a custom tooling and production subcontractor.¹¹⁸ These detailed drawings showed both precise dimensions and material requirements corresponding to the claimed invention.¹¹⁹

In a handwritten note on a February 25, 1981, engineering diagram, Pfaff indicated that the first order would be for 25,000 sockets.¹²⁰ On April 8, 1981, a company acting on behalf of TI issued a purchase order to Pfaff for 30,100 sockets for \$91,155.¹²¹ This purchase order confirmed an earlier, verbal order on March 17, 1981, and specified the materials to be used and the delivery date.¹²² The sockets were shipped to and accepted by TI after they were manufactured by the subcontractor in July 1981 and performance tested by Pfaff.¹²³

The district court found that more than a mere concept was on sale given the completion of engineering drawings, the ordering of production tooling, and the commencement of fabrication of the tooling necessary to manufacture the invention for a specific customer.¹²⁴ Even though a prototype of the invention had not been built prior to the TI sale, the district court found that, based on his drawings, Pfaff was confident this invention would work.¹²⁵ Indeed, Pfaff testified that "it was his practice to produce his inventions without building any prototypes and that he had almost always been successful with this approach."¹²⁶

Pfaff argued, on appeal to the Federal Circuit, that the on-sale bar should not apply because no sockets were tested before the critical date to ensure that the device would work.¹²⁷ In particular, Pfaff asserted that he could not have known that the invention would work in advance of the results of the performance testing, months after the critical date.¹²⁸ The Federal Circuit rejected these contentions,

117. See *Pfaff v. Wells Elecs., Inc.*, 124 F.3d 1429, 1432, 43 U.S.P.Q.2d (BNA) 1928, 1930 (Fed. Cir. 1997).

118. See *id.*, 43 U.S.P.Q.2d (BNA) at 1930.

119. See *id.*, 43 U.S.P.Q.2d (BNA) at 1930.

120. See *id.* at 1433, 43 U.S.P.Q.2d (BNA) at 1931.

121. See *id.*, 43 U.S.P.Q.2d (BNA) at 1931.

122. See *id.* at 1432-33, 43 U.S.P.Q.2d (BNA) at 1930-31.

123. See *id.* at 1432, 43 U.S.P.Q.2d (BNA) at 1930.

124. See *id.* at 1434, 43 U.S.P.Q.2d (BNA) at 1932.

125. See *id.*, 43 U.S.P.Q.2d (BNA) at 1932.

126. *Id.*, 43 U.S.P.Q.2d (BNA) at 1932.

127. See *id.* at 1435, 43 U.S.P.Q.2d (BNA) at 1932.

128. See *id.*, 43 U.S.P.Q.2d (BNA) at 1932 (discussing plaintiff's fears of invention malfunction prior to performance testing).

reasoning that the claimed invention was on-sale under 35 U.S.C. § 102(b) because Pfaff's invention was substantially complete at least by the time of the pre-critical date offer to sell and receipt of the purchase order.¹²⁹

The Supreme Court affirmed the Federal Circuit's decision.¹³⁰ The Court held that an invention should refer to a concept that is complete, rather than merely one that is substantially complete.¹³¹ The Court acknowledged that reduction to practice ordinarily provides the best evidence that an invention is complete, but that proof of reduction to practice is not necessary in every case.¹³²

The Supreme Court concluded "that the on-sale bar applies when two conditions are satisfied before the critical date."¹³³ First, a commercial offer for sale of the product must have occurred.¹³⁴ Second, "the invention must be ready for patenting."¹³⁵ This second condition may be satisfied by proof that before the critical date the inventor had reduced to practice, or prepared drawings or other descriptions of the invention sufficiently specific to enable a person skilled in the art to practice the invention.¹³⁶

This change in the law allows a court to step back from a focus on the technical aspects of the invention and to look, instead, to relevant non-technical evidence.¹³⁷ In particular, the Supreme Court has changed the focus of the inquiry to more objective criteria, which would belie any technically based assertion that the invention was not ready for patenting.¹³⁸ For example, the patent applicant's own expression in business records or activities might well establish the

129. *See id.*, 43 U.S.P.Q.2d (BNA) at 1933 (distinguishing plaintiff's case from standing precedent and pointing to the lack of authority supporting plaintiff's position that courts should give greater latitude to an innovative patent).

130. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 50, 68 (1998) (finding support for the Federal Circuit's decision on both textual and policy grounds).

131. *See id.* at 66 (holding that the requirement of having an invention be complete provides a definite standard which Congress intended).

132. *See id.* (stating that an invention can be complete and ready for patenting before reduction to practice).

133. *Id.* at 67.

134. *See id.*

135. *Id.*

136. *See id.* at 68 (ascertaining that the second condition was met in the case at bar as Pfaff sent drawings "to the manufacturer before the critical date fully disclosed the invention").

137. *See id.* (focusing on non-technical aspects of the invention, specifically the date at which the invention was ready for patenting and when the invention went on sale).

138. *See id.* at 65-66 (advancing that the relevant inquiry should be based upon more objective criteria, such as whether the inventor's concept has been described with sufficient clarity and precision to enable those skilled in the art to practice the invention, rather than technically based assertions that the invention was not ready for patenting because it had not been "reduced to practice").

basis for the application of a statutory bar to patentability.¹³⁹

Perhaps the most recent significant controversy regarding a standard of review by the Federal Circuit in patent-related cases deals primarily with the question of who will have an advantage in the determination of patentable subject matter.¹⁴⁰ Although this dispute does not directly confront the boundaries of scientific adjudication, its collateral implications include a possible shift away from the recent Federal Circuit and Supreme Court trend to resolve patent cases without parsing the intricacies of the technology.¹⁴¹ In this regard, the adoption by the Federal Circuit of more searching standards of review represents the unfortunate creation of additional procedural mechanisms by which the court inadvertently could open a Pandora's Box of technical controversy.

II. DETERMINING THE APPROPRIATE STANDARD OF REVIEW

In the early days of the Federal Circuit, the attempt to reconcile inconsistent applications of the patent laws appeared to be the paramount concern of the court.¹⁴² Indeed, the early precedential opinions of the Federal Circuit devoted considerable effort to providing guidance on substantive legal issues and an initial jurisdictional delineation.¹⁴³ Gradually, the attention of the court shifted to more procedural questions, including those regarding trial and appellate conduct.¹⁴⁴ Soon enough, the Federal Circuit began to consider the importance of clarity and consistency in its own operation by setting forth and adhering to specific standards of review.¹⁴⁵

This section of the Article considers several relatively recent cases

139. See *id.* at 62-64 (providing that plaintiff's own business records proved that the plaintiff had engaged in activities over a year before filing the patent application thereby invoking the statutory bar to patentability).

140. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 1995) (en banc) (holding that construction of patent claims is a matter of law exclusively for the court), *aff'd*, 517 U.S. 370 (1996); *In re Zurko*, 111 F.3d 887, 889, 42 U.S.P.Q.2d (BNA) 1476, 1478 (Fed. Cir. 1997) (determining that obviousness is a legal question based on underlying factual determinations and therefore, subject to *de novo* review).

141. See *infra* Parts II.A -B (discussing *Markman* and *Zurko* in detail).

142. See *Archer*, *supra* note 14, at 835-37 (stating that the disparity in the application of patent law in the regional circuits was a major purpose of the establishment of the Federal Circuit and describing the early attempts of the Federal Circuit to reconcile the inconsistencies in the regional circuits).

143. See *generally* Newman, *supra* note 10, at 523-27 (discussing the first ten years of the Federal Circuit and its attempts to introduce "patent law into the legal mainstream").

144. See *Archer*, *supra* note 14, at 836-39 (discussing the inconsistency that existed within the Federal Circuit and the standards of review that recent decisions have promulgated to address those inconsistencies).

145. See *id.*

in which the Federal Circuit addressed the appropriate standards of review on various issues.¹⁴⁶ In particular, these standards of review have appeared to vest the Federal Circuit with increasing authority to conduct plenary reviews of its lower tribunal decisions.¹⁴⁷ In addition, the Federal Circuit reaffirmed the propriety of its historical standard of review of USPTO factual findings.¹⁴⁸ By creating more opportunities for substantive analyses of the science underlying patent-related cases, these standards of review open the Federal Circuit to heightened challenges to the propriety of its adjudication from a scientific perspective. With less deferential standards of review, the public might perceive that the Federal Circuit is attempting to introduce its own notions regarding the technical merits of the case, which can foster criticism inappropriately focused on an alleged misunderstanding of the underlying science, rather than on the sound application of the patent laws.

A. *Markman v. Westview Instruments, Inc.*

In *Markman v. Westview Instruments, Inc.*,¹⁴⁹ the Federal Circuit resolved an apparent inconsistency in its precedent regarding the respective roles of judge and jury in proper claim construction.¹⁵⁰ The appellate court faced a jury's claim interpretation that seemingly diverged from the trial judge's claim construction on post-trial motions.¹⁵¹ The Federal Circuit held unequivocally that claim construction is a purely legal conclusion, which falls exclusively within the district court's province.¹⁵² The Federal Circuit thus affirmed the district court's judgment of noninfringement as a matter of law, notwithstanding the jury verdict of infringement.¹⁵³

Markman sued Westview alleging infringement of its patent to an

146. See *supra* Parts II.A-B (extrapolating the relevant information regarding *Markman* and *Zurko*).

147. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 1995) (holding that patent claims are "reviewed de novo on appeal").

148. See *In re Zurko*, 111 F.3d 887, 890, 42 U.S.P.Q.2d (BNA) 1476, 1479 (Fed. Cir. 1997) (reviewing the USPTO's findings and deciding that "on the record, the obviousness of the claimed invention has not been established").

149. 52 F.3d 967, 34 U.S.P.Q.2d (BNA) 1321 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

150. See *id.* at 979, 34 U.S.P.Q.2d (BNA) at 1329 (finding that it was not an error for the district court judge to remove the issue of claim construction from consideration by the jury).

151. See *id.*, 34 U.S.P.Q.2d (BNA) at 1329 (commenting that Markman felt that the jury's implied construction of the claim was the correct interpretation while the district court's interpretation was incorrect).

152. See *id.*, 34 U.S.P.Q.2d (BNA) at 1329 (stating that the interpretation of the meaning and scope of patent claims is matter of law reviewed *de novo* on appeal).

153. See *id.* at 988-89, 34 U.S.P.Q.2d (BNA) at 1337 (finding noninfringement because the term "inventory" does include articles of clothing within its meaning).

automated inventory system for monitoring articles of clothing throughout the steps of commercial laundry and dry cleaning.¹⁵⁴ The claims of the patent recited an “inventory control and reporting system” that could “*localize spurious additions to inventory*” and that included, *inter alia*, a “*means to maintain an inventory total*.”¹⁵⁵ The meaning of “inventory” was the crux of the case.¹⁵⁶ To inform the meaning of “inventory,” Markman introduced at trial the testimonies of the inventor, a technical expert, and a patent law expert.¹⁵⁷ These individuals stated that one of ordinary skill in the art would not necessarily have construed “inventory” to include articles of clothing.¹⁵⁸

The trial judge instructed the jury to construe the claims in view of the patent documents from the perspective of those of ordinary skill in the art.¹⁵⁹ The jury found Westview liable for infringement on two of Markman’s claims.¹⁶⁰ Notwithstanding the jury verdict, the district court granted Westview’s deferred motion for judgment as a matter of law.¹⁶¹ The district court relied upon its own claim construction and held that “inventory” included articles of clothing.¹⁶² The parties did not dispute that even though Westview’s system could register transactions and cash totals, it could not maintain information regarding particular articles of clothing.¹⁶³ The district court thus entered judgment for Westview as a matter of law, based on the absence of this claim limitation in the accused system.¹⁶⁴

154. *See id.* at 971-72, 34 U.S.P.Q.2d (BNA) at 1322-24 (noting that the patent claimed to be infringed upon was U.S. Reissue Patent No. 33,054, reissued from U.S. Patent No. 4,550,246).

155. *See id.* at 972, 34 U.S.P.Q.2d (BNA) at 1323.

156. *See id.* at 974-75, 34 U.S.P.Q.2d (BNA) at 1325-26 (discussing whether “inventory” requires as part of its meaning “articles of clothing”).

157. *See id.* at 973, 34 U.S.P.Q.2d (BNA) at 1324.

158. *See id.* at 983, 34 U.S.P.Q.2d (BNA) at 1332-33 (finding that the testimony of Markman’s experts amounted to no more than legal opinion and therefore, entitled to no deference).

159. *See id.* at 973, 34 U.S.P.Q.2d (BNA) at 1324 (instructing the jury that to determine the meaning of the claims, “considerations that show how the terms of a claim would normally be understood by those of ordinary skill in the art” are relevant).

160. *See id.*, 34 U.S.P.Q.2d (BNA) at 1324.

161. *See id.*, 34 U.S.P.Q.2d (BNA) at 1324 (stating that notwithstanding the jury verdict that Westview infringed claims 1 and 10, the district court granted Westview’s deferred motion for judgment as matter of law because Westview’s device could not function the way claims required).

162. *See id.*, 34 U.S.P.Q.2d (BNA) at 1324 (holding that “‘inventory’ as used in the claims meant ‘articles of clothing’ and not simply transaction totals of dollars”).

163. *See id.*, 34 U.S.P.Q.2d (BNA) at 1324 (noting that Westview’s system could not track articles of clothing through the dry-cleaning process and could only produce a list of invoices and cost total of the inventory).

164. *See id.*, 34 U.S.P.Q.2d (BNA) at 1324 (stating that Westview’s device did not have the “means to maintain an inventory total” and could not “detect and localize spurious additions to inventory” and therefore, directed a verdict of non-infringement as a matter of law).

On appeal, Markman relied upon Federal Circuit precedent holding that a district court should submit to the jury any underlying factual disputes about meanings of claim terms.¹⁶⁵ The Federal Circuit, *en banc*, rejected Markman's contention, however, and affirmed the district court's entry of judgment as a matter of law.¹⁶⁶ In so ruling, the court implicitly overruled precedent contrary to its present holding that the district court alone must construe patent claims as a matter of law.¹⁶⁷ The appellate court reasoned that its holding was entirely consistent with the fundamental legal principle that "the construction of a written evidence is exclusively with the court."¹⁶⁸

The Federal Circuit emphasized that placing sole responsibility for claim construction with the trial judge did not deprive parties to a patent infringement case of their Seventh Amendment right to trial by jury.¹⁶⁹ In addition, although the dissent, one of the concurring opinions, and certain of the *amici* agreed with Markman's contention, the majority opinion specifically discounted the argument that the assignment of claim construction to the court's exclusive province

165. See *id.* at 973-74, 34 U.S.P.Q.2d (BNA) at 1324-25 (holding that when the meaning of a claim term is disputed, a factual question arises that should be resolved by the trier of fact) (citing *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 974, 226 U.S.P.Q. (BNA) 5, 8 (Fed. Cir. 1985)).

166. See *id.* at 979, 34 U.S.P.Q.2d (BNA) at 1329 (finding that "Markman's principal argument that the district court erred in taking the issue of claim construction away from the jury is itself legally erroneous").

167. See *id.* at 976-77, 34 U.S.P.Q.2d (BNA) at 1327-28 (finding that "if . . . the meaning of a term of art in the claim is disputed and extrinsic evidence is needed to explain the meaning, construction of the claim could be left to the jury") (citing as inconsistent precedent *McGill Inc. v. John Zink Co.*, 736 F.2d 666, 672, 221 U.S.P.Q. (BNA) 944, 948 (Fed. Cir. 1984)); see, e.g., *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H.*, 945 F.2d 1546, 1550, 20 U.S.P.Q.2d (BNA) 1332, 1336 (Fed. Cir. 1991) (concluding that "[i]nterpretation of the claim words required the jury give consideration and weight to several underlying factual questions"); *Perini Am., Inc. v. Paper Converting Mach. Co.*, 832 F.2d 581, 584, 4 U.S.P.Q.2d (BNA) 1621, 1624 (Fed. Cir. 1987) (stating that any disputes over the meaning of terms in a claim must be resolved before the claim can be interpreted as matter of law); *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 389, 2 U.S.P.Q.2d (BNA) 1926, 1929 (Fed. Cir. 1987) (stating that although claim construction is reviewed as a matter of law, evidentiary material may be necessary to interpret a claim and this would be an issue of fact); *Moeller v. Ionetics, Inc.*, 794 F.2d 653, 657, 229 U.S.P.Q. (BNA) 992, 995 (Fed. Cir. 1986) (stating that extrinsic evidence may produce factual disputes precluding summary judgment on claim construction); *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 974, 226 U.S.P.Q. (BNA) 5, 8 (Fed. Cir. 1985) (stating that a factual issue results when extrinsic evidence is required to explain the meaning of a disputed term and the trier of fact or jury should determine the construction of the claim); *Bio-Rad Labs., Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 614, 222 U.S.P.Q. (BNA) 654, 661 (Fed. Cir. 1984) (reasoning that in claim construction cases there may be factual issues triable by jury);.

168. See *Markman*, 52 F.3d at 978, 34 U.S.P.Q.2d (BNA) at 1328 (quoting *Levy v. Gadsby*, 7 U.S. (3 Cranch) 180, 186 (1805)).

169. See *id.* at 983-84, 34 U.S.P.Q.2d (BNA) at 1333 (holding that the right to a jury trial in patent infringement cases has not been deprived by holding "that part of the infringement inquiry, constructing and determining the scope of the claims in a patent, is strictly a legal question for the court").

conflicted with Supreme Court precedent.¹⁷⁰ The majority distinguished the cases cited by *Markman* as anachronistic or inapposite.¹⁷¹ Responding further to the dissenting and concurring opinions, the majority used, as an analytical framework, the analogy of a patent to a statute to support the judge's interpretation of patent claims, rather than the analogy of a patent to a contract.¹⁷² Although the majority recognized the inherent limitations of such analogies, it nevertheless noted that general principles of statutory interpretation were germane to patent claim construction cases.¹⁷³

In *Markman*, the Federal Circuit provided clear guidance to the district courts about the relative significance of certain evidence regarding the meaning of claim terms.¹⁷⁴ The court embraced precedent stating that proper claim interpretation derives from consideration of the relevant patent-related documents.¹⁷⁵ This "intrinsic" evidence includes: (1) the patent itself, i.e., the specification and the claims; and (2) the prosecution history, i.e., the record of proceedings before the USPTO.¹⁷⁶ The court also approved the examination of "extrinsic" evidence, such as expert and inventor testimony, dictionaries, and learned treatises, to inform the state of the technology, or "prior art," at the time of the invention.¹⁷⁷ The Federal Circuit emphasized, however, that extrinsic evidence is only to be used to assist in the court's understanding of the patent, not to clarify ambiguity in claim language, much less to vary or contradict the meaning of claim terms.¹⁷⁸ Specifically, the court noted that

170. *See id.* at 987, 34 U.S.P.Q.2d (BNA) at 1336-37 (stating that the majority is not persuaded by the cited case law that assigning claim construction to judges conflicts with Supreme Court precedent).

171. *See id.* at 987-88, 34 U.S.P.Q.2d (BNA) at 1336-37 (distinguishing *Silsby v. Foote*, 55 U.S. (14 How.) 218 (1852) and *Bischoff v. Wethered*, 76 U.S. (9 Wall.) 812 (1869), upon which dissenting and concurring opinions along with *Markman* relied).

172. *See id.* at 987, 34 U.S.P.Q.2d (BNA) at 1336 (finding that the statutory interpretation, which as a matter of law is for a court to decide, is the more appropriate analogy for interpreting patent claims than a contractual interpretation analogy).

173. *See id.*, 34 U.S.P.Q.2d (BNA) at 1336 (noting the differences between a patent and a statute, but finding that as they are both public instruments the statutory interpretation model is a more accurate model than the contractual one).

174. *See id.* at 979-83, 34 U.S.P.Q.2d (BNA) at 1329-33 (describing evaluation of evidence of record to interpret meaning of claims).

175. *See id.* at 979-80, 34 U.S.P.Q.2d (BNA) at 1329-30 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966)); *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396-98, 155 U.S.P.Q. (BNA) 697, 701-03 (Ct. Cl. 1967) (relying on specification and included claims).

176. *See Markman*, 52 F.3d at 979-80, 34 U.S.P.Q.2d (BNA) at 1329-30 (stating that the claims, specification, and prosecution history must be examined to interpret the meaning of the claims).

177. *See id.* at 980, 34 U.S.P.Q.2d (BNA) at 1330 (defining extrinsic evidence as "all evidence external to the patent and prosecution history" in addition to listing examples of and the correct uses of extrinsic evidence).

178. *See id.* at 981, 34 U.S.P.Q.2d (BNA) at 1331 ("Extrinsic evidence is to be used for the

evidence of the subjective intent of the inventor during claim drafting deserves little or no probative weight in claim interpretation unless otherwise documented in the prosecution history.¹⁷⁹

The Supreme Court affirmed the Federal Circuit decision in *Markman*.¹⁸⁰ Although the Court found no guidance in its own decisions on the issue, it concluded that claim construction, notwithstanding its evidentiary underpinnings, was analogous to many other responsibilities assigned to the judge.¹⁸¹ Accordingly, the Court held that “construction of a patent, including terms of art within its claims, is exclusively within the province of the court.”¹⁸²

The Supreme Court further articulated a social policy rationale for the assignment of claim construction to judges. The Court stated:

Finally, we see the importance of uniformity in the treatment of a given patent as an independent reason to allocate all issues of construction to the court. . . . “The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.” Otherwise, a “zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field. . . .” and “[t]he public [would] be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights.” It was just for the sake of such desirable uniformity that Congress created the Court of Appeals for the Federal Circuit as an exclusive appellate court for patent cases, observing that increased uniformity would “strengthen the United States patent system in such a way as to foster technological growth and industrial innovation.” Uniformity would, however, be ill served by submitting issues of document construction to juries. Making them jury issues would not, to be sure, necessarily leave evidentiary questions of meaning wide open in every new court in which a patent might be litigated, for principles of issue preclusion would ordinarily foster uniformity. But whereas issue preclusion

court’s understanding of the patent, not for the purpose of varying or contracting the terms of the claims.”).

179. *See id.* at 983, 34 U.S.P.Q.2d (BNA) at 1332-33 (stating that testimony of the inventor of patent-in-suit and of someone of ordinary skill in art pertaining to proper claim construction amounted only to legal opinion, which the court was not required to follow). “[T]he court has complete discretion to adopt the expert legal opinion as its own, to find guidance from it, or to ignore it entirely, or even to exclude it.” *Id.*, 34 U.S.P.Q.2d (BNA) at 1332.

180. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996).

181. *See id.* at 390 (concluding that a judge in the normal course of trial should decide construction of terms). The Court further noted that by virtue of their “training in exegesis,” judges are more likely to conduct a proper claim construction than juries. *See id.* at 388-89.

182. *See id.* at 372.

could not be asserted against new and independent infringement defendants even within a given jurisdiction, treating interpretive issues as purely legal will promote (though it will not guarantee) intrajurisdictional certainty through the application of *stare decisis* on those questions not yet subject to interjurisdictional uniformity under the authority of the single appeals court.¹⁸³

The Court thus appears to embrace the notion that the attendant plenary, or *de novo*, standard of review by the Federal Circuit on claim construction issues accomplishes the objective of promoting uniformity in the administration of the patent law. Although such centralization may facilitate clarity and consistency, the shift in authority may bring an increased likelihood of technology adjudication, a move which would undermine the recent trend of the Federal Circuit.

B. Dickinson v. Zurko

The Supreme Court faced a similar challenge to its recent implicit caution against technology adjudication in considering the appeal in *Dickinson v. Zurko*.¹⁸⁴ In this case, the USPTO asked the Court to require the Federal Circuit to exercise greater deference to the factual findings of the USPTO Board of Patent Appeals and Interferences.¹⁸⁵

The Administrative Procedure Act ("APA") sets forth a standard for judicial review of federal agency determinations.¹⁸⁶ The Federal Circuit presently applies the same standard of review in appeals from both the U.S. district courts and the USPTO.¹⁸⁷ The court reviews

183. *Id.* at 390-91 (internal citations omitted).

184. 142 F.3d 1447, 46 U.S.P.Q.2d (BNA) 1691 (Fed. Cir. 1997), *rev'd*, *Dickinson v. Zurko*, 119 S.Ct. 1816 (1999).

185. *See id.* at 1450, 46 U.S.P.Q.2d (BNA) at 1693-94 (discussing how the various standards differ in the amount of deference they contemplate).

186. Administrative Procedure Act § 10(e), 5 U.S.C. § 706 (1994). The statute provides that the reviewing court shall:

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute.

5 U.S.C. § 706(2)(A), (E).

187. *Compare* *Heisig v. United States*, 719 F.2d 1153, 1158 (Fed. Cir. 1983) (explaining that the Federal Circuit applies a clearly erroneous standard to a district court's findings of fact and upholds its legal conclusions unless they are incorrect), *with In re Kulling*, 897 F.2d 1147, 1149, 14 U.S.P.Q.2d (BNA) 1056, 1057 (Fed. Cir. 1990) (noting that the Federal Circuit is bound by USPTO's findings of fact unless clearly erroneous), *and In re Caveney*, 761 F.2d 671, 674, 226 U.S.P.Q. (BNA) 1, 3 (Fed. Cir. 1985) (observing that the standard for reviewing legal conclusions of the USPTO "is correctness or error as a matter of law").

questions of law *de novo*¹⁸⁸ and questions of fact under a clearly erroneous standard.¹⁸⁹ With regard to the Federal Circuit's review of the USPTO's factual findings, the clearly erroneous standard is more stringent than the APA's arbitrary and capricious or substantial evidence standard.¹⁹⁰

Since the Supreme Court's holding in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*,¹⁹¹ the USPTO has asserted entitlement to the judicial deference afforded other federal agencies.¹⁹² The presumed agency expertise rationale, which typically militates judicial deference to agency actions, however, may be less significant with the USPTO.¹⁹³ The specialized subject matter jurisdiction of the Federal Circuit and the exclusivity of its appellate relationship with the USPTO undercut the basis for judicial deference under the APA.¹⁹⁴

The USPTO adopted the practice of raising the standard of review issue in its briefs to the Federal Circuit.¹⁹⁵ The Federal Circuit, in

188. See, e.g., *In re Donaldson Co.*, 16 F.3d 1189, 1192, 29 U.S.P.Q.2d (BNA) 1845, 1848 (Fed. Cir. 1994) (en banc) (noting that questions of law receive *de novo* review); *In re Kathawala*, 9 F.3d 942, 945, 28 U.S.P.Q.2d (BNA) 1785, 1786 (Fed. Cir. 1993) (same).

189. See, e.g., *In re Baxter Travenol Labs.*, 952 F.2d 388, 390, 21 U.S.P.Q.2d (BNA) 1281, 1283 (Fed. Cir. 1991) (noting that questions of fact are not reversed unless clearly erroneous); *In re Woodruff*, 919 F.2d 1575, 1577, 16 U.S.P.Q.2d (BNA) 1934, 1935 (Fed. Cir. 1990) (same).

190. See, e.g., *In re Napier*, 55 F.3d 610, 614, 34 U.S.P.Q.2d (BNA) 1782, 1785 (Fed. Cir. 1995) (acknowledging that the current standard of review of a USPTO finding is "more stringent than" the APA's standard); *In re Brana*, 51 F.3d 1560, 1569, 34 U.S.P.Q.2d (BNA) 1436, 1444 (Fed. Cir. 1995) (finding the Board's error reversible under both clear error and arbitrary and capricious standards, but declining to address change from clearly erroneous standard).

191. 467 U.S. 837 (1984). In *Chevron*, the Court applied a deferential standard of review to an Environmental Protection Agency order. See *id.* at 862; see also R. Carl Moy, *Judicial Deference to the PTO's Interpretations of the Patent Law*, 74 J. PAT. [& TRADEMARK] OFF. SOC'Y 406, 426-39 (1992) (discussing the applicability of *Chevron* deference to the USPTO).

192. See *Napier*, 55 F.3d at 614, 34 U.S.P.Q.2d (BNA) at 1785 (rejecting the Commissioner's plea to apply APA standard of review to USPTO decisions); see also *Brana*, 51 F.3d at 1568-69, 34 U.S.P.Q.2d (BNA) at 1443 (noting Commissioner's contention that USPTO decisions should be afforded deferential standard of review); Jeffrey W. Rennecker, *Ex Parte Appellate Procedure in the Patent Office and the Federal Circuit's Respective Standards of Review*, 4 TEX. INTELL. PROP. L.J. 335, 368-69 (1996) (suggesting that the Federal Circuit's failure to address the controversy regarding its standard of review of the USPTO decisions might reflect an internal split among the court's judges).

193. See Moy, *supra* note 191, at 434-35 ("Congress took the unusual step of consolidating all patent appeals into the Federal Circuit for the purpose of providing that court with overall doctrinal responsibility for the law of patents.") (emphasis added).

194. See *id.* at 435 (noting that the Federal Circuit was given doctrinal responsibility for patent law in order to increase expertise of court).

195. For example, in *In re Wodkiewicz*, No. 95-1280, 1995 WL 550401, (Fed. Cir. Sept. 14, 1995) (unpublished disposition), the principal brief of the USPTO Solicitor contained the following footnote:

The Commissioner believes that the standard of review for factual determinations made by the agency should be the arbitrary and capricious standard set forth in the Administrative Procedure Act, 5 U.S.C. § 706. However, in this case the findings are not clearly erroneous and thus should survive review under either standard.

several precedential opinions, recognized the USPTO's position on this matter but declined to decide the issue.¹⁹⁶ For example, in *In re Brana*,¹⁹⁷ the Federal Circuit held that the disposition of the case did not turn on the standard of review.¹⁹⁸ Similarly, in *In re Napier*,¹⁹⁹ the Federal Circuit held it unnecessary to decide the question as to which standard of review is appropriate.²⁰⁰

The respective opinions of the court in *Brana* and *Napier* clarified that the Federal Circuit would not consider the appropriate standard of review of USPTO determinations until squarely faced with an appeal in which the standard of review was dispositive.²⁰¹ Finally, in 1997, the Federal Circuit faced such a case.²⁰²

In *In re Zurko*,²⁰³ the Federal Circuit reversed the USPTO Board of Patent Appeals and Interferences, which upheld the patent examiner's rejection of the applicants' claims as obvious under 35 U.S.C. § 103.²⁰⁴ In 1990, applicant Mary E. Zurko applied for a patent on improved ways of maintaining a secure environment in computer systems.²⁰⁵ Specifically, the claimed methods involved processing a trusted command with untrusted code, sending that command to the trusted computing environment, and then seeking user verification via a trusted pathway before executing the command.²⁰⁶

The prior art to the claimed invention included the UNIX operating system and a software program known as the FILER2.²⁰⁷ Zurko acknowledged that the UNIX operating system described the

Brief for Appellee at 12 n.1, *Wodkiewicz*, 1995 WL 550401.

196. See, e.g., *In re Lueders*, 111 F.3d 1569, 1574-78, 42 U.S.P.Q.2d (BNA) 1481, 1484-87 (Fed. Cir. 1997) (declining to apply heightened deference to the Board); *In re Mac Dermid, Inc.*, 111 F.3d 890, 890-91, 42 U.S.P.Q.2d (BNA) 1479, 1480 (Fed. Cir. 1997) (deciding not to address the issue because precondition for an *en banc* hearing was not satisfied); *In re Kemps*, 97 F.3d 1427, 1430-31 & nn.4-6, 40 U.S.P.Q.2d (BNA) 1309, 1312-13 & nn.4-6 (Fed. Cir. 1996) (concluding that the issue was not ripe at the time).

197. 51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995).

198. See *id.* at 1569, 34 U.S.P.Q.2d (BNA) at 1444 (commenting that in order to address the issue meaningfully it must arise in a case where the final decision turns on a resolution of the issue).

199. 55 F.3d 610, 34 U.S.P.Q.2d (BNA) 1782 (Fed. Cir. 1995).

200. See *id.* at 614, 34 U.S.P.Q.2d (BNA) at 1785 (deciding that because both standards were met it was not necessary to decide which one to use).

201. See *supra* notes 197-200 and accompanying text (outlining the Court's opinions regarding when it would address standard of review).

202. See *infra* notes 203-25 and accompanying text (discussing *In re Zurko* and its legal status regarding the correct standard of review to apply).

203. 111 F.3d 887, 42 U.S.P.Q.2d (BNA) 1476 (Fed. Cir. 1997).

204. See *id.* at 890, 42 U.S.P.Q.2d (BNA) at 1479; see also 35 U.S.C. § 103 (1994) (holding that the Board had failed to show that this problem had been previously identified anywhere in the prior art).

205. See *Zurko*, 111 F.3d at 887-88, 42 U.S.P.Q.2d (BNA) at 1477-78. The application at issue was U.S. Patent Application Serial No. 07/479,666. See *id.*, 42 U.S.P.Q.2d (BNA) at 1477-78.

206. See *id.* at 888 & n.1, 42 U.S.P.Q.2d (BNA) at 1477-78 & n.1.

207. See *id.* at 888, 42 U.S.P.Q.2d (BNA) at 1478.

feasibility of having an untrusted program recognize a trusted command, such as a user keyboard entry, and then execute the command in a trusted computing environment.²⁰⁸ The applicants also acknowledged that the FILER2 program disclosed a mechanism for repeating potentially dangerous user commands and requesting confirmation from the user before command execution.²⁰⁹

The patent examiner rejected Zurko's claims, *inter alia*, as obvious in light of the UNIX and FILER2 prior art references.²¹⁰ The patent examiner determined that one of ordinary skill in the art having the benefit of the cited prior art would have been led from these teachings to take the trusted command parsed in the untrusted environment and submit it to the trusted computing environment, as taught by UNIX, and then display the parsed command to the user for confirmation prior to execution, as suggested by FILER2.²¹¹

On appeal from the patent examiner's rejection, the Board agreed.²¹² In particular, the Board determined that communication in a trusted environment normally would be assumed by artisans to be over trusted paths, so that the use of such a path for verification, in a system designed to ensure security, was explicit, or alternatively inherent or implicit, in the prior art.²¹³ In so finding, the Board rejected Zurko's argument that the use of a trusted (as opposed to untrusted) path to seek and receive verification from the user before command execution constituted a non-obvious advance over the prior art.²¹⁴

Zurko appealed the Board's decision to the Federal Circuit, which ultimately concluded that the decision should be reversed.²¹⁵ The Federal Circuit noted at the outset that obviousness is a legal question based on underlying factual determinations.²¹⁶ Furthermore, the court indicated that what a prior art reference teaches and "whether

208. *See id.*, 42 U.S.P.Q.2d (BNA) at 1478 (reciting the admission in the applicants' information disclosure statement that "the prior art includes an untrusted program parsing a command and then executing the command by calling a trusted service that executes in a trusted computing environment").

209. *See id.*, 42 U.S.P.Q.2d (BNA) at 1478 (noting the applicants' description in their information disclosure statement of the FILER2 as a program that "repeats back potentially dangerous user commands and requests confirmation from the user prior to execution").

210. *See id.*, 42 U.S.P.Q.2d (BNA) at 1478.

211. *See id.*, 42 U.S.P.Q.2d (BNA) at 1478 (suggesting that a trusted path is inherent in the prior art).

212. *See id.*, 42 U.S.P.Q.2d (BNA) at 1478.

213. *See id.*, 42 U.S.P.Q.2d (BNA) at 1478.

214. *See id.*, 42 U.S.P.Q.2d (BNA) at 1478.

215. *See id.* at 890, 42 U.S.P.Q.2d (BNA) at 1479 (holding that the Board clearly erred in its finding of inherency from a prior art and concluding that the obviousness of the claimed invention had not been established).

216. *See id.* at 888-89, 42 U.S.P.Q.2d (BNA) at 1478.

it teaches toward or away from the claimed invention are questions of fact.”²¹⁷ Reviewing the references cited by the Board, the Federal Circuit held that neither UNIX nor FILER2 teaches communication with the user over a trusted pathway.²¹⁸ The Federal Circuit ruled that the Board impermissibly used hindsight in evaluating the claimed invention.²¹⁹ The court thus held that the Board clearly erred in finding that the prior art teaches, either explicitly or inherently, the step of obtaining confirmation over a trusted pathway.²²⁰

The Federal Circuit acknowledged the argument by the USPTO that the court should review findings by the Board using a more deferential standard.²²¹ The Federal Circuit panel reminded the parties that only the court sitting *en banc* could answer the question of whether a different standard of review of the Board’s findings should apply.²²² Moreover, the court appeared to encourage the suggestion of an *en banc* rehearing.²²³

In considering the suggestion by the USPTO for rehearing *en banc*, the Federal Circuit agreed that the outcome of this appeal turned on the standard of review applied to the Board’s factual findings.²²⁴ Accordingly, the Federal Circuit agreed to consider, *en banc*, whether the Board’s factual findings should be reviewed under the APA standard of review instead of the presently applied clearly erroneous standard.²²⁵

The Federal Circuit, *en banc*, determined that it would adhere to its traditional standard of review, rather than apply the standards prescribed by the APA.²²⁶ First, the court noted that the substantial

217. See *id.* at 889, 42 U.S.P.Q.2d (BNA) at 1478-79 (citing *In re Bell*, 991 F.2d 781, 784, 26 U.S.P.Q.2d (BNA) 1529, 1531 (Fed. Cir. 1993)).

218. See *id.*, 42 U.S.P.Q.2d (BNA) at 1479 (concluding that communication with the user takes place in the UNIX only over an untrusted pathway).

219. See *id.*, 42 U.S.P.Q.2d (BNA) at 1479 (explaining that achieving the claimed invention in the absence of any suggestion or motivation in the cited prior art constitutes an impermissible hindsight reconstruction).

220. See *id.* at 889-90, 42 U.S.P.Q.2d (BNA) at 1479 (reversing the Board’s decision because the obviousness was not established on the record).

221. See *id.* at 889 n.2, 42 U.S.P.Q.2d (BNA) at 1478 n.2 (noting the request for the application of the standard of review set forth by the APA).

222. See *id.*, 42 U.S.P.Q.2d (BNA) at 1478 n.2 (stating that petitions appropriately suggested an *en banc* rehearing so that the court could rule on the Board’s standard of review).

223. See *id.*, 42 U.S.P.Q.2d (BNA) at 1478 n.2 (asserting that a suggestion for rehearing *en banc* would be appropriate where, as in this case, a panel of the court had determined that the Board’s decision would be reversed under a non-APA standard of review).

224. See *In re Zurko*, 142 F.3d 1447, 1449, 46 U.S.P.Q.2d (BNA) 1691, 1693 (Fed. Cir. 1998) (*en banc*) (reversing the Board of Patent Appeals and Inferences and holding that the Board’s decision was based on clearly erroneous findings of fact).

225. See *id.*, 46 U.S.P.Q.2d (BNA) at 1693.

226. See *id.*, 46 U.S.P.Q.2d (BNA) at 1693 (“We believe section 559 of the Administrative Procedure Act permits, and *stare decisis* warrants, our continued application of the clearly erroneous standard in our review of these fact-findings.”).

evidence or arbitrary and capricious standards of reviewing agency factual findings under the APA would require the Federal Circuit to review the Board's decisions on the Board's reasoning.²²⁷ In contrast, the clearly erroneous standard would dictate affirmance of the Board's findings so long as the Federal Circuit lacked a definite conviction that a mistake had occurred.²²⁸ Moreover, such a determination would require the court to review Board decisions on the Federal Circuit's reasoning.²²⁹ Thus, the present Federal Circuit standard of review differed from those prescribed by the APA both in character and the degree of deference contemplated.²³⁰

After discussing the history and general purposes of the APA, the Federal Circuit noted that the USPTO had been the subject of specific attention during the drafting and enactment of the APA.²³¹ The Federal Circuit acknowledged that Congress had specifically contemplated exempting the work of the Patent Office from the purview of the APA, but ultimately did not take such action.²³² Nevertheless, the Federal Circuit interpreted the history of the APA as suggesting that Congress drafted the APA to apply to agencies generally, but that it did not intend the APA to alter the review of substantive USPTO decisions by the courts.²³³

The Federal Circuit reviewed at some length the history of patent law, including the various mechanisms historically provided for administrative and judicial review of decisions to grant or deny patents.²³⁴ The court noted that no statute addressed the standard of review to be used by courts to examine administrative decisions in

227. *See id.*, 46 U.S.P.Q.2d (BNA) at 1693 (referring to the substantial evidence standard of the APA under 5 U.S.C. § 706(2)(E) and the arbitrary and capricious standard under 5 U.S.C. § 706(2)(E)).

228. *See id.*, 46 U.S.P.Q.2d (BNA) at 1693 ("Currently, we affirm decisions as long as we lack a definite and firm conviction that a mistake has been made.").

229. *See id.* at 1449-50, 46 U.S.P.Q.2d (BNA) at 1693-94 (noting that the clearly erroneous standard requires the court to review Board decisions based upon the court's reasoning).

230. *See id.* at 1450, 46 U.S.P.Q.2d (BNA) at 1694 ("The substantial evidence, arbitrary and capricious, and clear error standards differ both in character and the amount of deference they contemplate.").

231. *See id.* at 1450-51, 46 U.S.P.Q.2d (BNA) at 1694-95 (finding that Congress specifically considered excluding the USPTO from the APA's standard of review).

232. *See id.* at 1451, 46 U.S.P.Q.2d (BNA) at 1695 (suggesting that the lack of an exemption for the USPTO in the final text of the APA is because Congress thought it redundant in light of 5 U.S.C. § 559 which allows for *de novo* review).

233. *See id.* at 1452, 46 U.S.P.Q.2d (BNA) at 1695 ("[B]ecause of existing common law standards and the availability of trial de novo . . . Congress did not intend the APA to alter the review of substantive Patent Office decisions."). The Federal Circuit construed 5 U.S.C. § 559, as "preserving those standards of judicial review that had evolved as a matter of common law [before the APA's enactment in 1946], rather than compelling that all such standards of review be displaced by the [APA]." *Id.* at 1452, 46 U.S.P.Q.2d (BNA) at 1696.

234. *See id.* at 1452-56, 46 U.S.P.Q.2d (BNA) at 1695-99.

patent cases.²³⁵ However, the common law apparently recognized several standards before 1947, including “clear error and its close cousins.”²³⁶ The more searching *clear error* standard of review that the Federal Circuit has applied in lieu of the substantial evidence standard of the APA represents an “additional requirement” noted in the cases before 1947.²³⁷ Accordingly, the Federal Circuit concluded that it will continue to apply the *clear error* standard under the exception in section 559 of the APA.²³⁸

The court found additional support for its holding in the principle of *stare decisis*.²³⁹ Through its choice of standard, the court hoped to “encourage administrative records that more fully describe the metes and bounds of the patent grant than would a more deferential standard of review.”²⁴⁰ Finally, the Federal Circuit advocated that the clearly erroneous standard would “preserve the confidence of inventors who have relied on this standard in prosecuting their patents,” “promote consistency between [the court’s] review of the patentability decisions of the board and the district courts in infringement litigation,” and “help avoid situations where board fact finding on matters such as anticipation or the factual inquiries underlying obviousness become virtually unreviewable.”²⁴¹

The briefs submitted to the Supreme Court by the petitioner, respondent, and *amici* generally present arguments focusing on the

235. See *id.* at 1456, 46 U.S.P.Q.2d (BNA) at 1700 (finding no patent statute which sets forth a standard for review).

236. See *id.* at 1457, 46 U.S.P.Q.2d (BNA) at 1700 (listing cases which prove that “[s]ince the creation of this court, we have consistently applied the clearly erroneous standard when reviewing factual findings of the board”).

237. See *id.*, 46 U.S.P.Q.2d (BNA) at 1700.

238. See *id.*, 46 U.S.P.Q.2d (BNA) at 1700. Having concluded that there had been a “settled practice of reviewing factual findings of the board’s patentability determinations for clear error,” the Federal Circuit held that its “interpretation of section 559 . . . permit[ted]” it to continue that practice, “because no statute speaks directly to a required standard, and review for clear error was certainly recognized in the cases—though perhaps not exclusively or intentionally—before 1947.” *Id.* at 1458, 46 U.S.P.Q.2d (BNA) at 1701. The court added that use of a non-APA standard was “justif[ied]” by “the premises underlying review for clear error.” *Id.*, 46 U.S.P.Q.2d (BNA) at 1701. The court continues:

By making it clear that we review factual findings for clear error, and thereby review board decisions on our own reasoning, we hope the board understands that we are more likely to appreciate and adopt reasoning similar to its reasoning when it is both well articulated and sufficiently founded on findings of fact.

Id., 46 U.S.P.Q.2d (BNA) at 1701.

239. See *id.* at 1457-58, 46 U.S.P.Q.2d (BNA) at 1700 (asserting that the court finds no reason to vacate a standard without a compelling reason to do so).

240. *Id.* at 1458, 46 U.S.P.Q.2d (BNA) at 1701.

241. *Id.*, 46 U.S.P.Q.2d (BNA) at 1701. Having concluded that “section 559 and *stare decisis* together justify our continued application of . . . [a] heightened level of scrutiny to decisions by the board,” the Federal Circuit ratified the holding of the original panel that applied such a standard and reversed the Board’s decision in this case. See *id.* at 1459, 46 U.S.P.Q.2d (BNA) at 1701.

merits based on administrative law of compliance with the APA, or the dangers in changing the traditionally applied standard of review.²⁴² Several briefs addressed the relative technical expertise of the USPTO and the Federal Circuit.²⁴³ None, however, specifically considered whether granting greater deference to the factual findings of the USPTO might have the unfavorable effect of encouraging technical adjudication of patent cases.²⁴⁴ The Supreme Court heard oral argument in *Zurko* on March 24, 1999.²⁴⁵

242. The amicus briefs filed with the Supreme Court in *Zurko* suggest overwhelming public support for the perpetuation of the clearly erroneous standard of review. The sole amicus brief in support of the position of the USPTO takes issue with the Federal Circuit circumvention of the APA standards through an illusory exception in § 559. See Brief of Amicus Intellectual Property Professors in Support of Petitioner at 23-27, *Dickinson v. Zurko*, 119 S. Ct. 1816 (1999) (No. 98-377). Furthermore, the amicus proposes that the Supreme Court, in *Morgan v. Daniels*, 153 U.S. 120 (1894), essentially ratified a judicial standard of review of USPTO factual findings more deferential than that applied in appellate review of lower courts. See Intellectual Property Professor Brief at 12-15, *Zurko* (No. 98-377), 1998 WL 876969, at *12-15 (Dec. 15, 1998).

243. In its brief filed with the Supreme Court, the USPTO argued:

[Zurko's] argument that the PTO "does not have a better view of the facts than the Federal Circuit" ignores both the nature of the factual questions often (and here) at issue and the relative technical expertise of PTO examiners and federal judges. As we have explained, the PTO personnel assigned to review particular patent applications are selected in important part on the basis of their expertise in relevant technical areas. The PTO informs us, for example, that of the three members of the Board who rendered the final administrative decisions in this case, one holds a degree in electrical engineering, one holds a degree in electronics and has had extensive career experience in computer technology, and one holds an advanced degree in computer science and two in electrical engineering.

By way of contrast, the Federal Circuit, although generally considered a relatively specialized court, has exclusive or primary appellate jurisdiction over a variety of matters, including not only patent cases but also government contract cases, takings claims, federal employment controversies, and international trade cases, as well as internal revenue cases. Its judges are thus familiar with patent litigation, but are not necessarily experts in patent law; and they will seldom if ever possess the sort of expertise that the PTO's examiners-in-chief are statutorily required to possess in the various technical fields (such as chemistry, biology, physics, mechanical or electrical engineering) in which an inventor may claim to have made a non-"obvious" advance over the prior art. Thus, far from supporting the position adopted by the court of appeals, the complex and technical nature of patent proceedings makes doubly plain why it is inappropriate for an appellate court to engage in more-rigorous-than-usual review of the factual determinations made by a quintessentially expert administrative agency.

Brief of Petitioner at 37-38, *Zurko* (No. 98-377) (internal citations omitted), 1998 WL 886731, at *37-38 (Dec. 19, 1998).

244. One amicus brief provided instances of Supreme Court commentary on the expertise of the Federal Circuit and contended that the agency-judiciary dynamic perhaps more typical with other applications of the APA is inapposite. See Brief of Amicus Dallas-Fort Worth Intellectual Property Law Association in Support of Respondents at 13-16, *Zurko* (No. 98-377) ("The Federal Circuit's review of PTO decisions, therefore, does not present the usual circumstance of a generalist court reviewing a specialist agency, with the attendant danger that judicial review will dilute agency expertise."). Indeed, an equally significant danger would be a mandate, somehow, that the Federal Circuit conduct its future appellate reviews with independent investigations of the underlying science. See *Zurko*, 1998 WL 31201, at *12-13.

245. See Victoria Slind-Flor, *Court Hears Key Patent Case*, NAT'L. L.J., Apr. 5, 1999, at B1. Since

If the Supreme Court mandates a change in the Federal Circuit standard of review of the factual findings of the USPTO Board of Patent Appeals and Interferences, relatively few cases are likely to have different outcomes than they would have under the existing standard.²⁴⁶ Moreover, given the apparent trend of the Federal Circuit and the Supreme Court to encourage better disclosure by patent applicants, the greater degree of deference to the USPTO on factual findings related to technical concerns may be inconsequential.²⁴⁷

A likely public perception of a Supreme Court ruling in favor of the APA standard of review, however, would be the ratification of the agency expertise of the USPTO and the undermining of the authority of the Federal Circuit.²⁴⁸ Whether or not grounded in reality, the effect of such action seemingly would buttress the notion that patent cases turn purely on the scientific merits of the technology.²⁴⁹

the submission of this Article for publication, the Supreme Court, on June 10, 1999, issued its decision in *Dickinson v. Zurko*, reversing and remanding the case to the Federal Circuit. 119 S. Ct. 1816 (1999). In short, the Court ruled that rather than being able to overturn USPTO fact-finders in patent cases if they are "clearly erroneous," the Federal Circuit must employ the more deferential APA standard of review. Accordingly, under the APA standard, the Federal Circuit now may overturn USPTO fact-finders only if deemed "arbitrary, capricious" or "unsupported by substantial evidence."

The Supreme Court based its holding principally on the rejection of the Federal Circuit's reasoning that the clearly erroneous standard of review with respect to USPTO fact-finders constituted an additional requirement recognized by law under 5 U.S.C. § 559. *Id.* at 1822. Writing for the 6-3 majority of the Court, Justice Breyer further noted that:

These features of review underline the importance of the fact that, when a Federal Circuit judge reviews PTO factfinding, he or she often will examine that finding through the lens of patent-related experience and properly so, for the Federal Circuit is a specialized court. The comparative expertise, by enabling the Circuit better to understand the basis for the PTO's finding of fact, may play a more important role in assuring a proper review than would a theoretically somewhat stricter standard.

Id. at 1823.

246. This prediction is best informed by the lengthy journey taken by the USPTO to deliver even one case in which the resolution would depend upon the difference in the standard of review applied. See David Malakoff, *High Court to Review Standard for Appeal*, 282 SCIENCE 1622, 1622 (1988) ("Any ruling that changes the appeals process is likely to affect just a handful of cases directly.").

247. At least one commentator, however, has noted that fact-finding in *ex parte* proceedings like those before the USPTO may involve logistical problems, which may further militate against relaxing the Federal Circuit standard of review of facts found by the Board in USPTO decisions. See Lawrence B. Ebert, *Zurko and the Optimization of Fact-finding: Who Can You Believe?*, 6 INTELL. PROP. TODAY 32, 32 (1999).

248. See Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1422-23 (1995) (challenging the existing Federal Circuit standard of review of decisions by the USPTO as a "less than optimal balance of interpretive power").

249. See Neil A. Smith & Seong-Kun Oh, *US Courts to Keep Sharp Eye on PTO*, IP WORLDWIDE Sept.-Oct. 1998, at 35, 35-37; Robert C. Scheinfeld & Parker H. Bagley, *The Federal Circuit and Its Standard of Review*, N.Y. L.J., May 27, 1998, at 3, 6 (reporting the Federal Circuit decisions in *Cybor* and *Zurko* regarding the appellate court's standards of review and noting that the courts confirmed that patent claim construction is a matter of law for the court, not a matter of fact for a jury).

Unfortunately, armed with this misbelief, interested observers will likely mark their judicial scorecards with continuing instances of apparent conflict between scientific reality and justice under the patent law.²⁵⁰

Such perceptions are likely to persist without a more balanced understanding of the crucial relationship between the standards of review and the resolution of patent-related appeals at the Federal Circuit.²⁵¹

III. APPLICABLE FEDERAL CIRCUIT STANDARDS OF REVIEW

In appeals relating to patent law issues, the Federal Circuit applies several standards of review. First, this section provides a background discussion regarding the applicable standards of review, including definitions and distinctions based on the tribunal from which the appeal arises.²⁵² Second, this section considers the standards of review for patent enforcement issues, including infringement and damages.²⁵³ Third, this section surveys the standards of review of patentability and patent invalidity issues.²⁵⁴ This section concludes with the standards of review of procedural, jurisdictional, and appellate issues.²⁵⁵

A. General Standards

Perhaps the earliest detailed explication in a published Federal Circuit opinion of the generally applicable standards of review

250. See Malakoff, *supra* note 246, at 1622 (noting the close scrutiny by computer and biomedical inventors and investors on the resolution of *Zurko*).

251. See *infra* Part III (detailing the standards of review used to resolve various patent issues). Indeed, the Supreme Court recognized in *Dickinson v. Zurko* that its mandate to the Federal Circuit to apply the APA standard of review might be a distinction without a practical difference. See *Dickinson v. Zurko*, 119 S. Ct. 1816, 1823 (1999) (“[T]he difference is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome.”). When considered in isolation, the requirement in *Dickinson* for the Federal Circuit to apply the APA standard of review to USPTO fact-findings arguably reigns in the Federal Circuit’s ability to question the USPTO’s assessment of the scientific merit of the claimed technology in a patent application. When viewed in concert with the other standards invoked by the Federal Circuit to review USPTO decisions, however, it becomes more apparent that the adjudication of patentability does not take a technology-based measure.

252. See *infra* notes 256-78 and accompanying text (reviewing applicable standards of review, definitions, and distinctions based upon the originating tribunal).

253. See *infra* notes 279-357 and accompanying text (discussing standards of review for patent enforcement issues, infringement, and damages).

254. See *infra* notes 358-425 and accompanying text (surveying the standards of review of patentability and patent invalidity).

255. See *infra* notes 454-558 and accompanying text (outlining standards of review for procedural, jurisdictional, and appellate issues).

occurred under the authorship of Judge Nies, who provided her additional views in *SSIH Equipment S.A. v. United States International Trade Commission*.²⁵⁶

The standards of appellate review of factual determinations, in contrast to the quantum of proof required at the trial level, are usually statutorily imposed. The standards most commonly specified are “de novo,” “clearly erroneous,” “supported by substantial evidence” and “factual determinations, in contrast to the quantum of proof required arbitrary or capricious,” which I translate roughly into questions of increasingly narrow focus: is a finding of fact right; is it wrong; is it unreasonable; is it irrational?

A “*de novo*” standard provides the widest latitude for review of facts. The court in “*de novo*” review must exercise its independent judgment on the evidence of record and weigh it as a trial court. The court is not, however, required to ignore the decision below

With respect to “clearly erroneous,” the next level in the hierarchy . . . :

A finding is “clearly erroneous” when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.

The standard commonly associated with review by an appellate court of agency determinations is “supported by substantial evidence.” This standard (perhaps because of its inept name) appears to be the least comprehended. To begin, a “substantial evidence” standard restricts an appellate court to a greater degree than “clearly erroneous” review. The Supreme Court . . . undertook to set out the development and various interpretations which had been given to “substantial evidence” as a standard of review.

Beginning with its previously defined standard:

“[s]ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” Accordingly, it “must do more than create a suspicion of the existence of the fact to be established . . . it must be enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury”

The narrowest latitude to a reviewing court is where the

256. 718 F.2d 365, 379-83, 218 U.S.P.Q. (BNA) 678, 690-93 (Fed. Cir. 1983) (Nies, J., additional views) (reviewing and distinguishing standards of proof).

court can reverse a decision only by finding it “arbitrary or capricious”. . . . Suffice for purposes here to say that the standard is whether the decision was based on the relevant factors and whether there has been a clear error of judgment.²⁵⁷

B. Federal Circuit Statutory Interpretation

In reviewing the decisions of its lower tribunals, the Federal Circuit must parse the meaning of various enabling and substantive statutes before the court can assess compliance with such law.²⁵⁸ The issue of statutory interpretation is a question of law, which the Federal Circuit reviews *de novo*.²⁵⁹

1. Choice of law

The Federal Circuit often undertakes a choice of law inquiry to decide whether to establish or follow its own precedent or to apply the law of the appropriate regional circuit.²⁶⁰ This consideration involves competing policy interests between “the general policy of minimizing confusion and conflicts in the federal judicial system,”²⁶¹ and the congressional intent “to bring about uniformity in the area of

257. *Id.* at 381-83, 218 U.S.P.Q. (BNA) at 691-93 (Fed. Cir. 1983) (Nies, J., additional views) (internal citations omitted).

258. As a practical matter, the relative infrequency of the Supreme Court’s review of patent-related cases from the Federal Circuit effectively renders the Federal Circuit the final arbiter of the legal effect of the patent statutes. See Ian Ayres & Paul Klemperer, *Limiting Patentees’ Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 1023 (1999) (noting that the Supreme Court rarely reverses Federal Circuit decisions, giving the court the final word on patent law statutes). This role is entirely consistent with the court’s legislative purpose. See Howard T. Markey, *The Court of Appeals for the Federal Circuit: Challenge and Opportunity*, 34 AM. U. L. REV. 595, 596 (1985) (revealing that as early as June 10, 1887, the Supreme Court appeared to approve of the creation of a “national court of last resort” to hear appeals in patent cases from all lower courts and the USPTO).

259. See *In re Portola Packaging, Inc.*, 110 F.3d 786, 788, 42 U.S.P.Q.2d (BNA) 1295, 1297 (Fed. Cir. 1997) (maintaining that when appellate review is based on statutory interpretation it is a question of law, which the court reviews *de novo*); see also *Abbott Lab. v. Novopharm Ltd.*, 104 F.3d 1305, 1308, 41 U.S.P.Q.2d (BNA) 1535, 1537 (Fed. Cir. 1997) (same); *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549, 38 U.S.P.Q.2d (BNA) 1347, 1351 (Fed. Cir. 1996) (same); *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1134, 36 U.S.P.Q.2d (BNA) 1641, 1645 (Fed. Cir. 1995) (same); *In re Chu*, 66 F.3d 292, 296, 36 U.S.P.Q.2d (BNA) 1089, 1092-93 (Fed. Cir. 1995) (same); *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 395, 13 U.S.P.Q.2d (BNA) 1628, 1630 (Fed. Cir. 1990) (same).

260. See *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 855-58, 20 U.S.P.Q.2d (BNA) 1252, 1256-59 (Fed. Cir. 1991), *cert. denied*, 504 U.S. 980 (1992) (outlining the reasons for determining whether Federal Circuit or regional circuit law applies).

261. *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574, 223 U.S.P.Q. (BNA) 465, 471 (Fed. Cir. 1984) (stating that “the possibility of different [sets of] requirements should be minimized especially where a dispute is totally unrelated to patent issues and the resolution of that dispute does not impinge on the goal of patent law uniformity”).

patent law.”²⁶² Accordingly, the Federal Circuit defers to regional circuit law when reviewing issues not unique to patent law.²⁶³

2. Lower tribunals

The Federal Circuit has exclusive jurisdiction to hear patent-related appeals from the U.S. International Trade Commission (“ITC”), the USPTO Board of Patent Appeals and Interferences, and the U.S. District Courts.

a. United States International Trade Commission

The Federal Circuit has exclusive jurisdiction over final determinations of the ITC relating to unfair practices in import trade, made under section 337 of the Tariff Act of 1930.²⁶⁴ The court reviews a final determination of the ITC in accordance with Chapter 7 of the APA, 5 U.S.C. §§ 701-706 (1994).²⁶⁵ Accordingly, the Federal Circuit reviews factual findings of the ITC under the substantial evidence standard.²⁶⁶

Although the Federal Circuit generally reviews ITC interpretations of statutory provisions *de novo*, the court sometimes grants deference to agency interpretation, especially when technical issues that require some expertise are involved.²⁶⁷ The Federal Circuit will affirm the

262. *Id.*, 223 U.S.P.Q. (BNA) at 470.

263. *See* U.S. Philips Corp. v. Windmere Corp., 861 F.2d 695, 701-02, 8 U.S.P.Q.2d (BNA) 1885, 1890 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1068 (1989) (applying regional circuit law in an antitrust counterclaim); *see also* Joan E. Schaffner, *Federal Circuit “Choice of Law”: Erie Through the Looking Glass*, 81 IOWA L. REV. 1173, 1175 n.8 (1996) (suggesting that the self-ascribed choice of law inquiry undertaken by the Federal Circuit in confronting issues outside its exclusive jurisdiction may be characterized more accurately as a choice between independent judgment and deference); *cf.* Chrysler Motors Corp. v. Auto Body Panels of Ohio, Inc., 908 F.2d 951, 952-53, 15 U.S.P.Q.2d (BNA) 1469, 1470 (Fed. Cir. 1990) (suggesting substantive matters not exclusive to the Federal Circuit receive regional circuit law application and substantive procedural issues receive application of Federal Circuit law).

264. *See* 28 U.S.C. § 1295(a) (6) (1994).

265. *See* 19 U.S.C. § 1337(c) (1994) (stating that those adversely affected by a § 337 determination may appeal to the Federal Circuit for review in accordance with chapter 7 of Title 5); *see also* Fischer & Porter Co. v. United States Int’l Trade Comm’n, 831 F.2d 1574, 1576, 4 U.S.P.Q.2d (BNA) 1700, 1701 (Fed. Cir. 1987) (reviewing an ITC decision under the jurisdiction of § 1337).

266. *See* 5 U.S.C. § 706(2)(E) (1994) (setting forth the substantial evidence standard of review); *see also* Checkpoint Sys., Inc. v. United States Int’l Trade Comm’n, 54 F.3d 756, 759, 35 U.S.P.Q.2d (BNA) 1042, 1045 (Fed. Cir. 1995) (same); Intel Corp. v. United States Int’l Trade Comm’n, 946 F.2d 821, 832, 20 U.S.P.Q.2d (BNA) 1161, 1171 (Fed. Cir. 1991) (same); Tandon Corp. v. United States Int’l Trade Comm’n, 831 F.2d 1017, 1019, 4 U.S.P.Q.2d (BNA) 1283, 1284-85 (Fed. Cir. 1987) (same). Under the substantial evidence standard, the Federal Circuit will not disturb the Commission’s factual findings if they are supported by “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” Surface Tech., Inc. v. United States Int’l Trade Comm’n, 801 F.2d 1336, 1340-41, 231 U.S.P.Q. (BNA) 192, 196 (Fed. Cir. 1986).

267. *See* Farrell Corp. v. United States Int’l Trade Comm’n, 949 F.2d 1147, 1151, 20 U.S.P.Q.2d (BNA) 1912, 1916 (Fed. Cir. 1991); *see also* 5 U.S.C. § 706(2)(A) (1994) (stating that

ITC's interpretation of section 337 if it is reasonable in light of the statute's language, policies, and legislative history.²⁶⁸

b. USPTO Board of Patent Appeals and Interferences

The Federal Circuit has exclusive jurisdiction over final determinations of the USPTO Board of Patent Appeals and Interferences.²⁶⁹ The Federal Circuit generally reviews the USPTO's interpretations of statutory provisions *de novo*.²⁷⁰ In addition, the Federal Circuit traditionally has reviewed factual findings of the Board under the clearly erroneous standard,²⁷¹ the propriety of which was recently under review by the Supreme Court.²⁷²

Before appealing to the Federal Circuit, a party receiving an adverse ruling from the Board may seek reconsideration.²⁷³ Whether a party properly raised an issue is a question of law based on "subsidiary factual findings."²⁷⁴

c. District Court

The Federal Circuit has exclusive jurisdiction over final orders and

such deference is limited to the clear meaning of the statute "as revealed by its language, purpose, and history" (citing *AlTech Speciality Steel Corp. v. United States*, 745 F.2d 632, 642 (1984)); *YBM Magnex, Inc. v. United States Int'l Trade Comm'n*, 145 F.3d 1317, 1320, 46 U.S.P.Q.2d (BNA) 1843, 1845 (Fed. Cir. 1998).

268. See *Enercon GmbH v. United States Int'l Trade Comm'n*, 151 F.3d 1376, 1381, 47 U.S.P.Q.2d (BNA) 1725, 1729 (Fed. Cir. 1998).

269. See 28 U.S.C. § 1295(a)(6) (1994) (noting exclusive jurisdiction over registration applications and "other proceedings").

270. See *Astra v. Lehman*, 71 F.3d 1578, 1580, 37 U.S.P.Q.2d (BNA) 1212, 1214 (Fed. Cir. 1995). While the interpretation by the USPTO of a statute it administers is entitled to deference, see *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984), "the courts are the final authorities on issues of statutory construction. They must reject administrative constructions of the statute, whether reached by adjudication or by rulemaking, that are inconsistent with the statutory mandate or that frustrate the policy Congress sought to implement." *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1425, 7 U.S.P.Q.2d (BNA) 1152, 1154 (Fed. Cir. 1988).

271. See *In re Borden*, 90 F.3d 1570, 1576, 39 U.S.P.Q.2d (BNA) 1524, 1527 (Fed. Cir. 1996) (reviewing the factual determinations of the Board under a clearly erroneous standard); *In re GPAC, Inc.*, 57 F.3d 1573, 1577, 35 U.S.P.Q.2d (BNA) 1116, 1119 (Fed. Cir. 1995) (same); *In re Vaeck*, 947 F.2d 488, 495, 20 U.S.P.Q.2d (BNA) 1438, 1444 (Fed. Cir. 1991) (same); *In re Woodruff*, 919 F.2d 1575, 1577, 16 U.S.P.Q.2d (BNA) 1934, 1935 (Fed. Cir. 1990) (same); *In re King*, 801 F.2d 1324, 1326, 231 U.S.P.Q. (BNA) 136, 137 (Fed. Cir. 1986) (same); *In re Longi*, 759 F.2d 887, 892, 225 U.S.P.Q. (BNA) 645, 648 (Fed. Cir. 1985) (same); *In re De Blauwe*, 736 F.2d 699, 703, 222 U.S.P.Q. (BNA) 191, 194 (Fed. Cir. 1984) (same); *In re Kunzmann*, 326 F.2d 424, 426, 140 U.S.P.Q. (BNA) 235, 237 (C.C.P.A. 1964) (same).

272. See *supra* note 245.

273. See *Cooper v. Goldfarb*, 154 F.3d 1321, 1331, 47 U.S.P.Q.2d (BNA) 1896, 1904 (Fed. Cir. 1998) ("A party cannot wait until after the board has rendered an adverse decision then present new arguments in a request for reconsideration.").

274. See *id.*, 47 U.S.P.Q.2d (BNA) at 1904 (explaining that the court will consider only those issues raised in the parties' briefs at the final hearing).

judgments from the U.S. district courts nationwide.²⁷⁵ Patent cases may be tried to the jury or to the district court judge sitting as the finder of fact. When the jury applies the law to the facts, the verdict is viewed as having resolved the material factual issues in favor of the verdict winner.²⁷⁶

In a case tried without a jury, or with an advisory jury, Federal Rule of Civil Procedure 52(a) provides that a district court "shall find the facts specially and state separately its conclusions of law thereon."²⁷⁷ This facilitates a meaningful review of bench rulings by the appellate court, which reviews the district court decision for errors of law and clearly erroneous findings of fact.²⁷⁸

C. Patent Infringement Standards

A U.S. patent is a government grant for exclusive rights to an invention for a limited amount of time.²⁷⁹ One who engages without permission in statutorily proscribed conduct relating to a patented invention is, subject to available defenses, a patent infringer.²⁸⁰

Every patent concludes with at least one numbered paragraph called a "claim."²⁸¹ The claim defines the patented invention.²⁸²

275. See 28 U.S.C. § 1295(a)(6) (1994).

276. See *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765, 9 U.S.P.Q.2d (BNA) 1417, 1423 (Fed. Cir. 1988) ("Judges must accept the factual findings, presumed from a favorable jury verdict, which are supported under the substantial evidence/reasonable juror standard.")

277. FED. R. CIV. P. 52(a). But see Maureen McGirr, *Panduit Corp. v. Dennison Manufacturing Co.: De Novo Review and the Federal Circuit's Application of the Clearly Erroneous Standard*, 36 AM. U. L. REV. 963, 969-70 (1987) (questioning the Federal Circuit's attendance to the clearly erroneous standard set forth under Federal Rule of Civil Procedure 52(a)).

278. See *King Instruments Corp. v. Perego*, 65 F.3d 941, 945, 36 U.S.P.Q.2d (BNA) 1129, 1131 (Fed. Cir. 1995) (distinguishing the standards of review for factual findings and legal conclusions); *Interspiro USA, Inc. v. Figgie Int'l, Inc.*, 18 F.3d 927, 930, 30 U.S.P.Q.2d (BNA) 1070, 1072 (Fed. Cir. 1994) (same).

279. The U.S. Constitution contemplates the statutory grant of intellectual property rights. See U.S. CONST. art. I, § 8, cl. 8 (vesting Congress with the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"). Title 35 of the United States Code sets forth the statutory scheme for domestic patent protection. See generally 35 U.S.C. § 100-200 (1994) (providing for application and award of patents). In addition, the USPTO has promulgated regulations concerning the prosecution of patent applications. See generally 37 C.F.R. § 1.31-1.378 (1998) (stating national processing provisions).

280. See 35 U.S.C. § 271(a), (4)(B)-(C) (stating that if there is a finding of infringement, the court will grant injunctive relief and a damages award against the infringers).

281. The specification of a United States patent contains several parts, namely a title, an abstract, a summary of the invention, any drawings, and one or more claims. See 37 C.F.R. §§ 1.71-1.77 (setting forth the required elements and order of patent application). Although technically part of the specification, a patent claim has heightened importance as the legally recognized description of the invention. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("[T]he claims made in the patent are the sole measure of the grant . . .").

282. See UNITED STATES DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(k), at 600-63 (7th ed. 1998) [hereinafter

Moreover, the claim sets forth the scope of the patent holder's legal right to exclude others, during the patent term, from making, using, offering for sale, selling the patented invention throughout the United States, or importing that invention into the United States.²⁸³ The correct interpretation of a claim is paramount in virtually all patent-related matters.²⁸⁴ Indeed, judicial determinations regarding the patentability, validity, or infringement of a patent claim all rely on the same claim interpretation.²⁸⁵

D. Claim Construction

The construction of a patent claim is within the exclusive domain of the court.²⁸⁶ The Federal Circuit reviews claim interpretation *de novo*, including any allegedly fact-based questions relating to claim construction.²⁸⁷

The proper construction of a means-plus-function limitation requires the court to interpret the limitation in light of the corresponding structure, material, or acts described in the written description, and equivalents thereof, to the extent that the written description provides such disclosure.²⁸⁸ "A determination of corresponding structure is a determination of the meaning of the 'means' term in the claim and is a matter of claim construction."²⁸⁹

MPEP] ("35 U.S.C. § 112 requires that the applicant shall particularly point out and distinctly claim the subject matter which he or she regards as his or her invention. The portion of the application in which he or she does this forms the claim or claims.").

283. See *Zenith Lab., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1424, 30 U.S.P.Q.2d (BNA) 1285, 1290 (Fed. Cir. 1994) ("[T]he claim . . . sets the metes and bounds of the invention entitled to the protection of the patent system."); see also 35 U.S.C. § 271 (1994) (codifying Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809, 4983-85 (1994) and amending § 271 to include as infringing conduct an unauthorized offer for sale of patented invention in United States, or importation of patented invention into United States after January 1, 1996).

284. The Federal Circuit has rejected the notion that claim construction and claim interpretation are different. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 n.6, 34 U.S.P.Q.2d (BNA) 1321, 1326 n.6 (Fed. Cir. 1995) (en banc) ("[I]n our view, the terms mean one and the same thing in patent law."), *aff'd*, 517 U.S. 370 (1996). This Article uses the terms "claim construction" and "claim interpretation" interchangeably throughout.

285. See *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 882, 8 U.S.P.Q.2d (BNA) 1468, 1471 (Fed. Cir. 1988) ("[C]laims must be interpreted and given the same meaning for purposes of both validity and infringement analyses.").

286. See *Markman*, 517 U.S. at 376 (affirming the appellate court's holding that patent claim interpretation is solely within the province of the courts).

287. See *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 U.S.P.Q.2d (BNA) 1169, 1174 (Fed. Cir. 1998) (en banc) (asserting that claim construction is a question of law); see also *Markman*, 52 F.3d at 981, 34 U.S.P.Q.2d (BNA) at 1331 (providing that construing claims is a matter of law).

288. See *In re Donaldson Co.*, 16 F.3d 1189, 1193, 29 U.S.P.Q.2d (BNA) 1845, 1848 (Fed. Cir. 1994) (en banc) (noting that this construction applies "regardless of the context in which the interpretation of means plus-function language arises").

289. See *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1308,

Structure disclosed in the specification, however, is only “corresponding” structure to the claimed means under § 112, ¶ 6 if the structure is clearly linked by the specification or the prosecution history to the function recited in the claim.²⁹⁰ To determine the specific function associated with the means limitation requires construction of the claim language, which is a question of law that the Federal Circuit reviews *de novo*.²⁹¹

E. Literal Infringement

Patent infringement liability arises with the unauthorized manufacture, use, offer for sale, or sale in the United States of a patented invention, or importation of that invention into the United States.²⁹² The determination of infringement is a two-step inquiry, beginning with a proper claim construction.²⁹³ The second step of the infringement analysis involves the comparison of the accused product or process to the properly construed claim.²⁹⁴ A patent holder who alleges infringement has the burden of proving at trial, by a preponderance of the evidence, that the accused infringer’s

46 U.S.P.Q.2d (BNA) 1752, 1755-56 (Fed. Cir. 1998) (characterizing the “means” term as a “general reference for the corresponding structure disclosed in the publication”); *B. Braun Med., Inc. v. Abbott Lab.*, 124 F.3d 1419, 1424, 43 U.S.P.Q.2d (BNA) 1896, 1990 (Fed. Cir. 1997) (explaining that the patent description is reviewed to find correspondence between the structure and the means); *see also Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934, 4 U.S.P.Q.2d (BNA) 1737, 1739 (Fed. Cir. 1987) (en banc) (“To determine whether a claim limitation is met literally, where expressed as a means for performing a stated function, the court must compare the accused structure with the disclosed structure, and must find equivalent structure as well as identity of claimed function for that structure.”).

290. *See Chiuminatta*, 145 F.3d at 1308, 46 U.S.P.Q.2d (BNA) at 1755 (determining correspondence to the means limitation by comparing the “accused structure” with the “disclosed structure”).

291. *See Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1213-14, 48 U.S.P.Q.2d (BNA) 1010, 1016-17 (Fed. Cir. 1998) (discussing the means-plus-function claim construction analysis); *B. Braun Med.*, 124 F.3d at 1424-25, 43 U.S.P.Q.2d (BNA) at 1899-1900 (advancing the “adequate disclosure” requirement mandated when patent claims are drafted in a “means-plus function format”); *cf. Markman*, 52 F.3d at 977 n.8, 34 U.S.P.Q.2d (BNA) at 1327 n.8 (reserving only the question whether a determination of equivalence under § 112, ¶ 6 is a question of law or fact).

292. *See* 35 U.S.C. § 271(a) (1994). For a statistical study of the Federal Circuit’s dispositions in appeals from infringement findings, *see* Donald R. Dunner et al., *A Statistical Look at the Federal Circuit’s Patent Decisions: 1982-1994*, 5 FED. CIR. B.J. 151, 176 tbl. 5 (1995), which covers the period from October 1, 1982 to March 15, 1994.

293. *See Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.*, 15 F.3d 1573, 1576, 27 U.S.P.Q.2d (BNA) 1836, 1839 (Fed. Cir. 1993) (stating that the patent claim must be properly construed to determine its scope and meaning).

294. *See North Am. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1574, 28 U.S.P.Q.2d (BNA) 1333, 1335 (Fed. Cir. 1993) (noting that the second step of the analysis is an issue of fact); *see also Lemelson v. General Mills, Inc.*, 968 F.2d 1202, 1206, 23 U.S.P.Q.2d (BNA) 1284, 1287 (Fed. Cir. 1992) (indicating that step two of the analysis determines “whether a particular claim ‘reads on’ the accused structure or process”); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1280, 6 U.S.P.Q.2d (BNA) 1277, 1282 (Fed. Cir. 1988) (illustrating the application of step two in an infringement analysis case).

product or process contains every limitation of at least one of the asserted claims of the patent, either literally or by equivalence.²⁹⁵ Where a jury or the ITC makes a finding of fact that a patent infringement has occurred, the Federal Circuit will review the finding under the substantial evidence standard.²⁹⁶ The Federal Circuit reviews infringement questions under the clearly erroneous standard when the trial judge acted as the fact-finder.²⁹⁷

In order to meet a means-plus-function limitation, an accused device must first perform the identical function recited in the means limitation and second, perform that function using the structure disclosed in the specification or an equivalent structure.²⁹⁸ The Federal Circuit reviews this factual determination for substantial evidence to support the jury's verdict,²⁹⁹ or the ITC's findings for clear error where the trial judge was the fact-finder.

F. *Infringement Under the Doctrine of Equivalents*

A literal infringement results when every limitation recited in a patent claim is present exactly in an accused product or process.³⁰⁰ A

295. See *Conroy v. Reebok Int'l Ltd.*, 14 F.3d 1570, 1573, 29 U.S.P.Q.2d (BNA) 1373, 1374-75 (Fed. Cir. 1994) ("[T]he patentee must prove that the accused device embodies every limitation in the claim, either literally or by a substantial equivalent."); *Key Mfg. Group, Inc. v. Microdot, Inc.*, 925 F.2d 1444, 1449, 17 U.S.P.Q.2d (BNA) 1806, 1810 (Fed. Cir. 1991) ("To support an infringement determination, an accused device must embody exactly each claim limitation or its equivalent."); *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758, 221 U.S.P.Q. (BNA) 473, 477 (Fed. Cir. 1984) (providing that infringement is found when "the accused device falls within the scope of the asserted claims as properly interpreted").

296. See *Lemelson*, 968 F.2d at 1207, 23 U.S.P.Q.2d at 1288 ("[The substantial evidence test] requires us to decide for ourselves whether reasonable jurors viewing the evidence as a whole could have found the facts needed to support the verdict in light of the applicable law.>").

297. See *Young Dental Mfg. Co. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1141, 42 U.S.P.Q.2d (BNA) 1589, 1592 (Fed. Cir. 1997) (using a clear error standard of review to determine whether all claim limitations were present either literally or equivalently); see also *Hilton-Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1520-21, 35 U.S.P.Q.2d (BNA) 1641, 1657 (Fed. Cir. 1995) (en banc); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 936, 4 U.S.P.Q.2d (BNA) 1737, 1740 (Fed. Cir. 1987) (en banc) (explaining that clear error occurs when the reviewing court, after examining all the evidence, is convinced that a mistake has been committed); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1125, 227 U.S.P.Q. (BNA) 577, 589 (Fed. Cir. 1985) (en banc).

298. See *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388-89, 21 U.S.P.Q.2d (BNA) 1383, 1387 (Fed. Cir. 1992).

299. See *Young Dental Mfg.*, 112 F.3d at 1141, 42 U.S.P.Q.2d (BNA) at 1592; see also *Texas Instruments Corp. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1562, 231 U.S.P.Q. (BNA) 833, 834-35 (Fed. Cir. 1986) (affirming the ITC noninfringement finding based on the existence of substantial evidence in the record).

300. See *Strattec Sec. Corp. v. General Automotive Specialty Co.*, 126 F.3d 1411, 1418, 44 U.S.P.Q.2d (BNA) 1030, 1036 (Fed. Cir. 1997) (restating literal infringement as "when the properly construed claim reads on the accused device exactly"). For illustrations of how courts have analyzed literal infringement cases, see *Key Mfg. Group*, 925 F.2d at 1449, 17 U.S.P.Q.2d (BNA) at 1810; *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1580, 12 U.S.P.Q.2d (BNA) 1382, 1384 (Fed. Cir. 1989); *ZMI v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1582, 6 U.S.P.Q.2d (BNA) 1557, 1562 (Fed. Cir. 1988); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054, 5

finding of infringement, however, does not require that the accused product or process literally embody every limitation of the claim.³⁰¹ Even when a patent holder cannot prove literal infringement, a finding of infringement may be appropriate under the doctrine of equivalents.³⁰²

U.S.P.Q.2d (BNA) 1434, 1441 (Fed. Cir. 1988); *Stewart-Warner Corp. v. City of Pontiac*, 767 F.2d 1563, 1570, 226 U.S.P.Q. (BNA) 676, 681 (Fed. Cir. 1985).

301. See *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934-35, 4 U.S.P.Q.2d (BNA) 1737, 1739-40 (Fed. Cir. 1987) (en banc) (explaining that the doctrine of equivalents allows a finding of infringement if the accused product performs substantially the same function in substantially the same way to obtain the same result as the claimed device); see also *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1259, 9 U.S.P.Q.2d (BNA) 1962, 1967 (Fed. Cir. 1989) (clarifying that each claim limitation need not be "literally" found in the accused product—an equivalent of the stated limitation found in the accused product is sufficient to support a verdict of infringement); *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1282, 230 U.S.P.Q. (BNA) 45, 46 (Fed. Cir. 1986) (same).

In *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950), the Supreme Court set forth a tripartite test to decide infringement under the doctrine of equivalents. See *id.* at 608. The Court held that the absence of literal infringement did not preclude a finding of infringement under the doctrine of equivalents when the accused device "performs substantially the same function in substantially the same way to obtain the same result." *Id.* (stating that the essence of the doctrine is that one may not practice fraud on the patent). This holding soon received shorthand reference as the function-way-result test of *Graver Tank*. Cf. *International Visual Corp. v. Crown Metal Mfg.*, 991 F.2d 768, 774, 26 U.S.P.Q.2d (BNA) 1588, 1593 (Fed. Cir. 1993) (stating that there may be instances in which the function-way-result test is satisfied, but when the facts may not justify application of the doctrine of equivalents).

The present touchstone for determining whether an element in an accused device is equivalent to a claimed limitation is the substantiality of their differences. See *Dawn Equip. Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1015-16, 46 U.S.P.Q.2d (BNA) 1109, 1114-15 (Fed. Cir. 1998). In order to infringe under the doctrine of equivalents, the element must differ only insubstantially from the asserted claim limitation. See *Dawn Equip.*, 140 F.3d at 1015-16 (acknowledging the inadequacies of the "insubstantial differences" test and how the function-way-result test provides "additional guidance" on the issue of equivalence); see also *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1518, 35 U.S.P.Q.2d (BNA) 1641, 1645 (Fed. Cir. 1995) (en banc) (applying the function-way-result test to deduce the substantiality of differences), *rev'd on other grounds*, 520 U.S. 17 (1997).

302. In other cases, however, the Federal Circuit indicates circumstances where a patentee may otherwise lose the right to assert coverage of allegedly equivalent structure or matter by making statements during prosecution of a patent application that essentially disclaimed the asserted equivalent. See, e.g., *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1475, 45 U.S.P.Q.2d (BNA) 1498, 1501 (Fed. Cir. 1998) (stating that arguments made in Petition to Make Special limit the range of equivalents); *Tanabe Seiyaku Co. v. United States Int'l Trade Comm'n*, 109 F.3d 726, 732, 41 U.S.P.Q.2d (BNA) 1976, 1981-82 (Fed. Cir. 1997) (noting that statements made during prosecution demonstrated that ketone solvents other than acetone could not be asserted as equivalents); *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304, 41 U.S.P.Q.2d (BNA) 1364, 1368 (Fed. Cir. 1997) (grounding denial of asserted equivalent on statement made in information disclosure statement); *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1107, 39 U.S.P.Q.2d (BNA) 1001, 1006 (Fed. Cir. 1996) (explaining that doctrine of equivalents should not extend to disclosed, but unclaimed, subject matter); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1574, 40 U.S.P.Q.2d (BNA) 1481, 1489-90 (Fed. Cir. 1996) (explaining that written description demonstrated that a certain function must be performed by claimed process, and accused process that did not perform that function could not be asserted as an equivalent); *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 988 F.2d 1162, 1174, 26 U.S.P.Q.2d (BNA) 1018, 1025 (noting that unmistakable assertions made by the applicant preclude assertion of equivalency).

G. Prosecution History Estoppel

The prosecution history of a patent consists of the entire record of proceedings before the USPTO.³⁰³ In *Markman*, the Federal Circuit held that proper claim construction requires consideration of, *inter alia*, arguments and amendments made during the prosecution of a patent application.³⁰⁴ The prosecution history also may be relevant to an infringement analysis under the doctrine of equivalents.³⁰⁵

Prosecution history estoppel limits the scope of protection available under the doctrine of equivalents.³⁰⁶ Prosecution history estoppel thus precludes a patent holder from asserting a range of equivalency in an infringement suit encompassing subject matter that it disclaimed during prosecution of the patent application to obtain allowance of the claims in their issued form.³⁰⁷ Prosecution history estoppel is a question of law that the Federal Circuit reviews *de novo*.³⁰⁸

303. See *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452, 227 U.S.P.Q. (BNA) 293, 296 (Fed. Cir. 1985) (stating that “prosecution history (sometimes called file wrapper and contents) of [patents] consists of the entire record of proceedings” before USPTO); see also *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 397, 155 U.S.P.Q. (BNA) 697, 702 (Ct. Cl. 1967) (holding that patent’s prosecution history, or file wrapper, is part of patent); cf. *Jonsson v. Stanley Works*, 903 F.2d 812, 818, 14 U.S.P.Q.2d (BNA) 1863, 1869 (Fed. Cir. 1990) (providing that prosecution history of original application is also relevant to understanding scope of claims issuing from continuation-in-part application).

304. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980, 34 U.S.P.Q.2d (BNA) 1321, 1330 (Fed. Cir. 1995) (en banc) (stating that claim should be construed upon consideration of patent’s prosecution history).

305. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1270, 229 U.S.P.Q. (BNA) 805, 811 (Fed. Cir. 1986) (“While it is true that the effect of prosecution history arises as an estoppel when applying infringement analysis under the doctrine of equivalents, the prosecution history can and should, where relevant, be assessed (along with claim language and specification) in properly interpreting claim language.”); *McGill Inc. v. John Zink Co.*, 736 F.2d 666, 673, 221 U.S.P.Q. (BNA) 944, 949 (Fed. Cir. 1984) (“Prosecution history may be used not only in an estoppel context but also as a claim construction tool.”).

306. See *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1218, 36 U.S.P.Q.2d (BNA) 1225, 1230 (Fed. Cir. 1995) (noting that prosecution history estoppel applies even if there is a factual finding that the devices are equivalent).

307. See *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1432, 44 U.S.P.Q.2d (BNA) 1103, 1113 (Fed. Cir. 1997) (“A patentee is not free to retrade or renege on a deal struck with the PTO during patent prosecution.”); see also *Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co.*, 66 F.3d 285, 291, 36 U.S.P.Q.2d (BNA) 1095, 1099-1100 (Fed. Cir. 1995) (recognizing that prosecution history estoppel “serves as a check on the applicability of the doctrine of equivalents”); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1580, 34 U.S.P.Q.2d (BNA) 1673, 1680 (Fed. Cir. 1995) (proffering that when the doctrine of prosecution history estoppel is applied, courts must analyze what subject matter was surrendered and the reason for the surrender).

308. See, e.g., *Wang Lab., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1577, 41 U.S.P.Q.2d (BNA) 1263, 1269 (Fed. Cir. 1997) (explaining how the reviewing court examines the patent actions and statements to determine “what a competitor reasonably may conclude the patentee surrendered to gain issuance of the patent”); *Southwall Techs.*, 54 F.3d at 1579, 34 U.S.P.Q.2d (BNA) at 1679; *Wang Lab., Inc. v. Toshiba Corp.*, 993 F.2d 858, 867, 26 U.S.P.Q.2d (BNA) 1767, 1775 (Fed. Cir. 1993); *LaBounty Mfg., Inc. v. United States Int’l Trade Comm’n*, 867 F.2d 1572, 1576, 9 U.S.P.Q.2d (BNA) 1995, 1998 (Fed. Cir. 1989).

H. Design Patent Infringement

A design patent protects the nonfunctional aspects of a claimed ornamental design.³⁰⁹ Design patent infringement liability attaches if, visually, the accused design is substantially the same as the patented design³¹⁰ and if the accused design appropriates the novelty in the patented design that distinguishes the patented design from the prior art.³¹¹ The relevant comparison is between the accused design and the claimed design, not the commercial embodiment of the claimed design.³¹²

Similar to the infringement determination for utility patents, this determination for design patents is a two-step inquiry involving a proper claim construction followed by the comparison of the accused design for overall visual similarity.³¹³ A design patent holder must prove infringement by a preponderance of the evidence.³¹⁴ The

309. See 35 U.S.C. § 171 (1994); see also *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1405, 43 U.S.P.Q.2d (BNA) 1641, 1647 (Fed. Cir. 1997) (agreeing with the lower court's interpretation of looking at the ornamental visual impression rather than the broader concept of the item); *KeyStone Retaining Wall Sys., Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1450, 27 U.S.P.Q.2d (BNA) 1297, 1302 (Fed. Cir. 1993) (noting that the appearance of the design as a whole is controlling in determining questions of patentability and infringement).

310. In *Gorham Manufacturing Co. v. White*, 81 U.S. (14 Wall.) 511, 528 (1872), the Court stated:

[I]n the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other, the first patented is infringed by the other.

Id. at 528; see also *L.A. Gear, Inc. v. Thom McAnn Shoe Co.*, 988 F.2d 1117, 1125, 25 U.S.P.Q.2d (BNA) 1913, 1918 (Fed. Cir. 1993) (requiring a determination as to whether the designs are substantially the same); *Lee v. Dayton-Hudson Corp.*, 838 F.2d 1186, 1187, 5 U.S.P.Q.2d (BNA) 1625, 1625 (Fed. Cir. 1988) (applying the test set forth in *Gorham*); *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1444, 221 U.S.P.Q. (BNA) 97, 109 (Fed. Cir. 1984) (same).

311. See *Oakley, Inc. v. International Tropic-Cal, Inc.*, 923 F.2d 167, 169, 17 U.S.P.Q.2d (BNA) 1401, 1403 (Fed. Cir. 1991) (observing that the fact-finder must consider the overall similarity of the design as well as whether the accused device appropriates the novelty in the patented design that distinguishes it from the prior art); see also *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1565, 7 U.S.P.Q.2d (BNA) 1548, 1554 (Fed. Cir. 1988) (stating that in addition to *Gorham*'s similarity test, the accused device must also evidence aspects of the patented device which separate it from the prior art). For a more detailed discussion of the applicable standards for design patent infringement, see Harry C. Marcus & Mark J. Abate, *Design Patent Infringement Put to Sea Without Guiding Charts*, 22 AM. INTELL. PROP. L. ASS'N Q.J. 135 (1994).

312. See *Payless Shoesource, Inc. v. Reebok Int'l Ltd.*, 998 F.2d 985, 990, 27 U.S.P.Q.2d (BNA) 1516, 1520-21 (Fed. Cir. 1993) (stating that the proper application of the *Gorham* test requires comparison of the accused design to the claimed design and not to the commercial embodiment).

313. See *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1577, 36 U.S.P.Q.2d (BNA) 1417, 1420 (Fed. Cir. 1995) (describing the two-step analysis for determining whether a design patent has been infringed); *Braun, Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 820, 24 U.S.P.Q.2d (BNA) 1121, 1125 (Fed. Cir. 1992) (noting that the two products involved met the test set forth in *Gorham* requiring such similarity).

314. See *L.A. Gear, Inc.*, 988 F.2d at 1124, 25 U.S.P.Q.2d (BNA) at 1918 (stating that design infringement is a question of fact and must be proven by a preponderance of the evidence).

Federal Circuit applies the same standards of review with respect to infringement of design patents as it does for utility patents.³¹⁵

I. Plant Patent Infringement

One who discovers and asexually reproduces a distinct and new variety of plant may obtain plant patent protection.³¹⁶ In general, the same patent rights and remedies pertain to both utility patents and plant patents.³¹⁷ The Federal Circuit applies the same standards of review with respect to infringement of plant patents as it does for utility patents.³¹⁸

J. Remedies

A prevailing plaintiff patent holder has several available statutory remedies, including damages,³¹⁹ injunctive relief,³²⁰ and reasonable attorney fees.³²¹ A patent holder prevailing in an infringement action is entitled to recover damages, interest, and costs.³²² In general, such damages must be adequate to compensate for infringement.³²³ However, damages may not be less than a reasonable royalty.³²⁴ One measure of damages depends on the sales and profits that the patent holder lost because of the infringement.³²⁵ If the prevailing patent

315. See *Elmer*, 67 F.3d at 1577, 36 U.S.P.Q.2d (BNA) at 1420-21 (explaining that, like utility patents, claims for design patent infringement must be properly construed and then the claim may be compared to the accused design for a determination of similarity).

316. See 35 U.S.C. § 161 (1994).

317. See *id.* (stating that provisions of Title 35 regarding invention patents shall be applicable to plants as well).

318. See *Imazio Nursery, Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1568, 36 U.S.P.Q.2d (BNA) 1673, 1680 (Fed. Cir. 1995) (stating that where Congress uses the same statutory construction in separate statutes, the courts presume that Congress intended similar interpretation of the statutes).

319. See 35 U.S.C. §§ 284-285 (1994).

320. See *id.* § 283.

321. See *id.* § 285.

322. See *id.* § 284.

323. See *id.* (requiring courts to award adequate damages).

324. *Id.* (requiring damages to be not less than a reasonable royalty, plus interest and costs fixed by the court). A reasonable royalty is what a licensee would be willing to pay the inventor while still making a reasonable profit from the use of the patented invention.

325. To recover lost profits, the patent holder must show that the infringer actually caused the economic harm for which the patentee seeks compensation. See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545, 35 U.S.P.Q.2d (BNA) 1065, 1069 (Fed. Cir. 1995) (en banc) (noting that a patent holder must show that, but for infringing sales, the patent holder would not have suffered the loss). In the context of lost profits, causation requires evidence of "a reasonable probability that [the patent holder] would have made the asserted profits absent infringement." *King Instruments Corp. v. Perego*, 65 F.3d 941, 952, 36 U.S.P.Q.2d (BNA) 1129, 1137 (Fed. Cir. 1995). The Federal Circuit reviews a trial court's finding of causation for clear error. See *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 926 F.2d 1161, 1165, 17 U.S.P.Q.2d (BNA) 1922, 1925 (Fed. Cir. 1991) (upholding the trial court's rejection of a claim for lost profits because the decision was not clearly erroneous). In addition to causation, the patent holder bears the burden of proving the amount of the award. See *id.* at 1164, 17 U.S.P.Q.2d (BNA) at

holder cannot establish lost profits, then the court may determine a reasonable royalty by using a hypothetical royalty negotiation between the patent holder and a willing licensee at the time of the alleged infringement.³²⁶ In addition, where the patent holder's product embodies unpatented and patented components, the court must assess whether the reasonable royalty may derive from the entire market value of the combination.³²⁷

K. Patent Marking

Patent law provides for infringement damages from the time the patentee either marked the product (i.e., providing constructive notice)³²⁸ or notified the accused infringer of its infringement, whichever was earlier.³²⁹ The patentee bears the burden of pleading and proving compliance with the statutory marking requirement.³³⁰ The Federal Circuit reviews this issue as a question of fact, examining the record for substantial evidence to support the jury's verdict or for clear error where the trial judge is the fact-finder.³³¹

L. Damages

The Federal Circuit reviews a district court's damages award for substantial evidence to support the jury's verdict,³³² or for clear error

1925 (agreeing with the trial court that damages are a finding of fact to be proven by a preponderance of the evidence). Quantum is an issue of fact, which the Federal Circuit reviews for clear error. *See* *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1579, 38 U.S.P.Q.2d (BNA) 1288, 1292 (Fed. Cir. 1996) (stating that the trial court has discretion for the method and calculation of the damage award and such discretion will review the amount only for clear error).

326. *See* *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1078, 219 U.S.P.Q. (BNA) 679, 682 (Fed. Cir. 1983) (articulating the use of a hypothetical licensee/licensor agreement for an infringing ski resort showing no profits); *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120, 166 U.S.P.Q. (BNA) 235, 238 (S.D.N.Y. 1970) (setting forth a comprehensive, albeit nonexclusive, list of relevant factors in determining a reasonable royalty), *modified and aff'd sub nom.*, *Georgia-Pacific Corp. v. Plywood-Champion Papers, Inc.*, 446 F.2d 295, 170 U.S.P.Q. (BNA) 369 (2d Cir. 1971).

327. *See* *Leesona Corp. v. United States*, 599 F.2d 958, 974, 202 U.S.P.Q. (BNA) 424, 439 (Ct. Cl. 1979) (holding that compensation included market value royalties).

328. *See* 35 U.S.C. § 287(a) (1994).

329. *See id.*; *American Med. Sys., Inc. v. Medical Eng'g Corp.*, 6 F.3d 1523, 1537, 28 U.S.P.Q.2d (BNA) 1321, 1331 (Fed. Cir. 1993) (stating that damages are available either from the time the patent holder began marking its product or when it notified the infringer of the infringement, whichever was earlier).

330. *See* *Dunlap v. Schofield*, 152 U.S. 244, 248 (1894) ("[T]he duty of alleging, and the burden of proving, either [actual or constructive notice] is upon the patent holder."); *see also* *Motorola, Inc. v. United States*, 729 F.2d 765, 770, 221 U.S.P.Q. (BNA) 297, 300-01 (Fed. Cir. 1984) (requiring patent owner to show that he complied with the marking requirement of the statute).

331. *See* *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111, 39 U.S.P.Q.2d (BNA) 1001, 1010 (Fed. Cir. 1996) (stating that the determination of compliance with the marking requirements is a question of fact to be reviewed for substantial evidence).

332. *See* *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 926 F.2d 1161, 1165, 17

where the trial judge is the fact-finder.³³³ The Federal Circuit, however, reviews the district court's award by an abuse of discretion standard.³³⁴

M. Reasonable Royalty

The amount of a reasonable royalty is a question of fact that the Federal Circuit reviews for substantial evidence to support the jury's verdict,³³⁵ or for clear error where the trial judge is the finder of fact.³³⁶

N. Prejudgment Interest

The patent law provides for the award of prejudgment interest to ensure adequate compensation for the infringement.³³⁷ Prejudgment

U.S.P.Q.2d (BNA) 1922, 1925 (Fed. Cir. 1991). In *SmithKline*, the Federal Circuit addressed an ambiguity in its precedent:

We have reviewed our precedent and find some confusing, if not conflicting, statements with respect to the nature of damage issues and the standard of review.

The conflict/confusion has not been directly addressed in any prior decision. Faced with this situation, the panel has been able to reconcile some statements in prior decisions as indicated in the text. In this situation, the authority we have chosen to follow, namely, that damages are reviewed as a question of fact, accords with our earliest precedent. It is also in line with the rule of decision in other fields, i.e., the amount of damages is a question of fact. There is no reason to adopt a special rule for patent cases. The damage award, thus, is reviewed under the clearly erroneous standard when fixed by the court and under the more restrictive substantial evidence standard when we review a denial of a motion for JNOV.

More particularly, we reject an interpretation of our precedent holding that a judge has "discretion" to choose the "methodology" in determining an award to mean that the judge may choose between basing an award on "lost profits" damages or on a reasonable royalty. That is not choosing methodology. If a winning patentee seeks and proves lost profits, he is entitled to an award reflecting that amount. A judge, however, may choose between reasonable alternative accounting methods for determining the amount of lost profits or may adopt in its discretion a reasonable way to determine the number of infringing units. Such subsidiary choices are left to the court's sound discretion under our precedent.

Id. at 1164-65 n.2, 17 U.S.P.Q.2d (BNA) at 1925 n.2 (internal citations omitted).

333. *See id.*, 17 U.S.P.Q.2d (BNA) at 1925 n.2 (explaining that reversal of the trial judge's holding is reviewed according to the clearly erroneous standard).

334. *See* *Unisplay, S.A. v. American Elec. Sign Co.*, 69 F.3d 512, 517 n.8, 36 U.S.P.Q.2d (BNA) 1540, 1544 n.8 (Fed. Cir. 1995) (stating that there was no intention by the court to overrule the distinction in *SmithKline* between the clearly erroneous review of the damages amount and the abuse of discretion review of methodology); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573-77, 12 U.S.P.Q.2d (BNA) 1026, 1028 (Fed. Cir. 1989) (same).

335. *See* *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1552-53, 41 U.S.P.Q.2d (BNA) 1801, 1808 (Fed. Cir. 1997) (upholding as reasonable the jury's decision to base a royalty in the value of the entire accused machines).

336. *See* *SmithKline*, 926 F.2d at 1164-65 n.2, 17 U.S.P.Q.2d (BNA) at 1925 n.2.

337. *See* 35 U.S.C. § 284 (1994); *see also* *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655-56 (1983) (noting that an award of interest from the time royalty payments should have been received serves only to make the patent holder whole); *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389, 219 U.S.P.Q. (BNA) 569, 576 (Fed. Cir. 1983) (holding the prejudgment interest may only be applied to the actual damages, not to punitive

interest has no punitive purpose, but merely seeks to compensate the patent owner for the use of its money between the date of injury and the date of judgment.³³⁸ The Federal Circuit reviews the grant or denial of prejudgment interest under an abuse of discretion standard.³³⁹

O. *Willful Infringement*

Deliberate disregard of another's patent rights, as opposed to actions taken by an accused infringer under a reasonable belief that it did not infringe the patent, may support a finding of willful infringement.³⁴⁰ A plaintiff patent holder must prove by clear and convincing evidence that, based on the totality of the circumstances, the defendant's infringement was willful.³⁴¹ Willfulness is a question of fact that the Federal Circuit reviews for substantial evidence to support the jury's verdict,³⁴² or for clear error where the trial judge

damages that may also be charged).

338. *See* Bio-Rad Lab., Inc. v. Nicolet Instrument Corp., 807 F.2d 964, 969, 1 U.S.P.Q.2d (BNA) 1191, 1195 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 915 (1987) (explaining that the court's discretion regarding the rate of the prejudgment interest must be guided by the underlying principle that the award of such interest strictly serves to make the patent holder whole, rather than to provide for punitive damages).

339. *See* Lummus Indus., Inc. v. D.M. & E. Corp., 862 F.2d 267, 274, 8 U.S.P.Q.2d (BNA) 1983, 1988 (Fed. Cir. 1988) (stating that the trial judge has discretion in determining prejudgment interest awards and therefore, any award decision will be reviewed for abuse of discretion).

340. *See* Stickle v. Heublein, Inc., 716 F.2d 1550, 1565, 219 U.S.P.Q. (BNA) 377, 388 (Fed. Cir. 1983) (noting that the deliberate disregard, as opposed to inadvertence, indicated willfulness). An important factor in determining whether infringement was willful is whether the infringer obtained a competent opinion by independent counsel of noninfringement, invalidity, or unenforceability. *See* Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 944, 22 U.S.P.Q.2d (BNA) 1119, 1126 (Fed. Cir. 1992) (explaining that an opinion letter by counsel may be an important factor in a determination of willful infringement). Prudent behavior generally requires that competent legal advice was obtained before the commencement of the infringing activity. *See* Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc., 976 F.2d 1559, 1580, 24 U.S.P.Q.2d (BNA) 1321, 1339 (Fed. Cir. 1992) (noting that an opinion of counsel is a factor but does not guarantee protection from a finding of willfulness); *see also* Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft, 829 F.2d 1075, 1084, 4 U.S.P.Q.2d (BNA) 1044, 1051 (Fed. Cir. 1987) (stating that an opinion from counsel is generally within the affirmative duty of care owed by a potential infringer).

341. *See* SRI Int'l, Inc. v. Advanced Tech. Labs., Inc., 127 F.3d 1462, 1465, 44 U.S.P.Q.2d (BNA) 1422, 1424 (Fed. Cir. 1997) (upholding the trial court's conclusion that defendants' reliance on several general legal opinions was not justified and defendants were aware of such infringement); *see also* BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 1 F.3d 1214, 1222, 27 U.S.P.Q.2d (BNA) 1671, 1678 (Fed. Cir. 1993) (noting that a separate, three-day trial was held to make full inquiry into the issue of willfulness); Read Corp. v. Portec, Inc., 970 F.2d 816, 829, 23 U.S.P.Q.2d (BNA) 1426, 1437 (Fed. Cir. 1992) (rejecting the jury's finding of willfulness based on a variety of factors, including advice of counsel); E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1440, 7 U.S.P.Q.2d (BNA) 1129, 1137 (Fed. Cir.) (rejecting the argument that willfulness need only be proven by a preponderance of the evidence), *cert. denied*, 488 U.S. 986 (1988).

342. *See* Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1583, 38 U.S.P.Q.2d

sits as the finder of fact.³⁴³ Furthermore, a finding of willful infringement may form the basis for an exceptional case determination.³⁴⁴

P. Exceptional Case

A district court may award attorneys' fees and costs in an exceptional case.³⁴⁵ A party must prove an exceptional case by clear and convincing evidence.³⁴⁶ The Federal Circuit reviews the factual determination that a case is exceptional under the clearly erroneous standard.³⁴⁷

Q. Enhanced Damages

A district court's decision to enhance damages for willful infringement and the extent of the enhancement is reviewed for an abuse of discretion.³⁴⁸

(BNA) 1126, 1132 (Fed. Cir. 1996) (noting if substantial evidence supports a verdict of willfulness, the verdict will not be reversed on appeal); *see also* Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1581, 1 U.S.P.Q.2d (BNA) 1081, 1091 (Fed. Cir. 1986) (explaining that a determination of willfulness is based on the totality of the circumstances and that a jury determination of willfulness will be upheld if there is substantial evidence to support the finding).

343. *See* Slimfold Mfg. Co. v. Kinkead Indus., Inc., 932 F.2d 1453, 1459, 18 U.S.P.Q.2d (BNA) 1842, 1847 (Fed. Cir. 1991) (asserting that findings of willful infringement and exceptional circumstances are both questions of fact to be revised only if clearly erroneous); *see also* Spindelfabrik Suessen-Schurr v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft, 829 F.2d 1075, 1083, 4 U.S.P.Q.2d (BNA) 1044, 1051 (Fed. Cir. 1987) (explaining that the question on review is whether the finding of willful infringement is clearly erroneous in light of the underlying facts), *cert. denied*, 484 U.S. 1063 (1988).

344. *See* S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc., 781 F.2d 198, 201, 228 U.S.P.Q. (BNA) 367, 369 (Fed. Cir. 1986) (willful infringement may support a finding of exceptional circumstances, but it is not a guarantee of a finding of exceptional circumstances); *cf.* Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 455, 227 U.S.P.Q. (BNA) 293, 298 (Fed. Cir. 1985) (enumerating other circumstances, such as inequitable conduct, litigation misconduct, vexatious litigation, and frivolity, that are appropriate grounds for an exceptional case finding).

345. *See* 35 U.S.C. § 285 (1994) ("The court in exceptional cases may award reasonable attorney fees to the prevailing party."); *see also* Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480, 45 U.S.P.Q.2d (BNA) 1498, 1504 (Fed. Cir. 1998) (rejecting a claim for attorney's fees by the non-prevailing party).

346. *See* Reactive Metals & Alloys Corp. v. ESM, Inc., 769 F.2d 1578, 1582, 226 U.S.P.Q. (BNA) 821, 824 (Fed. Cir. 1985) (stating that the award of attorney's fees is at the discretion of the trial judge only after proof demonstrated by the patent holder, by clear and convincing evidence, that exceptional circumstances exist).

347. *See* L.A. Gear, Inc. v. Thom McAnn Shoe Co., 988 F.2d 1117, 1128, 25 U.S.P.Q.2d (BNA) 1913, 1921 (Fed. Cir. 1993) (explaining that whether or not a case is exceptional is a factual question reviewed only for clear error); *see also* Revlon, Inc. v. Carson Prods. Co., 803 F.2d 676, 679, 231 U.S.P.Q. (BNA) 472, 474 (Fed. Cir. 1986) (upholding the trial judge's finding that the case was exceptional, absent any clear error).

348. *See* SRI Int'l, Inc. v. Advanced Tech. Labs., Inc., 127 F.3d 1462, 1469, 44 U.S.P.Q.2d (BNA) 1422, 1427 (Fed. Cir. 1997) (upholding trebling of the three percent royalty award for punitive damages granted by the trial court because such an award was within the court's discretion); *see also* Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 792, 35 U.S.P.Q.2d (BNA) 1255, 1260 (Fed. Cir. 1995) (stating that willfulness of infringement is the sole basis for the court's

R. Attorney Fees and Costs

In addition, a district court has inherent authority to assess attorney fees as a sanction against a party for bad faith litigation conduct.³⁴⁹ The Federal Circuit reviews the propriety of a district court's award of attorney fees and costs for abuse of discretion.³⁵⁰

S. Injunctive Relief

In a patent infringement suit, the district court may grant a preliminary injunction pending trial and a permanent injunction after a full determination on the merits.³⁵¹ The grant of a preliminary injunction depends on the likelihood of success on the merits, irreparable harm, balance of hardships, and the public interest.³⁵² The moving party bears the burden of showing that these elements support the award of a preliminary injunction.³⁵³

The Federal Circuit generally has viewed the grant of a preliminary injunction as a matter of procedural law not unique to the exclusive

enhancement of damages); *Rite-Hite Corp. v. Kelley Co.*, 819 F.2d 1120, 1126, 2 U.S.P.Q.2d (BNA) 1915, 1919 (Fed. Cir. 1987) (finding no basis for lower court's discretion to award attorney's fees where no willfulness or exceptional circumstances were shown). "[W]hen a trial court denies attorney fees in spite of a finding of willful infringement, the court must explain why the case is *not* 'exceptional' within the meaning of the statute." *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 543, 16 U.S.P.Q.2d (BNA) 1622, 1626 (Fed. Cir. 1990) (citing *S.C. Johnson & Son, Inc.*, 781 F.2d at 201, 228 U.S.P.Q. (BNA) at 369 (Fed. Cir. 1986)). Where such an explanation is provided, the Federal Circuit reviews the decision not to award attorney fees for an abuse of discretion. *See National Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1197, 37 U.S.P.Q.2d (BNA) 1685, 1693 (Fed. Cir. 1996) (granting the trial judge discretion over attorney fees allows the judge latitude to consider a variety of factors, such as culpability of the infringer and litigation behavior, that will assist on the issuance of justice).

349. *See* FED. R. CIV. P. 11, 37; *see also Refac Int'l, Ltd. v. Hitachi, Ltd.*, 921 F.2d 1247, 1256, 16 U.S.P.Q.2d (BNA) 1347, 1354 (Fed. Cir. 1990) (awarding attorney fees as a sanction for the frivolous nature of the appeal).

350. *See Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 629, 225 U.S.P.Q. (BNA) 634, 644 (Fed. Cir.) (noting that an award of attorney fees is a discretionary decision to be exercised only in cases involving exceptional circumstances), *cert. denied*, 474 U.S. 976 (1985).

351. *See* 35 U.S.C. § 283 (1994) (providing for the grant in equity of injunctions of a reasonable scope to prevent the violation of patent rights).

352. *See Reebok Int'l, Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555, 31 U.S.P.Q.2d (BNA) 1781, 1783 (Fed. Cir. 1994) (determining that the trial court's decision to issue a preliminary injunction was discretionary); *see also New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882, 23 U.S.P.Q.2d (BNA) 1622, 1625 (Fed. Cir. 1992) (setting standard for movant in order to obtain "extraordinary relief" or an injunction prior to trial); *Nutrition 21 v. United States*, 930 F.2d 867, 869, 18 U.S.P.Q.2d (BNA) 1347, 1348-49 (Fed. Cir. 1991) (discussing the four factors that the moving party must show to obtain a preliminary injunction); *Hybritech, Inc. v. Abbott Lab.*, 849 F.2d 1446, 1451, 7 U.S.P.Q.2d (BNA) 1191, 1195 (Fed. Cir. 1988) (explaining that the four factors are not dispositive; rather the district court must weigh and measure each factor against the others and against the "form and magnitude of requested relief").

353. *See H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 388, 2 U.S.P.Q.2d (BNA) 1926, 1928 (Fed. Cir. 1987) (establishing that the burden is always on the moving party to show entitlement to a preliminary injunction).

jurisdiction of the court and therefore, has applied the procedural law of the appropriate regional circuit.³⁵⁴ The Federal Circuit reviews the district court's grant of a preliminary or permanent injunction for an abuse of discretion.³⁵⁵

The district court may require the posting of a supersedeas bond to preserve the status quo while protecting the non-appealing party's rights pending appeal.³⁵⁶ The conditions that trigger a surety's obligations under a supersedeas bond depends on the interpretation of the terms of the bond, which is a matter of law that the Federal Circuit reviews *de novo*.³⁵⁷

T. Patentability Standards

To obtain patent protection, the claimed invention must involve statutory subject matter that is useful, novel, and nonobvious.³⁵⁸ In addition, the applicant must satisfy the statutory disclosure requirements.³⁵⁹ A defendant to an infringement suit may raise, as an

354. See *National Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1185 n.2, 37 U.S.P.Q.2d (BNA) 1685, 1686 n.2 (Fed. Cir. 1996); *Abbott Lab.* 849 F.2d at 1449, 7 U.S.P.Q.2d (BNA) at 1194 (applying procedural law of the District of Columbia).

355. See *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367, 37 U.S.P.Q.2d (BNA) 1773, 1775 (Fed. Cir. 1996) (holding that granting or denying a preliminary injunction pursuant to 35 U.S.C. § 283 is within the district court's discretion); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 772, 28 U.S.P.Q.2d (BNA) 1378, 1380 (Fed. Cir. 1993) ("An abuse of discretion may be established by showing that the district court either made a clear error of judgement in weighing relevant factors, or exercised its discretion based on an error of law or in findings which were clearly erroneous."); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 945, 22 U.S.P.Q.2d (BNA) 1119, 1127 (Fed. Cir. 1992) (claiming Federal Circuit reviews a district court's decision to grant an injunction and the scope of that injunction for abuse of discretion); *Abbott Lab.*, 849 F.2d at 1449, 7 U.S.P.Q.2d (BNA) at 1194 (stating that a review of a district court's grant of a preliminary injunction is limited to determining whether the district court abused its discretion, committed an error of law, or seriously misjudged the evidence); *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1579, 219 U.S.P.Q. (BNA) 686, 691 (Fed. Cir. 1983) (reiterating that a party denied a preliminary injunction must meet the "heavy burden" of showing that a lower court abused its discretion).

356. See *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 930 F.2d 1572, 1574, 18 U.S.P.Q.2d (BNA) 1548, 1550 (Fed. Cir. 1991) (ordering New England to increase the supersedeas bond to \$52 million if it wanted to continue to stay the judgment pending a further appeal).

357. See *id.*, 18 U.S.P.Q.2d (BNA) at 1550 (stating that the interpretation of a bond's term is a "unique task").

358. See 35 U.S.C. §§ 101-103 (1994) (discussing the patentability of inventions).

359. See *id.* § 112. The statute provides in relevant part:

[T]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Id.

affirmative defense, patent invalidity based on these grounds.³⁶⁰ An issued patent, however, carries a statutory presumption of validity.³⁶¹ A party must overcome this presumption by proving invalidity with clear and convincing evidence.³⁶²

U. Statutory Subject Matter

Patent protection extends only to certain types of inventions as set forth by statute.³⁶³ Such inventions include “new and useful processes, machines, manufactures, compositions of matter, or any new and useful improvement.”³⁶⁴ In recent years, the patentability of computer-related technology, for example, has been the focus of the Federal Circuit’s inquiries into patentable subject matter.³⁶⁵

V. Utility

To receive patent protection, the invention must have utility and must be capable of being used to effect the object proposed.³⁶⁶

360. The statute sets out the following affirmative defenses:

The following shall be defenses in any action involving the validity infringement of a patent and shall be pleaded:

- (1) Noninfringement, absence of liability for infringement or unenforceability,
- (2) Invalidity of the patent or any claim in suit on ground specified in part II of this title as a condition for patentability,
- (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,
- (4) Any other fact or act made a defense by this title.

Id. § 282.

361. *See id.* (presuming validity of patent independently of other claims).

362. *See* *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375, 231 U.S.P.Q. (BNA) 81, 87 (Fed. Cir. 1986) (“Notwithstanding that the introduction of prior art not before the examiner may facilitate the challenger’s meeting the burden of proof on invalidity, the presumption remains intact and on the challenger throughout the litigation, and the clear and convincing standard does not change.”), *cert. denied*, 480 U.S. 947 (1987). For a statistical study of the Federal Circuit’s dispositions in appeals from the USPTO regarding §§ 102, 103, and 112 rejections, see Dunner, *supra* note 292, at Charts 1C, 2C, and 3C.

363. *See* 35 U.S.C. § 101 (1994).

364. *Id.* (assuming conditions and requirements of the title are met); *see also* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (holding that availability of patent protection applies to “anything under the sun that is made by man”) (quoting S. REP. NO. 82-1979, at 5 (1952) and H.R. REP. NO. 82-1923, at 6 (1952)).

365. *See* *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 47 U.S.P.Q.2d (BNA) 1596 (Fed. Cir. 1998) (holding that computer algorithms and business methods are not unpatentable per se); *In re Alappat*, 33 F.3d 1526, 1545, 31 U.S.P.Q.2d (BNA) 1545, 1588 (Fed. Cir. 1994) (en banc) (reversing the rejection of claims to computer operating pursuant to software as nonstatutory subject matter under § 101).

366. *See* *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”); *see also* *Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. (BNA) 739, 742 (Fed. Cir. 1985) (claiming that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed).

Whether an invention claimed in a patent lacks utility is a question of fact, which the Federal Circuit reviews under the clearly erroneous standard.³⁶⁷

W. Novelty

To receive patent protection, the invention must be novel, i.e., not anticipated by the prior art.³⁶⁸ An invention is anticipated, and therefore invalid, if a single prior art reference expressly or inherently discloses each and every limitation of the claimed invention.³⁶⁹ A party must prove anticipation by clear and convincing evidence.³⁷⁰ Anticipation is a question of fact that the Federal Circuit

367. See *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 U.S.P.Q. (BNA) 592, 596 (Fed. Cir. 1983).

368. See 35 U.S.C. § 102(a)-(b) (1994) (describing conditions of patentability, novelty, and loss of right to patent).

369. See, e.g., *Glaxo, Inc. v. Novopharm, Ltd.*, 52 F.3d 1043, 1047, 34 U.S.P.Q.2d (BNA) 1565, 1567 (Fed. Cir. 1995) (holding that the invention was not anticipated); *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052, 32 U.S.P.Q.2d (BNA) 1017, 1019 (Fed. Cir. 1994) (stating that anticipation must be proven by clear and convincing evidence); *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.*, 976 F.2d 1559, 1565, 24 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 1992) (assessing that a party alleging an anticipation claim must demonstrate identity of invention); *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d (BNA) 1133, 1136 (Fed. Cir. 1992) (suggesting that defendant must convince jury that a third party disclosed each and every element of plaintiff's invention in order to prove anticipation); see also *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d (BNA) 1001, 1010 (Fed. Cir. 1991) ("Invalidity for anticipation requires that all of the elements and limitation of the claim are found within a single prior art reference."); *In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2d (BNA) 1655, 1657 (Fed. Cir. 1990) (indicating that the first step in an inquiry for anticipation requires that all elements of claimed invention be described in a single reference); *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d (BNA) 1566, 1567 (Fed. Cir. 1990) (finding that every element of a claimed invention must be "identically shown in a single reference"); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d (BNA) 1913, 1920 (Fed. Cir. 1989) (holding that a district court correctly instructed the jury that an invention is anticipated if the device, including all the claim limitations, is shown in a single prior art reference); *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138, 231 U.S.P.Q. (BNA) 644, 646 (Fed. Cir. 1986) (requiring every element of the claimed invention to be literally present as arranged in the claim); *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1571, 230 U.S.P.Q. (BNA) 81, 84 (Fed. Cir. 1986) (affirming the district court's finding that the patent claim was not anticipated pursuant to § 102); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 U.S.P.Q. (BNA) 669, 673 (Fed. Cir. 1984) (presuming that the jury found no anticipation because of the differences between the claimed invention and the prior art); *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1444, 221 U.S.P.Q. (BNA) 385, 388 (Fed. Cir. 1984) (involving expressed disclosure of each element of claimed invention); *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 772, 218 U.S.P.Q. (BNA) 781, 789 (Fed. Cir. 1983) ("[t]o be an anticipation a prior patent must include all the teachings necessary to accomplish what the allegedly invented patent succeeds in doing.").

370. See *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987) (reasoning that the precise issue in the case is whether Union Oil's evidence is so clear and convincing that reasonable jurors could only conclude that the claims were invalid); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 U.S.P.Q. (BNA) 763, 770 (Fed. Cir. 1984) (arguing that convincing a court of invalidity by clear and convincing evidence is a constant and never changing burden).

reviews for substantial evidence to support the jury's verdict,³⁷¹ or otherwise for clear error.³⁷²

X. *Statutory Bars to Patentability: Public Use and On-Sale*

The patent law bars patent protection of an invention that was in public use or on-sale more than one year before the filing date of the United States patent application for that invention.³⁷³ The public use and on-sale bars to patentability derive from the same public policy.³⁷⁴

371. See *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1361, 48 U.S.P.Q.2d (BNA) 1225, 1231 (Fed. Cir. 1998) (reversing jury's verdict of invalidity for anticipation claim).

372. See, e.g., *In re Graves*, 69 F.3d 1147, 1151, 36 U.S.P.Q.2d (BNA) 1697, 1700 (Fed. Cir. 1995) (establishing that prior art reference is a question of fact that is reviewed under the clearly erroneous standard); *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 45 F.3d 1550, 1554, 33 U.S.P.Q.2d (BNA) 1496, 1498 (Fed. Cir. 1995) (holding that the district court's finding with respect to anticipation is reviewed for clear error); *In re Baxter Travenol Lab.*, 952 F.2d 388, 390, 21 U.S.P.Q.2d (BNA) 1281, 1283 (Fed. Cir. 1991) (affirming the Board's decision because clear error was not found); *Scripps Clinic & Research Found.*, 927 F.2d at 1576, 18 U.S.P.Q.2d (BNA) at 1010 (discussing clear and convincing standard as applied to anticipation claims in a summary judgment proceeding); *Chester v. Miller*, 906 F.2d 1574, 1576, 15 U.S.P.Q.2d (BNA) 1333, 1335 (Fed. Cir. 1990) (finding no clear error in the Board's decision that applicant's claim was unpatentable due to anticipation by prior art); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d (BNA) 1315, 1317 (Fed. Cir. 1988) ("A patent challenger must show by clear and convincing evidence that a claim is anticipated."); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 321 U.S.P.Q. (BNA) 81, 90 (Fed. Cir. 1986) (same); *In re King*, 801 F.2d 1324, 1326, 231 U.S.P.Q. (BNA) 136, 138 (Fed. Cir. 1986) (claiming that review of a finding of anticipation is the same whether it was made by district court or the Board); *Ralston Purina Co. v. Far-Mar-Co. Inc.*, 772 F.2d 1570, 1574, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985) ("A finding is clearly erroneous when although there is evidence to support it, the reviewing court on the entire evidence is left with definite and firm conviction that a mistake has been committed."); *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 U.S.P.Q. (BNA) 481, 485 (Fed. Cir. 1984) (concluding district court's finding of anticipation was clearly erroneous); see also *In re Napier*, 55 F.3d 610, 613, 34 U.S.P.Q.2d (BNA) 1782, 1784 (Fed. Cir. 1995) (recognizing that what a prior art reference teaches is also a question of fact that the Federal Circuit reviews under the clearly erroneous standard); *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d (BNA) 1746, 1749 (Fed. Cir. 1991) (holding that whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced).

373. See 35 U.S.C. § 102(b) (1994).

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Id.

374. Compare *Tone Bros., Inc. v. Sysco Corp.*, 28 F.3d 1192, 1198, 31 U.S.P.Q.2d (BNA) 1321, 1324 (Fed. Cir. 1994) (discussing public policy rationale underlying public use), with *Envirotech Corp. v. Westech Eng'g, Inc.*, 904 F.2d 1571, 1574, 15 U.S.P.Q.2d (BNA) 1230, 1232 (Fed. Cir. 1990) (describing policies and purposes underlying the on-sale bar). The policies underlying § 102(b) are as follows:

- (1) discouraging the removal, from the public domain, of inventions that the public reasonably has come to believe are freely available;
- (2) favoring the prompt and widespread disclosure of inventions;
- (3) allowing the inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and
- (4) prohibiting the inventor from commercially exploiting his invention beyond the

The rationales for these patentability bars include the encouragement of prompt disclosure of inventions to the public and the discouragement of commercial exploitation of the invention while deferring the start of the patent protection term.³⁷⁵

A party asserting patent invalidity based on public use must prove by clear and convincing evidence that the invention was used in public before the critical date and primarily for purposes other than experimentation.³⁷⁶ Factors relevant to a public use inquiry include public access to, and awareness of, the activity, the degree of confidentiality imposed on observers, indicia of bona fide experimentation, and the financial aspects of the activity.³⁷⁷ The Federal Circuit reviews *de novo* the district court's ultimate conclusion of public use, and reviews for clear error the underlying factual findings.³⁷⁸

A party asserting patent invalidity based on on-sale activity must prove by clear and convincing evidence that a definite sale or offer to sell occurred before the critical date and that the subject matter of the sale or offer to sell either anticipated the claimed invention or would have rendered the claimed invention obvious.³⁷⁹ The Federal Circuit reviews *de novo* a district court's conclusion of on-sale activity and reviews for clear error the underlying factual findings.³⁸⁰

statutorily prescribed time.

King Instrument Corp. v. Otari Corp., 767 F.2d 853, 860, 226 U.S.P.Q. (BNA) 402, 406 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1016 (1986).

375. See *Envirotech*, 904 F.2d at 1574, 15 U.S.P.Q.2d (BNA) at 1232 (claiming that none of the policy reasons support the on-sale bar in this case).

376. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266, 229 U.S.P.Q. (BNA) 805, 808 (Fed. Cir. 1986) (finding that the district court's conclusions on public use was consistent with policies underlying the bar and therefore, the decision should be affirmed), *cert. denied*, 479 U.S. 1030 (1987).

377. See *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564, 4 U.S.P.Q.2d (BNA) 1210, 1214 (Fed. Cir. 1987) (determining that underlying facts of each case must be considered in light of all circumstances).

378. See *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 U.S.P.Q.2d (BNA) 1587, 1591 (Fed. Cir. 1990) (suggesting that to determine whether an invention was in public use, the court must consider how the totality of the circumstances comports with the policies underlying the public use bar).

379. See *UMC Elecs. Co. v. United States*, 816 F.2d 647, 656, 2 U.S.P.Q.2d (BNA) 1465, 1472 (Fed. Cir.) (noting that the party asserting patent invalidity based on on-sale activity must prove that there was definite sale or offer to sell one year prior to filing for subject patent), *cert. denied*, 484 U.S. 1025 (1987).

380. See *Pfaff v. Wells Elec., Inc.*, 124 F.3d, 1429, 1432, 43 U.S.P.Q.2d (BNA) 1928, 1931 (Fed. Cir. 1997) (determining that because there were no facts in dispute, the only question remaining was whether the § 102 on-sale bar invalidates the patent, which is reviewed *de novo*); *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1540, 41 U.S.P.Q.2d (BNA) 1829, 1832 (Fed. Cir. 1997) (concluding that relevant fact-findings by the district court were not clearly erroneous); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544, 41 U.S.P.Q.2d (BNA) 1238, 1243-44 (Fed. Cir. 1997) ("Application of the on-sale bar under Section 102 is a question of law based upon underlying issues of fact."); *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1566, 33 U.S.P.Q.2d (BNA) 1512, 1514-15 (Fed. Cir. 1995) (reviewing ultimate determination *de novo*

Y. *Inventorship*

Under the patent law, an inventor is the person who conceived the patented invention.³⁸¹ A party asserting patent invalidity based on incorrect inventorship must prove this claim by clear and convincing evidence.³⁸² The Federal Circuit reviews inventorship *de novo* as a question of law based on underlying factual findings.³⁸³

Z. *Derivation*

Derivation is a basis for patent invalidity premised on the assertion that the designated inventor did not actually invent the subject matter of the patent because that person derived the invention from another.³⁸⁴ The Federal Circuit reviews a finding of derivation as a question of fact and requires acceptance of the district court's findings, unless clearly erroneous or predicated on an improper legal foundation.³⁸⁵ To show derivation, the party asserting invalidity must

and subsidiary fact-findings for clear error); *Keystone Retaining Wall Sys., Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1453, 27 U.S.P.Q.2d (BNA) 1297, 1303 (Fed. Cir. 1993); *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836, 23 U.S.P.Q.2d (BNA) 1481, 1483 (Fed. Cir. 1992) (emphasizing that appellate review of an on-sale bar proceeds as a question of law); *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1562-64, 4 U.S.P.Q.2d (BNA) 1210, 1213-14 (Fed. Cir. 1987).

381. See *Collar Co. v. Van Dusen*, 90 U.S. (23 Wall.) 530, 563-64 (1874); *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1227-18, 32 U.S.P.Q.2d (BNA) 1915, 1919 (Fed. Cir. 1994) ("Conception is the touchstone of inventorship.").

382. See *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980, 41 U.S.P.Q.2d (BNA) 1782, 1785 (Fed. Cir. 1997) (holding that the burden of proving misjoinder or nonjoinder of inventors is by clear and convincing evidence because there is a strong temptation for witnesses to reconstruct their testimony in a light more favorable to their own position so that they can gain some credit for the invention); cf. 35 U.S.C. § 256 (1994) (stating that an error in "omitting inventors or naming persons who are not inventors" does not invalidate the patent if the error is correctable and there was not deceptive intent).

383. See *Sewall v. Walters*, 21 F.3d 411, 415, 30 U.S.P.Q.2d (BNA) 1356, 1358 (Fed. Cir. 1994) (maintaining that factual findings based on the question of inventorship, who conceived the subject matter and whether the subject matter is stated in an application or in a count in an interference, are reviewed by the clearly erroneous standard).

384. See 35 U.S.C. § 102(f) (1994) (stating that a patent should be issued unless the person seeking the patent did not invent that which he or she is trying to patent); *Price v. Symsek*, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d (BNA) 1031, 1033 (Fed. Cir. 1993) (clarifying that although derivation and priority of invention are similar in that both focus on inventorship and both may be resolved by the Board, the two are different concepts). A claim that a patentee derived an invention addresses originality— who invented the subject matter before the court, rather than which of two self-proclaimed inventors actually was first. See *Price v. Symsek*, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d (BNA) 1031, 1033 (Fed. Cir. 1993).

385. See *Hess*, 106 F.3d at 980, 41 U.S.P.Q.2d (BNA) at 1785 (finding that, although there was some conflict in the question of co-inventorship, the district court's finding that the plaintiff was not a co-inventor was not clearly erroneous); see also *Price*, 988 F.2d at 1190, 26 U.S.P.Q.2d (BNA) at 1033 (requiring that the party attacking the patent must establish prior conception of the claimed subject matter and communication of the conception to the adverse claimant); *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 U.S.P.Q. (BNA) 592, 596 (Fed. Cir. 1983) (stating that district court determinations must be accepted unless they are predicated on an improper legal foundation).

prove by clear and convincing evidence both prior conception of the invention by another and communication of that conception to the patentee.³⁸⁶ The Federal Circuit reviews a determination of proper inventorship as a question of law based on underlying factual findings relating to conception.³⁸⁷

AA. Abandonment, Suppression, or Concealment

The abandonment, suppression, or concealment of an invention may preclude an inventor from obtaining patent protection.³⁸⁸ No particular period of delay is unreasonable *per se*.³⁸⁹ The Federal Circuit reviews the question of abandonment for substantial evidence to support the jury's verdict of the ITC's determination,³⁹⁰ or otherwise for clear error.³⁹¹ On the other hand, suppression or concealment is a question of law, which the Federal Circuit reviews *de novo*.³⁹²

BB. Nonobvious

To receive patent protection, an invention must be nonobvious at the time of the invention to one of ordinary skill in the relevant art.³⁹³ An accused infringer must prove obviousness by clear and convincing evidence.³⁹⁴ Obviousness is a question of law that the Federal Circuit

386. See *Amax Fly Ash Corp. v. United States*, 514 F.2d 1041, 1047, 182 U.S.P.Q. (BNA) 210, 215 (Ct. Cl. 1975) (maintaining plaintiff's assertion that the evidence must be "clear and convincing").

387. See *Advanced Cardiovascular Sys.*, 106 F.3d at 980, 41 U.S.P.Q.2d (BNA) at 1786 (establishing *de novo* review for residuary questions of law).

388. See 35 U.S.C. § 102(g) (1994) (stating that "[a] person shall be entitled to a patent unless— . . . (g) before the applicant's invention thereof, the invention was made in this country by another who had not abandoned, suppressed, or concealed it").

389. See *Paulik v. Rizkalla*, 760 F.2d 1270, 1273, 226 U.S.P.Q. (BNA) 224, 226 (Fed. Cir. 1985) (stating that the determination of abandonment rests on the application of equitable principles and public policy to the facts of the case); *Shindelar v. Holdeman*, 628 F.2d 1337, 1343, 207 U.S.P.Q. (BNA) 112, 117 (C.C.P.A. 1980), *cert. denied*, 451 U.S. 984 (1981) (noting that because each case must be considered on its own facts, no established time frame exists for determining when abandonment occurs).

390. See *Checkpoint Sys., Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 759-60, 35 U.S.P.Q.2d (BNA) 1042, 1044 (Fed. Cir. 1995) (indicating that the Federal Circuit will not disturb the ITC's factual findings if they are supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion").

391. See *Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 15 (1939) (describing various issues of fact, such as negligence or delayed application, that can lead to a determination of abandonment).

392. See *Brokaw v. Vogel*, 429 F.2d 476, 480, 166 U.S.P.Q. (BNA) 428, 431 (C.C.P.A. 1970) (disagreeing with appellee, the court asserted that whether there was suppression or concealment under the statute is a conclusion of law based on facts of record).

393. See 35 U.S.C. § 103 (1994) (describing conditions of patentability, including nonobvious subject matter).

394. See *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716, 21 U.S.P.Q.2d (BNA) 1053, 1055 (Fed. Cir. 1991) (stating the court's obviousness test as: (1) scope and content of previous art;

reviews *de novo*.³⁹⁵ Nonetheless, the conclusion of obviousness is subject to underlying factual findings.³⁹⁶ These findings include the scope and content of the prior art, the level of ordinary skill in the art at the time of the invention, objective evidence of nonobviousness, and differences between the prior art and the claimed invention.³⁹⁷ Relevant secondary considerations of nonobviousness include commercial success, long felt but unsolved needs, failures of others, and copying.³⁹⁸ The Federal Circuit reviews the underlying factual findings for clear error.³⁹⁹

An obviousness determination takes into account analogous art.⁴⁰⁰

(2) variations between pieces in conflict; and (3) degree of skill); *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1558, 229 U.S.P.Q. (BNA) 561, 562-63 (Fed. Cir.) (concluding that judges must carry out a totality of evidence test in determining the obvious/nonobvious question), *cert. denied*, 479 U.S. 850 (1986).

395. See *In re Lueders*, 111 F.3d 1569, 1571, 42 U.S.P.Q.2d (BNA) 1481, 1482 (Fed. Cir. 1997) (noting that courts will utilize a *de novo* review for all legal conflicts of obviousness); *Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1127, 37 U.S.P.Q.2d (BNA) 1816, 1828 (Fed. Cir. 1996) (same); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 U.S.P.Q.2d (BNA) 1314, 1317-18 (Fed. Cir. 1996) (same); *In re Donaldson Co.*, 16 F.3d 1189, 1192, 29 U.S.P.Q.2d (BNA) 1845, 1848 (Fed. Cir. 1994) (en banc) (same); *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.*, 976 F.2d 1559, 1572-73, 24 U.S.P.Q.2d (BNA) 1321, 1332-33 (Fed. Cir. 1992) (same); *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d (BNA) 1438, 1442 (Fed. Cir. 1991) (same); *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1182, 20 U.S.P.Q.2d (BNA) 1094, 1102 (Fed. Cir. 1991) (same); *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 989, 6 U.S.P.Q.2d (BNA) 1601, 1606 (Fed. Cir. 1988) (same); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297 n.24, 227 U.S.P.Q. (BNA) 657, 667 n.24 (Fed. Cir. 1985) (same); *Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1393, 222 U.S.P.Q. (BNA) 943, 946 (Fed. Cir. 1984) (same); *Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1344, 220 U.S.P.Q. (BNA) 777, 782 (Fed. Cir. 1984) (same).

396. See *Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479, 44 U.S.P.Q.2d (BNA) 1181, 1183 (Fed. Cir. 1997) (contrasting the notion that obviousness necessitates an analysis of the facts, but is still a conclusion of law); *Miles Lab., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 U.S.P.Q.2d (BNA) 1123, 1128 (Fed. Cir. 1993) (defining the court's review of obviousness facts under a "clearly erroneous" standard); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566-68, 1 U.S.P.Q.2d (BNA) 1593, 1595-97 (Fed. Cir. 1987).

397. See *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881, 45 U.S.P.Q.2d (BNA) 1977, 1981 (Fed. Cir. 1998) (basing the court's holding on the scope of the prior art); see also *In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d (BNA) 1443, 1445-46 (Fed. Cir. 1992) (deciding that simplicity is not correlative to ordinary skill); *In re Gorman*, 933 F.2d 982, 986-87, 18 U.S.P.Q.2d (BNA) 1885, 1888 (Fed. Cir. 1991) (questioning ordinary skill as a solitary factor, rather than a collective factor); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1270, 20 U.S.P.Q.2d (BNA) 1746, 1750 (Fed. Cir. 1991) (affirming the four basic factors utilized by the courts to determine obviousness); *In re Young*, 927 F.2d 588, 591, 18 U.S.P.Q.2d (BNA) 1089, 1091 (Fed. Cir. 1991); *Panduit Corp.*, 810 F.2d at 1566-68, 1 U.S.P.Q.2d (BNA) at 1595-97.

398. See *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) (emphasizing the significance of additional factors).

399. See *In re Woodruff*, 919 F.2d 1575, 1577, 16 U.S.P.Q.2d (BNA) 1934, 1935 (Fed. Cir. 1990) (utilizing *de novo* review for legal analysis and a clearly erroneous standard for fact-finding); *In re Beattie*, 974 F.2d 1309, 1311, 24 U.S.P.Q.2d (BNA) 1040, 1041 (Fed. Cir. 1992) (same); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050, 5 U.S.P.Q.2d (BNA) 1434, 1438 (Fed. Cir. 1988) (same); *Panduit Corp.*, 810 F.2d at 1565-66, 1 U.S.P.Q.2d (BNA) at 1594-95 (same).

400. See *In re Clay*, 966 F.2d 656, 658-59, 23 U.S.P.Q.2d (BNA) 1058, 1060 (Fed. Cir. 1992) (maintaining that there are two criteria for determining whether prior art is analogous).

Two criteria have evolved for determining whether prior art is analogous: “(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.”⁴⁰¹ Whether a reference in the prior art is analogous is a factual question, which the Federal Circuit reviews for substantial evidence to support the jury’s verdict, or otherwise for clear error.⁴⁰²

CC. Obviousness-type Double Patenting

Obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit.⁴⁰³ This doctrine requires rejection of an application claim when the claimed subject matter is not patentably apart from the subject matter claimed in a commonly owned patent.⁴⁰⁴ Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner.⁴⁰⁵ The Federal Circuit reviews *de novo* a rejection under the doctrine of obviousness-type double patenting as a legal conclusion,⁴⁰⁶ and reviews for clear error any factual findings underlying that decision.⁴⁰⁷

DD. Written Description

To obtain patent protection, an inventor must set forth an adequate written description of the invention.⁴⁰⁸ This statutory requirement ensures that the subject matter of a claim presented after the filing date of the patent application sufficiently was disclosed at the time of filing, and thus, the *prima facie* date of invention can

401. *Id.*, 23 U.S.P.Q.2d (BNA) at 1060 (stating that under the clearly erroneous standard the analogous argument is two-fold).

402. *See Panduit Corp.*, 810 F.2d at 1568 n.9, 1 U.S.P.Q.2d (BNA) at 1597 n.9 (differentiating factors falling under fact analysis from those under legal review).

403. *See In re Braat*, 937 F.2d 589, 592, 19 U.S.P.Q.2d (BNA) 1289, 1291-92 (Fed. Cir. 1991) (establishing the difficult judicial standard for ensuring that additional patents are not given for “merely an obvious variation”).

404. *See id.*, 19 U.S.P.Q.2d (BNA) at 1291-92.

405. *See In re Goodman*, 11 F.3d 1046, 1052, 29 U.S.P.Q.2d (BNA) 2010, 2015 (Fed. Cir. 1993) (describing the two part test for determining double patenting as: “1) is the same invention claimed twice, and 2) is one claim merely an obvious variation of the earlier”).

406. *See Texas Instruments, Inc. v. United States Int’l Trade Comm’n*, 988 F.2d 1165, 1179, 26 U.S.P.Q.2d (BNA) 1018, 1029 (Fed. Cir. 1993); *General Foods v. Studiengesellschaft Kohl MbH*, 972 F.2d 1272, 1277, 23 U.S.P.Q.2d (BNA) 1839, 1843 (Fed. Cir. 1992).

407. *See In re Caveney*, 761 F.2d 671, 674, 226 U.S.P.Q. (BNA) 1, 3 (Fed. Cir. 1985) (noting that the court’s review of facts is clearly erroneous, rather than *de novo*).

408. *See* 35 U.S.C. § 112, ¶ 1 (1994).

fairly be held to be the filing date of the application.⁴⁰⁹ This issue arises, for example, out of an assertion of entitlement to the filing date of a previously filed application under 35 U.S.C. § 120.⁴¹⁰ The adequacy of a written description is a question of fact that the Federal Circuit reviews for substantial evidence to support the jury's verdict⁴¹¹ or otherwise for clear error.⁴¹²

EE. Indefiniteness

To obtain patent protection, an inventor must set forth a claim that reasonably apprises those of skill in the art of its scope.⁴¹³ Whether a claim is invalid for its indefiniteness depends upon "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification."⁴¹⁴ Indefiniteness is a legal conclusion that the Federal Circuit reviews *de novo*.⁴¹⁵

FF. Enablement

In addition, an inventor must provide a disclosure sufficient to enable any person skilled in the art to practice the invention.⁴¹⁶ The specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue

409. *See* Hyatt v. Boone, 146 F.3d 1348, 1354-55, 47 U.S.P.Q.2d (BNA) 1128, 1132 (Fed. Cir. 1998) (holding that not only is the subject matter critical, but clarity and specificity are integral to the court carrying out such analysis); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d (BNA) 1111, 1116 (Fed. Cir. 1991) (relying on the clarity factor); *In re* Smith, 481 F.2d 910, 914, 178 U.S.P.Q. (BNA) 620, 623-24 (C.C.P.A. 1973) (focusing on the specificity factor).

410. *See* Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571, 41 U.S.P.Q.2d (BNA) 1961, 1965-66 (Fed. Cir. 1997) (explaining the importance of the written description requirement in relation to the filing date).

411. *See* Wang Lab., Inc. v. Toshiba Corp., 993 F.2d 858, 865, 26 U.S.P.Q.2d (BNA) 1767, 1774 (Fed. Cir. 1993) (defining the standard for the written description requirement).

412. *See* Vas-Cath, Inc., 935 F.2d at 1563, 19 U.S.P.Q.2d (BNA) at 1116 (maintaining that compliance with the written description requirement is a question of fact that is reviewed under the clearly erroneous standard); *In re* Gosteli, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d (BNA) 1614, 1618 (Fed. Cir. 1989) (same); *see also* Utter v. Hiraga, 845 F.2d 993, 998, 6 U.S.P.Q.2d (BNA) 1709, 1714 (Fed. Cir. 1988) (clarifying distinctions between court choice of analysis); Ralston Purina Co. v. Far-Mar-Co., 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985) (describing analysis that can be used by court during a written description requirement review).

413. *See* 35 U.S.C. § 112, ¶ 2 (1994) (requiring that the patent "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention").

414. *See* Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 U.S.P.Q.2d (BNA) 1081, 1088 (Fed. Cir. 1986).

415. *See* North Am. Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1579, 28 U.S.P.Q.2d (BNA) 1333, 1339 (Fed. Cir. 1993) (establishing the court's standard of review); Carl Zeiss Stiftung v. Renishaw plc, 945 F.2d 1173, 1181, 20 U.S.P.Q.2d (BNA) 1094, 1101 (Fed. Cir. 1991) (same).

416. *Cf.* Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365-66, 42 U.S.P.Q.2d (BNA) 1001, 1004 (Fed. Cir. 1997) (noting that lack of disclosure alone does not result in a failure of the enabling requirement).

experimentation.⁴¹⁷ A party must prove lack of enablement by clear and convincing evidence.⁴¹⁸ Enablement is a question of law that the Federal Circuit reviews *de novo*.⁴¹⁹ The court reviews for clear error any underlying facts to the enablement conclusion.⁴²⁰

GG. Best Mode

To obtain patent protection, an inventor must disclose the best mode of carrying out the invention personally known at the time of filing the application.⁴²¹ The best mode inquiry focuses on the inventor's state of mind based on personal knowledge of available facts.⁴²² A party must prove a best mode violation by clear and convincing evidence.⁴²³ Compliance with the best mode requirement is a factual question that the Federal Circuit reviews for substantial evidence to support the jury's verdict,⁴²⁴ or otherwise for clear error.⁴²⁵

417. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. (BNA) 81, 94 (Fed. Cir. 1986) (specifying degree of experimentation necessary).

418. See *Morton Int'l Co. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469, 28 U.S.P.Q.2d (BNA) 1190, 1194 (Fed. Cir. 1993) (assessing the amount of evidence necessary to prove infringement).

419. See *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 U.S.P.Q.2d (BNA) 1618, 1623 (Fed. Cir. 1996) (stating the court's standard of review); *In re Wands*, 858 F.2d 731, 735-37, 8 U.S.P.Q.2d (BNA) 1400, 1402-04 (Fed. Cir. 1988) (same); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268, 229 U.S.P.Q. (BNA) 805, 811 (Fed. Cir. 1986) (same); *Quaker City Gear Works, Inc. v. Skil Corp.*, 747 F.2d 1446, 1453-54, 223 U.S.P.Q. (BNA) 1161, 1166 (Fed. Cir. 1984) (same).

420. See *Gould v. Quigg*, 822 F.2d 1074, 1077, 3 U.S.P.Q.2d (BNA) 1302, 1303-04 (Fed. Cir. 1987) (noting the court's use of a clearly erroneous test for factual determinations).

421. See 35 U.S.C. § 112, ¶ 1 (1994) (requiring that the patent specification "set forth the best mode contemplated by the inventor of carrying out his invention").

422. See *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927, 16 U.S.P.Q.2d (BNA) 1033, 1036 (Fed. Cir. 1990) (stating that the fact-finder must consider not only the inventor's state of mind at the time the application is filed, but also the level of skill in art and the scope of the claimed invention); see also *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535, 3 U.S.P.Q.2d (BNA) 1737, 1745 (Fed. Cir. 1987) (noting that there is no clear objective standard to judge the adequacy of the best mode disclosure, but that evidence of accidental or intentional concealment is considered); *Hybritech Inc.*, 802 F.2d at 1384-85, 231 U.S.P.Q. (BNA) at 94.

423. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 560, 32 U.S.P.Q.2d (BNA) 1077, 1084 (Fed. Cir. 1994) (stating that in determining the best mode requirement the court must consider: "(1) whether the inventor knew of a mode of practicing the claimed invention that he considered to be better than any other at the time he filed his application; and (2) to compare what he knew with what he disclosed . . ."); see also *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1517, 220 U.S.P.Q. (BNA) 929, 939-40 (Fed. Cir. 1984) (setting forth the burden of proving facts in relation to the best mode requirement upon the offering party).

424. See generally *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1550, 41 U.S.P.Q.2d (BNA) 1801, 1806 (Fed. Cir. 1997) (describing the court's use of the evidence to review the jury's verdict in regards to the best mode requirement); *Wang Lab., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1583, 41 U.S.P.Q.2d (BNA) 1263, 1273 (Fed. Cir. 1997) (same); *Great N. Corp. v. Henry Molded Prods., Inc.*, 94 F.3d 1569, 1572, 39 U.S.P.Q.2d (BNA) 1997, 2000 (Fed. Cir. 1996); *Therma-Tru Corp. v. Peachtree Doors, Inc.*, 44 F.3d 988, 993, 33 U.S.P.Q.2d (BNA) 1274, 1277 (Fed. Cir. 1995); *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1536, 25 U.S.P.Q.2d (BNA) 1241, 1248 (Fed. Cir. 1992); *Shearing v. Iolab Corp.*, 975 F.2d 1541,

HH. Noninfringement Defense Standards

In addition to patent invalidity, noninfringement is another affirmative defense available to an accused infringer.⁴²⁶

1. Repair versus reconstruction

Infringement liability does not attach to the repair of a patented combination of unpatented components.⁴²⁷ The distinction between permissible repair and impermissible reconstruction does not depend on whether the replaced element is an essential or distinguishing part of the claimed combination.⁴²⁸ Permissible repair includes any repair necessary for the maintenance or use of the whole patented combination, such as the replacement of spent, unpatented elements.⁴²⁹ Whether defendant's actions constitute a permissible repair or an infringing reconstruction is a question of law, which the Federal Circuit reviews *de novo*.⁴³⁰

2. License and implied license

A defense to an infringement charge may involve the existence of a license agreement relating to the otherwise unauthorized activity.⁴³¹ The proper construction of the parties' license agreement is a question of contract interpretation under state law, which the Federal Circuit reviews *de novo*.⁴³²

In addition, when a patent holder sells or authorizes a sale of the

1545-46, 24 U.S.P.Q.2d (BNA) 1133, 1137-38 (Fed. Cir. 1992).

425. See generally *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d (BNA) 1016, 1024 (Fed. Cir. 1991) (noting the court's use of the clearly erroneous standard for fact-findings); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535-36, 3 U.S.P.Q.2d (BNA) 1737, 1745 (Fed. Cir. 1987) (same); *DeGeorge v. Bernier*, 768 F.2d 1318, 1324, 226 U.S.P.Q. (BNA) 758, 763 (Fed. Cir. 1985) (same); *Coleman v. Dines*, 754 F.2d 353, 356, 224 U.S.P.Q. (BNA) 758, 763 (Fed. Cir. 1985) (same); *McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 676, 221 U.S.P.Q. (BNA) 944, 951 (Fed. Cir. 1984) (same).

426. See 35 U.S.C. § 282, ¶ 1 (1994) (stating that noninfringement, absence of liability for infringement, or unenforceability shall be defenses in actions involving the validity or infringement of a patent).

427. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 346 (1961) (describing the replacement of individual parts after the original is spent as the owners' "lawful right" to repair their own property).

428. See *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 217 (1980) (discussing distinction between repair and reconstruction) (citing *Aro Mfg.*, 365 U.S. at 344).

429. See *Aro Mfg.*, 365 U.S. at 346.

430. See *Dawson Chem.*, 448 U.S. at 217 (utilizing the *de novo* standard for a distinctly legal, rather than factual, question); *Sage Prods., Inc. v. Devon Indus., Inc.*, 45 F.3d 1575, 33 U.S.P.Q.2d (BNA) 1765, 1766-67 (Fed. Cir. 1995) (same).

431. See *Studiengesellschaft Kohle M.B.H. v. Hercules, Inc.*, 105 F.3d 629, 633, 41 U.S.P.Q.2d (BNA) 1518, 1521 (Fed. Cir. 1997) (discussing the "free" license versus the "paying" license as protection from infringement violations).

432. See *Cyrix Corp. v. Intel Corp.*, 77 F.3d 1381, 1384, 37 U.S.P.Q.2d (BNA) 1884, 1887 (Fed. Cir. 1996) (holding that contract interpretation is a question of law deserving *de novo* review).

patented product, a court may recognize an implied license.⁴³³ The Federal Circuit reviews the existence of an implied license *de novo*, as a question of law.⁴³⁴

II. Unenforceability

1. Inequitable conduct

Patent applicants and their representatives have a duty of candor, good faith, and honesty in their dealings with the USPTO.⁴³⁵ Breach of this duty constitutes inequitable conduct.⁴³⁶ A party alleging inequitable conduct must prove by clear and convincing evidence that the patent applicant intentionally misrepresented or withheld material information from the patent examiner.⁴³⁷ Information is material if a substantial likelihood exists that a reasonable examiner would have considered it necessary to a proper patentability assessment of an invention.⁴³⁸ Circumstantial evidence may allow the court to infer an intent to deceive the USPTO.⁴³⁹ Evidence of gross negligence alone, however, cannot support a finding of deceptive intent.⁴⁴⁰

433. See *United States v. Univis Lens Co.*, 316 U.S. 241, 250-51 (1942) (noting that the patent holder's sale of an unfinished patented item constituted both a transfer of ownership and a license to complete the patented procedure without further payment).

434. See *Guinn v. Kopf*, 96 F.3d 1419, 1421, 40 U.S.P.Q.2d (BNA) 1157, 1159 (Fed. Cir. 1996) (noting that the single issue, whether the commissioner properly promulgated 37 C.F.R. § 1.662(c) under the authority of Congress, involves only contract interpretation); *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687, 231 U.S.P.Q. (BNA) 474, 476 (Fed. Cir. 1986) (stating that the issue is a question of law).

435. See *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 818 (1945) (stating that persons with pending applications at the Patent Office have an "uncompromising duty to report to it all facts concerning possible fraud or inequity underlying the applications in issue").

436. See *id.* (explaining that only through requiring disclosure can the USPTO prevent inequitable conduct, thereby protecting the public from "fraudulent patent monopolies"); 37 C.F.R. § 1.555 (1998) (describing the intentional failure to report material information as inequitable conduct).

437. See *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1556-57, 33 U.S.P.Q.2d (BNA) 1496, 1500 (Fed. Cir. 1995) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872, 9 U.S.P.Q.2d (BNA) 1384, 1389 (Fed. Cir. 1988)) (both cases discussing the standard for proving inequitable conduct).

438. See 37 C.F.R. § 1.555 (1998) (delineating duties to disclose information material to patentability).

439. See *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1189-90, 25 U.S.P.Q.2d (BNA) 1561, 1567 (Fed. Cir. 1993) (noting that there is no requirement of "smoking gun" evidence to prove intent to deceive); see also *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151, 219 U.S.P.Q. (BNA) 857, 861 (Fed. Cir. 1983) (stating that the presumption that one intends the natural consequences of one's acts can be used to prove the intent element of fraud).

440. See *Kingsdown Med. Consultants*, 863 F.2d at 876, 9 U.S.P.Q.2d (BNA) at 1392 (clarifying that all evidence, including good faith evidence, is necessary in determining the intent to deceive).

The Federal Circuit reviews the district court's determination of inequitable conduct for abuse of discretion.⁴⁴¹ Misrepresentation, materiality, and intent to deceive are underlying questions of fact that the Federal Circuit reviews for clear error.⁴⁴²

2. *Laches and equitable estoppel*

Laches and equitable estoppel are defenses to an allegation of patent infringement.⁴⁴³ An accused infringer invoking a laches defense must prove by a preponderance of the evidence that the plaintiff's unreasonable delay in bringing suit resulted in material prejudice to the defendant.⁴⁴⁴ Similarly, an accused infringer invoking equitable estoppel must prove by a preponderance of the evidence that: (1) the plaintiff misled the defendant into reasonably believing that the plaintiff had foregone enforcement of its patent rights against the defendant; (2) that the defendant relied on this belief; and (3) that material prejudice would result from survival of the claim.⁴⁴⁵ The Federal Circuit reviews for an abuse of discretion the district court's decision whether to apply the equitable defenses of laches or equitable estoppel.⁴⁴⁶

JJ. Claim and Issue Preclusion

Claim preclusion, or *res judicata*, bars the relitigation of claims already adjudicated.⁴⁴⁷ Similarly, issue preclusion, or collateral estoppel, bars the relitigation of issues already adjudicated.⁴⁴⁸ A party

441. See *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1541, 41 U.S.P.Q.2d (BNA) 1829, 1834 (Fed. Cir. 1997) (articulating the standard of review).

442. See *Kingsdown Med. Consultants*, 863 F.2d at 872, 9 U.S.P.Q.2d (BNA) at 1389 (stating that the findings on these issues will not be disturbed unless the Federal Circuit firmly believes that there has been a mistake).

443. See *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1292, 23 U.S.P.Q.2d (BNA) 1860, 1862 (Fed. Cir. 1992) (noting that both defenses are based on factual determinations made at the trial court's discretion).

444. See *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 988 F.2d 1157, 1161, 26 U.S.P.Q.2d (BNA) 1038, 1041 (Fed. Cir. 1993) (stating that the period of delay is measured from the time the plaintiff had actual notice of the claim or would reasonably have made an inquiry about the issue).

445. See *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041, 22 U.S.P.Q.2d (BNA) 1321, 1335-36 (Fed. Cir. 1992) (en banc) (noting that equitable estoppel, unlike laches, is not factually limited).

446. See *id.* at 1028, 22 U.S.P.Q.2d (BNA) at 1325 (articulating the standard of review); *Adelberg Lab., Inc. v. Miles, Inc.*, 921 F.2d 1267, 1274, 17 U.S.P.Q.2d (BNA) 1111, 1116 (Fed. Cir. 1990) (finding no such abuse where the lower court granted the defendant's motion for summary judgment on the grounds of estoppel and laches).

447. See *Young Eng'rs, Inc. v. United States Int'l Trade Comm'n*, 721 F.2d 1305, 1316, 219 U.S.P.Q. (BNA) 1142, 1152 (Fed. Cir. 1983) (finding a second infringement action was barred when the issues were litigated previously).

448. *Cf. Mother's Restaurant, Inc. v. Mama's Pizza, Inc.*, 723 F.2d 1566, 1569-70, 221 U.S.P.Q. (BNA) 394, 397 (Fed. Cir. 1983) (holding that a trademark cancellation proceeding

to a subsequent action invoking collateral estoppel regarding issue preclusion must prove that the prior action: (1) involved the same controlling facts and applicable law; (2) involved actual litigation of the identical issue; (3) concluded with a final judgment to which the identical issue was essential; and (4) permitted a “full and fair opportunity” to litigate that issue.⁴⁴⁹

As claim and issue preclusion are not matters unique to patent cases, the Federal Circuit applies the applicable law of the appropriate regional circuit rather than its own jurisprudence.⁴⁵⁰ The Federal Circuit likely would review *de novo* the propriety of the application of claim or issue preclusion.⁴⁵¹

KK. Patent Misuse

Patent misuse is an affirmative defense to an accusation of patent infringement, the successful assertion of which “requires that the alleged infringer show that the patentee has impermissibly broadened the ‘physical or temporal scope’ of the patent grant with anticompetitive effect.”⁴⁵² The Federal Circuit reviews *de novo* the conclusion of patent misuse and the underlying facts for substantial evidence where resolved by a jury.⁴⁵³

LL. Interference Proceedings

When a patent application claims the same subject matter as another pending application or an unexpired patent, the Commissioner of the USPTO may declare an interference to determine which party has priority, i.e., who was the first to invent the

that adjudicated the issue of similar service marks prevents further adjudication on the same issue).

449. See *In re Freeman*, 30 F.3d 1459, 1465-67, 31 U.S.P.Q.2d (BNA) 1444, 1449-50 (Fed. Cir. 1994) (describing and applying these conditions to determine whether a reissue claim, amended during a reexamination hearing, is subject to issue preclusion).

450. See *Epic Metals Corp. v. H.H. Robertson Co.*, 870 F.2d 1574, 1576, 10 U.S.P.Q.2d (BNA) 1296, 1298-99 (Fed. Cir. 1989) (noting that the application of res judicata principles is not exclusive to Federal Circuit jurisdiction) (citing *Hartley v. Mentor Corp.*, 869 F.2d 1469, 1471 n.1, 10 U.S.P.Q.2d (BNA) 1138, 1139 n.1 (Fed. Cir. 1989)).

451. See *United Techs. Corp. v. Chromalloy Gas Turbine Corp.*, 189 F.3d 1338, 1342-43, 51 U.S.P.Q.2d (BNA) 1838, 1840-41 (Fed. Cir. 1999) (“Whether, based on the facts of the case, a claim is barred by the doctrine of res judicata is a question of law that we review *de novo*.”); *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376, 50 U.S.P.Q.2d (BNA) 1033,1036 (Fed. Cir. 1999) (reviewing the district court’s application of collateral estoppel *de novo*).

452. *Windsurfing Int’l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001, 228 U.S.P.Q. (BNA) 562, 566 (Fed. Cir. 1986) (quoting *Blonder-Tongue Lab., Inc. v. University of Ill. Found.*, 402 U.S. 313, 343 (1971)).

453. See *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868, 45 U.S.P.Q.2d (BNA) 1225, 1231-32 (Fed. Cir. 1997).

claimed subject matter.⁴⁵⁴ An initial step in the interference proceeding is defining an interference count, the interpretation of which is a question of law that the Federal Circuit reviews *de novo*.⁴⁵⁵

In determining priority of invention, the USPTO Board of Patent Appeals and Interferences must consider the “respective dates of conception and reduction to practice of the invention . . . [as well as] the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.”⁴⁵⁶ Accordingly, priority of invention “goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice.”⁴⁵⁷

The Federal Circuit reviews the issue of priority *de novo* and reviews the Board’s factual findings underlying that determination for clear error.⁴⁵⁸ Likewise, the Federal Circuit reviews the issue of conception *de novo* and reviews the Board’s factual findings underlying that determination for clear error.⁴⁵⁹

Conception is the touchstone to determining inventorship.⁴⁶⁰ Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, including every feature or limitation of the claimed invention.⁴⁶¹

454. See 35 U.S.C. § 135(a) (1994) (outlining the interference procedure); *Hahn v. Wong*, 892 F.2d 1028, 1030, 13 U.S.P.Q.2d (BNA) 1313, 1315 (Fed. Cir. 1989) (setting forth a brief description of the procedures and practices of the USPTO in conducting interference proceedings under its new rules).

455. See *Davis v. Loesch*, 998 F.2d 963, 967, 27 U.S.P.Q.2d (BNA) 1440, 1444 (Fed. Cir. 1993) (reviewing the interpretation of an interference count *de novo*); *DeGeorge v. Bernier*, 768 F.2d 1318, 1321, 226 U.S.P.Q. (BNA) 758, 760 (Fed. Cir. 1985) (same).

456. 35 U.S.C. § 102(g) (1994).

457. *Price v. Symsek*, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d (BNA) 1031, 1033 (Fed. Cir. 1993).

458. See *Holmwood v. Sugavanam*, 948 F.2d 1236, 1238, 20 U.S.P.Q.2d (BNA) 1712, 1714 (Fed. Cir. 1991) (“Reduction to practice is a legal determination subject to *de novo* review.”); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 U.S.P.Q. (BNA) 81, 87 (Fed. Cir. 1986) (same).

459. See *Bosies v. Benedict*, 27 F.3d 539, 542, 30 U.S.P.Q.2d (BNA) 1862, 1864 (Fed. Cir. 1994) (noting that the legal question of conception is reviewed *de novo*).

460. See *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1227-28, 32 U.S.P.Q.2d (BNA) 1915, 1919 (Fed. Cir. 1994) (articulating the test for conception as whether the inventor had an idea that was “definite and permanent” enough that one skilled in the art could understand the invention).

461. See *Coleman v. Dines*, 754 F.2d 353, 359, 224 U.S.P.Q. (BNA) 857, 862 (Fed. Cir. 1985) (setting forth the burden of proof for conception). Conception must be proven by corroborating evidence showing that the inventor disclosed to others his complete thought expressed in such clear terms as to enable those skilled in the art to make the invention. See *id.*, 224 U.S.P.Q. (BNA) at 862. The sufficiency of corroborative evidence is determined by the “rule of reason,” which requires a reasonable analysis of all of the pertinent evidence to determine whether the inventor’s testimony is credible. See *Price*, 988 F.2d at 1195, 26 U.S.P.Q.2d (BNA) at 1037.

To prove a reduction to practice, an applicant must show that the embodiment relied upon as evidence of priority actually worked for its intended purpose.⁴⁶² The Federal Circuit applies the “rule of reason” standard when reviewing the sufficiency of evidence about reduction to practice.⁴⁶³ Reduction to practice is a legal conclusion subject to *de novo* review.⁴⁶⁴ The Federal Circuit reviews the Board’s factual findings supporting its legal conclusions regarding reduction to practice for clear error.⁴⁶⁵

The Board or the Examiner-in-Chief may impose an appropriate sanction, including granting judgment in an interference, against a party who fails to comply with the rules governing interferences, including filing deadlines.⁴⁶⁶ The Federal Circuit reviews a Board’s decision pursuant to the permissive rules governing an interference for abuse of discretion.⁴⁶⁷

MM. Reissue

The patent law provides for the reissue of a patent deemed wholly or partly inoperative or invalid as a result of error without any

462. See *Estee Lauder, Inc. v. L’Oreal S.A.*, 129 F.3d 588, 593, 44 U.S.P.Q.2d (BNA) 1610, 1614 (Fed. Cir. 1997) (noting that there is no reduction to practice until an inventor has knowledge that the invention will serve its intended purpose); see also *Burroughs Wellcome*, 40 F.3d at 1228, 32 U.S.P.Q.2d (BNA) at 1919 (“[T]he discovery that an invention actually works is part of its reduction to practice.”); *Hahn v. Wong*, 892 F.2d 1028, 1032, 13 U.S.P.Q.2d (BNA) 1313, 1317 (Fed. Cir. 1989) (stating that reduction to practice of a chemical compound is established by a showing that the inventor prepared the compound knowing it would work); *Mikus v. Wachtel*, 542 F.2d 1157, 1159, 191 U.S.P.Q. (BNA) 571, 573 (C.C.P.A. 1976) (explaining the need for independent corroboration of reduction to practice); see also *UMC Elec. Co. v. United States*, 816 F.2d 647, 652, 2 U.S.P.Q.2d (BNA) 1465, 1468 (Fed. Cir. 1987) (“[T]here cannot be a reduction to practice of the invention . . . without a physical embodiment which includes all limitations of the claim.”).

463. See *Holmwood*, 948 F.2d at 1238-39, 20 U.S.P.Q.2d (BNA) at 1714 (noting that the “rule of reason” analysis “requires the Patent & Trademark Office to examine, analyze, and evaluate reasonably all pertinent evidence when weighing the credibility of an inventor’s story”).

464. See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564, 39 U.S.P.Q.2d (BNA) 1895, 1899 (Fed. Cir. 1996); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 U.S.P.Q. (BNA) 81, 87 (Fed. Cir. 1986).

465. See *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100, 30 U.S.P.Q.2d (BNA) 1626, 1628 (Fed. Cir. 1994).

466. See 37 C.F.R. § 1.616 (1998) (setting forth sanctions for failure to comply with interference regulations or orders).

467. See *Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050-51, 29 U.S.P.Q.2d (BNA) 1615, 1617 (Fed. Cir. 1994) (describing four situations where there is abuse of discretion); see also *Gerritsen v. Shirai*, 979 F.2d 1524, 1527-28, 24 U.S.P.Q.2d (BNA) 1912, 1915-16 (Fed. Cir. 1992) (stating that decisions made under a permissive statute that concern only USPTO practices are reviewed for abuse of discretion). Abuse of discretion will be found where a decision: “(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact-findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision.” *Abrutyn*, 15 F.3d at 1050-51, 29 U.S.P.Q.2d (BNA) at 1617.

deceptive intention.⁴⁶⁸ Reissue error may include an attorney's failure to appreciate the full scope of the invention, but does not give the patentee a second bite at the apple.⁴⁶⁹ "The deliberate cancellation of a claim of an original application in order to secure a patent . . . [may] prevent the applicant from obtaining the cancelled claim by reissue," but is not dispositive.⁴⁷⁰ This "recapture" rule bars the patentee from acquiring, through reissue, claims that are of the same or of broader scope than those claims that were cancelled from the original application.⁴⁷¹

Whether the statutory requirement of "error" has been met is an issue of law, which the Federal Circuit reviews *de novo*.⁴⁷² This legal conclusion is based on underlying factual inquiries, which the Federal Circuit reviews for substantial evidence to support the jury's verdict, or for clear error where the trial judge sits as the fact-finder.⁴⁷³

To the extent that its claims are identical with the original patent, a reissued patent constitutes a continuation of the original patent.⁴⁷⁴ Claims are identical if they are without substantive change.⁴⁷⁵ Thus, the scope of the claim must be identical, but the words need not be identical.⁴⁷⁶ A determination of whether the scope of a reissue claim is identical with the scope of the original claim is a question of law that the Federal Circuit reviews *de novo*.⁴⁷⁷

468. See 35 U.S.C. § 251 (1994). The inoperativity or invalidity may arise by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent. See *id.*

469. See *In re Wilder*, 736 F.2d 1516, 1519, 222 U.S.P.Q. (BNA) 369, 370-71 (Fed. Cir. 1984) (noting that such attorney error is a common source of patent defects).

470. *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 995-96, 27 U.S.P.Q.2d (BNA) 1521, 1524-25 (Fed. Cir. 1993) (quoting *In re Wilingham*, 282 F.2d 353, 357, 127 U.S.P.Q. (BNA) 211, 215 (C.C.P.A. 1960)); *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 U.S.P.Q. (BNA) 568, 574 (Fed. Cir. 1984) (same); *Ball Corp. v. United States*, 729 F.2d 1429, 1438, 221 U.S.P.Q. (BNA) 289, 296 (Fed. Cir. 1984) (same).

471. *But see Mentor Corp.*, 998 F.2d at 996, 27 U.S.P.Q.2d (BNA) at 1525 (noting that reissue claims may avoid the effect of the recapture rule if they are narrower in certain respects and broader in others).

472. See *In re Clement*, 131 F.3d 1464, 1468, 45 U.S.P.Q.2d (BNA) 1161, 1163 (Fed. Cir. 1997) (stating that the Board's findings are sustained unless clearly erroneous); *Mentor Corp.*, 998 F.2d at 994, 27 U.S.P.Q.2d (BNA) at 1524 (same).

473. See *In re Kemps*, 97 F.3d 1427, 1430, 40 U.S.P.Q.2d (BNA) 1309, 1312 (Fed. Cir. 1996) (rejecting the arbitrary and capricious standard of review).

474. See 35 U.S.C. § 252 (1994).

475. See *Seattle Box Co.*, 731 F.2d at 827-28, 221 U.S.P.Q. (BNA) at 574-75 (interpreting "identical" as "without substantive change" rather than the stricter standard of "essentially identical").

476. See *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1115, 1 U.S.P.Q.2d (BNA) 1563, 1565 (Fed. Cir. 1987) (stating that "identical" does not exclude a minor word change).

477. See *Tillotson, Ltd. v. Walbro Corp.*, 831 F.2d 1033, 1037, 4 U.S.P.Q.2d (BNA) 1450, 1452 (Fed. Cir. 1987) (holding that the scope of a claim is a "legal issue" that is reviewed *de novo*).

NN. Reexamination

Patent law provides a procedural mechanism in the USPTO, known as a reexamination proceeding, which allows for the amendment of, or addition to, the claims in an issued U.S. patent.⁴⁷⁸ A patentee of a reexamined patent is entitled to infringement damages, *inter alia*, for the period between the date of issuance of the original claims and the date of issuance of the reexamined claims, if the original and reexamined claims are “identical.”⁴⁷⁹

Reexamined claims are “identical” to their original counterparts if they are “without substantive change.”⁴⁸⁰ If substantive changes have been made to the original claims, the patentee is entitled to infringement damages only for the period following the issuance of the reexamination certificate.⁴⁸¹ The Federal Circuit reviews without deference the district court’s conclusion that the reexamined claims remained identical in scope.⁴⁸²

OO. Federal Court Jurisdiction

The procedural aspects of patent enforcement in the district courts and the Federal Circuit include jurisdiction, disposition, and control of cases.⁴⁸³ As courts vested under Article III, section 2 of the U.S. Constitution, the district courts and the Federal Circuit must remain cognizant of their limited jurisdiction.⁴⁸⁴ The failure of the parties at

478. See 35 U.S.C. § 305 (1994) (“No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding . . .”).

479. See 35 U.S.C. §§ 252, 307(b) (1994) (describing the legal effects of a reissued patent); *Tennant Co. v. Hako Minuteman, Inc.*, 878 F.2d 1413, 1417, 11 U.S.P.Q.2d (BNA) 1303, 1306 (Fed. Cir. 1989) (stating that amended claims identical to the original claims are given an effective date of the original patent).

480. See *Seattle Box*, 731 F.2d at 827-28, 221 U.S.P.Q. (BNA) at 574-75. In determining whether substantive changes have been made, the courts discern whether the scope of the claims are identical, not merely whether different words are used. See *Slimfold Mfg.*, 810 F.2d at 1115, 1 U.S.P.Q.2d (BNA) at 1565.

481. See *Bloom Eng’g Co. v. North Am. Mfg. Co.*, 129 F.3d 1247, 1249-50, 44 U.S.P.Q.2d (BNA) 1859, 1861 (Fed. Cir. 1997) (stating that infringement damages are available only if the amended claims are identical to the original claims).

482. See *Minco, Inc. v. Combustion Eng’g, Inc.*, 95 F.3d 1109, 1115, 40 U.S.P.Q.2d (BNA) 1001, 1005 (Fed. Cir. 1996) (holding that claim construction is subject to independent review).

483. See 28 U.S.C. § 1338(a) (1994) (granting to federal district courts original jurisdiction over any civil action arising under a congressional act relating to patents); 28 U.S.C. § 1295(a)(1) (establishing U.S. Courts of Appeals for the Federal Circuit as having exclusive jurisdiction over any appeal based on a § 1338 claim).

484. See *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 913, 23 U.S.P.Q.2d (BNA) 1921, 1923 (Fed. Cir. 1992) (stating that federal courts are limited to enumerated cases and controversies). Original jurisdiction in the federal courts depends upon both constitutional and congressional mandate. To satisfy the first prerequisite, Article III of the U.S. Constitution requires a case or controversy. See *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-41 (1937) (delineating the limited extent of the federal judicial powers). Second, Article III empowers federal courts to hear cases “arising under” federal law. See U.S. CONST. art. III, § 2, cl. 1. With respect to patent subject matter jurisdiction, “[t]he district courts shall

any time during the litigation to satisfy the requirements of Article III divests the federal courts of jurisdiction to hear the case.⁴⁸⁵ In addition, the district courts and the Federal Circuit may dispose of and control their cases as appropriate under the applicable federal rules.⁴⁸⁶

PP. Subject Matter Jurisdiction

The Federal Circuit applies its own precedent, rather than the law of the relevant regional circuit, in reviewing the propriety of a district court's dismissal for lack of subject matter jurisdiction.⁴⁸⁷ Whether a trial court properly granted a motion to dismiss for lack of subject matter jurisdiction is a question of law, which the Federal Circuit reviews *de novo*.⁴⁸⁸

Only a patentee may bring an action for patent infringement.⁴⁸⁹ The patent law recognizes a patentee as any party to which the patent issued, or as any successors in title to the patentee.⁴⁹⁰ A licensee is not entitled to bring suit in its own name as a patentee, unless the licensee holds "all substantial rights" under the patent, which effectively renders it an "assignee," and thus, a patentee.⁴⁹¹

Thus, although a patentee has standing to sue in its own name, an exclusive licensee that does not have all substantial rights has standing to sue third parties only as a co-plaintiff in conjunction with the patentee.⁴⁹² One exception to this general rule arguably exists

have original jurisdiction of any civil action arising under any Act of Congress relating to patents Such jurisdiction shall be exclusive of the courts of the states in patent . . . cases." 28 U.S.C. § 1338(a) (1994). The appellate jurisdiction of the Federal Circuit derives in turn from the proper jurisdiction of the district court. *See id.* § 1295(a)(1) (stating that the Federal Circuit has exclusive jurisdiction over appeals from federal district courts whose jurisdiction was based on § 1338).

485. *See Preiser v. Newkirk*, 422 U.S. 395, 401 (1975) (stating that a case or controversy must exist at all stages of a litigation for a federal court to have jurisdiction) (quotation omitted).

486. *See infra* notes 506-58 and accompanying text.

487. *See Sanders Assocs., Inc. v. Summagraphics Corp.*, 2 F.3d 394, 395, 27 U.S.P.Q.2d (BNA) 1853, 1854 (Fed. Cir. 1993) (holding that where the issue on appeal is jurisdiction, the Federal Circuit will determine its jurisdiction independently); *Woodard v. Sage Prods., Inc.*, 818 F.2d 841, 844, 2 U.S.P.Q.2d (BNA) 1649, 1651 (Fed. Cir. 1987) (en banc) (stating that deference to the district court is inappropriate where the issue on appeal is jurisdiction).

488. *See GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 481, 39 U.S.P.Q.2d (BNA) 1463, 1465 (Fed. Cir. 1996) (stating that the proper standard for reviewing for § 1338(a) jurisdiction is *de novo*); *BP Chems., Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978, 28 U.S.P.Q.2d (BNA) 1124, 1127 (Fed. Cir. 1993) (holding that whether a case or controversy exists is a question of law).

489. *See* 35 U.S.C. § 281 (1994).

490. *See id.* § 100(d).

491. *See Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875-76, 20 U.S.P.Q.2d (BNA) 1045, 1048-50 (Fed. Cir. 1991) (holding that an assignment of the full "bundle of rights" included in a patent confers standing to sue on an assignee).

492. *See Abbott Lab. v. Diamedix Corp.*, 47 F.3d 1128, 1130-33, 33 U.S.P.Q.2d (BNA) 1771, 1773-76 (Fed. Cir. 1995) (holding that patentee must be joined before the licensee has right to

where such an exclusive licensee has standing to sue in its own name when “necessary to prevent an absolute failure of justice.”⁴⁹³ The question of standing to sue for patent infringement is one that the Federal Circuit reviews *de novo*.⁴⁹⁴

When reviewing a conclusion of the district court that the causes of action in a case are not ripe for adjudication, the Federal Circuit applies the law of the regional circuit in which the district court sits.⁴⁹⁵

QQ. Declaratory Judgment Jurisdiction

The Declaratory Judgment Act⁴⁹⁶ established a procedural mechanism for the resolution of actual controversies between interested parties.⁴⁹⁷ A determination of an actual controversy requires the existence of a reasonable apprehension of immediate harm.⁴⁹⁸ The party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy.⁴⁹⁹ Declaratory judgment jurisdiction is a question of law that the

sue for infringement).

493. See *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891); *Littlefield v. Perry*, 88 U.S. (21 Wall.) 205, 223 (1874) (conferring standing on a licensee where the infringer of the patent was the patentee itself); *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1030, 34 U.S.P.Q.2d (BNA) 1444, 1446 (Fed. Cir. 1995) (stating that remedies normally available to the licensee are unavailable absent extraordinary circumstances).

494. See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1551, 35 U.S.P.Q.2d (BNA) 1065, 1074 (Fed. Cir. 1995) (en banc) (stating that standing is a jurisdictional issue subject to *de novo* review by the appellate court).

495. See *Cedars-Sinai Med. Ctr. v. Watkins*, 11 F.3d 1573, 1580, 29 U.S.P.Q.2d (BNA) 1188, 1194 (Fed. Cir. 1993) (stating that the law of the regional circuit applies where ripeness of claims is the issue); *Molins PLC v. Quigg*, 837 F.2d 1064, 1066, 5 U.S.P.Q.2d (BNA) 1526, 1527 (Fed. Cir. 1988) (holding that the regional circuit law applies to ripeness issues because ripeness focuses on justiciability in district courts, not the Federal Circuit).

496. 28 U.S.C. §§ 2201-2202 (1994).

497. See generally Lawrence M. Sung, Comment, *Intellectual Property Protection or Protectionism? Declaratory Judgment Use By Patent Owners Against Prospective Infringers*, 42 AM. U. L. REV. 239, 249-56 (1992) (discussing the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 (1988), and the application of declaratory judgment jurisprudence to patent cases).

498. An actual controversy requires: “(1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.” *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978, 28 U.S.P.Q.2d (BNA) 1124, 1126 (Fed. Cir. 1993). In this inquiry, the “first prong looks to [the patentholder’s] conduct; [the] second to that of [the declaratory judgment] plaintiff.” *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736, 6 U.S.P.Q.2d (BNA) 1685, 1689 (Fed. Cir. 1988).

499. See *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937) (stating that a declaratory judgment action requires an actual controversy); *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810, 39 U.S.P.Q.2d (BNA) 1451, 1453 (Fed. Cir. 1996) (stating that the facts alleged in a declaratory judgment proceeding must show the presence of a controversy), *cert. denied*, 519 U.S. 1101 (1997); *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1053, 35 U.S.P.Q.2d (BNA) 1222, 1223 (Fed. Cir. 1995) (holding that declaratory judgment actions require an “objectively reasonable apprehension that suit will be brought”); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634, 19 U.S.P.Q.2d (BNA) 1545, 1547 (Fed. Cir. 1991) (stating that an actual controversy must be established by the declaratory judgment plaintiff).

Federal Circuit reviews *de novo*.⁵⁰⁰ The Federal Circuit, however, reviews for an abuse of discretion the district court's refusal to accord jurisdiction under the Declaratory Judgment Act.⁵⁰¹

RR. Personal Jurisdiction

Personal jurisdiction over an out-of-state defendant is appropriate if the relevant state's long-arm statute permits the assertion of jurisdiction without violating federal due process.⁵⁰² The existence of personal jurisdiction is a question of law that the Federal Circuit reviews *de novo*.⁵⁰³ This conclusion may be based on subordinate questions of fact that the Federal Circuit reviews for clear error.⁵⁰⁴ Furthermore, the Federal Circuit applies its own precedent, rather than the law of the relevant regional circuit, to review a district court's decision concerning personal jurisdiction.⁵⁰⁵

500. See *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058, 35 U.S.P.Q.2d (BNA) 1139, 1142 (Fed. Cir. 1995) (holding that whether an actual controversy exists in a declaratory judgment action is subject to plenary review); *BP Chems.*, 4 F.3d at 978, 28 U.S.P.Q.2d (BNA) at 1127 (same).

501. See *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570, 42 U.S.P.Q.2d (BNA) 1257, 1264 (Fed. Cir. 1997) (applying a deferential standard of review to declaratory action once an actual controversy is established); *Serco Servs. Co. v. Kelley Co.*, 51 F.3d 1037, 1039, 34 U.S.P.Q.2d (BNA) 1217, 1218 (Fed. Cir. 1995) (stating that an abuse of discretion standard requires the lower court to make a reasoned judgment concerning whether to allow the action to proceed).

502. See *Graphic Controls Corp. v. Utah Med. Prods., Inc.*, 149 F.3d 1382, 1385, 47 U.S.P.Q.2d (BNA) 1622, 1625 (Fed. Cir. 1998) ("Determining whether jurisdiction exists over an out-of-state defendant involves two inquiries: whether a forum state's long-arm statute permits the assertion of jurisdiction and whether assertion of personal jurisdiction violates federal due process."); *Dainippon Screen Mfg. Co., v. CFMT, Inc.*, 142 F.3d 1266, 1269-70, 46 U.S.P.Q.2d (BNA) 1616, 1619 (Fed. Cir. 1998) (same); *Genetic Implant Sys., Inc. v. Core-Vent Corp.*, 123 F.3d 1455, 1458, 43 U.S.P.Q.2d (BNA) 1786, 1788 (Fed. Cir. 1997) (same); *Viam Corp. v. Iowa Export-Import Trading Co.*, 84 F.3d 424, 427, 38 U.S.P.Q.2d (BNA) 1833, 1834 (Fed. Cir. 1996) (same); *Akro Corp. v. Luker*, 45 F.3d 1541, 1543, 33 U.S.P.Q.2d (BNA) 1505, 1507 (Fed. Cir. 1995) (same); *North Am. Philips Corp. v. American Vending Sales, Inc.*, 35 F.3d 1576, 32 U.S.P.Q.2d (BNA) 1203, 1204 (Fed. Cir. 1994) (same).

503. See *Graphic Controls*, 149 F.3d at 1384, 47 U.S.P.Q.2d (BNA) at 1624; *Dainippon Screen Mfg.*, 142 F.3d at 1269, 46 U.S.P.Q.2d (BNA) at 1619 (same); *Genetic Implant Sys.*, 123 F.3d at 1457, 43 U.S.P.Q.2d (BNA) at 1788 (same).

504. See *Dainippon Screen Mfg.*, 142 F.3d at 1270, 46 U.S.P.Q.2d (BNA) at 1620 (noting that underlying questions of fact concerning personal jurisdiction are reviewed for clear error).

Specific jurisdiction exists when a non-resident defendant purposefully establishes minimum contacts with the forum state, the cause of action arises out of those contacts, and jurisdiction is constitutionally reasonable. See *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472, 476-77 (1985) (discussing requirements for personal jurisdiction). The Federal Circuit employs a three-prong minimum contacts test for determining if specific jurisdiction exists: (1) whether the defendant purposefully directed its activities at residents of the forum; (2) whether the claim arises out of or relates to those activities; and (3) whether assertion of personal jurisdiction is reasonable and fair. See *Dainippon Screen Mfg.*, 142 F.3d at 1270 n.2, 46 U.S.P.Q.2d (BNA) at 1620 n.2; *Genetic Implant Sys.*, 123 F.3d at 1458, 43 U.S.P.Q.2d (BNA) at 1789.

505. See *Akro*, 45 F.3d at 1543, 33 U.S.P.Q.2d (BNA) at 1506 (stating that jurisdiction over an out-of-state infringer presents a question of Federal Circuit law); *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1564-65, 30 U.S.P.Q.2d (BNA) 1001, 1006 (Fed. Cir. 1994) (noting that the application of Federal Circuit law to jurisdictional issues promotes "national

*SS. District Court Practice**1. Defenses*

A defendant may move, before filing a responsive pleading, to dismiss the complaint.⁵⁰⁶ The court must deny such a motion unless it appears beyond doubt that the plaintiff will be unable to prove any set of facts in support of its claim entitling it to relief.⁵⁰⁷ Whether a complaint states a claim upon which relief can be granted is a conclusion of law, which the Federal Circuit reviews *de novo* by applying the relevant law of the appropriate regional circuit.⁵⁰⁸

2. Amendment of pleadings

Federal Rule of Civil Procedure 15 provides that leave to amend a party's pleadings "shall be freely given when justice so requires."⁵⁰⁹ The grant or denial of leave to amend the complaint is within the discretion of the district court and the Federal Circuit will reverse this decision only for an abuse of discretion.⁵¹⁰ In reviewing an order denying a motion to amend, a subject that is not unique to patent law, the Federal Circuit defers to the law of the regional circuit.⁵¹¹

3. Indispensable party

Whether a party is indispensable under Federal Rule of Civil Procedure 19(b) is a matter of regional circuit law and is reviewed for abuse of discretion.⁵¹²

4. Intervention

Federal Rule of Civil Procedure 24 governs party intervention.⁵¹³

uniformity in the field of patent law").

506. See FED. R. CIV. P. 12(b)(6) (stating that a defendant may move for dismissal before filing a responsive pleading on the grounds that the complaint stated no claim upon which relief could be granted).

507. See *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 988 F.2d 1157, 1160, 26 U.S.P.Q.2d (BNA) 1038, 1041 (Fed. Cir. 1993) (noting the requirements to prevail on a motion to dismiss).

508. See *id.* (stating that no deference is given to the district court's decision concerning a motion to dismiss) (citing *Eades v. Thompson*, 823 F.2d 1055, 1060 (7th Cir. 1987)).

509. FED. R. CIV. P. 15.

510. See *Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 666, 231 U.S.P.Q. (BNA) 363, 367 (Fed. Cir. 1986) (stating that the abuse of discretion standard of review comports with the policy of permitting the amending of pleadings) (citing *Howey v. United States*, 481 F.2d 1187, 1190 (9th Cir. 1973)).

511. See *Senza-Gel*, 803 F.2d at 666, 231 U.S.P.Q. (BNA) at 367 (applying Ninth Circuit law); *Cornwall v. United States Constr. Mfg., Inc.*, 800 F.2d 250, 252, 231 U.S.P.Q. (BNA) 64, 66 (Fed. Cir. 1986) (deferring to Eleventh Circuit law).

512. See *In re Cambridge Biotech Corp.*, 186 F.3d 1356, 1368-69, 51 U.S.P.Q.2d (BNA) 1321, 1329 (Fed. Cir. 1999) (applying First Circuit law).

513. See FED. R. CIV. P. 24.

The denial of a motion to intervene constitutes a procedural matter not unique to patent law, and thus, the Federal Circuit applies the relevant law of the appropriate regional circuit.⁵¹⁴ The standard of review for a motion for permissive intervention is an abuse of discretion.⁵¹⁵

5. *Discovery matters*

Because an order compelling discovery is not unique to patent law, the Federal Circuit applies the relevant regional circuit law with respect to the standard of review.⁵¹⁶ The Federal Circuit reviews a district court's rulings regarding pre-trial discovery for a clear showing of an abuse of discretion.⁵¹⁷

The decision to admit or exclude evidence is within the sound discretion of the trial court and will be reversed on appeal only for a clear abuse of that discretion.⁵¹⁸ In patent-related cases, to show that a district court abused its discretion in excluding the prior art evidence, the affected party must demonstrate that the exclusion prejudiced its substantive rights.⁵¹⁹

6. *Sanctions*

A district court has inherent authority to control its docket, which may involve imposing sanctions on the parties.⁵²⁰ Severe sanctions, such as taking allegations as established and awarding judgment on that basis, dismissal, and default judgment are authorized under Federal Rule of Civil Procedure 37 only in extreme circumstances, which include willfulness, bad faith, or fault.⁵²¹ The Federal Circuit

514. See *Haworth, Inc. v. Steelcase, Inc.*, 12 F.3d 1090, 1092, 29 U.S.P.Q.2d (BNA) 1368, 1370 (Fed. Cir. 1993) (applying Sixth Circuit law).

515. See *id.* (describing the standard of appellate review) (citing *Bradley v. Milliken*, 828 F.2d 1186, 1193-94 (6th Cir. 1987)).

516. See *American Standard, Inc. v. Pfizer, Inc.*, 828 F.2d 734, 739, 3 U.S.P.Q.2d (BNA) 1817, 1819 (Fed. Cir. 1987) (applying Seventh Circuit law to motion to compel discovery); *Truswal Sys. Corp. v. Hydro-Air Eng'g, Inc.*, 813 F.2d 1207, 1209, 2 U.S.P.Q.2d (BNA) 1034, 1036 (Fed. Cir. 1987) (deferring to Eighth Circuit law on reviewing order quashing subpoena); *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1022 n.4, 228 U.S.P.Q. (BNA) 926, 929 n.4 (Fed. Cir. 1986) (applying Fourth Circuit law to review an order quashing subpoena).

517. See *Dorf & Stanton Communications, Inc. v. Molson Breweries*, 100 F.3d 919, 922-23, 40 U.S.P.Q.2d (BNA) 1761, 1764 (Fed. Cir. 1996) (applying an abuse of discretion standard under Second Circuit law).

518. See *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1547, 31 U.S.P.Q.2d (BNA) 1746, 1750 (Fed. Cir. 1994) (applying the abuse of discretion standard to order excluding prior art evidence).

519. See *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 428, 231 U.S.P.Q. (BNA) 276, 280-81 (Fed. Cir. 1986) (stating that a party must show that its substantive rights have been affected).

520. See *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936) (stating that there is an inherent power in every court to control its docket).

521. See *Refac Int'l, Ltd. v. Hitachi, Ltd.*, 921 F.2d 1247, 1253, 16 U.S.P.Q.2d (BNA) 1347, 1352 (Fed. Cir. 1990) (holding that "[t]he district court must take into account: (1) the

reviews for an abuse of discretion the propriety of the district court's sanctions.⁵²² In addition, the Federal Circuit applies the relevant law of the appropriate regional circuit.⁵²³

7. *Subpoena*

The Federal Rules of Civil Procedure allow examination of a deponent concerning any matter, not privileged, which is relevant to the subject matter involved in the pending action.⁵²⁴ Rule 45 allows a person served with a discovery subpoena to move for a protective order, an order to quash, or an order to modify the subpoena.⁵²⁵ The Federal Circuit reviews the district court's order to quash a subpoena under an abuse of discretion standard and applies the appropriate regional circuit law.⁵²⁶

8. *Judgment as a matter of law ("JMOL")*

The Federal Rules of Civil Procedure permit a district court to grant a motion for judgment as a matter of law on an issue where no legally sufficient evidentiary basis exists for a reasonable jury to find for the moving party on that issue.⁵²⁷ In reviewing rulings under Federal Rule of Civil Procedure 50, the Federal Circuit generally defers to the law of the appropriate regional circuit.⁵²⁸

The Federal Circuit reviews a district court's grant of JMOL under Rule 50(a) *de novo*, reapplying the JMOL standard.⁵²⁹ The Federal

public's interest in expeditious resolution of litigation; (2) the court's need to manage its docket; (3) the risk of prejudice to the defendants; (4) the public policy favoring disposition of cases on their merits; and (5) the availability of less drastic sanctions").

522. See *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990) (stating that an appellate court should use an abuse of discretion standard when reviewing sanctions); *S. Bravo Sys., Inc. v. Containment Techs. Corp.*, 96 F.3d 1372, 1374-75, 40 U.S.P.Q.2d (BNA) 1140, 1142-43 (Fed. Cir. 1996) (stating that sanctions are to be reviewed under an abuse of discretion standard); *Refac Int'l*, 921 F.2d at 1253-54, 16 U.S.P.Q.2d (BNA) at 1352 ("In reviewing Rule 37 sanctions, the question is whether the district court abused its discretion."); *cf. Gerritsen v. Shirai*, 979 F.2d 1524, 1528, 24 U.S.P.Q.2d (BNA) 1912, 1915 (Fed. Cir. 1992) (adopting an abuse of discretion standard for reviewing a sanction imposed by the USPTO).

523. See *Refac Int'l*, 921 F.2d at 1253-54, 16 U.S.P.Q.2d (BNA) at 1352 (applying the law of the Ninth Circuit).

524. See FED. R. CIV. P. 26(b).

525. See FED. R. CIV. P. 45(d)(1).

526. See *Truswal Sys. Corp. v. Hydro-Air Eng'g, Inc.*, 813 F.2d 1207, 1209, 2 U.S.P.Q.2d (BNA) 1034, 1035-36 (Fed. Cir. 1987) (reviewing the quashing of a subpoena under an abuse of discretion standard and stating that applying regional circuit law is appropriate); *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1022 & n.4, 228 U.S.P.Q. (BNA) 926, 929 & n.4 (Fed. Cir. 1986) (deferring to Fourth Circuit law).

527. See FED. R. CIV. P. 50(a).

528. *Cf. Sjolund v. Musland*, 847 F.2d 1573, 1576, 6 U.S.P.Q.2d (BNA) 2020, 2023 (Fed. Cir. 1988) (applying Ninth Circuit law to the review of the entry of judgment notwithstanding the verdict).

529. See *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1563, 39 U.S.P.Q.2d (BNA) 1492, 1496 (Fed. Cir. 1996) (stating that a court reviews the JMOL *de novo* by

Circuit will reverse a denial of a motion for JMOL only if the jury's factual determinations are not supported by substantial evidence or the legal conclusions implied from the verdict cannot be supported in law by those findings.⁵³⁰

9. *Special master*

A district court has the inherent discretion to appoint, without the consent of the parties, a special master to assist the court in a case.⁵³¹ The Federal Rules of Civil Procedure define authority of a district court to assign issues to a special master.⁵³² The Federal Circuit reviews this reference for an abuse of discretion.⁵³³

reapplying the JMOL standard); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975, 34 U.S.P.Q.2d (BNA) 1321, 1326 (Fed. Cir. 1995) (en banc) (stating that factual findings made by a jury "are to be upheld unless the party moving for JMOL shows that . . . there is not substantial evidence to support a finding in favor of the nonmovant"); *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821, 23 U.S.P.Q.2d (BNA) 1426, 1431 (Fed. Cir. 1992) (stating that a JNOV should be reviewed *de novo* by reapplying the JNOV standard); *Dana Corp. v. IPC, Ltd. Partnership*, 860 F.2d 415, 417, 8 U.S.P.Q.2d (BNA) 1692, 1694 (Fed. Cir. 1988) (stating that a court must determine if there is substantial evidence to support the JNOV and if the jury's findings are legally sufficient to warrant the JNOV).

530. See *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1559, 41 U.S.P.Q.2d (BNA) 1225, 1228-29 (Fed. Cir. 1997) (stating that the court determines whether there was substantial evidence to support the jury's verdict); *Markman*, 52 F.3d at 975, 34 U.S.P.Q.2d (BNA) at 1325-26 (stating that on review the court determines whether the jury's verdict is supported by substantial evidence and in law) (en banc); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1547-48, 31 U.S.P.Q.2d (BNA) 1746, 1751 (Fed. Cir. 1994) (same); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1235, 9 U.S.P.Q.2d (BNA) 1913, 1919 (Fed. Cir. 1989) (stating that on review a court should apply the reasonable jury/substantial evidence standard); *Unidisco, Inc. v. Schattner*, 824 F.2d 965, 967, 3 U.S.P.Q.2d (BNA) 1439, 1441 (Fed. Cir. 1987) (stating that the court determines whether the jury's verdict and legal conclusions are supported by substantial evidence when reviewing a JNOV standard); *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 425, 231 U.S.P.Q. (BNA) 276, 278-79 (Fed. Cir. 1986) (same); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893, 221 U.S.P.Q. (BNA) 669, 673 (Fed. Cir. 1984) (noting that the standard of review for a JNOV is whether the jury's verdict is supported by substantial evidence that supports its legal conclusions); *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512-13, 220 U.S.P.Q. (BNA) 929, 936 (Fed. Cir. 1984) (stating that on review of a JNOV the court must determine whether there is evidence to support the jury's verdict, and if the evidence supports the jury's legal conclusions); see also *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619, 225 U.S.P.Q. (BNA) 634, 636 (Fed. Cir. 1985) ("In reviewing a decision denying a motion for judgment notwithstanding the verdict, we do not approach the issues as if there had been no trial. We review the evidence as a whole, and ascertain whether the verdict is in accordance with law, and whether there was substantial evidence in support of the jury's verdict.").

531. See *Ex parte Peterson*, 253 U.S. 300, 311-12 (1920) (appointing an auditor as the special master to parse out issues for trial); see also *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1566-67, 7 U.S.P.Q.2d (BNA) 1057, 1060-61 (Fed. Cir. 1988) (stating that a court has the inherent power to appoint a special master).

532. See FED. R. CIV. P. 53.

533. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 72 F.3d 857, 867, 37 U.S.P.Q.2d (BNA) 1161, 1166 (Fed. Cir. 1995) (finding that the court did not abuse its discretion in appointing a special master).

10. Summary judgment

A district court must enter summary judgment in the absence of a genuine dispute of material fact.⁵³⁴ The propriety of summary judgment is a question of law that the Federal Circuit reviews *de novo*.⁵³⁵ In addition, the Federal Circuit applies the relevant law of the appropriate regional circuit based on the underlying claim.⁵³⁶

11. New trial

The Federal Rules of Civil Procedure permit a district court to grant a new trial on all or part of the issues already tried.⁵³⁷ The Federal Circuit generally defers to the law of the appropriate regional circuit on such a consideration.⁵³⁸ The denial of a motion for new trial can be reversed only if the district court abused its discretion.⁵³⁹

534. Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). Summary judgment is improper "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, all of the nonmovant's evidence is to be believed, and all justifiable inferences are to be drawn in its favor. *See id.* at 255.

535. *See Aktiebolag v. E.J. Co.*, 121 F.3d 669, 672, 43 U.S.P.Q.2d (BNA) 1620, 1622 (Fed. Cir. 1997) (stating that a grant of summary judgment is reviewed *de novo*); *Young Dental Mfg. Co. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1141, 42 U.S.P.Q.2d (BNA) 1589, 1592 (Fed. Cir. 1997) (same); *Ekchian v. Home Depot Inc.*, 104 F.3d 1299, 1302, 41 U.S.P.Q.2d (BNA) 1364, 1366 (Fed. Cir. 1997) (same); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 528, 41 U.S.P.Q.2d (BNA) 1001, 1004 (Fed. Cir. 1996) (same); *Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 1425, 40 U.S.P.Q.2d (BNA) 1201, 1203 (Fed. Cir. 1996) (same); *Astra v. Lehman*, 71 F.3d 1578, 1580, 37 U.S.P.Q.2d (BNA) 1212, 1214 (Fed. Cir. 1995) (same); *Gasser Chair Co. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 773, 34 U.S.P.Q.2d (BNA) 1822, 1824 (Fed. Cir. 1995) (same); *Lantech, Inc. v. Keip Mach. Co.*, 32 F.3d 542, 545, 31 U.S.P.Q.2d (BNA) 1666, 1669 (Fed. Cir. 1994) (same); *Stark v. Advanced Magnetics, Inc.*, 29 F.3d 1570, 1572-73, 31 U.S.P.Q.2d (BNA) 1290, 1292 (Fed. Cir. 1994) (same); *Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 U.S.P.Q.2d (BNA) 1373, 1377 (Fed. Cir. 1994) (same); *Keystone Retaining Wall Sys., Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1449, 27 U.S.P.Q.2d (BNA) 1297, 1301 (Fed. Cir. 1993) (same); *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 395, 13 U.S.P.Q.2d (BNA) 1628, 1630 (Fed. Cir. 1990) (same).

536. *See Carroll Touch, Inc. v. Electro Mechanical Sys.*, 15 F.3d 1573, 1583, 27 U.S.P.Q.2d (BNA) 1836, 1844 (Fed. Cir. 1993) (applying Seventh Circuit law to determine the standard of review for a grant of summary judgment) (citing *Aetna Cas. & Sur. Co. v. Chicago Ins. Co.*, 994 F.2d 1254, 1256 (7th Cir. 1993)).

537. *See* FED. R. CIV. P. 59(a).

538. *See Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1358, 47 U.S.P.Q.2d (BNA) 1516, 1519 (Fed. Cir. 1998) (relying on Ninth Circuit precedent and reviewing a denial of a motion for a new trial under an abuse of discretion standard) (citing *Landes Constr. Co. v. Royal Bank of Canada*, 833 F.2d 1365, 1371 (9th Cir. 1987)); *Standard Havens Prods. Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1367, 21 U.S.P.Q.2d (BNA) 1321, 1327 (Fed. Cir. 1991) (relying on Eighth Circuit precedent and reviewing denial of a motion for a new trial under an abuse of discretion standard) (citing *Leichihman v. Pickwick Int'l*, 814 F.2d 1263, 1267 (8th Cir. 1987)).

539. *See DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 427, 231 U.S.P.Q. (BNA) 276, 280 (Fed. Cir. 1986) (stating that the denial of a motion for a new trial is reviewed under an abuse of discretion standard); *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512, 220 U.S.P.Q. (BNA) 929, 935-36 (Fed. Cir. 1984) (same).

12. *Relief from judgment*

The Federal Rules of Civil Procedure permit a district court to grant relief from the judgment for various reasons.⁵⁴⁰ In reviewing rulings based on Rule 60(b), the Federal Circuit generally defers to the law of the regional circuit in which the district court sits because such rulings commonly involve procedural matters that are not unique to patent law.⁵⁴¹ The Federal Circuit reviews the district court's ruling under Rule 60(b) to determine whether an abuse of discretion occurred.⁵⁴²

13. *Contempt*

A patent holder may bring contempt proceedings against a party enjoined by court order from further infringement.⁵⁴³ The patent holder must prove contempt by clear and convincing evidence.⁵⁴⁴ The Federal Circuit reviews for an abuse of discretion the district court's finding of contempt.⁵⁴⁵ Given the summary nature of contempt proceedings, the Federal Circuit generally admonishes against them.⁵⁴⁶

The district court may award damages in a civil contempt proceeding, which requires proof of both the fact of injury to the aggrieved party and the amount of damages the aggrieved party has suffered.⁵⁴⁷ The Federal Circuit applies the relevant law of the

540. See FED. R. CIV. P. 60(b).

541. See *Fraige v. American-National Watermattress Corp.*, 996 F.2d 295, 299-300, 27 U.S.P.Q.2d (BNA) 1149, 1152-53 (Fed. Cir. 1993) (deferring to Ninth Circuit law to set aside a jury verdict and order a new trial on the issue of patent validity); *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 977 F.2d 558, 561 n.3, 24 U.S.P.Q.2d (BNA) 1451, 1453 n.3 (Fed. Cir. 1992) (applying Third Circuit law in declining to modify a consent order following a change of law); *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1550, 3 U.S.P.Q.2d (BNA) 1412, 1421 (Fed. Cir. 1987) (applying Tenth Circuit law in reviewing the denial of a 60(b) motion since it involved a procedural issue not unique to patent law); *Ashland Oil, Inc. v. Delta Oil Prods. Corp.*, 806 F.2d 1031, 1033, 1 U.S.P.Q.2d (BNA) 1073, 1075 (Fed. Cir. 1986). *But see* *Broyhill Furniture Indus. Inc. v. Craftmaster Furniture Corp.*, 12 F.3d 1080, 1083, 29 U.S.P.Q.2d (BNA) 1283, 1285 (Fed. Cir. 1993) ("The issues before us are whether a consent judgment enjoining infringement of a patent should be set aside pursuant to certain subsections of Rule 60(b) following a judicial determination that the patent was procured through inequitable conduct in the PTO. Because we perceive a clear need for uniformity and certainty in the way the district courts treat this issue, we resolve it as a matter of Federal Circuit law.").

542. See *Fraige*, 996 F.2d at 297, 27 U.S.P.Q.2d (BNA) at 1150 (stating that an order denying a Rule 60(b) motion is reviewed under an abuse of discretion standard).

543. See *KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1530, 227 U.S.P.Q. (BNA) 676, 682 (Fed. Cir. 1985) (stating that contempt proceedings can go forward only when there is not more than a "colorable difference" between the patented devices).

544. See *id.*, 227 U.S.P.Q. (BNA) at 682.

545. See *id.* at 1532, 227 U.S.P.Q. (BNA) at 684 (stating that without an abuse of discretion, the Federal Circuit will defer to the district court's ruling).

546. See *id.* at 1530, 227 U.S.P.Q. (BNA) at 682-83 (holding that allowing patentees to go ahead in contempt proceedings would deter other parties from legitimate endeavors).

547. *Graves v. Kemsco Group, Inc.*, 864 F.2d 754, 756, 9 U.S.P.Q.2d (BNA) 1404, 1406 (Fed.

appropriate regional circuit.⁵⁴⁸ The Federal Circuit reviews the district court's award for an abuse of discretion and considers whether the award was based on clearly erroneous factual findings.⁵⁴⁹

14. Settlement

The judicial system favors dispute resolution through voluntary settlements.⁵⁵⁰ Accordingly, a party seeking to invalidate a settlement agreement bears a heavy burden of persuasion.⁵⁵¹ The Federal Circuit reviews *de novo* trial court orders such as consent orders, consent judgments, and consent decrees.⁵⁵²

15. Remand

On remand from the Federal Circuit, a district court may issue rulings based implicitly or explicitly on its interpretation of the appellate mandate.⁵⁵³ On subsequent appeal from such a ruling, the Federal Circuit's interpretation of its own mandate is a question of law, which the court reviews *de novo*.⁵⁵⁴

The Federal Circuit reviews the district court's refusal to allow the parties to supplement the record on remand for abuse of discretion, applying the appropriate regional circuit law.⁵⁵⁵

16. Writ of mandamus

The Federal Circuit has authority to issue extraordinary writs.⁵⁵⁶ Only when there has been a clear abuse of discretion or usurpation

Cir. 1988).

548. *See id.* at 755, 9 U.S.P.Q.2d (BNA) at 1406 (stating that the court should apply the law of the regional circuit in reviewing damage awards).

549. *See id.* at 756-57, 9 U.S.P.Q.2d (BNA) at 1407 (finding that the lower court has discretion to determine the amount of damages and whether abuse of discretion existed).

550. *See S & T Mfg. Co. v. County of Hillsborough*, 815 F.2d 676, 678, 2 U.S.P.Q.2d (BNA) 1280, 1281 (Fed. Cir. 1987) (reiterating the well established notion that courts favor voluntary settlement).

551. *See id.*, 2 U.S.P.Q.2d (BNA) at 1281 (holding that a party attacking a settlement bears "a properly heavy burden").

552. *See Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 950, 42 U.S.P.Q.2d (BNA) 1897, 1899 (Fed. Cir. 1997) (stating that both consent order judgments and decrees are reviewed *de novo*) (citing *Kenny v. Quigg*, 820 F.2d 665, 670 (4th Cir. 1987)); *Turner v. Orr*, 759 F.2d 817, 821 (11th Cir. 1985) (same); *United States v. National Steel Corp.*, 767 F.2d 1176, 1183 (6th Cir. 1985) (same).

553. *See Laitram*, 115 F.3d at 951, 42 U.S.P.Q.2d (BNA) at 1900 (stating that the district court's interpretation should be consistent with the appellate mandate under a *de novo* standard).

554. *See id.* at 950, 42 U.S.P.Q.2d (BNA) at 1899 (ruling that the court should interpret its own appellate mandate under a *de novo* standard).

555. *See Westvaco Corp. v. International Paper Co.*, 991 F.2d 735, 745, 26 U.S.P.Q.2d (BNA) 1353, 1362 (Fed. Cir. 1993) (holding that denial of a motion to supplement the record is reviewed under an abuse of discretion standard).

556. *See* 28 U.S.C. § 1651 (1994).

of judicial authority will orders under review by extraordinary writ be overturned.⁵⁵⁷ The petitioner has the burden of establishing that its right to obtain the writ is clear and indisputable.⁵⁵⁸

CONCLUSION

The standard of review employed by the Federal Circuit in patent-related cases facilitates predictable outcomes based upon a framework for the disposition of technology-based cases without resort to uninformed or misinformed assessments of the underlying scientific merits. The explicit and faithful application of such standards by the Federal Circuit will help alleviate public dissatisfaction with the administration of U.S. patent protection by dispelling any misapprehension that technical merit alone drives the resolution of patent cases. In the present climate of growing public discord, charging the hindrance to innovation by a runaway scope of patent protection, the Federal Circuit's conduct in this regard will fall under increasing scrutiny.

557. See *In re* Regents of the Univ. of Cal., 964 F.2d 1128, 1135, 22 U.S.P.Q.2d (BNA) 1748, 1754 (Fed. Cir. 1992) (stating that the writ of mandamus is an extraordinary remedy requiring a showing of judicial usurpation of power); *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988) (same); *In re* Calmar, Inc., 854 F.2d 461, 464, 7 U.S.P.Q.2d (BNA) 1713, 1715 (Fed. Cir. 1988) (same).

558. See *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 35 (1980) (stating that the petitioner must show that his/her right to issuance of the writ is clear and indisputable); *In re* Regents of the Univ. of Cal., 101 F.3d 1386, 1387, 40 U.S.P.Q.2d (BNA) 1784, 1785 (Fed. Cir. 1996) (finding that the petitioner has the burden of showing that he/she has a clear and indisputable right to the issuance of the writ).