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 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

REPLY BRIEF

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INTRODUCTION AND SUMMARY OF ARGUMENT

The petition demonstrates that the rule of law adopted in *Schering Corp.* v. *Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir.), *reh'g and reh'g en banc denied*, 348 F.3d 992 (Fed. Cir. 2003), and expanded in the decision below, conflicts with *Tilghman* v. *Proctor*, 102 U.S. 707 (1881), *Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), and other decisions. The consequences for patent law and its purposes are profound and harmful. In response, Apotex melodramatically claims that SmithKline Beecham proposes to violate fundamental tenets of patent law and offers three sets of arguments in opposing certiorari. But, in fact, petitioner *embraces* the principles of patent law recited by Apotex; and, as we now show, it is Apotex which seeks to do violence to the established law of inherent anticipation.

First, Apotex claims that there is no conflict in authority. To illustrate this point, Apotex asserts that it has the unanimous support of the Federal Circuit – a claim that is easily disproved. Apotex also cites clearly inapposite cases and unsuccessfully attempts to distinguish *Tilghman*, *Eibel*, and other decisions holding that an unappreciated invention or discovery is *not* inherently anticipated by the prior art. In fact, the Federal Circuit's expansive new doctrine of inherent anticipation contravenes this Court's precedent, and for that reason alone warrants review.

Second, Apotex wrongly claims that SmithKline Beecham advocates a rule of inherent anticipation that would deprive the public of its right to practice the prior art of an expired patent. Petitioner fully agrees that a patent cannot prohibit practice of the prior art or remove something from the public domain. However, the hemihydrate, unknown and undetected, was never within the public domain, and thus Apotex cannot be properly said to be practicing the

procedures of the Ferrosan patent. Accordingly, petitioner's position is wholly consistent with the practice of prior art in the public domain.

Finally, Apotex contends that the rule of law at issue is not important to patent law and its underlying public policies. This claim ignores the threat to innovation that judges and numerous others conclude is presented by the radical expansion of the doctrine of inherent anticipation that now governs in the Federal Circuit. See Briefs of Pharmaceutical Research and Manufacturers of America and Washington Legal Foundation, filed Nov. 16, 2005; B. Bretschneider, *Making Us Crazy: The US Court of Appeals Messes with Inherent Anticipation*, Patent World, Nov. 2005, at 17-19.

ARGUMENT

I. THE FEDERAL CIRCUIT'S RULE CONFLICTS WITH THIS COURT'S DECISIONS AND ESTABLISHED PATENT LAW.

Apotex asserts that under established law, a patent claim is inherently anticipated whenever the claimed subject matter becomes the inevitable product of the prior art, even if that subject matter was wholly unappreciated in the prior art. This Court's decisions say the opposite; accordingly, Apotex's claims are meritless.

Initially, Apotex contends that there is no disagreement among Federal Circuit judges on this issue by claiming that no judge dissented from the denial of rehearing *en banc* below. Opp. 7, 15. That assertion is badly misleading. Clearly, Judge Newman, who dissented from the *initial* denial of rehearing *en banc*, strongly disagrees with the Federal Circuit's holding. App. 57a-59a. She also concluded that the decision conflicts with *Tilghman* and *Eibel*. *Id.* Moreover, in *Schering*, Judges Newman, Lourie and Gajarsa voted to rehear *en banc* the decision that jettisoned half of the established test for inherent anticipation. 348 F.3d at 994.

Second, Apotex claims that authority from both this Court and the Federal Circuit supports its position, but the cited cases do not find inherent anticipation based on the prior unappreciated invention of a novel product. Instead, these cases stand only for the unexceptional proposition that unappreciated *characteristics* of products and processes described in the prior art are inherently anticipated. The lone case cited from this Court, *Foley* v. *United States*, 260 U.S. 667 (1923), involved precisely this situation. The product created by the process at issue was known, and the allegedly novel invention simply identified a new characteristic of the product. In contrast, petitioner does not assert that a prior product has a newly-discovered characteristic, but instead claims a wholly new product unappreciated by the prior art.

Similarly, in *Atlas Powder Co.* v. *IRECO Inc.*, 190 F.3d 1342 (Fed. Cir. 1999), the Federal Circuit did not find inherent anticipation in an unappreciated creation of the prior art. Instead, the prior art disclosed a blasting compound but did not recognize the existence of interstitial air (*i.e.*, sufficient aeration). The court found that the requirement of interstitial air was inherently anticipated by the prior art because the prior art compositions contained sufficient air. *Id*. at 1345. As the court explained,

> [a]rtisans of ordinary skill may not recognize the *inherent characteristics or functioning of the prior art*. However, the discovery of a previously unappreciated *property* of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. [*Id.* at 1347 (emphasis supplied; internal citations omitted).][1]

[1] The court specifically analogized *Atlas Powder* to *Titanium Metals Corp.* v. *Banner*, 778 F.2d 775, 777 (Fed. Cir. 1985), where a prior art reference disclosed a metal alloy, but not its corrosive-resistant properties.

Like *Foley* and *Atlas Powder*, the court in *Eli Lilly & Co.* v. *Barr Laboratories, Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001), found that a claim is inherently anticipated by a prior art patent because the later claim disclosed only a characteristic of the prior art product (not a novel product).[2] These cases show that scientific advances revealing the inherent characteristics of a product or process described in the prior art do not result in patentable claims. None finds inherent anticipation of an unappreciated, separate *product* in prior art.

Third, Apotex parrots the Federal Circuit's attempted distinction of *Tilghman* and *Eibel*, arguing that in both cases the prior art may have produced the claimed invention only *accidentally*, and that in neither case was it certain that the prior art produced the subject matter of the later claim. Opp. 11-12. As the petition explained (12-17), this crabbed reading of that precedent is inconsistent with its language and its application by other federal courts. In both *Tilghman* and *Eibel*, this Court expressly assumed that the prior art inevitably produced the newly-claimed invention, and nonetheless held that the new invention was *not anticipated because it had not previously been appreciated*. In *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403 (1902), too, the Court declined to find inherent anticipation, relying in part on the fact that the subject matter of the claim had not been appreciated. This Court's cases thus demonstrate that even where a claimed invention is necessarily disclosed in the prior art, it is not inherently anticipated unless a person skilled in the art appreciated that fact.

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[2] *W.L. Gore & Assocs.* v. *Garlock*, 721 F.2d 1540 (Fed. Cir. 1983), and *Ecolochem, Inc.* v. *Southern Cal. Edison Co.*, 863 F. Supp. 1165 (C.D. Cal. 1994), *aff'd in part, rev'd in part by* 91 F.3d 169 (Fed. Cir. 1996). are distinguishable for the same reason. *See Gore*, 721 F.2d at 1548 (the "consistent reproducible use of" a patented process was inherently anticipated by prior art describing the same process even if the operators of the machine failed to appreciate aspects of that process); *Ecolochem*, 863 F. Supp. at 1179 n.17 (cation exchange resins have the characteristic quality of removing cation contaminants).

Next, Apotex makes a wholly unpersuasive attempt to distinguish numerous lower court decisions that read *Tilghman* and *Eibel* as SmithKline Beecham does. Two of these cases involved the production of unrecognized trace amounts of tetracycline while practicing the prior art to produce aureomycin. Apotex irrelevantly says that these cases raised the question whether Pfizer's patent on tetracycline should be cancelled because Pfizer had failed to inform the Patent Office that trace amounts of tetracycline were produced in the manufacture of aureomycin. Opp. 14. In both cases, the court found that Pfizer's omission did not constitute fraud and that the prior art did not inherently anticipate tetracycline *because the co-production of that substance had been undetected and unappreciated.* See *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 498 F. Supp. 28 (E.D. Pa. 1980) ("[c]oproduction of small amounts of tetracycline in the prior art which was unrecognized at the time . . . could not act as a bar to a patent on tetracycline"), *aff'd* 676 F.2d 51 (3d Cir. 1982); *North Carolina* v. *Chas. Pfizer & Co.*, 384 F. Supp. 265, 278 n.17 (E.D.N.C. 1974) (same), *aff'd*, 537 F.2d 67 (4th Cir. 1976).

Apotex's attempt to distinguish *Ritter* v. *Rohm & Haas Co.*, 271 F. Supp. 313 (S.D.N.Y. 1967), fares no better. Apotex contends that *Ritter* stands only for the proposition that the prior art results must be inevitable to anticipate a patent claim, and does not support the assertion that an unappreciated product in the prior art is not anticipated by that prior art. But, *Ritter* holds that the prior use of a process that produced esters did not preclude a patent on the same process to produce amides, an unappreciated product. The court's analysis focused *not* on inevitability, but instead on lack of appreciation:

> A previously unrecognized process . . . is not anticipated merely because a separate, known process . . . leading to a totally different result (an ester), happens to have the same reaction conditions and initial ingredients.

> Similarly, where products are "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 hold that this is anticipation." [*Id.* at 345-46.]

Least persuasive is the attempted distinction of *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964). Apotex asserts that the court found that the prior art did not anticipate the discovery of an isotope that was the unappreciated co-product of that prior art based on the court's "considerable doubt as to whether operation of the reactor in fact produced the claimed isotope." Opp. 14. To the contrary, the opinion makes clear that the prior process inevitably produced trace amounts of the new isotope and that inherent anticipation was *denied* because that isotope had been the unappreciated co-product of the prior art. See 328 F.2d at 999.[3]

Finally, Apotex asserts that *Schering* resolved the conflict among prior cases about whether appreciation is required for inherent anticipation. Petitioner agrees that *Schering*, as applied and expanded below, states the controlling rule of law in the Federal Circuit, the only circuit with appellate jurisdiction over patent questions. The problem, however, is that the Federal Circuit's rule is wrong and conflicts with the doctrine of inherent anticipation articulated in this Court's decisions and established law.[4]

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[3] Apotex acknowledges that *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), hold that prior art does not anticipate where the inventor does not appreciate the newly-claimed subject matter, Opp. 15, but asserts that these cases are distinguishable because they involve prior inventions whose rules of inherent anticipation allegedly differ from those applicable to prior discoveries. Apotex cites no support for this claimed distinction. In fact, there is a single rule – prior art does not anticipate a subsequent claim for an unappreciated product of that prior art.

[4] Twice Apotex seeks to dissuade the Court from granting review by suggesting that the existence of the hemihydrate was both known and

II. THE RULE OF LAW PETITIONER ADVOCATES WOULD NOT PREVENT THE PRACTICE OF THE PRIOR ART IN AN EXPIRED PATENT.

Apotex expends significant energy describing a tenet of patent law holding that the public is entitled to practice the subject matter of prior art once the patent on that prior art expires, and arguing that SmithKline Beecham's position would deprive the public of that right. Opp. 5-7. SmithKline Beecham, however, wholeheartedly endorses this basic proposition: A patent cannot prohibit practice of the prior art or remove subject matter from the public domain. But, the hemihydrate, undetected and unappreciated, was not within the public domain, and Apotex thus cannot properly be said to be practicing the prior art described in the 1977 Ferrosan patent. Accordingly, Apotex's contention that SmithKline Beecham is seeking to block the practice of prior art in the public domain is clearly wrong.

More specifically, Apotex does not propose to practice the claims of the prior art patent producing a paroxetine product as described by the 1977 Ferrosan patent. Instead, Apotex proposes to produce that product with hemihydrate. Indeed, in 1988, SmithKline Beecham's scientists published that seeds of hemihydrate and water are factors that cause conversion of the anhydrate to the hemihydrate. P.C. Buxton et al., *Solid-State Forms of Paroxetine Hydrochloride*, 42

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knowable at the time of the Ferrosan patent. Opp. 1, 13 (citing testimony that polymorphism was a "known phenomenon") This is contrary to both lower courts' factual findings. *See* App. 9a, 15a, 17a, 125a-126a, 131a ("the hemihydrate polymorph of paroxetine was unknown either when the patent application was filed or in 1977 when the patent was granted. Nor has Apotex shown that hemihydrate, the invention claimed by patent 723, was obvious given the prior art"). Indeed, the district court did not find clear and convincing evidence that the hemihydrate *existed* in the prior art, *id.* at. 132a; and expert testimony in the trial court confirmed that the existence of the hemihydrate could not have been predicted. *See* Trial Tr. 138-39. In any event, SmithKline Beecham does not seek to patent polymorphism, but instead the undetected, unappreciated hemihydrate.

Int'l J. Pharm. 135 (1988). Nevertheless, Apotex brought hemihydrate into its facilities, seeding its facilities with hemihydrate. App. 129a. More-over, Apotex uses an *aqueous* coating for its tablets. *Id.* at 128a-130a. In these circumstances, Apotex cannot be practicing the prior art as described in the 1977 Ferrosan patent.

Apotex's reliance on the maxims that patent claims "must be construed the same way for infringement as for invalidity," and "that which infringes, if later, anticipates if earlier," Opp. 6, is similarly misplaced. SmithKline Beecham fully accepts this principle. Its patent claim is to hemihydrate, and it asserts infringement based on Apotex's manufacture of the hemihydrate component of its product. Hemihydrate was not recognized before the inventors of the '723 patent's discovery. In contrast, there is no question that the hemihydrate in Apotex's product is recognized and appreciated. Petitioners' position is wholly consistent with all tenets of patent law that Apotex cites.

III. APOTEX'S ATTEMPTS TO MINIMIZE THE IMPORTANT, RECURRING NATURE OF THE ISSUE PRESENTED ARE WEAK AND WRONG.

Apotex maintains that the Federal Circuit's rule of inherent anticipation will not discourage innovation because, although it invalidated SmithKline Beecham's patent claim for the hemihydrate, it did not invalidate other SmithKline Beecham patent claims involving the hemihydrate. Opp. 16.

This argument wholly misses the critical point. The decision below presents an issue of recurring importance because it adopts and expands a *rule of law* that will generally thwart settled expectations embodied in extant patents and threaten the innovation that patent laws are designed to protect. As Judge Newman stated, the Federal Circuit's expanded doctrine of inherent anticipation calls into question "the patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products" and

gives rise to "uncertainty as to existing patents, as well as the negation of searches for the beneficial components of existing materials." App. 59a. As the Petition describes, not only Judge Newman, but Professor Chisum and numerous other commenters have recognized the critical importance and potentially damaging impact of the Federal Circuit's broad, new inherent anticipation doctrine. See Pet. 21-24. No use of effective claim drafting techniques (Opp. 15-16) can forestall the resulting uncertainty's damage to embedded expectations and incentives for innovation.

Moreover, the Federal Circuit's expansion of the doctrine of inherent anticipation will allow products and processes that were unknown and undetected to spring to life as patent-defeating prior art upon their discovery at some future date. This leads to the absurd result that a subject matter becomes prior art by its mere existence, though its existence was unknown and unknowable at the time of invention. This defect in the Federal Circuit's ruling cannot be remedied by artful drafting. The result will be uncertainty with respect to existing and future patents – an uncertainty that will discourage innovation by pharmaceutical drug manufacturers and all inventors who must invest millions to develop new products. See Pet. 23.

Apotex does concede that the important issue raised by the petition is recurring, but attributes its recurrence to repeated attempts by drug companies to block generic versions of drug products based on expired patents. Opp. 17. This is a red herring designed to distract the Court's attention from the vast, damaging implications of the Federal Circuit's rule. If Apotex were marketing the product described in the Ferrosan patent, SmithKline Beecham would have no quarrel with it. And, the myriad cases and differing circumstances raising the issue of inherent anticipation illustrate that the question presented extends far beyond the realm of post-patent expiration generic drugs. Under the Federal Circuit's expanded inherent-anticipation doctrine, a patent may be

invalidated by a later discovery that the claimed subject matter existed prior to the filing of the patent application – even if it existed in an undetected, undetectable quantity and thus was not part of the store of useful human knowledge.

Finally, Apotex contends that if the Court were to grant the petition, it would also "be obliged" to consider all grounds advanced in support of affirmance. Opp. 18. This is clearly wrong. The Court's standards for certiorari review, see Sup. Ct. R. 10, do not require the Court to address issues that lack general importance. *Roberts* v. *Galen of Va., Inc.*, 525 U.S. 249, 253-54 (1999). The notion that a grant of certiorari to review a specific legal issue should be accompanied by a broad review of unrelated factual issues is inconsistent with this Court's rules and practices. This Court reviews specific legal questions, not findings of fact. Apotex has made no effort to demonstrate that the additional issues it seeks to raise satisfy Rule 10.

CONCLUSION

For the foregoing reasons and those in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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