United States Court of Appeals for the Federal Circuit

03-1575

GLAXO GROUP LIMITED
and SMITHKLINE BEECHAM CORP.,

Plaintiffs-Appellees,

v.

APOTEX, INC.,

Defendant-Appellant.

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

Judge Robert W. Gettleman

United States Court of Appeals for the Federal Circuit

03-1575

GLAXO GROUP LIMITED
and SMITHKLINE BEECHAM CORP.,

Plaintiffs-Appellees,

v.

APOTEX, INC.,

Defendant-Appellant.

DECIDED: July 27, 2004

Before SCHALL, GAJARSA, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA. Opinion concurring-in-part and dissenting-in-part filed by Circuit Judge DYK.

GAJARSA, Circuit Judge.

Apotex, Inc. ("Apotex") appeals the judgment of the United States District Court for the Northern District of Illinois, which found that Apotex's filing of an Abbreviated New Drug Application ("ANDA") for a generic version of the antibiotic Ceftin® willfully infringed U.S. Patent No. 4,562,181 (the "'181 patent") and U.S. Patent No. 4,820,833 (the "'833 patent") owned by Glaxo Group Limited and SmithKline Beecham Corp. (collectively "Glaxo"). Glaxo Group Ltd. v. Apotex, Inc., 268 F. Supp. 2d 1013 (N.D. Ill. 2003). While we affirm the district court's determination that Apotex's ANDA infringes the '181 and '833 patents pursuant to 35 U.S.C. § 271(e)(2), and also affirm that the patents at issue are not invalid, we reverse the district court's finding that Apotex's ANDA filing constituted

willful infringement. We hold that the mere filing of an ANDA cannot constitute an act of willful infringement compensable by attorney's fees under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.

I. BACKGROUND

A. The '181 and '833 patents

Glaxo is the owner by assignment of a series of patents directed to antibiotics in the cephalosporin family. In the 1970s, Glaxo developed the cephalosporin compound of cefuroxime, the subject of U.S. Patent No. 3,974,153. Cefuroxime required intravenous or intramuscular injection because of bioabsorption difficulties and was therefore of limited usefulness. Glaxo then synthesized a family of cefuroxime esters that were capable of oral administration and obtained U.S. Patent No. 4,267,320 (the "'320 patent"), which issued May 12, 1981. The '320 patent claimed, among other compounds, a compound known as cefuroxime axetil (hereinafter "CA"). The '320 patent disclosed CA in the forms of (1) an impure amorphous compound and (2) a purer crystalline compound. Crystalline compounds contain a structure whereby molecules are arranged in a regularly repeating order. By contrast, amorphous is often defined as the opposite of crystalline and refers to a structure where molecules are randomly distributed with respect to one another. See Glaxo Group Ltd. v. Ranbaxy Pharms., Inc., 262 F.3d 1333, 1335 (Fed. Cir. 2001) (explaining that amorphous compounds lack an "ordered arrangement").

After the issuance of the '320 patent, Glaxo scientists continued development on CA because of persistent difficulties with bioabsorption. On July 29, 1983, Glaxo filed the application that matured into the '181 patent, a continuation of U.S. Patent Application Ser. No. 781,505 (the "'505 application"). The '181 patent is directed to a highly pure amorphous form of CA that offers superior bioavailability and stability than crystalline forms of CA. According to the patent, the discovery that an amorphous CA compound provided a better pharmaceutical formulation ran counter to the expectations of those familiar with cephalosporin compounds. '181 patent, col. 2, ll. 3-9. The

'181 patent issued on December 31, 1985, and expired on July 29, 2003.

The '181 patent has fourteen claims, of which Claims 1 and 8 are most relevant to the current appeal:

> 1. Cefuroxime axetil in amorphous form essentially free from crystalline material, and having a purity of at least 95% aside from residual solvents.
> 8. An antibacterial pharmaceutical composition containing an antibacterially effective amount of cefuroxime axetil according to claim 1 in admixture with one or more pharmaceutical carriers or excipients.

Id. at col. 13, ll. 4-8; col. 14, ll. 1-4 (emphasis added).

In addition to the '181 patent, Glaxo holds the '833 patent claiming a method for preparing highly pure amorphous CA. The '833 patent, which, like the '181 patent, is a continuation of the '505 application, issued on April 11, 1989. The '833 patent contains a terminal disclaimer and expired on July 31, 2003, along with the '181 patent. The one independent claim of the '833 patent reads:

> 1. A process for preparing a highly pure, substantially amorphous form of cefuroxime axetil which comprises preparing a highly pure solution of cefuroxime axetil and spray drying said solution to recover highly pure, substantially amorphous cefuroxime axetil.

'833 patent, col. 14, ll. 4-8 (emphasis added). Spray drying is a technique by which a solution is atomized into droplets and then instantaneously dried, creating an amorphous rather than a crystalline form of the compounds suspended in the solution. See id. at col. 8, ll. 27-41.

The commercial embodiment of the '181 and '833 patents is Ceftin®, a drug formulation approved by the Food and Drug Administration ("FDA") that has been very successful in the marketplace. Glaxo has generated almost $4 billion in sales from Ceftin® in the drug's fifteen years on the market.

B. ANDA

On April 5, 2000, Apotex filed an ANDA seeking approval by the FDA to market a generic version of Ceftin®. Apotex creates its generic drug by: (1) dissolving excipients zinc chloride and sorbitol into a solution of water and acetone along with approximately 98% pure crystalline CA; (2)

mixing the resulting solution; (3) spray drying the solution under nitrogen; (4) collecting, compacting, and milling the resulting spray dried amorphous particles into granules; (5) mixing the granules with additional excipients; (6) compressing the resulting blend into a tablet core; and (7) coating the tablet. Apotex's spray dried solution creates an amorphous "co-precipitate" comprised of 90% CA, 9% sorbitol, and 1% zinc chloride by mass. On November 26, 2002, the patent office issued to Apotex U.S. Patent No. 6,485,744 (the "'744 patent") relating to Apotex's unique use of zinc chloride as a stabilizing excipient for CA.

Apotex's ANDA filing is atypical in that it did not contain a certification pursuant to 21 U.S.C. § 355(j)(2)(A). Under the Hatch-Waxman Act, most patentees and NDA holders must list patents related to their approved drugs in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book"). 21 U.S.C. § 355(b)(1). Reciprocally, a generic company has an obligation to consult the Orange Book before filing an ANDA and certify that either (I) no patent information is listed in the Orange Book for the proposed generic drug; (II) that the listed patents have expired; (III) that the listed patents will expire before the generic company markets its product; or (IV) that the patents listed are invalid or will not be infringed by the generic drug (a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(I)-(IV).

In the current case, however, CA was approved under 21 U.S.C. § 357, a now-repealed provision of the Federal Food, Drug, and Cosmetic Act relating to antibiotics. Drug manufacturers who utilized Section 357 to obtain FDA approval are exempt from listing the patents related to their antibiotic in the Orange Book. Correspondingly, ANDA applicants attempting to market generics of such antibiotics are not required to file a certification under 21 U.S.C. § 355(j)(2)(A). See Pub. L. 105-115, Title I, §125 (d), 11 Stat. 2326 (1997). Accordingly, Glaxo did not list the '181 or '833 patent in the Orange Book, and Apotex therefore did not file a paragraph IV certification in its ANDA application.

C. Procedural History

Glaxo brought a declaratory judgment action against Apotex after the filing of Apotex's ANDA, alleging anticipatory infringement and "artificial" infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

Section 271(e)(2)(A) provides a jurisdictional basis for a declaratory judgment suit against a generic manufacturer and states:

> (2) It shall be an act of infringement to submit—
>
> > (A) an application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . [i]f the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A); see also Glaxo, Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997) (stating that "§ 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity"); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990) (explaining that 35 U.S.C. § 271(e)(2) and (e)(4) have a "very limited and technical purpose" and that such purpose is "to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend").

On June 10, 2002, the district court issued a preliminary injunction preventing Apotex from marketing its generic CA product pending resolution of the case. As part of its order enjoining Apotex, the court issued a claim construction for Claim 1 of the '181 patent, finding that the phrase "cefuroxime axetil . . . having a purity of at least 95%" meant that the CA claimed must have "no more than 5% degrading, unwanted impurities." The district court further clarified that impurities do not include excipients. This Court affirmed the preliminary injunction in its unpublished decision of Glaxo Group Ltd. v. Apotex, Inc., 64 Fed. Appx. 751 (Fed. Cir. 2003).

After issuance of the preliminary injunction, the district court conducted a bench trial. At trial, the district court found that Apotex infringed the '181 patent because Apotex's ANDA stated that its products do not contain more than 1% impurities, excluding excipients.[1] With respect to the '833 patent, the court construed the term "pure" in Claim 1 to mean the absence of impurities, where excipients are not considered to be impurities. The court then dismissed Apotex's argument that Claim 1's phrase "a highly pure solution of cefuroxime axetil" required that the solution consist only of CA.

Instead, the court found that Claim 1 encompassed the spray drying of solutions like that used by Apotex, which consist of CA and excipients, and found Apotex to infringe the '833 patent.

The district court also dismissed Apotex's counterclaim of invalidity. The district court rejected the evidence of anticipation proffered by Apotex's witness Dr. Jay Siegel. Dr. Siegel testified that he was able to use the '320 patent to create highly pure amorphous CA. He admitted, however, to deviating from the example of the '320 patent in which amorphous CA synthesis is disclosed. In addition, Dr. Siegel had reviewed the '181 patent prior to performing his experiments. Both facts led the district court to conclude that Dr. Siegel's experiments were "highly suspect" and therefore insufficient to prove invalidity by clear and convincing evidence.

As its final determination, the district court found Apotex's infringement to be willful and awarded Glaxo attorney's fees under 35 U.S.C. § 285 as an exceptional case. Relying heavily on the fact that Apotex did not receive an opinion from competent patent counsel, the district court found that Apotex did not exercise due care in filing its ANDA.

II. DISCUSSION

A. Standard of Review

Apotex appeals to this Court and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). Claim construction is a matter of law that we review de novo on appeal. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). A determination of whether a patent satisfies the written description and definiteness requirements of 35 U.S.C. § 112 is also a question of law that we review de novo. Union Pac. Res. Co. v. Chesapeake Energy Co., 236 F.3d 684, 692 (Fed. Cir. 2001); Amgen, Inc. v Chugai Pharm. Co., 927 F.2d 1200, 1212 (Fed. Cir. 1991).

Whether an accused product infringes is a question of fact reviewed for clear error. Apex Inc. v. Raritan Computer, Inc., 325 F.3d 1364, 1371 (Fed. Cir. 2003). Likewise, the question of whether a prior art reference expressly or inherently discloses every claim limitation is reviewed under the clearly erroneous standard. Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999). A finding

is clearly erroneous when, despite some supporting evidence, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948).

We review a district court's award of legal fees under 35 U.S.C. § 285 by first reviewing de novo whether the court applied the proper legal standard. We then review the court's factual findings, including whether the case is exceptional, for clear error. Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1378 (Fed. Cir. 2001). If the district court finds the case to be exceptional and awards legal fees to the prevailing party, we review such an award for an abuse of discretion. Cybor Corp., 138 F.3d at 1460.

An appellate court's preliminary injunction opinion has no conclusive bearing at the trial on the merits and is not binding on a subsequent panel. Univ. of Tex. v. Camenisch, 451 U.S. 390, 395 (1981); Int'l Cmty. Materials v. Ricoh Co., 108 F.3d 316, 318-19 (Fed. Cir. 1997) ("We do not regard it as our function [in a preliminary injunction appeal] to definitively construe" claim language or to review claim construction "as if from final judgment"); see also Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

B. Infringement of the '181 Patent[2]

On appeal, Apotex argues that the district court erred in construing the phrase "having a purity of at least 95%" of Claim 1 of the '181 patent to cover formulations with more than 5% of other ingredients. Apotex argues that Claim 1 covers only pure CA and that any other compounds added to CA render the CA impure for purposes of meeting the 95% purity limitation of Claim 1. Under this definition, Apotex's formulation, which contains only 90% amorphous CA, would not infringe the '181 patent.

To properly construe a claim term, a court first considers the intrinsic evidence, starting with the language of the claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claim terms should be construed consistently with their ordinary and customary meanings, as

determined by those of ordinary skill in the art. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003). In construing the terms of a patent, the court must also examine the specification to determine whether the patentee used the claim term consistent with its ordinary meaning or acted as his own lexicographer in defining the term. See, e.g., Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1988); Brookhill-Wilk, 334 F.3d at 1299.

In the present case, Apotex's construction of the phrase "having a purity of at least 95%" is both contrary to the ordinary meaning of such a phrase in the pharmaceutical arts and belied by the specification of the '181 patent. The specification describes in detail the types of molecules that are considered impurities, including among the "typical impurities" compounds related to CA such as the Δ^2-isomer and E-isomer of CA. '181 patent, col. 2, ll. 36-38. The patent therefore uses the term impurities in a manner similar to its ordinary usage, where impurity is considered as an unwanted reaction product formed during synthesis. Glaxo, 268 F. Supp. 2d at 1026. In contrast, excipients are inactive ingredients that are routinely and purposefully added to the active ingredient to enhance the performance of the active ingredient. Id. at 1023. To one of ordinary skill in the art, excipients are almost universally used with the active ingredient, and therefore do not act to affect the purity of the drug. Id. at 1026. This common understanding of purity is aptly demonstrated by Apotex's patent application for its co-precipitate, which stated that, "In the case of pure amorphous cefuroxime axetil, the process of manufacture will preferably be to dissolve the zinc salt along with the cefuroxime axetil in suitable solvent and then evaporate the solvent . . . ." Apotex's statement strongly suggests that the purity of CA remains unaffected by the addition of excipients such as the zinc chloride used by Apotex in its generic product.

Apotex's construction also violates the principle that claims should rarely, if ever, be construed to exclude a preferred embodiment. Vitronics, 90 F.3d at 1583. Were we to count excipients as impurities for purposes of Claim 1, we would be forced to limit Claim 8 to pharmaceutical formulations in which CA composed at least 95% of the formula. The specification of the '181 patent provides, however, that "[c]ompositions may contain between 0.1 - 99 % of the active ingredient . . . ." '181 patent, col. 5, ll. 17-37, 59-61; col. 6, ll. 1-5. The specification also provides a list of pharmaceutical

examples related to Claim 1, all of which contain less than 95% amorphous CA.

Because Apotex's construction (1) conflicts with the ordinary understanding of the phrase "having a purity of at least 95%," (2) would exclude all preferred embodiments of Claim 8, and (3) is in conflict with the specification of the '181 patents, this Court affirms the district court's construction of the '181 patent. Based on this construction, Apotex's ANDA admission that its generic CA products contain less than 2% by weight impurities of CA supports the district court's finding of infringement of the '181 patent.

C. Infringement of the '833 Patent

Apotex's arguments as to the proper claim construction for the '833 patent fail on the same logic as the '181 patent. Apotex argues that the district court erred in construing the term "pure" to mean the absence of impurities, where excipients are not considered to be impurities. Under Apotex's definition of "pure," Claim 1 of the '833 patent would cover methods of spray drying where the solution to be spray dried contained only highly pure CA. Because the term "pure" should be construed such that it is consistent with the ordinary meaning of that term, we construe the '833 patent consistently with the '181 patent and affirm the district court's construction. Based on this construction, a "highly pure solution of cefuroxime axetil" may include a solution that contains excipients along with pure CA. Apotex's method of producing its amorphous CA product by spray drying excipients and pure CA therefore infringes the claims of the '833 patent.

D. Invalidity

On appeal, Apotex advances two theories for invalidating the '181 and '883 patents: (1) that the district court's claim construction of "purity" and "pure" renders the patents invalid for purposes of 35 U.S.C. § 112, and (2) that Glaxo's '320 patent enables one of ordinary skill in the art to produce 97% pure CA in an amorphous form, thereby anticipating or rendering obvious the '181 and '833 patents pursuant to 35 U.S.C. § 102(b). We hold that neither of Apotex's theories overcomes the presumption of validity provided to an issued patent by 35 U.S.C. § 282.

1. 35 U.S.C. § 112

Apotex argues that the district court's claim construction of "purity" and "pure" renders the patents at issue in this litigation hopelessly indefinite. According to Apotex, one of ordinary skill in the art would not know that the '181 patent claimed CA that had more than 5% of other ingredients. In addition, Apotex argues that a skilled artisan would not realize that the '833 patent covered a process by which excipients are mixed with CA prior to spray drying. These arguments are disingenuous. As discussed previously, the '181 patent specifically states that the pharmaceutical compositions covered by the invention may contain between 0.1 to 99% of the active ingredient, CA. '181 patent, col. 5, ll. 59-62. CA formulations with more than 5% other ingredients were thus pointed out to the public in the '181 patent. The written description of the '833 patent is similarly explicit. In the written description, Glaxo discloses that the pharmaceutical compositions of CA may be produced by spray-drying "a suspension of pure amorphous cefuroxime axetil with the excipients appropriate for said tablets, capsules or granules." '883 patent, col. 5, ll. 40-45. Glaxo therefore informed the public that combining CA with excipients prior to spray drying was contemplated under the '833 patents. These detailed disclosures clearly convey to one of ordinary skill in the art that the patentee "invented what is claimed," and also give notice to the public of the limits of the invention. Vas-Cath, Inc. v. Mahurkar, 935 F.3d 1555, 1563 (Fed. Cir. 1991); see also Miles Lab., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993); United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 232 (1942).

2. Anticipation and Obviousness

On appeal, Apotex also argues that the district court erred by finding that the '320 patent does not anticipate or make obvious the '181 and '833 patents. Apotex has the burden of showing invalidity by clear and convincing evidence. Robotic Vision Sys., Inc. v. View Eng'g, Inc., 189 F.3d 1370, 1377 (Fed. Cir. 1999). This burden is "especially difficult" when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution. Al-Site Corp v. VSI Int'l Inc., 174 F.3d 1308, 1323 (Fed. Cir. 1999).

Apotex argues that the district court erred in discrediting Dr. Siegel's experiments for their

failure to follow Example 1 of the '320 patent. Apotex is of course correct that anticipation requires that all limitations of the claimed invention are described in a single reference, rather than a single example in the reference. See In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990). At the same time, however, Apotex did not sufficiently convince the district court that the deviations from the example provided by the '320 patent for the synthesis of an amorphous form of CA were not the result of impermissible hindsight. Inherent anticipation requires that the "missing characteristic is necessarily present, or inherent, in the single anticipating reference." Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003); see also Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002). In the present case, the missing claim limitations, which increased the purity of the amorphous CA considerably, were not found to be inherent by the district court. Dr. Siegel, by benefit of reading the '181 patents prior to conducting his experiments, knew that he needed to prepare a highly pure amorphous form of CA and used a mixture of methods, some even from the synthesis of crystalline compounds, to meet this goal. Glaxo demonstrated that every deviation from the teaching of the '320 patent increased purity. It was therefore not incorrect for the district court to discredit Dr. Siegel's testimony and experiments as to whether the '320 patent inherently yields highly pure amorphous CA.

We also affirm the district court's determination that the '181 patented invention would not have been obvious in light of the '320 patent. The '320 patent does not suggest that highly pure amorphous CA product would have better bioavailability and stability than a crystalline form. This surprising discovery by Glaxo scientists formed the basis for the issuance of the '181 patent. Even Dr. Siegel admitted that the '320 patent did not provide a teaching or suggestion that amorphous CA would have a superior combination of stability and bioabsorption properties as compared to crystalline CA forms. Secondary factors of non-obviousness—commercial success, long felt but unresolved need, and unexpected results—also favor the non-obviousness determination reached by the district court. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

E. Willful Infringement

The final issue we address on appeal is whether the district court clearly erred in finding that the

infringement of the '181 and '883 patents was willful.[3] Apotex argues that: (1) it has never committed an act of infringement with respect to the '181 and '883 patents except for the filing of its ANDA; (2) it did not provide a paragraph IV certification and therefore never certified that the patent was invalid or non-infringed; and (3) the district court ignored evidence that Apotex took due care. Because we agree with Apotex that the mere filing of an ANDA cannot constitute grounds for a willful infringement determination, we reverse the district court's award of attorney's fees to Glaxo.

The act of filing an ANDA constitutes a "highly artificial" act of infringement under 35 U.S.C. § 271(e)(2). Eli Lilly, 496 U.S. at 678. This highly artificial act of infringement gives rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4). The remedies available to the innovator company under Section 271(e)(4) are:

> (4) For an act of infringement described in paragraph (2)—
>
> > (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
> >
> > (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.
>
> > The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(emphasis added). Under this provision, courts are permitted to award monetary damages only when commercial activity has actually occurred in the United States or when the commercial product has been imported. 35 U.S.C. § 271(e)(4)(C). The exception to this provision is in the case of attorney's fees awarded pursuant to 35 U.S.C. § 285. Section 285 permits attorney's fees to be awarded to the prevailing party in "exceptional cases." This court has recognized many types of misconduct that may create an exceptional case for purposes of awarding fees, including inequitable conduct before the PTO,

litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement. See Hoffmann-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1365 (Fed. Cir. 2000); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1548 (Fed. Cir. 1984).

While a myriad of factual circumstances may give rise to a finding that a case is exceptional for purposes of 35 U.S.C. § 285, this court has limited what types of conduct may give rise to an award of attorney's fees for purposes of Section 271(e)(4). In Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc., this Court determined that a baseless and "wholly unjustified" paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding. 231 F.3d 1339, 1346 (Fed. Cir. 2000). In Yamanouchi, the district court had found that the generic company's ANDA filing constituted willful infringement, but we did not adopt that rationale on appeal. Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 21 F. Supp. 2d 366, 376 (S.D.N.Y. 1998). Instead we cautioned that the trial court "need not have elevated the ANDA certification into a finding of willful infringement" and held that Danbury's entire conduct justified the award of attorney's fees, noting that the generic company failed to present even a prima facie case of invalidity in filing its paragraph IV certification, hence making a baseless filing, and proceeded to present its case in litigation despite "glaring weaknesses." Yamanouchi, 231 F.3d at 1347. Therefore, in Yamanouchi, we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification. Such unjustified litigation and misconduct has always justified a finding of an exceptional case.

Consequently, as suggested by Yamanouchi, we now hold that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4). The Supreme Court has emphasized that 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(e)(4) create an "artificial" act of infringement only for a "very limited and technical purpose that relates only to certain drug applications." Eli Lilly, 496 U.S. at 623. This purpose, as the Supreme Court explains, is to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at

issue. Id. at 624; see also 35 U.S.C. § 271(e)(1) (exempting generic manufacturers from an infringement action when their use is for the purposes of developing and researching generic alternatives to obtain premarket approval by the FDA). In evaluating 35 U.S.C. § 271(e)(2), we have in our past decisions considered this provision to be primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action. See Allergan, Inc. v. Alcon Labs., 324 F.3d 1322, 1330 (Fed. Cir. 2003) (stating that while § 271(e)(2) is not strictly a jurisdictional statute, it acts to permit a district court to exercise jurisdiction under 28 U.S.C. § 1338(a) in situations where an ANDA has been filed). The district court therefore erred in hanging a finding of willfulness on such a special-purpose peg.

Because 35 U.S.C. § 271(e)(2) is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts, we hold that the district court committed clear legal error in finding that Apotex's mere filing of an ANDA could form the basis of a willful infringement finding. The district court did not find that Apotex engaged in any litigation misconduct, and Apotex did not file a paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity such as that filed in Yamanouchi. A district court abuses its discretion in awarding attorney's fees when its decision is based on clearly erroneous findings of fact, an erroneous interpretation of the law, or is clearly unreasonable, arbitrary, or fanciful. Fraige v. American-National Watermattress Corp., 996 F.2d 295, 297 (Fed. Cir. 1993). As a legal error, the district court's award of legal fees based on its finding that Apotex committed willful infringement under 35 U.S.C. § 271(e)(2) constitutes an abuse of discretion which we hereby reverse.

Because the district court did not award attorney's fees on any basis other than willful infringement, we therefore reverse the award of attorney's fees to Glaxo.

III. CONCLUSION

We affirm the district court's claim construction of the '181 and '833 patents and find that Apotex infringed the patents pursuant to 35 U.S.C. § 271(e)(2) by the filing of its ANDA application directed to a generic version of amorphous CA. We further affirm the district court's dismissal of

Apotex's claim that the '181 and '833 patents are invalid. We reverse, however, the finding of willful infringement of the '181 and '833 patents based on Apotex's ANDA filing. Such a filing cannot constitute willful infringement for purposes of establishing an exceptional case and the award of attorney's fees under 35 U.S.C. § 271(e)(4). We therefore

AFFIRM-IN-PART AND REVERSE-IN-PART

IV. COSTS

No costs.

United States Court of Appeals for the Federal Circuit

03-1575

GLAXO GROUP LTD. and
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Plaintiffs-Appellees,

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APOTEX, INC.,

Defendant-Appellant.

DYK, Circuit Judge, concurring-in-part and dissenting-in-part.

I agree with the majority's disposition of the dispute as to the preliminary injunction bond and the claim for willful infringement. Given that disposition, the questions of infringement and invalidity are moot since, as the parties conceded at oral argument, there are no past damages being sought for infringement, and the patents have expired. I dissent from the majority's decision to address the issues of infringement and invalidity in the absence of a live case or controversy.

[1] The district court also construed the phrase "amorphous form essentially free from crystalline material" in Claim 1 of the '181 patent in a manner that conforms to this Court's decision in Glaxo Group Ltd v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333 (Fed. Cir. 2001). In Ranbaxy, we construed the disputed phrase to mean that the compound contains "a maximum crystalline content of less than 10%." Id. at 1337. Apotex does not appeal the district court's determination that Apotex's product meets this limitation of the '181 patent.

[2] The dissent argues that we should not address Apotex's infringement and invalidity arguments before turning to the issue of willful infringement because there are no past damages awarded for the infringement and because the patents have expired. We disagree. Willful infringement requires that the defendant infringe a valid patent without a reasonable belief that its actions would avoid infringement. Vulcan Eng'g Co. v. FATA Aluminium, Inc., 278 F.3d 1366, 1378-79 (Fed. Cir. 2002). We thus find it appropriate to speak to the threshold issues of infringement and validity before turning our attention to willful infringement.

[3] Apotex additionally asserted that the district court improperly ordered the release of Glaxo's preliminary injunction bond. Because the entry of a permanent injunction obviates the need for a preliminary injunction bond, we find this issue to be moot. See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1313 (Fed. Cir. 1998) (affirming release of preliminary injunction bond upon entry of permanent injunction).