

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 23, 2004

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 paroxetine hydrochloride anhydrate product produced by Apotex Corp., Apotex, Inc., and TorPharm, Inc. (collectively Apotex) will not infringe claim 1 of U.S. Patent No. 4,721,723 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). Claim 1 of the '723 patent recites, in its entirety, "Crystalline paroxetine hydrochloride hemihydrate." Upon this court's revision of the trial court's erroneous claim construction, Apotex's product will infringe this claim. Nonetheless because the public use bar of 35 U.S.C. § 102(b) renders claim 1 of the '723 patent invalid, this court affirms the district court's judgment in favor of Apotex.

I.

In the late 1970s, a British company called Ferrosan invented a new class of compounds, including a compound that became known as paroxetine. See U.S. Patent No. 4,007,196. 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, a chemist in SmithKline's Worthing, England laboratory, Alan Curzons, created a new crystalline form of PHC while attempting to improve PHC production. Curzons' test results established that the new product was the hemihydrate form of PHC (PHC hemihydrate), while 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.

Further review of the SmithKline samples showed that the Harlow plant had unwittingly made PHC hemihydrate as early as December 1984. In May 1985, SmithKline began double-blind clinical tests in the United States to determine the safety and efficacy of PHC hemihydrate capsules to treat depression symptoms. In these clinical tests, the doctors and patients were aware of the drug being tested, but were not aware which patients were taking a placebo and which were taking the actual drug.

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, "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 intended 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 the 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 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 grafted 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 detectable or 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. As Ferrosan and its successors improved the manufacturing and testing procedures for PHC, the compound “morphed” into a more pure and stable form, namely the PHC hemihydrate discovered in SmithKline’s facilities. Once this new form or polymorph exists, SmithKline’s experts explained, the general environment becomes “seeded” with crystals of the new polymorph. In this seeded environment, the old polymorph converts to the new polymorph upon its inevitable contact with seeds of the new polymorph. In other words, the creation of a pure version of the old polymorph becomes extremely difficult, if not impossible; the old polymorph has effectively disappeared and been replaced by the new.

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 seeding and the disappearing polymorph theory supported the inference that Apotex's PHC anhydrate tablets will contain at least trace, or 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 anhydrate tablets convert to PHC hemihydrate in the stomach of a patient due to the increased humidity and pressure. 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 select tablets from the testing without reasonable explanation.

Id. at 1032-42. The trial court found these excluded tablets to represent best 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 trial 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 determines whether summary judgment is appropriate 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 may show that the parties have conceded, and the district court has 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 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 of seeding and disappearing polymorphs. 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. 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. 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. 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. 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.” 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 Microsystems, 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 the PHC compound. 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.” Morton, 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. In this case, 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. 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 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 appeal that ruling.

SmithKline’s disappearing polymorph theory makes its apparently inconsistent positions possible. 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 cabined the infringement with a new equitable defense. 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 also created a seeded environment that, under the facts found by this district

court, makes the practice of the prior art an infringement, while precluding 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 for public use 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.

Public use - § 102(b)

A patent claim is not valid if "the invention was . . . in public use . . . 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). Whether a patent is invalid due to public use under § 102(b) is a question of law based on underlying questions of fact. See 3M Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed. Cir. 2002). Thus, without genuine factual disputes underlying the public use inquiry, the issue is ripe for judgment as a matter of

law.

In Pfaff v. Wells Electronics, Inc., 525 U.S. 55 (1998), the Supreme Court rejected the former “substantially complete under a totality of circumstances” test for the on sale bar under § 102(b) and adopted a two-prong test. That test bars a patent when the claimed invention, before the critical date, was the subject of a commercial offer for sale and was ready for patenting. Id. at 67. A similar analysis applies to the public use bar under § 102(b). Although the commercial sale prong is inapplicable, “[p]ublic use under 35 U.S.C. § 102(b) includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor.” Netscape Communications Corp. v. Konrad, 295 F.3d 1315, 1321 (Fed. Cir. 2002) (emphasis added). Thus, § 102(b) erects a bar where, before the critical date, the invention was ready for patenting and was used by a person other than the inventor who is under no confidentiality obligation.

“Experimental use negates public use; when proved, it may show that particular acts, even if apparently public in a colloquial sense, do not constitute a public use within the meaning of section 102.” Baxter Int'l, Inc. v. Cobe Labs., Inc., 88 F.3d 1054, 1059 (Fed. Cir. 1996) (citing TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 971 (Fed. Cir. 1984)); see also City of Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126, 134 (1877). The experimental use doctrine is not an “exception” to the public use bar because it does not shift the burden of proof from the accused infringer to the patentee. Rather, it operates to negate application of the public use bar. See EZ Dock, Inc. v. Schafer Sys., Inc., 276 F.3d 1347, 1351-52 (Fed. Cir. 2002) (“This court has repeatedly stressed that evidence of experimental use does not give rise to a free-standing doctrinal exception to statutory bars, but instead operates to negate application of section 102(b)”).

In other words, once the challenger of the patent has proven by clear and convincing evidence that the invention was in public use before the critical date, the burden of production shifts to the patentee to provide sufficient evidence to create a genuine issue of material fact that the use qualifies as experimental. The ultimate burden, however, remains on the challenger to prove by clear and convincing evidence that the non-experimental use was public under § 102(b). Id.

With these burdens and legal standards in mind, this court agrees with the district court and the parties that no material facts relating to the public use bar are in dispute. The record shows that PHC hemihydrate was in public use before the critical date of the '723 patent. Specifically, SmithKline placed PHC hemihydrate in public clinical trials in the United States in May 1985. The critical date under § 102(b) for the '723 patent is October 23, 1985. Moreover, SmithKline administered PHC hemihydrate to patients without any apparent confidentiality restrictions on the patients or the administering physicians. SmithKline does not question the public disclosure of its clinical trials. Rather, SmithKline asserts that the clinical trials constitute an experimental use negating the apparent public use. In SmithKline's own words, the purpose of the clinical trials was "to establish that [PHC hemihydrate] actually worked (and was safe) as an antidepressant."

Taking the facts in the light most favorable to SmithKline, this court assumes that the clinical trials were subject to satisfactory controls and otherwise properly conducted to fulfill their intended purpose – namely, to establish the efficacy and safety of PHC hemihydrate as an antidepressant drug for humans. The determinative inquiry in this case is whether SmithKline tested the invention of the asserted claim. "[T]esting or experimentation performed with respect to non-claimed features of the device does not show that the invention was the subject of experimentation." W. Marine Elecs., Inc. v. Furuno Elec. Co., 764 F.2d 840, 847 (Fed. Cir. 1985). In other words, an experimental use only negates a statutory bar when the inventor was testing claimed features of the invention. In re Theis, 610 F.2d 786, 793 (CCPA 1979) ("It is settled law that . . . [an] experimental sale . . . does not apply to experiments performed with respect to non-claimed features of an invention."); LaBounty Mfg. Inc. v. U.S. Int'l Trade Comm'n., 958 F.2d 1066, 1074 (Fed. Cir. 1992); In re Brigance, 792 F.2d 1103, 1109 (Fed. Cir. 1986).

Indeed the Supreme Court case that created the experimental use negation, City of Elizabeth, 97 U.S. at 126, acknowledged the purpose of this doctrine: "The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as such a [public] use." In other words, the doctrine extends to experimentation on the claimed invention to bring it to perfection. The negation does not

extend beyond the claimed invention or beyond the purpose of perfecting the invention. See, e.g., In re Smith, 714 F.2d 1127 (Fed. Cir. 1983) (“[E]xperimental use . . . does not include market testing”).

This court has already defined the invention of claim 1 as the PHC hemihydrate compound without further limitation regarding efficacy, commercial use, or pharmaceutical viability. SmithKline itself espouses that proper claim construction. With that definition of the invention in mind, however, clinical trials designed to establish the efficacy and safety of the compound as an antidepressant for FDA approval are not experimental uses of that claimed invention. In other words, the claim covers the compound regardless of its use as an antidepressant. The antidepressant properties of the compound are simply not claimed features. Consequently, the clinical tests, which measured the efficacy and safety of the compound as an antidepressant, did not involve the claimed features of the invention. The 1985 clinical tests, therefore, do not qualify as an experimental use to negate the statutory bar.

In making this ruling, this court is aware of cases that acknowledged an experimental use negation when the testing did not focus on an expressly claimed feature. See EZ Dock, 276 F.3d at 1353; Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1320, 1324 (Fed. Cir. 1996); Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 550-51 (Fed. Cir. 1990). To some extent, this apparent confusion arises from a separate requirement of patent law to test an invention for utility, i.e., to show that it works for its intended purpose. See Scott v. Finney, 34 F.3d 1058, 1061 (Fed. Cir. 1994). This court has noted the potential overlap of utility and experimental use testing. EZ Dock, 276 F.3d at 1352. As suggested by their different origins and purposes, however, utility testing (reduction to practice) and experimental use testing are not synonymous.

Testing to reduce an invention to practice shows completion of an invention and establishes its utility. See, e.g., Holmwood v. Sugavanam, 948 F.2d 1236 (Fed. Cir. 1991). The focus is on whether the totality of the testing at the relevant time period was sufficient to prove an actual reduction to practice of the invention. See Scott, 34 F.3d at 1061-62. Experimental testing, on the other hand, negates evidence that an inventor has fatally postponed filing beyond a bar date. See City of Elizabeth,

97 U.S. at 126. Here, the focus is on whether the specific testing in question was necessary to reduce the claimed invention to practice. That is, after the invention is reduced to practice, further testing will not qualify as experimental use for purposes of negating a bar under § 102(b). See Continental Plastic Containers v. Owens Brockway Plastic Prods., 141 F.3d 1073 , 1079 (Fed. Cir. 1998) (“The policy behind experimental use negation is to give the inventor an opportunity to reduce the invention to practice. . . . Thus, experimental use can not occur after a reduction to practice”) (citations ommitted).

Due to these different origins and purposes, the narrower experimental use negation does not extend beyond perfecting claimed features. In any event, even the cases above that acknowledge experimentation on features beyond those expressly claimed remain faithful to these strict limits of the experimental use negation. Each of those cases permitted testing to negate the bar when the experimentation improves or verifies a feature inherent in the express claims of the invention.

In Manville, for example, the claimed invention covered a light pole for highways that maintenance workers could lower for repairs. See 917 F.2d at 547-48. At the outset, this court decided Manville on the basis that the applicant retained the invention confidential and at no time placed it in the public domain. Id. The purported experimental use tested the illuminating device under severe weather conditions. Neither party asserted that this experimentation exceeded the literal scope of the claims, probably because the use occurred in a remote Wyoming rest area not yet open to the public at the top of a 150-foot pole. Indeed this court noted: “Manville did nothing to lead the public to believe that its iris arm invention was in ‘the public domain.’” Manville, 917 F.2d at 549. In other words, the use was either not public or properly confidential. This court also noted: “Manville marked its design drawing with a confidentiality notice.” Id. To the limited extent that this case also relied on the experimental use negation, this court explained: “[D]urability in an outdoor environment is inherent to the purpose of the invention.” Id. at 551. Thus, the experimentation verified features inherent in the claimed invention.

In Seal-Flex, the claimed invention covered an all-weather activity mat (or track). Seal-Flex, 98 F.3d at 1320-21. The patentee alleged that the product it sold was not the completed invention because

it was still being tested for its performance in harsh weather conditions. Id. At the outset, it is significant to note that this court decided Seal-Flex under standards for public use overruled by Pfaff. Therefore, this court weighed a “totality of circumstances” that no longer apply. Id. at 1322-23. Again, the parties did not raise the issue of limiting testing to claimed features. Like the Manville case, however, the scope of the claimed invention in Seal-Flex carried the inherent implication of performance in severe weather conditions. It was an all-weather track. Id. at 1324. Thus, the experimentation again focused on features inherent to the claimed invention. Importantly, this court in Seal-Flex did not affirmatively find that there was no on-sale bar under § 102(b) or that the activities constituted an experimental use. Rather, this court vacated the district court’s summary judgment and remanded the case. Id.

In EZ Dock, the claim covered a “floating dock.” EZ Dock, 276 F.3d at 1348. The testing involved the dock’s performance in rough, choppy water. Id. at 1353. Although the claim did not have an express “choppy water” limitation, the claim language “floating dock” carried the implication that the invention must perform in rough water. Thus, again, the experimentation verified or improved a feature inherent to the claimed invention. Again, the court vacated the summary judgment of invalidity and remanded for determination of the on-sale bar and experimental use issues. Id. at 1353-54. In sum, this court has remained faithful to the strict requirements of the experimental use negation by limiting it to testing to perfect claimed features, or, in a few instances, testing to perfect features inherent to the claimed invention.

In this case, SmithKline’s experimentation does not fit within the rule limiting the negation to tests on claimed features. See In re Theis, 610 F.2d at 793. In connection with the claim interpretation issue, SmithKline strenuously argues that nothing in the claim language, the specification, or the prosecution history indicates that the scope of claim 1 implicates any intended commercial significance or medical purpose. In fact, the claim does not carry any implication of commercial significance or medical purpose. While SmithKline benefits from the breadth of the meaning of its claim, that claim does not require testing tailored to ascertain the safety and effectiveness of a particular use. Thus, testing the medical efficacy and viability of PHC hemihydrate is not testing the claimed features of the

structural invention in claim 1.

SmithKline's assertion that the clinical tests constituted an experimental use of the invention of claim 1 is inconsistent with its claim construction position. This court also notes that these same clinical trials may serve to negate a public use bar with regard to the inventions claimed in the more specific claims of the '723 patent. Only claim 1, however, is before the court in this appeal. Nothing in the language of claim 1 can reasonably be read to carry an implication that the claimed compound will be used as an anti-depressant, or even a pharmaceutical for that matter. Because claim 1 covers the compound without further limitation, the invention of claim 1 was reduced to practice when that compound was first manufactured. Its efficacy as an anti-depressant is irrelevant to that determination.

Accordingly, a patentee should understand that testing the properties, uses, and commercial significance of a compound claimed solely in structural terms may start the clock under § 102(b) for filing a claim that is not limited by any property, commercially significant amount, or other use of the compound. Because these clinical trials tested only the safety and efficacy of PHC hemihydrate as an antidepressant, those trials were not an experimental use of the invention in claim 1. Consequently, this court determines that claim 1 of the '723 patent is invalid for public use under § 102(b) as a matter of law. This court reverses the district court's grant of summary judgment of validity in favor of SmithKline and reverses the district court's denial of summary judgment of invalidity in favor of Apotex.

Miscellaneous Issues

SmithKline also appealed the district court's decision to prevent SmithKline from pursuing its contributory infringement claim. In essence, that claim asserted that the ingestion of Apotex's PHC anhydrate tablet by a patient would result in conversion to the hemihydrate. In the interim, this court decided Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373 (Fed. Cir. 2003). In that case, this court determined that a compound claim was anticipated due to evidence that a prior art substance metabolized into the claimed compound upon ingestion by a patient. Recognition of the conversion process at the time of the prior art was not necessary to prove inherent anticipation. Id. at 1379-81.

Thus, if SmithKline proved contributory infringement by showing that PHC anhydrate metabolizes into PHC hemihydrate upon ingestion, SmithKline may also have proved that PHC hemihydrate was inherent in the prior art. Nevertheless, because claim 1 is invalid for public use under § 102(b), SmithKline's appeal concerning its contributory infringement claim 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 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 SmithKline's clinical trials constituted a public use under § 102(b) rendering claim 1 invalid. 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

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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 concur in the court's judgment finding Claim 1 of the '723 patent invalid, however, I reach the judgment by a different statutory provision. I would find Claim 1 invalid because it encompasses subject matter that is unpatentable under 35 U.S.C. § 101.^[1]

I.

A. 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 though [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 contemporary patent law, 37 C.F.R. § 1.641 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 Protection 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 Chemical Co. v. Morton International, 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. University of Illinois Foundation, 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^[2] as “sufficient authority” to support this holding, id., which it saw as furthering a longstanding policy orientation: “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.

My belief that this case warrants a sua sponte Section 101 inquiry therefore falls well within a long if somewhat sparse tradition, driven in part by concerns of public policy but grounded entirely in legal authority. Where, as here, the facts are both unusual^[3] 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.

B. Claim Construction and Prior Use

Before discussing my reasons for finding Claim 1 of the ‘723 Patent invalid for claiming unpatentable subject matter, however, I do need to address a few preliminary matters. I agree with the majority that the “single crystal” theory^[4] provides the only construction that is entirely consistent with the Claim 1’s language claiming “crystalline paroxetine hydrochloride hemihydrate” (“paroxetine hemihydrate”). I also agree with the majority that the paroxetine hemihydrate “made” in Apotex’s seeded manufacturing facilities through the natural conversion of the off-patent paroxetine anhydrate and water vapor present a prima facie case of infringement.

I agree with the district court, however, that SKB is entitled to summary judgment that the ‘723 patent is not invalidated by prior public use, Smithkline Beecham v. Apotex Corp., 286 F. Supp. 2d 925, 938 (N.D. Ill. 2001) (“SK I”), because “the control [SKB] actually exercised over the trials was sufficient to demonstrate that the trials were in the nature of experimentation rather than mere commercial use,” id. at 934, and because

SKB's experiments designed to assess the product's efficacy as an antidepressant, *id.* at 932, were relevant to the '723 patent in the same way that the experimental use doctrine preserved the validity of the patents in our previous cases. See Manville Sales Corp. v. Paramount Sys. Inc., 917 F.2d 544, 550 (Fed. Cir. 1990); Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318 (Fed. Cir. 1996); EZ Dock, Inc. v. Schafer Sys. Inc., 276 F.3d 1347 (Fed. Cir. 2002).

In EZ Dock, for example, the patent at issue claimed a polyethylene floating dock—like the claim at issue here, a product claim. *Id.* at 1348. The district court determined that the patentee had offered the claimed dock for sale in the United States. more than one year before filing the patent application. *Id.* at 1350. We noted that though the defendant had presented a prima facie case against EZ Dock, EZ Dock's evidence could convince a jury that the sales were experimental. *Id.* at 1352. We explained that though the “experiments” did not test features actually claimed in the patent, an experimental use defense was still available because “[the inventor] testified that he sold the dock . . . to determine whether it was capable of performing its intended purpose in its intended environment.” *Id.* at 1353.

We noted that this application of the experimental use doctrine, like our earlier assessment of experimental use in Manville, 917 F.2d at 550, extended the notion of experimentation beyond features claimed explicitly in the patent to include the intended purpose of those features. EZ Dock, 276 F.3d at 1353. The majority notes this extension with approval, and even points to the title of the patents at issue in Seal-Flex, 98 F.3d at 1324, as evidence of the relationship between the features tested and the “inherent implication” of the claimed features. Yet somehow, the majority finds no such “inherent implication” when SKB conducted a series of double-blind tests to determine whether the product claimed in Claim 1 of a patent titled “Anti-depressant Crystalline Paroxetine Hydrochloride Hemihydrate,” worked as an anti-depressant in humans. I see no principled grounds on which to distinguish this case from our precedent. See Manville, 917 F.2d at 550; Seal-Flex, 98 F.3d at 1324; EZ Dock, 276 F.3d at 1353. The district court was correct in finding that, under our precedent, the prior-use bar did not invalidate the '723 Patent. SKI, 286 F. Supp. 2d at 938. The majority seems to be trying to reach an ultimate conclusion of invalidity while avoiding the road less traveled.

Nevertheless, because the district court misconstrued the claim, I cannot share its conclusion that Claim 1 is “valid against the various attacks on it made by Apotex.” SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011, 1052 (N.D. Ill. 2003) (“SK II”). Claim 1 of the ‘723 patent is invalid because it is broad enough to claim subject matter that is unpatentable under Section 101. The troubling implications of this impermissible breadth explain the various anomalies that engaged the district court. Under normal circumstances, patented products do not simply “appear” in ways that convert noninfringing products into infringing products.

The district court found as a matter of fact that paroxetine hemihydrate is an exception to this general rule. SK II, 247 F. Supp. 2d at 1022-23. I agree with the majority that the record supports the district court’s factual findings, and that these findings provide the appropriate background for our legal conclusions—specifically including the district court’s findings concerning seeding and conversion.

II.

A. 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 Systems, Inc. v. Containment Technologies, 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 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 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.

B. Findings of Fact

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[5] 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.* 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.

III.

A. Public Notice

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 hemihydrated 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).

Were we to nevertheless hold Apotex liable as an infringer of Claim 1, we would effectively remove a valuable public-domain antidepressant, paroxetine anhydrate, from the market, and likely motivate potential inventors of superior grades of paroxetine to refocus their efforts elsewhere. This result is inconsistent with patent policy and—more importantly for the purposes of this court—it is incompatible with patent law. We would be holding valid a patent incapable of serving its important public notice function.

Claim 1 therefore cannot be held 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.

B. 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 therefore . . .” 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 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.^[6] 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 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.

C. Invalidity

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.

IV.

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.

Though the majority's approach to invalidating Claim 1 of the '723 patent under Section 102(b) defuses these negative consequences with respect to paroxetine, it does so at the cost of creating unfortunate precedent that will complicate future considerations of the experimental use doctrine. It also fails to address the central anomaly that the district court identified. We do no one any favors by allowing this important question to remain open. We should announce, as a court, that the patent law does not sanction the concept of inevitable infringement—lest someone mistakenly believe that it does.

I would hold that 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.

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[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.

[2] Telephone Cases, 167 U.S. 224 (1897); United States v. U. S. 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); and MacGregor v. Westinghouse Elec. & Mfg. Co., 329 U.S. 402 (1947); Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892); Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969).

[3] 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.

[4] The district court defined the “single crystal” theory of Claim 1 as encompassing:

all manifestations of the hemihydrate, no matter how or where produced, or in what quantity relative to the mixture of which it is a part; even if the production was inadvertent, unavoidable though undesired, and wholly without benefit to the producer or detriment to SmithKline in the sense of cutting into SmithKline's market; and even if the amount is so tiny as to be beyond the limits of detection of any instrument present or foreseeable and the product in which it unexpectedly pops up does not compete with anything made or sold by SmithKline.

SK II, 247 F.Supp.2d at 1026 (emphasis in original).

[5] 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.

[6] 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.