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Nimalka Wickramasekera

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PUBLIC USE OR EXPERIMENTAL USE: ARE CLINICAL TRIALS SUSCEPTIBLE TO ANOTHER ATTACK SIMILAR TO THAT IN *SMITHKLINE BEECHAM CORP. V. APOTEX CORP.*?

NIMALKA WICKRAMASEKERA*

“The Holy Grail of chemical composition of matter claims is often something like: ‘Crystalline paroxetine hydrochloride hemihydrate.’”¹

INTRODUCTION

In what may appear, at first glance, to be a ground breaking decision, the United States Court of Appeals for the Federal Circuit² (“the Federal

* J.D. Candidate, May 2006, The John Marshall Law School. For their constant support, the author would like to thank her parents, Ursula and Hemasiri Wickramasekera, her brothers, Duminda and Ananda Wickramasekera, her sister-in-law, Ramani Damera, and her nephew and niece, Sohan and Sonali Wickramasekera. The author would also like to thank the members and board of The John Marshall Law Review for their editorial assistance, especially Manish Mehta. Last, but not least, the author would like to give a special thanks to her husband, Adam Storer, for his limitless patience and constant support.

1. Ivor R. Elrifi & Nicholas P. Triano, III, *The Paxil Case: Composition of Matter Claims, Polymorphs and ‘Follow-on’ Patents*, 9 INTELL. PROP. STRATEGIST 3 (2003) (reciting independent Claim 1 of U.S. Patent No. 4,721,723 (filed Oct. 23, 1986) (issued January 26, 1988), the active ingredient in GlaxoSmithKline’s blockbuster anti-depressant drug Paxil®).

2. The federal district courts have original and exclusive jurisdiction over civil actions arising under any act of Congress relating to patents. 28 U.S.C. § 1338 (2000). In 1982, Congress created the United States Court of Appeals for the Federal Circuit pursuant to the Federal Courts Improvement Act of 1982. 32 AM. JUR. 2D *Federal Courts* § 603 (2004). The Court of Appeals for the Federal Circuit has exclusive appellate jurisdiction over all federal district court cases relating to patents, regardless of the circuits in which the district courts are located. 28 U.S.C. § 1295 (2000). The Court of Appeals for the Federal Circuit was a consolidation of its two predecessor courts, the United States Court of Claims and the United States Court of Customs and Appeals. 32 AM. JUR. 2D *Federal Courts* § 603. The Court of Claims and the Court of Customs and Appeals were merged into a single Court of Appeals. Daniel J. Meador, *United States Court of Appeals for the Federal Circuit Tenth Anniversary Commemorative Issue: Article: Origin of the Federal Circuit: A Personal Account*, 41 AM. U.L. REV. 581, 620 (1992). This, in effect, allowed the Federal Circuit to promote “procedural efficiency, judicial structure, and heightened coherence in [patent] law.” *Id.* The Court of Appeals for the Federal Circuit adopted as binding precedent the holdings of its predecessor courts. *South Corp. v. United States*, 690 F.2d 1368, 1369-71 (Fed. Cir. 1982). The Federal Circuit has nationwide jurisdiction over appeals involving patents and is headquartered in Washington, D.C., but may hold sessions where any Court of Appeals may sit. 32 AM. JUR. 2D *Federal Courts* § 603.

Circuit”) held in *SmithKline Beecham Corp. v. Apotex Corp.*³ that a patent claim to paroxetine hydrochloride hemihydrate,⁴ the active ingredient of GlaxoSmithKline’s antidepressant drug Paxil®,⁵ was invalid under the 35 U.S.C. § 102(b) public use bar.⁶ The Federal Circuit initially found the patent claim invalid because the clinical trials conducted to test the drug constituted public use within the meaning of the statute.⁷ This decision sparked concern in the intellectual property community,⁸ and produced headlines such as, “Tests to Establish Safety of Drug Bar Patentability.”⁹

One commentator expressed concern over the adverse effects of the decision on brand name pharmaceutical manufacturers and their ability to develop new drugs.¹⁰ She urged the legislature and the courts to handle the

3. *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1317-18 (Fed. Cir. 2004), *vacated as to issue of experimental use by* 403 F.3d 1328 (Fed. Cir. 2005), *superseded by* 403 F.3d 1331 (Fed. Cir. 2005) (invalidating patent claim as inherently anticipated under 35 U.S.C. § 102(b)).

4. The claim at issue, independent claim 1 of the ‘723 patent, entitled Anti-Depressant Crystalline Paroxetine Hydrochloride Hemihydrate, recites, in its entirety, “Crystalline paroxetine hydrochloride hemihydrate.” *Id.*

5. Paxil.com, An Introduction to Paxil®, http://www.paxil.com/about/nw_int.html (last visited Nov. 1, 2004).

6. 35 U.S.C. § 102 (2000) (“A person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . . .”).

7. *SmithKline Beecham Corp.*, 365 F.3d at 1318. The court first defined the *invention* in Claim 1 as the bare paroxetine hydrochloride hemihydrate compound because the patent recited only the compound name without any further language regarding its efficacy, commercial value, or pharmaceutical value. *Id.* The court then held that the clinical trials designed to test the safety and efficacy of the compound as an antidepressant for FDA approval cannot constitute experimental use because the pharmaceutical benefits of the drug as an antidepressant were not features of the *claimed invention*. *Id.* See discussion *infra* Part IV § 1 (stating that experimental use must pertain to the invention claimed).

8. Susan K. Knoll & Michelle Replogle, *Prior Art Under 35 U.S.C. Section 102 (a) and (b)*, 793 P.L.I./PAT 9, 13 (2004). “[A] patent claim to a drug compound was invalid under the § 102(b) public use bar when the patentee conducted clinical trials on the safety and efficacy of the drug more than one year before to [sic] the filing of [f] the patent.” *Id.* Furthermore, “[i]n the present case, the critical date for the 102(b) bar is Oct. 23, 1985, leaving the question of whether the clinical trials beginning in May 1985 qualify as experimental use.” *Appellate Panel Issues Ruling On Experimental Use Negation, Claim Clock*, 12-15 MEALEY’S LITIG. REP. INTELL. PROP. 11 (2004).

9. Kathlyn Card-Beckles, *Tests to Establish Safety of Drug Bar Patentability*, 10 INTELL. PROP. STRATEGIST 7 (2004).

10. Teresa O. Bittenbender & John W. Ryan, *Recent Developments in Pharmaceutical Patent Litigation*, 16 J. PROPRIETARY RTS. 5, 7 (2004).

In *SmithKline Beecham Corp. v. Apotex Corp.*, the Federal Circuit held that a patent claiming the active ingredient of the antidepressant Paxil was infringed by the generic drug maker Apotex by very small amounts of the claimed compound but that clinical trials required for FDA approval conducted prior to filing the patent application barred SmithKline from patent protection. Because the patent claim was directed to the compound itself as opposed to its commercial embodiments, the clinical trials on patients could not be considered experimental use. When a claim is directed to a compound and does not recite use of the compound, the experimental use doctrine terminates when the compound is synthesized. Put another way, in

intellectual property rights of the pharmaceutical industry with the same regard afforded to other technologies, and called for a halt to holding the pharmaceutical industry to a "much higher standard" in patent protection.¹¹

To obtain a United States patent, an inventor must file a patent application¹² within one year after placing the invention in public use in the United States.¹³ This requirement, commonly known as the public use bar,¹⁴ serves several public interests: It encourages the inventor to assert his or her rights promptly to protect the public from being deprived of new inventions;¹⁵ prevents the inventor from extending his or her monopoly beyond the statutorily prescribed period;¹⁶ and discourages the inventor from removing inventions from the public domain.¹⁷

To balance the scales between the rights of the public, which include the rights of inventors,¹⁸ American jurisprudence created the experimental

order to fall within the experimental use doctrine, the experimentation must be on a claimed element. This decision conflicts with numerous decisions of the Federal Circuit and limits the ability to experiment with a chemical compound before filing a patent application. This holding is likely to give pause to name brand manufacturers on how or where to conduct clinical trials on newly developed drugs, while still maintain protection of their intellectual property.

Id.

11. *Id.*

12. The critical date with respect to patent law is the date on which the patent application was filed. *See generally* 60 AM. JUR. 2D *Patents* §§ 262, 263 (2004) (explaining the importance of when the patent was filed in determining the validity of the patent). From this date forward, no use can be held against the inventor as constituting public use within the meaning of 35 U.S.C. § 102(b) (2000).

13. 35 U.S.C. § 102.

14. 35 U.S.C. § 102(b) embodies both the public use and the on sale bars to patentability. *See generally* Timothy R. Holbrook, *The More Things Change, The More They Stay The Same: Implications of Pfaff v. Wells Electronics, Inc. and the Quest for Predictability in the On-Sale Bar*, 15 BERKELEY TECH. L.J. 933 (2000) (offering helpful background regarding the on-sale bar).

15. Kurtis A. Kemper, Annotation, *When is Public Use of Invention, More Than One Year Before Patent Application, for Experimental Purposes, so That 35 U.S.C.A § 102(b) Does Not Prevent Issuance of Valid Patent*, 171 A.L.R. FED. 39 (2004). *See also* RCA Corp. v. Data Gen. Corp., 887 F.2d 1056, 1062 (Fed. Cir. 1989) (proposing that one policy behind the public bar is to disclose new inventions to the public).

16. Kemper, *supra* note 15; RCA Corp., 887 F.2d at 1062.

17. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550 (Fed. Cir. 1990) (citation omitted); *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1574 (Fed. Cir. 1995); Kemper, *supra* note 15, at 39.

18. *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984).

The general purpose behind all the [§ 102(b)] bars is to require inventors to assert with due diligence their right to a patent through the prompt filing . . . of a patent application. . . . In contrast to these considerations, the public interest is also deemed to be served by allowing an inventor time to perfect his invention, by public testing, if desired, and prepare a patent application.

Id. (citations omitted). *See generally* *Tone Bros., Inc., v. Sysco Corp.*, 28 F.3d 1192, 1198 (Fed. Cir. 1994) (listing underlying policies that define the public use bar as (1) discouraging removal of inventions the public reasonably believes are in the public domain; (2) encouraging prompt disclosure of inventions by the inventor; (3) allowing the inventor a reasonable amount of time to determine whether a patent has economic value; and (4) prohibiting the inventor from extending the monopoly conferred by the statute

use doctrine.¹⁹ This doctrine promotes the public interest by providing the inventor an opportunity to perfect the invention.²⁰ Use by the inventor²¹ that falls under the rubric of experimental use is not public use²² within the meaning of § 102(b),²³ and therefore, does not start the clock on the public use bar.²⁴

The main issue raised by the Federal Circuit decision in *SmithKline Beecham Corp.*²⁵ was whether clinical trials may constitute public use. Without discussing its reasons, the Federal Circuit, sitting *en banc*, subsequently vacated the portion of this decision regarding the issue of experimental use.²⁶ On remand, the Federal Circuit panel replaced the vacated decision with a new one invalidating the same patent claim for a different reason, inherent anticipation.²⁷ The issue of whether clinical trials may constitute public use, therefore, remains alive. This Comment will explore the reasoning behind the prior *SmithKline Beecham Corp.*²⁸ decision. As this Comment will discuss, *SmithKline Beecham Corp.*²⁹ did not stand for the sweeping proposition that clinical trials designed to test the safety and

through commercial exploitation of the invention); *Baxter Int'l, Inc. v. Cobe Labs., Inc.*, 88 F.3d 1054, 1058 (Fed. Cir. 1996); *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1119 (Fed. Cir. 1996).

19. William C. Rooklidge & Stephen C. Jensen, *Common Sense, Simplicity and Experimental Use Negation of the Public Use and On Sale Bars to Patentability*, 29 J. MARSHALL L. REV. 1, 8-10 (1995); see also Kemper, *supra* note 15, at 39 (discussing the implementation and function of the experimental use doctrine).

20. *TP Labs., Inc.*, 724 F.2d at 968.

21. The experimental use doctrine to which this Comment pertains is use by the inventor. Another experimental use doctrine pertains to use by an accused infringer. Shashank Upadhye, *To Use or Not to Use: Reforming Patent Infringement, the Public Use Bar, and the Experimental Use Doctrine as Applied to Clinical Testing of Pharmaceutical and Medical Device Inventions*, 4 MINN. INTELL. PROP. REV. 1, 11 (2002) [hereinafter *Reforming Patent Infringement*]. With scientific inventions, an accused infringer will often be a not-for-profit organization, such as a university, or a generic drug manufacturer. See generally Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271 (e): The Collisions Between Patent, Medical Device, and Drug Laws*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1 (2000) [hereinafter *Understanding Patent Infringement*]. Accused infringers often raise the defense that *their* conduct, and not that of the inventor, constituted experimental use and is thus non-infringing. *Id.*

22. It is worth mentioning that an accused patent infringer will raise public use by the inventor as a defense to infringement. Kemper, *supra* note 15, at 39. Public use is brought up during litigation to invalidate the patent, and thereby excuse the accused infringer. One commentator has described the public use bar as the "last refuge of the desperate infringer." Rooklidge, *supra* note 19, at 46.

23. 35 U.S.C. § 102. See generally *Reforming Patent Infringement*, *supra* note 21 (discussing the distinction between experimental use and public use by the inventor).

24. 35 U.S.C. § 102 has a one year time period from when the time the invention was offered for public use to file a patent application. *Reforming Patent Infringement*, *supra* note 21, at 4.

25. 365 F.3d 1306 (Fed. Cir. 2004).

26. 403 F.3d 1328, 1329 (Fed. Cir. 2005).

27. 403 F.3d 1331, 1345 (Fed. Cir. 2005) (invalidating patent claim as inherently anticipated under 35 U.S.C. § 102(b)).

28. 365 F.3d 1306 (Fed. Cir. 2004).

29. *Id.*

efficacy of an invention will necessarily constitute public use,³⁰ nor was the case irreconcilable with other Federal Circuit decisions.

Part II of this Comment will provide a background of the public use bar to patentability and will discuss the emergence of the judicially created experimental use doctrine. Part III will analyze whether *SmithKline Beecham Corp.*³¹ followed current case law. Part IV will allay concerns that the decision of *SmithKline Beecham Corp.* undermined certainty and predictability in patent law by proposing that the decision would have set forth clearer boundaries for the doctrine of experimental use.

I. EXPERIMENTAL USE NEGATION OF THE PUBLIC USE BAR

A. Public Use

1. The Patent Acts

The language of the Patent Act of 1793 prevented the issuance of a patent for an invention known or used before the application.³² The Patent Act of 1836 prevented the issuance of a patent for an invention that was in public use or on sale before the application.³³ The Patent Act of 1839 created a two-year period during which the invention could be in public use

30. A word on utility is warranted here. To obtain a patent on a process, machine, manufacture, or composition of matter, the discovery must not only be new, it must be useful. 35 U.S.C. § 101. According to 35 U.S.C. § 101, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” *Id.* This is known as the minimum utility requirement for inventions and may pose a significant problem for chemical inventions. 1-4 DONALD S. CHISUM, *CHISUM ON PATENTS* § 4.02 (2004). With chemical inventions, it can be difficult to demonstrate sufficient minimum utility. *Id.* A pharmaceutical drug may be patented by claiming only its chemical structure. *Id.* This chemical composition is subject to the same minimum utility requirements imposed on all other inventions, which would lead some to argue that clinical trial testing is the only experimental testing sufficient to prove utility. *Id.* It must be kept in mind, however, that the utility requirement is one of minimum utility, and that requirement is sufficiently met when a drug demonstrates that it has any pharmacological activity. *See Reforming Patent Infringement, supra* note 21, at 58 (citing *In re Chilowsky*, 229 F.2d 457, 461-62 (C.C.P.A. 1956)). The requirement of minimum utility can thus be met by *in vivo* testing, short of testing in humans. *See Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980) (The court stated that because “it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility”).

31. 365 F.3d 1306 (Fed. Cir. 2004).

32. Kemper, *supra* note 15, at 62 (discussing that the Patent Act of 1793 authorized a grant of a patent for an invention “not known or used before the application”). A strict reading of the language poses a problem because the inventor necessarily knows of the invention before the application for a patent. Rooklidge, *supra* note 19, at 9.

33. Kemper, *supra* note 15, at 62. A strict reading of the Patent Act of 1836 would also pose a problem because inventors may need to test an invention in the public domain before filing a patent application. Rooklidge, *supra* note 19, at 9.

or on sale before the application for a valid patent to issue.³⁴ The Patent Act of 1939 reduced the grace period to one year.³⁵

2. *The Early Cases — Illustrations of Public Use*

One of the first and best-known cases of public use is the case of *Egbert v. Lippmann*,³⁶ the “Corset Case.”³⁷ On July 17, 1866, Samuel H. Barnes applied³⁸ for a patent on several corset designs he invented between January and May 1855.³⁹ At the time of Barnes’s application, the Patent Act of 1839 was in effect, allowing an inventor a two-year period to use the invention publicly before application.⁴⁰ In 1855 and 1858, Barnes made the corset steels that embodied his patented invention and presented them to Egbert,⁴¹ who wore them for several years.⁴² Barnes also showed his corset inventions to Joseph H. Sturgis in 1863.⁴³ The Supreme Court was confronted the issue of whether Barnes’s use of the invention for over eleven years before application constituted public use within the meaning of the statute.⁴⁴

The Supreme Court, in holding that Barnes’s invention was in public use within the meaning of the statute,⁴⁵ posited three guidelines that would broadly define “public use” within the meaning of the statute.

First, the use of a single patented article in public is sufficient to constitute public use within the meaning of the statute.⁴⁶ Second, the use or knowledge of a single person, other than the inventor, is sufficient to constitute public use within the meaning of the statute.⁴⁷ Third, a use may be public although it is not observable by the public eye.⁴⁸

In the case of *Smith & Griggs Mfg. Co. v. Sprague*,⁴⁹ Smith & Griggs employed in their factory a machine that comprised all the elements contained within two patents.⁵⁰ They applied for the patents more than two

34. Kemper, *supra* note 15, at 62.

35. *Id.*

36. 104 U.S. 333 (1881).

37. 2-6 CHISUM, *supra* note 27, § 6.02.

38. *Egbert*, 104 U.S. at 333.

39. *Id.* at 335.

40. *Id.*

41. *Id.* Egbert later married Barnes. *Id.*

42. *Id.*

43. *Id.*

44. *Id.* at 336-37.

45. *Id.*

46. *Id.* at 336. The court further stated, “one well-defined case of such [public] use is just as effectual to annul the patent as many.” *Id.*

47. *Id.* “[S]uch use is public, even though the use and knowledge of the use may be confined to one person.” *Id.*

48. *Id.* The Court went on to describe inventions that may constitute parts of a machine that although unobservable are nevertheless public. *Id.*

49. 123 U.S. 249 (1887).

50. *Id.* The application that issued as U.S. Patent No. 228,136 was applied for in 1879. *Id.* at 250. The application that issued as U.S. Patent No. 231,199 was applied for in 1878. *Id.* The two patents claimed different parts and combinations to construct a single machine. *Id.*

years⁵¹ after the use.⁵² The Supreme Court, in holding that the use was public within the meaning of the statute, set forth experimental use as an exception “out of the prohibition of the statute”⁵³ if the use is “properly characterized as substantially for the purposes of experiment.”⁵⁴

B. Experimental Use

1. City of Elizabeth v. American Nicholson Pavement Co.⁵⁵

City of Elizabeth v. American Nicholson Pavement Co. was one of the first cases⁵⁶ exemplifying the judicially created doctrine of experimental use.⁵⁷ In *City of Elizabeth*, the inventor of a wooden road laid a seventy-five foot section of the road down on a private toll road for six years before applying for a patent.⁵⁸ In holding that the use of the road did not constitute public use,⁵⁹ the Supreme Court found it important that the purpose of laying down the road was to test its quality,⁶⁰ the road was installed by the inventor at his own expense,⁶¹ the inventor visited the road daily and inspected it,⁶² and the inventor chose the specific site because he wanted to test the road under different types of traffic.⁶³ In its holding, the Supreme Court found several issues pertinent to a determination of experimental use:⁶⁴ a) although a device may be tested in private, public testing is not dispositive of public use;⁶⁵ b) for an activity to constitute experimental use, an inventor need not

51. The two-year grace period was in effect during this time. *Id.* at 255.

52. *Id.* at 253.

53. *Id.* at 255.

54. *Id.* at 256.

55. 97 U.S. 126 (1877).

56. One commentator has suggested that the experimental use doctrine first arose in the case of *Morris v. Huntington*, 17 F. Cas. 818 (C.C.D.N.Y. 1824), with an instruction to the jury that although the language of the 1793 Patent Act specified that a patent will not issue if the invention is known or used before the application for patent, if an inventor has delayed his application because he has been practicing his invention with the intent of improving it, he should not be prejudiced by the language of the statute. *See Rooklidge, supra* note 19, at 9-10 (citing *Morris*, 17 F. Cas. at 818). Rooklidge went on to suggest that the Supreme Court adopted the experimental use doctrine as a negation to the public use bar when it stated that public use, within the meaning of the 1793 Patent Act, could not be understood as use by the inventor to perfect his invention. *See id.* at 11-13 (citing *Pennock v. Dialogue* 27 U.S. 1 (1829)). Rooklidge further noted that in *Shaw v. Cooper* the Supreme Court quoted in full the jury instruction regarding experimental use given by the court in *Morris v. Huntington*. *See id.* at 12-14 (citing *Shaw v. Cooper*, 32 U.S. 292 (1833)).

57. *See Rooklidge, supra* note 19, at 16-19 (explaining how courts applied their own doctrine despite the 1839 Patent Act); *see also Kemper, supra* note 15, at 39, 63-69, 87-88 (outlining the creation and implementation of the experimental use doctrine).

58. 97 U.S. at 129-33.

59. *Id.* at 135-36.

60. *Id.* at 133.

61. *Id.*

62. *Id.*

63. *Id.* at 134.

64. Rooklidge, *supra* note 19, at 18.

65. *See id.* (citing *City of Elizabeth*, 97 U.S. at 134-35).

alter the invention as a result of the use;⁶⁶ c) if durability is an inherent quality of the invention, then a long period of experimentation may be necessary for the inventor to determine if the invention is suitable for its intended purpose;⁶⁷ d) the experimental use does not have to occur on the inventor's own premises;⁶⁸ e) the public may derive a benefit from the invention that is incidental to the experimental use;⁶⁹ f) if the inventor maintains control over his invention, does not sell it for general use or allow others to make and use his invention, and uses the invention with the intent to test its qualities, then the use does not constitute a public use within the meaning of the statute;⁷⁰ and g) the inventor must monitor the use for it to be experimental.⁷¹

2. Public Use Factors

Commentators have identified several factors that courts weigh to determine whether the inventor's use was public or experimental in nature.⁷² Courts will give variable weight to these factors when considering the "totality of the circumstances"⁷³ to determine whether a particular use was experimental or public.

One factor the courts take into consideration is the number and length of experiments conducted.⁷⁴ These should comport with the nature of the invention.⁷⁵ The inventor should also maintain some control over the experiments,⁷⁶ which should be conducted under some constraints of

66. *City of Elizabeth*, 97 U.S. at 135.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. See generally *Reforming Patent Infringement*, *supra* note 21 (describing the factors of the "public use test"). But see Rooklidge, *supra* note 19, at 48-49 (contending, instead, that these are factors of experimental use and that the inquiry of whether use is experimental or public is distinct). It seems well established, however, that courts generally consider the inquiry of public use versus experimental use as one, with a finding that experimental use does not fall under public use within the meaning of the statute. Courts have stated that

it is incorrect to impose on the patent owner, as the trial court in this case did, the burden of proving that a public use was experimental. These are not two separable issues. It is incorrect to ask: Was it public use? and then, Was it experimental?

Rather, the court is faced with a single issue: Whether it public use under § 102(b).

TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 971 (Fed. Cir. 1984). See also *Reforming Patent Infringement*, *supra* note 21, at 50-51 (arguing that the question of experimental use is not divorced from the public use inquiry).

73. *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 498 (Fed. Cir. 1992). "[T]he court must look to the totality of the circumstances to determine whether there has been a public use within the meaning of section 102(b)." *Id.* Furthermore, "a decision on whether there has been a 'public use' can only be made upon consideration of the entire surrounding circumstances." *TP Labs., Inc.*, 724 F.2d at 972.

74. Kemper, *supra* note 15, at 66.

75. *Id.*

76. *Id.*

confidentiality.⁷⁷ Lastly, the experiments should be monitored by the inventor or by someone on behalf of the inventor.⁷⁸

3. *The Nature of the Experimental Use*

The courts are cognizant of several factors relating specifically to the invention when determining whether use is experimental or public.

a. Reduce the Invention to Practice

The use, to be experimental, must be undertaken to reduce the invention to practice.⁷⁹ Reduction to practice entails perfecting or completing the invention with respect to its claimed limitations.⁸⁰ For an invention to be reduced to practice, it must also be shown that the invention is suitable for its intended purpose.⁸¹

b. Use after Reduction to Practice

Use that occurs after reduction of the invention to practice cannot constitute experimental use.⁸² Because an inventor engages in experimental activity for the purpose of perfecting the invention, “experimental use ends upon reduction to practice.”⁸³

c. Lack of Reduction to Practice is not Dispositive

Use that occurs before reduction to practice is not always experimental.⁸⁴ The experimental activity must still be conducted for the purpose of perfecting the claimed invention.⁸⁵

d. The Claims Define the Invention

It is a well-known maxim in patent law that the claims define the invention.⁸⁶ The claims of a patent set the metes and bounds of an invention.⁸⁷ For an inventor’s use to fall under the rubric of experimental use, it must pertain to the invention as it is defined by the claims of the patent.⁸⁸

77. *Id.*

78. *Id.*

79. Rooklidge, *supra* note 19, at 24.

80. *Id.* at 25.

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.* at 26.

85. *Id.*

86. *Id.* at 35.

87. *Id.*

88. *Id.*

II. THE FEDERAL CIRCUIT CASES ON PUBLIC USE

In the prior decision of *SmithKline Beecham Corp.*,⁸⁹ the Federal Circuit found the administration of clinical trials to test a novel chemical composition to constitute public use⁹⁰ within the meaning of the statute.⁹¹ The main concern was whether the decision comported with other Federal Circuit decisions regarding public use.⁹²

In *SmithKline Beecham Corp.*, the majority opinion included a discussion of three major Federal Circuit decisions regarding the experimental use negation to public use,⁹³ *Manville Sales Corp. v. Paramount Sys., Inc.*,⁹⁴ *Seal-Flex, Inc. v. Athletic Track and Court Constr.*,⁹⁵ and *EZ Dock, Inc. v. Schafer Sys., Inc.*⁹⁶ The majority found these cases to be consistent with the rationale underlying the decision in *SmithKline Beecham Corp.*,⁹⁷ while the concurrence⁹⁸ and the Washington Legal Foundation, writing a brief as *Amicus Curiae* in support of *SmithKline Beecham Corp.*'s petition for rehearing *en banc*, found these cases to be irreconcilable with the majority's opinion.⁹⁹ This part of the Comment will address the concern that the prior *SmithKline Beecham Corp.* decision would have created an area of uncertainty in patent law.¹⁰⁰ First it will examine, in detail, the prior *SmithKline Beecham Corp.* decision and its rationale. Then

89. *SmithKline Beecham Corp.*, 365 F.3d 1306.

90. *Id.* at 1320.

91. 35 U.S.C. § 102.

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

Id.

92. Brief for Washington Legal Foundation as Amicus Curiae in Supporting Plaintiffs-Appellants' Petition for Rehearing en Banc, *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005)(No. 03-1285, 03-1313).

En banc review [of the Federal Circuit's decision in *SmithKline Beecham Corp.*] is warranted because the panel decision directly conflicts with numerous decisions of this Court regarding the scope of the public use bar. As a result of the panel decision, patent attorneys can no longer competently counsel clients regarding how to conduct clinical trials to determine whether a drug is effective for its intended use, without running significant risk that the public use bar will invalidate any patent later sought for the drug.

Id.

93. *SmithKline Beecham Corp.*, 365 F.3d at 1318.

94. 917 F.2d 544 (Fed. Cir. 1990).

95. 98 F.3d 1318 (Fed. Cir. 1996).

96. 276 F.3d 1347 (Fed. Cir. 2002).

97. 365 F.3d at 1318.

98. *Id.* at 1324-25 (Gajarsa, J., concurring).

99. Brief for Washington Legal Foundation as Amicus Curiae, *supra* note 89.

100. *SmithKline Beecham Corp.*, 365 F.3d at 1323 (Gajarsa, J., concurring) (arguing that the case presented unique circumstances because "something feels wrong about holding an infringer liable for inevitable, spontaneous infringement," so the majority tried to twist current case law to achieve the outcome, without addressing the issue head-on).

it will examine the Federal Circuit decisions in *Manville Sales Corp.*,¹⁰¹ *Seal-Flex, Inc.*,¹⁰² and *EZ Dock, Inc.*¹⁰³ in light of the rationale underlying *SmithKline Beecham Corp.* to determine whether the decisions did, in fact, conflict.

A. SmithKline Beecham Corp. v. Apotex Corp.

1. Background

During the late 1970s, Ferrosan, a British company, discovered a new class of chemical compounds having antidepressant and anti-Parkinson pharmacological properties.¹⁰⁴ This class of compounds came to be known as paroxetine.¹⁰⁵ Ferrosan developed a method to crystallize paroxetine, forming the crystalline hydrochloride salt of paroxetine or paroxetine hydrochloride (PHC) and licensed it to SmithKline Beecham Corp.¹⁰⁶ After obtaining the license, SmithKline Beecham Corp. started manufacturing paroxetine hydrochloride at its facility in England.¹⁰⁷

SmithKline Beecham Corp. manufactured the anhydrous crystalline form of paroxetine hydrochloride.¹⁰⁸ Approximately five years later, a chemist working for SmithKline Beecham Corp. discovered a new and more stable crystalline form of paroxetine hydrochloride, the hemihydrate.¹⁰⁹ Once this more stable crystalline form of paroxetine hydrochloride emerged in the laboratories, SmithKline argued that the original form of anhydrous paroxetine hydrochloride could no longer be made because of a theory they proposed, and the court adopted, regarding disappearing polymorphs.¹¹⁰ The

101. See 917 F.2d at 549-51 (holding that the use was not public because, under a totality of the circumstances, it was clear that experimentation was the primary objective).

102. See 98 F.3d at 1324 (holding that an inventor may engage in commercial activity and avoid the on-sale bar, provided that inventor is still ascertaining whether the invention will serve its intended purpose).

103. See 276 F.3d at 1353 (holding that summary judgment on the issue of invalidity is improper if the patentee provides evidence of experimentation sufficient to negate the statutory presumption).

104. See *SmithKline Beecham Corp.*, 365 F.3d at 1308 (attributing the invention of a new class of compounds which contain anti-depressant properties to Ferrosan (citing U.S. Patent No. 4,007,196 (filed July 23, 1975) (issued Feb. 8, 1977) as relating to all new 3-substituted 1-alkyl-4-phenylpiperidines that possessed antidepressant and anti-Parkinson's pharmacological activity).

105. *Id.*

106. *Id.* at 1308-09.

107. *Id.* at 1309.

108. *Id.* The anhydrous form of a crystal is a crystal without water bound to the crystalline lattice. *Id.*

109. *Id.* (explaining that the hemihydrate crystal is a crystal bound with water molecules in a one to two ratio). The hemihydrate crystalline form is more stable than the anhydrous form because the water molecules are already contained within the crystalline lattice, so the crystal tends to be less reactive with water. *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1017 (N.D. Ill. 2003).

110. See *SmithKline Beecham Corp.*, 247 F.Supp.2d at 1019-20 (adopting expert witness's testimony of "disappearing polymorphs"). Polymorph refers to different crystalline structures of the same chemical compound. *Id.* at 1016-17.

theory of disappearing polymorphs suggests that once a new and more stable polymorph emerges in a laboratory, the seeds of this crystal will forever be present and will tend to convert the less stable polymorph into the new polymorph despite efforts to produce the former.¹¹¹ Thus, because of conversion, efforts to produce the anhydrous form of paroxetine hydrochloride will necessarily produce the hemihydrate form of paroxetine hydrochloride.¹¹²

In May 1985, SmithKline Beecham Corp. began conducting double-blind clinical trials¹¹³ in the United States to determine the safety and efficacy of paroxetine hydrochloride hemihydrate as an antidepressant agent.¹¹⁴ On October 23, 1986, SmithKline Beecham Corp. filed a United States patent application¹¹⁵ for antidepressant crystalline paroxetine hydrochloride that issued on January 26, 1988 as U.S. Patent No. 4,721,723 (“the ‘723 patent”).¹¹⁶ The patent application was filed more than one year after commencement of the clinical trial study.¹¹⁷ SmithKline Beecham Corp. began marketing paroxetine hydrochloride hemihydrate as Paxil© in 1993, after FDA approval.¹¹⁸

In 1998, Apotex Corp. filed an Abbreviated New Drug Application¹¹⁹ (“ANDA”) with the Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j),¹²⁰ seeking approval of a generic paroxetine hydrochloride anhydrate with bioequivalence to the active ingredient of SmithKline Beecham Corp.’s Paxil©. Apotex Corp. certified that it intended to market the drug before expiration of the ‘723 patent¹²¹ because its active ingredient, paroxetine hydrochloride anhydrate, would not infringe the ‘723 patent.¹²²

111. *Id.* at 1019-21.

112. *SmithKline Beecham Corp.*, 365 F.3d at 1312; *SmithKline Beecham Corp.*, 247 F.Supp.2d at 1019-23.

113. In a double-blind clinical study, the participating individuals and the study staff are not apprised of “which participants are receiving the experimental drug and which are receiving a placebo.” ClinicalTrial.gov, Glossary of Clinical Trials Terms, <http://www.clinicaltrials.gov/ct/info/glossary> (last visited Nov. 1, 2004).

114. *SmithKline Beecham Corp.*, 365 F.3d at 1309.

115. U.S. Patent Application No. 922,530 (filed Oct. 23, 1986).

116. U.S. Patent No. 4,721,723 (filed Oct. 23, 1986) (issued Jan. 26, 1988).

117. *See* 35 U.S.C. § 102 (codifying that “a person shall be entitled to a patent unless . . . (b) the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States”).

118. *SmithKline Beecham Corp.*, 365 F.3d at 1309.

119. *Id.*

120. *See* 21 U.S.C. § 355(j) (2000) (providing for new (generic) drug approval using an abbreviated application). “An application for a new drug shall contain – information to show that the rate of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in the clause.” 21 U.S.C. §355(j)(2)(A)(iii). The applicant must “show that the new drug is bioequivalent to the listed drug.” 21 U.S.C. § 355(j)(2)(iv).

121. *SmithKline Beecham Corp.*, 365 F.3d at 1309.

122. The ‘723 patent recites six claims. Claim 1 recites only the structure of the chemical compound, “[c]rystalline paroxetine hydrochloride hemihydrate.” *Id.* Claims 2-6 are more specific, limiting the claims to substantially pure forms of the crystal or to chemical compositions of the crystal that have an antidepressant effect. *Id.* Claim 1 is the

Pursuant to 35 U.S.C. § 271(e)(2),¹²³ SmithKline Beecham Corp. initiated an infringement action against Apotex Corp.,¹²⁴ alleging that Apotex Corp. indicated in the ANDA that it intended to market a generic paroxetine hydrochloride anhydrate that would necessarily convert to paroxetine hydrochloride hemihydrate¹²⁵ and would, thus, infringe Claim 1 of the '723 patent.¹²⁶

broadest claim, giving SmithKline Beecham Corp. the right to exclude others from making, using, or selling paroxetine hydrochloride hemihydrate, even in the most minuscule amount (a single crystal) and regardless of whether the infringing chemical compound has any antidepressant effect. *Id.*

123. 35 U.S.C. § 271(e)(2)(A) (2000) "It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent. . . ." *Id.*

124. *SmithKline Beecham Corp.*, 365 F.3d at 1309.

125. *Id.*

126. *Id.* The right of Apotex Corp. to file an abbreviated drug application without conducting its own tests for safety and efficacy and SmithKline Beecham Corp. to sue Apotex Corp. for infringement have a common source, the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Amendments") that amended the Federal Food, Drug, and Cosmetics Act. Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 52 (2003). Until Hatch-Waxman, generic drug manufacturers had to perform the same safety and efficacy studies as brand name manufacturers to get approval. *Id.* The generic manufacturer could not demonstrate the safety and efficacy of its "bio-equivalent" drug by relying on the animal and human studies conducted by the brand name manufacturer. *Id.* If the generic manufacturer attempted to conduct safety and efficacy tests before the expiration of the patent, however, it would necessarily infringe the patent by making and using a patented product for commercial purposes, as opposed to mere scientific inquiries, which would have been allowable. *Roche Prods., Inc., v. Bolar Pharm. Co. Inc.*, 733 F.2d 858, 863 (Fed. Cir. 1984). The *Roche Prods., Inc.* decision effectively extended the period of exclusivity for the patent owner beyond the term of the patent to include the time generic manufacturers would need from expiration of the patent until completion of their clinical studies. *SmithKline Beecham Corp.*, 247 F. Supp. 2d at 1018. In the efforts to promote the availability of affordable generic alternatives to pharmaceutical drugs, Congress responded with the Hatch-Waxman Amendments in 1984. Sarah E. Eurek, Comment, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 18, 19 (2003). The Hatch-Waxman Amendments allowed generic manufacturers to file abbreviated new drug applications, whereby the generic manufacturer needs only to demonstrate to the FDA that its drug is the bioequivalent of the brand name drug to satisfy the safety and efficacy requirements. Robinson, *supra*, at 52. The Hatch-Waxman Amendments also created an exception to the rule against infringement for generic drug manufacturers seeking FDA approval, giving the generic manufacturer the right to make and use the generic version of the drug before patent expiration. *Id.* The Hatch-Waxman Amendments did not leave the brand name manufacturers without recourse. *Id.* at 53-55. If a generic drug manufacturer wants to enter the market with its generic version of a patented drug before the patent term expires, it must file a paragraph IV certification and provide notice to the brand name manufacturer. *Id.* at 55-56. Paragraph IV certification requires the generic manufacturer to indicate that it believes either it is not infringing the brand name manufacturer's patent or the brand name manufacturer's patent is invalid. *Id.* Under Hatch-Waxman, a paragraph IV certification, in turn, gives the brand name manufacturer the opportunity to bring action against the generic drug manufacturer for infringement. *Id.* at 56.

2. '723 Patent is Infringed

The majority began its analysis by construing the scope of Claim 1 of the '723 patent.¹²⁷ Claim 1 recites "crystalline paroxetine hydrochloride hemihydrate."¹²⁸ The majority found this claim language to be unambiguous and to clearly claim a chemical structure.¹²⁹ The majority, adopting the disappearing polymorph theory, also found that because the more stable hemihydrate of paroxetine had emerged, any attempt by Apotex Corp. to manufacture the unclaimed paroxetine anhydrate would necessarily fail because the anhydrate would convert into the hemihydrate form.¹³⁰ Thus, any attempt by Apotex Corp. to manufacture the non-infringing anhydrous product would lead to infringement of the '723 patent because some miniscule amount of paroxetine hemihydrate would always form. Apotex Corp., therefore, infringed the '723 patent by making and using paroxetine hydrochloride hemihydrate (albeit, in miniscule amounts).¹³¹

3. '723 Patent is Invalid for Public Use

The majority, however, did not stop after finding infringement of the '723 patent. It went on to discuss the crucial aspect of the case — did SmithKline Beecham Corp.'s clinical trials constitute public use?¹³² The majority stated that 35 U.S.C. § 102(b) creates a bar to obtaining a patent if the invention was ready for patenting and was used by one other than the inventor who is not under the constraints of confidentiality more than one year before filing a patent application.¹³³

The majority found that SmithKline Beecham Corp.'s clinical trials did not constitute experimental use because the doctrine applied only to *features of the claimed invention*.¹³⁴ The majority focused on the language and scope of the claim.¹³⁵ Claim 1 of the '723 patent claimed a naked chemical structure, with no reference to the safety of the chemical for human use or its efficacy as an antidepressant.¹³⁶ The majority espoused the rule that experimental testing cannot occur once an invention is reduced to practice.¹³⁷ For infringement, SmithKline Beecham Corp. argued that the scope of Claim

127. *SmithKline Beecham Corp.*, 365 F.3d at 1313.

128. *Id.* at 1315.

129. *Id.*

130. *Id.* at 1312-13.

131. *Id.* at 1315.

132. *Id.* at 1316.

133. *Id.* at 1316-17. The majority posited this two-part test for the public use bar upon the incorrect assumption that the two-part test for the on sale bar established in *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998), also applies to public use. See *infra* Part IV for a discussion of the majority's characterization of the two-part test for public use.

134. *SmithKline Beecham Corp.*, 365 F.3d at 1317-18. See also, *LaBounty Mfg. v. United States ITC*, 958 F.2d 1066, 1074 (Fed. Cir. 1992) (stating that the law is well settled that an experimental sale can only apply to claimed features of the invention).

135. *SmithKline Beecham Corp.*, 365 F.3d at 1318.

136. *Id.* "The antidepressant properties of the compound are simply not claimed features." *Id.*

137. *Id.* at 1318-19.

1 of the '723 patent did not imply any intended commercial significance or pharmaceutical benefit; it argued, therefore, that Apotex Corp. would infringe even if it makes trace amounts of the patented chemical, even if the amount of the chemical is so miniscule that it confers no antidepressant effect.¹³⁸ The majority turned SmithKline Beecham Corp.'s own argument around to conclude that if efficacy is not an element of the claimed invention when evaluating infringement, then it is also not available when evaluating whether experiments were conducted to test features of the claimed invention.¹³⁹

The rationale of the majority is best summed up by the statement: A use can only be experimental if it is limited to explicit or inherent features of the claimed invention.¹⁴⁰

The question now is whether this rationale applies to the Federal Circuit's public use cases.

B. Manville Sales Corp. v. Paramount Sys., Inc.

1. The Claimed Invention

The Manville Sales Corp. owned U.S. Patent No. 3,847,333 ("the '333 patent") for an apparatus designed to maintain a ring-like luminaire support centered around a light pole.¹⁴¹ The claims specified that the apparatus must maintain the ring-like object around the external surface of a post or a predetermined location.¹⁴²

2. The Alleged Public Use

Manville constructed the assembly and then had it placed on a light pole in a remote Wyoming rest area, which was not yet open to the public, to determine whether the light assembly could withstand the outdoor environment.¹⁴³

3. Was the Use Experimental?

The court found that durability was inherent to the *purpose* of the invention.¹⁴⁴ This, however, can be reconciled with the decision in *SmithKline Beecham Corp.* because in order to *maintain* the ring-like

138. *Id.* at 1320.

139. *Id.*

140. *Id.* at 1319-20.

141. U.S. Patent No. 3,847,333 (issued Nov. 12, 1974). The language of claims 1 and 9 call for "an apparatus for maintaining a ring-like object support in a predetermined location around the external surface of a post." *Id.* Claims 10, 15, and 16 call for "an apparatus adapted for centering a ring-like object support about the axis of a longitudinal member." *Id.* Claim 11 calls for a "luminaire assembly comprising . . . a ring-like support member concentrically disposed around said post." *Id.*

142. *Id.*

143. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550 (Fed. Cir. 1990).

144. *Id.* at 551.

structure around a pole, the apparatus must be durable; therefore, durability is an inherent feature of the claimed invention.

C. Seal-Flex, Inc. v. Athletic Track and Court Constr.

1. *The Claimed Invention*

Seal-Flex owned U.S. Patent No. 4,539,622, which claimed an “activity mat over a foundation.”¹⁴⁵

2. *The Alleged Public Use*

Seal-Flex sold its athletic track to, and installed it in, a local high school.¹⁴⁶ Seal-Flex continued to monitor the track after installation and student use, and made repairs and design alterations.¹⁴⁷

3. *Was the Use Experimental?*

The court concluded that the use was experimental and needed to show that the invention worked for its *intended purpose*.¹⁴⁸ Applying the *SmithKline Beecham Corp.* rationale, the experiments tested the inherent features of the invention because an activity mat implies, as a claimed feature, durability under use.

D. EZ Dock, Inc. v. Schafer Sys., Inc

1. *The Claimed Invention*

EZ Dock owned U.S. Patent No. 5,281,055, which claimed a “floating dock.”¹⁴⁹

2. *The Alleged Public Use*

EZ Dock sold the invention to a person who used it on rough water and monitored it after installation, making repairs to the dock and changes to the design.¹⁵⁰

3. *Was the Use Experimental?*

The court held that the use was experimental because “floating docks, by their nature, must endure all kinds of water conditions.”¹⁵¹ The court therefore concluded that the experiment tested an inherent feature of the claimed invention.

145. U.S. Patent No. 4,529,622 (issued July 16, 1985).

146. Seal-Flex, Inc. v. Athletic Track and Court Constr., 98 F.3d 1318, 1320 (Fed. Cir. 1996).

147. *Id.*

148. *Id.* at 1323.

149. U.S. Patent No. 5,281,055 (filed July 17, 1992) (issued Jan. 25, 1994).

150. EZ Dock, Inc. v. Schafer Sys., Inc., 276 F.3d 1347, 1349 (Fed. Cir. 2002).

151. *Id.* at 1353.

IV. PROMOTING CERTAINTY IN PATENT LAW

The Federal Circuit sitting in a three-judge panel wrote the prior *SmithKline Beecham Corp.* decision.¹⁵² On June 4, 2004, SmithKline Beecham Corp. petitioned for *en banc* review following the panel's decision on public use.¹⁵³ The Washington Legal Foundation filed a brief as *Amicus Curiae* in support of SmithKline Beecham Corp.'s petition for rehearing *en banc*, arguing that *en banc* review was warranted because *SmithKline Beecham Corp.* conflicted with prior decisions with respect to public use and created uncertainty with its characterization of the reach of the experimental use doctrine.¹⁵⁴ This part of the Comment will address the Washington Legal Foundation's concerns. The Comment will propose that the majority's characterization of the experimental use doctrine was technically correct and in accord with previous case law, and will then discuss the majority's two-part test for public use.

A. *Delineating the Boundaries of Experimental Use*

Predictability, certainty, and consistency are the most important aspects of patent law, where significant property interests are at stake.¹⁵⁵ Attorneys often counsel clients on issues regarding whether certain actions by the inventor may constitute public use to bar the issuance of a patent.¹⁵⁶ Courts may view actions that intuitively seem necessary to develop an invention as public use. The Federal Circuit's lack of discussion in vacating the prior *SmithKline Beecham Corp.* decision has left open whether clinical trials may, in the future, be considered public use.

Several commentators have suggested that despite creation of the Federal Circuit to promote consistency in patent law, there is, in fact, little consistency in the decisions regarding public use.¹⁵⁷ Moreover, the Washington Legal Foundation expressed great concern that the prior *SmithKline Beecham Corp.* decision dealt another blow to the consistency of Federal Circuit decisions by holding that "a clinical study . . . [that] fits most everyone's understanding . . . of an 'experimental use' of a product" constitutes public use.¹⁵⁸ This assertion lies on faulty reasoning. The experimental use doctrine applies to an *invention*, not to a product.¹⁵⁹

152. *SmithKline Beecham Corp.*, 365 F.3d at 1307 (Fed. Cir. 2004).

153. *SmithKline Beecham Corp. v. Apotex Corp.*, No. 99-CV-4304, 2004 U.S. Dist. LEXIS 13907, at *12-13 (E.D. Pa. July 16, 2004).

154. Brief for Washington Legal Foundation, *supra* note 89.

155. Katherine E. White, Note, *A General Rule of Law is Needed to Define Public Use in Patent Cases*, 88 KY. L.J. 423, 423 (2000).

156. Brief for Washington Legal Foundation, *supra* note 89.

157. *See generally* White, *supra* note 152 (finding a lack of consistency in public use and on-sale bar cases); Margaret L. Begalle, Note, *Eliminating the Totality of the Circumstances Test for the Public Use Bar Under Section 102 (B) of the Patent Act*, 77 CHI.-KENT. L. REV. 1359 (2002) (suggesting that alternatives to the totality of the circumstances test may provide more consistency in patent law decisions).

158. Brief for Washington Legal Foundation, *supra* note 89.

159. *See infra* note 157 and accompanying text (discussing experimental use as it applies to inventors).

Additionally, the prior *SmithKline Beecham Corp.* decision outlined the boundaries of the experimental use doctrine by positing a clear definition of experimental use that would have enabled a more accurate prediction of what activities would qualify under the negation.

1. *Experimental Use Must Pertain to the Claimed Invention*

If there is one maxim in patent law, it is that claims define the invention.¹⁶⁰ Determining the scope of the claim depends upon the claim language.¹⁶¹ Another well-settled principle in patent law is that experimental use must pertain to the claimed invention.¹⁶² The majority in the prior *SmithKline Beecham Corp.* decision merely restated this principle and appropriately refined the definition of experimental use to cover both express and implied features of a claimed invention.¹⁶³

2. *SmithKline Beecham Corp. was Consistent with the Accepted Definition of Experimental Use*

In all of the Federal Circuit cases discussed in Part III, the claim language implied features of the invention that must be present for the invention to perform as claimed.¹⁶⁴ In *SmithKline Beecham Corp.*'s '723 patent, by contrast, Claim 1 recites nothing more than a chemical structure that implies no commercial or pharmaceutical value.¹⁶⁵ The remaining

160. "It is a bedrock principle of patent law that the claims of a patent define the invention. . . ." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1115-16 (Fed. Cir. 2004) (citing, *inter alia*, *Altoona Publix Theaters, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935) ("Under the statute it is the claims of the patent which define the invention."); *Smith v. Snow*, 294 U.S. 1, 11 (1935) ("The claims of a patent, not its specifications, measure the invention."); *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) ("In making his claim the inventor is at liberty to choose his own form of expression, and while the courts may construe the same in view of the specifications and the state of the art, they may not add to or detract from the claim.") (quoting *Cimiotti Unhairing Co. v. Am. Fur Ref. Co.*, 198 U.S. 399, 410 (1905)); *White v. Dunbar*, 119 U.S. 47, 52 (1886) ("The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public . . . to construe it in a manner different from the plain import of its terms."); *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) ("[The statutorily required] distinct and formal claim is, therefore, of primary importance, in the effort to ascertain precisely what it is that is patented to the appellant in this case."); *SRI Int'l v. Matsushita Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc) ("It is the claims that measure the invention.").

161. *Innova/Pure Water, Inc.*, 381 F.3d at 1116.

162. *In re Brigance*, 792 F.2d 1103, 1109 (Fed. Cir. 1986) (stressing that "the experimental use exception does not apply to experiments performed with respect to non-claimed features of an invention"); *W. Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 847 (Fed. Cir. 1985) ("[T]esting or experimentation performed with respect to non-claimed features of the device does not show that the *invention* was the subject of experimentation."); *In re Theis*, 610 F.2d 786, 793 (C.C.P.A. 1979) ("It is settled law that the experimental sale exception does not apply to experiments performed with respect to non-claimed features of an invention.").

163. *SmithKline Beecham Corp.*, 365 F.3d at 1319-20.

164. See *supra* notes 142, 146, 150 and accompanying text.

165. '723 patent. "We claim . . . crystalline paroxetine hydrochloride hemihydrate." *Id.*

claims are more specific, and limit the scope of the invention by adding commercial (“paroxetine hydrochloride in substantially pure form”) and pharmaceutical (“an antidepressant pharmaceutical composition”) significance.¹⁶⁶ SmithKline Beecham Corp. conceded this point by arguing that the claim had no implications beyond the express language of the claim.¹⁶⁷ In fact, SmithKline Beecham Corp. proposed this claim construction to allow the court to broadly construe the scope of Claim 1 of the ‘723 patent, enabling it to capture Apotex’s attempt to manufacture a non-infringing product.¹⁶⁸ This broad claim construction would have eviscerated any careful attempt to make the unpatented paroxetine hydrochloride anhydrate without infringing the patent covering the hemihydrate. This would have effectively extended SmithKline Beecham Corp.’s patent to unpatented material.¹⁶⁹

3. SmithKline Beecham Corp. *Would not have Disturbed a Patentee’s Efforts to Test for Utility*

The majority’s prior definition of experimental use would not have interfered with a patentee’s ability to test for utility of an invention. A composition of matter claim, such as Claim 1 of the ‘723 patent, must have sufficient minimum utility to obtain a patent.¹⁷⁰ How can a patentee determine sufficient minimum utility of a novel pharmacological compound without subjecting it to human clinical trials? In *Fujikawa v. Wattanasin*, the Federal Circuit held that *any pharmacological activity*, including *in vitro* testing, could sufficiently establish minimum utility.¹⁷¹ Therefore, regardless of whether a patentee seeks to market a chemical composition for a specific

166. *Id.*

167. *SmithKline Beecham Corp.*, 365 F.3d at 1319.

168. ‘723 patent claimed paroxetine hydrochloride hemihydrate. Apotex, however, was attempting to manufacture and market the anhydrate version of the drug. *SmithKline Beecham Corp.*, 365 F.3d at 1309.

169. And, in this case, unpatentable material. Recall that Ferrosan obtained U.S. Patent No. 4,007,196 (issued Feb. 8, 1977) over paroxetine hydrochloride in 1977. ‘196 Patent. Ferrosan’s patent covered the anhydrous form. *Id.* Therefore, under 35 U.S.C. § 102 (b), the anhydrous form of paroxetine hydrochloride hemihydrate was unpatentable in the United States. 35 U.S.C. § 102.

During the prior decision, the panel overlooked the alternative ground upon which to decide the case. The court paid little attention to the scope of Ferrosan’s ‘196 patent beyond noting that it covered the anhydrous form of paroxetine hydrochloride. Had the court focused on the scope of the ‘196 patent and the fact that there is no evidence to suggest that the chemist who “discovered” the new and more stable crystalline form of paroxetine hydrochloride was doing anything other than practicing the prior art (the ‘196 patent), the court may have recognized inherent anticipation as an alternative ground for invalidating SmithKline Beecham Corp.’s ‘723 patent. The Federal Circuit stated that a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent. *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Applying the previous case law, the same panel subsequently invalidated claim 1 of the ‘723 patent on remand on the ground of inherent anticipation. *SmithKline Beecham Corp.*, 403 F.3d at 1345.

170. 1-4 CHISUM, *supra* note 27, § 4.02.

171. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564-66 (Fed. Cir. 1996).

purpose, such as a pharmaceutical agent, the patentee can establish sufficient minimum utility of the chemical composition *before* subjecting it to clinical tests. In this situation, emphasis must be placed again on the scope of the claim. A chemical composition of matter claim pertains only to a chemical structure.¹⁷² If the claim is narrower than a mere chemical composition, and recites specific limitations upon the chemical composition, such as stating that it is an effective antidepressant agent, then minimum utility must include evidence that the invention functions as claimed, namely, as an antidepressant.¹⁷³ In that situation, clinical trials would be appropriate, if not necessary, modes of experimentation to test the claimed invention. Therefore, an attorney counseling a client on whether the inventor's actions constitute experimental use need not look further than the inventor's patent.

B. SmithKline Beecham Corp. Attempted to Create a New Two-Part Test for Public Use

The majority in the prior *SmithKline Beecham Corp.* decision erroneously applied a two-part test for public use. The majority correctly stated that in *Pfaff v. Wells Electronics, Inc.*¹⁷⁴ the Supreme Court eliminated the totality of the circumstances test for the on sale bar, adopting a two-part test.¹⁷⁵ *Pfaff*, however, does not apply to public use cases.¹⁷⁶ The Federal Circuit established the totality of the circumstances test for public use in *TP Lab., Inc., v. Professional Positioners, Inc.*¹⁷⁷ The three-judge panel that decided *SmithKline Beecham Corp.* was not competent to overrule *TP Lab., Inc.* because Federal Circuit panel decisions are binding on all subsequent panels, unless overruled *en banc*.¹⁷⁸

172. 1-4 CHISUM, *supra* note 27, § 4.02.

173. See generally *SmithKline Beecham Corp.*, 365 F.3d 1306 (Fed. Cir. 2004).

174. 525 U.S. 55 (1998).

175. *Id.* at 66-67. The Court stated:

We conclude, therefore, that the on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.

Id. at 67.

176. See *White*, *supra* note 152, at 424 (discussing the need to eliminate the totality of the circumstances test for public use and to create a two-part test fashioned after *Pfaff* that replaces the first prong of the *Pfaff* test with the condition that the invention must be dedicated to the public or there must be detrimental public reliance that the invention is in the public domain); *Begalle*, *supra* note 154.

177. 724 F.2d 965, 972 (Fed. Cir. 1984).

178. *El-Shifa Pharm. Indus. Co. v. United States* 378 F.3d 1346, 1352 (Fed. Cir. 2004). “[T]o overrule a precedent, the court must rule *en banc*.” *Id.* “This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *en banc*.” *Newell Co., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988).

CONCLUSION

In the aftermath of *SmithKline Beecham Corp.*, questions remain as to whether clinical trials may constitute public use. With the Federal Circuit's decision to vacate the prior *SmithKline Beecham Corp.* decision regarding experimental use without discussion, it has left open the question. The reasoning behind the panel's prior decision would have promoted certainty in patent law by reinforcing the limitation of experimental use to explicit or inherent features of the claimed invention. Application of that reasoning to clinical trials, however, seems unpalatable in light of the enormous amounts of time, effort, and money that pharmaceutical companies pour into research and development. The reasoning seems less controversial, however, when applied to other patented inventions, such as a dock, activity mat, or light assembly to be mounted on a light pole.

Moreover, clinical trials would still constitute experimental use if the inventor is diligent in testing the claimed features of the invention. This outcome breathes equity into patent law by allowing an inventor to predict whether an experimental activity is permissible by simply looking to the language of the claim.

