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United States Court of Appeals for the Federal Circuit

04-1194

BAYER AG and BAYER CORPORATION,

Plaintiffs-Appellees,

v.

HOUSEY PHARMACEUTICALS, INC.,

Defendant-Appellant.

DECIDED: April 4, 2005

Before CLEVENGER, RADER, and BRYSON, Circuit Judges.

RADER, Circuit Judge.

The United States District Court for the District of Delaware found U.S. Patent Nos. 4,980,281 (issued Dec. 25, 1990) (the '281 patent), 5,266,464 (issued Nov. 30, 1993) (the '464 patent), 5,688,655 (issued Nov. 18, 1997) (the '655 patent), and 5,877,007 (issued March 2, 1999) (the '007 patent) (collectively, the Housey patents) unenforceable due to inequitable conduct. Bayer AG v. Housey Pharm., Inc., Civ. No. 01-148-SLR, 2003 U.S. Dist. LEXIS 22411 (D. Del. Dec. 4, 2003). Because the district court clearly erred in making the factual findings underlying its determination, this court vacates and remands.

I.

Dr. Gerard M. Housey is the named inventor of the Housey patents. Dr. Housey's patents claim research methods used by pharmaceutical companies for discovering drugs. All of the Housey patents trace their priority to the application that matured into the '281 patent. The '281 patent claims a process for determining whether a chemical inhibits or activates the production of a protein of interest within a cell. '281 patent, col. 24, l. 45 – col. 26, l. 36. The claimed invention tests the cancer-fighting potential of new drugs. After the '281 patent issued, Dr. Housey assigned his patent rights to Housey Pharmaceuticals, Inc. (Housey).

On March 6, 2001, a group of plaintiffs, including Bayer AG and Bayer Corp. (collectively Bayer), sued Housey in the United States District Court for the District of Delaware. Bayer sought declaratory judgments of invalidity, noninfringement, and unenforceability due to inequitable conduct with regard to the Housey patents. On November 12, 2002, the district court issued a claim-construction ruling on the disputed terms in the '281 patent. This ruling was not favorable to Housey. At that point, Bayer entered into a stipulation with Housey, agreeing that if the district court's claim construction was upheld on appeal, Housey would not appeal a finding by the district court that the Housey patents were invalid and not infringed. The district court then entered a final judgment of invalidity and noninfringement for all of the Housey patents. Housey then appealed three of the district court's five claim construction holdings to the United States Court of Appeals for the Federal Circuit. On May 7, 2004, this court upheld one of the district court's claim constructions, which rendered the '281 patent

invalid and not infringed. Housey Pharm., Inc. v. Astrazeneca, UK, Ltd., 366 F.3d 1348 (Fed. Cir. 2004).

Meanwhile, Bayer continued to pursue its claim that the '281 patent was unenforceable due to inequitable conduct. The application that matured into the '281 patent contained the results of several experiments demonstrating the performance of aspects of the claimed process. See '464 patent, col. 26, ll. 1-35. One of these examples, reported in Table 3 of the application (the soft-agar experiment), illustrated the use of the claimed process to demonstrate the cancer-inhibiting effects of two known cancer-inhibiting chemicals on cells grown in soft-agar. Id. The results of the soft-agar experiment were key to the issuance of the '281 patent because it was the only demonstration in the application that the process worked for inhibitors of cell activity. Dr. Housey specifically relied on the data presented in Table 3 to overcome some of the patent examiner's objections to patentability.

The district court held that Dr. Housey fabricated the experimental results of the soft-agar experiment, based on several subsidiary findings. Bayer AG, 2003 U.S. Dist. LEXIS 22411, at *47. First, the district court found that an article written by Dr. Housey and others, Gerard M. Housey et al., Overproduction of Protein Kinase C Causes Disordered Growth Control in Rat Fibroblasts, 52 Cell 343 (1988) (Cell Paper), disclosed much of the framework of the claimed invention. Id. at *10. Second, the district court found that this 1988 paper published all of the experimental evidence reported in Dr. Housey's patent application, except for the results of the soft-agar experiment. Id. at *17. Third, the district court found that some of the experimental results in the patent application were identical to experimental results credited to Dr.

Housey's colleagues in the paper, yet Dr. Housey did not credit his colleagues' contributions in his patent application. Id. at *19.

The district court also found it relevant that none of Dr. Housey's colleagues from the Weinstein lab remembered seeing Dr. Housey working on the soft-agar experiment. Id. at *20-24. The district court found that it was unlikely that Dr. Housey could have performed the soft-agar experiment without his co-workers' knowledge, because the Weinstein laboratory had only two rooms, where twelve to fifteen scientists shared chemicals, work space, and a single cell incubator. Id. The district court found the lack of his colleagues' recollection of the soft-agar experiment even more striking because Dr. Housey claims he used 24-well cell culture plates when the Weinstein lab used only single-well culture plates at that time. Id. Finally, the district court found it suspicious that Dr. Housey's laboratory notebooks contained no record of the soft-agar experiment; on other projects Dr. Housey kept meticulous notes. Id.

The district court found Dr. Housey's testimony with regard to the soft-agar experiment not credible. This credibility finding, in turn, was dispositive of the issue of whether he performed the experiment. Id. at *47.

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). These elements must be shown with clear and convincing evidence. Id. The district court properly applied the pre-1992 standard for materiality, because three of the four patents were still pending when 37 C.F.R. § 1.56 (1992) was adopted.

Under the pre-1992 standard, information is material if “there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” See Molins, 48 F.3d at 1179 n.8. 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).

The district court concluded that Dr. Housey committed inequitable conduct before the United States Patent and Trademark Office (PTO). Bayer AG, 2003 U.S. Dist. LEXIS 22411, at *46-48. The district court found Dr. Housey’s testimony not credible because he actively concealed his work from his colleagues, failed to provide clear acknowledgement of his colleagues’ contributions, and knowingly withheld material prior art. Id. at *47. Because these findings reflect clear error, this court vacates and remands to provide the district court an opportunity to present additional bases for its determination.

Secretive acts have sound basis in patent law. 35 U.S.C. § 102(a) states:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

35 U.S.C. § 102(a) (2004) (emphasis added). An invention may be “known or used” in the event of public disclosure without a deliberate attempt to maintain confidentiality. See W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1549 (Fed. Cir. 1983); see also MPEP § 2132 (8th ed., rev. 2 2001). Very little use and publicity may constitute a public use. See Donald S. Chisum, Chisum on Patents, § 6.02[5] at 6-41 (2003). For

example, in Egbert v. Lippmann, 104 U.S. 333, 336 (1881), the Supreme Court said that “one well-defined case of [public use] is just as effectual to annul the patent as many.” In addition, public use or knowledge may jeopardize some foreign rights. See Rambus Inc. v. Infineon Technologies AG, 318 F.3d 1081, 1102 n.9 (Fed. Cir. 2003). Because patent law acknowledges the necessity of secretive activity before filing a patent application, the district court erred in considering Dr. Housey’s secretive acts as evidence of inequitable conduct.

The district court also erred in finding that the Weinstein laboratory only had one incubator and did not use multi-well plates. Bayer AG, 2003 U.S. Dist. LEXIS 22411, at *20-21. The passages the district court cites in support of its one-incubator finding offer no support. Id. The first passage expressly uses the plural term “incubators.” The second passage says nothing that relates to the one-incubator finding and the third passage says only that Dr. Johnson used “an incubator” for certain experiments. It says nothing about whether or not there was only one incubator in the Weinstein laboratory.

With respect to the multi-well plates finding, Dr. Guadagno testified that the Weinstein laboratory scientists used “six-well” dishes.” In addition, the lab notebooks of Dr. Krauss, Dr. Housey, and Dr. Ueffing indicate the use of multi-well plates. Thus, the record shows that the district court erroneously concluded that no scientist at the Weinstein laboratory used multi-well plates.

The district court also erred in determining that Dr. Housey did not acknowledge the contributions of his colleagues. Two of the district court’s findings reveal this error. First, the district court found that “Dr. Housey did not believe the Cell Paper taught the invention as Dr. Housey understood it.” Bayer AG, 2003 U.S. Dist. LEXIS 22411, at

*16. Second, Drs. Weinstein and Hsiao conceded that they were not co-inventors of the invention as Dr. Housey understood it (i.e., disclosing a method for identifying substances which directly bind or interact with a specific protein). Id. at 32-33. Thus, because the inventor did not consider the 1988 paper material to his invention and the purported co-inventors disclaimed any inventorship, the record does not support the district court's inference of dishonesty in failing to acknowledge inventorship.

In addition, the district court erred in finding that Dr. Housey knowingly withheld the material prior art references referred to as Hsiao 1986 and Uehara 1985. Id. at *26, 30, 47. The district court itself found that Dr. Housey did not believe that these references were material. Id. at *26. Moreover the district court also found that Dr. Housey disclosed these references in the '281 patent's specification. Id. at *30. The Background of the Invention section lists the Uehara 1985 reference as prior art, '281 patent, col. 2, ll. 12-27, and the References section also lists it, id. at col. 24, ll. 7-13. Similarly, the Detailed Description of the Invention section mentions the Hsiao 1986 reference, id. at col. 5, l. 58, and the References section also lists it, id. at col. 22, ll. 16-19. Thus, Dr. Housey did not knowingly withhold the Uehara 1985 and Hsiao 1986 references from the PTO. He clearly disclosed them by including them in the '281 patent's specification.

In sum, upon review of the district court's reasons for finding inequitable conduct, this court holds that the reasons given by the district court for finding Dr. Housey's testimony not credible were insufficient to support the court's conclusion. The district court based its conclusion on findings that Dr. Housey actively concealed work from his colleagues, failed to provide clear acknowledgement of his colleagues' contributions,

and knowingly withheld material prior art. Id. at *47. The record does not supply adequate support for these findings. As a result, this court vacates and remands for the district court to present additional bases for its credibility determination.

The purpose of the remand is not to open the record for further evidence or to allow further argument by the parties. Here, if one is to believe Housey, then the grounds asserted by Bayer for material misrepresentation by Housey to the PTO, with the requisite intent to deceive, dissolve. The reasons stated by the district court for its disbelief of Housey do not alone support this result. From the somewhat cursory explanation of its reasons by the district court, this court is unable to discern whether the district court fully elaborated its grounds for finding Housey incredible. The purpose of the remand is simply to permit the district court to provide any further reason it may have to find Housey incredible.

Housey also appeals the district court's claim construction. However, because this court construed the claims and affirmed the district court's judgment of invalidity in Housey Pharms., Inc. v. AstraZeneca UK, Ltd., 366 F.3d 1348 (Fed. Cir. 2004), this court lacks jurisdiction to address this issue. Mendenhall v. Barber-Greene Co., 26 F.3d 1573, 1577-78 (Fed. Cir. 1994); Blonder Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 349-50 (1971) (an invalidity judgment renders the patent invalid in all later actions).

III.

In conclusion, because the district court clearly erred in making the factual findings that support its credibility determination, this court vacates and remands.