United States Court of Appeals for the Federal Circuit

03-1354,-1355,-1386,-1387

REC'D by APPEALS
JUN 07
CLARENCE MADDOX
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ELAN CORPORATION, PLC,

Plaintiff-Appellant,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant-Cross Appellant.

JUDGMENT

ON APPEAL from the UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

in Case NO(S). 98-CV-7164 and 00-CV-7057 - AJ

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

REVERSED AND REMANDED

CERTIFIED COPY
I HEREBY CERTIFY THIS DOCUMENT IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE.
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT
By: Gregory Thorne Date: 5/27/04

ENTERED BY ORDER OF THE COURT

DATED MAY - 5 2004

Jan Horbaly, Clerk

ISSUED AS A MANDATE: MAY 27 2004

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United States Court of Appeals for the Federal Circuit

03-1354, -1355, -1386, -1387

ELAN CORPORATION, PLC,

Plaintiff-Appellant,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant-Cross Appellant.

James B. Monroe, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiff-appellant. With him on the brief were Michael J. Flibbert and Paul W. Browning. Of counsel was James R. Barney.

Martin P. Endres, Hedman & Costigan, P.C., of New York, New York, argued for defendant-cross appellant. With him on the brief were James V. Costigan and Kathleen A. Costigan. Of counsel on the brief was Gerald J. Houlihan, Houlihan & Partners, P.A., of Miami, Florida.

Appealed from: United States District Court for the Southern District of Florida

Judge Adalberto Jordan

United States Court of Appeals for the Federal Circuit

03-1354, -1355, -1386, -1387

ELAN CORPORATION, PLC,

Plaintiff-Appellant,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant-Cross-Appellant.

DECIDED: May 5, 2004

Before MICHEL, LOURIE, and DYK, Circuit Judges.

LOURIE, Circuit Judge.

Elan Corporation, PLC ("Elan") appeals from the decision of the United States District Court for the Southern District of Florida declaring U.S. Patent 5,637,320 invalid under the on-sale bar of 35 U.S.C. § 102(b). Elan Corp. v. Andrx Pharms., Inc., Nos. 98-7164-CIV-JORDAN, 00-7057-CIV-JORDAN, slip op. at 1 (S.D. Fla. Mar. 14, 2002) ("Final Judgment"). Because the district court erred in concluding that Elan had offered to sell the patented invention more than one year prior to filing its patent application and that the on-sale bar had accordingly been triggered, we reverse and remand.

BACKGROUND

The sodium salt of (S)-6-methoxy-α-methyl-2-naphthyleneacetic acid, commonly known as "naproxen sodium," is a non-steroidal anti-inflammatory drug sold under various tradenames, including NAPROSYN® and ALEVE®. Syntex Corporation, the manufacturer of NAPROSYN®, owned U.S. Patent 3,998,966, directed to, inter alia,

compositions and methods for treating inflammation, pain, pyrexia, and pruritus in mammals using 6-substituted 2-naphthyleneacetic acid derivatives such as naproxen. In the 1980s, in preparation for the December 21, 1993, expiration of the '966 patent, Elan began development of a controlled-release naproxen formulation for once-daily administration. In a letter dated August 7, 1987, Kenneth E. McVey, Elan's Executive Vice President for Business Planning and Commercial Development, wrote the following to K. Michael Forrest, Vice President of Lederle Laboratories:

> It was a pleasure to meet you and your colleagues on August 5, and I hope you found our discussions on naproxen . . . of interest.
>
> With regard to naproxen, I would like to confirm to you our licensing and development plans for our once daily tablet aimed at a launch in the U.S.A. by the patent expiry date. On product development, we plan to be in a position to file an I.N.D. by early 1988, and believe that we will need a clinical program involving enrollment of 500 patients and running for up to two years to generate the necessary data for N.D.A. filing.
>
> On the licensing side, we are actively seeking a partner and believe Lederle's marketing strengths make you ideal in this respect. Ideally, we want to have our partner determined this year so that they can actively participate in the planning of the clinical studies, even though Elan would remain responsible for conducting them.
>
> As I indicated to you, we see any license as involving two types of payment - a licensing fee in the form of recoverable advance royalties and a charge for the clinical program as patients become enrolled. On the former, the total licensing fee would be $2.75 million dollars, payable:
>
> (i) $500,000 on contract signature,
> (ii) $500,000 on I.N.D. filing,
> (iii) $750,000 on N.D.A. filing, and
> (iv) $1,000,000 on N.D.A. approval,
>
> all recoverable against a 5% running royalty by withholding one-third of each payment due.
>
> On the clinical side, we would ask for a payment of $250,000 upon enrollment of each 50 new patients, up to a maximum of $2.5 million dollars.

> Finally, I would confirm that we would take responsibility for supplying bulk tablets with our objective being to achieve a price structure allowing you an initial gross margin based on current naproxen prices of not less than 70% after taking into account our processing charge (at current exchange rates, around $60/1000 x 500 mg tablets, excluding A.I. cost), A.I. cost, packaging and royalty.
>
> As I mentioned above, we would value having Lederle as a partner in this project, and I look forward to having your decision in this matter and more detailed discussions on the contract in the near future.

Elan Corp. v. Andrx Pharms., Inc., Nos. 98-7164-CIV-JORDAN, 00-7057-CIV-JORDAN, slip op. at 9-10 (S.D. Fla. Mar. 14, 2002) (Findings of Fact). Over the following year, Elan officers sent similar letters to Schering Laboratories, Warner-Lambert, and Wyeth Ayerst Laboratories. Id. at 10-12.

On January 14, 1991, Elan filed a U.S. patent application directed to a controlled-release naproxen formulation, based on an Irish priority application filed on January 15, 1990. Id. at 2. After filing a series of continuation applications from that 1991 application, Elan was issued U.S. Patent 5,637,320 on June 10, 1997. The '320 patent includes one independent claim and sixteen dependent claims. Claim 1 reads as follows:

> 1. A naproxen formulation for once-daily oral administration comprising naproxen in a multi-particulate pellet form, each pellet having a core of naproxen or a pharmaceutically acceptable salt thereof in association with an organic acid, the naproxen or pharmaceutically acceptable salt thereof and the organic acid being present in a ratio of from 20:1 to 1:1, and a multi-layer membrane surrounding said core and containing a pharmaceutically acceptable film-forming, water insoluble polymer and optionally a pharmaceutically acceptable film-forming, water soluble polymer and having a dissolution rate which when measured in vitro in a type 1 dissolution basket apparatus according to U.S. Pharmacopoeia XXI in phosphate buffer at pH 7.2 and at 75 r.p.m. corresponds to the following dissolution pattern:
>
> a) from 0 to 50% of the total naproxen is released after 1 hour of measurement in said apparatus;

b) from 20 to 70% of the total naproxen is released after 2 hours of measurement in said apparatus; and
c) not less than 50% of the total naproxen is released after a total of 4 hours of measurement in said apparatus.

'320 patent, col. 16, l. 59 - col. 17, l. 12.

In 1994, Elan filed a New Drug Application ("NDA") at the Food and Drug Administration ("FDA"), directed to its once-daily formulation. Findings of Fact, slip op. at 2. The FDA approved the NDA on January 5, 1996, and Elan launched the approved formulation under the tradename NAPRELAN® in April 1996.

In 1998, Andrx submitted an Abbreviated New Drug Application ("ANDA") under the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, at the FDA, seeking approval to market its own once-daily naproxen formulation. Elan then sued Andrx for infringement of the '320 patent under 35 U.S.C. § 271(e)(2)(A). Andrx defended by arguing that Elan's patent is invalid under the on-sale bar of § 102(b) as a result of its having offered to supply the patented tablets to Lederle, Warner-Lambert, Schering, and Wyeth, as well as having advertised in a 1988 article ("the SCRIP article") that it had developed a once-daily naproxen formulation.

The district court found that, although Elan's SCRIP article did not start the running of the clock for the on-sale bar, its letter offering to supply tablets to Lederle did do so. The court noted that that letter had included a price term and referred to a proposed contract. The court also concluded that the formulation that Elan had offered to supply to Lederle was "ready for patenting" and was the same composition that was eventually claimed.

Elan now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal, Elan argues that the district court erred by holding the '320 patent invalid under the on-sale bar. According to Elan, the plain language of the letter and the unrebutted testimony of both the letter's author and its recipient establish that the letter was not a definite offer, but merely an initial inquiry into whether Lederle would be interested in further discussions about a potential licensing and development project for a product that had not yet been developed and that could not be marketed until at least six years later. Elan explains that an offer to license an invention is not "an offer for sale" under § 102(b) and that its letter to Lederle lacked the hallmarks of a commercial offer, such as mention of prices, quantities, time and place of delivery, and product specifications. Elan also asserts that the "processing charge" estimate in the Lederle letter was not a "price quote."

Elan further contends that the court made numerous other errors of law, including failing to construe any of the claims of the patent; failing to address the validity of each claim individually; placing the burden on Elan to prove that the letter did not concern subject matter within the scope of the claims, rather than on Andrx to provide clear and convincing evidence that it did; and concluding that the subject matter of each claim of the patent was complete and ready for patenting at the time of the Lederle letter. Indeed, Elan asserts that the 1987 formulation was experimental only and was changed significantly before Elan arrived at the final formulation that it ultimately marketed. Elan also points out that the Lederle letter itself states that Elan was not yet in a position to file an Investigational New Drug ("IND") application in 1987.

Andrx responds by arguing that Elan has mischaracterized the invalidating commercialization of its product as "licensing/developmental use." According to Andrx, Elan's letter to Lederle offered the patented product in bulk at a specified price, and there were at least nine other instances of offers and/or public uses prior to the critical date. Andrx also argues that the district court's decision was firmly based on the applicable case law and correct findings of fact. According to Andrx, Elan's theory that the Lederle letter does not concern the patented product is raised for the first time on appeal and Elan manufactured more than 88 kg of its patented naproxen sodium beads in July 1987.

Andrx also argues, in an improper cross-appeal, that the district court erred by not deciding that the Warner-Lambert agreement also triggered the on-sale bar. That cross-appeal was improper, and is therefore dismissed, because it merely asserted another ground for affirming the same judgment, a matter that an appellee may assert without a cross-appeal. See Bailey v. Dart Container Corp. of Mich., 292 F.3d 1360, 1362 (Fed. Cir. 2002). Additionally, Andrx argues that the district court properly exercised its discretion by not deciding the infringement, validity under § 103, and unenforceability questions in this action, but that answering those questions would have provided alternative grounds for affirmance. Elan responds to Andrx's argument concerning the Warner-Lambert agreement, contending that the district court made no factual findings regarding the content of that agreement that would support appellate review. In any event, Elan argues, that agreement was merely a draft that was subject to negotiation and therefore also did not constitute an offer for sale.

We agree with Elan that the district court incorrectly characterized the Lederle letter as an offer to sell that constituted an on-sale bar. "A person shall be entitled to a patent unless . . . (b) the invention was . . . on sale 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 (2000). Application of the "on-sale bar" to patentability is a matter of law, and we therefore review de novo the district court's ultimate conclusion that the '320 patent is invalid under that bar. Brasseler, U.S.A. L.P. v. Stryker Sales Corp., 182 F.3d 888, 889 (Fed. Cir. 1999). Patents are presumed to be valid, 35 U.S.C. § 282 (2000), and an accused infringer challenging the validity of a patent under the on-sale bar must demonstrate by "clear and convincing evidence that 'there was a definite sale or offer to sell more than one year before the application for the subject patent, and that the subject matter of the sale or offer to sell fully anticipated the claimed invention,'" Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1045-46 (Fed. Cir. 2001) (quoting UMC Elecs. Co. v. United States, 816 F.2d 647, 656 (Fed. Cir. 1987)), or rendered it obvious.

Because Elan's application was filed on January 14, 1991, the critical date for the purpose of § 102(b) is January 14, 1990. In other words, if the once-daily naproxen formulation that is the subject of the '320 patent was on sale in the United States prior to January 14, 1990, that patent should not have been granted and is therefore invalid. Thus, the question before us is whether Elan's letter to Lederle or any of its letters to other potential licensees prior to January 14, 1990, contained "offers for sale."

In Pfaff v. Wells Electronics, Inc., 525 U.S. 55 (1998), the United States Supreme Court explained that "the on-sale bar applies when two conditions are satisfied before

the critical date. First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting." Id. at 67. The latter requirement may be satisfied in at least two ways: "by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." Id. at 67-68.

Following Pfaff, this court held in Group One that "[o]nly an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance . . . , constitutes an offer for sale under § 102(b)." 254 F.3d at 1048. We further explained that "a sale of rights in a patent, as distinct from a sale of the invention itself, is not within the scope of the statute, and thus does not implicate the on-sale bar." Id. at 1049. In In re Kollar, 286 F.3d 1326 (Fed. Cir. 2002), we held that an offer to license a patent claiming an invention after future research and development had occurred, without more, is not an offer to sell the invention. Id. at 1331; see also Mas-Hamilton Group v. LeGard, Inc., 156 F.3d 1206, 1217 (Fed. Cir. 1998) (determining that a patent was not invalid under the on-sale bar because, inter alia, the conveyance of "production rights in the invention" and/or "the exclusive right to market the invention" was not "a sale or an offer to sell the devices themselves"); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1267 (Fed. Cir. 1986) ("[A]n assignment or sale of the rights in the invention and potential patent rights is not a sale of 'the invention' within the meaning of section 102(b).").

Based on the principles articulated in Pfaff, Group One, and Kollar, we conclude that the district court erred in concluding that Elan's product was the subject of a

commercial offer for sale based on Elan's letter to Lederle. An offer to enter into a license under a patent for future sale of the invention covered by the patent when and if it has been developed, which is what the Lederle letter was, is not an offer to sell the patented invention that constitutes an on-sale bar. Kollar, 286 F.3d at 1331. The letter to Lederle is clear on its face that Elan was not offering to sell naproxen tablets to Lederle, but rather granting a license under the patent and offering Lederle the opportunity to become its partner in the clinical testing and eventual marketing of such tablets at some indefinite point in the future. Although no particular language is required to be present in order for an offer of a license to constitute an offer for sale of the licensed product, a communication that fails to constitute a definite offer to sell the product and to include material terms is not an "offer" in the contract sense. Restatement (Second) of Contracts § 33(3) (1981) ("The fact that one or more terms of a proposed bargain are left open or uncertain may show that a manifestation of intention is not intended to be understood as an offer."). The letter to Lederle lacked any mention of quantities, time of delivery, place of delivery, or product specifications beyond the general statement that the potential product would be a 500 mg once-daily tablet containing naproxen. Moreover, the dollar amounts recited in the fourth paragraph of the letter to Lederle are clearly not price terms for the sale of tablets, but rather the amount that Elan was requesting to form and continue a partnership with Lederle. Indeed, the letter explicitly refers to the total as a "licensing fee."

Of course, if Elan had simply disguised a sales price as a licensing fee it would not avoid triggering the on-sale bar. Nonetheless, that is not what Elan did here. If Lederle had accepted Elan's offer, it would have owed Elan $500,000 at contract signing

and additional amounts at various milestones in the collaboration. There is no statement in the letter of how many tablets Elan would supply in exchange for those funds, and there is no suggestion that the number of tablets supplied would depend in any way on those payments (although the payments were to be keyed to the number of patients enrolled in clinical trials per the fifth paragraph of the letter).

The sixth paragraph of the letter refers to a pricing structure for the eventual supplying of bulk tablets to Lederle. The district court read that paragraph to constitute a price term for the sale of the tablets. On closer inspection, however, it is clear that the letter recites no such term. Rather, it simply states that Elan would supply tablets at a price that would enable Lederle to achieve an initial gross profit margin of not less than 70% based on "current naproxen prices," i.e., once Syntex's patent had expired and Lederle could begin selling the tablets. Until the formulation had been finalized and proven to be safe and efficacious for its intended use and Syntex's patent had expired, however, there was no way that it could have been determined what "current naproxen prices" and hence the offering price would be. Furthermore, the cost of the active ingredient, packaging, and processing, as well as the exchange rate, are all factors that would need to be factored into that price term, and it could not have been known in 1988 what those costs would be in 1993. Although the fact that Elan's processing cost excluding the cost of the active ingredient was $60 per thousand tablets at the then-prevailing exchange rate may have given Lederle some guidance as to the order of magnitude of such costs, that information could be of little value without the active ingredient cost.

The remaining agreements in the record—i.e., those between Elan and Schering, Elan and Warner-Lambert, and Elan and Wyeth—are similarly deficient in failing to set out critical terms of any proposed agreement of sale, and we conclude that they likewise do not evidence any offer to sell a once-daily naproxen formulation prior to the critical date.

Because we hold that there was no offer for sale, we need not address Elan's contention that the invention was not "ready for patenting" at the time that Andrx alleged the on-sale clock to have begun ticking, and that the second prong of the Pfaff test was therefore not satisfied. Pfaff, 525 U.S. at 67; Group One, 254 F.3d at 1049. Nor do we need to address the district court's further error in failing to construe each of the claims in the patent in order to determine, claim by claim, which of those claims, if any, would have been barred under § 102(b) had Elan actually offered to sell some portion of the claimed subject matter before the critical date. See Dana Corp. v. Am. Axle & Mfg., Inc., 279 F.3d 1372, 1375 (Fed. Cir. 2002) ("[T]he court erred in invalidating all of the claims without evaluating whether the subjects of the alleged bars met the limitations of those claims. . . . When the asserted basis of invalidity is a public use or on-sale bar, the court should determine 'whether the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention.'" (quoting Scaltech Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1383 (Fed. Cir. 1999))).

CONCLUSION

Accordingly, we reverse the district court's invalidation of the '320 patent under 35 U.S.C. § 102(b). Elan's patent infringement suit is remanded for further proceedings consistent with this opinion. The court's decision is

REVERSED AND REMANDED.

COSTS

Each party to bear its own costs.

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UNITED STATES COURT OF APPEALS
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By: Christy Flemer Date: 5/27/04