

United States Court of Appeals for the Federal Circuit

2008-1124

ACUMED LLC,

Plaintiff-Appellee,

v.

STRYKER CORPORATION, STRYKER SALES CORPORATION,
STRYKER ORTHOPAEDICS, and HOWMEDICA OSTEONICS CORPORATION,

Defendants-Appellants.

Gregory J. Vogler, McAndrews, Held & Malloy Ltd., of Chicago, Illinois, argued
for plaintiff-appellee. With him on the brief were Sharon A. Hwang and Dennis H.
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Frederick C. Laney, Niro, Scavone, Haller & Niro, of Chicago, Illinois, argued for
defendants-appellants. With him on the brief were Paul K. Vickrey, Robert A. Vitale, Jr.
and Richard B. Megley, Jr.

Appealed from: United States District Court for the District of Oregon

Judge Anna J. Brown

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Defendants-Appellants.

Appeal from the United States District Court for the District of Oregon
in Case No. 04-CV-513, Judge Anna J. Brown.

DECIDED: December 30, 2008

Before MAYER, LOURIE, and GAJARSA, Circuit Judges.

LOURIE, Circuit Judge.

Stryker Corporation, Stryker Sales Corporation, Stryker Orthopaedics, and Howmedica Osteonic Corporation (collectively, "Stryker") appeal from the decision of the United States District Court for the District of Oregon granting Acumed LLC's motion for a permanent injunction. Acumed LLC v. Stryker Corp., No. 04-CV-513-BR, 2007 U.S. Dist. LEXIS 86866 (D. Or. Nov. 20, 2007) ("Injunction Opinion"). Because we conclude that the district court did not abuse its discretion in granting the motion for a permanent injunction, we affirm.

BACKGROUND

Acumed LLC (“Acumed”) is the assignee of U.S. Patent 5,472,444 (“the ‘444 patent”), which is directed to a proximal humeral nail (“PHN”), a type of orthopedic nail used for the treatment of fractures of the humerus, or the upper arm bone. The PHN is inserted lengthwise into the shaft of a broken humerus, and screws secure the bone fragments to the nail, thus fixing the bone pieces to each other and to the shaft. Acumed sells its PHN under the name Polarus.

In April 2004, Acumed sued Stryker, alleging that Stryker’s T2 PHN infringed the ‘444 patent. On September 20, 2005, a jury found that Stryker had willfully infringed certain valid claims of the patent and awarded damages based on Acumed’s lost profits and a reasonable royalty. During a hearing on February 22, 2006, the district court granted Acumed’s motion for a permanent injunction, applying “the general rule [in patent cases] that an injunction will issue, once infringement and validity have been adjudged . . . unless there are some exceptional circumstances that justify denying injunctive relief.” Transcript of Record at 53, Acumed LLC v. Stryker Corp., No. CV-04-513 (D. Or. Feb. 22, 2006) (quoted in Acumed LLC v. Stryker Corp., 483 F.3d 800, 811 (Fed. Cir. 2007) (“Remand Opinion”)).

While Stryker’s appeal to this court was pending, the Supreme Court decided eBay Inc. v. MercExchange, L.L.C., which held that the traditional four-factor test for permanent injunctions must be faithfully applied in patent cases as in other types of cases. 547 U.S. 388, 394 (2006). Accordingly, on April 12, 2007, we affirmed the district court’s finding of willful infringement, but vacated the permanent injunction (which had been stayed) and remanded the case to the district court for reconsideration

of the four-factor test for injunctive relief in light of eBay. Remand Opinion, 483 F.3d at 811-12.

On June 14, 2007, Acumed accordingly filed a new motion and supporting memorandum in district court for a permanent injunction directed to the T2 PHN. Stryker submitted an opposition memorandum supported by the declarations of five physicians attesting to their use of the T2 PHN. Acumed then submitted a reply memorandum that contained arguments based on previously unsubmitted sales figures and a brochure relating to the Polaris nail. On July 27, 2007, Stryker filed a motion to strike the new arguments and evidence contained in Acumed's reply memorandum.

On November 20, 2007, the district court denied Stryker's motion to strike and granted the permanent injunction. In its opinion, the court noted that Acumed submitted the evidence and arguments at issue in response to Stryker's response, which itself included new affidavits and new citations from the trial transcript. The court also stated that Stryker had sufficient opportunity to rebut Acumed's submissions at oral argument.

The court then applied the four-factor test for injunctive relief in accordance with eBay. First, the court considered the first two prongs of the test together and found that Acumed had established an irreparable injury that had no adequate remedy at law. The court noted that the jury had already found lost profits and sales, and the court diminished the significance of licenses Acumed had previously granted under the '444 patent. The court also found persuasive three cases cited by Acumed in which permanent injunctions based on lost market share were granted. Second, the court concluded that the balance of hardships favored Acumed. The court referred to Acumed's argument about the relative size of the parties, viz., that Acumed is much

smaller and the Polarus is its flagship product. The court also declined to consider Stryker's expenses in developing the T2 PHN as justifying a conclusion that the balance of hardships favored Stryker. The court stated that the fact that Stryker did not offer a straight nail design to avoid infringement (the '444 patent claims curved nails) in the United States was a business decision that did not tip the balance of hardships in Stryker's favor. Finally, the court concluded that there was not sufficient objective evidence of any public health issue in the form of screw back-out problems with the Polarus products such that the public interest would be disserved by a permanent injunction. The court stated that if physicians did not want to use the Polarus nails, other noninfringing alternatives existed. In sum, applying the four-factor test for injunctive relief, the district court concluded that a permanent injunction should issue against the T2 PHN.

Stryker timely appealed the district court's entry of a permanent injunction. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. Permanent Injunction

Following eBay, a patentee must satisfy the well-established four-factor test for injunctive relief before a court may grant a permanent injunction:

- (1) that [the plaintiff] has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

547 U.S. at 391. We review a district court's decision to grant a permanent injunction for abuse of discretion. Id. Abuse of discretion may be found on a showing "that the

court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.” Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1379 (Fed. Cir. 2008) (quotation omitted). Since the district court considered the first two factors, irreparable harm and lack of an adequate remedy at law, in connection with each other, we will address them in the same manner.

1. Irreparable Harm and Lack of Adequate Remedy at Law

Stryker first argues that the district court erred in giving no weight to Acumed’s previous decisions to license the ’444 patent to two large competitors, Smith & Nephew and Zimmer. Stryker asserts that Acumed’s past willingness to grant licenses, especially to settle litigation with Smith & Nephew during which Acumed also pursued a permanent injunction, demonstrates that money damages in the form of a reasonable royalty are an adequate remedy. Stryker argues that the court improperly failed to estop Acumed from arguing that it had not licensed its patent to a direct competitor. Stryker also asserts that the court erred by relying on the analyses of three inapposite district court cases, Tivo Inc. v. Echostar Communications Corp., 446 F. Supp. 2d 664 (E.D. Tex. 2006), Smith & Nephew, Inc. v. Synthes, 466 F. Supp. 2d 978 (W.D. Tenn. 2006), and Visto Corp. v. Seven Networks, Inc., No. 2:03-CV-333-TJW, 2006 WL 3741891 (E.D. Tex. Dec. 19, 2006).

In response, Acumed argues that the amount of weight given to a patentee’s prior willingness to grant licenses is solely within the discretion of the district court. Acumed asserts that it has a legitimate business interest in preventing the irreparable harm that would be caused by Stryker. Acumed argues that the lost profits award by

the jury necessarily means that direct competition existed between Stryker and Acumed, which shows the existence of irreparable harm with no adequate legal remedy. Finally, Acumed argues that whether the court chose to follow the three district court cases, which were on point, was well within the court's discretion.

We agree with Acumed that the district court did not abuse its discretion. The essential attribute of a patent grant is that it provides a right to exclude competitors from infringing the patent. 35 U.S.C. § 154(a)(1) (2000). In view of that right, infringement may cause a patentee irreparable harm not remediable by a reasonable royalty. While the fact that a patentee has previously chosen to license the patent may indicate that a reasonable royalty does compensate for an infringement, that is but one factor for the district court to consider. The fact of the grant of previous licenses, the identity of the past licensees, the experience in the market since the licenses were granted, and the identity of the new infringer all may affect the district court's discretionary decision concerning whether a reasonable royalty from an infringer constitutes damages adequate to compensate for the infringement. The district court here weighed these factors and determined, consistent with eBay, that money damages constituted adequate compensation only for Stryker's past infringement and that no adequate remedy at law existed for Stryker's future infringement. Thus, the district court concluded that an injunction was needed.

Contrary to Stryker's argument that the district court assigned no weight to the two licenses granted by Acumed, the court considered the previous licenses and distinguished them, albeit briefly, from the circumstances of this case. See Injunction Opinion, 2007 U.S. Dist. LEXIS 86866, at *14-*15 ("In addition, Acumed points out it

licensed the '444 Patent to Smith & Nephew as part of the settlement of an action against Smith & Nephew. Also, when Acumed licensed the '444 Patent to Zimmer, it was not a direct competitor of Acumed.”). Absent clear error of judgment, which is not evident here, the weight accorded to the prior licenses falls squarely within the discretion of the court. A plaintiff’s past willingness to license its patent is not sufficient per se to establish lack of irreparable harm if a new infringer were licensed. See eBay, 547 U.S. at 393 (rejecting the district court’s conclusion that “a plaintiff’s willingness to license its patents and its lack of commercial activity in practicing the patents would be sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue”) (quotations omitted); see also Smith & Nephew, 466 F. Supp. 2d at 983 (quoting eBay). Adding a new competitor to the market may create an irreparable harm that the prior licenses did not. In this case, the fact that Acumed licensed the '444 patent under two particular sets of circumstances does not mean that the district court abused its discretion in not holding that Acumed must now grant a further license to Stryker and receive only a royalty as compensation.*

Furthermore, it was not an abuse of discretion for the district court to have declined to distinguish prior cases in the manner desired by Stryker. The district courts in TiVo, Visto, and Smith & Nephew all granted permanent injunctions after the eBay decision, and the court in the instant case discussed and quoted all three at length

* We decline to consider whether it would be appropriate under other circumstances to deny injunctive relief because the patentee had licensed the patented technology to other competitors. We simply note that the district court did not abuse its discretion here when it considered the licenses granted by Acumed along with all the other relevant factors and ultimately concluded that Acumed would suffer irreparable harm from Stryker’s continued infringement with no adequate remedy at law.

when considering Acumed's argument about lost market share causing irreparable injury with no adequate remedy at law. Injunction Opinion, 2007 U.S. Dist. LEXIS 86866, at *9-*15. Stryker argues that Acumed had previously licensed the '444 patent, unlike the patentees in the three prior cases, and that the court abused its discretion by failing to distinguish the instant action for this reason. However, the court clearly did consider Stryker's argument. See Injunction Opinion, 2007 U.S. Dist. LEXIS 86866, at *14 ("In support of their position, Defendants point out that Acumed licensed the '444 Patent to Zimmer and to Smith & Nephew, two of Acumed's competitors."). The court simply did not find this argument persuasive. We see no abuse of discretion, as there was no error of law or clearly erroneous factual finding in the court's treatment of those cases. Thus the court did not abuse its discretion in finding that Acumed suffered irreparable harm from Stryker's infringement with no adequate remedy at law.

2. Balance of Hardships

Stryker next argues that the district court erred in finding that the balance of hardships favored Acumed. Stryker asserts that the court abused its discretion in relying on Acumed's argument that a non-commercial straight nail depicted in a Stryker patent application was an acceptable and available alternative to the T2 PHN. Stryker argues that the court failed to realize that enjoining the manufacture, use, sale, offer for sale, or importation of the T2 PHN would create hardship for Stryker, its customers, and patients. Stryker asserts that Acumed has identified no harm from its other licensing to two larger competitors of similar size to Stryker, and Stryker argues that Acumed would actually benefit from receiving a royalty because many of Stryker's customers would otherwise be inaccessible to Acumed.

Acumed argues that the district court properly weighed the evidence concerning the relative size of the companies and the commercial effect that the injunction would have on the parties when determining the balance of hardships. Acumed points to the fact that Stryker is the world's largest orthopedic implant company with the T2 PHN representing only a small portion of Stryker's sales, whereas the Polarus against which Stryker would compete is one of Acumed's flagship products. Acumed asserts that Stryker has at all times had the option to use its own non-infringing straight nail design, rather than the T2 PHN, and could eliminate any potential hardship on itself by adopting that design.

We agree with Acumed that the district court did not abuse its discretion in determining that the balance of hardships tips in favor of Acumed. As a preliminary matter, the balance considered is only between a plaintiff and a defendant, and thus the effect on customers and patients alleged by Stryker is irrelevant under this prong of the injunction test. See eBay, 547 U.S. at 391 ("[C]onsidering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted."). We also see no abuse of discretion in the court's decision not to consider Stryker's expenses in designing and marketing the T2 PHN, since those expenses related to an infringing product. See Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986) ("One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."); see also Smith & Nephew, 466 F. Supp. 2d at 984 (district court's declining to consider expenses incurred as a consequence of patent infringement). Similarly, we see no abuse of discretion regarding the court's discussion of the straight

nail alternative. The court acknowledged that the straight nail was not presently offered in the United States, but characterized Stryker's decision that it was not "feasible to offer a straight-nail design in the United States" as a business decision that did not "tip the balance of hardships in Defendants' favor." Injunction Opinion, 2007 U.S. Dist. LEXIS 86866, at *17. We do not believe the court erred in considering Stryker's decision on this point, especially since the evidence regarding the medical desirability of a curved nail was equivocal. Accordingly, we see no abuse of discretion in the court's treatment of the balance of hardships between Stryker and Acumed.

3. Public Interest

Finally, Stryker argues that the district court abused its discretion in essentially placing the burden on Stryker, rather than on Acumed, with regard to the public interest factor. Stryker asserts that the public interest is particularly important in this case because, Stryker argues, the T2 PHN is demonstrably safer and superior to the Polarus. Stryker contends that objective evidence, including trial testimony, declarations from surgeons, and studies of the Polarus nail, identifies a screw back-out problem with the Polarus that is only partially remedied by using tension band sutures or screw caps. Stryker also argues that Acumed is estopped from arguing that certain alternatives to the Polarus exist, given Acumed's limited view of the market at trial, and that Acumed failed to demonstrate that the alternatives that are available do not suffer screw back-out.

Acumed argues that the district court did not shift the burden to Stryker but rather weighed the evidence on the screw back-out issue and concluded that Stryker's argument was unsupported. Acumed argues that it admitted at trial that there had been

a screw back-out problem with the Polarus but that the issue has since been minimized by the screw cap and improved design of the Polarus. Acumed also asserts that alternatives to the Polarus were identified in the record.

We agree with Acumed that the district court did not abuse its discretion in concluding that “there is not sufficient objective evidence of any public-health issue in the form of screw back-out problems with the Polarus product to find that public interest would be disserved by a permanent injunction.” Injunction Opinion, 2007 U.S. Dist. LEXIS 86866, at *19-*20. The court did not, as Stryker asserts, shift the burden to Stryker; rather, the court found that Acumed had made “a prima facie showing that their screw works.” Transcript of Hearing at 14, Acumed LLC v. Stryker Corp., No. CV-04-513 (D. Or. Sept. 27, 2007). In its opinion, the court examined the testimony at trial, the five declarations submitted by Stryker from physicians who used the T2 PHN, and a survey cited by Acumed involving the Polarus. In doing so, the court noted that there was “considerable dispute at trial” whether Stryker’s evidence was the product of biased experts. Injunction Opinion, 2007 U.S. Dist. LEXIS 86866, at *19. Again, the weight given to particular evidence falls well within the discretion of the court. Given the court’s review of the evidence presented, the court was within its discretion to conclude that the public interest was not disserved by an injunction.

Furthermore, we do not believe that the district court abused its discretion by assuming that physicians could choose noninfringing alternatives to the Polarus. Stryker concedes that the licensed Zimmer nail and a Synthes nail would still be available alternatives. Because the court did not find Stryker’s public health argument persuasive, it did not have to state explicitly that the available alternatives to the Polarus

also did not suffer from screw back-out problems. To find otherwise would be to require the court to acknowledge the non-existence of a problem of which the court had already found there was insufficient evidence.

For the foregoing reasons, we also find no abuse of discretion regarding the final factor of the injunction test. We acknowledge that in another case, the public interest factor may so strongly weigh against enjoining the infringer that an injunction would be inappropriate. However, this is not such a case. The district court was in the best position to assess the credibility of the witnesses and affiants and to weigh the evidence to determine whether enjoining Stryker would cause a public health problem. On this record, we conclude that the district did not abuse its discretion because it performed the required analysis, and in so doing, committed no legal error and made no clearly erroneous factual findings.

B. Motion to Strike

"A grant or denial of a motion to strike is not an issue unique to patent law, and we therefore apply the law of the regional circuit" in deciding that question. Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1313 (Fed. Cir. 2003). The Ninth Circuit reviews a district court's decision to deny a motion to strike for abuse of discretion. Bliesner v. Commc'n Workers of Am., 464 F.3d 910, 915 (9th Cir. 2006).

Stryker argues that the district court abused its discretion by allowing Acumed to introduce new evidence and arguments in support of its motion for a permanent injunction without giving Stryker a meaningful opportunity to respond. In response, Acumed points out that the new evidence and arguments contained in its reply memorandum were made in response to Stryker's reliance on new evidence and

arguments in its own opposition memorandum. Regardless, Acumed argues, the court made clear that the absence of Acumed's new evidence would not have influenced the decision to grant the permanent injunction.

We agree with Acumed that the district court's denial of Stryker's motion to strike was not an abuse of discretion. Generally speaking, a court should not consider new evidence presented in a reply without giving the other party an opportunity to respond. See Provenz v. Miller, 102 F.3d 1478, 1483 (9th Cir. 1996). Here, however, Acumed was given the opportunity to respond to new evidence submitted by Stryker, but Acumed responded with new arguments and evidence of its own. Although it is true that Stryker was not then given the opportunity to respond on paper, a district court must be allowed to halt the exchange of reply memoranda at some point. Given the discussion of the new arguments and evidence in the context of the discussion on the merits of the permanent injunction, it is clear that the court gave Stryker an opportunity to present its rebuttal arguments to Acumed's new evidence orally. See Transcript of Hearing at 12-13, 30-31, 38-39, Acumed LLC v. Stryker Corp., No. CV-04-513 (D. Or. Sept. 27, 2007). We thus conclude that the court did not abuse its discretion by denying Stryker's motion to strike.

We have considered the other arguments raised by Stryker and find them unconvincing. Ultimately, this was a close case, especially with regard to the irreparable harm and lack of adequate remedy at law prongs of the four-factor test, in view of past licenses having been granted, and the public interest prong, in light of testimony that the accused product was a medically superior one. Nonetheless, the standard of review, viz., abuse of discretion, compels our decision to affirm the district

court.

CONCLUSION

For the foregoing reasons, we affirm the decision of the district court to enter a permanent injunction directed to the T2 PHN.

AFFIRMED