CORRECTED: MAY 13, 2004

United States Court of Appeals for the Federal Circuit

03-1285, -1313

SMITHKLINE BEECHAM CORPORATION
and BEECHAM GROUP, P.L.C.,

Plaintiffs-Appellants,

v.

APOTEX CORP., APOTEX, INC., and TORPHARM, INC.,

Defendants-Cross Appellants.

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Appealed from: United States District Court for the Northern District of Illinois

Judge Richard A. Posner

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DECIDED: April 8, 2005

Before RADER, BRYSON, and GAJARSA, Circuit Judges.[*]

Opinion for the court filed by Circuit Judge RADER. Concurring opinion filed by Circuit Judge GAJARSA.

RADER, Circuit Judge.

Following a bench trial, the United States District Court for the Northern District of Illinois determined that the generic paroxetine hydrochloride anhydrate product to be produced by Apotex Corp., Apotex, Inc., and TorPharm, Inc. (collectively Apotex) will not infringe claim 1 of U.S. Patent No. 4,721,723 ('723 patent) owned by SmithKline Beecham Corp. and Beecham Group, P.L.C. (collectively SmithKline). SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011, 1052 (N.D. Ill. 2003). Based on this court's revision of the trial court's erroneous claim construction, Apotex's product

[*] Pursuant to an order issued by this court en banc, the present opinion replaces this panel's prior opinion entered on April 23, 2004, as amended April 28, 2004, and reported at 365 F.3d 1306 (Fed. Cir. 2004).

would infringe claim 1 of the ’723 patent. Nonetheless, because claim 1 of the ’723 patent is invalid as anticipated under 35 U.S.C. § 102(b), this court affirms the district court’s judgment in favor of Apotex.

I.

In the late 1970s, a British company, Ferrosan, invented a new class of compounds, including a compound that became known as paroxetine. See U.S. Patent No. 4,007,196 (’196 patent). The ’196 patent claims paroxetine and its salts and discloses their antidepressant properties. Ferrosan eventually developed a process to produce the crystalline hydrochloride salt of paroxetine, or paroxetine hydrochloride (PHC). In 1980, Ferrosan licensed the ’196 patent and its other PHC-related technology to SmithKline. SmithKline began manufacturing PHC in its Harlow plant in England.

In March 1985, Alan Curzons, a chemist in SmithKline’s Worthing, England laboratory, discovered a new crystalline form of PHC while attempting to improve PHC production. Curzons’s test results established that the new product was the hemihydrous form of PHC (PHC hemihydrate). Ferrosan’s original form was anhydrous PHC (PHC anhydrate). PHC anhydrate comprises crystals of PHC without bound water molecules. PHC hemihydrate comprises PHC crystals with one bound water molecule for every two PHC molecules. PHC hemihydrate proved more stable, and thus more easily packaged and preserved, than PHC anhydrate.

SmithKline filed a patent application in the British Patent Office on October 25, 1985 relating to “crystalline paroxetine hydrochloride, its preparation and its uses as a therapeutic agent.” The British application identified the invention as both the

hemihydrate and the anhydrate form of PHC, as well as mixtures that contain a major portion of either form. One year later, on October 23, 1986, SmithKline filed a U.S. application claiming priority to the British application that issued as the '723 patent in 1988. The '723 patent does not claim PHC anhydrate and does not claim mixtures of the two PHC forms. The only claim at issue in this case is claim 1, which reads in its entirety: "Crystalline paroxetine hydrochloride hemihydrate."

In 1993, after completing the necessary FDA approval process, SmithKline placed its antidepressant drug with PHC hemihydrate as the active ingredient on the market under the name Paxil®. In 1998, TorPharm, Inc., an Apotex affiliate and manufacturer of Apotex's generic antidepressant, filed an Abbreviated New Drug Application (ANDA) with the FDA, under 21 U.S.C. § 355(j), seeking approval to market its own PHC antidepressant drug. Apotex identified the active ingredient in its antidepressant as PHC anhydrate. Apotex's ANDA included a paragraph IV certification, see 21 U.S.C. § 355(j)(2)(A)(IV), that indicated Apotex's intent to market the drug before the expiration of the '723 patent because its drug would not infringe that patent.

In 1998, SmithKline initiated this infringement action against Apotex under 35 U.S.C. § 271(e)(2) on the basis of Apotex's ANDA filing. SmithKline alleges that Apotex's proposed drug will infringe claim 1 of the '723 patent. SmithKline does not allege that claim 1 of the '723 patent covers PHC anhydrate. After all, PHC anhydrate – the Ferrosan discovery – is prior art for the '723 patent. SmithKline asserts that Apotex will infringe by manufacturing PHC anhydrate tablets that necessarily contain, by a conversion process discussed below, at least trace amounts of PHC hemihydrate.

The parties filed various summary judgment motions, including cross motions for summary judgment that claim 1 of the '723 patent was invalid (or valid) under 35 U.S.C. § 102(b) for an impermissible public use. The § 102(b) motions acknowledged that clinical trials occurred more than one year before SmithKline's filing date for the '723 patent, but disputed whether those tests qualified for the experimental use negation. The district court denied Apotex's motion and granted SmithKline's motion, holding that the '723 patent was not invalid for public use under § 102(b). The district court reasoned that the clinical trials qualified as experimental uses. See SmithKline Beecham Corp. v. Apotex Corp., 286 F. Supp. 2d 925, 932-38 (N.D. Ill. 2001).

The district court then held a bench trial to determine the proper interpretation of claim 1 and to resolve the remaining infringement and validity issues. On the question of claim construction, the district court limited claim 1 to PHC hemihydrate in commercially significant amounts. SmithKline Beecham Corp., 247 F. Supp. 2d at 1030. The trial record contained uncontested testimony that a PHC anhydrate-hemihydrate mixture would need to possess a percentage of PHC hemihydrate in the "high double digits" if the hemihydrate component were to contribute any commercial value. Id. The district court imported that commercial significance into the claim and held that Apotex's proposed PHC drug will not infringe claim 1 of the '723 patent. The district court found, as a factual matter, that Apotex's PHC anhydrate tablets will not contain commercially significant amounts of PHC anhydrate and rejected SmithKline's evidence to the contrary. Id. at 1031-39. The trial court also determined that claim 1 is not invalid.

SmithKline contested the district court's claim interpretation noting that claim 1 is clear on its face and encompasses PHC hemihydrate in any amount, however small or insignificant. In rejecting that proposed claim interpretation, the district court also opined that SmithKline's proposed construction would render claim 1 indefinite. The district court reasoned that SmithKline's interpretation would place potential infringers in the untenable position of never knowing whether their product infringes because even a single undetectable crystal of PHC hemihydrate would infringe. Id. at 1029-30.

To show that manufacture of PHC anhydrate tablets necessarily creates PHC hemihydrate, SmithKline proffered expert testimony on the so-called "seeding" or "disappearing polymorph" theory. Under this theory, Ferrosan may have originally created a crystalline compound, namely PHC anhydrate, in a relatively unstable form. For presently unknown reasons, the PHC anhydrate "morphed" into a more stable form, namely the PHC hemihydrate discovered in SmithKline's facilities. With this new form or polymorph in existence, SmithKline's experts explained, the general environment became "seeded" with crystals of PHC hemihydrate. In this seeded environment, the PHC anhydrate converts to the PHC hemihydrate upon its inevitable contact with seeds of PHC hemihydrate. In other words, the creation of pure PHC anhydrate became extremely difficult, if not impossible; the old polymorph, PCH anhydrate, has effectively disappeared in its pure form because it changes naturally into the new polymorph, PCH hemihydrate.

SmithKline's experts applied the "disappearing polymorph" theory to show that Apotex's PHC anhydrate tablets inevitably convert to hemihydrate when combined with moisture, pressure, and practically ubiquitous PHC hemihydrate seeds. The district

court found that SmithKline's evidence on the "seeding" and the "disappearing polymorph" theories supported the inference that Apotex's PHC anhydrate tablets will contain at least trace, even if undetectable, amounts of PHC hemihydrate. Id. at 1042-43. Thus, under SmithKline's claim construction, the district court held that Apotex's PHC anhydrate drug would infringe claim 1 of the '723 patent. Id.

Alternatively, if claim 1 was construed to cover any amount of PHC hemihydrate and was, therefore, infringed, the district court purported to create a new equitable defense to infringement in favor of Apotex. Id. at 1043-45. Under this new defense, SmithKline was responsible for producing the hemihydrate, which, by virtue of SmithKline's "disappearing polymorph" theory, seeded the environment. Consequently, SmithKline caused the alleged infringement. The district court reasoned that Apotex should enjoy the right to practice the prior art by manufacturing PHC anhydrate. Accordingly, under its alternative equitable defense, the district court absolved Apotex of liability for the consequences of SmithKline's own conduct that rendered the practice of the prior art impossible without infringing the '723 patent. The district court also held that its inherent equitable powers and the equitable nature of injunctions in general placed the injunction mandated by 35 U.S.C. § 271(e)(4)(A) within the discretion of the district court. Id. at 1045-52.

SmithKline also sought to assert a claim of induced infringement against Apotex on the theory that PHC anhydrate tablets convert to PHC hemihydrate in the stomach of a patient due to the increased humidity and pressure present inside the stomach. Id. at 1014-15. The district court excluded SmithKline's evidence on this issue, finding that SmithKline would likely not meet its burden of showing "gastrointestinal infringement."

Id. at 1014-15. Finally, the district court considered other alternative claim constructions, which would allow claim 1 to cover PHC hemihydrate in amounts detectable either by methods available at the time the '723 patent was filed or by any means that later became available. Id. at 1052. The record shows that SmithKline presented the results of tests on various samples of Apotex tablets. These tests showed PHC hemihydrate in the Apotex product. The district court rejected this evidence as unreliable, mainly because SmithKline's counsel excluded certain tablets from the testing without reasonable explanation. Id. at 1032-42. The trial court found these excluded tablets to represent the product Apotex would manufacture upon ANDA approval. Id. Accordingly, the district court held that SmithKline did not prove that Apotex's tablets will contain any detectable amount of PHC hemihydrate.

SmithKline presents five arguments on appeal. First, the district court erred in limiting claim 1 to commercially significant amounts of PHC hemihydrate. Second, contrary to the district court's ruling, a claim construction that covers PHC hemihydrate in any amount does not render claim 1 indefinite. Third, the district court erred in creating an equitable defense to infringement based on SmithKline's contribution to causing the infringement. Fourth, the district court erred in holding that the injunctive relief required under 35 U.S.C. § 271(e)(4) is within the district court's discretion. Fifth, the district court abused its discretion in excluding SmithKline's evidence of induced infringement.

In its cross-appeal, Apotex argues that the district court erred in granting summary judgment that SmithKline's clinical tests qualified as an experimental use. In particular, Apotex asserts that claim 1 of the '723 patent is invalid for public use under

35 U.S.C. § 102(b) as a matter of law. This court has jurisdiction over these appeals under 28 U.S.C. § 1295(a)(1).

II.

Standards of Review

This court reviews summary judgments without deference. See Beech Aircraft Corp. v. Edo Corp., 990 F.2d 1237, 1245 (Fed. Cir. 1993). Of course, a denial of summary judgment, by itself, is not a final judgment amenable to appeal like a grant of summary judgment. However, when both parties move for summary judgment, each motion "must be independently assessed on its own merit." California v. United States, 271 F.3d 1377, 1380 (Fed. Cir. 2001). In such circumstances, this court reviews summary judgment under the standard rules of FED. R. CIV. P. 56.

In this case, both parties sought summary judgment; the district court granted one and denied the other. Thus, the record shows that the parties conceded, and the district court found, that no material factual issues remain in dispute. See Beech Aircraft, 990 F.2d at 1245. If this court determines that no material facts remain in dispute, it may proceed to determine entitlement to judgment under the law. See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed. Cir. 2001) ("[R]eversal is required if the district court 'engaged in a faulty legal analysis in applying the law to the facts and a correct application of the law to those facts might bring a different result.'" (quoting Litton Indus. Prods., Inc. v. Solid State Sys. Corp., 755 F.2d 158, 164 (Fed. Cir. 1985))); see also Anderson v. Liberty Lobby Inc., 477 U.S. 242, 248 (1986).

This court reviews a district court's judgment following a bench trial for errors of law or clearly erroneous findings of fact. See Allen Eng'g Corp. v. Bartell Indus., Inc.,

299 F.3d 1336, 1343-44 (Fed. Cir. 2002). Patent infringement proceeds under a two-step analysis. First, the court interprets the claims to determine their proper scope and meaning. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). Next, the court measures the accused product or process against the standard of the properly interpreted claims. Id.

This court reviews claim construction without deference. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). This court reviews the second step, measurement of the accused product or process against the claim, as a question of fact. See Allen Eng'g, 299 F.3d at 1343-44; Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 981 (Fed. Cir. 1997). The review of indefiniteness under 35 U.S.C. § 112, paragraph 2, proceeds as a question of law without deference. See Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1377 (Fed. Cir. 2000); Personalized Media Communications, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 702 (Fed. Cir. 1998).

Factual Findings

As an initial matter, this court holds that the record, for the most part, supports the district court's factual findings. In particular, the district court did not clearly err in concluding that Apotex's PHC anhydrate product will include trace amounts of PHC hemihydrate based on the record evidence that the anhydrate form inevitably changes into the hemihydrate form. See SmithKline Beecham Corp., 247 F. Supp. 2d at 1019-23.

The district court also did not clearly err in finding that Apotex's anhydrate product will not contain detectable quantities of PHC hemihydrate because SmithKline

selectively tested the Apotex samples without explaining its reasons for excluding some Apotex products from the examination. Specifically, the district court's discretionary exclusion of SmithKline's unreliable evidence on this issue does not render the subsequent factual finding clearly erroneous.

Although the district court clearly accepts as true the theories of "disappearing polymorphs" and "seeding," it did not make findings of fact regarding precisely how or when PHC hemihydrate first came into existence. Indeed, traces of PHC hemihydrate in PHC anhydrate pills were not detectible in amounts less than five percent before 1985. However, Curzons undisputedly made his serendipitous discovery of PHC hemihydrate while making PHC anhydrate presumably pursuant to the teachings of the '196 patent. Moreover, although Curzons does not claim to have discovered PHC hemihydrate until March 1985, further review of samples of SmithKline's PHC anhydrate revealed that SmithKline's Harlow plant had unwittingly made PHC hemihydrate as early as December 1984. These undisputed facts conclusively establish that PHC anhydrate made in accordance with the '196 patent converts into PHC hemihydrate both with and without seeding. Accordingly, this court decides the legal issues in this appeal against the factual background as determined by the district court.

Claim Construction & Indefiniteness

Claim interpretation requires the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of invention. ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1378 (Fed. Cir. 2003); Phillips Petroleum Co. v. Huntsman Polymers Corp., 157 F.3d 866, 871 (Fed. Cir. 1998). This task requires the court to place the claim language in its proper technological and temporal context. The best tools for this

enterprise are the various forms of intrinsic evidence and, when appropriate, extrinsic evidence. See Vitronics, Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The intrinsic evidence, "i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history . . . is the most significant source of the legally operative meaning of disputed claim language." Id.

Of course, at all times, the language of the claims governs their scope and meaning. See Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1372 (Fed. Cir. 2001). Unless the intrinsic evidence compels a contrary conclusion, the claim language carries the meaning accorded those words in the usage of skilled artisans at the time of invention. See id.; Vitronics, 90 F.3d at 1582.

As stated earlier, claim 1 of the '723 patent reads: "Crystalline paroxetine hydrochloride hemihydrate." This language is not ambiguous but rather describes a very specific compound. The record repeatedly shows that artisans in this area of technology at the time of invention would have understood that the claim embraces PHC hemihydrate without further limitation.

The inquiry proceeds to the remainder of the intrinsic record to determine if the patent applicant gave these unambiguous words some unexpected definition. The district court limited claim 1 to commercially significant amounts of PHC hemihydrate. The trial court found support for this limitation in portions of the '723 patent that discuss the pharmaceutical and commercial properties of PHC hemihydrate. SmithKline Beecham Corp., 247 F. Supp. 2d at 1029-30. For example, the specification discusses the superior handling properties of the hemihydrate form that improve the manufacture of PHC. Those references, however, do not redefine the compound in terms of its

commercial properties, but emphasize that the new compound exhibits favorable characteristics. A description of characteristics does not redefine a compound with an established and unambiguous structural definition.

Moreover, nothing in the '723 patent limits that structural compound to its commercial embodiments. Rather, the '723 specification discloses PHC hemihydrate as a compound without reference to its commercial applications. For example, the specification states that the "present invention provides crystalline paroxetine hydrochloride hemihydrate as a novel compound." '723 patent, col. 1, ll. 57-58. Furthermore, nothing in the prosecution history of the '723 patent defines the invention in terms of commercially significant quantities. Thus, reading claim 1 in the context of the intrinsic evidence, the conclusion is inescapable that the claim encompasses, without limitation, PHC hemihydrate – a crystal form of paroxetine hydrochloride that contains one molecule of bound water for every two molecules of paroxetine hydrochloride in the crystal structure.

The district court openly discussed the policies that led to its insertion of commercially significant quantities as a limitation on the meaning of the claimed compound. SmithKline Beecham Corp., 247 F. Supp. 2d at 1028-30. The district court observed that a claim construction that covers trace amounts of PHC hemihydrate would likely preclude attempts to make the prior art PHC anhydrate compound. Id. After explaining the "in terrorem effect" of such a "broad" claim construction, the district court rejected the literal scope of claim 1 because it would produce "absurd results" and would "not serve any policy of patent law." Id. Claim construction, however, is not a policy-driven inquiry. As stated earlier, it is a contextual interpretation of language. The

scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning. See Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("[I]t is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims."). For this precise reason, this court has repeatedly stated that a court must construe claims without considering the implications of covering a particular product or process. See Neomagic Corp. v. Trident Microsys. Inc., 287 F.3d 1062, 1074 (Fed. Cir. 2002); SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1118 (Fed. Cir. 1985).

The district court also justified its commercial-significance limitation to preserve the claim's validity in the face of a challenge to its definiteness under § 112, second paragraph. In essence, the district court considered the claim indefinite if construed to cover undetectable trace amounts of PHC hemihydrate. In other words, the trial court feared that potential infringers would not be able to determine (and avoid) infringement if they cannot detect the claimed compound. See Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1469-70 (Fed. Cir. 1993). This reasoning misses the proper purpose of the definiteness requirement.

The second paragraph of § 112 requires the specification of a patent to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2000). To satisfy this requirement, the claim, read in light of the specification, must apprise those skilled in the art of the scope of the claim. See Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993). Moreover, claims need not "be plain on their face in order to avoid condemnation for indefiniteness; rather, what [this

court has] asked is that the claims be amenable to construction, however difficult that task may be." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). In this case, the claim covers a definite chemical structure. To a chemist in this field, this claim is plain on its face. Thus, claim 1 of the '723 patent cannot be invalid for indefiniteness under § 112.

In Morton, this court affirmed a district court's judgment of indefiniteness because "one skilled in the art could not determine whether a given compound was within the scope of the claims." 5 F.3d at 1470. Thus, the claims at issue were "not sufficiently precise to permit a potential competitor to determine whether or not he is infringing." Id. The Morton case, therefore, does not hold that the inability to detect the claimed compound in the infringing device renders a compound claim indefinite. Rather, Morton stands for the unremarkable proposition that a compound claim, to be definite, must apprise a skilled artisan of the bounds of the claim. The record in Morton contained "considerable evidence showing that those skilled in the art could not make the claimed compounds using the procedures of the specification, and no evidence that such compounds even exist." Id. at 1469-70.

This case bears little similarity to Morton. Here, claim 1 unambiguously identifies the bounds of the claim. It states: "Crystalline paroxetine hydrochloride hemihydrate." Thus, this claim recites in clear terms a discernible chemical structure. It would be difficult to imagine a more clear and definite claim.

The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention. In this

case, the problem for Apotex is that it cannot accurately ascertain the nature of its own product. The scope of this claim is clear; the infringement of the Apotex product is not. Even if a claim is broad enough to embrace undetectable trace amounts of the claimed invention, "[b]readth is not indefiniteness." In re Gardner, 427 F.2d 786, 788 (CCPA 1970). Stated more precisely, this claim is neither broad nor narrow, but definitive of this particular chemical structure. For inventing and disclosing this structure, the inventor enjoys the exclusive right to practice that invention for the patent's limited term. Accordingly, claim 1, as construed above, is not indefinite under 35 U.S.C. § 112, second paragraph.

Infringement and Equity

Having interpreted claim 1 to cover PHC hemihydrate without further limitation, this court turns to infringement. In anticipation of this very scenario, the district court performed a factual infringement analysis based on this correct claim construction. The district court held that the evidence showed that Apotex's PHC anhydrate tablets would contain trace amounts of PHC hemihydrate. SmithKline Beecham Corp., 247 F. Supp. 2d at 1043. As indicated above, the record supports this factual finding. This court, therefore, affirms the district court's finding that Apotex's product will infringe under this court's claim construction.

Because Apotex seeks to practice the prior art, and because that practice infringes, the next logical inquiry involves anticipation. That is, if the prior art infringes now, logically the prior art should have anticipated the claim before the filing of the '723 patent. See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378 (Fed. Cir. 2001) (restating the axiom that "that which would literally infringe if later in

time anticipates if earlier"). At trial, Apotex asserted that Ferrosan's process of making PHC anhydrate inherently resulted in trace amounts of the hemihydrate prior to the '723 patent and thus inherently anticipated that patent. The district court, however, determined that Apotex did not present clear and convincing evidence of inherent anticipation. According to the district court's findings, "no one knows when the hemihydrate form of paroxetine came into existence, although it is a reasonable inference that it did not exist in a detectable amount until" SmithKline's "serendipitous" discovery. SmithKline Beecham Corp., 247 F. Supp. 2d at 1022, 1025. Apotex does not dispute that PHC hemihydrate was first detected by Curzons in 1985, or that it is unable to prove precisely when PHC hemihydrate came into existence.

SmithKline argues that practicing the '196 patent infringes claim 1 of the '723 patent, but that the '196 patent does not anticipate claim 1 of the '723 patent. SmithKline uses the "disappearing polymorph" theory to justify its apparently inconsistent positions. On the one hand, SmithKline asserts that the creation of a prior art compound will result in a product containing at least trace amounts of their patented compound. On the other hand, SmithKline contends that the creation of the prior art compound before SmithKline's discovery of its compound did not have the same result. For this reason, the district court was understandably uncomfortable about allowing claim 1 to embrace its literal scope. The district court feared such a construction would result in "a considerable extension in the effective patent term of paroxetine because it might become difficult or even impossible to manufacture the pure anhydrous form after the Ferrosan patent expired." Id. at 1019. While these concerns are certainly legitimate, claim construction, as noted before, proceeds independent of its policy

implications. Fortunately, the district court had the foresight to consider alternative analyses in this unique situation.

The district court, in its alternative infringement analysis, properly found infringement, but created a new equitable defense to shield Apotex from liability for that infringement. Id. at 1043-45. In short, the defense would apply where the patentee significantly contributed to causing the infringement. After all, SmithKline's creation of the hemihydrate form of PHC created a seeded environment that, under the facts found by this district court, makes the practice of the prior art an infringement, while arguably precluding the operation of anticipation by inherency. In this unique and unprecedented circumstance, the trial court understandably reached out to find an equitable remedy to protect Apotex. In any event, notwithstanding the potential merit of a new equitable doctrine in this unprecedented instance, this court can resolve this case without its application because claim 1 is invalid as inherently anticipated under 35 U.S.C. § 102(b). Accordingly, this court declines to address the trial court's proposed equitable defense.

The concurring opinion seeks to remedy the perceived inequity in this case by applying 35 U.S.C. § 101, arguing the subject matter of claim 1 does not cover patentable subject matter. Unfortunately, the concurrence confuses patent eligibility under § 101 with patentability under other provisions in the Patent Act, such as 35 U.S.C. § 102. The concurrence admits that PHC hemihydrate is a synthetic, man-made compound eligible for patent protection. In fact, the claimed invention is without question a "composition of matter" or an article of "manufacture" within the terms of

§ 101. Accordingly, the claimed invention represents subject matter eligible for patent protection under § 101. With that conclusion, the inquiry under § 101 ends.

The concurring opinion, however, would expand the subject matter eligibility analysis under § 101 to encompass some review of the scope of the claims. To the contrary, "[e]ither the subject matter falls within Section 101 or it does not." Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930 (Fed. Cir. 1991). The scope of the claims is not relevant to subject matter eligibility. Subject matter does not take on a different eligibility status with adjustments in the scope of the proposed claim. Patent eligibility under § 101 is simply not an issue in this case.

Anticipation - § 102(b)

A patent claim is not valid 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. . . ." 35 U.S.C. § 102(b) (2000). For prior art to anticipate a claim "it must be sufficient to enable one with ordinary skill in the art to practice the invention." Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed. Cir. 2002) (citing In re Borst, 345 F.2d 851, 855 (CCPA 1965)). "Whether a prior art reference is enabling is a question of law based upon underlying factual findings." Id. (citing Crown Operations Int'l Ltd. v. Solutia, Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002)). Anticipation is a question of fact. See id. However, without genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law.

The '196 patent is undisputed prior art under 35 U.S.C. § 102(b), even though the '196 patent discloses how to make PHC anhydrate and does not discuss PHC

hemihydrate. PHC hemihydrate was not even discovered until years after the '196 patent was filed. Nonetheless, the '196 patent anticipates claim 1 of the '723 patent because the '196 inherently discloses PHC hemihydrate.

This court recently set forth the standards for anticipation by inherency:

> A patent is invalid for anticipation if a single prior art reference discloses 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 without disclosing a feature 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).

Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003). In Schering Corp., this court also decided that the doctrine of inherent anticipation applies to the entire claimed subject matter just as it does to a single claimed feature. Id. at 1379 ("Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter."). Moreover, this court reiterated in Schering Corp. 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. at 1377 (citing In re Cruciferous Sprout Litig., 301 F.3d 1343, 1351 (Fed. Cir. 2002); Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999); Atlas Powder Co. v. Hanex Prods., Inc., 190 F.3d 1342, 1348-49 (Fed. Cir. 1999)).

The district court addressed the issue of inherent anticipation in this case, but it found in favor of SmithKline because Apotex did not prove by clear and convincing evidence that it was impossible to make pure PHC anhydrate in the United States

before the critical date of the ’723 patent. See SmithKline Beecham Corp., 247 F. Supp. 2d at 1026 (“[I]t is equally possible, as far as anyone knows, that practicing patent [’]196 in non-seeded premises – and goodness knows there were some in the United States as of [the critical] date – would not have produced any hemihydrate.”). The district court erred in requiring Apotex to meet this standard of proof, which is too exacting. Apotex did not need to prove that it was impossible to make PHC anhydrate in the United States that contained no PHC hemihydrate, but merely that “the disclosure [of the prior art] is sufficient to show that the natural result flowing from the operation as taught [in the prior art] would result in” the claimed product. In re Oelrich, 666 F.2d 578, 581 (CCPA 1981); accord Mehl/Biophile Int’l Corp., 192 F.3d at 1366; see also Atlas Powder, 190 F.3d at 1349-50 (affirming the district court’s finding of inherent anticipation despite a finding that the inherent element could be avoided by taking “extraordinary measures” when practicing the prior art). Contrary to this court’s precedents, the district court’s analysis of inherent anticipation did not consider the teachings of the ’196 patent separately from the actual production of PHC hemihydrate. See Schering Corp., 339 F.3d at 1380 (“Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure.” (citing In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985)). Thus, whether it was actually possible to make pure PCH anhydrate before the critical date of the ’723 patent is irrelevant. The ’196 patent suffices as an anticipatory prior art reference if it discloses in an enabling manner the production of PHC hemihydrate. See id. The ’196 patent discloses a method of manufacturing PHC anhydrate that naturally results in the production of PHC hemihydrate. Consequently, applying the facts as

found by the district court to the correct standard, this court holds that claim 1 of the ’723 patent is invalid for anticipation by the ’196 patent.

The record shows, and SmithKline admits through its proffered arguments, that producing PHC anhydrate according to the ’196 patent inevitably results in the production of at least trace amounts of anticipating PHC hemihydrate. The parties do not dispute that the first known existence of PHC hemihydrate resulted from an attempt to produce PHC anhydrate according to the ’196 patent. In December 1984, SmithKline serendipitously made PHC hemihydrate at its Harlow plant while attempting to manufacture PHC anhydrate according to the ’196 patent. As discussed previously, Curzons’s discovery of PHC hemihydrate in Worthing also occurred while he was making PHC anhydrate according to the ’196 patent. Both of these undisputed events support a finding that practicing the ’196 patent naturally results in the production of PHC hemihydrate. The district court also found, and the parties do not dispute, that neither Apotex nor SmithKline can presently produce PHC anhydrate that does not contain at least trace amounts of PHC hemihydrate. See, e.g., SmithKline Beecham Corp., 247 F. Supp. 2d at 1044 (“Apotex cannot eliminate all crystals of hemihydrate . . . .” (emphasis in original)). In sum, the record shows that the manufacture of PHC anhydrate according to the ’196 patent necessarily results in the production of PHC hemihydrate. This fact finds further record support in the holding that Apotex would infringe claim 1 of the ’723 patent under the “single crystal” claim construction. Id. at 1043.

The district court made these findings, at least in part, because PHC anhydrate produced at the parties’ manufacturing facilities would convert to PHC hemihydrate

because the facilities had been "seeded" with PHC hemihydrate crystals. Id. SmithKline takes the position that Apotex's infringement will result wholly from the PHC hemihydrate "seeds" present in Apotex's facility, and that Apotex could avoid infringement if it manufactured PHC anhydrate in a facility clean of hemihydrate "seeds." While PHC hemihydrate "seeds" will certainly exacerbate the presence of PHC hemihydrate in Apotex's PHC anhydrate pills, this court does not accept SmithKline's assertion that the hemihydrate "seeds" will be the sole cause of the undesired PHC hemihydrate in Apotex's anhydrate pills. Indeed, SmithKline argued at trial that PHC hemihydrate "seeds" are not necessary to produce PHC hemihydrate.

SmithKline's position on the source of Apotex's alleged infringement is inconsistent with the undisputed creation of PHC hemihydrate as discussed supra. The production of PHC anhydrate at both SmithKline's Harlow and Worthing plants resulted in the serendipitous production of PHC hemihydrate. The only plausible explanation for this appearance of PHC hemihydrate at the Harlow plant and the likely explanation for its appearance at the Worthing plant is that PHC hemihydrate arises as a natural derivative of practicing the '196 patent. SmithKline did not offer any evidence that pure PHC anhydrate can be produced in facilities that are not seeded. Id. at 1035 (district court noting the absence of any experiments by SmithKline to show the difference between PCH anhydrate manufactured in a facility both before and after it is "seeded"). SmithKline's only counter to this explanation is that it had been manufacturing PHC anhydrate according to the '196 patent for years before the hemihydrate was first detected in 1995. SmithKline would have the court infer from this argument that it is possible to make pure PHC anhydrate according to the '196 patent in unseeded

conditions. The district court, however, properly dismissed this logic noting that "existence and detection are not the same thing." Id. at 1022. The district court went on to explain that PHC hemihydrate may have existed in undetectable amounts since Ferrosan first produced PHC anhydrate in the 1970s, particularly because the technology to detect PCH hemihydrate in small amounts did not exist until 1985. The district court reasoned that it may also be possible for PHC anhydrate to coexist with low levels of PHC hemihydrate without further conversion, thereby rejecting SmithKline's argument that the absence of conversion in early batches of PHC anhydrate prove that the hemihydrate form did not exist prior to 1984. See id. at 1022-23 (reconciling conflicting expert testimony by discussing a possible equilibrium point at which conversion plateaus at a few percentage points), 1031 ("[H]emihydrate in small amounts does nothing for the anhydrate with which it is mixed.") & 1035 (noting that inconsistent test results "impl[y] that the hemihydrate and the anhydrate can coexist in an equilibrium").

Because 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, this court holds that the '196 patent inherently anticipates claim 1 of the '723 patent under 35 U.S.C. § 102(b). Consequently, it was legal error for the district court to base its finding of no inherent anticipation upon a finding that Apotex did not present clear and convincing evidence that PHC hemihydrate existed before the critical date of the '723 patent. Additionally, the district court's supposition that Apotex could possibly prevent PHC anhydrate from converting to PHC hemihydrate by building a new plant that was not seeded with PHC hemihydrate, or by preventing the PHC

anhydrate from being exposed to moisture, does not change this result. This court's law does not require Apotex to take extraordinary measures to practice the prior art without infringing claim 1 of the '723 patent. See Atlas Powder, 190 F.3d at 1349-50 (affirming the district court's finding of inherent anticipation despite a finding that the inherent element could be avoided by taking "extraordinary measures" when practicing the prior art).

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. In Atlas Powder, this court noted that one of the principles underlying the doctrine of inherent anticipation is 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." 190 F.3d at 1348; accord Schering Corp., 339 F.3d at 1379-80. Invalidating claim 1 of the '723 patent for inherent anticipation by the '196 patent furthers this policy of allowing the public to practice expired patents.

This holding is also in accord with this court's precedent. In re Seaborg, 328 F.2d 996 (CCPA 1964), held that claims for an isotope of americium made by a nuclear reaction were not inherently anticipated by a prior art patent disclosing a similar nuclear reaction process but with no disclosure of the claimed isotope. In finding no anticipation, this court's predecessor found "no positive evidence" that the claimed isotope was inherently produced by the prior art process. Id. at 999. The court properly held that the mere "possibility" that the small amount of the claimed element "may have been produced" was insufficient to invalidate the claim for anticipation. Id. Similarly, it

is undisputed that SmithKline's and Apotex's practice of the '196 patent results in the production of the claimed PHC hemihydrate in trace amounts.

As noted in Schering Corp., a patentee may obtain patent protection for an inherently anticipated compound through proper claiming. 339 F.3d at 1381. This court's holding today merely precludes patent protection for the bare compound PHC hemihydrate as claimed in claim 1 of the '723 patent because the compound is inherently anticipated by the '196 patent.

Miscellaneous Issues

SmithKline also appealed the district court's decision to prevent SmithKline from pursuing its contributory infringement claim. As discussed above, that claim asserted that the ingestion of Apotex's PHC anhydrate tablet by a patient would result in conversion to PHC hemihydrate. Again, SmithKline's allegations of contributory infringement based upon the theory that PHC anhydrate converts into PHC hemihydrate upon ingestion further supports this court's finding of inherent anticipation. Nevertheless, because claim 1 is invalid for anticipation under § 102(b), SmithKline's appeal on contributory infringement is moot.

Similarly, SmithKline's appeal of the district court's ruling that injunctive relief under 35 U.S.C. § 271(e)(4) is within the district court's discretion is also moot. That ruling was not necessary for the district court's judgment below and is immaterial to the determination of this appeal. This court, therefore, does not address that issue in this opinion.

III.

In summary, this court reverses the claim construction of the district court and holds that claim 1 of the '723 patent covers any amount of crystalline paroxetine hydrochloride hemihydrate without further limitation. Based on the factual findings of the district court, this court affirms the district court's finding that Apotex's PHC anhydrate product will infringe claim 1 under that broad construction. Notwithstanding that conclusion, this court holds, based on the undisputed facts, that claim 1 of the '723 patent is invalid for inherent anticipation by the '196 patent under § 102(a). Apotex is, therefore, not liable for infringing claim 1 of the '723 patent. This court affirms the district court's judgment.

COSTS

Each party shall bear its own costs.

AFFIRMED

United States Court of Appeals for the Federal Circuit

03-1285, -1313

SMITHKLINE BEECHAM CORPORATION
and BEECHAM GROUP, P.L.C.

Plaintiffs-Appellants,

v.

APOTEX CORP., APOTEX, INC., and TORPHARM, INC.

Defendants-Cross Appellants.

GAJARSA, Circuit Judge, concurring.

I join in the judgment of the court, however, I reach the judgment by a different road. I would find that the trial court erred in construing Claim 1 of the '723 patent. Under the correct construction, SmithKline Beecham ("SKB") has proven a prima facie case that Apotex's product will infringe Claim 1. Claim 1, however, is invalid because it encompasses subject matter that is unpatentable under 35 U.S.C. § 101.[1] I would affirm the district court's judgment in favor of Apotex on the basis that Claim 1 encompasses unpatentable subject matter pursuant to § 101 contrary to the finding of the majority that claim 1 is invalid pursuant to § 102(b). Although the majority outlines the factual background, I deem it necessary to add more specificity to the historical background.

[1] "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

In the 1970s, scientists at the Danish company of A/S Ferrosan ("Ferrosan") first synthesized a new class of chemical compounds. At least some of these compounds were reported to selectively inhibit the reuptake of serotonin, a naturally occurring chemical in the brain. Several commercial antidepressants common at the time inhibited the neuronal reuptake of serotonin. Ferrosan's laboratory tests indicated that its new compounds inhibited serotonin-uptake in a manner comparable to that exhibited by these existing antidepressant drugs.

Ferrosan applied for, and on February 8, 1977, was assigned, U.S. Patent No. 4,007,196 ("the '196 patent"). Paroxetine was among the compounds that Ferrosan discovered and that the '196 patent protected. In 1980, Ferrosan granted Beecham Group Limited (now part of SKB) an exclusive license to make, to have made, to use, and to sell paroxetine throughout the world (save for specified Scandinavian countries).

In 1981, SKB began manufacturing paroxetine hydrochloride in its Harlow (U.K.) plant. These early manufacturing activities did not lead to a commercial product immediately. Before a new pharmaceutical drug can be placed on the U.S. market, it must undergo elaborate testing for safety and efficacy. Quantities of paroxetine hydrochloride were distributed to different parts of the world, including the U.S., for use in clinical trials. SKB scientists also experimented with paroxetine hydrochloride in its bulk form (i.e., its form prior to being made into pills) to improve the production of the bulk material.

SKB's experimentation on bulk form paroxetine led to an important discovery. On May 29, 1985, an SKB scientist named Alan Curzons issued a memorandum entitled "Paroxetine Polymorphism." In the memorandum, Curzons stated that

paroxetine "had been shown to exist in two discreet [sic] crystalline polymorphic FORMS," a stable, nonhygroscopic hemihydrate and a hygroscopic anhydrate. Curzons's tests confirmed that the anhydrate and the hemihydrate were indeed distinct crystalline forms of paroxetine.

Crystallinity is central to understanding both Curzons's reference to polymorphism and this case. "Polymorphs" are distinct crystalline structures containing the same molecules. These structural differences can affect various properties of the crystals, such as melting points and hardness (e.g., graphite and diamonds are both crystalline forms of carbon). The two forms of paroxetine hydrochloride that Curzons discovered were technically "pseudopolymorphs," though pseudopolymorphs are often loosely called polymorphs (an apparently common looseness that the district court adopted and that I have retained in this opinion). Pseudopolymorphs not only have their molecules arranged differently but also have a slightly different molecular composition. A common type of pseudopolymorph is a solvate, which is a crystal in which the molecules defining the crystal structure "trap" molecules of a solvent. The crystal molecules and the solvent molecules then bond to form an altered crystalline structure. When the trapped and bonded solvent is water, the solvate is called a hydrate. Hydrates bonding one water molecule to every two of the other molecules constituting the unit crystal cell are called hemihydrates. Paroxetine hydrochloride hemihydrate ("paroxetine hemihydrate") is a crystalline structure binding one water molecule to every two paroxetine hydrochloride molecules. Despite the presence of water molecules, a hemihydrate is a solid, a powder, at room temperature.

Prior to Curzons's discovery, the only known form of paroxetine hydrochloride

had been an anhydrate, a crystalline form of paroxetine that does not contain a bound water molecule. In May 1985, Curzons made a batch of paroxetine, added isopropyl alcohol, a solvent, and found that the batch crystallized as a hemihydrate rather than as an anhydrate. Curzons immediately recognized the significance of the hemihydrate—its superior handling properties—as well as its potential for a new patent relating to those properties.

These superior handling properties are natural effects of water bonded into the paroxetine hemihydrate. The anhydrous form of crystalline paroxetine hydrochloride ("paroxetine anhydrate") is hygroscopic; that is, it attracts water. This water is not attached to the paroxetine anhydrate by molecular bonds. As a result, the water is easily dispersed by heating paroxetine anhydrate at a significantly lower temperature than would be required to liberate the water molecule bound in paroxetine hemihydrate crystals. The anhydrate's hygroscopicity makes it difficult to handle in the manufacturing process; measures must be taken to control humidity and other sources of moisture, lest "soggy" anhydrate degrade into other compounds in ways that might impair the safety or the efficacy of the product. Because the hemihydrate is not hygroscopic, it is easier to handle with fewer precautionary measures protecting its safety and efficacy.

Beecham applied for a British patent on Curzons's discovery on October 25, 1985, and for a U.S. patent on October 23, 1986. On January 26, 1988, the U.S. Patent and Trademark Office (PTO) issued the '723 patent, entitled "Anti-depressant Crystalline Paroxetine Hydrochloride Hemihydrate," which, according to the Abstract, "provides crystalline paroxetine hydrochloride hemihydrate, processes for its

preparation, compositions containing the same and its therapeutic use as an anti-depressant." '723 patent.

The claims as issued were identical to those in the original application. The '723 patent combines product claims (Claims 1, 2, 3, and 5), process claims (Claim 4), and use claims (Claims 5 and 6). Only Claim 1 is at issue in the current litigation. It reads:

1. Crystalline paroxetine hydrochloride hemihydrate.

Subsequent experimentation taught SKB a few additional lessons about paroxetine hemihydrate. First, SKB learned that hemihydrate likely existed at least as early as December 1984 (and possibly earlier), even though Curzons did not identify it as such until 1985. Second, and more significantly, SKB learned that the two forms of paroxetine are related through a phenomenon known as "disappearing polymorphs."[2] At times, the appearance of a new polymorph (or pseudopolymorph) – hemihydrate – may affect the process that was previously used to make the old polymorph – anhydrate. The result is such that the same process will no longer produce the old polymorph—at least (as here) in its pure form.

The causal mechanism of polymorphic creation and transformation is not clear. Modern science does not yet understand the full complexity of the atomic interactions at play in the phenomenon of polymorphism, and specifically in the disappearance of some polymorphs. Scientists have, however, identified three factors believed to be significant. First, later-appearing polymorphs tend to be more stable than earlier ones. Because a stable crystalline form is not as likely to change into a less stable one than

[2] Dr. Joel Bernstein, one of SmithKline's expert witnesses at the trial, is an authority on "disappearing polymorphs." See Joel Bernstein, Polymorphism in Molecular Crystals 89-92 (2002); J.D. Dunitz & J. Bernstein, "Disappearing Polymorphs," 28 Accounts of Chem. Res. 193 (1995).

vice versa, there tends to be a “natural” drift toward more stable polymorphs. Second, impurities retard crystallization, including crystallization into new forms. Technological progress in manufacturing—including chemical manufacturing—has allowed manufacturers to reduce the impurities in their products. Because of this increased purity technology creates increasingly favorable conditions for the “natural” drift towards stability. Third, and most significantly to this case, once a new and more stable crystal emerges, should it be mixed, even in very small quantities, with the old, less stable crystal, the old form may convert to the new.

This process of "seeding" a batch of the old crystalline structure with its new, stable polymorphs can serve as a method of manufacturing the new polymorph by “converting” the old into the new. Seeding and conversion can also be accidental side-effects of new, stable crystals becoming airborne and "contaminating" the laboratory or plant in which the old crystal is being manufactured. While controlled conversions in the former case are obviously desirable production methods, natural conversion in the latter case may be undesirable interferences with the production of the old polymorph.

Seeding and conversion are central to this case. A single crystal of paroxetine hemihydrate can seed an environment to induce conversion—and to render the production of pure paroxetine anhydrate in that environment impossible. While it is often possible, at least in theory, to build clean unseeded environments in which the old process will produce pure forms of the original polymorph, that possibility often remains only a matter of theory; seeds introduced into the environment frequently permeate all parts of the globe and render it impossible to develop such clean environments. No one knows whether it is possible today to build clean environments in which a

pharmaceutical company could produce pure paroxetine anhydrate. Nor, for that matter, is anyone certain precisely what caused the first crystal of paroxetine hemihydrate to form—though it does appear likely that a crystal from that December 1984 batch of paroxetine hemihydrate seeded Curzons's laboratory prior to his initial identification of the paroxetine hemihydrate polymorph.

As noted, scientific uncertainty surrounds the entire phenomenon of disappearing polymorphs, as well as its particular manifestation in paroxetine. Apotex's expert,[3] in fact, testified that the phenomenon does not manifest itself in paroxetine, and that paroxetine anhydrate and paroxetine hemihydrate can coexist happily in a single batch of paroxetine.

After weighing the testimony of all of the experts, the district court hypothesized that while the presence of paroxetine hemihydrate seeds in a batch of paroxetine anhydrate is likely, only a small percentage of the paroxetine anhydrate is likely to convert to hemihydrate under normal conditions of humidity, temperature, or pressure. The district court continued to hypothesize that given enough humidity, heat, or pressure, conversion may continue until it reaches 100 percent, and that by the same token, with much tighter controls less, maybe no, conversion will take place despite the presence of seeds. Finally, the district court noted that the clearest case of limited conversion occurs where there are no water molecules in the environment of the anhydrate.

For the purposes of this case, the district court admitted all proffered expert testimony concerning both disappearing polymorphism as a scientific phenomenon and

[3] Dr. Terrence Threlfall.

its applicability to paroxetine, and found it to be a credible explanation of various factual occurrences in the discovery and the spread of paroxetine hemihydrate.

This language is all straightforward, and Claim 1 — containing only four words — is the most straightforward of all. The plain language of a claim asserting rights to "crystalline paroxetine hydrochloride hemihydrate" claims any amount of "crystalline paroxetine hydrochloride hemihydrate." The plain language of this claim is precisely the "single crystal" theory that the district court rejected on other grounds. The district court explicitly recognized that the claim's plain language included even a single crystal of hemihydrate; the district court rejected that construction on the grounds that it would have "absurd consequences."

The district court suggested that even SKB had expressed some discomfort with the implications of the "single crystal" construction of Claim 1. As a result, throughout the course of this litigation, both parties and two trial judges have considered multiple limitations that could be read into the claim—each of which proposed a minimum amount considerably larger than a single crystal. During the summary judgment hearing, Judge Kocoras dismissed several attempts to introduce such limitations. Though he himself never adopted a construction, his ruling that SKB could admit evidence of infringement developed using all available testing techniques implies that SKB could pursue an infringement claim against anyone making, using, or selling detectable amounts of paroxetine hemihydrate. In his ruling following the bench trial, Judge Posner noted that under "ordinary" circumstances, claims with unambiguous plain language should be interpreted in a manner consistent with that plain language. There is little doubt that the "single crystal" interpretation is the only one consistent with

the claim's plain language.

Nevertheless, many of the "absurd consequences" that that the district court foresaw are, in fact, absurd, and would ill-serve the public were they the law. The proper place for resolutions of such conflicts between patent law and patent policy, however, is Congress, not the courts. For the most part, though, such absurdities are likely to lie not in the law itself, but rather in misapplications of the law. Here, the district court applied two additional elements of patent law to avoid the perceived absurdities. The district court found the single crystal theory indefinite, and applied various rules of claim construction to save the claim by limiting its scope. The district court introduced a limitation explicitly excluding hemihydrate produced by involuntary conversion of a proportion of an anhydrous mixture so small as to lack any commercial significance.

This conclusion, however, misinterprets the meaning of indefiniteness. The district court was certainly correct that indefinite claims could create socially undesirable "zone[s] of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942). Such zones would undoubtedly "discourage invention only a little less than [would] unequivocal foreclosure of the field." Id. The district court nevertheless erred in concluding that the mere possibility that a single crystal interpretation might discourage innovation and experimentation necessarily rendered the claim indefinite. The proper standard for assessing whether a patent claim satisfies the statutory requirement of definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993); Exxon, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

As the Supreme Court has noted, all patents are capable of discouraging at least some innovation. Brenner v. Manson, 383 U.S. 519, 534 (1966) ("[H]ow likely is disclosure of a patented process to spur research by others into the uses to which the product may be placed? To the extent that the patentee has power to enforce his patent, there is little incentive for others to undertake a search for uses."). This discouragement, however, is simply part of the cost that the public bears to promote an overall patent system whose goal is to motivate more innovation than it deters. It is certainly possible that some individual patents will not have the desired effect, and will deter more innovation than they motivate. While such a result would hardly serve the public interest, this negative policy outcome is insufficient alone to render a patent claim indefinite. Indefiniteness must be examined within the framework provided by statute as clarified by our case law. We recently explained that "[a] claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." Amgen Inc. v. Hoechst Marion Roussel, 314 F.3d 1313, 1342 (Fed. Cir. 2003). The contrapositive of this statement is also true. If the claim, read in light of the specification, reasonably apprises those skilled in the art of the scope of the invention, it is definite within the meaning of 35 U.S.C. § 112(2).

Given that standard, the district court's error is evident. The plain language of Claim 1 is unambiguous. It claims "crystalline paroxetine hydrochloride hemihydrate," unambiguously meaning all "crystalline paroxetine hydrochloride hemihydrate," without any exceptions. Nothing in the claim language contradicts this straightforward interpretation—nor, for that matter, does anything in the patent's written description, the patent's figures, or the prosecution history. There is no reason for anyone, much less

one skilled in the art, to read this plain language as meaning anything else, nor to believe that the patent meant to exclude small or trace amounts of crystalline paroxetine hydrochloride hemihydrate from its coverage. Those skilled in the art should certainly have appreciated the scope of the invention—even if they also viewed its breadth as damaging to their own efforts in experimentation and invention.

The district court read limitations from the written description into the claim language for reasons that appear to have stemmed from its public policy concerns. The court's motivation notwithstanding, the practice of reading limitation from written descriptions into claims invariably leads to misconstrued claims. Simply pointing to discussions in the specification or prosecution history cannot rebut the presumption that claims should be afforded their ordinary meanings. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). "We recognize that there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." Comark Communications v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (citations omitted). In this case, there is little doubt that the district court crossed that line.

The "single crystal" theory provides the only interpretation that is entirely consistent with the language of Claim 1 of the '723 patent. This interpretation meets the statutory requirement for definiteness. It puts those skilled in the art on notice that the '723 patent protects crystalline paroxetine hydrochloride hemihydrate, in all amounts, and that any manufacture, use, or sale of this compound—including inadvertent manufacture, use, or sale—would infringe the '723 patent. The correct construction of Claim 1 adheres to the single crystal theory.

Because the '723 patent claims every single crystal of paroxetine hemihydrate, and because Apotex's paroxetine product contains at least some hemihydrate crystals, SKB has proven that Apotex's product prima facie infringes – if Claim 1 is valid. Because Claim 1 is broad enough to encompass both patentable and unpatentable subject matter, however, I would find that it is invalid under 35 U.S.C. § 101.

I.

Authority

The question of patentability under section 101 does not arise often, and a court's decision to raise it sua sponte is even less common. The centrality of patentable subject matter to the entire scope of the patent law suggests that there are times when such inquiries are critical. The Supreme Court established long ago that "the question whether the invention, which is the subject-matter in controversy, is patentable or not is always open to the consideration of the court, whether the point is raised by the answer or not." Slawson v. Grand St. R.R., 107 U.S. 649, 652 (1882). See also Richards v. Chase Elevator Co., 158 U.S. 299, 301 (1895). These precedents remain good law, though the courts have relied upon them infrequently. The policy that drove them, however, remains vibrant. Less than a decade after Slawson, in the context of an interference, the Supreme Court stressed that

> [t]he parties to the present suit appear to have been willing to ignore the question as to patentability in the present case, and to have litigated merely the question of priority of invention, on the assumption that the invention was patentable. But neither the Circuit Court nor this court can overlook the question of patentability.

Hill v. Wooster, 132 U.S. 693, 698 (1890). In our law, 37 C.F.R. § 41.77(b) specifically allows an administrative patent judge to raise the issue of patentability sua sponte as to claims designated to correspond to a count of an interference.

Beyond administrative proceedings, courts have found the occasional need to raise section 101 issues sua sponte—even subsequent to the 1952 revisions to the Patent Act. At least three of our sister circuits, whose rulings on patent law prior to 1982 do not bind this court but retain persuasive value, raised section 101 issues that the parties had not addressed. The Ninth Circuit announced that "it is the duty of the court to dismiss a patent infringement suit whenever it affirmatively appears that the patent is invalid." Barkeij v. Lockheed Aircraft Corp., 210 F.2d 1, 2 (9th Cir. 1954). According to the Second Circuit, "[e]ven were section 101 not raised by appellees, it was not error for the district court to consider it since it had the power to do so. Section 101 deals with the subject matter of patents and, as such, it is always open to the consideration of the court . . . ." Howes v. Great Lakes Press Corp., 679 F.2d 1023, 1028 (2d Cir. 1982). And the Third Circuit explained that

> [i]t has been clear from an early date, that the court could dismiss a bill because the invention described in the patent was not patentable, even when no defense of invalidity was set up in the answer. . . . Accordingly, when a party brings suit on a patent alleging infringement, it is accountable for the validity of the patent. . . .

Borden Co. v. Clearfield Cheese Co., 369 F.2d 96, 99-100 (3d Cir. 1966).

The Federal Circuit has independently raised section 101 concerns without prompting from the parties at least once before. In Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985), we considered a patent that the PTO had rejected as both anticipated under Section 102 and obvious under Section 103. Id. at 776. The district court reversed, and issued an order authorizing the Commissioner of Patents and Trademarks to issue the patent. Titanium Metals Corp. v. Mossinghoff, 603 F. Supp. 87, 91 (D.D.C. 1984). The government appealed. The matter therefore reached

this court on issues relevant to sections 102 and 103, not to section 101. We explained, however, that

> [t]he patent law imposes certain fundamental conditions for patentability, paramount among them being the condition that what is sought to be patented, as determined by the claims, be new. The basic provision of Title 35 applicable here is § 101 . . . . The title of the application here involved is "Titanium Alloy," a composition of matter. Surprisingly, in all of the evidence, nobody discussed the key issue of whether the alloy was new, which is the essence of the anticipation issue. . . .

Titanium Metals, 778 F.2d at 781. We concluded that "the decision and order of the district court holding that claims 1, 2, and 3 are directed to patentable subject matter and authorizing the issuance of a patent thereon were clearly erroneous and are reversed." Id. at 783. In other words, we recognized that we could neither affirm nor reverse the district court's holdings under Sections 102 and 103 in a principled way without addressing the underlying erroneous assumption that the invention at issue met the requirements of section 101. See also Brassica Prot. Prods. LLC v. Sunrise Farms (In re Cruciferous Sprout Litig.), 301 F.3d 1343, 1350 (Fed. Cir. 2002) (characterizing as "common sense" Titanium Metals' rationale, including the injection of section 101 into an anticipation analysis).

Both this court and the Supreme Court have recognized that there is a significant public policy interest in removing invalid patents from the public arena. In Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 100 (1993), the Supreme Court reversed our practice of vacating findings of invalidity where the court found non-infringement in light of the strong public interest in resolving questions of patent validity. In Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313 (1971), the Supreme Court commented at length on the wasteful consequences of relitigating the validity of a

patent after it has once been held invalid. In United States v. Glaxo Group, Ltd., 410 U.S. 52, 57-58 (1973), the Supreme Court ruled that the government, like patent licensees, could always challenge the validity of a patent in the course of prosecuting an antitrust action "to vindicate the public interest in enjoining violations of the Sherman Act." The Court cited numerous cases[4] as "sufficient authority" to support this holding, id., which it saw as furthering a longstanding policy: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly. . . ." Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892).

These decisions mirror our own recognition that "[p]ublic policy requires that only inventions which fully meet the statutory standards are entitled to patents." Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1564 (Fed. Cir. 1988) (citations omitted), and that "[t]here is a stronger public interest in the elimination of invalid patents than in the affirmation of a patent as valid." Nestier Corp. v. Menasha Corp.-Lewisystems Div., 739 F.2d 1576, 1581 (Fed. Cir. 1984). The best way to ensure that patents issue only for inventions in full compliance with the statutory standards is to allow "the validity of a patent, which was originally obtained in ex parte proceedings in the PTO, [to] be challenged in court." Constant, 848 F.2d at 1564.

The sua sponte section 101 inquiry that this case warrants therefore falls well within a long if somewhat sparse tradition, driven in part by concerns of public policy but

[4] Telephone Cases, 167 U.S. 224 (1897); United States v. United States Gypsum Co., 333 U.S. 364 (1948); Sola Elec. Co. v. Jefferson Elec. Co., 317 U.S. 173 (1942); Edward Katzinger Co. v. Chicago Metallic Mfg. Co., 329 U.S. 394 (1947); MacGregor v. Westinghouse Elec. & Mfg. Co., 329 U.S. 402 (1947); Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892); and Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969).

grounded entirely in legal authority. Where, as here, the facts are both unusual[5] and undisputed, where the legal implication of these facts is clear, and where a consideration of fundamental aspects of law and policy is necessary to maintain the integrity of the patent law, a sua sponte inquiry into the patentability of the claimed subject matter is appropriate.

II.

Theory of Infringement

Because the proper construction of Claim 1 follows the "single crystal" theory, SKB must prove that Apotex's product does and will continue to contain at least some hemihydrate. Though SKB's legal burden is only to prove infringement by a preponderance of the evidence, S. Bravo Sys., Inc. v. Containment Techs. Corp., 96 F.3d 1372, 1376 (Fed. Cir. 1996), SKB nevertheless faces a significant challenge. As the district court found, Apotex wants to manufacture pure anhydrate; any hemihydrate present in its product is an undesirable impurity. See SK II, 247 F. Supp. 2d at 1015, 1025 & 1045. Both SKB and the district court explicitly rejected the possibility that the anhydrous and hemihydrous forms of paroxetine came into existence simultaneously, and that every batch of paroxetine ever manufactured (or that ever will be

[5] The district court's maze of alternative claim constructions and theories finding Apotex not liable for infringement, plus the theory added by the majority, attest to the unique circumstances of this case. The district court's opinion, and in particular its attempt to introduce a novel equitable defense, SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011, 1043-45 (N.D. Ill. 2003) ("SK II"), strongly imply that something "feels wrong" about holding an infringer liable for inevitable, spontaneous infringement. We therefore face a choice. We can either address the issue head-on and explain why an attempt to patent unpatentable subject matter leads to so many apparent anomalies, or we can try to contort the aspects of patent law raised by the parties in order to avoid those anomalies. I believe that the law is best served by adopting the straightforward approach.

manufactured) contains at least trace elements of hemihydrate—an argument that would not only prove SKB's point about Apotex's product, but would also invalidate the '723 patent as inherent in the prior art. Id. at 1025.

SKB's basic theory of infringement, which the district court recognized as establishing a prima facie case of infringement when applied to the single crystal construction, id. at 1043, rests upon two scientific principles that remain matters of controversy within the scientific community, both as a general phenomena and as applied to paroxetine: seeding and conversion. See id. at 1021-23. Under this infringement theory, the form of paroxetine discovered in the 1970s was, indeed, pure anhydrate; hemihydrate did not exist until late 1984.

> [SKB's expert] Dr. Bernstein testified that he was 'absolutely convinced' that no hemihydrate had existed before December 1984. . . Dr. Terence Threlfall, Apotex's expert on polymorphism, testified [that] Dr. Bernstein's absolute certainty . . . is not tenable. No one knows when the hemihydrate form of paroxetine came into existence, although it is a reasonable inference that it did not exist in a detectable amount until then.

Id. at 1022. From that date forward, however, it was impossible to produce pure anhydrate in a "seeded" environment because even under normal climactic conditions, at least some of the anhydrate would "convert" to become hemihydrate.

> This process of 'seeding' the old with the new can be deliberate—that is, can be a method of manufacturing the new polymorph—or adventitious, a result of the fact that some of the crystals become airborne and 'contaminate' the laboratory or plant in which the old crystal is being manufactured. . . . [T]he seeds relevant to this case are seeds that cause one polymorph to convert to another and these seeds are crystals of the form to which conversion occurs. A single tiny crystal, constituting a single seed, might induce conversion. . . . The creation of the new polymorph is likely to make the laboratory or plant where it is produced seeded, with the result that efforts to produce the old polymorph may instead produce the new one, since it is the more stable form. In principle it should be possible to re-create the old polymorph, just by replicating the exact procedure by which it used to be created, only this time in a seed-

> free environment. . . . [I]n practice efforts to re-create old polymorphs do not always succeed, probably because the critical mass of molecules that is required to cause conversion is so minute. . . .

Id. at 1020. SKB therefore argues that any paroxetine manufactured in a seeded environment must inevitably contain at least some hemihydrate, that this condition has only prevailed since some time in late 1984, and that Apotex's facilities have been or inevitably will become seeded.

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

Id. at 1024.

III.

SKB's proof supporting this theory must rest upon factual demonstrations. As an appellate court, we accept all facts found by the district court unless they are clearly erroneous. Shockley v. Arcan, Inc., 248 F.3d 1349, 1357 (Fed. Cir. 2001). The district court, however, stated its most significant finding as an hypothesis:

> The conflicting testimony of Bernstein . . . on the one hand and of Threlfall on the other can largely be reconciled on the following hypothesis: while the presence of hemihydrate seeds in a batch of anhydrate is likely, provided the ambient humidity and temperature are no lower than is normal in the temperate zone, to produce conversion within a short time, once the amount converted reaches a few percent of the mixture further conversion is unlikely without substantially greater humidity, temperature, or pressure.

SK II, 247 F. Supp. 2d at 1022-23. Findings of fact stated as hypotheses pose particularly challenging problems for appellate courts. Did the district court accept this hypothesis as a fact upon which legal arguments and conclusions can rest, or was the

district court merely trying to make sense of the scientific testimony that the two experts proffered?

The district court's own legal conclusions make it clear that the court accepted them as facts, by stating, for example, that "[Apotex's] BCI plant is seeded as a result of the mid-1990s experiments," id. at 1032 (emphasis added), and that "the anhydrate as it proceeds through the process [at the BCI plant] will at several junctures be exposed to air that contains enough water molecules to permit conversion of anhydrate to hemihydrate." Id. These statements make sense only if the district court found that both seeding and conversion are valid scientific facts, at least as applied to paroxetine for the purposes of this case.

The district court's understandable hedging of its language when dealing with controversial scientific theories nevertheless led it to definitive factual conclusions: "BCI probably will be 'making' at least some hemihydrate crystals and therefore infringing, at least prima facie, patent 723 if claim 1 is interpreted to cover single crystals of the hemihydrate." Id. (emphasis added). "Some conversion from anhydrate to hemihydrate is likely to occur in a seeded facility in which the anhydrate is exposed to air; BCI's plant is seeded; and the anhydrate manufactured there is exposed to nondehumidified air before it leaves the plant." Id. (emphasis added). But in concrete syllogistic conclusion, "[t]his evidence is sufficient to support an inference that BCI will be making at least tiny amounts of the hemihydrate if it is permitted to manufacture the anhydrate." Id. (emphasis added).

The district court therefore found, as a matter of fact, that paroxetine anhydrate in a seeded environment characterized by normal climactic conditions can convert itself

spontaneously into paroxetine hemihydrate. Id. The district court further found that SKB had met its burden of proving, by a preponderance of the evidence, that such conversion was inevitable at Apotex's BCI manufacturing facility. Id. at 1042-43.

The district court next turned to consider Apotex's defenses. "If . . . claim 1 is valid and will be infringed . . . by a single crystal of hemihydrate . . . [then] Apotex has a complete affirmative defense that SmithKline is the cause of the infringement." Id. at 1052. This conclusion makes sense only after a factual finding that Apotex's legal experimentation with Paxil[6] seeded the BCI plant. Id. at 1024. "Apotex cannot eliminate all crystals of hemihydrate; under a single-crystal interpretation of claim 1, [and] SmithKline is the sole cause of infringement." Id. at 1044 (emphasis in the original).

Finally, the district court explained that

> it is difficult, and in some cases it may be impossible (paroxetine hydrochloride hemihydrate may be one of those cases—no one knows), to destroy all the seeds in seeded premises. . . . Dr. Bernstein testified that if Apotex, desperate to avoid a charge of infringement built a new plant in Antarctica where no hemihydrate seeds had ever been and started manufacturing anhydrate there, and a depressed worker in the plant dropped a Paxil on the floor, the result might be to seed the plant and make it impossible from then on to produce pure anhydrate there.

Id. at 1020-21.

In short, the district court made four critical factual findings: (1) Hemihydrate crystals did not exist before their first emergence in an SKB laboratory in late 1984, id.

[6] Under the Hatch-Waxman Act, a generic drug manufacturer is allowed to experiment with a patented drug to prove that its planned product is bioequivalent to one already approved by the Food and Drug Administration (FDA). The district court viewed this statutory permission as an implied license, SK II, 247 F.Supp.2d at 1018, and attributed liability for the consequent seeding to SKB. Id. at 1044.

at 1025; (2) Hemihydrate seeds spread easily, and increasingly large parts of the environment are becoming seeded, id. at 1020-21; (3) Under normal climactic conditions in a seeded environment, at least some anhydrate crystals will convert spontaneously to become hemihydrate crystals, id. at 1022-23; and (4) Apotex's manufacturing facilities have been seeded, id. at 1024.

IV.

These findings of fact highlight the unique challenge that the infringement analysis of the '723 patent poses: infringing matter has an unusual tendency to "appear" even where it is unwanted. Such a spontaneous appearance of a patented product vitiates the public notice function of patents. See id. at 1028. Under normal circumstances,

> one of ordinary skill in the art should be able to read a patent, to discern which matter is disclosed and discussed in the written description, and to recognize which matter has been claimed. The ability to discern both what has been disclosed and what has been claimed is the essence of public notice. It tells the public which products or processes would infringe the patent and which would not.

PSC Computer Prods. v. Foxconn Int'l, 355 F.3d 1353, 1359 (Fed. Cir. 2004). When the claimed product can be "made" via the spontaneous conversion of a noninfringing product into an infringing one, adequate notice is impossible—even if the claimed product was initially synthesized in a laboratory.

Long before 1952, when Section 112 formalized the modern written description requirement, the Supreme Court observed that:

> Whoever discovers that a certain useful result will be produced, in any art, machine, manufacture, or composition of matter, by the use of certain means, is entitled to a patent for it; provided he specifies the means he uses in a manner so full and exact, that any one skilled in the science to which it appertains, can, by using the means he specifies, without any

> addition to, or subtraction from them, produce precisely the result he describes. And if this cannot be done by the means he describes, the patent is void. And if it can be done, then the patent confers on him the exclusive right to use the means he specifies to produce the result or effect he describes, and nothing more.

O'Reilly v. Morse, 15 How. 62, 119 (1853). The Supreme Court further explained that

> [a]ccurate description of the invention is required by law, for several important purposes: 1. That the government may know what is granted, and what will become public property when the term of the monopoly expires. 2. That licensed persons desiring to practise the invention may know during the term how to make, construct, and use the invention. 3. That other inventors may know what part of the field of invention is unoccupied.

Bates v. Coe, 98 U.S. 31, 39 (1878). While these pre-1952 cases may not apply directly to the modern written description requirement of Section 112, they do demonstrate the longstanding centrality of the public notice function to patent policy.

Paroxetine hemihydrate forces us, for the first time, to confront the requirement that "a patentee specify in a manner so full and exact, that any one skilled in the science to which it appertains, can, by [avoiding] the means he specifies," O'Reilly, 15 How. at 119, avoid producing the claimed product. Otherwise, there will be no way for "other inventors [to] know what part of the field of invention is unoccupied." Bates, 98 U.S. at 39. Effective notice is impossible if a natural physical process can convert a noninfringing product into an infringing one.

The district court was correct in concluding that Claim 1 of the '723 patent, subject to the proper single crystal construction, fails to provide suitable notice. SK II, 247 F. Supp. 2d at 1028, 1052. A paroxetine anhydrate manufacturer, such as Apotex, could exert reasonable efforts to manufacture only products already in the public domain, could direct its entire production process toward developing only products that

scrupulously respected all patent rights, and could nevertheless infringe because a natural physical process acting upon its legitimate anhydrous product "made" new hemihydrous crystals that Apotex then "sold" to the public. "Apotex has tried to prevent conversion of its product to the patented form and a principal issue in this case is whether it has succeeded; there is no suggestion that Apotex desires conversion." SK II, 247 F. Supp. 2d at 1015 (emphasis in original).

Claim 1 therefore cannot be valid. But the failure of notice is a consequence of its invalidity, not the source of it. We must consider whether or not the '723 patent covers only patentable subject matter. See Slawson, 107 U.S. at 652.

V.

Patentable Subject Matter

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof . . . ." 35 U.S.C. § 101. The Supreme Court has interpreted this statutory range of patentable subject matter to be quite broad, but hardly universal. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980). That wide scope nevertheless excludes laws of nature, natural phenomena, and abstract ideas. "Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" Id. at 309, (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)). See also Diamond v. Diehr, 450 U.S. 175, 185 (1981); Parker v. Flook, 437 U.S. 584, 589 (1978).

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." Gottschalk v. Benson, 409 U.S. 63, 67 (1972). A single standard applies to product claims and process claims alike. Id. "[W]hether patents are allowable for [challenged subject matter] is not a matter of discretion, but of law. . . . Either the subject matter falls within Section 101 or it does not." Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 929-30 (Fed. Cir. 1991). And as a matter of law, the critical distinction guiding all section 101 inquiries into the patentability of subject matter is that human-made, or synthetic, products or processes are patentable, while products and processes of nature are not. See Chakrabarty, 447 U.S. at 313; J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, 534 U.S. 124, 130 (2001).

The district court found as a matter of fact that at some point, likely in late 1984, something occurred in SKB's laboratories that gave rise to two new phenomena simultaneously. SK II, 247 F. Supp. 2d at 1021-22. The first was a synthetic crystal later named paroxetine hemihydrate, id., ostensibly a patentable human-made invention under Chakrabarty. The second was a natural physical process whereby paroxetine anhydrate (a pre-existing synthetic crystal that today is in the public domain) could, under normal climactic conditions and with no human intervention, bond with water molecules and convert itself into paroxetine hemihydrate, SK II, 247 F. Supp. 2d at 1021-22, ostensibly an unpatentable, newly discovered natural process under Chakrabarty.

This distinction between the synthetic product and its natural "reproduction" process is subtle, but critical. Paroxetine hemihydrate is not the first invention to blur

the line between a natural process and a synthetic product, nor is it the first to engender confusion in the patent law. In the Nineteenth Century, the conflation of the natural acoustical principles of telephony with the invention of telephone equipment gave rise to massive litigation. See Telephone Cases, 126 U.S. 1 (1888). In disentangling this complex patent litigation, the Supreme Court noted that:

> In one of the cases on appeal . . . the court says: "There can be no patent for a mere principle. The discoverer of a natural force or a scientific fact cannot have a patent for that." But it proceeds to make this exception nugatory by confounding the natural process (or scientific fact) with the invented process for working the apparatus; sustaining the patent for the last upon a construction which blindly sweeps in the first.

Id. at 270-71. The '723 patent similarly confounds the scientific fact of paroxetine conversion with the invented product of paroxetine hemihydrate—and SKB similarly asks us to "sustain[ ] the patent for the last upon a construction which blindly sweeps in the first." Id. We should not only decline to do so, as the majority has and as the district court did in the alternative, but we should be clear about both the character and the implications of the underlying request.

Paroxetine hemihydrate is presumably a synthetic compound, created by humans in a laboratory, never before existing in nature, that is nevertheless capable of "reproducing" itself through a natural process. SK II, 247 F. Supp. 2d at 1022-23. This crystalline compound raises a question similar to one that might arise when considering the invention of a fertile plant or a genetically engineered organism, capable of reproduction, released into the wild. Consider, for example, what might happen if the wind blew fertile, genetically modified blue corn protected by a patent, from the field of a single farmer into neighboring cornfields. The harvest from those fields would soon contain at least some patented blue corn mixed in with the traditional public domain

yellow corn—thereby infringing the patent. The wind would continue to blow, and the patented crops would spread throughout the continent, thereby turning most (if not all) North American corn farmers into unintentional, yet inevitable, infringers.[7] The implication—that the patent owner would be entitled to collect royalties from every farmer whose cornfields contained even a few patented blue stalks—cannot possibly be correct. The underlying question that engaged the district court, and that led it to develop numerous alternative holdings, is why this implication is incorrect.

At oral argument, when faced with this hypothetical, SKB expressed its belief that such a blue-corn patent would be "very strong." Such a belief is misplaced. The implicit concept of "inevitable infringement" stems from the inevitable failure of the patent to provide public notice—which, in turn, stems from the inherently unpatentable nature of the claimed subject matter.

This section 101 problem therefore brings us full circle, back to the impossibility of public notice. Under normal circumstances, inventors other than the patentee will understand how to avoid infringing a patent by avoiding the claimed product. Because products, such as our hypothetical blue corn or SKB's paroxetine hemihydrate, that can be "made" through a natural process of spontaneous conversion imply inevitable infringement, no combination of claim language and written description could possibly teach even one skilled in the art how to avoid infringement. It is unsurprising that a requirement considered so trivial for most patentable products that we are content to let it remain implicit, namely a lesson in infringement avoidance, is effectively impossible

[7] Although intent is not a factor in determining infringement, public notice is required as a predicate to the validity of a patent. Jurgens v. CBK, Ltd., 80 F.3d 1566, 1570 n.2 (Fed. Cir. 1996). The hypothetical causes unavoidable infringement even in situations where the public would, in good faith, want to avoid infringing.

for subject matter unpatentable under section 101. In short, patent claims drawn broadly enough to encompass products that spread, appear, and "reproduce" through natural processes cover subject matter unpatentable under section 101—and are therefore invalid.

The majority asserts that a patentability analysis under section 101 does not consider whether a claimed product includes within its coverage naturally occurring compositions. The majority's view is not, and has never been, the law. Patentability "requires an examination of the contested claims to see if the claimed subject matter as a whole" comes within the subject matter described in section 101. See AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352, 1357 (Fed. Cir. 1999); accord In re Allapat, 33 F.3d 1526, 1557 (Fed. Cir. 1994) (en banc). As this court has stated, "[t]he substantive issue at hand, whether the [patent] is invalid for failure to claim statutory subject matter under § 101, is a matter of both claim construction and statutory construction." State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1370 (Fed. Cir. 1998). Both AT&T and State Street considered the scope of patent claims to determine their validity under section 101. The analysis provided by this concurrence is fully consistent with that approach.

Both Animal Legal Defense Fund, which the majority relies upon, and Chakrabarty, which Animal Legal Defense Fund relies upon, considered the patentability of "non-naturally occurring" organisms. Animal Legal Def. Fund, 932 F.2d at 927. The PTO rule at issue in Animal Legal Defense Fund announced that "nonnaturally occurring non-human multicellular living organisms" were patentable within section 101. Id. at 928. The same rule specifically announced that it "did not

affect the principle that products found in nature will not be considered" patentable. Id. When the court, as the majority quotes, asserted that "[e]ither the subject matter falls within section 101 or it does not," it adverted to that underlying taxonomy. Whether subject matter is patentable under section 101 cannot be decided without classifying it as "nonnaturally occurring" or "found in nature."

Because the claimed PHC hemihydrate falls into both categories, it is not patentable under section 101. Merely limiting the claim to "synthetic PHC hemihydrate" would have solved the problem. But SmithKline Beecham did not.

VI.

Technological advances have forced this court, our predecessor court, and the Supreme Court to consider the line between the natural and the non-natural—including such inventions as non-naturally occurring plants and bacteria—several times over the past few decades. See, e.g., In re Bergy, 596 F.2d 952 (CCPA 1979), rev'd sub nom Diamond v. Chakrabarty, 447 U.S. 303 (1980); Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Agric. Supply, Inc., 200 F.3d 1374 (Fed. Cir. 2000), aff'd 534 U.S. 124 (2001). Paroxetine hemihydrate now appears to be the first patent litigated that forces the courts to consider the patentability of products and/or processes launched in a laboratory and released into nature.

Despite the complexity of the issue, the analysis is straightforward. An invention synthesized for the first time in a laboratory is eligible for patent protection under section 101. Processes for producing this synthetic product in the laboratory and/or for using this synthetic product may also be eligible for patent protection under section 101. However, a natural reproduction process, whether sexual, asexual, part of a chain

reaction, or a process of decay, is ineligible for patent protection under section 101. Chakrabarty, 447 U.S. at 309; Funk Bros., 337 U.S. at 130. An item reproduced by such a natural process, whether an inorganic structure or a life form, must ipso facto be ineligible for patent protection under section 101.

The Supreme Court has cited with approval the Congressional Record surrounding the adoption of the Plant Patent Act of 1930:

> [A] plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man. . . .” S. Rep. No. 315, supra, at 6; H. R. Rep. No. 1129, supra, at 7. Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.

Chakrabarty, 447 U.S. 303 (emphasis added). In its recent ruling confirming that hybrid plants are patentable subject matter under section 101, the Supreme Court noted that “[h]ybrid plants . . . generally do not reproduce true-to-type, i.e., seeds produced by a hybrid plant do not reliably yield plants with the same hybrid characteristics. Thus, a farmer who wishes to continue growing hybrid plants generally needs to buy more hybrid seed.” J.E.M., 534 U.S. at 128.

The principle unifying these statements about patentability made in 1930, 1980, and 2001, is that products capable of being “reproduced by nature unaided by man,” Chakrabarty, 447 U.S. 303, are not patentable subject matter under section 101. Though the parties have not briefed this question directly, they and the district court have provided more than sufficient facts to obtain a dispositive and incontrovertible legal determination that Claim 1 of the ’723 patent is invalid under section 101.

The ’723 patent, correctly construed, claims every single crystal of paroxetine hemihydrate, including those crystals arising through natural conversion. The district

court properly admitted SKB's proffered expert testimony about the scientific mechanism underlying natural conversion, SK II, 247 F. Supp. 2d at 1019-20, under Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), and General Electric v. Joiner, 522 U.S. 136 (1997), weighed it in conjunction with contradictory testimony proffered by Apotex's experts, SK II, 247 F. Supp. 2d at 1022, and concluded that at least some of Apotex's anhydrate would convert itself to hemihydrate. SK II, 247 F. Supp. 2d at 1022-23.

These findings lead to an inescapable conclusion—a conclusion that the majority attempts to dismiss as a question of "scope," rather than of patentability. Had SKB claimed "synthetic or non-naturally occurring crystalline paroxetine hydrochloride hemihydrate," the claim would have covered only patentable subject matter, and Apotex would be entitled to a judgment of noninfringement. Had SKB explicitly claimed the crystals converted in Apotex's facilities, as either "the natural process of converting paroxetine anhydrate to paroxetine hemihydrate" or "crystalline paroxetine hydrochloride hemihydrate arising through natural conversion," unpatentability under section 101 would be manifest; though the claimed matter would be a useful composition, it would be one that occurred in nature. See Chakrabarty, 447 U.S. at 309; Funk Bros., 337 U.S. at 130. By claiming simply "crystalline paroxetine hydrochloride hemihydrate" with no reference to how it was produced, SKB effectively claimed "crystalline paroxetine hydrochloride hemihydrate whether non-naturally occurring or arising through natural conversion." Claim 1, as issued, therefore combines patentable and unpatentable subject matter, and is invalid under section 101. The "confusion" to which the majority alludes should never arise because we cannot

reach Section 102 unless the claimed matter can overcome the hurdle of section 101.

Inventors wishing to claim products that can either be synthesized in laboratories or generated by natural processes may protect themselves by incorporating negative limitation terms like "non-natural" or "non-human" into the claims that they submit for examination. See Amgen Inc. v. Hoechst Marion Roussel, 314 F.3d 1313, 1329 (Fed. Cir. 2003); Animal Legal Def. Fund, 932 F.2d at 923; In re Wakefield, 422 F.2d at 904. SKB made no such distinction. SKB, despite an early recognition of seeding and conversion, SK II, 247 F. Supp. 2d at 1022, claimed all paroxetine hemihydrate crystals, including both those "born" of natural conversion without human intervention and those "made" in a laboratory through explicit human effort. SKB further demonstrated its claim to a possessory right in naturally occurring crystals by pursuing this litigation, and articulated this claim explicitly during oral argument.

The asserted breadth of Claim 1 makes sense only under the erroneous belief that patents may protect products spread and reproduced by natural processes, directly contradicting our well established understanding of the limits imposed by section 101. Given current scientific trends, such a belief could easily lead to misdirected research investments, to inappropriately issued patents, and to a widespread in terrorem effect crippling entire industries whose artisans learn that even their best efforts to respect patent rights may not save them from liability as inadvertent, inevitable infringers. As the district court recognized, the notice function of patents is meaningless in such an environment, SK II, 247 F. Supp. 2d at 1028. The lack of suitable notice could easily chill innovation, inquiry, experimentation, and commercial development. The patent law does not sanction the concept of inevitable infringement.

Because SKB's assertion of the single crystal theory provides the correct construction of Claim 1, the '723 patent claims paroxetine hemihydrate crystals reproduced by nature unaided by man—unpatentable subject matter—and is therefore invalid under 35 U.S.C. § 101.