United States Court of Appeals for the Federal Circuit

04-1478, -1496

PHARMACIA CORPORATION, PHARMACIA AB,
PHARMACIA ENTERPRISES S.A., and PHARMACIA & UPJOHN COMPANY,

Plaintiffs-Cross Appellants,

and

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK,

Plaintiff,

v.

PAR PHARMACEUTICAL, INC.,

Defendant-Appellant.

Jack B. Blumenfeld, Morris, Nichols, Arsht & Tunnell, of Wilmington, Delaware, argued for plaintiffs-cross appellants. With him on the brief were Maryellen Noreika, Rodger D. Smith, II, and Leslie A. Polizoti. Of counsel on the brief was Robert D. Rhoad, Dechert LLP, of Princeton, New Jersey.

Glenn J. Pfadenhauer, Williams & Connolly LLP, of Washington, DC, argued for defendant-appellant. With him on the brief were John G. Kester and Jessamyn S. Berniker. Of counsel was Aaron P. Maurer.

Appealed from: United States District Court for the District of New Jersey

Judge Stanley R. Chesler

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PAR PHARMACEUTICAL, INC.,

Defendant-Appellant.

DECIDED: August 10, 2005

Before RADER, SCHALL, and LINN, Circuit Judges.

RADER, Circuit Judge.

Par Pharmaceutical, Inc. (Par) filed Abbreviated New Drug Application (ANDA) No. 76-218, seeking approval to market and sell a generic version of a glaucoma medication called Xalatan. Because the United States District Court for the District of New Jersey did not abuse its discretion in finding only U.S. Patent No. 5,422,368 (the '368 patent) unenforceable due to inequitable conduct, this court affirms.

I.

Glaucoma is a chronic disease manifested by an increased fluid pressure in the eye, known as intraocular pressure. Treatments include topical medications, oral

medications and surgery. Xalatan treats glaucoma by topical application. The United States Food & Drug Administration's (FDA) "Orange Book," a register that provides notice of patents covering name brand drugs, shows that multiple patents cover Xalatan. Two of these patents, U.S. Patent No. 5,296,504 (the '504 patent) and the '368 patent, are collectively owned by Pharmacia Corp., Pharmacia AB, Pharmacia Enterprises S.A. and Pharmacia & Upjohn Co. (Pharmacia).

Under requirements for an ANDA, Par notified Pharmacia on November 6, 2001 of its intent to seek to market a generic version of Xalatan. In response to this notice, Pharmacia filed suit on December 21, 2001 in the U.S. District Court for the District of New Jersey, alleging infringement by virtue of Par's ANDA submission.[1]

At trial, Par admitted infringement of the '368 and '504 patents, and did not assert any invalidity defenses based on prior art or 35 U.S.C. § 112. Instead, Par asserted that inequitable conduct rendered the patents unenforceable. Specifically, Par alleged that the patent applicants issued a declaration and terminal disclaimer during prosecution of the '368 patent with an intent to deceive the Patent Office on a point of material significance. After a bench trial, the district court found only the '368 patent unenforceable due to inequitable conduct. Thus, the '504 patent remained enforceable. Pharmacia Corp. v. Par Pharm., Inc., No. 01-6011 (D.N.J. July 6, 2004) (Final Judgment). As noted, Par had conceded that it infringed the '504 patent. Thus, the district court entered judgment for Pharmacia on the '504 patent and for Par on the '368 patent. Id., slip op. at 59. This appeal followed.

[1] The district court's findings as to improper inventorship and inequitable conduct with respect to U.S. Patent No. 4,599,353 (the '353 patent), owned by the Trustees of Columbia University and licensed to Pharmacia, have not been appealed and thus are not addressed by this opinion.

II.

The ’368 patent and the ’504 patent are siblings, filed simultaneously on December 8, 1992 as continuations of U.S. Patent Application No. 07/469,442 (the ’442 application). During prosecution of the ’368 patent, the U.S. Patent & Trademark Office (PTO) issued an October 21, 1993 Office Action (the Office Action) including two rejections at the heart of the alleged inequitable conduct.

The first rejection involved a prior art rejection under 35 U.S.C. § 103(a). Specifically, the PTO rejected various claims directed at 13,14-dihydro-15-keto-17-phenyl-18,19,20-trinor $PGF_{2\alpha}$ isopropyl ester (the 17-phenyl compound) as being obvious in light of U.S. Patent No. 5,151,444 (the Ueno patent). The Ueno patent disclosed a group of compounds including the 17-phenyl compound. In response to this rejection, Pharmacia argued the Ueno patent preferred 13,14-dihydro-15-keto-20-ethyl $PGF_{2\alpha}$ isopropyl ester (the 20-ethyl compound) and thus failed to appreciate the benefits of phenyl-substituted prostaglandins, such as the claimed 17-phenyl compound. Pharmacia supported its argument with a 37 C.F.R. § 1.132 declaration (the declaration) comparing the 17-phenyl compound to the 20-ethyl compound. This declaration includes inaccurate statements that the district court found highly material.

While the parties dispute the accuracy of several statements in the declaration, paragraphs 9 and 10 are representative:

> 9. Thus at a dose of 5 µg, the 17-phenyl compound shows a statistically significant decrease in [intraocular pressure (IOP)] ($p<0.05$) after 8 hours, while the 20-ethyl compound does not.
>
> 10. Even at dosages of 45 µg, the 20-ethyl compound does not cause statistically significant decrease in IOP.

Paragraph 10 conflicts with an article co-authored by the declarant, Dr. Stjernschantz. In fact, paragraph 10 also conflicts with two Japanese articles cited in that Stjernschantz article. The Stjernschantz article, co-authored with Bahram Resul, carries the title *Structure-Activity Relationships of Prostaglandin Analogues as Ocular Hypotensive Agents*, Current Opinion in Therapeutic Patents, and appeared in June 1993 (the Stjernschantz article). Citing two Japanese articles for authority, the Stjernschantz article states (emphasis added) that "[t]opical application of [45 µg of the 20-ethyl compound] causes a statistically significant IOP reduction without appreciable ocular side-effects." In contrast, the declaration states that the 20-ethyl compound does not cause a statistically significant decrease in IOP at 45 µg. The patent applicants did not bring either the Stjernschantz article or the two Japanese articles to the attention of the PTO.

Pharmacia acknowledges the inconsistency in paragraph 10, but argues that Stjernschantz, because he was a foreign national, simply used the wrong verb tense in saying that the 20-ethyl compound "does not" reduce IOP. According to Pharmacia, replacing "does not" with "did not" would limit this statement to only those tests actually conducted by Stjernschantz, rather than including conflicting tests by other researchers. The district court rejected this explanation.

In addition, paragraph 9 in the declaration states that the 17-phenyl compound shows a particular result after 8 hours. Beyond that the paragraph adds that, at a dose of 5 µg, the 20-ethyl compound does not show a statistically significant decrease in IOP ($p<0.5$) in the same time period. Despite the implicit suggestion in this language, Stjernschantz never tested a 5 µg dose of the 20-ethyl compound.

Once again Pharmacia has an explanation. Pharmacia points out that the declaration focused on showing that the claimed 17-phenyl compound was more potent than the 20-ethyl compound. Because a much larger dose, 45 µg of the 20-ethyl compound, produced a smaller decrease in IOP than 5 µg of the 17-phenyl compound, Stjernschantz had good reason to believe that the 17-phenyl compound was more potent than the prior art 20-ethyl compound at 5 µg as well. Indeed evidence presented at trial confirms this common sense proposition. Nonetheless, the district court rejected this explanation because the declaration suggests that Stjernschantz conducted a test (on a 5 µg dose of 20-ethyl compound) that he in fact never conducted.

Based on the conflict between the declaration in paragraph 10 and prior Stjernschantz article, the district court found that Stjernschantz submitted a declaration to the PTO that he knew or should have known was inaccurate and misleading. The district court held that this misleading declaration was crucial to overcoming the PTO's rejection over the Ueno patent and thus highly material. Based on these circumstances, the district court inferred intent. Having found Stjernschantz intentionally filed a misleading and highly material declaration, the district court found clear and convincing evidence that the '368 patent was unenforceable due to inequitable conduct. Final Judgment, slip op. at 1.

Par also asserted this inequitable conduct tainted the '504 patent as well as the '368 patent. The second rejection in the Office Action discussed above forms the basis of Par's inequitable conduct theory on the '504 patent. Specifically, the second rejection involved an obviousness-type double patenting rejection in view of co-pending application 987,520 (which eventually matured into the '504 patent) and co-pending

application 988,389 (which eventually matured into U.S. Patent No. 5,321,128). To overcome this rejection, Pharmacia filed terminal disclaimers on these two applications. According to Par, these terminal disclaimers effectively combine the '368 patent and the '504 patent. Under this theory, the inequitable conduct on the '368 patent applies automatically to the '504 patent as well. The district court rejected this argument, finding instead that "any conduct occurring in connection with the '368 patent cannot reach the '504 patent." Final Judgment, slip op. at 55.

Par appealed the district court's findings on the '504 patent and Pharmacia appealed the district court's findings on the '368 patent. This court consolidated the appeals. This court has jurisdiction under 28 U.S.C. § 1295(a)(1) (1994).

II

"[I]nequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). This court reviews a determination of inequitable conduct for abuse of discretion and reviews the underlying factual issues of materiality and intent for clear error. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003). "A district court abuses its discretion when its decision is based on clearly erroneous findings of fact, is based on erroneous interpretations of the law, or is clearly unreasonable, arbitrary or fanciful." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc).

A.

Turning first to the '368 patent, the district court did not commit clear error in determining the underlying factual issues of materiality and intent. Paragraph 10 conflicts with the prior Stjernschantz article and supporting Japanese articles, which were never disclosed to the PTO. On the point of materiality, the applicants submitted these statements in support of patentability over the sole prior art reference relied upon by the Examiner. Thus these misleading declarations go to the very point of novelty. The district court properly found paragraph 10 highly material. 37 C.F.R. § 1.56(b) (2004); see Bruno Indep. Living Aids, Inc. v. Acorn Mobility Serv., Ltd., 394 F.3d 1348, 1352-53 (Fed. Cir. 2005) (applying the PTO's Rule 56(b) to determine materiality).

Contrary to Pharmacia's assertion against materiality, the record does not show that the Examiner consulted only the arguments in the April 20, 1994 response or looked only to the "potency" discussion in the declaration. The Notice of Allowance did not contain any explanation that the Examiner thus limited his inquiry. In sum, paragraph 10 is, as the district court correctly found, highly material.

Given the highly material nature of these misleading statements and the failure to submit a directly conflicting article co-authored by the declarant himself, the district court did not clearly err in inferring an intent to deceive. Molins PLC, 48 F.3d at 1180 ("Intent need not be proven by direct evidence."). The district court's analysis and conclusions were well reasoned, supported by the evidence, and certainly do not constitute clear error. Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1375 (Fed. Cir. 2000) ("Proof of high materiality and that the applicant knew or should have known of that materiality makes it difficult to show good faith to

overcome an inference of intent to mislead."); Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997) ("The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa."). Thus, the district court acted within its discretion in finding the '368 patent unenforceable due to inequitable conduct stemming from the misleading nature of paragraph 10 in the declaration. As such, this court need not reach the issue of whether paragraph 9 in the declaration also supports the district court's findings.

B.

Because the district court acted within its discretion in finding the '368 patent unenforceable due to inequitable conduct, this court also must address the district court's finding that the terminal disclaimer was not, without more, sufficient to render the '504 patent unenforceable as well. Par has not asserted on appeal that the '504 patent is unenforceable under a general unclean hands theory; i.e., that a broad pattern of inequitable conduct transfers inequitable conduct from one patent to another. See Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 812 (Fed. Cir. 1990) (discussing an unclean hands theory arising from actions that occurred during prosecution before the PTO). Instead, Par asserts that a terminal disclaimer can bind two related patents together so that inequitable conduct in procuring a later prosecuted patent will automatically infect an earlier issued patent. The district court correctly rejected that assertion.

Indeed "[a] terminal disclaimer ties the affected patents together; they expire on the same date and are enforceable only during periods in which they are owned by the

same person." Donald S. Chisum, Chisum on Patents, § 9.04[5] at 9-107 (2003); see In re Van Ornum, 686 F.2d 937 (CCPA 1982) (upholding the PTO's non-alienation requirement). Strong policies dictated the judicial creation of this doctrine governing the co-expiration and co-ownership of sufficiently related patents. In re Griswold, 365 F.2d 834 (CCPA 1966) (noting the co-ownership requirement is a creative solution to potential harassment suits from two separate patents); Ortho Pharm. Corp. v. Smith, 959 F.2d 936 (Fed. Cir. 1992) (discussing the requirement that a patentee disclaim any extension of patent protection for the later filed application of two terminally disclaimed applications). Beyond their shared expiration date, however, two disclaimed patents maintain significant attributes of individuality. Ortho Pharm. Corp. v. Smith, 18 U.S.P.Q.2d 1977, 1990-91 (E.D.Pa. 1990), aff'd 959 F.2d 936 (Fed. Cir. 1992) (noting patents tied by a terminal disclaimer are still independently presumed valid). For example, Pharmacia pays two sets of maintenance fees – one for each of the '368 and '504 patents. If Pharmacia does not pay the maintenance fee on one of the patents, that oversight would have no effect on the validity or enforceability of the other patent. This individuality between terminally disclaimed patents indicates something more than a naked terminal disclaimer is required.

The specific terminal disclaimer in this case illustrates that the two patents retain individual attributes. The language of the terminal disclaimer in this case emphasizes that validity doctrines will apply separately to the two patents that share an expiration date (emphasis added):

> In making the above disclaimer, petitioner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent as presently [shortened] by any terminal

> disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer.

This language shows that the patentee justifiably expected individual treatment of the patents beyond their shared expiration date.

The case law of this court does not disturb that justifiable expectation. This court has held that a finding of inequitable conduct in the acquisition of even a single claim of a patent renders the remaining claims of that patent unenforceable, even those without the taint of inequitable conduct. See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc in pertinent part) ("When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable."); Hewlett-Packard Co. v. Baush & Lomb Inc., 882 F.2d 1556, 1563 (Fed. Cir. 1989) (inequitable conduct that occurs during prosecution of a reissue application renders all the claims of the reissued patent, including the original claims, unenforceable). This case law, however, applies only to claims in one patent. Even Hewlett-Packard, which Par argued involves two patents (i.e., an original patent and a reissue patent), rendered only the claims in the single reissue patent invalid for inequitable conduct. Hewlett Packard voluntarily surrendered the original patent in order to enter reissue proceedings. Hewlett-Packard, 882 F.2d at 1564 (discussing the surrender of an original patent to initiate reissue proceedings); see also 37 C.F.R. § 1.178(a) (2004) (requiring an offer to surrender the original patent or statement that the original is lost or inaccessible to initiate reissue proceedings). Thus, this court's

inequitable conduct cases do not extend inequitable conduct in one patent to another patent that was not acquired through culpable conduct. In other words, these cases simply do not apply to the facts of this case, which involves two separate patents.

The district court correctly concluded that the terminal disclaimer alone did not bind the ’368 patent and the ’504 patent together for purposes of unenforceability due to inequitable conduct. Because the record shows no inequitable conduct during prosecution of the ’504 patent itself, the district court did not abuse its discretion in finding the ’504 patent to be valid and enforceable. In fact, the ’504 patent had already issued before the inequitable conduct occurred. The ’504 patent issued on March 22, 1994; Stjernschantz executed his declaration on April 20, 1994. Thus, this court affirms the district court’s decision.

III

In sum, this court affirms the district court’s finding that the ’368 patent is unenforceable due to inequitable conduct. This court also affirms the district court’s finding that the ’504 patent is enforceable and infringed by Par.

COSTS

Each party shall bear its own costs.

AFFIRMED