
**Resolving Uncertainty in Biotechnology Patent Law: Foreword
to the Second Annual Journal of High Technology Law
Symposium**

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On November 18, 2005, Suffolk University Law School's Advanced Legal Studies program presented a conference entitled: "*Safe Harbour/Experimental Use, Inherency, Obviousness, and Utility: Resolving Uncertainty in Biotechnology Patent Law.*" The conference was co-sponsored by the Intellectual Property Law Concentration at Suffolk University Law School, the Boston Patent Law Association, Hamilton, Brook, Smith & Reynolds, P.C., and the *Journal of High Technology Law* (JHTL). The conference brought together distinguished patent attorneys, corporate counsel for biotechnology companies, and officials from the United States Patent and Trademark Office in Alexandria, Virginia.

As advisors to the JHTL and Directors of the Intellectual Property Law Concentration at Suffolk University Law School, we are pleased to introduce the Second Annual JHTL Symposium issue. The articles in this issue, first presented at the above conference, are doctrinal, policy-driven, and reform-minded. Together, they offer insightful commentary on recent Supreme Court and Federal Circuit decisions that affect both the patentability and the scope of protection afforded biotechnology innovations.

The title of the symposium issue reflects the dilemmas faced by the biotechnology industry in light of unclear messages from the federal judiciary. The articles focus on important biotechnology patent law issues such as the statutory safe harbor exemption, common law experimental use, utility, written description, nonobviousness and anticipation. This introduction will briefly review the four articles comprising this Symposium issue.

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**“In re Dane K. Fisher: An Exercise in Utility,” by N. Scott
Pierce**

As America enters the new millennium, the future of biotechnology patent law remains in doubt because recent Federal Circuit decisions do not appropriately balance the rights of inventors against the needs for scientific innovation. Pursuant to the Patent Act³ an invention must satisfy the novelty, utility, and nonobviousness requirements to receive patent protection.⁴ The role of the United States Patent and Trademark Office (PTO) patent examiner is to determine whether a patent application fulfills these requirements. In the field of biotechnology patents, unlike other areas of technology, utility is often a difficult issue.

N. Scott Pierce, a partner at Hamilton, Brook, Smith & Reynolds P.C. in Concord, Massachusetts and an adjunct professor of law in the Intellectual Property Law Concentration at Suffolk University Law School, authored a monograph length study of the concept of utility in the wake of the recent Federal Circuit decision in *In re Dane K. Fisher and Raghunath V. Lalgudi*.⁵ The Court “denied patentability to expressed sequence tags (ESTs)”⁶ because they were “only tools to be used along the way in the search for a practical utility” and therefore lacked “an immediate real world benefit”⁷ which is a requirement for a finding of substantial utility.⁸ Pierce contends that *In re Dane K. Fisher and Raghunath V. Lalgudi* misconstrues the utility concept. Worse yet, the Federal Circuit’s decision threatens the long-term viability of the biotechnology industry by blocking “the patentability of many inventions, the benefit of which may be immediate but not fully appreciated until much later.”⁹

Part I of Pierce’s article is a magisterial historical study of the utility concept tracing the path of the law from the Patent Act of 1793 to 2005 cases. He cites the bellwether decision by Circuit Justice

3. 35 U.S.C. §§1-376 (2005) (codification of 1952 Patent Act).

4. 35 U.S.C. §§101-103, 112 (2005).

5. 421 F.3d 1365 (Fed. Cir. 2005).

6. “An EST is a short sequence of nucleotides. Knowing the chemical identity of the genetic tags is an important first step to allow researchers to monitor gene changes and other actions in the plant.” Brenda Sandburg and Pamela A. Maclean, “Scores of Biotech Patent Cases Likely to Be Tossed,” Palm Beach (Fla.) Daily Business Review, Sept. 21, 2005 at 226 (available on LEXIS/NEXIS CURNWS library).

7. *Id.* (discussing *In re Dane K. Fisher and Ragnunath V. Lalgudi*).

8. N. Scott Pierce, *In Re Dane K. Fisher: An Exercise in Utility*, 6 J. HIGH TECH L. 1, 1 (2006).

9. *Id.*

Joseph Story in *Bedford v. Hunt, et. al.*¹⁰ which defined utility to mean that an invention only be “capable of use,” and not contrary to “sound morals and policy,” to satisfy Section 1 of the Patent Act of 1793. Next, he examines other Justice Story opinions construing the statutory interpretation of utility.¹¹ Nineteenth century opinions concurred in whole with Justice Story’s circumscribed view of utility.¹²

Pierce next demonstrates that English common law interpretations of utility were consistent with Justice Story’s perspective.¹³ He provides sure-footed historical and doctrinal evidence that the historical meaning of utility drawn from early jurisprudence is at odds with the Federal Circuit’s recent reconceptualization of utility. Pierce’s article next completes a content analysis of Patent Law treatises of the late nineteenth century. His unequivocal conclusion is that that the Anglo-American concept of “new” was equated with “comparative and relative utility,”¹⁴ at odds with recent Federal Circuit jurisprudence.

Early twentieth century cases occasionally considered the concept of “utility” to be separate and distinct from “suitability for an intended use.”¹⁵ Later, the only requirement for utility was an “assertion of utility and an indication of the use or uses intended.”¹⁶ Pierce cites several examples of Federal Court decisions which reversed the PTO’s “rejection of claims on the basis of lack of utility in view of the presence of only broad statements of use in the specification.”¹⁷ Pierce notes how the Supreme Court was widely perceived to have held broadly that being the “subject of scientific research was an inadequate basis in support of ‘utility.’”¹⁸ He adds that Justice Harlan suggested “that the fact that a product may be the subject of research may indeed be a sufficient utility.”¹⁹

Pierce next reexamines Chief Judge Rich’s dissenting opinion in two cases where the Supreme Court’s *Brenner* opinion was applied.²⁰ In Judge Rich’s view *Brenner* was limited to its narrow holding and

10. *Id.* at 4 (citing *Bedford*, 3 F. Cas. at 37).

11. *Id.* at 5 (discussing *Lowell v. Lewis and Kneass v. Schulykill Bank*).

12. Pierce, *Fisher*, at 5-9

13. *Id.* at 11-12.

14. *Id.* at 13.

15. *Id.* at 16.

16. *Application of Brenner*, 182 F. 2d 216 (C.C.P.A. 1950).

17. Pierce, *Fisher*, at 20.

18. *Id.* at 34 (discussing *Brenner v. Manson*).

19. *Id.* at 38.

20. *Id.* at 41-42.

did not reverse the prior path of the law.²¹ Judge Rich deconstructed the Court's argument that utility was part of a larger social contract, "the *quid pro quo* for obtaining a patent monopoly."²² Pierce lays out the significance of Judge Rich's analysis of the purpose of the utility requirement. According to Judge Rich, the stakes were no less than pushing back the frontiers of chemistry by making compounds available to the world.²³ Pierce completes his historical survey by tracing late twentieth century federal circuit court opinions interpreting utility. Pierce contends that the Federal Circuit's recent jurisprudence is likely to stymie the development of science.²⁴

Part II of Pierce's article is a superb doctrinal deconstruction of Judge Michel's opinion. He concludes that the basis for the court's holding is inconsistent with both statutory and case law developments since the 1790s. He states that the court's constrained view of utility "threatens patentability of a wide variety of inventions."²⁵ Pierce makes a convincing case for the Federal Circuit to revisit the Patent Act as well as subsequent case law developments to reverse course when it comes to utility. This article raises important ideas which can help facilitate a reevaluation of the utility requirement by legislators, jurists, practitioners, and academics.

"Merck KGaA v. Integra: More Answers Than Questions?" by Ken Burchfiel

In the wake of recent Supreme Court and Federal Circuit decisions there is great uncertainty regarding the continued vitality of previously well-established patent law doctrines. Kenneth J. Burchfiel, a partner in the Washington D.C. law firm of Sughrue, Mion, PLLC and author of a treatise on biotechnology patent law,²⁶ examines the recent Supreme Court decision in *Merck KGaA v. Integra Lifesciences*.²⁷ Merck KGaA reinterpreted the statutory infringement exemption in §271(e) (1), which has long been subject to "vacillating pronouncements" by the Federal Circuit.²⁸ He notes how the Supreme Court decision reverses course by rejecting the

21. *Id.* at 43.

22. Pierce, *Fisher*, at 45.

23. *Id.* at 46.

24. *Id.* at 52-53.

25. *Id.* at 78.

26. Burchfiel, Ken, "Biotechnology and the Federal Circuit." (BNA Books (1995).

27. 125 S.Ct. 2372 (2005).

28. Ken Burchfiel, "Merck KGaA v. Integra: More Answers Than Questions?" 6 J. HIGH TECH. L. 79, 79 (2006).

Federal Circuit's constrained interpretation of the exemption²⁹ in its "holding that the exemption includes information reasonably related to the development of information submitted for approval of a new drug, as well as a generic equivalent."³⁰ Burchfiel next discusses the implications of the divergent interpretations of the statutory exemption, 35 U.S.C. §271(e) (1).³¹

Burchfiel explains how the conceptual gap between Federal Circuit opinions about the reach of the statutory safe harbor exemption and the Supreme Court's more expansive interpretation creates uncertainty about the continuing vitality of the court-constructed doctrine of "temporal" limitation.³² He describes Judge Rader's concept of temporal limitation as a bifurcated model in which "research tools would be exempt from an infringement claim after a threshold event in the chain occurs such as New Drug Applications."³³ Under Judge Rader's model, any use of patented invention prior to the threshold event would not be protected by the statutory safe harbor.³⁴ Burchfiel notes how Judge Newman was skeptical about this false dichotomy, predicting that the constrained view of the exemption would "create a 'limbo' of infringing activity between initial experimentation protected by a common-law research exemption, and the subsequent filing of a New Drug Application."³⁵

Burchfiel observes that the Supreme Court failed to address the dilemma of "research tool" patents identified as a problem by the Federal Circuit.³⁶ He examines how the Supreme Court squarely rejected the temporal threshold model proposed by the Federal Circuit,³⁷ and contends that the Supreme Court's construction of the safe harbor was "tailored to the specific facts at issue."³⁸ He identifies a number of other unanswered questions such as whether the "subject matter 'penumbra' of the Supreme Court's chemical compound safe harbor exempts use of compounds that are essential intermediates for producing drug candidate compounds or methods that are used for synthesizing drug candidate compounds."³⁹

29. *Id.* at 80-86.

30. *Id.* at 79-80.

31. *Id.* at 80

32. *Id.*

33. Burchfiel, *Merck*, at 80-81.

34. *Id.* at 81.

35. *Id.* (quoting Newman's dissenting opinion in the appellate decision of *Integra*).

36. *Id.*

37. *Id.* at 81.

38. Burchfiel, *Merck*, at 82.

39. *Id.*

Burchfiel argues that the Supreme Court has imploded the “definite threshold event in the drug development or FDA approval process at which the statutory exemption arises.”⁴⁰ He notes that the issue is complicated by the Court’s view that no bright line may be drawn as to the reach of the statutory safe harbor based upon the stage of regulatory approval.⁴¹ He reads the Court opinion as signaling that “at least some uses of patented compounds which later become the subject of new drug applications” may be outside the safe harbor.⁴² However, he interprets preclinical studies using patented compounds as protected by the exemption.⁴³

Burchfiel predicts that future decisions must determine how far the exemption applies “down the chain of experimentation.”⁴⁴ Future decisions must also determine whether specific intent to develop a particular drug will exempt “random experimentation with patented compounds.”⁴⁵ The final part of his article looks at the undecided question of whether “experimental use or the common law research exception applies to the screening and testing of drug candidate compounds prior to developing and submitting material to the FDA.”⁴⁶ Burchfiel concludes that the Federal Circuit’s concept of “research tools” is in urgent need of clarification, contending that the research tool exception will constrain basic research, blocking new scientific developments.⁴⁷

**“The Experimental Use Exception: Looking Towards a
Legislative Alternative,”
by Denise W. DeFranco, Carla Miriam Levy and Miriam L.
Pogach**

This policy-based article sheds light on the contours of the experimental use exception, proposing a legislative solution. Denise W. DeFranco and Carla Miriam Levy of Boston’s Foley, Hoag is joined in this article by Miriam L. Pogach of the Boston law firm of Lowrie, Lando and Anastasi LLP. The authors begin with a cogent explanation of the basic concept that one who uses a patented invention without permission is deemed a patent infringer.⁴⁸

40. *Id.* at 86.

41. *Id.*

42. *Id.*

43. Burchfiel, *Merck* at 86.

44. *Id.* at 87.

45. *Id.* at 88.

46. *Id.* at 90.

47. Burchfiel, *Merck*, at 90

48. Denise W. DeFranco, et. al., “The Experimental Use Exception: Looking

DeFranco and her co-authors next explain that the common-law experimental exception immunizes the use of a “patented invention where the use was motivated by an experimental purpose.”⁴⁹

Part I of this article examines the doctrinal development of the experimental use exception proposing a policy-driven alternative. It begins with a discussion of the emblematic case of *Embrex v. Service Engineering Corp.*,⁵⁰ which made it crystal clear that the experimental use exception did not include commercial use.⁵¹ Next, the authors examine *Madley v. Duke University*,⁵² another Federal Circuit case, which held that use at an academic institution was not protected by the exemption when related to legitimate business interests.⁵³ According to the authors, *Madley* stands for the proposition that university research pursued with commercial goals in mind are not shielded by the exception.⁵⁴

The authors next argue that the effect of these decisions is to substantially cut back on the experimental use exception. DeFranco and her collaborators contend that these decisions “render almost any use of a patented invention for testing or designing around infringing,” unless there is no causal connection to a legitimate business purpose.⁵⁵ The experimental use exception and the statutory exemption under §271(e) (1) are examined through the lens of the Federal Circuit decision in *Roche*⁵⁶ and the U.S. Supreme Court’s *Integra* decision.⁵⁷ The authors describe the *Roche* court’s holding that the “use of a patented invention to collect information for compliance with the FDA approval process for generic drugs” as outside the scope of the exemption.⁵⁸ Congress rejected this narrow interpretation of the exemption when it enacted the Hatch-Waxman Act.⁵⁹ This Act broadly exempts from infringement “uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”⁶⁰ The authors next demonstrate how the Court’s *Integra Lifesciences* decision casts further doubt on the

Towards a Legislative Alternative,” 6 J. HIGH TECH. L. 93, 94 (2006).

49. *Id.* at 94.

50. 216 F.3d 1343 (Fed. Cir. 2000).

51. *Id.* at 95-96.

52. 307 F.3d 1351 (Fed. Cir. 2002).

53. DeFranco, “The Experimental Use Exception,” *Id.* at 96.

54. *Id.* at 98.

55. *Id.* at 97.

56. *Id.* at 100.

57. *Id.* at 102.

58. DeFranco, *The Experimental Use Exception*, at 99-100.

59. *Id.* at 101.

60. *Id.* (quoting amended 35 U.S.C. §271(e)(1)).

Federal Circuit's overly conservative interpretation of the experimental exception.⁶¹ The authors conclude that a legislative solution is needed to broaden the experimental use exception.⁶²

Any legislative solution needs to properly balance the realities of research against patent rights.⁶³ The authors argue that the Federal Circuit's judicially created experimental use exception "should be abandoned,"⁶⁴ drawing upon the work of Rebecca Eisenberg in arguing for a legislative solution that strikes the appropriate balance between science and intellectual property rights.⁶⁵ DeFranco and her colleagues propose a principled legislative solution to experimental use that will clarify and improve patent law. At present, the experimental use exception is of minimal value because of the chilling impact of potential patent infringement claims.⁶⁶

"Looking at Federal Circuit Developments 2005: The Year in Review," by Michael R. Dzwonczyk

In the final article, Michael R. Dzwonczyk, a partner at Sughrue Mion, PLLC, reviewed Federal Circuit decisions during the 2005 term. Dzwonczyk begins his comprehensive roundup of cases with a detailed study of how the Federal Circuit is revivifying the extraterritorial effect of United States patent law. Under the extraterritoriality doctrine, infringing actions taking place entirely outside the United States are not actionable under United States patent law.⁶⁷ He closely examines *Eolas Technologies, Inc. v. Microsoft Corp.*,⁶⁸ describing the case as an "extraordinary extension of patent law §271(f) to capture foreign sales."⁶⁹ Next, he describes the famous Blackberry case, which also raises the limits of the extraterritoriality doctrine.⁷⁰

Part II of the article examines the Federal Circuit's interpretation of claim construction in the wake of *Phillips*.⁷¹ Dzwonczyk describes the post-*Phillips* period as one of relative stability where the Court

61. *Id.* at 102-105.

62. *Id.* at 105.

63. DeFranco, *The Experimental Use Exception*,

64. *Id.* at 106.

65. *Id.* at 107.

66. *Id.* at 111.

67. See, e.g., *Subafilms, Ltd. V. MGM-Pathe Communications Co.*, 24 F.3d 1088 (9th Cir. 1999) (en banc).

68. 399 F.3d 1325 (Fed. Cir. 2005) (Rader, J.).

69. Michael R. Dzwonczyk, "Looking at Federal Circuit Developments 2005: The Year in Review," 6 *J. High Tech L.* 113, 115 (2006).

70. *Id.* at 116.

71. *Id.* at 119.

has been responsive to various stakeholders such as the patent bar.⁷² However, the field of claim construction is a placid island in a sea of uncertainty when it comes to Federal Circuit decisions in 2005.

His 2005 survey next examines the doctrine of inequitable conduct, which has “fallen in and out of favor with the Federal Circuit almost since the creation of the court in 1982.”⁷³ Decisions demonstrating the continuing vitality of the doctrine marked 2005.⁷⁴

Dzwonczyk’s roundup of Federal Circuit cases finally examines decisions interpreting “intent to deceive” in patent applications⁷⁵ and enablement decisions.⁷⁶ Court decisions throughout 2005 have revealed an uncertain state of the law with regard to infringement under patent law §271(f), but greater clarity when it comes to claim construction.⁷⁷ This survey provides useful guideposts to the evolving jurisprudence of the Federal Circuit.

Conclusion

The contributions in the Second Annual Symposium issue will be of great interest to a larger audience of legal practitioners, scientists, scholars, licensing officers, industry leaders, legal academics, and jurists who could not attend the conference at Suffolk University Law School. Each of the articles sheds light on important doctrinal, policy, and reform-minded issues that will determine the future path of the biotechnology industry. The publication of this superb volume signals the growing reputation of the JHTL as a journal that presents cutting-edge scholarship to the legal academy, policymakers, and practitioners.

Professors Andrew Beckerman-Rodau and Michael L. Rustad.

72. *Id.* at 122.

73. *Id.*

74. Dzwonczyk, *Looking at Federal Circuit Developments*, at 123.

75. *Id.* at 124-26.

76. *Id.* at 126-27.

77. *Id.* at 128.