
SmithKline Beecham Corp. v. Apotex: Experimental Use as Applied to Claim Scope

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ABSTRACT

Claims now must explicitly or inherently include a feature or intended use that is the subject of experimentation in order to negate a finding of public use under 35 U.S.C. § 102(b).¹ Reasoning that experimental use cannot extend beyond improvement or verification of express or inherent features of an invention as claimed, the Court of Appeals for the Federal Circuit (CAFC) held that testing of a claimed compound, where the language of the claim is silent as to “any property, commercially significant amount, or use of the compound,”² such as its safety or efficacy, may not, as a matter of law, qualify as negation of public use. This prohibition is based on a misinterpretation by the court of case precedent and will have a chilling effect on experimentation. The full scope of patent protection that previously has been available will now be denied to an inventor making “a *bona fide* effort to bring his invention to perfection.”³

INTRODUCTION

In *SmithKline Beecham Corp. v. Apotex, Corp.*,⁴ decided April 23, 2004, Circuit Judge Randall Rader of the CAFC affirmed a decision by the United States District Court for the Northern District of Illinois in

¹ 35 U.S.C. § 102 (“Conditions for patentability; novelty and loss of rights to patent. 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 sale in this country, more than one year prior to the date of the application for patent in the United States . . .”).

² *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306; 70 U.S.P.Q.2d 1737, 1748 (Fed. Cir. 2004).

³ *Elizabeth v. Am Nicholson Pavement Company*, 97 U.S. 126, 137, 24 L.Ed. 1000 (1877).

⁴ 70 U.S.P.Q.2d at 1737 (Fed Cir. 2004).

favor of Apotex Corp., Apotex, Inc., and TorPharm, Inc. (Apotex) on the basis that SmithKline Beecham's U.S. Patent No. 4,721,723 ('723 patent), directed to paroxetine hydrochloride hemihydrate, was invalid for public use under 35 U.S.C. § 102(b) as a matter of law. According to the court record, the hemihydrate form of paroxetine hydrochloride (PHC) was "serendipitously"⁵ discovered by a chemist in the Worthing, England laboratory of SmithKline Beecham Corp. (SmithKline) in March 1985.⁶ Paroxetine and its salts were previously known as antidepressants and were the subject of an earlier patent, U.S. Patent No. 4,007,196. Under a "disappearing polymorph" theory, which both the district court and the CAFC accepted, once the hemihydrate form of PHC is created, earlier known forms of PHC (i.e., PHC anhydrate) inevitably convert, or morph, to hemihydrate. Therefore, once an environment becomes seeded with the hemihydrate, any PHC anhydrate formed in that environment will contain at least trace, or undetectable, amounts of PHC hemihydrate.⁷ Although Apotex was seeking to obtain approval to market PHC anhydrate, any PHC anhydrate produced by Apotex would be contaminated with hemihydrate because the manufacturing plant in which Apotex produced the anhydrate was seeded with hemihydrate crystals.⁸ Therefore, it would be impossible under the "disappearing polymorph" theory for Apotex to produce PHC anhydrate tablets that did not include PHC hemihydrate, even if the amount was a trace, or undetectable, amount.⁹

⁵ *Id.* at 1744.

⁶ *Id.* at 1739.

⁷ *Id.* at 1740 ("To show that manufacture of PHC anhydrate tablets necessarily creates PHC hemihydrate, SmithKline proffered expert testimony on the so-called 'seeding' or 'disappearing polymorph' theory Once this new [hemihydrate] form exists, SmithKline's experts explained, the general environment becomes 'seeded' with crystals of the new polymorph. In this seeded environment, the old polymorph converts to the new polymorph upon inevitable contact with seeds of the new polymorph. In other words, the creation of a pure version of the old polymorph becomes extremely difficult, if not impossible; the old polymorph has effectively disappeared and been replaced by the new.").

⁸ *Id.* at 1752 ("According to SmithKline, the BCI plant [in which Apotex manufactures anhydrate] is seeded with hemihydrate crystals because it was there that Apotex, exercising the broadened experimental-use privilege conferred by the Hatch-Waxman Act, used and made hemihydrate in the course of developing its anhydrous product.").

⁹ *Id.* at 1740-1742 ("The district court found that SmithKline's evidence on seeding and the disappearing polymorph theory supported the inference that Apotex's PHC anhydrate tablets will contain at least trace, or undetectable, amounts of PHC hemihydrate. . . . As an initial matter, this court holds that the record supports the district court's factual findings. In particular, the district court did not clearly err in concluding that Apotex's PHC anhydrate product will include trace amounts of PHC hemihydrate based on the record evidence of seeding and disappearing polymorphs The district court also did not clearly err in finding that Apotex's anhydrate product will not contain detectable quantities of PHC hemihydrate . . ." (citations omitted)).

The only claim at issue of the '723 patent was Claim 1, which reads as follows:

1. Crystalline paroxetine hydrochloride hemihydrate.

Apotex challenged the validity of claim 1 of the '723 patent on the ground that double-blind clinical tests conducted by SmithKline in the United States to determine the safety and efficacy of PHC hemihydrate capsules to treat depression symptoms started in May 1985, prior to the critical date of October 23, 1985, and in violation of the proscription against public use under 35 U.S.C. § 102(b).¹⁰ SmithKline asserted that the clinical trials were experimental and, therefore, negated public use.¹¹

THE OPINION

The CAFC held that SmithKline's clinical testing could not be considered a negation of public use because the testing was with respect to non-claimed features. More particularly, because claim 1 of the '723 patent was directed to a compound and did not include any reference to antidepressant properties or to features of "efficacy" or "safety," clinical trials conducted by SmithKline of the claimed compound with respect to these features could not be considered to be a negation of public use under 35 U.S.C. § 102(b).¹²

The court distinguished testing an invention for utility (i.e., that an invention works for its intended purpose) as overlapping, but not synonymous with, experimental use testing.¹³ Judge Rader stated that testing must be limited to "perfecting claimed features"¹⁴ or "testing to perfect features inherent to the claimed invention" in order to qualify for experimental use negation.¹⁵

¹⁰ *Id.* at 1741.

¹¹ *Id.*

¹² *Id.* at 1746 ("The antidepressant properties of the compound are simply not claimed features. Consequently, the clinical tests, which measure the efficacy and safety of the compound as an antidepressant, did not involve the claimed features of the invention. The 1985 clinical tests, therefore, do not qualify as an experimental use to negate this statutory bar.")

¹³ *Id.* at 1747 ("This court has noted the potential overlap of utility and experimental use testing. *EZ Dock*, 276 F.3d at 1352. As suggested by their different origins and purposes, however, utility testing (reduction to practice) and experimental use testing are not synonymous.")

¹⁴ *Id.* at 1746 ("Due to these different origins and purposes, the narrower experimental use negation does not extend beyond perfecting claimed features. In any event, even the cases above that acknowledge experimentation on features beyond those expressly claimed remain faithful to these strict limits of the experimental use negation.")

¹⁵ *Id.* at 1747 ("In sum, this court has remained faithful to the strict requirement of the experimental use negation by limiting it to testing to perfect claimed features, or, in a few instances, testing to perfect features inherent to the claimed invention.")

According to the court, the subject matter of claim 1, being directed strictly to a compound, “was reduced to practice when that compound was first manufactured.”¹⁶ With respect to SmithKline’s clinical testing, the court stated that claim 1 of the ‘723 patent included no language that could “reasonably be read to carry an implication that the claimed compound will be used as an anti-depressant, or even as a pharmaceutical for that matter.”¹⁷ As stated by Judge Rader:

Accordingly, a patentee should understand that testing the properties, uses, and commercial significance of a compound claimed solely in structural terms may start the clock under § 102(b) for filing a claim that is not limited by any property, commercially significant amount, or other use of the compound. Because these clinical trials tested only the safety and efficacy of PHC hemihydrate as an anti-depressant, those trials were not an experimental use of the invention in claim 1. Consequently, this court determines that claim 1 of the ‘723 patent is invalid for public use under § 102(b) as a matter of law.¹⁸

Therefore, testing with respect to efficacy as an anti-depressant was irrelevant to a determination of when the subject matter of claim 1 was reduced to practice¹⁹ and, accordingly, there could be no experimental use that would negate public use under 35 U.S.C. § 102(b).

ANALYSIS OF THE OPINION

Judge Rader identified four cases as support for the proposition that only experimentation performed with regard to claimed features will negate public use:²⁰ *Western Marine Electronics v. Furuno Electric Co.*, *In re Theis*, *LaBounty Mfg., Inc. v. U.S. Int’l Trade Commission* and *In re Brigrance*.²¹ Contrary to Judge Rader’s suggestion, however, a finding of experimental use was denied in each of these cases because the claimed invention was not being tested, and not simply because some tested feature of the invention was not claimed.

¹⁶ *Id.* (“Because claim 1 covers the compound without further limitation, the invention of claim 1 was reduced to practice when that compound was first manufactured.”).

¹⁷ *Id.*

¹⁸ *Id.* at 1747-48.

¹⁹ *Id.* (“[T]he invention of claim 1 was reduced to practice when that compound was first manufactured. Its efficacy as an antidepressant is irrelevant to that determination.”).

²⁰ *Id.* at 1745 (“In other words, an experimental use only negates a statutory bar when the inventor was testing claimed features of the invention.”).

²¹ 764 F.2d 840 (Fed. Cir. 1985), 226 U.S.P.Q. 334; 610 F.2d 786 (CCPA 1979), 204 U.S.P.Q. 188; 958 F.2d 1066 (Fed. Cir. 1992), 22 U.S.P.Q.2d 1025; and 792 F.2d 1103 (Fed. Cir. 1986), 229 U.S.P.Q. 988.

In the first case, *Western Marine*, a system for scanning and detecting schools of fish in a body of water was found not to be a negation of public use; the use was held by the court to be primarily commercial rather than experimental.²² Testing was limited to a dual frequency characteristic that was unnecessary to demonstrate any stated object of the invention,²³ such as to “stabilize the transducer against the pitching and rolling motions of a ship.”²⁴ The court in *Western Marine* held that this testing was insufficient to show that the *invention* was the subject of experimentation:

The trial court properly recognized that testing or experimentation performed with respect to non-claimed features of the device does not show that the *invention* was the subject of experimentation.²⁵

In the second case identified by Judge Rader, *In re Theis*, experimentation was found not to negate an on-sale bar to patentability under 35 U.S.C. § 102(b) because the experimental use was of a telephone interface between the claimed apparatus and the telephone system to which it was connected. The court in *In re Theis* found that use of the claimed invention in conjunction with a telephone system was not inherent to the system because “the claims do not require that the system be used with a telephone system.”²⁶ As support, the court in *In re Theis* stated that the patent specification referenced a number of applications that did not utilize a telephone system.²⁷ Therefore, the telephone interface was not a component of the claimed invention and testing of the telephone interface was not experimental use of the claimed invention.²⁸

22 764 F.2d at 847 (“In sum, we must agree that Wesmar’s June 7 offer letter together with the surrounding instructions evidence a primarily commercial rather than experimental purpose.”).

23 *Id.* at 847 (“Brinkerhoff testified that the main thing he was interested in was the sonar’s dual frequency characteristic and that he ‘really [didn’t] remember how the stabilization operated.’”).

24 *Id.* at 842 (“One of the objects of the Sublett invention was to stabilize the transducer against the pitching and rolling motions of a ship.”).

25 *Id.* at 847 (emphasis in original).

26 610 F.2d at 793.

27 *Id.* at 788 (“Although one of the principal uses contemplated by appellant for his system is in conjunction with a telephone system wherein the respondent is a telephone caller, the claims are not limited to include telephone apparatus. Appellant’s specification states that ‘the system has a number of applications that do not utilize the telephone system,’ and cites several examples on non-telephone related applications.”).

28 *Id.* (“It is settled law that the experimental sale exception does not apply to experimental use performed with respect to non-claimed features of an invention. *Minnesota Mining & Manufacturing Co. v. Kent Industries, Inc.*, supra. It appears from the record 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.” *In re Theis*, 793.)

In the third case, *LaBounty Mfg., Inc. v. U.S. Int'l Trade Commission*, the court held that the public use of claimed scrap shears was not experimental²⁹ because it was for a customer's particular need.³⁰ In the fourth case, *In re Brigrance*, evidence of experimental use was held to be subjective and, accordingly, unpersuasive.^{31 32} In all four of the above cases, testing of a feature that was a claim element could negate public use; however, experimental use negation was applied by the court more broadly, ultimately hinging on whether the invention (i.e., as a whole, or any element or subcombination of elements of the invention) was being tested.

The court distinguished three other cases as examples of permissible experimental use to "perfect claimed features" or "to perfect features inherent to the claimed invention":³³ *Manville Sales Corporation v. Paramount Systems, Inc.*, *Seal-Flex, Inc. v. Athletic Track and Court Constr.* and *EZ Dock, Inc. v. Schafer Systems, Inc.*³⁴ Although, as stated by Judge Rader, experimental use as a negation of public use was found, in each of these cases the feature of the claimed invention that was tested was neither expressly claimed nor inherent.

For example, with respect to *Manville*, the court in *SmithKline* stated that "experimentation verified features inherent in the claimed invention" because it was acknowledged that "[d]urability in an outdoor environment is inherent to the purpose of the invention."³⁵ However, an examination of the subject patent, U.S. Patent No. 3,847,333 ('333 patent), reveals that none of the claims make reference to an outdoor environment or provide any limitation that would cause suitability for outdoor use of the claimed apparatus to be inherent in the meaning of the claims. All of the claims are directed to "an apparatus for maintaining a ring-like object support in a predetermined location around the external

²⁹ 958 F.2d at 1074.

³⁰ *Id.* ("Similarly, that the Ace and Adamo/Dodge shears performed unsatisfactorily for the users' particular need and eventually were returned does not mandate the conclusion of no on-sale bar." *LaBounty* 1074.)

³¹ 792 F.2d. at 1108 ("While objective indicia are valuable in determining whether the inventor's use of his invention is experimental, the inventor's expression of his subjective intent to experiment is, without more, of little value, particularly if expressed after initiation of litigation.")

³² *In dicta*, the court found that, to the extent there was any experimentation, it was of a feature "embodied solely by [independent] claim 8, and not by rejected claims 1, 3-5 and 7." *Id.* at 1109.

³³ 70 U.S.P.Q.2d at 1746.

³⁴ 917 F.2d 544 (Fed. Cir. 1990), 16 U.S.P.Q.2d 1587; 98 F.3d 1318 (Fed. Cir. 1996), 40 U.S.P.Q.2d 1450; and 276 F.3d 1347 (Fed. Cir. 2002), 61 U.S.P.Q.2d 1289.

³⁵ 70 U.S.P.Q.2d at 1747.

surface of a post” (claims 1-9), “an apparatus adapted for centering ring-like objects for support about the axis of a longitudinal member” (claims 10, 15-17), or a “luminaire assembly” (claims 11-14). The only references to outdoor use of the apparatus are found in a description of the prior art in the specification of the ‘333 patent.³⁶ There is nothing in the specification of the ‘333 patent or in the claims to indicate that the apparatus must be suitable for use in an outdoor environment. Therefore, contrary to the suggestion by the CAFC in *SmithKline*, the claims do not inherently require durability in such an environment.

The CAFC stated that the court in *Seal-Flex*, like the court in *Manville*, found an experimental use negation in view of features inherent to the claimed invention. In particular, the court in *SmithKline* characterized the claimed invention of U.S. Patent Nos. 4,474,833 (‘833 patent) and 4,529,622 (‘622 patent), which were the subject patents in *Seal-Flex*, as being directed to an “all-weather activity mat (or track)” and that, because it was an “all-weather” track, the claimed invention “carried the inherent implication of performance in severe weather conditions.”³⁷ The claims of the ‘833 and ‘622 patents do not include the phrase “all-weather.” Rather, the claims are directed to “methods for constructing an activity mat over a foundation.”³⁸ Further, none of the stated objects of the invention, as set forth in the patent specifications, specify “all weather,” or “severe weather conditions.”³⁹ As with *Manville*, there is no indication in the claims or in the specification that

36 E.g., “Recently, there has been a large emphasis placed on providing proper lighting on urban streets, roads and highways, thereby resulting in placement of more and more outdoor luminaries on or near such areas.” Col. 1, lines 13-16.

37 70 U.S.P.Q.2d at 1747 (“In *Seal-Flex*, the claimed invention covered an all weather activity mat (or track).”).

38 E.g., the title “Method for Constructing All-Weather Surface.”

39 U.S. Patent No. 4,529,622, Col. 1, line 53 through Col. 2, line 6.

(“Accordingly, it is a primary object of the present invention to provide a method for constructing surfaces of this type which have improved characteristics and are highly durable and do not require excessive maintenance procedures.

In the achievement of the foregoing object it is an important object of the present invention to provide a construction process wherein a desirable bond is achieved between the activity mat and the surface of the underlying foundation.

A yet further object of the invention is to provide a method wherein an improved bond is achieved between the discrete rubber particles of the mat so that the structural integrity and durability of the mat is enhanced.

Still another object of the present invention is to provide a process wherein the susceptibility of the materials to the deleterious effects of sunlight, moisture and weathering are substantially decreased.

These and other aims and objectives of the present invention will be further explained or will become apparent from the following description and explanation of the invention.”)

the claimed invention must be suitable for use in "all weather" conditions, or, in particular, to "severe weather conditions."

The third case distinguished by the court in *SmithKline, EZ Dock*, was directed to a patent claiming a floating dock. The court interpreted the experimental nature of the negating public use to be a verification of an inherent feature of the claimed invention, namely, that a "floating dock" be able to "perform in rough water."⁴⁰ Although, as stated by the court, the claims are directed to a "floating dock," there is no mention in the claims or elsewhere in the patent that the docks must be able to perform in rough water.⁴¹

Further, as with *Manville, Seal-Flex* and *EZ Dock*, statements of intended use can be found in the specification of SmithKline's '723 patent,⁴² all of which are directed to use of PHC hemihydrate as an anti-depressant in a pharmaceutically acceptable form. Testing of suitability of the compound for this use reasonably would include trials relating to safety and efficacy. As suggested by Judge Gajarsa in his concurring opinion, if inherency of intended use, such as durability in an outdoor environment, performance in harsh weather or performance in rough water, can be considered "features inherent to a claimed invention," as they were in *Manville, Seal-Flex* and *EZ Dock*, respectively, then safety and efficacy of PHC hemihydrate as an anti-depressant in pharmaceutically acceptable form can be found as an inherent feature of

40 70 U.S.P.Q.2d at 1747.

41 In the Background of the Invention portion of U.S. 5,281,055, which was the patent at issue, with reference to the prior art, the specification states that "[t]hese [prior art] modules, however, suffer from many disadvantages, such as deteriorating in certain environments and are, therefore, limited in their applications." Further, the specification states at column 5, lines 61-64: "The anchors, being made of rubber, are capable of being subjected to repeated compression and torsional forces that normally occur on lakes from the action of the wind and waves without failing." There is no reference to "rough" or "choppy water" in the claims or in the remainder of the patent specification. Further, although anchors are components of the claims, the only reference to an anchor being made of rubber is in dependent claim 4. Further, of the three cases cited by the court as examples of permissible use to "perfect claimed features," only *EZ Dock* indicated that there was any change in a claimed feature of the invention (the inclusion of a generally frustraconically shaped pylon identified in dependent claim 8 of the '055 patent).

42 For example, the Abstract of the patent states: "The invention provides crystalline paroxetine hydrochloride hemihydrate, processes for its preparation, compositions containing the same and its therapeutic use as an anti-depressant." Col. 1, line 1 states: "This invention relates to crystalline paroxetine hydrochloride hemihydrate, its preparation and its use as a therapeutic agent." Col. 1, lines 57-59 states: "The present invention provides crystalline paroxetine hydrochloride hemihydrate as a novel material, in particular in pharmaceutically acceptable form."

claim 1 of the '723 patent.⁴³ Therefore, the majority in *SmithKline* is, in addition to misinterpreting case precedent, being inconsistent in its application of that precedent.

The distinction between *Western Marine*, *In re Theis*, *LaBounty* and *In re Brigance* on the one hand, and *Manville*, *Seal-Flex* and *EZ Dock* on the other, is not found in improvement or verification of a feature inherent in the express claims of the invention, as suggested by Judge Rader.⁴⁴ Rather, as has been stated in each of the cited cases, negation of a bar from patent protection for public use hinges upon whether testing, if any, was of the claimed invention. Like *Manville*, *Seal-Flex* and *EZ Dock*, experimental testing by SmithKline was of the claimed invention (i.e. "crystalline paroxetine hydrochloride hemihydrate"). To be consistent with case precedent, the court in *SmithKline* should have held that SmithKline's clinical testing of the claimed compound negated its public use.

CONCLUSION

Permitting experimental use negation only where a claim explicitly or inherently includes a functional limitation that is the subject of the experimental use is contrary to the stated policy set forth in *Elizabeth v. Am. Nicholson Pavement Co.*:

It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a *bona fide* effort to bring his

⁴³ *Id.* at 1751 ("The majority notes this extension with approval and attempts to distinguish the present matter from our precedent by focusing on reduction to practice. According to the majority, SKB's testing of paroxetine hemihydrate's performance as a human antidepressant was not necessary to reduce paroxetine hemihydrate to practice. The majority does not make clear, however, why testing a light pole's performance at illumination under severe weather conditions was necessary to reduce the light pole to practice, *Manville*, 917 F.2d at 547-48, why testing an all-weather activity mat's performance in harsh weather was necessary to reduce the mat to practice, *Seal-Flex*, 98 F.2d at 1320-21, or why testing a floating dock's performance in rough, choppy water was necessary to reduce the dock to practice, *EZ-Dock*, 276 F.3d at 1353-54. 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.").

⁴⁴ *Id.* at 1746.

invention to perfection, or to ascertain whether it will answer the purpose intended. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it.⁴⁵

Experimental use should not only be broad enough to incorporate explicit and inherent limitations of claimed subject matter, but also, as has been so until *SmithKline*, inclusive of any tests of the claimed invention conducted to verify suitability for an intended use.

Unfortunately, experimental use may now qualify as a negation of public use under 35 U.S.C. § 102(b) only if it is an intended use that is expressly claimed or found by a court to be inherent. As a consequence, inventors will delay or avoid testing their inventions. Otherwise, experimental use of an invention may limit the scope of subject matter that can be claimed, curtailing the ability of inventors to protect their creations.

⁴⁵ 97 U.S. 126, 137, 24 L.Ed. 1000 (1877).