United States Court of Appeals for the Federal Circuit

04-1098

CORDIS CORPORATION,

Plaintiff-Appellant,

v.

BOSTON SCIENTIFIC CORPORATION
and SCIMED LIFE SYSTEMS, INC.,

Defendants-Appellees.

DECIDED: May 28, 2004

Before RADER, BRYSON, and GAJARSA, Circuit Judges.

RADER, Circuit Judge.

The United States District Court for the District of Delaware denied Cordis Corp.'s (Cordis's) motion for a preliminary injunction that would have enjoined sales of Boston Scientific Corp.'s (BSC's) drug-eluting stent. Cordis Corp. v. Boston Sci. Corp., Civ. No. 03-027-SLR, 2003 U.S. Dist. LEXIS 21338 (D. Del. Nov. 21, 2003). Because the district court did not abuse its discretion in denying Cordis's motion, this court affirms.

I.

Cordis Corp. owns U.S. Patent No. 4,739,762, which claims a balloon-expandable coronary stent. This court recently considered this patent in Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352 (Fed. Cir. 2003). Three claims of the '762 patent are relevant to this appeal (underlining indicates disputed claim terms):

13. An expandable intraluminal vascular graft, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

14. The expandable intraluminal vascular graft of claim 23, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

A stent framework assists with the immediate opening of a narrowed blood vessel, but that blood vessel may subsequently narrow. That adverse reaction, called restenosis, is caused by an inflammatory response, that is, the growth of scar tissue (smooth muscle cells). The claimed stent may include a drug-eluting feature. The drug-eluting feature applies a drug to the vessel wall to facilitate healing without the growth of smooth muscle cells, thus reducing the probability of restenosis in patients. While not explicitly referenced in the claims, this drug-eluting portion may coat the claimed framework.

BSC's accused devices consist of a bare stent, named "Express," and a drug-eluting stent, named "Taxus." The Express stent serves as the framework for the Taxus stent. At the time the motion for a preliminary injunction was pending before the district court, Cordis was the only FDA-approved manufacturer of a drug-eluting coronary stent. Cordis's product is named "Cypher." Cordis sought to preliminarily enjoin sales of BSC's Taxus stent but not its Express stent. After the district court denied Cordis's motion but before the parties could argue this appeal, the FDA approved Taxus.

In denying Cordis's motion for a preliminary injunction, the district court weighed the standard four factors: reasonable likelihood of success on the merits; irreparable harm to the patentee in the

absence of a preliminary injunction; the balance of the hardships on the patentee and the alleged infringer; and the impact of an injunction on the public interest. At the outset, the district court determined that Cordis would likely succeed on the merits. This court's prior opinion on claim construction in conjunction with expert testimony on infringement suggests that BSC's Taxus stent infringes claim 23 of the '762 patent. Next, the district court determined that a denial would not irreparably harm Cordis. The trial court reasoned that Cordis delayed approximately sixteen months in filing the motion and expressed willingness to accept monetary relief for the Express stent. Moreover, Cordis has licensed the '762 patent to competitors. Finally, Cordis's sales of Cypher would only comprise approximately 5% of Johnson & Johnson's sales (Johnson & Johnson is Cordis's parent company).

Applying the next step of the test for a preliminary injunction, the district court balanced the hardships in favor of BSC. The trial court noted that the injunction would threaten BSC's most important business and affect the worldwide supply of Taxus stents. Finally, the district court reasoned that grant of the injunction would harm the public interest because Cordis cannot ensure an adequate supply of drug-eluting stents. Thus, balancing the first prong favoring Cordis against the other three favoring BSC, the district court declined to grant a preliminary injunction.

II.

This court "review[s] the district court's decision for an abuse of discretion, a lapse that occurs when the decision is premised on an error of law, a clearly erroneous finding of fact, or a clear error of judgment in weighing the factors. To the extent the court's decision depends upon an issue of law, [this court] review[s] that issue de novo." Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed. Cir. 2003) (citation omitted). But "when a preliminary injunction is denied, the movant carries a heavier burden to obtain a reversal." New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882 (Fed. Cir. 1992). "If a preliminary injunction is denied, the absence of an adequate showing with regard to any one of the four factors may be sufficient, given the weight or lack of it discretionarily assigned the other factors by the trial court, to justify the denial." Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed. Cir. 1994).

A. Likelihood of Success on the Merits

BSC argues that its Express stent does not infringe claim 23 of the '762 patent, focusing on three limitations: "wall surface"; "substantially uniform surface"; and "thin-walled." In separate litigation, the district court construed them as follows:

(3) **"Thin-walled."** The wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters.
(4) **"Wall surface."** The outer surface of the tubular member must be disposed in a common cylindrical plane.
(5) **"Substantially uniform thickness."** The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially the same. Variances as little as .001 inches fall outside the scope of "substantially uniform."

Cordis Corp. v. Medtronic AVE, Inc., 194 F. Supp. 2d 323, 332 (D. Del. 2002) (emphasis original). Without discussing the other two claim terms in this appeal, this court revised the construction of "substantially uniform thickness" to mean that "the walls must be of largely or approximately uniform thickness" and that "a wall that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either literally or by equivalents." Cordis, 339 F.3d at 1360, 1362.

With respect to "wall surface," BSC argues that the district court erred because the accused stent does not have at least one elongate member. Claim 23, however, does not recite "at least one elongate member." Moreover, claim differentiation supports not requiring an elongate member; claim 14 expressly recites that limitation. See Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (suggesting "a presumption that each claim in a patent has a different scope"). Accordingly, this court concurs with the district court's conclusion on this preliminary record.

With respect to "substantially uniform thickness," BSC argues that the district court erred because the accused stent has a 100% thickness variation and because Cordis did not show that the accused stent met this limitation. This court, however, concurs with the district court's conclusion on this preliminary record. This court has already rejected the way that BSC would measure the thickness. The shape of the cross-section – that is, ellipto-rectangular as opposed to circular – is not important. See Cordis, 339 F.3d at 1362 (concluding that "a stent formed from struts with circular or ellipto-rectangular cross-sections can have a wall of substantially uniform thickness"). Moreover, the preliminary record

shows that the BSC stent uses a stainless-steel tube having a substantially uniform thickness, which lends support to the notion that the end-product also has a substantially uniform thickness. In sum, Cordis presented sufficient evidence for the district court to conclude, on a preliminary basis, that BSC's Taxus stent likely has a uniform thickness even upon expansion.

With respect to "thin-walled," BSC argues that the previous construction necessarily depends on the context. It further argues that the context is informed by the prosecution history, which supposedly limits "thin-walled" to thicknesses no greater than 0.0045 inches. On this preliminary record, however, this court concurs with the district court's determination. The record includes testimony that other infringing stents had thicknesses greater than 0.0045 inches. Accordingly, none of the district court's conclusions resting on the preliminary construction of claim 23 disclose a reversible error.

This court also considers BSC's validity challenges based on section 112, first paragraph, but agrees with the district court that they are unlikely to succeed.

B. Irreparable Harm

Once a patentee shows a likelihood of success on the merits, this court's law presumes an irreparable harm. See, e.g., Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983). Naturally, however, this presumption is rebuttable. See, e.g., Rosemount, Inc. v. United States Int'l Trade Comm'n, 910 F.2d 819, 821-22 (Fed. Cir. 1990). On appeal, Cordis attacks each part of the district court's rationale for rebutting the presumption. This court holds that the district court did not err in finding BSC adequately rebutted the presumption of irreparable harm.

1. Delay

The district court determined that Cordis delayed filing its motion for injunction relief approximately sixteen months after learning about the Taxus stent. Cordis responds that it sought a preliminary injunction as soon as it became likely that FDA would approve the product. Delay is a factor in evaluating irreparable harm. See, e.g., High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1557 (Fed. Cir. 1995). Thus, the district court did not err in weighing the

delay in its irreparable harm calculus. The trial court also properly considered Cordis's explanation for the delay.

2. Licenses

Cordis argues that its decision to license the '762 patent to competitors, some of whom could make a noninfringing drug-eluting stent, is not relevant to the irreparable harm decision. Cordis contends that the patent owner alone may decide who may make or use the '762 invention. This court, however, has permitted trial courts to weigh licenses as part of the case rebutting the presumption of irreparable harm. See T.J. Smith & Nephew, Ltd. v. Consol. Med. Equip., Inc., 821 F.2d 646, 648 (Fed. Cir. 1987). Indeed, BSC notes that it could transfer its Taxus approval to a licensed competitor, in which case Cordis could not prevent competition. The '762 patent reads on bare metal stents, a market with many noninfringing alternatives. Even though the '762 patent acts as a blocking patent (because a drug-eluting stent necessarily builds on a bare framework of a stent), Cordis would not likely be able to prevent its licensees from entering the market for drug-eluting stents.[1] Accordingly, the district court did not err in considering licenses in rebutting the presumption of irreparable harm.

3. Monetary Relief

The district court determined that Cordis was willing to seek money damages after trial. Before this court, however, Cordis denies willingness to accept monetary damages for the Taxus stent. Cordis contends that it was only willing to accept monetary damages for the Express stent. The record shows the reason for Cordis's contention: With noninfringing alternatives in the market for bare metal stents (some with the armor of licenses granted to Cordis's competitors), Cordis cannot prevent sales of the Express stent. In sum, the availability of monetary damages cannot alone rebut the presumption of irreparable harm, see High Tech Med., 49 F.3d at 1557, but this court detects no reversible error in the district court's consideration of monetary damages in conjunction with other factors that rebutted finding irreparable harm in this case.

4. Percentage of Johnson & Johnson's Sales

Drug-eluting stents constitute a relatively small portion of Johnson & Johnson's overall sales. Cordis correctly notes that this percentage is irrelevant to any irreparable harm Cordis may suffer. Nevertheless, relative market effects may factor into balancing the relative hardships. See, e.g., Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 708 (Fed. Cir. 1997). Because this information is part of the overall injunction calculus, this court does not detect reversible error in the district court's consideration of the proportion of Johnson & Johnson's business that comprises sales of drug-eluting stents relative to the effect on Cordis's business. See Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 981 (Fed. Cir. 1997) (stating that this court "review[s] judgments, not opinions").

C. Balance of the Relative Hardships

Cordis argues that the district court required it, in effect, to prove that the injunction would not impose an irreparable harm on BSC. To the contrary, the district court properly considered the effect that an injunction would have on BSC. Indeed, BSC highlights some of the harms that it would suffer, including the loss of hundreds of jobs, ruination of a core BSC business, and hindrance of development of new medical devices. See, e.g., Litton Sys., Inc. v. Sundstrand Corp., 750 F.2d 952, 959-61 (Fed. Cir. 1984) (finding "that entry of the preliminary injunction . . . would be catastrophic" to the defendant). In light of BSC's plant in Ireland that could produce stents for sale outside the United States, the district court may have erroneously determined that an injunction would damage the extraterritorial supply of Taxus. Nonetheless, the district court did not err overall in considering the harms that an injunction would impose on BSC in balancing the hardships.

D. Public Interest

Cordis argues that the district court factually and legally erred in weighing the public's interest in favor of BSC. Cordis first asserts that it could adequately produce drug-eluting stents to meet market demand, citing testimony that it was taking steps to ensure ability to meet entire market demand. By the same token, the district court was also entitled to credit other testimony that showed Cordis's initial difficulty in meeting demand. Accordingly, the district court did not abuse its discretion in considering whether Cordis could satisfy market demand. See, e.g., E.I. DuPont de Nemours & Co. v. Phillips

Petroleum Co., 835 F.2d 277, 278 (Fed. Cir. 1987).

Cordis also asserts that the public's interest lies in upholding the exclusive rights of a patentee. See Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."); see also Eli Lilly & Co. v. Premo Pharm. Labs., Inc., 630 F.2d 120, 138 (3d Cir. 1980) ("Congress has determined that it is better for the nation in the long-run to afford the inventors of novel, useful, and nonobvious products short-term monopolies on such products than it is to permit free competition in such goods."). While crediting the validity of this point, this court also acknowledges that it cannot control in every case without obliterating the public interest component of the preliminary injunction inquiry. Thus, for good reason, courts have refused to permanently enjoin activities that would injure the public health. See Vitamin Tech., Inc. v. Wis. Alumni Res. Found., 146 F.2d 941, 944 (9th Cir. 1945); City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 593 (7th Cir. 1934).

In this case, a strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either Cordis's Cypher or BSC's Taxus stent. Nevertheless, this court notes that Cypher may have, for example, safety or efficacy concerns beyond those shared by Taxus. See Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1401 (N.D. Cal. 1987), aff'd, 927 F.2d 1565 (Fed. Cir. 1991) (stating that the public would be harmed by an injunction because the accused product had the possibility of eliminating safety risks present in other products). Moreover, the record contains evidence that some doctors prefer the Taxus stent over the Cypher stent. See Datascope Corp. v. Kontron, Inc., 611 F. Supp. 889, 895 (D. Mass. 1985), aff'd, 786 F.2d 398 (Fed. Cir. 1986) (stating that the public would be harmed by an injunction because some physicians prefer the defendant's product). Accordingly, this court holds that the district court did not err in considering the public's interest in the issuance of an injunction.

E. Overall Balancing

Cordis argues that the district court erred in finding that "it would be inequitable to grant such

drastic relief based on patented old technology when it is new unpatented technology driving the business decision to file suit." Cordis, slip op. at 6, 2003 U.S. Dist. LEXIS 21338, at *7. Even if it erred in requiring a nexus between the likely infringement and the claim for irreparable harm (a question this court need not reach), the district court did not abuse its discretion in weighing all the factors and declining to preliminarily enjoin the sales of Taxus.

III.

Because the district court did not abuse its discretion in denying Cordis's motion for a preliminary injunction, this court affirms.

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[1] Cordis did not show that the licenses contain enforceable field-of-use restrictions that would preclude its licensees from entering the drug-eluting stent market.