No. 05-489

In the Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, ET AL.,
PETITIONERS

v.

APOTEX CORPORATION, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether a compound that is inevitably produced by the prior art is inherently anticipated by the prior art, and thus not novel under 35 U.S.C. 102.

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This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

Petitioners GlaxoSmithKline P.L.C., SmithKline Beecham Corporation d/b/a GlaxoSmithKline Inc., SmithKline Beecham P.L.C. and Beecham Group, P.L.C. filed suit alleging that respondent Apotex, Inc., and affiliates of Apotex were infringing U.S. Patent No. 4,721,723 (the '723 patent) by preparing to sell a generic version of the anti-depressant drug Paxil. Following a bench trial, the district court entered judgment for respondents, and the court of appeals affirmed.

1. In the 1970s, a company called A/S Ferrosan obtained U.S. Patent No. 4,007,196 (the '196 patent) on a set of man-made compounds known as paroxetine and its salts. When paroxetine salt is combined with other substances, it acts as an anti-depressant. Ferrosan licensed the '196 patent to petitioners, who began producing paroxetine hydrochloride (PHC), the crystalline hydrochloride salt of paroxetine. Pet. App. 2a, 113a.

In 1985, a SmithKline chemist noticed that PHC molecules in SmithKline's laboratory had bound with water to create a different form of PHC. The resulting compound is called a hemihydrate, while the original form discovered by Ferrosan is known as an anhydrate. Petitioners later discovered that a batch of paroxetine produced at their manufacturing facility in December 1984 had been PHC hemihydrate as well. Pet. App. 2a-3a, 114a, 125a-126a.

Petitioners obtained the '723 patent on (i) PHC hemihydrate; (ii) PHC hemihydrate in substantially pure form, in a particular configuration, or in an effective anti-depressant drug; and (iii) related manufacturing and treatment methods. In 1993, petitioners began marketing PHC hemihydrate under the name Paxil. Paxil is now a leading anti-depressant drug with annual sales of $3.2 billion worldwide. The '723 patent will expire at the end of 2006. Pet. App. 2a-3a, 110a, 127a, 192a.

In 1998, respondents sought approval from the Food and Drug Administration to market PHC anhydrate as a generic version of Paxil. By that time, the '196 patent, which covers PHC anhydrate, had expired. Respondents argued that the anhydrate is bioequivalent to Paxil but does not infringe the '723 patent because that patent is limited to PHC hemihydrate. See Pet. App. 3a, 119a.

2. Petitioners sued respondents for patent infringement. Petitioners argued that respondents' manufacture of PHC anhydrate would inevitably produce trace amounts of PHC hemihydrate, and therefore infringe the '723 patent. According to petitioners, the factory where respondents plan to produce the anhydrate was "seeded" with the hemihydrate when respondents experimented on Paxil, and the process of turning PHC anhydrate into a pill would cause further conversion of the anhydrate into PHC hemihydrate. Pet. App. 129a-130a.[1]

After a bench trial, the district court held that the '723 patent is not invalid, but that respondents' generic version of Paxil would not infringe the patent and that petitioners would not be entitled to relief in any event. Pet. App. 109a-182a. The court first considered whether PHC hemihydrate was "inherent in patent 196 because anyone who followed the directions in that patent would inevitably produce hemihydrate." *Id.* at 131a. Citing scientific uncertainty and the presumption of patent validity, the court ruled that PHC hemihydrate was not inherent in PHC anhydrate because it is possible that practicing the '196 patent in a non-seeded laboratory would not have produced any PHC hemihydrate. *Id.* at 132a-133a.

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[1] "Seeding" refers to a process by which a particular (and typically more stable) crystalline form of a substance having more than one crystalline form—a "seed"—is introduced into a particular environment, such as a laboratory or manufacturing facility, and then, by a molecular process that is not well understood, interacts with another (typically less stable) form of the substance and converts it into the same form as the "seed." "Seeding" a facility with PHC hemihydrate would facilitate the conversion of PHC anhydrate into PHC hemihydrate. Pet. App. 114a-116a, 121a-124a.

Nevertheless, the court concluded that petitioners could not prevail. Although claim 1 in the '723 patent covers "crystalline paroxetine hydrochloride hemihydrate," the court construed it not to claim trace amounts of the hemihydrate. Pet. App. 132a-142a. In the alternative, the court concluded that equity does not support granting petitioners relief, in part because they bear some responsibility for the seeding effect. *Id.* at 164a-169a.

3. The court of appeals affirmed. Pet. App. 1a-55a. In its initial opinion (*id.* at 60a-108a), the court rejected the district court's claim construction, and held that claim 1 applies by its terms to any amount of PHC hemihydrate. *Id.* at 69a-70a. The court then concluded that the claim is invalid under 35 U.S.C. 102(b) because PHC hemihydrate had been publicly used in clinical trials for more than one year before petitioners applied for the patent. Pet. App. 75a-82a.

The en banc court of appeals vacated the panel's original opinion addressing the issue of public use, and remanded the matter to the panel. Pet. App. 56a-57a. Simultaneously, the panel issued a new opinion which, instead of relying on the public use exception, holds that claim 1 of the '723 patent was inherently anticipated by the prior art covered by the '196 patent. *Id.* at 1a-55a.

Under 35 U.S.C. 102(b), a patent claim is invalid if "the invention was patented or described in a printed publication in this * * * country * * * more than one year prior to the date of the application for patent in the United States." The court of appeals explained that "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." Pet. App. 18a (quoting *Schering*

Corp. v. *Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)). Further, "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the art at the time the prior art is created." *Ibid.*

Reviewing the district court's factual findings, the court of appeals concluded that manufacturing PHC anhydrate pursuant to the '196 patent "inevitably results in the production of at least trace amounts of" PHC hemihydrate. Pet. App. 19a; accord *id.* at 20a, 22a. Thus, the court concluded, "the '196 patent inherently anticipates claim 1 of the '723 patent under 35 U.S.C. § 102(b)." *Id.* at 22a.

Because "SmithKline has sued Apotex for infringement of the '723 patent in an express attempt to prevent Apotex from practicing the '196 patent upon its expiration," the court emphasized that "[i]nvalidating claim 1 of the '723 patent for inherent anticipation by the '196 patent furthers th[e] policy of allowing the public to practice expired patents." Pet. App. 22a-23a. The court stressed that its holding "merely precludes patent protection for the bare compound PHC hemihydrate," and that narrower patent claims could be valid. *Id.* at 23a.

Judge Gajarsa concurred. Pet. App. 25a-55a. In his view, claim 1 is invalid because it covers not only man-made PHC hemihydrate, but also naturally occurring PHC hemihydrate, and thus "encompasses subject matter that is unpatentable under 35 U.S.C. § 101." *Id.* at 25a.

Judge Newman dissented from the order denying rehearing en banc. Pet. App. 57a-59a. She opined that if the "existence" of a compound "is not reasonably known to persons of skill in the field, its later discovery cannot be retrospectively 'inherently anticipated.'" *Id.* at 59a.

DISCUSSION

A COMPOUND THAT IS INEVITABLY PRODUCED BY THE PRIOR ART IS INHERENTLY ANTICIPATED BY THAT ART

The patent claim at issue in this case asserts exclusive rights to PHC hemihydrate—regardless of the amount, purity, or use of that compound—even though PHC hemihydrate was inevitably produced by the practice of the prior art. The court of appeals correctly held that the patent claim is invalid because PHC hemihydrate was inherently anticipated by the prior art that inevitably produced it.

Petitioners argue (Pet. 11-13) that the court of appeals departed from decisions of this Court holding that inherent anticipation occurs only if persons skilled in the art recognized the inherent matter at the time the prior art was created (as opposed to the later time when the patent applicant made the alleged discovery). This Court has squarely rejected that contention, however, by holding that a characteristic of a pre-existing product is not patentable even if no one had previously recognized that characteristic. *General Elec. Co.* v. *Jewel Incandescent Lamp Co.*, 326 U.S. 242, 247 (1945); *Ansonia Brass & Copper Co.* v. *Electric Supply Co.*, 144 U.S. 11, 18 (1892). PHC hemihydrate is a characteristic of PHC anhydrate because the anhydrate inevitably produces the hemihydrate.

The cases relied on by petitioners are distinguishable for at least three reasons: they did not involve attempts to patent pre-existing products; they did not involve patents that would prevent the public from practicing the prior art; and it was not clear in those cases that the prior art had in fact inevitably produced the allegedly inherent result. By contrast, upholding a patent claim

on a product that is inevitably produced by those practicing the prior art would effectively remove that prior art from the public domain. As the court of appeals correctly held, petitioners are not entitled to such a patent.

A. In Order To Protect The Public's Right To Exploit The Public Domain, Patent Protection Applies Only To Novel Inventions

The Constitution grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. Art. I, § 8, Cl. 8. As this Court has explained, the Patent Clause "contains both a grant of power and certain limitations upon the exercise of that power." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Of particular relevance here, "when [a] patent expires the monopoly created by it expires, too, and the right to make the article * * * passes to the public." *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 230 (1964); see *Bonito Boats*, 489 U.S. at 152-153. "Congress may not * * * 'authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.'" *Id.* at 146 (quoting *Graham* v. *John Deere Co.*, 383 U.S. 1, 6 (1966)).

Pursuant to those directives, "§ 102 of the Patent Act * * * exclud[es] ideas that are in the public domain from patent protection." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998). In relevant part, Section 102 provides:

A person shall be entitled to a patent unless—

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in the country more than one year prior to the date of application for patent in the United States.

35 U.S.C. 102(a) and (b).

Section 102 is an integral part of the patent system's "carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff*, 525 U.S. at 63. When a patent expires, the knowledge disclosed in the patent is dedicated to the public. "Where the public has paid the congressionally mandated price for disclosure," "the subject matter of the patent passes to the free use of the public as a matter of federal law." *Bonito Boats*, 489 U.S. at 152; accord *Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23, 33-34 (2003). "[F]ree exploitation" of knowledge is the rule, "to which the protection of a federal patent is the exception." *Bonito Boats*, 489 U.S. at 151.[2]

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[2] In the pharmaceutical context, Congress has particularly emphasized the importance of protecting the public domain. Before 1984, "the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term," because the manufacturer of a generic drug could not begin to seek regulatory approval to market its drug until related patents expired. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 670 (1990). Congress responded by enacting a new

B. The Prior Art Inherently Anticipated PHC Hemihydrate Regardless Of Whether A Person Skilled In The Art Would Have Recognized That Inherent Disclosure At The Time The Prior Art Was Created

1. The prior art may anticipate a claimed invention, and thereby render it non-novel, either expressly or inherently. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002), cert. denied, 538 U.S. 907 (2003). Express anticipation occurs when the prior art expressly discloses each limitation (*i.e.*, each element) of a claim. *Ibid*. In addition, "[i]t is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." *Ibid*. Inherency looks to whether a matter is "necessarily" present in the prior art; it "may not be established by probabilities or possibilities." *Scaltech Inc.* v. *Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999). Thus, as petitioners correctly concede (Pet. 11), "[a] claimed invention may be inherently anticipated by a prior art disclosure if the claimed invention necessarily or inevitably flows from the prior art." See, *e.g.*, *Cruciferous Sprout*, 301 F.3d at 1349; *Atlas Powder Co.* v. *Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

The court of appeals correctly applied that undisputed legal principle in holding that, on the facts as found by the courts below, the '196 patent inherently anticipated PHC hemihydrate because "the record shows

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approval process for generic drugs in the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585, that permits competing drugs to be marketed as soon as related patents expire. *Eli Lilly*, 496 U.S. at 671.

that the manufacture of PHC anhydrate according to the '196 patent necessarily results in the production of PHC hemihydrate." Pet. App. 20a; see *id.* at 9a ("the anhydrate form inevitably changes into the hemihydrate form"); *id.* at 19a ("producing PHC anhydrate according to the '196 patent inevitably results in the production of at least trace amounts of anticipating PHC hemihydrate"); *id.* at 22a ("the record contains clear and convincing evidence that production of PHC anhydrate in accordance with the '196 patent inherently results in at least trace amounts of PHC hemihydrate"); *id.* at 19a ("The '196 patent discloses a method of manufacturing PHC anhydrate that naturally results in the production of PHC hemihydrate.").

As the court of appeals explained, the patent claim at issue here—which reads in its entirety "Crystalline paroxetine hydrochloride hemihydrate"—covers "PHC hemihydrate without limitation." Pet. App. 10a. In other words, it covers even "trace amounts" of the "bare compound." *Id.* at 23a. Because PHC anhydrate was part of the prior art and practicing that prior art inevitably produces PHC hemihydrate, the anhydrate inherently anticipated the hemihydrate.[3]

2. Petitioners nonetheless argue (Pet. 13-17) that the '196 patent did not inherently anticipate PHC hemihydrate because the hemihydrate's creation by the prior art was unintentional and unforeseen. According to petitioners (Pet. 14), "a person of ordinary skill in the art

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[3] One of petitioners' *amici* argues that the court of appeals' determination that the practice of the prior art inevitably produces the hemihydrate is not supported by the district court's findings. See PhRMA Am. Br. 6. That fact-bound contention does not warrant review, however, and moreover it does not appear to be included in the question presented. See Pet. i.

must have been able to know or appreciate th[e] inherent subject matter *before* the subsequent claim was made" in order for the doctrine of inherent anticipation to apply. Petitioners are mistaken.

In *General Electric*, this Court held invalid a patent related to a light bulb that was particularly strong because the interior surface of the glass was frosted by etchings. 326 U.S. at 246-249. The prior art included similarly frosted bulbs, but did not expressly disclose that the frosting improved the bulbs' strength. *Id.* at 247. This Court observed that although the patent applicant "found latent qualities in an old discovery and adapted it to a useful end," "[i]t is not invention to perceive that the product which others had discovered had qualities they failed to detect." *Id.* at 248-249. As the Court explained, "[i]f A without mentioning the element of strength patented a bulb which was extra strong, B could not obtain a patent on the bulb because of its strength, *though he was the first to recognize that feature*." *Id.* at 247 (emphasis added). The claimed "strengthening was inherent in the [prior art] method," and was therefore not patentable, even though the prior art had not "given any indication that [it] resulted in any strengthening of the glass." *Id.* at 246-247. Accord *Ansonia Brass*, 144 U.S. at 18 (holding that patent applicant "had no right to claim the feature of incombustibility as his invention" because a feature of an existing product or process is not patentable "even if the new result had not before been contemplated").

Following this Court's lead, the Federal Circuit has repeatedly held that "[i]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art" because "[a]rtisans of ordinary skill may not recognize the inherent characteristics or functioning of

the prior art." *Atlas Powder*, 190 F.3d at 1347; accord *Schering*, 339 F.3d at 1377; *Cruciferous Sprout*, 301 F.3d at 1349; *Titanium Metals Corp. of Am.* v. *Banner*, 778 F.2d 775, 780, 782 (1985). Those longstanding precedents of this Court and the Federal Circuit amply support the court of appeals' holding in this case 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." Pet. App. 18a.

3. Petitioners seek (Reply Br. 3-4) to distinguish the *General Electric* line of cases on the ground that they involve inherent characteristics of previously known products, as opposed to separate products. According to petitioners (*ibid.*), the hemihydrate is not a characteristic of the anhydrate, but instead is a separate product. As the Federal Circuit recognized in *Schering*, however, that is a distinction without a difference in this context, in which the manufacture of a previously known compound inevitably produces a newly identified one. 339 F.3d at 1379-1380. In that circumstance, the creation of the newly identified compound is an inherent characteristic of the prior art compound.

As the *Schering* court also recognized, a failure to apply ordinary principles of inherent anticipation in this context would enable patent applicants to withdraw prior art compounds from the public domain whenever those compounds (or their production or use) inevitably produce a newly discovered compound. 339 F.3d at 1379. The law simply does not permit that result. It is a bedrock principle of patent law that "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it

also covers subject matter not in the prior art." *Atlas Powder*, 190 F.3d at 1346; see *Schering*, 339 F.3d at 1379; pp. 7-8, *supra*.

That concern is especially pronounced here, because this case involves "an express attempt [by petitioners] to prevent [respondents] from practicing the '196 patent upon its expiration." Pet. App. 22a. Petitioners' theory is that respondents necessarily infringe the '723 patent because they cannot manufacture the prior art anhydrate covered by the '196 patent without creating undetectable but trace amounts of the hemihydrate at the same time. *Id.* at 14a.[4] Any such attempt to prevent a party from practicing the prior art is barred by the fundamental patent-law principle that "[t]hat which infringes if later, anticipates if earlier." *Miller* v. *Eagle Mfg. Co.*, 151 U.S. 186, 203 (1894) (citations omitted); see *Schering*, 339 F.3d at 1379; Pet. App. 14a. As the court of appeals correctly explained, "if the prior art infringes now, logically the prior art should have anticipated the claim before the filing of the '723 patent." *Id.* at 14a.

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[4] Although petitioners argue (Reply Br. 8) that respondents could avoid infringement by producing PHC anhydrate in a laboratory that had not been seeded with PHC hemihydrate, the court of appeals concluded that "PHC anhydrate made in accordance with the '196 patent converts into PHC hemihydrate both with and without seeding." Pet. App. 10a; see *id.* at 20a-21a. In any event, the prior art was not limited to production of PHC anhydrate solely in a laboratory carefully screened to be free of hemihydrate "seeding," so petitioner's theory would necessarily (and impermissibly) withdraw prior art activities from the public domain. As the court of appeals correctly explained, the "law does not require [respondents] to take extraordinary measures to practice the prior art without infringing claim 1 of the '723 patent." *Id.* at 22a (citing *Atlas Powder*, 190 F.3d at 1349-1350).

Petitioners attempt to avoid that conclusion by arguing that practicing the prior art (*i.e.*, manufacturing the anhydrate covered by the '196 patent) would *not* have infringed the '723 patent before petitioners' discovery of the hemihydrate, because it was only the "seeding" effect resulting from that discovery that caused the prior art to begin producing PHC anhydrate containing trace amounts of PHC hemihydrate. Pet. App. 15a. But that argument is simply inconsistent with the facts found by the courts below. The district court found that the hemihydrate was produced in detectable quantities by the operation of petitioners' *anhydrate* manufacturing process in December 1984. *Id.* at 125a. Thus, contrary to petitioners' suggestion, the manufacture of the anhydrate itself—*i.e.*, the practice of the prior art—led to the creation of the hemihydrate. The court of appeals thus concluded that "[t]he '196 patent discloses a method of manufacturing PHC anhydrate that naturally results in the production of PHC hemihydrate." *Id.* at 19a. The doctrine of inherent anticipation prevents petitioners from blocking the practice of the prior art covered by the expired '196 patent.

4. Although petitioners argue (Pet. 22) that the court of appeals' decision "threaten[s] the innovation that the patent laws are designed to protect," the decision below preserves ample incentives for innovation. As the court of appeals explained, its holding "merely precludes patent protection for the bare compound PHC hemihydrate," leaving narrower patent protection available "through proper claiming." Pet. App. 23a.

The patent at issue here claims not only the bare compound PHC hemihydrate (claim 1), but also PHC hemihydrate in "substantially pure form" (claim 2), as well as an "anti-depressant pharmaceutical composition

comprising an effective anti-depressant amount of crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier" (claim 5). Pet. App. 192a. The latter claims do not raise the concerns presented here, because their claimed subject matter is not inevitably created by the practice of the '196 patent. Providing patent protection for such claims would therefore reward innovation without preventing the public from practicing the prior art covered by the expired '196 patent.

Petitioners therefore err in asserting (Pet. 23) that the decision below will "substantially decrease[]" incentives to research new pharmaceutical compounds. Like petitioners in this case, researchers who discover novel drug compounds routinely include claims of varying scope and breadth in their patent applications rather than claiming only the "bare compound" in all-encompassing terms. In that fashion, they may retain protection for the actual, practical applications of their new discoveries even if their broader claims to the bare compound are ultimately rejected. The ability to obtain such patent protection provides ample incentives for innovation. What patent applicants cannot do is to receive patent protection for trace amounts of a substance that was inevitably produced by the practice of the prior art, and thereby withdraw that prior art from the public domain and make the exploitation of expired patents difficult or impossible.

C. The Court of Appeals' Decision Does Not Conflict With Decisions Of This Court Or Create Confusion In The Federal Circuit's Jurisprudence

1. Contrary to petitioners' contention, the court of appeals' decision does not conflict with decisions of this

Court involving unwitting or accidental discoveries. See Pet. 2-5, 11-13 (citing *Tilghman* v. *Proctor*, 102 U.S. 707 (1881); *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403 (1902); *Eibel Process Co.* v. *Minnesota & Ont. Paper Co.*, 261 U.S. 45 (1923)). The cases cited by petitioners are distinguishable for at least three reasons: they did not involve attempts to patent pre-existing products; they did not involve patents that would prevent the public from practicing the prior art; and it was not clear in those cases that the prior art had in fact inevitably produced the allegedly inherent result.

The court of appeals stressed that its holding "merely preclude[d] patent protection for [a] bare compound" that was inevitably created by the practice of the prior art. Pet. App. 23a. In contrast, neither *Tilghman* nor *Carnegie Steel* involved a patent on a product. The patents at issue in those cases were instead process patents, covering processes for purifying fats and oils, and for making steel, respectively. *Tilghman*, 102 U.S. at 708; *Carnegie Steel*, 185 U.S. at 430. That distinction is critical, because a process patent (unlike a patent on a particular composition of matter) is not anticipated merely by a showing that the ultimate output of the process was already known in the prior art. In *Carnegie Steel*, this Court expressly distinguished process from product patents by explaining that although "[a] mechanical patent is anticipated by a prior device of like construction and capable of performing the same function," "it is otherwise for process patents," which "can only be anticipated by a similar *process*." *Id.* at 424 (emphasis added). Thus, a patent on a new process does not prevent others from using prior art processes, whereas under petitioners' theory their patent on a "new" product would block others from manufacturing

the prior art product that inevitably produces the new one.

The *Eibel* patent, which involved substantially increasing the pitch of a wire cloth sieve used in papermaking machines in order to increase the rate of production, 261 U.S. at 46-47, is distinguishable on similar grounds. The inventor in *Eibel* did not seek a patent covering the pre-existing machine, but instead sought to patent an improved machine not disclosed by the prior art. *Id.* at 58-60. A prior art machine does not anticipate a newer and better machine, and a patent on the new machine does not preclude the practice of the prior art.

As the Federal Circuit recognized in *Schering*, 339 F.3d at 1378, it was also unclear in the cases relied on by petitioners whether the practice of the prior art had actually produced the allegedly inherent result. See *Tilghman*, 102 U.S. at 711-712 ("*If* the acids were accidentally and unwittingly produced * * * it would be absurd to say that this was an anticipation of Tilghman's discovery.") (emphasis added); *Eibel*, 261 U.S. at 66 ("[W]e find no evidence that any pitch of the wire, used before Eibel, had brought about such a result."); *Carnegie Steel*, 185 U.S. at 424 ("[N]one of [the prior art devices] in practical operation seems to have been effective to secure the desired result."). In contrast, the court of appeals stressed that "the manufacture of PHC anhydrate according to the '196 patent necessarily results in the production of PHC hemihydrate." Pet. App. 20a; see p. 10, *supra*.[5]

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[5] Petitioners' reliance (Pet. 18) on *Ritter* v. *Rohm & Haas Co.*, 271 F. Supp. 313, 346 (S.D.N.Y. 1967), is misplaced, because the district court there upheld a patent on a "new process, wholly unknown

2. Nor is there any confusion in the Federal Circuit's jurisprudence regarding inherent anticipation. Consistent with this Court's *General Electric* and *Ansonia Brass* decisions, the Federal Circuit has long held that characteristics of known products are inherently anticipated even if they were not previously recognized by persons skilled in the art. See, *e.g.*, *Atlas Powder*, 190 F.3d at 1347; *Cruciferous Sprout*, 301 F.3d at 1350; *Titanium Metals*, 778 F.2d at 782. And the Federal Circuit made clear in *Schering*, and reaffirmed in this case, that it "sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter," such as a compound that was inevitably created by practicing the prior art. *Schering*, 339 F.3d at 1379; see Pet. App. 18a.

In so holding, the Federal Circuit expressly distinguished the earlier decisions on which petitioners principally rely (Pet. 14, 19-20). *Schering* explained that *Continental Can Co. USA* v. *Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991), "does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date." 339 F.3d at 1377. Instead, the question in *Continental Can* was whether a prior art plastic bottle had in fact possessed a particular feature (hollow as opposed to solid ribs), and the court remanded for a factual determination of "whether [the prior art] necessarily produced 'hollow' ribs." *Continental Can*, 948 F.2d at 1269; see *Schering*, 339 F.3d at 1377-1378. In contrast, the court of appeals here held

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to" the prior art, as opposed to a product inevitably created by the prior art.

that the practice of the '196 patent inevitably produces PHC hemihydrate. Pet. App. 19a-20a.

Although *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964), contains some reasoning supportive of petitioners' position, the actual holding of the case was only that a substance was not anticipated by a prior art process when "[t]here [was] no positive evidence that [the substance] was produced inherently." *Id.* at 999. As the decision below explains, *Seaborg*'s holding is therefore consistent with the judgment in this case, because the record here reveals that the '196 patent does in fact "result[] in the production of the claimed PHC hemihydrate." Pet. App. 23a. To the extent, if any, that *Seaborg*'s reasoning is in tension with earlier and later holdings of the court of appeals and with this Court's decisions in *General Electric* and *Ansonia Brass*, it does not state the law, and provides no basis for review.[6]

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[6] Petitioners also rely (Pet. 18-19) on district court decisions for the proposition that the unrecognized production of a substance does not preclude a patent on that substance. Any perceived conflict between those cases and the decisions of the Federal Circuit, of course, would not merit review. Cf. Sup. Ct. R. 10(a). Moreover, those cases are inapposite. They involved the question whether a patent applicant had committed fraud on the patent office by not disclosing that tetracycline had been previously produced in trace amounts pursuant to a prior art method of producing a different substance. *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 498 F. Supp. 28, 35-36 (E.D. Pa. 1980), aff'd, 676 F.2d 51 (3d Cir. 1982); *North Carolina* v. *Charles Pfizer & Co.*, 384 F. Supp. 265, 277-278 (E.D. N. Car. 1974), aff'd, 537 F.2d 67 (4th Cir.), cert. denied, 429 U.S. 870 (1976). Although some courts found that there was no fraud on the patent office, the Federal Trade Commission concluded otherwise, and the Sixth Circuit affirmed that determination. *Charles Pfizer & Co.* v. *FTC*, 401 F.2d 574, 578 (1968), cert. denied, 394 U.S. 920 (1969). In any event, none of those cases involved an attempt to prevent the public from practicing the

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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prior art, and the Federal Circuit's subsequent decisions in *Schering* and this case have clarified that an applicant cannot obtain a patent on a bare compound that was inevitably produced by the prior art.