No. 05-489

IN THE
Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, *et al.*,

Petitioners,

v.

APOTEX CORPORATION, APOTEX, INC.
and TORPHARM, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

HUGH S. BALSAM*
HUGH L. MOORE
KEITH D. PARR
SCOTT B. FEDER
LORD, BISSELL & BROOK, LLP
115 South La Salle Street
Chicago, IL 60603
(312) 443-0700

** Counsel of Record* *Counsel for Respondents*

197857

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

CORPORATE DISCLOSURE STATEMENT

Respondents, Apotex Corp., Apotex, Inc. and Torpharm, Inc. are listed in the caption and are the real parties in interest. Parent corporations are Apotex Pharmaceutical Holdings, Inc. (parent of Torpharm, Inc. and Apotex, Inc.) and Apotex Holdings, Inc. (parent of Apotex Corp.).

No public company holds 10% or more of any of the corporate parties' stock.

TABLE OF CONTENTS

Contents

TABLE OF CITED AUTHORITIES

Page

Cases:

Cited Authorities

Cited Authorities

Cited Authorities

STATEMENT OF THE CASE

The '196 and '723 patents.

In 1977, a Danish company named Ferrosan obtained a patent—U.S. Patent No. 4,007,196 (the '196 patent)—on a new class of antidepressant compounds, particularly paroxetine and its salts. App. 2a, 113a. The '196 patent disclosed to the public how to make paroxetine salts, including paroxetine hydrochloride. *Id*. SmithKline later secured from Ferrosan a license to the patent and proceeded to commercialize paroxetine hydrochloride as an antidepressant drug. *Id*.

The '196 patent expired in 1992, and thus the public is free to make everything disclosed in it. *Id*. at 127a.

In 1985, a SmithKline employee noticed that recently made batches of paroxetine hydrochloride had somehow "morphed" from an anhydrate form to what he called a hemihydrate form. *Id*. at 114a. Although SmithKline's request for certiorari in this Court rests on the assumption that this hemihydrate crystalline form, *i.e.*, a different polymorph of paroxetine hydrochloride, was unknown and unknowable at the time (Pet. at 7-8), a SmithKline chemist, Ian Lynch, has admitted that polymorphism—*i.e.*, the tendency of the same chemical compound to exist in a variety of different crystalline forms—was a known phenomenon, and hence it was not unexpected. He explained that "polymorphism of an organic compound should not come as a surprise" and called it a "guilty until proven innocent situation." (Lynch Dep. 236:22 to 237:2, 237:5 to 238:17, 238:20 to 239:19, Tr. at 213:11-13, Pretrial Order at Ex. 43); (DTX 178 at 5).

In any event, SmithKline ultimately obtained a patent—U.S. Patent No. 4,721,723 (the '723 patent), the patent-in-suit here—on this hemihydrate form. The '723 patent expires in December 2006. App. 127a.

The '723 patent has six claims, but SmithKline asserted only claim 1 against Apotex, and thus that is the only claim that the Federal Circuit invalidated. *Id*. (SmithKline is thus wrong to imply, in the Question Presented and in other parts of its petition, that the entire patent was held invalid. (Pet. at i, 3, 8, 10)). Claim 1—the broadest of the claims—reads, simply, "[c]rystalline paroxetine hydrochloride hemihydrate." App. 3a. SmithKline urged, and the Federal Circuit adopted, a construction of claim 1 that extends to the limit of logic to include *any* amount of the hemihydrate, however insignificant—even a single unwanted and undetectable crystal in a batch of prior art anhydrate. *Id*. at 14a.

Apotex's product.

The active ingredient in Apotex's generic drug product is paroxetine hydrochloride anhydrate, *i.e.*, a public-domain form of paroxetine hydrochloride. *Id*. at 3a, 122a. At the infringement trial, however, SmithKline introduced testimony of its retained experts describing a "disappearing polymorph" theory. *Id*. at 120a. According to this theory, as applied to paroxetine hydrochloride, the paroxetine hydrochloride anhydrate that Ferrosan patented is unstable and morphs to some extent into a more stable form, which happens to be the hemihydrate. *Id*. at 126a-27a. SmithKline's experts theorized that the general environment has become "seeded" with crystals of the hemihydrate, and that the production of anhydrate will inevitably, due to the presence of hemihydrate "seeds," result in paroxetine hydrochloride anhydrate contaminated with some unavoidable trace amount of the hemihydrate. *Id*. at 122a-24a.

The district court rejected as fatally flawed SmithKline's efforts to demonstrate, using empirical tests, the presence of hemihydrate in Apotex's product. *Id*. at 144a. Consequently, SmithKline was forced to rely on a circumstantial inference, adopted by the district court and affirmed by the Federal Circuit, that Apotex's manufacture of paroxetine hydrochloride anhydrate inevitably would produce trace quantities of paroxetine hydrochloride hemihydrate through a process of conversion of a small amount of anhydrate to hemihydrate. *Id*. at 14a, 148a. Given the extremely broad "single crystal" construction of claim 1, and the inference, from the novel inevitable-production theory, that Apotex's product must contain at least one such crystal of the hemihydrate, the Federal Circuit determined that Apotex's anhydrate product infringes claim 1 of the '723 patent. *Id*. at 14a. Thus would SmithKline enjoin the public from practicing the prior art of the expired '196 patent.

Federal Circuit holds '723 patent invalid as anticipated by the '196 patent.

But one who lives by the sword also dies by the sword. The same inevitable production of trace or undetectable amounts of the hemihydrate that required a finding of infringement of claim 1 also served to invalidate claim 1, which covers even a single crystal of hemihydrate, for inherent anticipation. That is because a patent is invalid for anticipation if a single prior art reference—here the '196 patent—discloses, expressly or inherently, each and every limitation of the claimed invention. And because "[t]he '196 patent discloses a method of manufacturing PHC anhydrate that naturally results in the production of PHC hemihydrate," the Federal Circuit held that claim 1 of the '723 patent is inherently anticipated by the '196 patent. *Id*. at 19a. Hence,

the Federal Circuit thwarted SmithKline's effort to breathe new life into the '196 patent that expired 13 years ago.

And that is all it did. The Federal Circuit's ruling did not impact claims 2 through 6 of the '723 patent. Under those claims, SmithKline retains the exclusive right to make and sell pure and pharmaceutically useful amounts of the hemihydrate (the active ingredient in Paxil®) in the United States. Claim 2 claims "[c]rystalline paroxetine hydrochloride hemihydrate in substantially pure form." *Id*. at 192a. Claim 3 claims the same compound as characterized by the results of several analytical chemistry tests. *Id*. Claim 4 claims a process for making the compound. *Id*. Claim 5 claims a pharmaceutical composition (*i.e.*, a tablet, capsule, etc.) containing an effective amount of the compound. *Id*. And claim 6 claims a method of using an effective amount of the compound to treat depression. *Id*. Hence, this lawsuit has never been about impairment of SmithKline's exclusive right to make and sell the hemihydrate; but it is very much about SmithKline's effort to prevent others from making and selling prior art paroxetine hydrochloride anhydrate.

SmithKline sought rehearing *en banc* from the Federal Circuit's inherent-anticipation ruling, arguing that waiver precluded review of the district court's rejection of Apotex's inherent-anticipation argument. *Id*. at 220a. The rehearing petition did *not* argue that the appeals court's decision conflicted with any of this Court's rulings. At any rate, the entire Federal Circuit denied rehearing *en banc* without a single dissenting vote. *Id*.

REASONS FOR DENYING THE PETITION

The Federal Circuit's unremarkable decision in this unusual and highly fact-specific case breaks no new ground. To the contrary, it is firmly rooted in the most long-established and fundamental principles of patent law as announced and consistently applied by this Court, by the Federal Circuit, and by that court's predecessor. It is *SmithKline's* position that would truly be revolutionary, for it would contravene all the following tenets.

First and foremost, the public is entitled to practice the subject matter of the prior art. "It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property." *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896). "[T]he patent laws preclude the patentee of an expired patent and all others . . . from recapturing any part of the former patent monopoly; for those laws dedicate to all the public the ideas and inventions embodied in an expired patent." *Scott Paper Co. v. Marcalus Mfg. Co., Inc.*, 326 U.S. 249, 256 (1945). A patent claim may not "remove existent knowledge from the public domain, or . . . *restrict free access to materials already available*." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966) (emphasis added). In short, the patent statute's requirements of novelty and nonobviousness "express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of either that which is already available to the public or that which may be readily discerned from publicly available material." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989). Here, if claim 1 of the '723 patent, as construed by the Federal Circuit, were

in fact valid, Apotex and everyone else in the United States would be prohibited from producing prior art paroxetine hydrochloride anhydrate disclosed in the '196 patent, which expired in 1992. That is because, as the courts below found, it is impossible to produce paroxetine hydrochloride anhydrate without also producing at least a trace amount of paroxetine hydrochloride hemihydrate. App. 19a. This is an untenable result, and the Federal Circuit's decision precludes it.

Second, it is also axiomatic that claims must be construed the same way for infringement as for invalidity. *Burr v. Duryee*, 68 U.S. 579, 581 (1863). As this Court has held, a patentee who has sought and obtained a broad construction of a patent claim cannot later narrow it in order to avoid anticipation. *Smith v. Hall*, 301 U.S. 216, 232 (1937). To prove its infringement case, SmithKline obtained a construction of claim 1 that defines its invention structurally down to the smallest unit of crystalline paroxetine hydrochloride hemihydrate—*i.e.*, a single, undetectable crystal or any aggregation of such crystals. App. 11a. It was this broad construction, urged by SmithKline, that led the Federal Circuit inevitably to a holding of inherent anticipation. *Id*. at 22a. A holding that claim 1 is not anticipated would destroy this necessary logical symmetry that is a mainstay of the patent laws.

Third, and as a corollary to the above, an old maxim of patent law states that that which infringes, if later, anticipates if earlier. *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889); *Knapp v. Morss*, 150 U.S. 221, 228 (1893); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 203 (1894). As Professor Chisum states, the essential standard for infringement and anticipation is the same: whether a given product or process incorporates all the characteristics (*i.e.*, limitations) used to define the

invention in the claim of a patent. 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.02[1] (2005). In this case, because claim 1 of the '723 patent claims crystalline paroxetine hydrochloride hemihydrate in any amount, detectable or not, Apotex's paroxetine hydrochloride anhydrate product was held to infringe the claim because, as the district court inferred based on theories advanced by SmithKline's experts, Apotex's product inevitably will contain some amount, detectable or not, of the hemihydrate. App. 20a. But because paroxetine hydrochloride anhydrate made according to the disclosure of the '196 patent also inevitably would have contained at least a trace amount of the hemihydrate, the '196 patent anticipates claim 1 of the '723 patent. *Id.* at 22a.

The principles discussed above are inviolate: no decision of this Court or of the Federal Circuit has ever repudiated them, explicitly or implicitly. Not *Tilghman v. Proctor*, 102 U.S. 707 (1881). Not *Eibel Process v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). Not any of the court of appeals decisions that SmithKline says conflict with the Federal Circuit's decision in this case. Accordingly, SmithKline's claim of a conflict in the case law is not and cannot be correct. Pet. at 18.

Because SmithKline's position in this lawsuit is antithetical to the most basic principles of patent law, it is not surprising that not one of the 12 judges of the Federal Circuit dissented from the denial of SmithKline's request for rehearing *en banc*. App. 220a. In fact, *not a single judge* who has ever evaluated claim 1 under SmithKline's claim construction and infringement position has ventured the opinion that SmithKline can or should be able to effectively revive the expired '196 patent to prevent the public from making and selling public-domain anhydrate. Not a single

judge has agreed with SmithKline's argument that the same claim construction that led to a finding that Apotex infringes claim 1 somehow does not also lead to a finding that claim 1 is anticipated. This is, at root, an unremarkable case, with an unremarkable outcome that should be left undisturbed.

I. The Federal Circuit's decision is consistent with long-established law of inherent anticipation and presents no conflict with any decision of this Court.

The result in this case was mandated by the most basic principles of patent law and presents no conflict with prior decisions of this Court. This Court and the Federal Circuit have long held that a claim is invalid for anticipation if the scope of the claim is so broad as to encompass subject matter that is inevitably produced when one practices an expired patent or other prior art.

A. It has long been the law that a claim is invalid where its subject matter is inherent in the prior art, regardless of whether that subject matter was appreciated when the application for the patent was filed.

The Federal Circuit's decision is the latest in a long line of cases that find anticipation when the subject matter of the claim is inherent and inevitable in the prior art. The concept of the inevitable result as the hallmark of anticipation is illustrated by this Court's decision in *Foley v. United States*, 260 U.S. 667 (1923). There, the patent in suit claimed the use of "a vaporous or vapor-laden atmosphere" to reduce the level of retained solvent during the manufacture of gunpowder. On appeal, the patentee argued that, according to the laws of physics, the government's processes necessarily

would create the vapor-laden atmosphere of the patents, regardless of whether the government intended it or not. *Id*. at 676. This Court held that the same could be said of prior art processes and adjudged the patents to be "without justification," *i.e.*, anticipated. *Id*. at 676-77.

The Federal Circuit has held that a claim is invalid for anticipation not only where a property is inherent in the prior art but also where, as here, an ingredient is inherently and inevitably contained in the prior art:

> [The] same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The 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. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1348 (Fed. Cir. 1999); *see also Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1379-80 (Fed. Cir. 2003) (holding that inevitable production of the claimed metabolite upon consumption of the prior art drug rendered claim defining the metabolite *per se* inherently anticipated). *Atlas Powder* involved a claim to an explosive composition requiring "sufficient aeration," which was an inherent element in prior art blasting compositions. 190 F.3d at 1344. As noted, *Schering* involved a claim to a metabolite that was necessarily formed by carrying out the process disclosed in an expired patent. 339 F.3d at 1379-80. The claims at issue in these cases were held invalid because, as discussed above, the law does

not permit a patent claim to remove from the public domain subject matter of an expired patent or other prior art.

Contrary to SmithKline's contention (Pet. at 14), the law has never demanded that those skilled in the art must have recognized the inherent feature when the claimed invention was first made by others. In *W.L. Gore Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984), one of the first decisions of the Federal Circuit after that court was established, the court invalidated the broadest of several claims to a process for stretching Teflon to produce a material with unique waterproofing properties (Gore-Tex or an early version of it). Citing this Court's decisions in *Ansonia Brass & Copper Co. v. Electric Supply Co.*, 144 U.S. 11 (1892), and *General Electric Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242 (1945), the court held that operation of a previously patented machine was a "consistent and reproducible use" of the process defined by the claim, regardless of whether operators of the machine recognized the particular aspects of the process recited in the claim or the result achieved. 721 F.2d at 1548-49. To hold otherwise, the court said, would permit the patenting of "an old and unchanged process." *Id*. at 1549; *see also In re Shetty*, 566 F.2d 81, 86 (C.C.P.A. 1977) (noting that what "may be inherent is not necessarily known").

In cases after *Gore*, the Federal Circuit has consistently found inherent anticipation based on scientific evidence dating from after the patent application. In *Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (analyzed as obviousness-type double-patenting), the court found inherency based on scientific knowledge developed long after the patent issued. 251 F.3d at 969-70. Likewise, in *Atlas Powder*, the inherent ingredient in the prior art composition

was established using evidence produced by tests conducted after issuance of the patent. And, most recently, in *Schering v. Geneva*, the court expressly rejected "the contention that inherent anticipation requires recognition in the prior art." 339 F.3d at 1377, *citing In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1351 (Fed. Cir. 2002); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("Where . . . the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the result.").

In the face of this longstanding and consistent authority, SmithKline's claim that the Federal Circuit in the case at bar veered way off course and "vastly expand[ed]" the doctrine of inherent anticipation rings hollow. Pet. at 24. To the contrary, the truly revolutionary position is SmithKline's, for it would remove from the public domain subject matter of an expired patent.

B. There is no conflict with any decision of this Court.

There is also no conflict with any decision of this Court. To the extent that any general teaching can be derived from *Tilghman v. Proctor*, 102 U.S. 707 (1881), *Eibel Process v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), or *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403 (1902), it is that *accidental results*, obtained "in pursuit of other and different results," do not constitute anticipation. *Tilghman*, 102 U.S. at 711.

First, in each case there was an absence of proof that any of the prior art processes or machines *ever* duplicated the subject-matter of the patent claims in issue. *See Tilghman*, 102 U.S. at 711-12 ("We do not regard the accidental

formation of fat acid in Perkin's steam cylinder . . . (*if* the scum which rose on the water issuing from the ejection pipe was fat acid) as of any consequence. . . ." (emphasis supplied)); *Eibel*, 261 U.S. at 66 ("In the first place we find no evidence that any pitch of the wire, used before Eibel, had brought about such a result . . . and in the second place *if* it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation." (emphasis supplied)); *Carnegie*, 185 U.S. at 429 (failure of proof that prior art process incorporated the patented process). *See generally Schering*, 339 F.3d at 1378 ("In contrast to the present case, the record in *Eibel* and *Tilghman* did not show that the prior art produced the claimed subject matter.") The passages in these cases that SmithKline relies on are couched in the hypothetical. Pet. at 11-13. The decisions themselves simply do not address situations where, as here, the prior art reference naturally and inevitably contains or produces the subject-matter of the patent claim.

Second, if subject matter is naturally and inevitably produced by the prior art, then it cannot be said to have been accidental—anymore than the natural occurrence of rain can be said to be accidental. *See Ecolochem, Inc. v. Southern Cal. Edison Co.*, 863 F. Supp. 1165, 1179 n.17 (C.D. Cal. 1994) (natural and necessary consequence of a prior art process cannot be considered to be an accident), *aff'd in part, rev'd in part on other grounds*, 1996 U.S. App. LEXIS 13330 (Fed. Cir., June 5, 1996), *cert. denied*, 532 U.S. 974 (2001). In the case at bar, an ordinarily skilled chemist seeking to make the paroxetine hydrochloride of the '196 patent does not "accidentally" make paroxetine hydrochloride containing at least a trace amount of hemihydrate; he or she *inevitably* makes it.

Indeed, evidence in the record shows that far from being accidental, the production of paroxetine hydrochloride hemihydrate was not unexpected when the application for the '723 patent was filed. This was recognized by Ian Lynch, a SmithKline chemist, who testified at deposition in the case at bar that polymorphism of organic compounds was a known phenomenon that "has been documented historically for many, many years" and "should not come as a surprise." This deposition was put into evidence at trial. (Lynch Dep. 236:22 to 237:2, 237:5 to 238:17, 238:20 to 239:19, Tr. at 213:11-13, Pretrial Order at Ex. 43). Further, in a 1985 memorandum, Lynch noted that "[p]olymorphism should be treated as a guilty until proven innocent situation"—meaning polymorphism was the rule rather than the exception. (DTX 178 at 5). Lynch was undoubtedly a person of ordinary skill in the art, and to him, the production of polymorphs such as the hemihydrate was no accident.

Third, neither *Tilghman*, *Eibel*, nor *Carnegie* permitted the patentee to exclude the public from practicing the subject matter of the prior art. That is precisely what SmithKline is trying to do here, but none of this Court's or the Federal Circuit's case law authorizes such a perverse result.

C. SmithKline's other authority is not on point.

SmithKline relies heavily on two cases involving the antibiotic tetracycline to support its argument that the unrecognized emergence of trace quantities of PHC hemihydrate in its production of PHC anhydrate cannot be held to inherently anticipate claim 1 of its '723 patent. But in neither case was the issue of § 102 anticipation litigated.

In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions, 498 F. Supp. 28 (E.D. Pa. 1980), *aff'd*, 676 F.2d 51 (3d Cir. 1982) (Pet. at 19), involved a suit by the government against Pfizer for cancellation of its patent on tetracycline on the ground that Pfizer's representatives committed fraud on the Patent Office. The district court held that Pfizer's failure to inform the examiner that trace amounts of tetracycline were produced in the manufacture of the prior art aureomycin did not constitute fraud, a holding the Third Circuit affirmed. *State of North Carolina v. Chas. Pfizer & Co.*, 384 F. Supp. 265 (E.D.N.C. 1974) (Pet. at 19), is a companion antitrust case decided the same way. Neither court gave any consideration to the claims of the patent, and, indeed, both decisions appear to have been based on an assumption that the invention of the patent was a clinically useful quantity of tetracycline, not the trace amount that was found in the prior art aureomycin.

SmithKline's other "co-production" cases are no better. *Ritter v. Rohm & Haas Co.*, 271 F. Supp. 313 (S.D.N.Y. 1967) (Pet. at 18), involved a patent on a chemical process, not on a previously unrecognized chemical compound. The court held that a prior art patent on a different process that, if carried out under a specific set of conditions, would produce the same product as the patentee's process, did not anticipate. *Ritter* thus stands for the proposition that only *inevitable* results, not chance or accidental results, can anticipate a patent claim. In *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964) (Pet. at 19-20), the court reversed the Patent Office's rejection of claims to a newly discovered isotope of uranium as inherently anticipated by a prior patent on a nuclear reactor and its operation. The C.C.P.A.'s opinion reflects considerable doubt as to whether operation of the reactor in fact produced the claimed isotope.

Also inapplicable are *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373 (Fed. Cir. 2002), and *Silvestri v. Grant*, 496 F.2d 593 (C.C.P.A. 1974) (Pet. at 14, 14 n.5). These cases concern anticipation in the context of prior invention under § 102(g), under which recognition by the inventor has long been necessary to establish conception and reduction to practice. *Rosco*, 304 F.3d at 1381; *Silvestri*, 496 F.2d at 597. While *Rosco* also includes a discussion of inherent anticipation, its holding on that point was based on the lack of evidence that the allegedly inherent feature of the invention was inevitably present in the prior art reference. *Rosco*, 304 F.3d at 1380-81.

While language in some other Federal Circuit decisions can be interpreted as suggesting a recognition requirement in the doctrine of inherent anticipation, *see, e.g.*, *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991) (Pet. at 14), the Federal Circuit has since recognized that "*Schering Corp. v. Geneva Pharm., Inc.* has clarified any confusion on this score." *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320 (Fed. Cir. 2004). Thus, it is not surprising that not a single Federal Circuit judge dissented from the order denying *en banc* review in this case. App. 220a. The law governing this appeal is settled, and there is no need for this Court's review.

II. The Federal Circuit's decision does not discourage innovation.

SmithKline's attempt to portray this case as "important" because the Federal Circuit's decision threatens existing patents and will chill innovation (Pet. at 21-22) is based on a wholly erroneous premise. The Federal Circuit did not invalidate the entire '723 patent on paroxetine hydrochloride hemihydrate. App. 22a. The court invalidated a single broad

claim that, if allowed to stand, would have prevented others from practicing the prior art. *Id*. It is a well-known principle among patent claim drafters that the broader the claim, the more susceptible the claim is to read on the prior art. Thus, patent attorneys routinely include in a patent application a series of claims of different format and scope. According to the leading text on claim drafting, "[s]ome claims should be sufficiently detailed that even if the broad claims covering the inventor's concept are held invalid, anyone who copies any of the inventor's disclosed preferred embodiments will infringe a valid detailed claim." ROBERT FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING § X-2 (5th ed. 2001).

SmithKline's skilled drafters did just that with claims 2 through 6 of the '723 patent, which were unasserted in this lawsuit and remain fully in force. App. 192a. These additional claims are considerably narrower than claim 1. They define, for example, crystalline paroxetine hydrochloride hemihydrate "in substantially pure form"; or "[a]n anti-depressant pharmaceutical composition comprising an effective anti-depressant amount of crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier"; or "[a] method of treatment of depression in mammals, which method comprises administering an effective amount of crystalline paroxetine hydrochloride hemihydrate." *Id*. These claims effectively preclude the public from making, using, or selling the hemihydrate in any useful amount. They remain valid.

The use of proper claim drafting techniques to avoid inherent anticipation in cases like this one, where an inventor claims to have discovered a previously unrecognized constituent of a known product, is illustrated by *In re Kratz*, 592 F.2d 1169, 1174 (C.C.P.A. 1979) (claims to a chemical flavoring agent not invalid for inherent anticipation because they did not claim either

the chemical in its naturally occurring state as a constituent of strawberries or strawberries *per se*, but rather claimed a substantially pure, synthetically produced version of the chemical); and *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970) (claims to pure prostaglandin compounds extracted from sheep glands not inherently anticipated by either the naturally occurring compounds themselves or prior art extracts; inventors have not "claimed sufficiently broadly to encompass, what has previously existed . . . in nature's storehouse"). *See also Schering*, 339 F.3d at 1381 (discussing claim drafting techniques, citing *Kratz* and *Bergstrom*).

SmithKline calls the inherent-anticipation issue "recurring." Pet. at 21. If it is so, that is only because of a fad among some drug companies to obtain patents on some aspect of a previously marketed drug that include claims that can be used to try to block generic competitors whose drug products are based on expired patents. *See, e.g.*, *Schering*, 339 F.3d 1373 (claims in patent on metabolite of marketed drug Claritin® held invalid for inherent anticipation); *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002) (claims to method of administering metabolite of buspirone would be inherently anticipated if construed to cover administration of buspirone itself); *In re Omeprazole Patent Litigation*, 2001 U.S. Dist. LEXIS 7103 (S.D.N.Y. May 31, 2001) (claims to metabolite of Prilosec®; same analysis); *Eli Lilly*, 251 F.3d at 970-72 (claims on method of blocking "serotonin up-take" by administering Prozac® held invalid for obviousness-type double patenting based on earlier patent on Prozac®). If the Federal Circuit's decision discourages such abusive uses of the patent system, then the public interest will be served.

Last, SmithKline asserts at several points in its petition that patents are granted for contributions to the fund of human

knowledge, implying that its discovery of paroxetine hydrochloride hemihydrate entitled it to a patent. Pet. at 4, 16. This is too simplistic. Advances in human knowledge, however important, receive the reward of a patent only if they constitute patentable subject-matter under 35 U.S.C. § 101, and then only if they pass the tests of anticipation under § 102 and nonobviousness under § 103. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002), *cert. denied*, 538 U.S. 907 (2003). The subject matter defined by claim 1 of the '723 patent did not pass the test.

III. If the Court grants the writ, then review of other issues will be required.

In this Court, a prevailing party may defend the judgment on any ground that was raised below. *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 38 (1989). If the Court were to grant SmithKline's petition, we respectfully suggest that, in order to do justice between the parties, the Court would then be obliged to consider all the grounds that the district court and the Federal Circuit have advanced for Apotex prevailing, including:

- whether the Federal Circuit correctly construed claim 1 of the '723 patent;
- whether the evidence supported an inference of infringement under the single-crystal claim construction;
- whether claim 1 should have been held invalid because it violates the public-use bar of 35 U.S.C. § 102(b); and
- whether claim 1 should have been held invalid for indefiniteness.

CONCLUSION

For all the above reasons, the petition for certiorari should be denied.

Respectfully submitted,

HUGH S. BALSAM*
HUGH L. MOORE
KEITH D. PARR
SCOTT B. FEDER
LORD, BISSELL & BROOK, LLP
115 South La Salle Street
Chicago, IL 60603
(312) 443-0700

Counsel for Respondents

* *Counsel of Record*

November 16, 2005