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Judicial Fitness for Review of Complex Biotechnology Issues in Patent Litigation: Technical Claim Interpretation

By Megan E. Lyman*

This article focuses on two recent cases in biotechnology that have challenged both the district courts and the Federal Circuit in their ability to analyze complex innovations and apply principles of law and science to sound legal determinations. This article proposes that the current structure of the courts does not afford adequate protection to biotechnology and pharmaceutical inventions where an issue hinges on scientific interpretation. To remedy this inadequacy, changes in the background and expertise of judges should be made, or more firm guidelines by the courts should be constructed. Effecting changes in the structure of tribunals determining questions involving complex claim terminology will ensure confidence in the patent system and allow the continued progress of technology.

INTRODUCTION

The quantity of information required to understand the science underlying advancements in biotechnology has increased exponentially in the last twenty years.¹ The rise in the technical nature of biotechnology innovations has resulted in a plethora of patent applications as well as filings with the patent office to

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1. *Other News To Note*, 13 (135) BIOWORLD TODAY, July 12, 2002, available at 2002 WL 5615323.

invalidate patents and claims of infringement.² However, this increase has not been met with a concurrent rise in the expertise required of adjudicators in deciding these issues. The biotechnology industry has presented the courts with a whole new language that is difficult to understand even by the cohorts of those scientists bringing claims. Therefore, it is only natural that with this change in technology, the judicial system should respond to ensure that confidence in the system remains intact.

Current advances in the biotechnology field promise new therapeutics for genetic disease and cancers that have plagued our society for generations. For instance, the company ALS has launched a multi-million dollar research project to increase the rate at which genes involved in Lou Gehrig's disease are identified.³ Additionally, Geron Corp. has granted a nonexclusive license to Variagenics Inc., concerning their human telomerase⁴ reverse transcriptase technology for pharmacogenomic applications.⁵ Research and development in these areas requires a complex understanding of human physiology and drug delivery technologies.⁶ Consequently, the scientific community deserves courts that can understand their claims and apply the law appropriately and justly. To meet that call, there has been a rise in the number of law students

2. In 1999, the group handling patents in biotechnology, chemistry, and pharmaceuticals at the U.S. Patent and Trademark Office reported receipt of approximately 31,000 patent applications. Miguel Sanchez Padron & Mikel Gomez Uranga, *Protection of Biotechnological Inventions: A Burden Too Heavy For the Patent System*, 35(2) J. ECON. ISSUES 315 (2001) available at 2001 WL 21300784. Additionally, patent law itself has undergone many changes when looking at modifications made within one year of the American Inventors Protection Act of 1999. Nathaniel Hernandez, *Patent Lawyers Travel the Fast Lane to Keep Pace with Global Changes*, 24(4) CHICAGO LAWYER, April 9, 2001, at 8.

3. *Id.*

4. Telomerase is an enzyme that places "extra" DNA at the end of each chromosome (called the telomeres) after replication of DNA, it is thought that the shortening of telomeres may cause diseases having to do with aging. BRUCE ALBERTS, ET. AL., *MOLECULAR BIOLOGY OF THE CELL*, 364 (5th ed. 1994).

5. *Id.*

6. Drug delivery technologies encompass devices that are developed to deliver therapeutics to the patient.

with technical backgrounds that will be able to apply their scientific knowledge to the law.⁷

Amgen is currently the number one biotechnology corporation in the United States based on market capitalization and products introduced into the market.⁸ Amgen has continuously defended the validity of its patents and itself in infringement suits.⁹ Many of those decisions made at the district court have been upheld on appeal.¹⁰ Courts however, have had difficulty analyzing scientific issues and language as illustrated in *Genentech, Inc. v. Amgen, Inc.*¹¹ In that case the Federal Circuit vacated, in part, the decision of the district court because terms in the patent were interpreted incorrectly.¹² The terms that were misunderstood involve the “control region” of a gene that is inserted into bacteria to make large amounts of a target protein.¹³ More recently, a court had similar troubles in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*¹⁴ In that opinion, the Federal Circuit partially reversed the district court’s ruling, stating that the court had “eschewed the cardinal principle that the accused device must be compared to claims rather than to a preferred or commercial

7. Kelly Kordzik, *Small New World*, NAT’L L.J., Dec. 16, 2002, at C1.

8. *Amgen and Pfizer Top Market Capitalization Lists in Genetic Engineering News*, BUSINESS WIRE, June 3, 2002. Amgen’s rating is based on protein therapeutics, which can be distinguished from pharmaceutical products and their corporations. *Id.*

9. Apart from the two cases discussed in this article, Amgen has been a party in two other recent opinions. *Amgen, Inc. v. Scully*, 234 F. Supp. 2d 9 (D.D.C. 2002), *Jensen v. Amgen, Inc.*, 105 Cal. App. 4th 1322 (2003). Amgen has also been involved in disputes that have been settled out of court. *Amgen: Biotech company forecasts strong 2003 financial performance*, BIOTECH WK., Feb. 12, 2003, available at 2003 WL 9037781 (discussing Amgen’s recent settlement with Johnson and Johnson).

10. Pamela Sauer, *Amgen Prevails in Key EPO Patent Suit*, 259(5) CHEMICAL MARKET REP. 18 (2001), available at 2001 WL 8709537.

11. *Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761 (Fed. Cir. 2002).

12. *Id.*

13. *Id.*

14. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) (This case is now known as *Aventis Pharmaceuticals*).

embodiment.”¹⁵ These cases, albeit only focusing on one biotechnology company’s litigation in the past year, serve as examples of the complexities of biotechnology litigation and the urgent need for adjudicators with the appropriate experience and knowledge in this area, as well as clearly defined law to follow.

This comment makes various alternate proposals to remedy the current situation. Perhaps review of Patent and Trademark Office (“PTO”) determinations should be reviewed with more deference at the district court level, giving heed to the expertise that employees of that agency, which is nearly absent at the district court level. Alternatively, perhaps patent litigation should be appealed to the Federal Circuit, circumventing the district court. This alternative would give deference to the expertise and the ideology on which the court was created almost twenty years ago.¹⁶ To an even higher extent, Judges serving on the Federal Circuit could be required to have a general background in current technologies, acquired either through previous study, or even more helpful, through continuous education during their tenure. Alternatively, judges could employ special technical masters on a formal basis to aid in interpretation of these complex issues. It may be necessary for the courts to interpret rules in determining claim construction, and other issues that dealing primarily with the technicality of the science of the innovation with less ambiguity. This would provide a firm template for a reviewing court to follow, thus easing their burden of learning the science to the extent that it must be understood in order to render a fair verdict.

Section I of this article reviews the current structure of the PTO, in particular the rules used by that agency to make determinations of infringement or claim construction. Additionally, Section I discusses the standards of review applied at the trial and appellate level. Section II of this article is a “biotechnology primer” in order to understand the technical issues presented in *Genentech v. Amgen* and *Amgen v. Hoechst*. Section III outlines the *Genentech*, decision in the context of claim interpretation and also looks through *Hoechst*,

15. *Id.* at 1347.

16. The Federal Circuit’s predecessor was the Court of Customs and Patent Appeals (“CCPA”) which was formed in 1929. *In re Leuders*, 111 F.3d 1364, 1369 (Fed. Cir. 1997) (citing Pub.L. No. 914, 70th Cong. (Mar. 2, 1929)).

with its related issues decided by the Federal Circuit. Section IV proposes various modifications that could be made to the judicial system with respect to determinations involving issues in biotechnology. This comment is concluded in Section V.

I. CURRENT STRUCTURE OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

A. *Expertise of the Patent and Trademark Office*

The U.S. Patent and Trademark Office ("PTO") is a government agency operating in the Department of Commerce, and is authorized by Congress to issue patents to persons who invent products or processes that are novel, nonobvious, and useful.¹⁷ For a product or process to be considered novel, it must be new, and not introduced to the public prior to the patent application.¹⁸ Biotechnology companies may also obtain patent protection on both the equipment and processes developed to create novel genes and organisms.¹⁹ A patent

17. See 35 U.S.C. §§ 101-03 (2003).

18. 35 U.S.C. § 102 (2003).

19. See Theodore A. Feitshans, *A Review of U.S. Intellectual Property Law Applicable to Inventions in Biotechnology: U.S. Intellectual Property Law Continues to Demonstrate its Adaptability to New Technology*, 6 DRAKE J. AGRIC. L. 7, 8-9 (2001); Philip W. Grubb, *Patents for Chemicals*, PHARMACEUTICALS AND BIOTECHNOLOGY 225-27 (1999). The Supreme Court has held that living organisms or parts of living organisms are patentable. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980); Grubb at 233-34. Even though Louis Pasteur was granted a U.S. patent in 1873 for a living organism, this precedent was not followed by the USPTO until *Chakrabarty*. See Grubb, at 225-27. Patenting a living organism poses special issues for the patent system. Section 112 of the Patent Act requires:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor for carrying out his invention. 35 U.S.C. § 112 (2003).

application must be made in the name of the inventor, although that inventor may assign patent rights to other parties.²⁰

In order to retain protection for inventions, the inventor must file a patent application with the PTO within one year of the first commercial use or publication of the invention.²¹ Generally, a valid patent affords protection for a term of twenty years from the date of filing the application.²² This term of protection allows the owner to exclude all others from making, using, or selling any product or process that contains or uses the patented technology.²³ Once a patent is assigned, it is presumed to be valid; this presumption is overcome only by facts supported by clear and convincing evidence to the contrary.²⁴ When another party infringes on the patent, they are liable to the patent owner for damages, even when the infringer is unaware of the patent or the infringement.²⁵

Patent applications submitted to the PTO for review, claims of infringement, or requests for reexamination are first reviewed by examiners within the agency. PTO examiners are required to have technical backgrounds.²⁶ For example, a biotechnology patent examiner must have a bachelor's degree in biology, chemistry, biomedical engineering or biochemical engineering.²⁷ In the area of

20. 35 U.S.C. § 111 (2003).

21. § 102(b). This one-year statutory period is begun by satisfying the following two-part test established in *Pfaff v. Wells Electronics, Inc.*, "(1) the invention must be the subject of a commercial offer for sale; and (2) the invention must be ready to be patented." *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67-69 (1998). The second prong of the test can be satisfied by "proof of a reduction to practice," or by "proof that the inventor developed drawings or other materials sufficient to permit one skilled in the art to practice the invention." Feitshans, *supra* note 19 at 9 (citing Juan C. Gonzales, *The On-Sale Bar to Patentability: The U.S. Supreme Court Sheds Some Light*, 40 J.L. & TECH. 83, 88 (2000)). This test serves as a warning to biotech companies to install a comprehensible intellectual property policy to retain the fruits of their labors. *Id.* at 9.

22. 35 U.S.C. § 154(a)(2) (2003).

23. 35 U.S.C. § 271(a) (2003).

24. 35 U.S.C. § 282 (2003).

25. § 271.

26. Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 843 (1999) (citing USOPM-Job Details at <http://www.usajobs.com.opm.gov/wfjic/jobs/BG1809.HTM> (visited January 6, 2003)).

27. *Id.*

biotechnology alone, the PTO employs more than 150 PhDs.²⁸ Paradoxically, there is no such requirement for judges on the Federal Circuit. Moreover, in the PTO's appellate body, the Board of Patent Appeals and Interferences, examiners-in-chief are required by statute to be proficient both scientifically and legally.²⁹ Additionally, unlike the Federal Circuit, the "PTO can conduct public hearings to familiarize itself with technology in a particular industry."³⁰ This methodology, in contrast to those judges who do hire technical experts to aid them in patent litigation determinations, allows for a relatively unbiased interpretation of the technology from many different viewpoints.

B. Procedures Used by the Patent and Trademark Office ("PTO")

United States Code Title 35 and Title 37 of the Code of Federal Regulations, Patents, Trademarks and Copyrights govern the PTO.³¹ The statute is law, and cannot be ignored or waived by the PTO, although the rules may be suspended or waived as justice requires. The PTO is bound by the decisions handed down by the Federal Circuit and the Supreme Court. These decisions generally become available to examiners in the form of guidelines that are incorporated to the Manual of Patent Examining Procedure ("MPEP"). These three sources together allow the PTO to make determinations concerning applications for a patent, filing for infringement, and requesting amendments or reexamination of existing patents. Although the procedures outlined in the MPEP are not binding on a court of law, the Federal Circuit nonetheless regards them as firm guideposts.³² Further, the Federal Circuit has recognized that judicial

28. *Id.* (citing Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 57 OHIO ST. L. J. 1415, 1506 n.352 (1995)).

29. *Id.* (citing 35 U.S.C. § 6(a) (2002) (The examiners-in-chief or "administrative patent judges shall be persons of competent legal knowledge and scientific ability.")).

30. *Id.* (citing Nard, *supra* note 28, at 1501 and n.1818 ("discussing the PTO's public hearings with the biotechnology and computer software industries")).

31. 37 C.F.R. §§ 1-10; 35 U.S.C. §§ 1-376.

32. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 606 (Fed. Cir. 1985) (citing *In re Kaghan* 387 F.2d 398, 401 (C.C.P.A. 1967) (determining that appellants may rely on procedures outlined in the MPEP)).

notice may be given to the MPEP to the extent that it does not conflict with statute.³³

Certain sections of the Code are frequently cited and referred to in claims of infringement. The information herein is provided so as to understand claims presented in the cases below. Both cases involve claims of infringement. Infringement occurs when a person makes, sells, offers for sale, or imports, without authorization, any patented invention within the United States during the term of the patent.³⁴ Where one party alleges infringement, it almost always follows that the other will attack the patent's validity, thereby alleviating the infringement claim if the patent is found invalid.

A valid patent must comply with § 112 of the Patent Statute, which contains the requirements of specification.³⁵ The patent must contain "a written description of the invention, and of the manner and process of making and using it . . . [such] as to enable any person skilled in the art to which it pertains . . . to make and use the same . . ."³⁶ More simply, this statute conveys two separate and independent requirements for a valid patent: (1) an applicant must adequately describe the claimed invention and (2) enable its reproduction and use.³⁷ Additionally, the applicant must disclose what is considered the best mode of practicing the invention.

A valid application will also have sufficient claim definiteness.³⁸ The requirement of claim definiteness is satisfied where the claims in a patent are "sufficiently precise to permit a potential competitor to determine whether or not he is infringing."³⁹ This requirement is not stringent however, indefiniteness can be found where the claim is "insolubly ambiguous, and no narrowing construction can properly

33. 35 U.S.C. § 112 (2003). See *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 1324 (Fed. Cir. 2002) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995)).

34. See 35 U.S.C. § 271 (2003) (defining patent infringement).

35. § 112.

36. *Id.*

37. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

38. § 112.

39. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

be adopted.”⁴⁰ In *Amgen v. Hoechst*, the court adopts the rule in *Solomon v. Kimberly-Clark Corporation* stating that indefiniteness exists if “when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention.”⁴¹

Valid patents are issued where the invention was not known by others or described in a printed publication before the invention by the applicant, or there is no prior art describing the invention in total.⁴² Additionally, subject matter that would be deemed obvious at the time of the invention by another having ordinary skill in the art to which the invention applies is not patentable.⁴³

These rules are applicable to all patents. Generally, natural phenomena are not patentable.⁴⁴ However if the living matter is the result of human intervention, a valid patent may be issued.⁴⁵ To complicate matters further in the field of biotechnology, the PTO has not defined “gene.”⁴⁶ This prevents applicants from obtaining patent protection for nucleotide sequences with no known applications other than that they will be the subject for further research.⁴⁷ However, in the absence of a definition, inventors are afforded a broader spectrum of what can be considered a gene and what functional gene products will be patentable.

Patent law is fluid and has experienced many recent changes. These changes, however are often not subject to notice and comment rulemaking.⁴⁸ For instance, the PTO recently clarified the utility

40. *Exxon Research Camp Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

41. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) (citing *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378 (Fed. Cir. 2000) (citing *Personalized Media Comm., LLC v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998))).

42. 35 U.S.C. § 102(a) (2003).

43. 35 U.S.C. § 103 (2003).

44. *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980).

45. *Id.*

46. See 64 Fed. Reg. 71,427, 71, 431 (1999).

47. See Grubb, *supra* note 19, at 252.

48. Agencies are able to enact and write rules as proscribed in their enabling act. Under the Administrative Procedure Act, §553 rules made by agencies require a notice and comment period before implementation of the rule. 5 U.S.C. § 553

requirements for gene patents under sections 101 and 102 of the patent statute,⁴⁹ and the written description requirement under section 112, paragraph 1.⁵⁰ Both clarifications govern internal practices of the PTO and thus the changes are exempt from notice and comment rulemaking.⁵¹ Rules promulgated by the PTO are often interpreted and clarified at the court level. For instance, under 35 U.S.C. § 101 a patentable invention must have “utility.”⁵² This term has caused problems in interpretation. A recent decision by the Federal Circuit clarified that “[t]he threshold of utility is not high: An invention is useful under section 101 if it is capable of providing some identifiable benefit.”⁵³ Frequent changes in the law require diligence both in lawyering and in adjudication. These changes are often difficult to grasp and apply absent a firm scientific background. Understanding of the science underlying these technologies can aid the adjudicator in discerning how changes in the law affect a patent at issue.

C. Judicial Review of PTO Action by the District Court

The PTO follows the Federal Administrative Procedure Act (“APA”).⁵⁴ As such, under § 706 of the APA, standards of review by

(West, WESTLAW, through 1966 acts). Certain types of rules are exempt from the notice and comment rulemaking procedure, including those that govern internal practices. *Id.*

49. *See* 64 Fed. Reg. 71,440, 71,441 (1999).

50. *See* 64 Fed. Reg. 71,427, 71,427 (1999). *See* *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002).

51. *See* 64 Fed. Reg. 71,440, 71,441 (1999).

52. 35 U.S.C. § 101 (2003).

53. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

54. *Dickinson v. Zurko*, 527 U.S. 150 (1999). In this case a patent applicant appealed the decision of the Board of Patent Appeals and Interferences which rejected the patent application relating to a method for improving security systems. *Id.* The Federal Circuit reversed, 111 F.3d 887, and again reversed on rehearing en banc, 142 F.2d 1447 after applying the “clearly erroneous” standard of review. *Id.* The Federal Circuit claimed that it was exempt from the traditional standard of review for agency action upon 5 U.S.C. § 559 that states that the APA does “not limit or repeal additional requirements . . . recognized by law.” *Dickinson*, 527 U.S. at 154 (citing 5 U.S.C. § 559 (2003)). The Circuit asserted that the special tradition of strict review by the Court of Customs and Patent Appeals (“CCPA” the

the district court are dependent on whether the issue is a question of law or fact. In pertinent part, this section states that:

To the extent necessary . . . the reviewing court shall decide all relevant questions of law . . . and determine the meaning or applicability of the terms of an agency action. The reviewing court shall— . . . 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 the law; . . . (E) unsupported by substantial evidence . . .
55

This standard, however has not always been followed by district courts reviewing PTO determinations. Until the Supreme Court's decision in *Dickinson v. Zurko*, courts frequently applied the "clearly erroneous" test rather than the "substantial evidence" test proscribed by the APA.⁵⁶ In the Supreme Court's opinion, Justice Breyer held that the APAs standards governing the judicial review of findings of fact made by federal administrative agencies applies when the Federal Circuit reviews findings of fact made by the PTO.⁵⁷ Thus, the APAs "substantial evidence" standard of review, rather than the stricter "clearly erroneous" standard, was applied to the Federal Circuit's review of PTO findings of fact when reviewing PTOs denial of a patent application.⁵⁸ The distinction between "substantial evidence" and "clearly erroneous" is slight, the latter applies in appellate review of district court factual findings. The "substantial

predecessor court of the Federal Circuit) consequently amounted to an "additional requirement" that under § 559 trumps the requirements imposed by § 706. A dissenting opinion was filed by Justice Rehnquist, which Justices Kennedy and Ginsburg joined. *Id.*

55. 5 U.S.C. § 706(2)(A), (E) (2003).

56. *Dickinson*, 527 U.S. at 150. In *Dickinson* after closely examining 89 pre-APA CCPA determinations, the court found no well-established court/court standard. *Id.* at 155. Phrases such as "clear case of error," "clearly wrong," and "manifest error" do not conclusively signal a specific standard of review. *Id.* Although these phrases are not terms of art, they clearly demonstrate the intent to apply court/agency standard, not court/court.

57. *Id.*

58. *Id.*

evidence” standard is “highly deferential” and can be satisfied by showing “a rational connection . . . between an agency’s fact-findings and its ultimate action.”⁵⁹ The “clearly erroneous” standard, however, has been described by the Supreme Court as “somewhat” less deferential, requiring the reviewing judge to have a “‘definite and firm conviction’ that an error has been committed.”⁶⁰ Thus, it may be that application of either standard would not be outcome determinative in any case.⁶¹

The Court’s determination in *Dickinson* was later upheld in *In re Gartside* by the Federal Circuit applying the “substantial evidence” standard to PTO findings of fact.⁶² The Federal Circuit further opined that the “arbitrary and capricious” standard would be appropriate as default when the substantial evidence standard is not appropriate.⁶³ The substantial evidence standard will apply under the APA to review “on the record of an agency hearing provided by statute.”⁶⁴ Although the “substantial evidence” standard of review affords some deference to the PTO in their determinations, it would seem that the agency’s technical expertise in the area of science and technology

59. *In re Gartside*, 203 F.3d 1305, 1312-13 (Fed. Cir. 2000); *see also Dickinson v. Zurko*, 527 U.S. 150, 162 (1999) (explaining substantial evidence “as requiring a court to ask whether a ‘reasonable mind might accept’ a particular evidentiary record as ‘adequate to support a conclusion.’”) (citation omitted).

60. *Dickinson*, 527 U.S. at 162 (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948)); *Consolidated Edison*, 305 U.S. 206, 229(1938). The “substantial evidence” standard as applied to court/agency interactions requires a court to ask whether a “reasonable mind might accept” a particular evidentiary record as “adequate to support a conclusion.” *Id.* (quoting *Consolidated Edison*, 305 U.S.206, 229). In contrast the court/court “clearly erroneous” standard requires a reviewing judge to have a “definite and firm conviction” that error has been committed. *Id.* (*United States Gypsum Co.*, 333 U.S. at 395.)

61. Kenneth R. Adamo, Gregory A. Castanias, Mark N. Reiter & Lawrence D. Rosenberg, *Survey of the Federal Circuit’s Patent Law Decisions in 2000: Y2K in Review*, 50 AM. U. L. REV. 1435, 1441 (2001).

62. *In re Gartside*, 203 F.3d at 1315.

63. *Id.* at 1312.

64. *Id.* at 1313.

essential to understanding the basis for the invention would be accounted for by more deference to PTO determinations.⁶⁵

When courts review issues of claim construction in patent issues, the claim language defines the scope. The first step in an infringement analysis is to determine the meaning and scope of the claims that have been allegedly infringed.⁶⁶ In order to properly analyze the claims in the patent at issue the court must examine the claims, the rest of the specification, and if available, the prosecution history.⁶⁷ When interpreted correctly, claims can then be compared to the accused invention to determine whether the claims have been infringed either literally or equivalently.⁶⁸

The doctrine of equivalents is a judicially created doctrine that is applied in patent infringement issues.⁶⁹ The doctrine permits recovery for infringement when the accused device fails to fall within the literal scope of the claim.⁷⁰ The doctrine of equivalents teaches that even where a product or process does not literally infringe on patent claims there can be infringement where there is "equivalence" when comparing the elements of the accused product or process and those elements of the patented invention.⁷¹ The Supreme Court has stated that showing that the accused product is the overall equivalent will not be sufficient to establish infringement under the doctrine,

65. This contention is tempered by the PTOs interest in having patents, which may be unbiased as stated by other authors. *See generally* Rai, *supra* note 26, at 827.

66. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd* 517 U.S. 370 (1996) (holding that interpretation of language set forth in the claim is an issue for the judge rather than the jury).

67. *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

68. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed. Cir. 2003) (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 228 F.3d 1359, 1365 (Fed. Cir. 2002)).

69. JOHN GLADSTONE MILLS III, ROBERT C. HIGHLEY, & DONALD C. REILEY III, *PATENT LAW FUNDAMENTALS* § 18:49 (2d ed. 2002); *See* R. D. Hantman, *Patent Infringement*, 72 J. Pat. & Trademark Off. Soc'y 454 (1990).

70. MILLS III, *supra* note 69, at § 18:49; *Environmental Instruments, Inc., v. Sutron Corp.*, 877 F.2d 1561, 1565 (Fed. Cir. 1989) (disapproved on other grounds); *Cardinal Chem. Co. v. Morton Intern., Inc.*, 508 U.S. 83 (1993).

71. MILLS III, *supra* note 69, at § 18:49; *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997).

each claim of the invention must be analyzed separately.⁷² Infringement may be found where the accused product “performs substantially the same overall functions or work, in substantially the same way, to obtain substantially the same overall result as the claimed invention” even where a single claim in the patent can be read literally on the accused product.⁷³ Where the court is looking at claim construction for purposes of literal infringement the doctrine of equivalents is equally applicable.⁷⁴ Application of the doctrine is regarded as an exception rather than a rule.⁷⁵ The doctrine prevents the alleged infringer from avoiding liability by changing only minor or insubstantial details of the claimed invention while still retaining functionality.⁷⁶

D. Federal Circuit Review of District Court Findings

In order to preserve clarity and continuity in jurisprudence, the Federal Circuit adheres to specific standards of review over the decisions of its lower tribunals.⁷⁷ The Federal Circuit was established in 1982 to establish nationwide uniformity in the application and administration of patent laws.⁷⁸ The Federal Circuit, pursuant to

72. MILLS III, *supra* note 69, at §18:49.

73. MILLS III, *supra* note 69, at § 18:49; *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929); *Molinaro v. Hart Electronics Corp. of Scranton*, 209 U.S.P.Q. (BNA) 735, 738 (M.D. Pa) (citing Patent Law Fundamentals).

74. MILLS III, *supra* note 69, at §18:49; *Uniroyal, Inc. Rudkin-Wiley Corp.*, 939 F.2d 1540 (Fed. Cir. 1991).

75. MILLS III, *supra* note 69, at §18:49; *Extrel FTMS, Inc. v. Bruker Instruments, Inc.*, 954 F.2d 734 (Fed. Cir. 1992).

76. MILLS III, *supra* note 69, at §18:49; *Sage Prods, Inc. v. Devon Indus., Inc.*, 126 F.3d 1420 (Fed. Cir. 1997).

77. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) (citing *CCS Fitness, Inc. v Brunswick Corp.*, 288 F.3d 1359, 1365 (Fed. Cir. 2002)).

78. Lawrence M. Sung, *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*, 48 AM. U. L. REV. 1233, 1236 (1999) (citing S. Rep. No. 275, at 2 (1981), reprinted in 1982 U.S.C.C.A.N. 11, 12 (describing the legislative rationale for establishing the Federal Circuit by the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25, 37 (codified as amended at 28 U.S.C. § 1295 (2003))). The Federal Circuit’s predecessor was the CCPA, which had jurisdiction under essentially the same provisions.

statute,⁷⁹ has jurisdiction to hear appeals “arising under patent law in a district court.”⁸⁰ “Original appellate court jurisdiction is conferred by 35 U.S.C. § 141 (patents) and 15 U.S.C. § 1071(a) (trademarks).”⁸¹ The Federal Circuit was created in an effort to provide uniformity in patent law interpretation leading to a greater predictability in the outcome of patent cases.⁸² This, in turn, would increase confidence in the patent system and thereby “enhance willingness to make the business and economic investments that lie at the heart of the patent system’s abilities to spur innovation, to enhance technical growth, and to contribute to our nation’s industrial strength.”⁸³ Where the Federal Circuit is reviewing a district court judgment in a patent case, Federal Circuit law is applied to patent law issues, including procedural issues, but “the law of the circuit in which the district court sits” is applied to non-patent issues.⁸⁴

The Federal Circuit has authorized and encouraged the liberal use of summary judgment rulings to dispose of patent claims at the district court level.⁸⁵ The Federal Circuit’s reviews those decisions *de novo*.⁸⁶ Issues of law, including issues involving claim

79. See 28 U.S.C. § 1296(a)(1) (2003).

80. Thomas G. Field, Jr., *Direct Judicial Review of PTO Decisions: Jurisdictional Proposals*, 42 IDEA 537, 539 (2002).

81. *Id.* at 539. See also 28 U.S.C. § 1295(a)(4)(A) & (B) (2003). Jurisdiction is not exclusive, however; see 35 U.S.C. § 146 (2003) and 15 U.S.C. § 1071(b) (2003). Kenneth R. Adamo, Gregory A. Castanias, Mark N. Reiter & Lawrence D. Rosenberg, *Survey of the Federal Circuit’s Patent Law Decisions in 2000: Y2K in Review*, 50 AM. U. L. REV. 1435, 1441 (2001) (quoting *U.S. Valves, Inc. v. Dray*, 212 F.3d 1368, 1372 (Fed. Cir. 2000)).

82. Mark T. Banner, *Is Markman Right?* 7(3) THE ABA SECT. OF INTELLECTUAL PROP. L., CHAIR’S BULLETIN 1 (November 2002).

83. *Id.*

84. Adamo, *supra* note 81, at 1457 (quoting *Midwest Indust., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999) (en banc)).

85. Adamo, *supra* note 81, at 1441.

86. See *Vanmoor v. Wal-Mart Stores*, 201 F.3d 1363, 1365 (Fed. Cir. 2000) (citing *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1425 (Fed. Cir. 1996)); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1353 (Fed. Cir. 1998); *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 255 (1986). Review of district court determinations by the Federal Circuit is for clear error in patent claims of anticipation. *Ecolochem, Inc. v. S. Cal. Edison*, 227 F.3d 1361, 1367 (Fed. Cir. 2000) (citing *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984)).

construction⁸⁷ and enablement⁸⁸ determined at the district court are also reviewed *de novo*. In contrast, “[c]ompliance with the written description requirement is essentially a fact-based inquiry that will ‘necessarily vary depending on the nature of the invention claimed.’”⁸⁹ This fact-sensitive inquiry is thus reviewed for clear error on appeal.⁹⁰ Infringement errors determined by the trial court are also reviewed for clear error.⁹¹

Despite the Federal Circuit’s genesis as a court of technology and innovation, the majority of judges on the Federal Circuit do not have technical backgrounds, especially in the area of biotechnology.⁹² This begs the question: Why were they chosen specially to hear these types of cases?

Other authors have explored uncertainty regarding the credibility of judicial determinations at the Federal Circuit.⁹³ Particularly, Dr. Sung’s article addresses the difficulty of finding justice in patent law decisions made by the “Federal Circuit in the face of apparent misapplications, or seemingly intentional ignorance, of otherwise accepted scientific or engineering principles.”⁹⁴ Further, that “patent law treats science apart from innovation, but embraces both as important concerns to implement the social policy of fostering technological progress.”⁹⁵ The court has made attempts at closing this information gap. The modern development of rapidly advancing

87. *Cybor Corp. v. FAS Tech., Inc.*, 138 F.3d 1448, 1455 (Fed. Cir. 1998) (en banc) (characterizing claim construction as an issue of law).

88. *Bruning v. Hirose*, 161 F.3d 681, 686 (Fed. Cir. 1998) (describing enablement as an issue of law).

89. *Enzo Biochem v. Gen-Probe, Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002) (citation omitted).

90. *Purdue Pharma L. P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citations omitted).

91. *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1363 (Fed. Cir. 2000).

92. Rai, *supra* note 26, at 838 (noting that only Judges Gajarsa, Lourie, and Newman have an undergraduate or advanced degree in a natural science). *See generally* Almanac of the Federal Judiciary, Federal Circuit (available on Westlaw, 2003) (providing biographical information on Federal Circuit judges including their education).

93. Sung, *supra* note 78 at, 1238.

94. *Id.*

95. *Id.* at 1242.

technologies such as biotechnology and software has led the Federal Circuit to make extra efforts to provide detailed primers on relevant technical matters.⁹⁶ Additionally, some judges on the Federal Circuit employ clerks with technical backgrounds who are able to lend scientific expertise to their opinions. These actions, however, have not been enough for the Federal Circuit to keep up to date with rising technologies. Further, the Circuit has had to deal with district court rulings that are ambiguous and thus difficult to analyze at the appellate level.

In 2000, the Federal Circuit addressed the need for clear district court rulings in two instances.⁹⁷ In *Markman v. Westview Instruments, Inc.*⁹⁸ the Federal Circuit provided clear guidance to the district courts about the significance of evidence regarding the interpretation and meaning of claim terms.⁹⁹ The court also affirmed its precedent in considering relevant patent related documents for proper claim interpretation.¹⁰⁰ This “intrinsic” evidence includes both the patent itself (the specification and the claims) and the prosecution history (the record of proceedings before the PTO).¹⁰¹ 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

96. *Id.* at 1242 (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1203 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (explaining the technical background for a patent describing a method for producing erythropoietin)); *In re O'Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988) (needing a technical explanation of an invention in genetic engineering)).

97. *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000) (reversing the district court's grant of judgment as a matter of law on claims of non-infringement because the district court did not adequately justify its ruling); *Cultor Corp. v. A.E. Staley Manufacturing Co.*, 224 F.3d 1328 (Fed. Cir. 2000) (affirming the district court's denial without explanation of Cultor's motion to amend complaint because of the futility of the requested relief further indicating that full explanation by the district court is required).

98. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd* 517 U.S. 370 (1996) (determining the meaning of “inventory” as the main issue in a case alleging infringement of a patent for an automated inventory system for monitoring articles of clothing for commercial laundry and dry cleaning).

99. *Markman*, 52 F.3d at 979-83.

100. *Id.* at 979-80.

101. *Id.* at 980.

invention.¹⁰² The Circuit emphasized that extrinsic evidence is not to be used to clarify ambiguity in claim language or to vary or contradict the meaning of claim terms, but to assist in the court's understanding of the patent.¹⁰³

Generally, the Federal Circuit's review of legal conclusions of the Board of Patent Appeals and Interferences, the PTOs appellate tribunal, is "without formal deference."¹⁰⁴ Findings of fact made by the Board, however, are reviewed under the "substantial evidence" standard.¹⁰⁵ Whether a patent specification adequately describes the subject matter claims is a question of fact.¹⁰⁶ This allows the Board to apply its technical expertise with assurance that deference will be afforded to that determination in analyzing the actual "science" of the innovation. In order to properly review the Board's rulings, the Federal Circuit must have "a clear understanding of the grounds for the decision being reviewed."¹⁰⁷

II. SCIENCE PRIMER

In order to appreciate recent decisions by the Federal Circuit regarding biotechnology issues it is important to understand the basic science underlying the innovations at issue. Since 1953 it has been understood that the biological code for life was made up of a double helix strand of four repeating nucleotides, adenosine, guanine, cytosine, and thymine, known as DNA (deoxyribonucleic acid).¹⁰⁸ There are approximately 6 billion pairs of subunits of DNA in one

102. *Id.* at 980; Sung, *supra* note 78, at 1260.

103. Markman, 52 F.3d at 980; Sung, *supra* note 78, at 1260.

104. *In re Baker Hughes*, 215 F.3d 1297, 1300 (Fed. Cir. 2000) (citing 5 U.S.C. § 706 (2003)).

105. *Id.* at 1371 (quoting *In re Gartside* 203 F.3d 1305, 1315 (Fed. Cir. 2000)).

106. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

107. *In re Hyatt*, 211 F.3d 1367, 1371 (Fed. Cir. 2000) (quoting *Gechter v. Davison*, 116 F.3d 1454 (Fed. Cir. 1997) (explaining that the "central thrust of *Gechter*" is that the Patent Board must explain sufficiently its rulings in order to facilitate a meaningful judicial review)).

108. DANIEL J. FAIRBANKS & W. RALPH ANDERSEN, *GENETICS; THE CONTINUITY OF LIFE*, 25-26 (Thomas Learning 1999).

human cell.¹⁰⁹ A gene is a subunit of DNA that encodes a protein. All enzymes are made of protein, and those enzymes are responsible for driving human physiology. The process of obtaining the information from a sequence of DNA gene to make its protein is called transcription. This process is triggered through cellular machinery attaching to the DNA sequence located just before, or “upstream” from the start of the gene called the promoter.

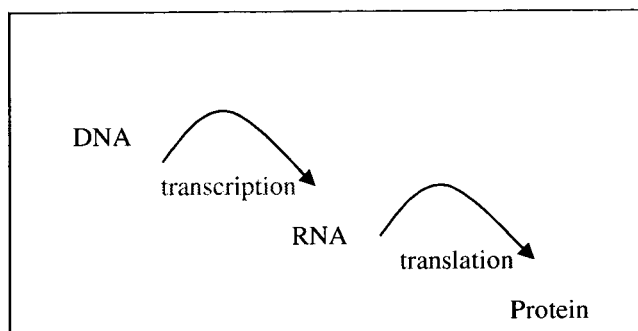


Figure 1: The process of transcription and translation

After the gene is activated, the DNA nucleotides of the gene are read by cellular machinery (RNA polymerase) and transcribed into mRNA (messenger ribonucleic acid) whose components are similar to DNA and contain guanine, adenosine, cytosine, and uracil rather than thymine. RNA is also distinguished from DNA by its sugar chemistry. The RNA sequence is less stable than DNA, and is read by other cellular machinery (ribosomes) in the process of translation to make an amino acid sequence that can fold into the functional protein (See Figure 2).¹¹⁰

109. *Id.* at 26.

110. Figure 2 is available at <http://www.engineering.ucsb.edu/~trevorc/images/tech/translation.jpg>.

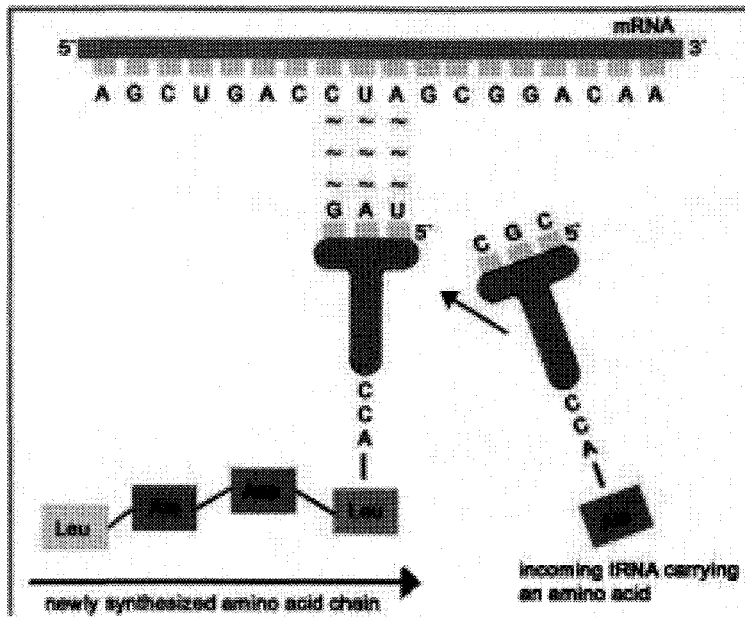


Figure 2: the process of transcription

In a bacterial cell, the initiation of translation occurs when the ribosomes read the mRNA and find the Shine-Dalgarno sequence (AGGAGG) followed by the three nucleotide sequence that encodes for the first amino acid, methionine (ATG).¹¹¹ During translation, cellular machinery continues to read the RNA sequence three nucleotides (one codon) at a time. Each set of three nucleotides encodes for one amino acid. This code is “degenerate” meaning that one amino acid may be translated by more than one codon.¹¹² Consequently, the mRNA, and therefore DNA, sequence cannot be deciphered by mere knowledge of the amino acid sequence. After translation is complete an amino acid sequence is produced and, once properly folded, will make the functional protein.

Biotechnologists have been able to decipher the genetic code and manipulate fast-growing organisms that allow the production of target proteins in mass quantities. Bacteria are often the organism of choice where scientists can insert the DNA gene and allow the

111. FAIRBANKS, *supra* note 108, at 108.

112. *Id.* at 91. If there were one amino acid per codon there would be 43 possibilities, or 64 different amino acids, however there are in fact only 20.

bacteria to go through the process of making the protein at a fast rate and in high quantities. Scientists are able to fine tune the production of a protein by inserting additional information either before or after the gene that allows production of the protein to begin after a triggering event, or allow control over the rate of production. Perhaps the most well known application of this process is that of producing insulin as a therapeutic remedy for patients with diabetes.¹¹³

This technology is discussed and analyzed in both cases discussed below. In *Genentech Inc. v. Amgen, Inc.*, Amgen's process of making a drug protein, called Neupogen® is "grown" by this method in bacterial cells.¹¹⁴ The dispute in that case arises over the DNA sequence that is before the gene that drives transcription, and consequently the production of protein.¹¹⁵ In *Amgen, Inc. v. Hoescht Marion Roussell, Inc.*, Amgen sued for infringement and Hoescht is attacking Amgen's patents concerning the process and product that produces Amgen's drug, Epogen®.¹¹⁶ Similar to Neupogen®, Epogen® is also "grown" in a cell system, but instead of bacteria, scientists have used mammalian cells¹¹⁷ to make a functional drug that will stimulate red blood cell production. In that case, Hoescht was able to make the same drug product called Dynepo™, but through a different process and Amgen sued for infringement of its

113. *Id.* at 92.

114. *Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761 (Fed. Cir. 2002). In 2001, Neupogen® had \$1.3 million in sales. *Genentech-Amgen Battle Back On*, CHEMICAL WK., PHARMACEUTICALS & FINE CHEMICALS 30, May 8, 2002, at 30.

115. *Genentech, Inc.*, 289 F.3d at 764.

116. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d. 1313 (Fed. Cir. 2003).

117. Amgen uses CHO, Chinese hamster ovary, cells in its production of Epogen®. *Id.* at 1321. Both Neupogen® and Epogen® are "blockbuster" drugs. The definition of "blockbuster" varies. One author has stated that a blockbuster drug is one that is expected to achieve annual sales of at least \$750 million by 2007. Ken Welsby, *Big Pharma Companies Play Game of Patents in Quest for Blockbuster*, BUSINESS A.M. (April 26, 2002). Another author defines "blockbuster" as those drugs that generate \$1 billion in sales per year. *Blockbuster Drugs Becoming Bigger Sources of Pharmaceutical Industry Profits*, NationsBanc Montgomery Securities Analyst Tells Investors, BUSINESS WIRE, September 23, 1998.

patents because the end product is the same.¹¹⁸ Additionally, the drug, Epogen®, has the same function as the endogenous hormone, erythropoiten, except in the drug the hormone is glycosolated. Glycosylation is where a carbohydrate (or sugar) is added to an amino acid in the protein. These are brief explanations, meant to serve only as a terse primer of what will be elaborated upon, in detail, below to illustrate the complexities of the science involved in biotechnological patents.

III. CASE STUDIES

A. *What is in a name? Interpretation of complex claim terminology: Genentech, Inc. v. Amgen, Inc.*¹¹⁹

Genentech, Inc. (“Genentech”) brought suit against Amgen, Inc. (“Amgen”) in 1996 for infringement on patents describing the use of a recombinant cloning vehicle that enables a unicellular organism¹²⁰ host to make large amounts of protein.¹²¹ Genentech’s patent issue lies in the construction of that vehicle, known as a plasmid, involved the use of the regulatory region, including the Shine-Dalgarno sequence and start-site, derived from the bacteriophage lamda.¹²² Those cloning techniques were used by Amgen to create the drug,

118. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1323 (Fed. Cir. 2003).

119. *Genentech, Inc.*, 289 F.3d 761.

120. In this case *E. coli*, the same organism found in the human gut, is the organism that is used to make the protein at issue. *Id.* *E. coli* is a very common choice for these types of applications. ALBERTS, *supra* note 4, at 417-20.

121. Denise Gellene, *Court Revives Genentech Lawsuit Against Amgen*, LOS ANGELES TIMES, April 30, 2002, at 5(3), available at 2002 WL 2472126. See generally *Genentech, Inc.*, 289 F.3d 761.

122. *Genentech, Inc.*, 289 F.3d at 766-67. Amgen’s plasmid’s regulatory region contains seventy-two base pairs which are identical to that contained in the bacteriophage lamda. *Id.* Note, a bacteriophage is “any virus that infects bacteria.” ALBERTS, *supra* note 4, at G-2. The bacteriophage lamda is commonly known in molecular biology as a cloning vector, or a means to insert DNA into a host organism, such as *E. coli*. *Id.*

Neupogen®, a protein that accelerates the replication of human white blood cells.¹²³

The district court found no literal infringement where it interpreted “determined that a ‘control region’ . . . must come from a single operon, and that a ‘ribosome binding site’ encompasses the S-D [Shine-Dalgarno] sequence, the start site as well as the linker base-pairs.”¹²⁴ The district court was affirmed in its decision to disallow Genentech from asserting infringement under the doctrine of equivalents as it was not alleged in the complaint.¹²⁵ However, the Federal Circuit determined that the district court had relied on an “erroneous claim construction in granting Amgen’s motion for summary judgment.”¹²⁶ The Federal Circuit vacated the district court’s summary judgment verdict that Amgen had not infringed on various patents held by Genentech.¹²⁷ This discussion focuses primarily on the portion of that opinion discussing the discrepancies in interpretation of claims having to do with the definition of the “control region” of the DNA.

The Federal Circuit properly reviewed the claim construction issue *de novo*.¹²⁸ The court stated that U.S. District Court Judge Alsup’s dismissal of the suit was “based on a faulty interpretation of terms used in the patents.”¹²⁹ The disputed terms describe the “control region” of the genes contained within the bacterial cells, which initiate the production of the human protein contained therein.¹³⁰ District Court Judge Smith, Judge Alsup’s predecessor in this case, interpreted the relevant terms in the claims of the patents at issue in his claim construction order given in May of 1999.¹³¹ After

123. Genentech, *Inc.*, 289 F.3d at 767. The production of Neupogen® is from the transcription and translation of the gene for met-hGCSF. *Id.* at 766 (citing Original Summary Judgment Order at 2).

124. *Id.* at 767.

125. *Id.*

126. *Id.* at 764.

127. *Id.*

128. *See* Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc).

129. Gellene, *supra* note 121, at C5.

130. Genentech, Inc. v. Amgen, Inc., 289 F.3d 761, 764 (Fed. Cir. 2002). *See* discussion of science primer, *supra* Sec. II, for further explanation.

131. Genentech, *Inc.*, 289 F.3d at 765-66.

Judge Smith issued this opinion, the case was transferred to Judge Alsup.¹³² Judge Alsup determined that it was improper for the district court to include linker DNA contained between the Shine-Dalgarno sequence and the start codon (ATG) as part of the “ribosome binding site.”¹³³ On review, the Federal Circuit concluded that the term “ribosome binding site” is properly defined as a “DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome and is thus necessary and sufficient to initiate translation.”¹³⁴ The Federal Circuit’s conclusion was similar to the interpretation of “ribosome binding site” asserted by Judge Smith, which ultimately was not accepted by Judge Alsup in his determination of the case at the district court level.¹³⁵ This discrepancy resulted in genuine issue as to whether the linker DNA was *necessary* to initiate translation, requiring the Federal Circuit to affirm in part,¹³⁶ vacate in part, and remand the district court’s determination.¹³⁷

The Federal Circuit agreed with Judge Smith’s finding that “DNA [comprising the control region] may be ‘taken from’ the listed sources: it may be physically obtained, cloned, partially chemically synthesized or totally chemically synthesized.”¹³⁸ These determinations were in contrast to the conclusions drawn by Judge Alsup who stated that “where the term ‘ribosome binding site’ reduced to the Shine-Dalgarno sequence and the start codon ATG, it would be impossible to determine whether a ribosome binding site was derived from the same operon¹³⁹ as the promoter¹⁴⁰ and the

132. *Id.*

133. *Id.* at 769-70.

134. *Id.* at 770 (quoting *Genentech, Inc. v. Amgen, Inc.*, No. C 96-3752 FMS, slip op. (N.D.Cal. May 17, 1999) (*Order*)).

135. *Id.* at 767.

136. The court affirmed those portions of the district court’s decision to bar the assertion of theory of infringement under to doctrine of equivalents as it was not alleged by Genentech. *Id.* at 774.

137. *Id.*

138. *Id.* at 770 (quoting *Genentech, Inc. v. Amgen, Inc.*, No. C 96-3752 FMS, slip op. 37-38 (N.D.Cal. May 17, 1999) (*Order*, at 50)).

139. An operon, as discussed in the Genentech case, is a cluster of genes that are transcribed as a single mRNA, but make separate proteins. FAIRBANKS, *supra* note 108, at 218.

operator,¹⁴¹ a requirement of the term ‘control region.’”¹⁴² Essentially, Judge Alsup determined that the control region possesses control elements that correspond to only one operon.¹⁴³ This interpretation prompted his conclusion that Amgen’s ribosome binding site DNA was not physically “taken from” the bacteriophage lambda and thus was not an infringement on Genentech’s patents.¹⁴⁴

On review, the Federal Circuit agreed with Genentech’s argument that Judge Alsup misinterpreted

the meaning of the claim term “control region” by requiring “(1) that the method used to construct the control region use only one operon, and (2) that to prove this single operon source requirement was satisfied, the sequence of each control element must correspond to a control element found in one, *and only one*, operon.”¹⁴⁵

The Federal Circuit continued to state that, this interpretation does not preserve the distinction between the sequence of the control

140. A promoter is defined as a sequence of DNA upstream (located before) from the sequence encoding the target protein where the RNA polymerase will bind. Genentech, Inc., 289 F.3d at 765.

141. An operator is a sequence of DNA located upstream from the encoding DNA sequence for the target protein, which controls transcription, and therefore protein expression. Genentech, Inc., 289 F.3d at 765.

142. *Id.* at 770 (quoting Genentech, Inc. v. Amgen, Inc., No. C 96-03752 WHA, slip op. (N.D.Cal. Aug. 28, 2000) (*Amended Summary Judgment Order* at 14)).

143. *Id.*

144. *Id.* at 770-71 (citing Genentech, Inc. v. Amgen, Inc., No. C 96-03752 WHA, slip op. (N.D.Cal. Aug. 28, 2000) (*Amended Summary Judgment Order* at 14)). Genentech’s patented plasmid is derived from the bacteriophage lambda. *Id.* at 766-67. The sequence in that plasmid that is contained between the Shine-Dalgarno sequence and the start codon is comprised of ten base pairs, “AATCCAGATG.” *Id.* at 767. In contrast, the sequence in Amgen’s plasmid is different in content and in number with thirteen base pairs, “GTAATAAATAATG.” *Id.* Thus, if the court determined that this linker sequence is essential, because Amgen’s sequence is *different*, there would not be infringement.

145. *Id.* at 771.

region and the method by which the control region is constructed.¹⁴⁶ Federal Circuit Judge Rader observed in a footnote that this confusion arises from the original claim construction's requirement that the control region "be taken from a single operon."¹⁴⁷ Judge Rader stated that "the method by which the control region is constructed and the sources from which it is derived are inapposite, thus negating any requirement that such methods or sources be discernable from the sequence of the control elements."¹⁴⁸ The Federal Circuit ultimately held that

the asserted claims require at least a promoter, operator, and a ribosome binding site that when transcribed into mRNA, is bound by the ribosome and is necessary and sufficient for the initiation of translation. The promoter, operator and ribosome binding site must correspond to the promoter, operator and ribosome binding site found in a single operon; the sources and methods used to construct the control region are irrelevant.¹⁴⁹

In summary, the Federal Circuit derived a very different interpretation to a essential term in the patent than the district court Judge. In essence, Genentech's claim of infringement rests, in part, on whether the court determines if thirteen base pairs that reside between the Shine-Dalgarno sequence and the start codon of Amgen's plasmid, are essential to drive cellular machinery to make Neupogen®.¹⁵⁰ This discrepancy prompted the Circuit court to vacate and remand this portion of the decision for further proceedings.¹⁵¹ The inherent complexity of this issue presents a formidable task to the court on remand. *Genentech, Inc. v. Amgen, Inc.* exemplifies the discontinuity of claim interpretation between the district court and the Federal Circuit

146. *Id.*

147. *Id.* at 771 n.4 (citation omitted). This terminology indicates that parts of the operon (or collection of genes) that are ultimately used in the bacterial cell may be derived from different origins such as different organisms or from synthesized methods.

148. *Id.* at 772.

149. *Id.*

150. *Id.* at 766-67.

151. *Id.* at 774.

and the importance of scientific knowledge in making such determinations in patent litigation.

*B. Process or Product? Amgen, Inc. v. Hoechst Marion Rousell, Inc. and Transkaryotic Therapies, Inc.*¹⁵²

Amgen's debut into the biotechnology industry began with its development and subsequent introduction of the blockbuster therapeutic erythropoietin, or Epogen® as it is commonly known. This product is a naturally occurring hormone that controls the formation of red blood cells in the bone marrow.¹⁵³ Amgen's drug product, Epogen®, has been very successful in the treatment of patients, like kidney dialysis patients, needing red blood cells that carry oxygen. Hoechst Marion Rousell, Inc. and Transkaryotic Therapies, Inc. (collectively known as "TKT") sought to develop a separate process for the production of Epogen® to create a commercially competitive product, Dynepo™. Amgen filed a declaratory judgment action in April of 1997 for infringement on various Amgen patents by TKT's Investigational New Drug Application ("INDA").¹⁵⁴ The court held a three day *Markman* hearing at which point the case was tried over the course of four months.¹⁵⁵ At the District Court for the District of Massachusetts, Judge Young granted judgment in part for Amgen, and in part for TKT.¹⁵⁶ The district court held that

(1) scope of asserted claims could not be limited to expression of exogenous DNA; (2) patent satisfied enablement requirement; (3) claims were product

152. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003). This case is now known as *Aventis Pharmaceuticals, Inc.*

153. ALBERTS, *supra* note 4, at 1169-70.

154. *Hoechst Marion Roussel, Inc.*, 314 F.3d at 1319.

155. A *Markman* hearing is held in the absence of a jury where the judge determines the scope of the claims in the patent for issues of infringement and validity. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd* 517 U.S. 370 (1996). Often these hearings will end a case where there is a narrow interpretation of the claims held within the patent.

156. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69 (D. Mass. 2001).

claims, not product by process claims; (4) alleged infringer could challenge only adequacy of disclosure of vertebrate or mammalian host cell, not human DNA itself; and (5) lack of description of, or limitation directed to, expression vector itself did not render invention inoperable.¹⁵⁷

TKT appealed urging that the Amgen's patents were unenforceable, that the district court's claim construction was erroneous, and even if the claim construction was correct, that the validity determinations were incorrect.¹⁵⁸ Amgen cross appealed asserting that the district court was wrong in comparing the process to the "examples in the specification rather than the limitations of the method claims" of the patents and in holding another patent invalid because it did not comply with 35 U.S.C. § 112, paragraph 1.¹⁵⁹ The Federal Circuit affirmed in part, vacated in part, and remanded.

In Judge Michel's opinion, the district court was commended for their thorough and precise work on what is termed a "legally difficult and technologically complex case."¹⁶⁰ Although reversal rates on claim construction issues has been reported at 33%¹⁶¹ and even at 47%,¹⁶² the Federal Circuit affirmed the district court in total on this matter.¹⁶³ Judge Michel also affirmed much of the district court's other rulings.¹⁶⁴ However, a number of determinations were vacated because the district court misapplied the law, and were consequently remanded to the district court to consider:

157. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003); *see Amgen*, 126 F. Supp. 2d 69.

158. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1320 (Fed. Cir. 2003).

159. *Id.* at 1320.

160. *Id.*

161. Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J.L. & TECH. 1, 3 (2001), *reprinted* in 12 FED. CIR. B. J. 1 (2002). Further, where district courts were reversed on claim construction, the Federal Circuit either reversed or remanded the decision 81% of the time. *Id.*

162. Victoria Slind-Flor, *The Markman Prophecies*, IP WORLDWIDE, March 13, 2002.

163. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1319.

164. *Id.*

(i) whether the '080, '349, and '422 patents are obvious in light of the Sugimoto prior art or anticipated or obvious in light of the Goldwasser prior art; (ii) whether the '422 patent is anticipated by Sugimoto reference (and whether Amgen can prove its nonenableness); (iii) whether the asserted claims of the '698 patent and '349 patent claim 7 are infringed by the accused method; and (iii) [sic] whether the '080 patent is infringed under the doctrine of equivalents.¹⁶⁵

Judge Michel vacated the district court's finding of no infringement because Amgen did not meet its burden by simply showing that "GA-EPO has glycosylation which differs from but one of the many heterogeneous urinary EPOs."¹⁶⁶ The district court recognized that this claim construction presented a "conundrum" to those in the art wishing to practice the invention, a requirement for a valid patent.¹⁶⁷ The Federal Circuit subsequently stated that understanding this "conundrum" should have ended the inquiry, because this type of ambiguity in claim scope is "at the heart of the definiteness requirement of 35 U.S.C. § 112, para 2" and that the patent was invalid.¹⁶⁸ Therefore, the judgment was vacated.

The Federal Circuit also vacated the district court's finding that an amendment to one of Amgen's patents was made to avoid a double patenting rejection.¹⁶⁹ This argument rested on the premise that the amendment qualified under the doctrine of equivalents.¹⁷⁰ Judge Michel stated that the Supreme Court's decision in *Festo* states that while there is no absolute bar to the doctrine of equivalents that "a narrowing amendment to satisfy any requirement of the Patent Act

165. *Id.* at 1319-20.

166. *Id.* at 1341 (quoting Amgen, 126 F. Supp. 2d at 129).

167. *Id.* at 1342.

168. *Id.* at 1342.

169. *Id.* at 1345 (citing Amgen, 126 F. Supp. 2d at 135).

170. *Id.*

may give rise to an estoppel.”¹⁷¹ Thus, this determination was vacated and remanded for analysis under the rule set forth in *Festo*.¹⁷²

Most interestingly, the district court analyzed infringement of Amgen’s patent by interpreting the phrase “operatively linked” in one of the claims of an Amgen patent.¹⁷³ According to that court, the phrase related to the relationship between the promoter DNA and the DNA transcribed downstream from the promoter DNA.¹⁷⁴ Amgen asserted that the phrase means “positioned such that it provides for initiation of transcription of a gene.”¹⁷⁵ TKT contended that “operatively linked” meant positioned adjacent “to the DNA encoding EPO in a way that maintains the capability to initiate transcription of EPO DNA.”¹⁷⁶ These definitions differ in that Amgen’s definition imposes no spatial restriction, and TKTs definition limited the location of the promoter as immediately adjacent to the gene encoding EPO.¹⁷⁷ The district court adopted the definition proffered by TKT and granted summary judgment of non-infringement.¹⁷⁸ On appeal, Amgen contended that this conclusion was not in accordance with law because the differences outlined above were considered “dispositive by the district court . . . [and were] not claimed and thus gave no bearing on proper infringement analysis.”¹⁷⁹ Amgen further argued that the court did not identify any limitation of the patent that the process failed to meet and did not explain why, if it did so by other equivalent means.¹⁸⁰ For this reason the issue was vacated.

The district court went the furthest astray in their analysis of the process claims at issue. Judge Michel notes that the court properly recognized the law to be followed in process claims, but after

171. *Id.* at 1345 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki*, 535 U.S. 722 (2002)) (internal quotation marks omitted).

172. *Id.*

173. *Id.* at 1346.

174. *Id.*

175. *Id.* (internal quotation marks omitted).

176. *Id.* (internal quotation marks omitted).

177. *Id.*

178. *Id.* (citing Amgen, 126 F. Supp. 2d at 90).

179. *Id.*

180. *Id.*

discussing the differences between process and infringement analysis, the court “eschewed the cardinal principle that the accused device must be compared to the claims rather than to a preferred commercial embodiment.”¹⁸¹ The court found that there was a fundamental distinction between the processes of Amgen and TKT in that TKT employs homologous rather than heterologous recombination, and Amgen “transfects”¹⁸² [CHO]¹⁸³ cells with a vector¹⁸⁴ that contains both viral promoter DNA and the human EPO gene.”¹⁸⁵ In recognizing the distinction, the district court missed the point that none of the claims at issue contained such a limitation.¹⁸⁶ Similarly, the Federal Circuit pointed out that the district court “found material the fact that TKT places its promoter and enhancer farther upstream than does Amgen.”¹⁸⁷ This assertion does not address the process, but the claim itself. Thus, the Federal Circuit found legal error in that the infringement analysis was not tied to the asserted claims. This issue was also vacated so that a proper infringement inquiry could be done.

In addition, the Federal Circuit vacated and remanded determinations by the district court having to do with “prior art” asserted by TKT to prove that Amgen’s patents were invalid because at the time they were filed the inventions were either obvious, or not novel.¹⁸⁸

Judge Clevenger filed a dissenting opinion stating that the claims lacked meaningful limitations on the structure of the erythropoietin-producing cells that the district court in looking at whether the claims met the requirements of enablement and written description

181. *Id.* at 1347 (citing Amgen, 126 F. Supp. 2d at 102).

182. Transfection is the process of getting the DNA into the cell of choice.

183. “CHO” is an acronym for Chinese Hamster Ovary cells. This cell line is frequently used in these types of processes.

184. A vector is a piece of DNA that is constructed so that it can go through the cell membrane and to the nucleus where it will be able to transcribe the functional gene.

185. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d at 1347 (Fed. Cir. 2003) (citing Amgen, 126 F. Supp. 2d at 102).

186. *Id.*

187. *Id.*

188. *Id.* at 1356.

provisions of 35 U.S.C. § 112, para. 1.¹⁸⁹ The dissent also expressed its disagreement in the majority's finding that the district court's application of the written description requirement was proper as expressed in *Regents of the University of California v. Eli Lilly & Co.*,¹⁹⁰ and *Gentry Gallery, Inc. v. Berkline Corp.*¹⁹¹

Like *Genentech, Inc. v. Amgen, Inc.* the district court in this case struggled with claim interpretation where background knowledge of the biological processes at issue was integral to making a just decision. Similarly, on appeal the Federal Circuit interpreted those claims differently than the district court mandating that the judgment be vacated and remanded for further proceedings. Determinations such as these undercut confidence in the courts. The result is that parties with similar claims must appeal decisions from the district court level, thereby incurring additional costs in order to assure a definite judgment.

IV. PROPOSAL

There is a challenge, as illustrated by *Genentech* and *Hoechst*, to help tribunals understand the content of patent claims so that decision-makers can ensure fair judgments through proper claim interpretation. Modifications to the way these types of inventions are analyzed in the district court and in the Federal Circuit will ensure that once a patent is granted, the owner can rest assured that the rights conferred to him will not be stripped due to faulty interpretation of the science behind his innovation. There are many alternatives to meeting this challenge.

Perhaps the simplest remedy would be to give more deference to determinations made in the PTO during examination and hearings before the Board of Patent Appeals and Interferences. This could be limited to those decisions that require the interpretation of the technology presented in the invention. As discussed above, the PTO has already implemented regulations requiring scientific expertise

189. *Id.* at 1358-59.

190. *Regents of the Univ. of Cal. V. Eli Lilly Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

191. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998).

and legal understanding by their adjudicators.¹⁹² Granting a heightened degree of deference to this agency would alleviate the burden placed on courts in learning the technologies presented on appeal and would allow those courts to focus on legal issues within their expertise.

Another relatively straightforward way to remedy this problem would be to modify drafting techniques so that they are written in plain English rather than legalese.¹⁹³ This trend has already had a positive effect in the field of life insurance policy drafting and interpretation.¹⁹⁴ The caveat to this suggestion is, of course, that in the drafting of patent documents a certain amount of scientific jargon is necessary to convey the invention accurately to the PTO and to members in the scientific community wishing to replicate or practice the invention. However, coupled with other suggestions, such as requiring technical clerks, or technical backgrounds from judges, changes in patent drafting could remedy the complex nature of patent language.

As suggested by Mark T. Banner, the chair of the ABA section of intellectual property, special procedures for treating claim construction litigation could be created either formally by statute or informally through judicial practice.¹⁹⁵ These new procedures could be mirrored after those adopted by the U.S. District Court for the Northern District of California.¹⁹⁶ That district has a very readable list of procedures, on their website, which are followed in patent proceedings on their website.¹⁹⁷ Specifically, in claim construction proceedings parties are ordered to meet and confer at various stages

192. See *supra* section I, notes 27-30.

193. S. Jay Plager, *Challenges for Intellectual Property Law in the Twenty-First Century: Indeterminacy and Other Problems*, 2001 U. ILL. L. REV. 69, 72 (2001) (suggesting that patent drafting follow the example of life insurance policies).

194. *Id.*

195. Mark T. Banner, *Is Markman Right?* 7(3) THE ABA SECT. OF INTELLECTUAL PROP. L., CHAIR'S BULLETIN 1, 2 (November 2002).

196.

[http://www.cand.uscourts.gov/cand/LocalRul.nsf/fec20e529a5572f0882569b6006607e0/4735a1c69bd18b418825695f00730cdd/\\$FILE/Pat1200-1.pdf](http://www.cand.uscourts.gov/cand/LocalRul.nsf/fec20e529a5572f0882569b6006607e0/4735a1c69bd18b418825695f00730cdd/$FILE/Pat1200-1.pdf) (last visited February 13, 2003)).

197. *Id.*

of litigation. They are further required to file a “Joint Claim Construction and Prehearing Statement” which contains, among many other things, that the parties state all “terms, phrases, or clauses” on which the parties agree and disagree.¹⁹⁸ Parties are also mandated to submit a wealth of references and extrinsic evidence supporting their interpretation of the claims at issue.¹⁹⁹ This type of standing order allows for predictability for both the parties and the adjudicator. Similar orders in other districts, and perhaps at the appellate level, would allow the courts to have a more precise procedure to follow when dealing with these types of claims. A more specific template of procedure to follow may narrow the issues that need to be determined by the court, and ease the burden of gaining an understanding of underlying technologies in claim interpretation issues.

It has also been suggested that juries be prohibited from hearing claim construction issues in order to attain more predictable and consistent results at the district court level.²⁰⁰ One Federal Circuit judge has noted that trial court determinations on infringement issues are often decided on summary judgment, making the judge’s decision the “best shot at claim construction and the parties’ agreement to appeal the decision rather than go through a lengthy trial process and get told years later by the [Federal Circuit] that the claim construction was wrong.”²⁰¹ This suggestion supports the current trend in moving away from jury findings as exemplified in *Markman v. Westview Instruments, Inc.*²⁰² In *Markman*, the Federal Circuit determined that it was for the judge to determine the scope of the claims at issue in patent litigation.²⁰³

Mr. Banner has also suggested formalizing the use of special technical masters for claim construction issues in either an advisory capacity to the court on technical questions, or to render advisory

198. *Id.* at § 4-3.

199. *Id.*

200. Plager, *supra*, note 193, at 72.

201. *Id.*

202. *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff’d* 517 U.S. 370 (1996) (holding that interpretation of language set forth in the claim is an issue for the judge rather than the jury).

203. *Id.*

opinions.²⁰⁴ This action would allow adjudicators immediate access to specialists capable of understanding the complexities of the patents at issue and who would be able to convey these technicalities in an understandable form. Some judges on the Federal Circuit currently employ these types of specialists in their chambers. Formalizing this process ensures preservation of the fairness within the court system by not conveying either a pro- or anti- patent stance. The placement of experts may also increase the integrity and perception of those scholars selected to serve as technical masters.

The legislature could also designate a specialized court, similar to that used for welfare recipients, that employs adjudicators with appropriate scientific and legal backgrounds that would allow them to make decisions efficiently. This alternative might be more appealing than having special technical masters, as an adjudicator would be in the best position to evaluate, in an unbiased manner, claim construction, technical matters, and experts. Equipped with the proper underlying knowledge of what the science of the innovation is, rather than relying on someone else to distinguish those scientific important scientific facts, would ensure a proper marriage between the science and the law in litigation.

Additionally, a background component could be required of a minimal percentage of judges on the Federal Circuit who hear cases having to do with complex issues such as biotechnology. This would guarantee, like the suggestion above, that scientific issues would be heard through a singular entity who understands the technology and who can apply the appropriate law in the case at hand. Arguably, requiring *all* judges to have the requisite scientific understanding would be unnecessary and cumbersome, disregarding the problem of availability of appropriate candidates. One of the judges could be reasonably charged with the responsibility of teaching the background technical information to the other judges on the case. Like other suggestions, this allows the adjudicator to weigh the importance of all evidence, technical or not, and apply the law in an appropriate manner.

Each of these suggestions, taken separately or in concert, would significantly increase confidence in determining issues of infringement and validity of inventions in the biotechnology field.

204. Banner, *supra* note 195, at 2.

Appreciation for the complexity of the advancements in technology dictates change in the system that protects those innovations. It is imperative that our legislature and judiciary give them serious consideration in formulating a better system.

V. CONCLUSION

Amgen and *Hoescht* illustrate the difficulty in determining patent issues where the subject matter includes complex biological processes. In both cases, district court judges looked at issues necessitating interpretation of biotechnical claims and made determinations requiring an understanding of the science underlying the invention. These interpretations were not correct when reviewed by the Federal Circuit who vacated and remanded those portions of the decisions in both cases. Although neither case was vacated in its entirety, it is evident that confidence in district court determinations requiring an interpretation of scientific cases is waning. Further, it is too much to expect the district courts, with their already crowded dockets, to dedicate an appropriate amount of time to gain a proper understanding of the scientific issues underlying patent claims. This deficiency may motivate parties to continue litigation beyond the district court, incurring more expenses, in order to assure an accurate determination.²⁰⁵ If decisions in patent cases continue to fall short of acknowledging public appreciation of technology or established legal paradigms, the patent system will erode.²⁰⁶

Identifying this deficiency at the district court level is not a novel concept. Other articles have addressed the diminished ability of the

205. In 1996 it was reported that the average cost of patent litigation was \$500,000. John J. O'Malley, *Insurance Protects Intellectual Property; Company's Most Important Asset Often Overlooked on Daily Basis*, THE LEGAL INTELLIGENCER, March 11, 1996 at S14. This amount has undoubtedly increased, as evidenced by Amgen's recent arbitrated settlement with Johnson & Johnson, where that company was ordered to pay \$150 million to Amgen, which included costs and attorney's fees. *Other News to Note*, 18(14) BIOWORLD TODAY, January 28, 2003.

206. Lawrence M. Sung, *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*, 48 AM. U. L. REV. 1233, 1236 (1999) (citing Paul R. Michel, *The Challenge Ahead: Increasing Predictability in the Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1245 (1994)).

district courts to handle these complex issues. Specifically, regarding the doctrine of equivalents, which states that something that is essentially the equivalent of something else cannot be patented, the district court has been scrutinized in its inability to deal with the evaluation of science.²⁰⁷

Problems in adjudicating patent issues do not stop at the district court level, but continue to the Federal Circuit. The communication between these two tribunals must become more consistent so that patent owners can maintain confidence in the system that protects their inventions to ensure the healthy progression of technologies.²⁰⁸ The Supreme Court has recognized this need in *Pfaff v. Wells Electronics Inc.*, where the Court established a new test for the on-sale bar to patentability under 35 U.S.C. § 102(b).²⁰⁹ In effect, this test allows the court to concentrate on relevant non-technical evidence rather than the technical and scientific aspects of the invention.²¹⁰ *Pfaff* does not encompass all issues in patent litigation requiring an interpretation of scientific issues. Consequently, the decision does not obliterate the need for adjudicators to have a means of understanding the technologies underlying litigation as demonstrated in *Genentech*, and *Hoechst*.

Although the suggestions above are proposed in the context of biotechnological patents, they are also relevant to other rapidly advancing technologies such as telecommunications, the internet, and nanotechnology. Advancements in technology and the scope of scientific ideologies employed in those technologies are too vast for one group of persons to understand and to adjudicate. The suggestions above do not undercut the value of the court system in

207. *Id.* at 1253 (citing *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)).

208. In 2000, the Federal Circuit reversed all three decisions of lower courts on the issue of priority in interference decisions. Kenneth R. Adamo, Gregory A. Castanias, Mark N. Reiter, and Lawrence D. Rosenberg, *Survey of the Federal Circuit's Patent Law Decisions in 2000: Y2K in Review*, 50 AM. U. L. REV. 1435, 1441 (2001) (citing *Genentech, Inc. v. Chiron Corp.*, 220 F.3d 1345, 1354 (Fed. Cir. 2000); *Singh v. Brake* 222 F.3d 1362 (Fed. Cir. 2000); *Eaton v. Evans*, 204 F.3d 1394 (Fed. Cir. 2000)).

209. *Pfaff v. Wells Electronics Inc.*, 525 U.S. 55 (1998), *aff'd* 124 F.3d 1429 (Fed. Cir. 1997); *Sung supra* note 78, at 1253.

210. *Id.* at 62.

determining these issues, but merely enhance what was begun nearly three decades ago with the establishment of the Federal Circuit. Rather than maintaining the status quo, the court and legislature, like the scientific community, should embrace continued improvement. Confidence in the judicial system through the protection of new inventions fosters motivation and enthusiasm in the science and promotes continued progress. It is necessary for our judicial system to respond to these changes to ensure that the validity of the patent system remains intact, thus fostering new innovation.