

THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



ABUSE OF PUBLIC USE? EXPLORING *SMITHKLINE V. APOTEX* AND THE
FUTURE OF PUBLIC USE

ARTEM N. SOKOLOV

ABSTRACT

In *SmithKline Beecham Corp. v. Apotex Corp.*, the court incorrectly applied the statutory public use bar and held the clinical trials did not constitute an experimental use. This ruling set the bar too high. Applying a narrow construction of the law, the CAFC invalidated a claim in a clear case of experimental use. The decision not only misapplied the precedent defining an “inherent” feature of the invention, but also essentially eliminated the need for applying the policies that underlie and define the public use bar under 35 U.S.C. § 102(b).

Copyright © 2005 The John Marshall Law School



Cite as Artem N. Sokolov, Comment, *Abuse Of Public Use? Exploring SmithKline v. Apotex and the Future of Public Use*, 4 J. MARSHALL REV. INTELL. PROP. L. 559 (2005).

ABUSE OF PUBLIC USE? EXPLORING *SMITHKLINE V. APOTEX* AND THE FUTURE OF PUBLIC USE

ARTEM N. SOKOLOV*

INTRODUCTION

Pharmaceutical companies invest heavily in research and development of new drugs. But, how can these companies be assured they will recoup the price of this investment if a new successful drug or therapy is developed? The United States Court of Appeals for the Federal Circuit (“CAFC”) in *SmithKline Beecham Corp. v. Apotex Corp.* (“*SmithKline*”) dealt a major blow to the security of pharmaceutical investments when it decided that clinical trials did not qualify for the experimental use negation of the public use bar under 35 U.S.C. § 102(b).¹

Created by judges, the experimental use doctrine and its underlying policies aim to strengthen an inventor’s faith in the patent system, while ensuring that the inventions are made available to society as quickly as possible.² By establishing a precedent where these policies have no effect on the outcome of the court’s decision, the CAFC failed to serve the purpose of the experimental use doctrine and the public use bar. Therefore, the court should reexamine the public use bar under § 102(b) so that the application of this bar produces predictable outcomes consistent with its underlying policies.³

There are three main purposes of the United States federal patent system: “first to foster and reward invention; second, to promote disclosure of inventions, to stimulate further innovation, and to permit the public to practice the invention once the patent expires; and third, to assure that ideas there for the free use of the public.”⁴

* J.D. Candidate, May 2006, The John Marshall Law School. The author would like to thank his family and friends for their continuous support. The author would also like to thank some of the people who made this article possible, Prof. Mark E. Wojcik, Prof. Doris Long, Troy A. Groetken, Mark W. Scott and Anatoliy N. Sokolov, in addition to many others. Last but not least the author would like to thank his editors and the entire board of The John Marshall Review of Intellectual Property Law for their help, support and editorial assistance.

¹ See generally *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004). On April 21, 2004, the CAFC overturned the District Court for the Northern District of Illinois and held that clinical trials did not constitute an experimental use because they were not aimed at testing claimed features of the invention. *Id.* at 1308.

² See generally *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134–35 (1877) (recognizing the experimental use doctrine for the first time).

³ On April 8, 2004 the CAFC granted en banc review of this case on the limited purpose of addressing the experimental use issue. *SmithKline Beecham Corp. v. Apotex Corp.*, No. 03-1285, 2005 U.S. App. LEXIS 5671, at *3 (Fed. Cir. 2005); see also 35 U.S.C. § 102(b) (2000). The statute states that:

A person shall be entitled to a patent unless . . . 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.

⁴ *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262–63 (1979).

The experimental use negation of the public use bar fits squarely into the first purpose articulated above. Experimental use allows the inventor to pursue an interest in testing and perfecting his invention while preserving his patent rights should a patent issue.⁵ Courts foster invention by assuring that the patent system instills confidence in all inventors, including pharmaceutical companies. This confidence results in pharmaceutical companies continuing to invest heavily in research and development of new drugs.

This comment focuses on analysis of reduction to practice, as well as the application and effect of the *SmithKline* decision on the future of the statutory public use bar under § 102(b). Part I provides background information regarding the development and the policy underlying the public use bar under § 102(b), the negation of this bar through experimental use and how courts determine a reduction to practice for the purpose of applying this statutory bar. Part I also introduces the parties involved in *SmithKline* and the appellate history of this infringement action. Part II analyzes and critiques the *SmithKline* decision to predict its effect on future cases and the interpretation of the experimental use doctrine. Part III sets forth proposed solutions and policy considerations. In particular, Part III suggests to adjust the application of the public use bar to realign it with the policies that shaped the bar's development. Finally, Part IV concludes the discussion by providing an overview of the problem and summarizing the potential solutions.

I. BACKGROUND

A. *Introduction to the Case Law, Statutes and the Analysis Employed by the Court in SmithKline*

The United States Constitution vested in Congress the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁶ This provision gave Congress the power to develop the national patent system and shape it as necessary, resulting in the system that exists today. The desire to further such progress has motivated the courts over the years to create the following policies and doctrines.

1. *Public Use*

The statutory bar under § 102(b) prevents a patent from issuing, or negates an already issued patent, if the invention becomes available in public use or on sale in

⁵ See 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. § 102(b) Does Not Prevent Issuance of Valid Patent*, 171 A.L.R. FED. 39 (2001).

⁶ U.S. CONST. art. I, § 8, cl. 8.

the United States, more than one year prior to the filing date of the application.⁷ Public use, for the purpose of this statute, occurs when someone other than the inventor uses the claimed invention without any confidentiality restriction.⁸ Several underlying policies drive the application of the public use bar. Courts must apply these policies when evaluating cases because the policies, in effect, define the public use bar.⁹ These policies include:

- i. Encouraging the inventor to promptly disclose new and useful information;
- ii. Preventing the extension of the length of patent protection by not allowing the inventor to reap commercial benefits for longer than the statutorily authorized time period; and
- iii. Discouraging “the removal of inventions from public domain which the public justifiably comes to believe are freely available.”¹⁰

Courts consider all three policies when determining whether to invalidate a claim for public use.¹¹ In particular, courts emphasize the discouragement of removing inventions believed by the public to be available.¹² However, these policies have historically taken a back seat to the interests of the inventor where the court found the public use occurred for the purpose of experimentation.¹³

2. *Experimental Use Doctrine*

Courts have recognized that an inventor may conduct extensive tests of his invention, even in the public eye, if the experiments¹⁴ aim to bring the invention to

⁷ See 35 U.S.C. § 102(b) (2000). For an extensive discussion of the history and development of the Public Use doctrine as well as the underlying policies, see generally 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 (2002).

⁸ See *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002) (finding lack of a confidentiality agreement significant because the disclosure was to a person skilled in the art of the invention who could easily demonstrate the invention to others). Further, the invention may be used by the public for the purpose of the statutory bar even if such use occurs outside of the “public eye.” See *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881).

⁹ See *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 1198 (Fed. Cir. 1994) (discussing the underlying policies of the public use bar and listing the underlying policies).

¹⁰ See *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550 (Fed. Cir. 1990); see also *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984).

¹¹ See *Cont'l Plastics Containers v. Owens Brockway Plastic Prods.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998).

¹² See *id.*

¹³ See Jay David Schainholz, *Note: The Validity of Patents After Market Testing: A New and Improved Experimental Use Doctrine*, 85 COLUM. L. REV. 371, 383 (1985); see also Upadhye, *supra* note 7, at 12 (discussing the experimental use doctrine historically).

¹⁴ See 2 CHISUM, *supra* note 14, § 6.02[7][b] (2005). Looking to the authority on what constitutes an experiment there seems to be a split: while some cases suggest an experiment should be performed with an eye toward “developing, perfecting, completing, or reducing to practice the invention.” *Id.*; see also *Aerovox Corp. v. Polymet Mfg. Corp.*, 67 F.2d 860, 862 (2d Cir. 1933) (holding that an inventor may test his invention “not only to put it into definitive form, but to see whether his ideas are worth exploiting, [however,] if in so doing he does in fact exploit the completed invention commercially he takes a chance that he may lose his patent”).

perfection or are designed to ascertain whether the invention will work for its intended purpose.¹⁵ Supreme Court decisions applying the experimental use doctrine seem to indicate that as long as public use of an invention remains restricted to experiments reasonably necessary to determine the practical utility of the invention, courts should avoid invalidating patents under 102(b).¹⁶ This line of thinking seems to directly conflict with the policies underlying the application of the statutory bar described above.¹⁷ In some cases, however, the importance of delivering completed inventions to the public outweighs the policies defining public use.¹⁸ Courts resolve this conflict of policies through the application of the reasonable purpose test.¹⁹

Additionally, court considers the totality of the circumstances when determining whether a use that is not experimental should be considered public within the

¹⁵ When the delay to take out a patent is justified by a *bona fide* effort “to bring [the] invention to perfection, or to ascertain whether it will answer the purpose intended” the inventor does not acquire an undue advantage over the public because it is in the public’s interest that “the invention should be perfect and properly tested before a patent is granted.” *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 933 (N.D. Ill. 2001) (quoting *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 64 (1999)).

¹⁶; In *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1877), seventy five feet of pavement was laid down on a publicly used road owned by the company for the purpose of testing its durability through constant use by different types of wagons and the effect of weather conditions on the road. *Id.* at 126–30. Explaining its decision not to apply the statutory public use bar the Court stated:

When the subject of invention is a machine, it may be tested and tried in a building, either with or without closed doors. In either case, such use is not a public use, within the meaning of the statute, so long as the inventor is engaged, in good faith, in testing its operation. He may see cause to alter it and improve it, or not. His experiments will reveal the fact whether any and what alterations may be necessary. If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished. And though, during all that period, he may not find that any changes are necessary, yet he may be justly said to be using his machine only by way of experiment; and no one would say that such a use, pursued with a *bona fide* intent of testing the qualities of the machine, would be a public use, within the meaning of the statute. So long as he does not voluntarily allow others to make it and use it, and so long as it is not on sale for general use, he keeps the invention under his own control, and does not lose his title to a patent.

Id. at 134–35. Other Supreme Court cases include: *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1877); *Egbert v. Lippman*, 104 U.S. 333 (1881); *Hall v. MacNeale*, 107 U.S. 90 (1883); *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249 (1887); *Int’l Tooth-Crown Co. v. Gaylord*, 140 U.S. 55 (1891); *Root v. Third Ave. R.R. Co.*, 146 U.S. 210 (1892); *see also* 2–6 CHISUM, *supra* note 14, § 6.02[7][a] (discussing the Supreme Court cases listed above).

¹⁷ *See TP Labs., Inc. v. Prof’l Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984).

¹⁸ *See Schainholz*, *supra* note 13, at 383 (explaining that this approach under the experimental use doctrine is evidence of “society’s willingness to accept the risk of detrimental reliance when, because of the nature of the product, public experimentation must take place”). The balance between the conflicting policies in this case is discussed *infra* Part III.C.

¹⁹ *See Kimball Int’l, Inc. v. Allen Organ Co.*, 212 U.S.P.Q. (BNA) 584, 586 (S.D. Ind. 1981) (“The determination of the inventor’s purpose, motive, intent, etc., is essential in the determination of the applicability of the experimental use doctrine.”); 2 CHISUM, *supra* note 14, § 6.02[7][b] (“If the purpose was experimental and the activity reasonable, it does not matter that the inventor benefits incidentally from the activity.”).

meaning of § 102(b).²⁰ Specifically, courts have utilized factors, including the length of the test period, receipt of payment for the testing, whether any obligations of confidentiality between the participants in the test and the inventor existed, records of testing kept by the inventor and any progress made, whether persons other than the inventor performed the testing, and finally the number of tests performed.²¹

The experimental use negation²² does not extend beyond the purpose of perfecting the invention or experiments performed with respect to features not claimed in the invention.²³ However, specific precedent exists where courts have allowed testing of features not expressly claimed in the patent application, when those tests concerned features “inherent” in the claimed invention.²⁴

3. *Reduction to Practice*

An important step in the public use analysis involves the determination of whether an inventor has reduced his invention to practice. Once reduced to practice,

²⁰ See *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544 (Fed. Cir. 1997) (explaining that “all of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighted against the policies underlying section 102(b)”).

²¹ See *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1535 (Fed. Cir. 1984) (finding lack of a confidentiality agreement when considered in conjunction with other factors enough to establish a public use for the purpose of § 102(b)); *Baxter Int'l, Inc. v. Cobe Labs., Inc.*, 88 F.3d 1054, 1060 (Fed. Cir. 1996) (listing evidentiary factors); *Netscape Communications Corp.*, 295 F.3d at 1320–21 (discussing and applying factors leading the court to hold the patent invalid).

²² *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1317 (Fed. Cir. 2004). In discussing the development of the experimental use doctrine Judge Rader stated: “The experimental use doctrine is not an ‘exception’ to the public use bar because it does not shift the burden of proof from the accused infringer to the patentee. Rather it operates to negate application of the public use bar.” *Id.* Therefore, the burden is on the challenger of the patent to prove that the non-experimental use was public under § 102(b). However, the patent owner is not completely relieved of any duty; once an accused infringer makes a prima facie case of public use, it becomes the duty of the patent owner to counter that showing. See *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984) (discussing the shifting burden of proof).

²³ *In re Smith*, 714 F.2d 1127, 1136 (Fed. Cir. 1983) (reasoning that when the party already knew the technical efficacy of their invention, tests measuring the efficacy were unnecessary). “Testing or experimentation performed with respect to non-claimed features of the device does not show that the invention was the subject of experimentation.” *W. Marine Elecs. v. Furuno Elec. Co.*, 764 F.2d 840, 847 (Fed. Cir. 1985); see also *In re Application of Theis*, 610 F.2d 786, 793 (C.C.P.A. 1979) (holding that “most of the ‘experimenting’ done on the systems was done for the purpose of correcting problems with the telephone interface. The claims do not require that the system be used with a telephone system. Thus, any work done to improve the operation of the system as it is used with telephone equipment does not aid appellant’s experimental use argument.”).

²⁴ See *EZ Dock, Inc. v. Schafer Sys. Inc.*, 276 F.3d 1347, 1353 (Fed. Cir. 2002). In this case, even though the patentee sold the dock more than one year before filing the patent application the court agreed that the use of the dock was experimental. *Id.* at 1353–54. Significantly, the court accepted evidence showing that the reason for the sale was to determine whether the dock would function in its intended environment even though the experiments did not test features claimed in the patent. *Id.*; see also *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1320, 1324 (Fed. Cir. 1996); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550–51 (Fed. Cir. 1990).

the invention works for the purpose intended and as such, concludes any need for further experimentation for the purpose of the § 102(b) bar.²⁵ In *Estee Lauder v. L'Oreal*, Judge Mayer applied a three-element test to determine a reduction to practice.²⁶ The specific elements of the test included: "(i) production of a composition of matter satisfying the limitations of the count, (ii) recognition of the composition of matter, and (iii) recognition of a specific practical utility for the composition."²⁷ The court held that an invention is reduced to practice under 35 U.S.C. § 112 when the inventor "actually prepare[s] the composition and [knows] that it will work."²⁸ This recognition of practical utility differs from the utility requirement under 35 U.S.C. § 101 discussed in the next section.²⁹

An invention cannot be reduced to practice by accident; the inventor must recognize the tests establishing a reduction to practice as successful.³⁰ Recognition of success directly intertwines with the utility requirement of patentability.³¹ A chemical compound, like all inventions, must have utility in order to qualify for patent protection.³² However, for a chemical compound, reduction to practice under § 112 cannot occur until such compound becomes completely composed.³³ Therefore, regardless of whether the claims of the patent contain any specific reference to

²⁵ See *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 935 (N.D. Ill. 2001); see also *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061 (Fed. Cir. 1989) (holding that "having been reduced to practice, a sale or offer to sell the Cole invention is no longer justifiable as experimental use.").

²⁶ 129 F.3d 588, 593 (Fed. Cir. 1997) (holding that when testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur).

²⁷ *Id.* at 592.

²⁸ *Id.*; see also *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989); *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). Reduction to practice is effected when the inventor's conception is in a form that is capable of practical and successful use. *Pyrene-Minimax Corp. v. Palmer*, 89 F.2d 505, 510 (D.C. Cir. 1937).

²⁹ Compare *Commonwealth Eng'g Co. v. Ladd*, 199 F. Supp. 51, 53 (D.D.C. 1961) (finding that if the invention possesses any degree of usefulness, it satisfies the utility requirements of § 101), with *Burroughs Wellcome Co.*, 40 F.3d at 1228 (holding that a reduction to practice requires "the discovery that an invention *actually works*" (emphasis added)).

³⁰ See *Josserand v. Taylor*, 138 F.2d 58, 65 (C.C.P.A. 1943) (finding that accidental practice of an invention is not a "conscious incorporation of the invention in issue such as would constitute a reduction to practice."); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1336 (Fed. Cir. 2001) (reasoning that "accidental, unappreciated reduction to practice should not constitute a 'true' reduction to practice").

³¹ See 35 U.S.C. § 101 (2000) (to get a patent the process at issue must be useful).

³² See *Blicke v. Treves*, 241 F.2d 718, 719 (C.C.P.A. 1957). In this case the appellant relies on the Supreme Court case of *Corona Cord Tire Co. v. Dovan Chemical Corp.* and argues that the making of a compound without testing is sufficient to show a reduction to practice. *Id.* However, the CAFC has repeatedly considered that decision and found that as it relates to the necessity of tests the decision is only dictum and cannot be taken to mean that the mere production of a compound without testing will always be sufficient for reduction to practice. *Blicke*, 241 F.2d at 720. Past court decisions have shown that a certain common sense approach should be applied when evaluating whether tests are necessary because some devices are so simple that once constructed, are sufficient proof of reduction to practice. See, e.g., *Gordon v. Hubbard*, 347 F.2d 1001, 1006 (C.C.P.A. 1965) (mere construction can be used to show that the device functions satisfactorily).

³³ See *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 383 (1928).

utility, the invention remains incomplete unless the utility is obvious or established by proper tests.³⁴

4. *The Utility Requirement Under 35 U.S.C. § 101*

The legal requirements for patentability include novelty, utility and nonobviousness.³⁵ To meet the utility requirement under 35 U.S.C. § 101, an invention must perform a “useful” function, or some function that can benefit society.³⁶ However, the standard for proving utility under 35 U.S.C. § 101 is very low. If the invention possesses *any* degree of usefulness, it satisfies the utility requirements of § 101.³⁷

Courts do not require a higher standard of proof for utility when dealing with a chemical compound.³⁸ Many courts, however, have recognized the difficulty of predicting pharmaceutical behavior and proceeded cautiously before recognizing the utility of a compound without clinical proof.³⁹ For this reason, proof of utility of a chemical compound usually requires tests or other evidence of the asserted utility.⁴⁰ Furthermore, because of this higher standard, even when those skilled in the art know the behavior of analogous compounds, courts require evidence of utility.⁴¹

³⁴ See *Blicke*, 241 F.2d at 720. Reduction to practice is a question that must be decided based on the facts of the case involved. *Id.*

³⁵ See 35 U.S.C. §§ 101–03 (2000).

³⁶ See 1 CHISUM, *supra* note 14, § 4.02. The invention must be “more than a mere curiosity, a scientific process exciting wonder yet not producing physical results, or [a] frivolous or trifling article or operation not aiding in the progress nor increasing the possession of the human race.” *Id.* (citations omitted).

³⁷ See *Commonwealth Eng’g Co. v. Ladd*, 199 F. Supp. 51, 53 (D.D.C. 1961) (emphasis added).

³⁸ 1 CHISUM, *supra* note 14, § 4.04[2]. The test remains “whether one with ordinary skill in the art to which the invention pertains would question the assertion of utility, and if so, whether the inventor has supplied such evidence through tests or otherwise as would convince such a person of the invention’s asserted utility.” *Id.*

³⁹ See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996).

It may be difficult to predict, however, whether a novel compound will exhibit pharmacological activity, even when the behavior of analogous compounds is known to those skilled in the art. Consequently, testing is often required to establish practical utility In other words, there must be a sufficient correlation between the tests and an asserted pharmacological activity so as to convince those skilled in the art, to a reasonable probability, that the novel compound will exhibit the asserted pharmacological behavior.

Id. (citations omitted).

⁴⁰ “Proof of utility under this section may be established by clinical or *in vivo* or *in vitro* data, or a combination of these, which would be convincing to those skilled in the art.” 1 CHISUM, *supra* note 14, § 4.04[2]. Tests *in vitro* mean: “In an artificial environment, referring to a process or reaction occurring therein, as in a test tube or culture media.” STEDMAN’S MEDICAL DICTIONARY 919 (27th ed. 2000). Tests *in vivo* mean: “In the living body, referring to a process or reaction occurring therein.” *Id.* If the utility of the compound is solely for the treatment of humans, evidence of utility must generally be clinical evidence. CHISUM, *supra* § 4.04[2]. In *SmithKline*, the trial court held the clinical trials on humans necessary before the invention could be reduced to practice. *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 925, 936 (Fed. Cir. 2004).

⁴¹ *Fujikawa*, 93 F.3d at 1564 (finding that “it may be difficult to predict . . . whether a novel compound will exhibit pharmacological activity, even when the behavior of analogous compounds is

5. Claim Construction

The claims of a patent define the invention protected by the patent.⁴² However, claims function only as legal definitions and not descriptions; therefore, construing claims involves looking to the drawings and the specification.⁴³

When evaluating an invention for the purpose of applying the public use bar under § 102(b), courts consider each claim of the patent individually.⁴⁴ Additionally, when a court considers a claim it must afford that claim a presumption of validity.⁴⁵ To rebut this presumption, the movant must meet a standard of proof greater than a preponderance of the evidence.⁴⁶ Further, a patent application may only cover a single independent invention, however, using multiple claims can broaden the scope of that single invention.⁴⁷

known to those skilled in the art. Consequently, testing is often required to establish practical utility.”)

⁴² See *Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935); *Gen. Elec. Co. v. Wabash Appliance Corp.* 304 U.S. 364, 369 n.5 (1938).

An applicant for a patent must include in his application one or more claims which set forth the parameters of the invention. These claims measure the invention for determining patentability both during examination and after issuance when validity is challenged. They also determine what constitutes infringement. A claim recites a number of elements or limitations, and will cover or ‘read on’ only those products (or processes) that contain all such elements or limitations. Effective claims must be neither too broad (*i.e.*, cover the prior art or matter not adequately described in the specification) nor too narrow (*i.e.*, fail to cover all possible embodiments of the applicant’s invention). The applicant may for safety’s sake include a reasonable number of claims of varying scope.

1 CHISUM, *supra* note 14, *Glossary*, at 3.

⁴³ See *Maclaren v. B-I-W Group, Inc.*, 401 F. Supp 283, 301 (S.D.N.Y. 1975), *rev’d on other grounds*, 535 F.2d 1367 (2d Cir. 1976). Recitation of every element that is needed for practical utilization of claimed subject matter is not necessary in the claim. *Bendix Corp. v. United States*, 600 F.2d 1364, 1369 (Ct. Cl. 1979).

⁴⁴ See *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1122 n.5 (Fed. Cir. 1996).

⁴⁵ See 35 U.S.C. § 282 (2000) (patents are presumed valid); *see also* *Parker v. Motorola, Inc.*, 524 F.2d 518, 521 (5th Cir. 1975) (explaining that presumption of validity is based upon “the experience and expertise of patent office . . . and [thel] recognition that patent approval is a species of [an] administrative determination supported by evidence,” and the standard of proof to rebut this presumption is “greater than mere preponderance of evidence.”).

⁴⁶ See *Parker*, 524 F.2d at 521.

⁴⁷ See *Monsanto Chem. Co. v. Coe*, 145 F.2d 18, 19 n.41 (D.C. Cir. 1944).

Two or more independent inventions can not be claimed in one application; but where several distinct inventions are dependent upon each other and mutually contribute to produce a single result they may be claimed in one application: Provided, That more than one species of an invention, not to exceed three, may be claimed in one application if that application also includes an allowable claim generic to all the claimed species. In the first action on an application containing a generic claim or claims and claims to more than one species there under the examiner, if he is of the opinion after a complete search that no generic claim presented is allowable, shall require the applicant in his response to that action to elect that species of his invention to which his claims shall be restricted if no generic claim is finally held allowable.

Id.

B. Introduction to the Parties and the Lower Court Decision

1. The SmithKline Beecham Corporation

SmithKline Beecham Corporation (now GlaxoSmithKline) focuses its business on research, development, manufacture and sale of pharmaceutical products throughout the world.⁴⁸ SmithKline filed an application for the drug Paxil^{®49} on October 23, 1986, which established the “critical date”⁵⁰ for the purpose of this litigation.⁵¹ Before filing the application, SmithKline conducted clinical trials to test the safety and efficacy of the drug as an antidepressant.⁵²

2. The Apotex Corporation

The Apotex Corporation is a pharmaceutical company specializing in manufacturing, biotechnology research and distribution in the generic pharmaceuticals market. Apotex sought to create its own generic version of Paxil[®] and filed an ANDA application with the FDA in 1998.⁵³ Additionally, Apotex asserted in its case against SmithKline that its version of the antidepressant would not infringe SmithKline’s patent and therefore indicated through a Paragraph IV certification its intention to market the drug before the expiration of patent No. 4,721,723 (“723 patent”).⁵⁴

3. Case Development

⁴⁸ See *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 929 (N.D. Ill. 2001).

⁴⁹ See U.S. Patent No. 4,721,723 (issued Jan. 26, 1988).

⁵⁰ Critical date is the term used by the courts as the date on which the one-year term starts for the purpose of applying the public use bar § 102(b). *In re Epstein*, 32 F.3d 1559, 1564 n.5 (Fed. Cir. 1994).

⁵¹ The ‘723 patent in this case was issued in 1988, but the FDA approval process for marketing the drug was not completed until 1993. *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1309 (Fed. Cir. 2004). This means that the drug was not on the market for five years undergoing clinical trials strictly for the purpose of FDA approval. *Id.* The clinical trials had no effect on the time limit of patent protection of the ‘723 patent leaving the drug only thirteen out of the eighteen years available to market and sell the drug. *Id.*

⁵² The clinical trials began May 3, 1985 and were concluded on December 29, 1986. *SmithKline Beecham Corp.*, 286 F. Supp. 2d at 932. SmithKline designed a rigorous test protocol to be used by the investigators and conducted site visits to make sure the protocol was followed. *Id.* Patients involved in the study knew that the drug was used as part of the study but not if it was administered to them as five out of the seven tests used were “double blinded.” *Id.* A double-blind test is a control group test where neither the evaluator nor the subject knows which items are controls. See *SmithKline Beecham Corp.*, 365 F.3d at 1309. These tests are conducted to reduce error, self-deception and bias. *Id.* The patients did not have to pay to participate in the study and the clinical trials lasted less than two years. See *SmithKline Beecham Corp.*, 286 F. Supp. 2d at 935.

⁵³ See *SmithKline Beecham Corp.*, 365 F.3d at 1309.

⁵⁴ *SmithKline Beecham Corp.*, 365 F.3d at 1309; see 21 U.S.C. § 355(j)(2)(A)(IV) (2000).

On the Basis of Apotex's ANDA filing, SmithKline initiated an infringement action under 35 U.S.C. § 271 (e)(2), alleging multiple theories of infringement. However, this comment's focus is only upon the public use defense initiated by Apotex. The district court found that SmithKline exercised sufficient control of the clinical trials and that the clinical trials were experimental in purpose. Therefore, the lower court determined SmithKline's actions were consistent with the goals underlying the experimental use doctrine.⁵⁵ As such, the court declined to apply the statutory bar under § 102(b).⁵⁶ The CAFC reversed and applied the public use bar under § 102(b).⁵⁷ The following sections focus on the decision of the CAFC.

II. ANALYSIS

In *SmithKline*, the CAFC in a 2-1 decision reversed the district court, finding that SmithKline's clinical trials to determine the efficacy of the drug as an antidepressant constituted a public use under 35 U.S.C. § 102(b).⁵⁸ This section considers whether the CAFC erred in its application of the public use bar of § 102(b). Part A examines whether the court correctly analyzed claim 1 of the '723 patent. Part B discusses the decision and the precedent it advances. Part C analyzes whether the decision advanced the underlying policies of patent law and the public use bar.

A. *The Court Incorrectly Found That the Clinical Trials Involved Testing of Features Not Inherent to the Invention*

The antidepressant properties of the claimed compound, PHC hemihydrate, are inherent to the structure of the compound. Those properties had to be considered for the utility analysis under 35 U.S.C. § 101 and the reduction to practice analysis under § 112.⁵⁹ Therefore, courts should consider those same properties claimed features of the invention for the purpose of § 102(b) analysis. Part 1 of this section

⁵⁵ *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 934 (N.D. Ill. 2001) (applying the totality of circumstances test and finding that the strict protocol, visits to the site by SmithKline, the investigator agreement, lack of payment and the duration of the trials were all a strong indication that the trials were experimental in their nature and purpose).

⁵⁶ *Id.* at 936. In the opinion, Judge Kocoras stated that "the reduction to practice rule essentially mirrors the unchallenged requirement that any qualifying experimental use be aimed at perfecting the invention or testing its effectiveness." The Judge also found that further tests were necessary to determine whether the drug would function for its intended use. *See id.* at 938.

⁵⁷ *See SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1319 (Fed. Cir. 2004) (holding that the clinical trials were not directed at testing claimed features of the invention). However, on April 8, 2004 the CAFC granted en banc review of this case for the limited purpose of addressing the experimental use issue. *SmithKline Beecham Corp. v. Apotex Corp.*, No. 03-1285, 2005 U.S. App. LEXIS 5671, at *3 (Fed. Cir. 2005).

⁵⁸ *SmithKline*, 365 F.3d at 1320.

⁵⁹ Reduction to practice analysis is implicated in this case as one cannot experiment with an invention for the purpose of negating the statutory public use bar under § 102(b) if an invention is reduced to practice. *SmithKline Beecham Corp.*, 286 F. Supp. 2d at 935 (noting that experimental use necessarily ends when the invention at issue is reduced to practice).

discusses how a court determines an inherent feature and part 2 explains why the antidepressant properties of PHC hemihydrate are classified as inherent features.

1. *The Inherent Features Analysis*

Generally, the experimental use negation of the public use bar applies only to expressly claimed features of the invention.⁶⁰ However, in *SmithKline*, the CAFC acknowledged that instances exist where the experimental use doctrine remains applicable even though the experiments reflect features not claimed in the invention.⁶¹ In exceptional cases, courts have permitted the application of the experimental use doctrine to negate public use when an inventor experimented with features “inherent” to the express claims of his invention.⁶²

While patent law does not discuss what makes a feature “inherent”, case law sheds some light on this matter. In at least three instances, the CAFC characterized features of the invention as sufficiently “inherent” and therefore negated the public use aspect of experiments directed at those features.⁶³ For example, in *EZ Dock v. Schafer Systems*, the issue of the statutory bar under § 102(b) arose when the inventor tested his invention, a type of dock, in rough, choppy waters.⁶⁴ The claim at issue in *EZ Dock* did not specifically refer to the ability of the dock to function in

⁶⁰ See *In re Application of Theis*, 610 F.2d 786, 793 (C.C.P.A. 1979); *Minn. Mining & Mfg. Co. v. Kent Indus., Inc.*, 409 F.2d 99, 101 (6th Cir. 1969); *In re Brigance*, 792 F.2d 1103, 1109 (Fed. Cir. 1986).

⁶¹ *SmithKline*, 365 F.3d at 1318. The CAFC found that the antidepressant properties of the PHC hemihydrate are not inherent to the structure of the compound and held that “testing the medical efficacy and viability of PHC hemihydrate is not testing claimed features of the structural invention in claim 1.” *Id.* at 1320. However, Judge Gajarsa, while concurring in the decision, wrote a colloquial dissent, disagreeing with the majority on the issue of application of the public use bar, in which he stated:

In all four cases, the claims at issue were product claims that did not claim the tested features explicitly. In all four cases, the patentees possessed the claimed product in substantial enough form to test their products’ performance at their intended functions. The majority does not explain why only one of these four patentees had reduced its claimed invention to practice sufficiently to preclude the experimental use doctrine. I see no principled grounds on which to distinguish this case from our precedent. . . . The majority seems to be trying to reach an ultimate conclusion of invalidity while avoiding the road less traveled.

Id. at 1325 (discussing *EZ Dock, Inc. v. Schafer Sys. Inc.*, 276 F.3d 1347 (Fed. Cir. 2002); *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1320 (Fed. Cir. 1996); and *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990)).

⁶² See, e.g., *EZ Dock*, 276 F.3d at 1347; *Seal-Flex*, 98 F.3d at 1318; *Manville Sales*, 917 F.2d at 544.

⁶³ See *EZ Dock*, 276 F.3d at 1353 (reasoning that whether the feature of the invention is inherent, is determined by looking to the nature of the invention, the claim’s reference to the subject matter is enough to satisfy the “claimed feature” requirement of experimentation); *Manville Sales*, 917 F.2d at 550–51 (holding that “[w]hen durability in an outdoor environment is inherent to the purpose of the invention then further testing to determine the invention’s ability to serve that purpose will not subject the invention to a section 102(b) bar”); see also *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 133–34 (1877) (concluding that a road surface test for “durability” by observation over six years of exposure to heavily loaded wagons constituted an experimental use).

⁶⁴ *EZ Dock*, 276 F.3d at 1349–50.

rough choppy water; it covered the dock regardless of its durability.⁶⁵ The court, however, found the ability of the dock to function in such conditions a feature inherent to the ability of the dock to function as a dock. Therefore, it was covered by the claim.⁶⁶ In *EZ Dock*, the court focused on the nature and purpose of the invention. As a result, the court determined that features which are inseparable from the claimed invention should be included in the claimed feature analysis under § 102(b).⁶⁷ Similarly, in *Manville Sales Corp. v. Paramount Systems, Inc.*, the court looked to the purpose of the invention to determine whether the properties were inherent.⁶⁸ Therefore, a feature inseparable from the invention, or its purpose, qualifies as an inherent feature for the application of § 102(b) analysis.⁶⁹

2. *The Antidepressant Properties of PHC Hemihydrate are Inherent Inseparable Features of the Compound*

In *SmithKline*, the court found that claim 1, the only claim at issue, covered the compound, PHC hemihydrate, regardless of its use as an antidepressant, because the structural claim did not expressly claim the antidepressant properties as a feature.⁷⁰ Furthermore, the court did not consider the antidepressant properties of the compound features inherent to the compound.⁷¹ The court improperly construed the antidepressant properties for the reasons articulated below.

It is commonly accepted that the nature of chemical compounds is highly unpredictable, especially in the field of medicinal chemistry.⁷² Courts have taken this into consideration when looking at the structure of a compound to determine obviousness under 35 U.S.C § 103.⁷³ Similarly, courts should consider the highly

⁶⁵ The claims are no more specific than referring to the invention as a “floating dock.” See U.S. Patent No. 5,281,055 (issued Jan. 25, 1994).

⁶⁶ *EZ Dock*, 276 F.3d at 1353.

⁶⁷ See *id.* In *Seal-Flex*, even though the issue of limiting testing to features claimed in the patent did not arise here, the Federal Circuit Court applied the facts of the case to find that because the case involved an all-weather track, “the scope of the claimed invention . . . carried the inherent implication of performance in severe weather conditions” and therefore those features were inherent to the claimed invention. *SmithKline*, 365 F.3d at 1319 (discussing *Seal-Flex*); see also *EZ Dock*, 276 F.3d at 1353 (discussing the reasoning in *Manville Sales* that “the nature of the invention (luminaries) required durability so that the claims’ reference to the subject matter placed that topic within the proper frame of experimentation”).

⁶⁸ *Manville Sales*, 917 F.2d 544, 550–51 (Fed. Cir. 1990) (holding that “[w]hen durability in an outdoor environment is inherent to the purpose of the invention then further testing to determine the invention’s ability to serve that purpose will not subject the invention to a section 102(b) bar”).

⁶⁹ Black’s Law dictionary states that for something to be inherent is for it “[t]o exist as a permanent, inseparable, or essential attribute or quality of a thing.” BLACK’S LAW DICTIONARY 798 (8th ed. 2004). “Existing in someone or something as a natural and inseparable quality, characteristic, or right.” WEBSTER’S NEW UNIVERSAL UNABRIDGED DICTIONARY 943 (2d ed. 1979).

⁷⁰ See *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1318 (Fed. Cir. 2004).

⁷¹ See *Id.* at 1320.

⁷² 2 CHISUM, *supra* note 14, §5.04[6] n.3. “The unpredictable nature of chemical reactions is especially pronounced, of course, when dealing with medicinal chemistry, where the biological effects of chemical reactions may be exceedingly difficult to predict from the chemical structure of a compound.” *Id.*

⁷³ See *In re Mayne*, 104 F.3d 1339, 1342 (Fed. Cir. 1997).

unpredictable nature of chemicals when determining utility under 35 U.S.C. § 101, because this analysis also involves looking at the structure of the chemical. In a leading case in the field of chemical compounds, *In re Papesch*, the court held that due to the unpredictable nature of such chemicals, courts cannot consider structure alone as the basis for determining patentability.⁷⁴ The court stated “from the standpoint of patent law, a compound and all of its properties are inseparable.”⁷⁵

Properties of the chemical compound considered inseparable from the structure would qualify as inherent properties under the analysis of the court in *EZ Dock*. Additionally, in *Manville*, the court looked to the purpose of the invention to determine whether the properties of that invention qualified as inherent.⁷⁶ Similar to *In re Papesch*, *SmithKline* involved a chemical compound, therefore, making the properties of that compound inseparable from its structure. Additionally, the invention in *SmithKline* served as an antidepressant and the properties of the compound directly related to that purpose, thereby meeting the requirements announced by the court in *Manville*.⁷⁷ It follows then, that the antidepressant properties of PHC hemihydrate represent inherent properties of the compound.

Standards for the patenting of chemical entities have evolved. At one time, the PTO focused only on the “structural obviousness” of the chemical entity. Under this standard, the structural formula of the claimed compound was compared for similarity with the structural formulae of known compounds. This regime did not allow evidence of unexpected results to trump the conclusion of obviousness based on structure. Over thirty years ago, courts recognized that unexpected properties can show that a claimed compound that appeared to be obvious on structural grounds was not obvious when looked at as a whole.

Id.

⁷⁴ *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963).

⁷⁵ *Id.* (holding that failure to take into consideration the pharmaceutical or biological property of a compound on the ground that its structure would be obvious to one ordinarily skilled in the art is a fundamental error of law). Judge Rich stated:

From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, and the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. But a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it. And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison. An assumed similarity based on a comparison of formulae must give way to evidence that the assumption is erroneous.

Id.

⁷⁶ 917 F.2d at 550–51 (holding that “[w]hen durability in an outdoor environment is inherent to the purpose of the invention then further testing to determine the inventions ability to serve that purpose will not subject the invention to a section 102(b) bar.”).

⁷⁷ *See Id.* (if inherent to the purpose of the invention then further testing will not subject it to the §102(b) bar).

B. The Antidepressant Properties of PHC Hemihydrate Inherent to its Structure Would Establish Utility Under § 101 and § 112; Therefore, the Courts Must Consider Those Same Antidepressant Properties in a § 102(b) Analysis

In order for an invention to qualify for a patent, the invention must meet three basic requirements: it must be new, useful, and nonobvious.⁷⁸ Once a patent issues, the courts give that patent a presumption of validity.⁷⁹ This presumption exists because each patent application undergoes a series of rigorous tests in the United States Patent and Trademark Office (“USPTO”) before the application issues as a patent.⁸⁰

Claim 1 of the ‘723 patent made no specific reference to utility.⁸¹ Regardless of whether the claims of the patent contain any specific reference to utility, the invention remains incomplete unless its utility is either obvious or established by proper tests.⁸² The ‘723 patent itself proves that utility under both § 101 and § 112 existed during prosecution in the USPTO, and therefore, the ‘723 patent should remain valid until proven otherwise.⁸³

Since 35 U.S.C. § 101 has a low standard for establishing utility, if an invention has any degree of usefulness, it will meet the utility requirement.⁸⁴ If courts consider only the structure of PHC hemihydrate, the structure does not render the utility of the compound obvious because the structure alone does not suggest *any* utility.⁸⁵ However, if considered inherent, the properties of PHC hemihydrate would readily satisfy this low standard.⁸⁶

The CAFC in *SmithKline* found that the invention had been reduced to practice and, thus, did not apply the experimental use negation.⁸⁷ However, there exists a

⁷⁸ See 35 U.S.C. §§ 101–103 (2000).

⁷⁹ 35 U.S.C. § 282 (2000).

⁸⁰ See *Parker v. Motorola, Inc.*, 524 F.2d 518, 521 (5th Cir. 1975) (explaining that the presumption of validity is based upon the “experience and expertise of the patent office . . . and [a] recognition that patent approval is a species of administrative determination supported by evidence” and the standard of proof to rebut this presumption is “greater than [a] mere preponderance of evidence.”).

⁸¹ Claim 1 of the patent stated “paroxetine hydrochloride hemihydrate.” U.S. Patent No. 4,721,723 (issued Jan. 26, 1988).

⁸² “Unless the utility could have been foretold with certainty, sufficient testing to establish the practical utility of the compound is required to establish an actual reduction to practice.” *De Solms v. Schoenwald*, 15 U.S.P.Q.2d 1507, 1510–11 (Bd. Pat. App. & Int’f 1990). Evidence in *SmithKline* showed that their plants had unwittingly manufactured PHC hemihydrate as early as 1984. *SmithKline*, 365 F.3d at 1309. However, accidental practice of an invention is not a “conscious incorporation of the invention in issue such as would constitute a reduction to practice.” *Josserand v. Taylor*, 138 F.2d 58, 65 (C.C.P.A. 1943); see also *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1335 (Fed. Cir. 2001) (reasoning that accidental, unappreciated reduction to practice, should not constitute a “true” reduction to practice).

⁸³ See 35 U.S.C. § 282 (2000); see also *Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 26 (Fed. Cir. 2000) (finding “[o]ne attacking the validity of a patent must present clear and convincing evidence establishing facts that lead to the legal conclusion of invalidity”).

⁸⁴ See *Commonwealth Eng’g Co. v. Ladd*, 199 F. Supp. 51, 53 (D.D.C. 1961).

⁸⁵ See *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963).

⁸⁶ Use of a chemical compound as an antidepressant would also provide the needed degree of usefulness.

⁸⁷ *SmithKline*, 365 F.3d at 1320.

separate requirement of utility for reduction to practice.⁸⁸ This requirement has a higher standard than the utility requirement under § 101.⁸⁹ Utility for the purpose of reduction to practice requires that the invention not only work, but that it also accomplishes the purpose intended.⁹⁰ If a court considers the chemical properties of the compound for the lower standard of utility under § 101, that implies that those same properties will be considered for the higher standard of utility associated with reduction to practice. Because the utility of PHC hemihydrate based on its structure alone is not obvious, the court must consider the chemical properties of the compound to establish that utility.⁹¹ In *SmithKline*, the intended purpose of PHC hemihydrate was to work as an antidepressant.⁹² Therefore, according to *EZ Dock* and the related cases, the antidepressant properties of PHC hemihydrate are inherent to the compound. As such, the CAFC erred in not considering the antidepressant properties of PHC hemihydrate for the purpose of applying the public use bar under § 102(b).

Alternatively, if the courts choose not to consider the inherent properties of PHC hemihydrate to determine utility, then such utility may be established through the administration of proper tests.⁹³ It is important to note that even when those skilled in the art know the behavior of analogous compounds, courts continue to require evidence of utility.⁹⁴ In *SmithKline*, PHC hemihydrate was a novel compound and found to be more stable than its anhydrous form.⁹⁵ Therefore, tests done previously on the anhydrous compound alone would not satisfy the requirement of adequate testing. Since the clinical trials for PHC hemihydrate did not conclude until after the filing date of the '723 patent, the inventor never completed the proper tests to establish utility. However, because the USPTO granted the '723 patent, it can be implied that the USPTO considered the properties of the chemical in its analysis of

⁸⁸ See *Estee Lauder v. L'Oreal*, 129 F.3d 588, 593 (Fed. Cir. 1997) (holding that when testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur).

⁸⁹ See *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). Reduction to practice requires "the discovery that an invention *actually* works." *Id.* (emphasis added). Reduction to practice is effected when the inventor's conception is in a form that is capable of practical and successful use. *Pyrene-Minimax Corp. v. Palmer*, 89 F.2d 505, 510 (D.C. Cir. 1937).

⁹⁰ See *Burroughs Wellcome*, 40 F.3d at 1228; *Pyrene-Minimax*, 89 F.2d at 510.

⁹¹ In addition, "this court has held in several cases that it may be proper, in determining what tests are necessary to constitute a reduction to practice, to take into consideration statements in the specifications of the applications as well as limitations appearing in the counts of interference." *Blicke v. Treves*, 241 F.2d 718, 721 (C.C.P.A. 1957). The antidepressant properties of PHC hemihydrate are mentioned in the specifications of the *SmithKline* patent. U.S. Patent No. 4,721,723 (issued Jan. 26, 1988).

⁹² In fact, in *SmithKline's* own words, "the purpose of the clinical trials was to establish that PHC hemihydrate actually worked (and was safe) as an antidepressant." *SmithKline*, 365 F.3d at 1317.

⁹³ See *De Solms v. Schoenwald*, 15 U.S.P.Q.2d (BNA) 1507, 1510–11 (Bd. Pat. App. & Int'f 1990). Proper tests in this case would determine whether the invention actually works and accomplishes the purpose intended, which in this case is to serve as an antidepressant.

⁹⁴ See *Fujikawa*, 93 F.3d at 1564 (stating "It may be difficult to predict . . . whether a novel compound will exhibit pharmacological activity, even when the behavior of analogous compounds is known to those skilled in the art. Consequently, testing is often required to establish practical utility.").

⁹⁵ *SmithKline Beecham Corp.*, 365 F.3d at 1309.

validity.⁹⁶ If the court finds utility based solely on the novel structure of a compound, without considering the properties of the compound, it would essentially remove the utility requirement from patent law and equate utility with the already existing, separate requirement of novelty.⁹⁷ The *SmithKline* decision effectively does just that.

C. The Decision of the Court in SmithKline Sets a Dangerous Precedent That Future Courts Will Struggle to Apply

Courts look to the totality of the circumstances to qualify a use of an invention as experimental.⁹⁸ Applying this approach involves weighing several factors to determine the nature of the use.⁹⁹ Additionally, courts attempt to strike a balance between conflicting interests of the inventor and the public. This balancing of interests examines the reasonable purpose of the applicant's acts at issue.¹⁰⁰ The district court in *SmithKline* found the purpose of the use experimental, rather than commercial by applying both approaches.¹⁰¹

In this case, SmithKline brought suit only under claim 1 of the '723 patent. The CAFC turned a blind eye to the analysis of the lower court and the overwhelming evidence indicating the purpose and nature of the trials. In applying a narrow construction of the "claimed feature of the invention" precedent¹⁰² in conjunction with

⁹⁶ The patent application in this case was filed on October 23, 1986 and the clinical trials concluded on December 29, 1986, two months after the patent application was filed. *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 932 (N.D. Ill. 2001).

⁹⁷ See 35 U.S.C. §§ 101–103 (2000).

⁹⁸ See *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544 (Fed. Cir. 1997); *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 67 n.13 (1998) (observing that "whether a particular activity is experimental is often clear.").

⁹⁹ See discussion *supra* part I.A.2.

¹⁰⁰ See *Kimball Int'l, Inc. v. Allen Organ Co.*, 212 U.S.P.Q. (BNA) 584, 586 (S.D. Ind. 1981) ("The determination of the inventor's purpose, motive, intent, etc., is essential in the determination of the applicability of the experimental use doctrine."); 2 CHISUM, *supra* note 14, § 6.02[7][b] ("If the purpose was experimental and the activity reasonable, it does not matter that the inventor benefits incidentally from the activity.").

¹⁰¹ *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 934–35 (N.D. Ill. 2001) (the district court found the use to be experimental by weighing factors such as the length of the test period, lack of payment for trials, implementation of strict controls and the visits to ensure that they were followed, against the lack of a confidentiality agreement). Some cases have held that lack of a confidentiality agreement is not dispositive to a finding of public use. See *Tone Bros., Inc. v. Sysco Corp.*, 28 F. 3d 1192, 1200 n.8 (Fed. Cir. 1994); *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1576 (Fed. Cir. 1995); *TP Lab. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir. 1984). In *Netscape Communications Corp.*, while holding that a lack of a confidentiality agreement was significant, it was distinguishable from the case at hand because it involved disclosure of the invention to experts in the field who fully understood the technology, while in *SmithKline* the compound was distributed to a select group who were not in a position to know whether they were taking the drug or a placebo and would not know how to duplicate the drug. See 295 F.3d at 1321.

¹⁰² See *In re Application of Theis*, 610 F.2d 786, 793 (C.C.P.A. 1979). This court and its predecessor have noted that experimentation negates a bar when the inventor tests claimed features of the invention. *Id.* (agreeing that "[i]t is settled law that the experimental sale exception does not apply to experiments performed with respect to non-claimed features of an invention."); see also *Minn. Mining & Mfg. Co. v. Kent Indus., Inc.*, 409 F.2d 99, 101 (6th Cir. 1969); *In re Brigance*, 792 F.2d 1103, 1109 (Fed. Cir. 1986).

the claim-by-claim approach, the CAFC found claim 1 invalid.¹⁰³ The claim-by-claim approach limits the review of the court to each claim individually in order to determine whether the public use bar applies.¹⁰⁴ In this case the claim-by-claim approach limited the review of the court to just the claim at issue.¹⁰⁵ Under this approach however, courts should consider other evidence present in the case—precisely what the CAFC ignored in *SmithKline*.

The CAFC erred in its narrow construction of the claim-by-claim rule because it did not place enough emphasis on the evidence of purpose and nature of the clinical trials.¹⁰⁶ In effect, the court ignored the evidence provided by the application of the totality of the circumstances approach. In fact, the CAFC inadvertently undermined its own narrow construction by attempting to distinguish *SmithKline* from cases where courts had allowed experimental use on features not expressly claimed in the patent.¹⁰⁷ The mere presence of such cases serves as strong evidence that a narrow construction of the claim-by-claim approach will not work across the board. Furthermore, this precedent has developed as a way for the court to avoid decisions which, while technically applying the rules, do not make sense and do not advance the policies set out by the court.

The *SmithKline* decision establishes a dangerous precedent not only because a decision based on such a narrow construction will prove difficult for courts to apply in the future, but also because of the extreme potential changes to the settled expectations of inventors.¹⁰⁸ Additionally, this decision could undermine existing patents by encouraging challenges to patents whose owners, in reliance on established precedent, experimented with their invention prior to filing the application. This decision will also discourage further invention and funding of research, which strikes directly against the purpose of the patent system established

¹⁰³ See *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1320 (Fed. Cir. 2004) (holding claim 1 invalid).

¹⁰⁴ See *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002) (“The on-sale bar is evaluated on a claim-by-claim basis, so that some claims of a patent may be found to be barred while others are not.”); *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1122 n.5 (Fed. Cir. 1996) (“Each claim of the patent must be considered individually when evaluating a public use bar.”).

¹⁰⁵ See *SmithKline Beecham Corp.*, 365 F.3d at 1320 (holding that it must look to only the claim which is before it on appeal, but noting, however, that “the same clinical trials may serve to negate a public use bar with regard to the inventions claimed in the more specific claims of the ‘723 patent.”).

¹⁰⁶ This evidence is provided through the application of the totality of the circumstances approach. *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544 (Fed. Cir. 1997) (explaining that “all of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighted against the policies underlying section 102(b)”).

¹⁰⁷ See, e.g., *EZ Dock, Inc. v. Schafer Sys. Inc.*, 276 F.3d 1347, 1353 (Fed. Cir. 2002); *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1320, 1324 (Fed. Cir. 1996); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550–51 (Fed. Cir. 1990).

¹⁰⁸ See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (holding that “courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community” and that “the responsibility for changing them rests with Congress. Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property.”); see also *Warner-Jenkinson v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997).

by the United States Constitution.¹⁰⁹ Not only does this decision contradict established case law, but it also becomes difficult to reconcile considering the policies which underlie the statutory public use bar.¹¹⁰

D. Literal Construction of the Experimental Use Doctrine is Contrary to the Substantive Principles of Patent Law

The application of the public use statutory bar necessarily involves the application of several policies. Consideration of these policies is necessary because they define the public use bar.¹¹¹ Discussing these policies and their appropriate application will demonstrate that, in this case, the CAFC's decision neither advances, nor maintains, the policies underlying the public use bar.¹¹² Furthermore, this decision does not follow the general policies underlying the patent law system.¹¹³

The first policy deserving consideration in litigation is the presumption of validity a court must afford the inventor when evaluating the claims of a patent.¹¹⁴ Next, courts must consider the three policies underlying the statutory § 102(b) bar.¹¹⁵ However, *SmithKline* only involved the public use side of § 102(b) and had no implications of the on-sale statutory bar. Accordingly, the emphasis of the court's analysis should concentrate on the policy preventing the removal of inventions from

¹⁰⁹ For instance, this decision frustrates the confidence of investors in the United States patent system in protecting their intellectual property rights and allowing an adequate return on their investments. Inventors will be less willing to invest the money needed to develop new, potentially life saving therapies resulting in deterred progress of useful arts and sciences. Brief of Washington Legal Foundation as *Amicus Curiae* in Support of Plaintiffs-Appellants' Petition for Rehearing *En Banc* at 1, *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004) (Nos. 03-1285, 03-1313).

¹¹⁰ First, this decision contradicts established case law by not considering a "totality of the circumstances," the test established by case law discussed *supra* note 20. Second, this decision violates established case law by distinguishing this case from the precedent cases discussed *supra* note 24. Last, this decision conflicts with established practices of determining utility and it appears that the court wants to allow patenting based strictly on the novelty of the compound without establishing that the compound is useful. See *supra* notes 8–19 and accompanying text.

¹¹¹ See *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 1198 (Fed. Cir. 1994) (discussing how to apply the totality of the circumstances approach so that it reflects the underlying policies of the public use statutory bar).

¹¹² See *TP Labs., Inc. v. Profl Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984) (setting forth the policies); see also *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990).

¹¹³ This refers to not only the presumption of validity that must be given to a claim under 35 U.S.C. § 282 (2000), but also to the policy underlined in the U.S. constitution of promoting the progress of science and useful arts, U.S. CONST. art. I, § 8, cl. 8.

¹¹⁴ See 35 U.S.C. § 282; see also *Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 26 (Fed. Cir. 2000) (finding "[o]ne attacking the validity of a patent must present clear and convincing evidence establishing facts that lead to the legal conclusion of invalidity.").

¹¹⁵ See *TP Labs., Inc. v. Profl Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984). The three policies are: (1) encouraging the inventor to promptly disclose new and useful information; (2) preventing the extension of the length of patent protection by not allowing the inventor to reap commercial benefits for longer than the statutorily authorized period; and (3) discouraging the removal of inventions from public domain which the public justifiably comes to believe are freely available. See *id.*

the public eye only when the public has come to rely upon them.¹¹⁶ When applying this policy, the court must balance public reliance against the interest of the inventor, specifically the interest in perfecting the invention through experimentation.¹¹⁷ This balancing of policies involves an application of the reasonable purpose test.¹¹⁸

In *SmithKline*, no analysis of policy or balancing occurred. As discussed above, SmithKline performed the clinical trials for experimental purposes.¹¹⁹ Furthermore, the doctors and patients knew that the purpose of the clinical trials involved testing whether a drug would work for its particular purpose. Testing a drug for such a purpose necessarily means the drug is not yet a finished product, and cannot be considered available for use by the general public. Consequently, the trials would not warrant any expectation of further availability of the drug or detrimental reliance by the public on the drug.

Additionally, the decision in *SmithKline* does nothing to further the inventor's interest in perfecting his invention.¹²⁰ No tests were performed before the trials, which would showcase the drug as an effective antidepressant. In addition, as discussed above, testing performed on analogous compounds should not be taken into consideration.¹²¹ The district court, applying the balancing test, indicated that the reasonable purpose of the experiments was to achieve the perfection of an invention and found no detrimental reliance by the public in this case.¹²² If the public use bar is defined by its policies, then the decision of the CAFC in *SmithKline* has redefined the application of this bar and established precedent to effectively remove the necessary policies from consideration in a public use analysis.

¹¹⁶ *Cont'l Plastics Containers v. Owens Brockway Plastic Prods.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998) (explaining that the primary policy underlying § 102(b) is detrimental reliance).

¹¹⁷ *See Schainholz*, *supra* note 13, at 383 (explaining that this approach under the experimental use doctrine is evidence of "society's willingness to accept the risk of detrimental reliance when, because of the nature of the product, public experimentation must take place").

¹¹⁸ *See Kimball Int'l, Inc. v. Allen Organ Co.*, 212 U.S.P.Q. (BNA) 584, 586 (S.D. Ind. 1981) ("[t]he determination of the inventor's purpose, motive, intent, etc., is essential in the determination of the applicability of the experimental use doctrine."); 2 CHISUM, *supra* note 14, § 6.02[7][b] ("If the purpose was experimental and the activity reasonable, it does not matter that the inventor benefits incidentally from the activity.").

¹¹⁹ This decision came from the application of the totality of the circumstances test coupled with the policy analysis of the reasonable purpose test. The factual application of these tests is discussed *supra* in notes 18–21 and the accompanying text.

¹²⁰ Courts have recognized that an inventor may conduct extensive tests of his invention, even in the public eye, if the tests are aimed to bring the invention to perfection or ascertain whether it will work for the purpose intended. *See City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134–35 (1877).

¹²¹ *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996) ("[I]t may be difficult to predict . . . whether a novel compound will exhibit pharmacological activity, even when the behavior of analogous compounds is known to those skilled in the art. Consequently, testing is often required to establish practical utility.").

¹²² *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 935 (N.D. Ill. 2001).

III. PROPOSAL

To provide the public with proper notice and define the boundaries of legally permissible conduct, laws should remain consistent and predictable. Stare decisis provides consistency in judicial decision-making and allows the public to rely on case law with confidence by reapplying past law in a similar manner, under similar circumstances, in the future.¹²³ Confidence and the ability to rely on past law is especially important in patent law, because confidence equals investments and investments equal faster promotion and development of the useful arts and sciences. A consistent and predictable approach promotes a sense of justice in the decisions of the court. Such an approach based on stare decisis also allows the court to promote and further the policy underlying the law while keeping sight of the effect the decisions will have on the body of law. Policy in effect is a litmus test of law. If the decision furthers or at least maintains the policy underlying the set of laws applied, it is most likely correct. However, a decision that diminishes or undermines the underlying policy likely requires a change. This section proposes two solutions or adjustments to the application of the statutory bar under § 102(b) and the experimental use negation which would allow for a more consistent and predictable approach than the law currently permits.

A. The Claim-by-Claim Approach Should Be Eliminated in Evaluating Experimental Use

In *SmithKline*, the court attempted to set a bright line approach to the application of the public use bar.¹²⁴ However, such an approach is unnecessary, unjustified and undermines the definition of the public use bar. While a bright line approach may serve a function in creating consistent and predictable decisions, such an approach also diminishes those decisions because it does not reflect the purpose behind the underlying laws and disturbs the public's sense of justice.

The claim-by-claim approach applied to the public use bar sets a bright line test.¹²⁵ However, the language of § 102(b) does not justify its application. The claim-by-claim approach is unjustified because in order to apply it the court must look at each claim of the patent as an individual invention.¹²⁶

The statutory bar under § 102(b) applies when “the *invention* was . . . in public use . . . more than one year prior to the date of the application for patent in the

¹²³ BLACK'S LAW DICTIONARY 1443 (8th ed. 2004) (“To abide by, or adhere to, decided cases”).

¹²⁴ See *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1319–20 (Fed. Cir. 2004).

¹²⁵ *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002) (“The on-sale bar is evaluated on a claim-by-claim basis, so that some claims of a patent may be found to be barred while others are not.”); See *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1122 n.5 (Fed. Cir. 1996) (stating that each claim of the patent must be considered individually when evaluating a public use bar).

¹²⁶ See *SmithKline*, 365 F.3d at 1320 (finding the “trials were not an experimental use of the *invention* in claim 1” of the ‘723 patent) (emphasis added)).

United States.”¹²⁷ Similarly, the cases applying the experimental use negation refer to the “invention” as the subject of the tests.¹²⁸

The claims of a patent define the invention.¹²⁹ However, each patent can only have one claimed invention.¹³⁰ The court in *SmithKline* incorrectly characterizes the claim language of claim 1 of the ‘723 patent as “the invention of claim 1.”¹³¹ Such a characterization is misleading because it implies that the “invention” of claim 1 differs from what is stated in the other claims. The language of the claims differ in order to define the invention as broadly as possible. However, all of the claims define a single “invention.”¹³² Therefore, courts should view the claims of the patent as a whole when evaluating the claimed invention.

The definition of the term “invention” also supports this conclusion. Professor Chisum defines the word “invention” as “subject matter described and/or claimed in a patent, patent application or prior art reference (*e.g.*, a product or process).”¹³³ This definition refers to the subject matter claimed in the patent as a whole and not by individual claims. The experimental use negation is a judicially developed doctrine, and if the courts intended for the test to be applied individually to each claim they would undoubtedly refer to the claims of the patent and not the invention.

Courts should abandon the claim-by-claim approach as it applies to the statutory bar under § 102(b) because it yields results that do not advance the policies of the bar described above. Compliance with these policies is critical since the public use bar is in effect defined by policy.¹³⁴ When applying the public use bar, courts continue to emphasize the policy of preventing detrimental reliance on a product by the public.¹³⁵ No evidence of detrimental reliance on the part of the subjects involved

¹²⁷ 35 U.S.C. § 102(b) (2000) (emphasis added).

¹²⁸ See *SmithKline*, 365 F.3d at 1317–18 (finding that the experimental use negation does not apply to unclaimed features of the *invention*). “It is settled law that . . . [an] experimental sale . . . does not apply to experiments performed with respect to non-claimed features of an *invention*.” *In re Application of Theis*, 610 F.2d 786, 793 (C.C.P.A. 1979) (emphasis added).

¹²⁹ See *Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935); *Gen. Elec. Co. v. Wabash Appliance Corp.* 304 U.S. 365 n.5 (1938).

¹³⁰ See *Puett Elec. Starting Gate Corp. v. Harford Agric. & Breeders’ Ass’n*, 88 F. Supp. 360, 370 (D. Md. 1949) (“Only one invention can be embraced in single patent.”).

¹³¹ “Because claim 1 covers the compound without further limitation, the invention of claim 1 was reduced to practice when that compound was first manufactured.” *SmithKline Beecham Corp.*, 365 F.3d at 1320.

¹³² *Monsanto Chem. Co. v. Coe*, 145 F.2d 18, 19 n.1 (D.C. Cir. 1944) (“Two or more independent inventions can not be claimed in one application; but where several distinct inventions are dependent upon each other and mutually contribute to produce a single result they may be claimed in one application . . .”).

¹³³ Discussing the word invention, Professor Chisum states:

In patent law, the word “invention” has several different meanings. It may refer to (1) the act of invention through original conception and reduction to practice; (2) subject matter described and/or claimed in a patent, patent application or prior art reference (*e.g.*, a product or process); or (3) the patentability requirement of invention, first developed by the courts and now subsumed in the statutory requirement of nonobviousness.

¹ CHISUM, *supra* note 14, Glossary, at 3.

¹³⁴ See *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 1198 (Fed. Cir. 1994).

¹³⁵ *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990); see also *Upadhye supra* note 7; *Cont’l Plastics Containers v. Owens Brockway Plastic Prods.*, 141 F.3d 1073,

in the clinical trials existed in *SmithKline*. Thus, this decision significantly weakens the inventor's right to perfect his invention.¹³⁶

Abandoning the claim-by-claim approach would have no ill effects on any of the laws applied to the experimental use doctrine, such as the "claimed feature of the invention" precedent, because it refers to the subject matter of the patent as the "invention" and not the claims.¹³⁷ Applying the "invention as a whole" test proposed here would allow the court to not only apply its previous decisions that have developed the doctrine, but also drive the experimental use doctrine in a direction which will yield predictable and consistent results. Additionally the "invention as a whole" approach would produce results consistent with the policies underlying the statutory bar. Furthermore, the decisions would become predictable because as the United States Supreme Court in *Pfaff v. Wells Electronics* observed, "whether a particular activity is experimental is often clear," and in cases where it is not, the courts remain free to apply the precedent in the experimental use doctrine.¹³⁸

Applying the proposed analysis to *SmithKline*, the antidepressant properties of the chemical become expressly claimed features of the *invention*. The properties were outlined in claims 5 and 6 of the '723 patent.¹³⁹ Moreover, this decision would have no effect on the detrimental reliance on the drug by the public, while encouraging the inventor to perfect his invention.¹⁴⁰

1079 (Fed. Cir. 1998). For other policies considered by the court when applying the public use bar under § 102(b) see *TP Labs., Inc. v. Profl Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984).

¹³⁶ When the delay to take out a patent is justified by a *bona fide* effort "to bring [the] invention to perfection, or to ascertain whether it will answer the purpose intended" the inventor does not acquire an undue advantage over the public because it is in the public's interest that "the invention should be perfect and properly tested before a patent is granted." *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 933 (N.D. Ill. 2001) (quoting *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 64 (1999)). Through the reasonable purpose analysis it follows that if there is no detrimental reliance by the public on the invention and there is a significant interest on the part of the inventor to perfect his invention then the reasonable purpose of the tests is experimental and if in this circumstance the decision significantly harms the interest of the inventor the balance of the policies is not considered.

¹³⁷ "Testing or experimentation performed with respect to non-claimed features of the device does not show that the *invention* was the subject of experimentation." *W. Marine Elec. v. Furuno Elecs. Co.*, 764 F.2d 840, 847 (Fed. Cir. 1985). "Each of those cases permitted testing to negate the [public use] bar when the experimentation improves or verifies a feature inherent in the express claims of the *invention*." *SmithKline*, 365 F.3d at 1319 (emphasis added); see also *Cont'l Plastic Containers*, 141 F.3d at 1079 (explaining that tests of an *invention* that has been reduced to practice, will not qualify for experimental use for purposes of negating a bar under § 102(b)).

¹³⁸ See *Pfaff v. Wells Electronics*, 525 U.S. 55, 67 n.13 (1998).

¹³⁹ U.S. Patent No. 4,721,723 (issued Jan. 26, 1988). The claims state "5. An *anti-depressant* pharmaceutical composition comprising an effective *anti-depressant* amount of crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier." and "6. A *method of treatment of depression* in mammals, which method comprises administering an effective amount of crystalline paroxetine hydrochloride hemihydrate." *Id.* (emphasis added).

¹⁴⁰ An inventor may conduct extensive tests of his invention if the experiments are aimed to bring the invention to perfection or ascertain whether it will work for the purpose intended. See *Pfaff*, 525 U.S. 55, 64 (1999); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550 (Fed. Cir. 1990); see also *Cont'l Plastics*, 141 F.3d at 1079 (the primary policy behind § 102(b) is detrimental reliance).

B. Application of the Experimental Use Doctrine only to “Claimed Features of the Invention” Should be Considered as Factor in the Totality of the Circumstances Analysis of Public Use Under § 102(b)

As it stands now, whether the feature being tested is expressly included in the individual claim is a dispositive factor in applying the experimental use doctrine. However, this approach proves both erroneous and misleading.¹⁴¹ The court itself acknowledged that cases exist where experimentation with respect to features not expressly claimed in the patent will not invalidate the patent for public use because those features are considered “inherent” to the claim.¹⁴² The confusion over the definition of an inherent feature necessarily leads to inconsistent results.

The court should not abandon the necessary claimed “feature of the invention” test. However, modifying this test to align it with the goals underlying experimental use would create a test that yields consistent predictable results. Developing a burden of proof to establish a feature as inherent would allow the court to apply the current test only where a party could not meet that burden. However, once the burden is met, the court, as part of a balancing test should consider the degree of inherency of the feature to the actual claimed invention. The balancing test should consist of this factor weighed against the factors considered by the court as a part of the totality of the circumstances test,¹⁴³ and then evaluated with the goals of the aforementioned policies in mind.¹⁴⁴

This approach would allow the court flexibility in cases where applying a strict interpretation of the rules would be the same as trying to fit a square peg in a round hole given that the decision would not make sense on a policy level. The support of policies underlying experimental use is important because those policies define the statutory bar.¹⁴⁵

¹⁴¹ If the experiments are not testing a claimed feature of the invention, the experimental use doctrine cannot be applied. *See generally EZ Dock*, 276 F.3d at 1347; *Seal-Flex*, 98 F.3d at 1318; *Manville Sales*, 917 F.2d at 544. However, as of now, courts allow an exception of sorts when the tests are directed toward a feature that is “inherent” to the invention. *See generally EZ Dock*, 276 F.3d at 1347; *Seal-Flex*, 98 F.3d at 1318; *Manville Sales*, 917 F.2d at 544. Unfortunately the standard of proof needed to show a feature to be “inherent” is set extraordinarily high as a result of *SmithKline*. *See SmithKline*, 365 F.3d at 1320 (holding that testing of the antidepressant properties of the chemical structure is not testing an inherent feature).

¹⁴² *See generally EZ Dock*, 276 F.3d at 1347; *Seal-Flex*, 98 F.3d at 1318; *Manville Sales*, 917 F.2d at 544.

¹⁴³ *See Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544 (Fed. Cir. 1997) (explaining that “all of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighed against the policies underlying section 102(b).”). Specifically, courts have looked to factors, including but not limited to, length of test period, whether the inventor received payment for the testing, any obligation of confidentiality, whether any records of testing and progress were made, whether persons other than the inventor performed the testing, and the number of tests performed. *Baxter Int’l, Inc. v. Cobe Labs., Inc.*, 88 F.3d 1054, 1060 (Fed. Cir. 1996).

¹⁴⁴ *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550 (Fed. Cir. 1990); *see also TP Labs., Inc. v. Prof1 Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984); *Cont’l Plastics Containers v. Owens Brockway Plastic Prods.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998).

¹⁴⁵ *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 1198 (Fed. Cir. 1994) (“[P]olicies behind the bar, in effect, define it.”).

IV. CONCLUSION

By applying the statutory public use bar and holding the clinical trials in *SmithKline* did not constitute an experimental use, the CAFC has set the bar too high. Applying a narrow construction of the law, the CAFC invalidated a claim in a clear case of experimental use. The decision not only misapplied the precedent defining an “inherent” feature of the invention, but essentially eliminated the application of policies underlying the public use bar.

Such decisions severely alter the expectations of inventors by weakening their interest in perfecting their inventions and diminishing the need for the analysis of policy which drives the bar. Additionally, this decision encourages potential infringers to look for loopholes in patents based on the strict and narrow construction of experimental use advanced by the CAFC.¹⁴⁶ A new test should be applied which strengthens the rights of patent holders and encourages the progress of useful sciences as Congress intended. Therefore, the claim-by-claim approach should be eliminated in evaluating experimental use. The application of the experimental use doctrine to “claimed features of the invention” should only be considered as a factor in the totality of the circumstances analysis of public use under § 102(b).

¹⁴⁶ See generally Brief of Washington Legal Foundation as Amicus Curiae in Support of Plaintiffs-Appellants’ Petition for Rehearing En Banc, at 3, *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004).