No. 05-489

IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., GLAXOSMITHKLINE, P.L.C., AND BEECHAM GROUP, PLC,
Petitioners,
v.

APOTEX CORP., APOTEX, INC., AND TORPHARM, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

Date: November 16, 2005

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MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of Petitioners. Counsel for Petitioners has consented to the filing of this brief. WLF was unable to obtain the consent of Counsel for Respondents, thereby necessitating the filing of this motion.

WLF is a non-profit public interest law and policy center with supporters in all 50 states. WLF devotes a substantial

portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared before this Court and other federal courts in numerous cases raising important regarding the scope and validity of pharmaceutical patents. *See, e.g., Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd.* 359 F.3d 1361 (Fed. Cir. 2004) (scope of patent protection); *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir.) (scope of causes of action under 35 U.S.C. § 271(e)(2)), *cert. denied*, 540 U.S. 1048 (2003); *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (Hatch-Waxman Act procedures for resolving drug patent disputes), *cert. denied*, 537 U.S. 941 (2002). WLF also filed briefs in this case in support of Petitioners when the case was before the U.S. Court of Appeals for the Federal Circuit.

WLF fully supports Petitioners' request that the Court grant review in this case. WLF writes separately in order to emphasize its particular concern over the practical impact of the Federal Circuit's decision. The decision below and similar recent decisions of the Federal Circuit have had the effect of writing the "accidental anticipation" doctrine out of the patent law, thereby significantly decreasing the availability of patent protection for new and useful products and processes. WLF is concerned that the novel rule announced by the Federal Circuit in this case and *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 348 F.3d 992 (Fed. Cir. 2003), will undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights, and thus reduce incentives for companies to invest in new, life-saving therapies.

WLF is filing this brief because of its interest in promoting the welfare of the health care industry and the public at large; it has no direct interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct economic interests, WLF believes that it can assist the Court

by providing a perspective that is distinct from that of any party.

For the foregoing reasons, the Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
Washington Legal Foundation
2009 Massachusetts Ave, NW
Washington, DC 20036
(202) 588-0302

November 16, 2005

QUESTION PRESENTED

Whether the Federal Circuit erred in holding, in conflict with this Court's decision in *Tilghman v. Proctor*, 102 U.S. 7007 (1881), and its progeny, that the "unwitting" and "unappreciated" prior creation of a product renders a subsequent patent of that product invalid as "inherently anticipated" and thus not novel under Section 102 of the Patent Act.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

STATEMENT OF THE CASE

The Federal Circuit invoked the doctrine of "inherent anticipation" to invalidate a patent issued to Petitioners for crystalline paroxetine hydrochloride hemihydrate ("PHC hemihydrate"). The appeals held that an earlier patent (the "Ferrosan patent") "inherently" discloses PHC hemihydrate even though it does not do so literally, and thus that Claim 1 of Petitioners' patent is invalid as inherently anticipated under 35 U.S.C. § 102(b).[2] That ruling is consistent with recent Federal Circuit decisions that have steadily expanded the scope of the inherent anticipation doctrine. Under that doctrine, a patent can be deemed invalid based on the existence of prior art in which all the characteristics of the claimed invention are *inherently* present, even though the prior art may not affirmatively disclose those characteristics. *See, e.g., Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 348 F.3d 992 (Fed. Cir. 2003). The appeals court invalidated the SmithKline Beecham patent without once mentioning the "accidental anticipation" or "accidental prior use" doctrine, which holds that inherent anticipation is inapplicable where, even though a process or product may be inherent in the prior art, the process or product is not appreciated by the inventor or anyone else. Nor did the appeals court cite any of this Court's decisions from which the accidental prior use doctrine derives.

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[2] The Federal Circuit referred to the two relevant patents as the "'723 patent" and the "'196 patent," a reference to the numbers assigned to the patents by the patent office. For ease of understanding, WLF adopts the names employed in the Petition: Petitioners' patent is referred to herein as the "SmithKline Beecham patent" or the "hemihydrate patent," and the earlier patent is referred to as the "Ferrosan patent," a reference to the European company that obtained the earlier patent.

In the 1970s, scientists at the Danish company A/S Ferrosan ("Ferrosan") invented a new class of chemical compounds, including a compound that became known as paroxetine. In 1977, it obtained the Ferrosan patent on those compounds. Lacking the financial resources necessary to develop its invention commercially, Ferrosan later licensed its paroxetine technology to Petitioners and provided them with the results of its research – including its methodology for synthesizing a crystalline hydrochloride salt of paroxetine, or paroxetine hydrochloride (PHC). Ferrosan's methodology described the synthesis of an *anhydrous* form of PHC, meaning that it contains no water molecules in its crystal structure.

Scientists employed by Petitioners (collectively, "SmithKline") then spent several years working to improve the process for the manufacture of paroxetine and PHC. It was not until 1985 that a SmithKline scientist discovered a new crystalline form of PHC. This new crystalline form, PHC *hemihydrate*, contains one water molecule for every two molecules of paroxetine hydrochloride bound in the crystal. SmithKline obtained a patent on PHC hemihydrate in 1988, and determined that it would seek authority from the Food and Drug Administration (FDA) to market it as an antidepressant. That approval did not come until 1993, when SmithKline began marketing Paxil as an antidepressant, with PHC hemihydrate as its active ingredient. In the meantime, the Ferrosan patent had expired in 1992, one year before marketing of Paxil began.

SmithKline filed this patent infringement action in 1998, claiming that the PHC antidepressant drug that Respondents (collectively, "Apotex") proposed to market violated the hemihydrate patent. Apotex defended by claiming both patent invalidity and that its proposed marketing would not infringe the hemihydrate patent. In December 2001, the district court

rejected the invalidity defense and granted summary judgment to SmithKline on that issue. Pet. App. 189a-219a. In particular, it rejected Apotex's assertion that the SmithKline Beecham patent on PHC hemihydrate was anticipated by the Ferrosan patent. The court explained:

> If even one element is excluded from the prior art reference, the party seeking to invalidate the patent will not be able to show anticipation. . . . Ferrosan, even assuming that they did in fact produce hemihydrate, never realized that they had done so. They could not communicate to SmithKline something that they did not know, and any prior art reference to which [Apotex] could point would be lacking the single most important element of the [SmithKline Beecham] patent: the hemihydrate element. We therefore conclude that the hemihydrate was neither anticipated by Ferrosan's activities nor did Ferrosan conceive of the substance prior to Curzon's [a Smith Kline scientist] initial identification.

Id. 198a.

After a bench trial, the district court again rejected the invalidity defense, holding *inter alia* that the SmithKline Beecham patent was not invalid based on inherent anticipation. *Id.* 131a-132a. The court ultimately ruled in favor of Apotex, finding that Apotex had not infringed. *Id.* 109a-182a. SmithKline appealed the non-infringement finding, while Apotex cross-appealed on the issue of validity (albeit it did *not* raise the inherent anticipation argument).

In its initial decision, the Federal Circuit affirmed. *Id.* 60a-108a. The panel held that Apotex had, in fact, infringed Claim 1 of the hemihydrate patent and that the district court

had erred in finding otherwise. Turning to the issue of patent invalidity, the panel said that it was not addressing the inherent anticipation argument, because Apotex had not appealed the district court's rejection of that argument. *Id.* 73a. However, finding that PHC hemihydrate was in "public use" for more than a year prior to the patent application date, the panel held that the hemihydrate patent was invalid under the public use bar, 35 U.S.C. § 102(b). *Id.* 75a-82a.

The appeals court subsequently granted SmithKline's petition for rehearing *en banc*. It vacated the panel's "original opinion addressing the issue of experimental use" and remanded to the panel for further proceedings. *Id.* 57a. On that same day, the panel issued a new decision, this time finding the hemihydrate patent invalid based on inherent anticipation. *Id.* 1a-55a. Citing its prior decision in *Schering Corp.*, the court ruled that "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created." *Id.* 18a. It was enough, the court reasoned, that skilled practitioners using Ferrosan's methodology would *eventually* produce some quantity of PHC hemihydrate – albeit potentially many years later, even after the "critical date" for purposes of determining inherent anticipation (October 1985, one year before SmithKline filed its patent application). *Id.* Thus, the panel did not deem it relevant that, as all parties agree, whatever quantities of PHC hemihydrate may have existed prior to its 1985 discovery by SmithKline were so minute that they were never detected by the numerous scientists who had been studying PHC for years. The appeals court reasoned that its decision furthered one of the policy rationales underlying the inherent anticipation doctrine: "to ensure that '[t]he public remains free to make, use or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying

scientific principles which allow them to operate.'" *Id.* at 22a (quoting *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1348 (Fed. Cir. 1999). The appeals court did not discuss the accidental prior use doctrine, or any of this Court's cases that embody that doctrine.

REASONS FOR GRANTING THE PETITION

This case raises patent law issues of exceptional importance. The Federal Circuit now holds that patents can be invalidated on the ground that they are inherently anticipated by the prior art, even though there is no appreciation – even among experts in the field – that such prior art exists or could exist. That rule creates tremendous uncertainty among patent holders and would-be patent applicants. They now face the prospect that their patents could be invalidated based on the subsequent discovery that a patented compound or process was unwittingly (and even undetectably) practiced in the prior art.

Review is warranted to determine whether this dramatic expansion in the inherent anticipation doctrine is an appropriate application of the patent laws. Review is particularly warranted because the decision below directly conflicts with a line of cases from this Court that dates back to 1881. Those cases hold that even where the practice of the prior art results in the production of a substance, a patent for discovery of the substance or the process of its production is not precluded if no one, not even experts in the field, are aware of the substance's existence. This limitation on inherent anticipation doctrine is referred to as "accidental anticipation" or "accidental prior use" doctrine. In its recent expansion of the inherent anticipation doctrine, the Federal Circuit has made no mention of the "accidental prior use" doctrine or this Court's relevant case law. Indeed, the Federal Circuit gives

every appearance of having simply written the "accidental prior use" doctrine entirely out of the law.

Review is also warranted because the decision below threaten to severely undermine incentives for pharmaceutical companies to invest in new, life-saving therapies. The appeals court stated that its result serves the laudable purpose of increasing public access to prior art. To the contrary, the most effective method of increasing the flow of useful scientific information is to reward those who uncover the significance of previously unappreciated prior uses. It does the public no good if researchers are unwilling to invest the resources necessary to hunt for such unwitting uses. The appeals court may be correct that an expert in the field, using Ferrosan's methodology for synthesizing PHC anhydrate, would eventually serendipitously produce detectable quantities of PHC hemihydrate after a number of years, but the expert would have little incentive to engage in that multi-year effort if the patent system will not reward him for doing so. Thus, without the incentives provided by the patent system, unappreciated prior uses are likely to remain unappreciated. Nor can one point to patents on the prior art as providing the necessary incentives, particularly in areas such as the pharmaceutical industry in which the lag time necessary to bring a product to market can span decades. SmithKline's experience is a case in point: the Ferrosan patent expired one year *before* Paxil was finally brought to market.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH DECISIONS OF THIS COURT THAT ESTABLISH AN "ACCIDENTAL PRIOR USE" DOCTRINE

Under 35 U.S.C. § 102, an invention is anticipated, and therefore unpatentable, if a single prior art reference teaches each and every limitation of the claimed invention. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, a prior art reference may anticipate even though it does not disclose one of the features of the claimed invention if that missing characteristic is necessarily present, or "inherent," in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Precisely when a missing characteristic can be deemed "inherent" has been the subject of considerable litigation. For more than a century, courts have agreed that there is at least one situation to which "inherent anticipation" should not apply: where the prior art accidentally or unwittingly discloses the claimed subject matter, and no one – not even experts in the field – recognizes the existence of the disclosure. *See, e.g.*, *Tilghman v. Proctor*, 102 U.S. 707 (1881).

There has long been a fair amount of tension between these competing doctrines. There will always be cases that are near the line separating the two doctrines; in those instances it can be difficult to decide whether a claimed invention should be deemed inherently anticipated by prior art or whether the prior art's disclosure should be deemed wholly unwitting and unappreciated.

The Federal Circuit has opted to resolve that tension by essentially writing the accidental prior use doctrine out of the

law. In *Schering Corp.*, the court held flatly, "[I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure." *Schering Corp.*, 339 F.3d at 1377. Moreover, the court made clear that the inherent anticipation doctrine can apply even when *none* of the features of the claimed subject matter are explicitly revealed in the prior art. *Id.* The court below followed that same approach, citing *Schering Corp.* for the proposition that "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure of the prior art at the time the prior art is created." Pet. App. 18a. But if the inherent anticipation doctrine contains no requirement that anyone did or could have recognized the inherent disclosure within some reasonable time frame, then nothing is left of the accidental prior use doctrine. Under the Federal Circuit's new standard, an accidental prior use will *always* call for application of the inherent anticipation doctrine, because it no longer matters that the use was unwitting and unappreciated.

The Federal Circuit's rejection of the accidental prior use doctrine directly conflicts with the decisions of this Court. For example, in *Tilghman v. Proctor*, 102 U.S. 707 (1881), the Court upheld a patent for a process for obtaining fat free acids and glycerine from fatty bodies, rejecting a claim that the patent had been anticipated and was thus invalid. Although recognizing that prior art had achieved the separation of fat acids, the Court found it determinative that those conducting the prior art had "never fully understood" what they had accomplished or how it could be put to practical use. *Tilghman*, 102 U.S. at 711. The Court explained, "If the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that

this was an anticipation of Tilghman's discovery." *Id.* at 711-12.

The decision below also conflicts with the Court's decision in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). In *Eibel*, the Court upheld a patent for improvements on a machine for making newsprint. The court rejected an anticipation challenge to the patent, holding: (1) there was no evidence that the prior art had achieved the result sought and obtained by Eibel's patent; and (2) if the prior art "had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation." *Eibel*, 261 U.S. at 66 (citing *Tilghman*, 102 U.S. at 711).

The decision below also conflicts with more recent federal court decisions. For example, in *In Re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964), the court upheld a patent on an isotope of americium made by nuclear reaction, overturning a U.S. Patent and Trademark Office rejection of the claim on inherent anticipation grounds. The court explained that even though prior art apparently produced the product, the patent was still valid because the prior art produced the claimed product "in such minuscule amounts and under such conditions that its presence was undetectable." *Id*. at 998-99. *See also, Continental Can v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (inherent anticipation requires evidence both that "the missing descriptive matter is necessarily present in the thing described in the reference" *and* that "it would be so recognized by persons of ordinary skill").

The decision below makes no effort to distinguish any of these cases. *Schering Corp.* cites each of those cases but does not seek to distinguish them in any meaningful way. Rather, it suggests that anything said in *Tilghman* and *Eibel* about

accidental prior use is nonbinding *dicta* because in both cases the Court expressed doubt that the prior art actually produced the claimed subject matter. *Schering Corp.*, 339 F.3d at 1378. Even if the Federal Circuit were correct that the language in *Tilghman* and *Eibel* regarding inherent anticipation could more properly be categorized as *dicta* rather than holdings,[3] that would not lessen the urgency of granting review. Review is warranted any time a federal appeals court decides to ignore the guidance of a line of this Court's decisions.

Schering Corp. sought to distinguish *Seaborg* by pointing to evidence that, unlike in *Schering Corp.*, the substance in question was produced in such minute quantities that it was not detectable. *Id.* at 1379. But that distinction only serves to point out that the instant case is factually indistinguishable from *Seaborg*: here, as in *Seaborg,* any production of PHC hemihydrate before 1985 was in such minute quantities as to be undetectable.

There clearly are many cases in which the inherent anticipation doctrine is properly applicable even though the prior art does not expressly teach every limitation of a particular patent claim. Thus, for example, it is well accepted that "merely describing unexpected beneficial results of a known process does not entitle Plaintiffs to patent that process." *In re Cruciferous Sprouts Litigation*, 301 F.3d 1343, 1346 (Fed. Cir. 2002). If the product or process is well known and widely practiced, it does not matter that users are not fully aware of all the benefits of the practice. *Id*. (holding invalid a patent for the growing and eating of broccoli sprouts for the purpose of attaining newly discovered health benefits). But where, as here, no one (not even those experienced in the field

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[3] WLF's view is that the statements in question can best be categorized as alternative holdings rather than *dicta.*

who had been experimenting with PHC for years) had any inkling of the existence of hemihydrate PHC until 1985, a holding that the patent is invalid due to inherent anticipation can only be viewed as a complete rejection of the accidental prior use doctrine. Review is warranted to resolve the conflict created by this sharp break from the well-established patent case law of this Court and other federal courts.

II. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW THREATENS TO UNDERMINE DEVELOPMENT OF NEW, LIFE-SAVING THERAPIES

Review is also warranted because the decision below threaten to severely undermine incentives for pharmaceutical companies to invest in new, life-saving therapies. As Judge Newman declared in her dissent from the Federal Circuit's denial of rehearing *en banc*:

> The patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products would be called into question by this new ruling, giving rise to uncertainty as to existing patents, as well as negation of searches for the beneficial components of existing materials.

Pet. App. 59 (Newman, J., dissenting from order declining rehearing *en banc*).

In determining the proper scope of the inherent anticipation and accidental prior use doctrines, one must bear in mind the congressional purposes underlying those doctrines. Inherent anticipation doctrine is designed to "prevent[] the removal of features or properties that inherently exist, but are unknown and not taught in the prior art, from the public

domain." Paul G. Alloway, *Inherently Difficult Analysis for Inherent and Accidental Biotechnology Inventions*, 38 SUFFOLK U. L. REV. 73, 77 (2004). The accidental prior use doctrine is based on a recognition that "an unintended and unappreciated prior product or process does not provide knowledge to the public," and therefore that the patent law ought to provide incentives so that inventors will make an effort to ferret out those unintended and unappreciated prior products or processes. *Id.* In other words, both doctrines are designed to increase access to and use of scientific knowledge. Whether the inherent anticipation doctrine should be invoked in a patent dispute should turn largely on whether its invocation will serve that purpose.

The largely undisputed facts of this case make it relatively easy to predict the effects of the Federal Circuit's decision on the development of new pharmaceutical and biotechnology products. By depriving SmithKline of patent protection for PHC hemihydrate, the Federal Circuit has effectively told researchers that there are few rewards to be gained from expensive experiments of the type engaged in by SmithKline scientists regarding PHC anhydrate. If (as here) significant discoveries are made as a result of that type of research, the court will invoke inherent anticipation to deny patent protection to those discoveries. Given the decades-long wait often required to win marketing approval for a new drug, it is entirely plausible that an initial patent will have expired before any such approval is granted. Indeed, that is exactly what happened in this case: the Ferrosan patent expired in 1992, one year *before* Paxil was finally brought to market with its newly-developed active ingredient (PHC hemihydrate). Thus, despite devoting huge sums to development of a drug that has brought relief to millions of Americans, SmithKline

has received virtually no benefit from the patent laws.[4] One can assume that in the future, drug companies would be far less willing to undertake similar research given the decreased availability of financial rewards. *See generally*, Randy B. Boyer, *Schering Corporation v. Geneva Pharmaceuticals, Inc.: Requiem for the Recognition Requirement in the Law of Inherent Anticipation*, 14 FED. CIR. B.J. 677, 691-93 (2004/2005). The result could well be that future PHC hemihydrates will never be discovered, or that they will take many more years to be serendipitously produced.

On the plus side, the public will experience a short-term benefit from the invalidation of the SmithKline Beecham patent, as entry of generic competitors serves to drive down prices for drugs containing PHC hemihydrate. But those short-term benefits are likely to be outweighed significantly by the long-term costs in terms of decreased product development brought about by cutbacks in R&D expenditures. In light of the significant health-care costs imposed on American society by the Federal Circuit's abandonment of the accidental prior use doctrine, review of this case is warranted.

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[4] The only exclusivity that SmithKline ever received for Paxil sales came by virtue of the Federal Food, Drug, and Cosmetic Act, not patent law.

CONCLUSION

The Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
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2009 Massachusetts Ave., NW
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(202) 588-0302

Date: November 16, 2005