

Bayer v. Carlsbad Opinion

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

02-1077

BAYER AG and BAYER CORPORATION,

Plaintiffs-Appellees,

v.

CARLSBAD TECHNOLOGY, INC.,

Defendant-Appellant.

Fred H. Bartlit, Jr., Bartlit Beck Herman Palenchar & Scott, of Chicago, Illinois, argued for plaintiffs-appellees. With him on the brief were Mark L. Levine and Sean W. Gallagher. Of counsel on the brief were Charles W. Bradley and Stanley L. Amberg, Orrick, Herrington & Sutcliffe LLP, of New York, New York. Also of counsel on the brief were Bruce R. Genderson, Margaret A. Keeley, and Aaron P. Maurer, Williams & Connolly LLP, of Washington, DC.

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

Senior Judge Rudi M. Brewster

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Defendant-Appellant.

_____ DECIDED: August 14, 2002

Before RADER, GAJARSA, and PROST, Circuit Judges.

RADER, Circuit Judge.

On summary judgment, the United States District Court for the Southern District of California held that the expiration date of U.S. Patent No. 4,670,444 (the '444 patent) is December 9, 2003. Because the district court correctly concluded as a matter of law that the disclaimed term of the '444 patent was "due to" U.S. Patent No. 4,544,658, whose expiration date the Uruguay Round Agreements Act (URAA) amendments automatically changed from October 1, 2002 to December 9, 2003, this court affirms.

I.

Bayer AG and Bayer Corporation (collectively Bayer) filed a patent application on May 29, 1984 that ultimately issued as the '444 patent on June 2, 1987. The subject matter of the '444 patent includes the antibiotic ciprofloxacin sold by Bayer under the brand name CIPRO®. Bayer also obtained two related patents covering ciprofloxacin: U.S. Patent No. 4,544,658 issued on October 1, 1985 (the Peterson '658 patent) and U.S. Patent No. 4,556,658 issued on December 3, 1985 (the Grohe '658 patent).

In December 1991, Barr Laboratories, Inc. (Barr) notified Bayer of Barr's Abbreviated New Drug Application (ANDA) submission to the Food and Drug Administration (FDA). Barr alleged that the '444 patent was invalid and unenforceable due to obviousness, obviousness-type double patenting, and inequitable conduct. In response, Bayer filed an infringement suit against Barr in the United States District Court for the Southern District of New York. To counter Barr's allegation of double patenting of the '444 patent over the two '658 patents, Bayer filed a terminal disclaimer with the United States Patent and Trademark Office (PTO). Bayer AG v. Barr Lab., Inc., 798 F. Supp. 196, 24 USPQ2d 1864 (S.D.N.Y. 1992).

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On February 21, 1992, Bayer disclaimed “the terminal part of U.S. Patent No. 4,670,444 which extends beyond October 01, 2002, the earlier of the expiration dates of U.S. Patent Nos. 4,544,658 (issued October 01, 1985) and 4,556,658 (issued December 03, 1985).” Terminal Disclaimer filed February 21, 1992 (Terminal Disclaimer). This disclaimer language is the source of the present dispute. The April 21, 1992, issue of the PTO’s Official Gazette carried a notice of the disclaimer stating: “The term of this patent subsequent to October 1, 2002, has been disclaimed.”

In 1994, the URAA “harmonize[d] the term provision of United States patent law with that of our leading trading partners which grant a patent term of 20 years from the date of filing of the patent application.” Merck & Co. v. Kessler, 80 F.3d 1543, 1547, 38 USPQ2d 1347, 1349 (Fed. Cir. 1996). The URAA took effect on June 8, 1995, changing the patent term from seventeen years from the date of issuance to twenty years from the date of filing of the patent application. 35 U.S.C. § 154(a)(2) (2000). In addition, § 154(c)(1) allows “the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.” Id. § 154(c)(1). Consequently, the expiration date of the Peterson ‘658 patent changed from October 1, 2002 (seventeen years from grant) to December 9, 2003 (twenty years from filing of application) by operation of law.

On July 10, 1995, Bayer sought to reflect the change that the URAA made on the term of the ‘444 patent by submitting an “amended terminal disclaimer” and a “communication submitting amended terminal disclaimer.” Bayer requested the PTO amend the terminal disclaimer filed February 21, 1992 with new wording that “disclaims the terminal part . . . which would extend beyond the earlier of the expiration dates of the full statutory term . . . of U.S. Patent Nos. 4,544,658 . . . and 4,556,658” or, alternatively, to consider the communication a petition. The amended terminal disclaimer did not recite a specific date, but only referred to the expiration dates of the two ‘658 patents.

In view of the URAA, the PTO found Bayer’s original disclaimer ambiguous in that “it sets forth two (2) dates beyond which the terminal part of the [‘444 patent] is disclaimed: October 1, 2002, and December 9, 2003.” Decision on petition, Application No. 06/614,923, at 5 (Jan. 31, 1996) (Decision). The PTO responded that its rules of practice did not permit withdrawal of a terminal disclaimer in favor of an amended terminal disclaimer. Nonetheless, in considering Bayer’s request as a petition under its discretionary authority,^{*} the PTO stated:

In view of the ambiguity in the terminal disclaimer filed February 21, 1992 created by the changes to 35 U.S.C. § 154(c)(1) contained in Public Law 103-465, Office records will be changed to indicate that the term of the above-identified patent subsequent to December 9, 2003, the later of the two (2) dates set forth in the terminal disclaimer filed on February 21, 1992, has been disclaimed.

Id.

In April 2001, Carlsbad Technology, Inc. (CTI) notified Bayer of its ANDA on ciprofloxacin. Bayer filed suit in the district court in May 2001, asserting that the ‘444 patent on ciprofloxacin was valid until December 9, 2003. CTI counterclaimed that the ciprofloxacin claims in the ‘444 patent expire on October 1, 2002. The parties dispute whether the inclusion of the “October 01, 2002” date in the February 21, 1992 terminal

disclaimer created an ambiguity as to the relationship between the '444 patent and the two '658 patents. Bayer and CTI cross-moved for summary judgment. The district court denied CTI's motion and granted summary judgment in favor of Bayer. Bayer AG v. Carlsbad Tech., Inc., Civ. No. 01-867-B (LSP), slip op. at 11 (S.D. Cal. Nov. 1, 2001) (Summary Judgment). CTI timely appealed to this court, which has jurisdiction under 28 U.S.C. §1295(a)(1).

II.

This court reviews a district court's grant of summary judgment without deference. Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353, 47 USPQ2d 1705, 1713 (Fed. Cir. 1998). This court must decide "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In making this determination, this court views the record in a light most favorable to the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986); C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 672-73, 15 USPQ2d 1540, 1542-43 (Fed. Cir. 1990).

CTI does not dispute the facts of this case. Rather, it challenges the district court's application of the URAA to Bayer's original terminal disclaimer which upheld the PTO's determination that the '444 patent expires on December 9, 2003. CTI asserts that the 1992 disclaimer clearly and unambiguously fixed the '444 patent's expiration date to October 1, 2002. CTI notes that the PTO published the October 2002 date in the Gazette, indicating that the disclaimer set the expiration date for October 1, 2002.

Title 35 of the United States Code as amended in light of the URAA, states:

(a)(2) Term. Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

....

(c)(1) Determination. The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

35 U.S.C. §§ 154 (a)(2) and (c)(1). In response to public comments on its rules to implement the new twenty-year term, the PTO stated:

A patent that is in force on June 8, 1995, or a patent that issues after June 8, 1995, on an application filed before June 8, 1995, is automatically entitled to the longer of the 20-year patent term measured from the earliest U.S. effective filing date or 17 years from grant. This is automatic by operation of law. Patentees need not make

any election to be entitled to the longer term.

Changes to Implement 20-year Patent Term and Provisional Applications, 60 Fed. Reg. 20,195, 20,207 (April 25, 1995) (emphasis added).

In the present case, Bayer's February 21, 1992 terminal disclaimer recites in pertinent part:

Bayer . . . disclaims the terminal part of U.S. Patent No. 4,670,444 which extends beyond October 01, 2002, the earlier of the expiration dates of U.S. Patent Nos. 4,544,658 (issued October 01, 1985) and 4,556,658 (issued December 03, 1985), and hereby agrees that U.S. Patent No. 4,670,444 shall be enforceable only for and during such period that legal title to U.S. Patent No. 4,670,444 shall be the same as legal title to U.S. Patent Nos. 4,544,658 and 4,556,658 .

(Emphases added.) This disclaimer expressly sets the expiration date of the '444 patent at the "earlier of the expiration dates" of the two '658 patents. Before the URAA amendments took effect on June 8, 1995, the earlier of the expiration dates of the two '658 patents was October 1, 2002, i.e., seventeen years from date of issuance of the Peterson '658 patent. Hence, when filed in 1992, the language of the terminal disclaimer set the expiration date for the '444 patent for October 2002.

When the URAA amendments took effect on June 8, 1995, however, the earlier of the two expiration dates became December 9, 2003, i.e., twenty years from the date of filing of the Peterson '658 patent. 35 U.S.C. § 154(a)(2). This extension of patent term on the Peterson '658 patent was "automatic by operation of law." 60 Fed. Reg. at 20,207. Consequently, the terminal disclaimer of the '444 patent, as tied to the Peterson '658 patent, moved the expiration date of the '444 patent automatically to December 9, 2003. The disclaimer also mentioned the October 2002 date. In that situation, the PTO detected an ambiguity because the disclaimer now contained two dates: October 1, 2002 and December 9, 2003. The district court correctly relied on the PTO's analysis of the law and of the language of the original terminal disclaimer.

Although finding that the URAA amendments created an ambiguity in Bayer's original terminal disclaimer, the PTO declined Bayer's request to withdraw the original disclaimer and substitute a new one. The PTO explained that the rules of practice did not provide for the withdrawal of a terminal disclaimer. Decision, at 3. Section 253, which permits filing of a terminal disclaimer and "dedication to the public" of the terminal part of the term, does not include a mechanism for withdrawal or amendment of a terminal disclaimer. 35 U.S.C. § 253. Under 35 U.S.C. § 253, the PTO considers the terminal disclaimer part of the original patent. The PTO also noted that the clarification of the disclaimed date was not the correction of a clerical or typographical mistake under 35 U.S.C. § 255 and 37 C.F.R. § 1.323. Decision, at 2-3.

Nonetheless, because 35 U.S.C. § 154(a)(2) automatically extended the term of the Peterson '658 patent by operation of law, 60 Fed. Reg. at 20,207, the PTO corrected its records to indicate that Bayer had disclaimed the term of the '444 patent beyond December 9, 2003 in accordance with 35 U.S.C. § 154(c)(1). Decision, at 6. The district court correctly sustained the PTO's actions as a proper exercise of its authority under 37 C.F.R. § 1.182.

The district court properly accorded deference to the to the PTO's implementing regulations and to the PTO's interpretative "Decision", which it found complied with 35 U.S.C. §§ 154 (a)(2) and (c)(1), in accordance with Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944). See also Merck, 80 F.3d at 1550; United States v. Cleveland Indians Baseball Co., 532 U.S. 200, 220 (2001) ("Because [the agency's] interpretation [of its own regulation] is reasonable, it attracts substantial judicial deference."); Dethmers Mfg. v. Automatic Equip. Mfg., 272 F.3d 1365, 1379, 60 USPQ2d 1929, 1939 (Fed. Cir. 2001) (Dyk, J., concurring-in-part and dissenting-in-part) ("[W]e are obligated by clear Supreme Court precedent to give deference to the PTO's own interpretation of its regulations."). The PTO thoroughly considered the effect of the URAA on this terminal disclaimer and gave persuasive reasons for correcting its records to reflect the December 2003 expiration date for the '444 patent.

Beyond deference to the PTO analysis, the district court also examined the meaning and effect of the URAA. As noted, the URAA states that the "term of a patent . . . shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant." 35 U.S.C. § 154(c)(1) (2000). This language mandates the automatic substitution of a later expiration date for the prior expiration date of the Peterson '658 patent. Because Bayer linked its terminal disclaimer to the expiration date of the Peterson '658 patent, the terminal disclaimer date also automatically shifted to December 2003.

As the district court noted, the Senate Report on the URAA confirms this meaning of the statutory language as applied to terminal disclaimers:

A patent whose term has been under section 235 of Title 35 due to another patent on an invention that is not patentably distinct from but was owned by or subject to an obligation of assignment to the same person shall expire on the date of the other patent. A patent whose term has been disclaimed under section 235 independent of another patent shall be reduced by the length of the originally disclaimed period.

Summary Judgment, at 4-5 (quoting S. Rep. No. 103-412, at 229 (1994)) (emphases added). Applying this explanation of the statutory language, the district court found: "Bayer used language indicating interdependence between several patents." Id. For example, the disclaimer recites "the earlier of the expiration dates of . . ." which modifies the date by its source. Id. The disclaimer also states that Bayer "agrees" that the '444 patent "shall be enforceable only for and during such period that legal title to U.S. Patent No. 4,670,444 shall be the same as legal title to U.S. Patent Nos. 4,544,658 and 4,556,658." Id. at 10. Accordingly, the court concluded that the disclaimed term of the '444 patent was "due to" the Peterson '658 patent, rather than "independent of" that patent. Id. This court discerns no error in the trial court's conclusion.

CTI argues that the trial court should have resolved any ambiguity in the terminal disclaimer in favor of the public. CTI argues that Bayer renounced its rights in the '444 patent after October 1, 2002, and thereby dedicated part of the term of that patent to the public. According to CTI, the public was entitled to rely on Bayer's disclaimer.

Bayer's original terminal disclaimer recited the October 1, 2002 date as a correct application of the law then in effect. When the URAA altered patent terms, Bayer acted in a timely manner to rectify any ambiguity. Bayer petitioned the PTO to withdraw the disclaimer within one month of the adoption of the URAA amendments. Moreover, the PTO's decision on Bayer's petition became part of the public record on January 31, 1996, more than five years before CTI filed its ANDA in April 2001. Hence, CTI, as well as the public, undisputedly had access to the PTO's interpretation of Bayer's original terminal disclaimer at the time CTI filed its ANDA. Thus, Bayer's prompt action precluded any prejudice to CTI or the public.

Finally, as Bayer points out, "no patentee could have anticipated the URAA patent extension" at the time Bayer filed its terminal disclaimer in 1992. The "October 01, 2002" date was simply the date of expiration of the Peterson '658 patent as calculated under then-existing law. Furthermore, Bayer disclaimed part of the '444 patent term pursuant to its ANDA related suit against Barr to defend against Barr's allegation that the '444 patent was invalid for double patenting over the two '658 patents. Thus, in context, Bayer intended to disclaim the term from the "earlier of the expiration dates of U.S. Patents Nos. 4,544,658 (issued October 1, 1985) and 4,556,658 (issued December 3, 1985)." [Terminal Disclaimer](#).

As the district court correctly noted: "Bayer thereby voluntarily abandoned the protected term on the '444 patent to the extent that it exceeded the earlier patents, and agreed to enforce the '444 patent only up to the date on which the Peterson '658 patent would expire." [Summary Judgment](#), at 2. Because the URAA amendments automatically changed the expiration date of the Peterson '658 patent from October 1, 2002 to December 9, 2003, the expiration date of the '444 patent, which is contingent upon the expiration date of the Peterson '658 patent, also changed simultaneously to December 9, 2003.

III.

In sum, the district court properly upheld the PTO's determination that the expiration date of the '444 patent as it relates to ciprofloxacin is December 9, 2003.

COSTS

Each party shall bear its own costs.

AFFIRMED.

* The Patent and Trademark Office (PTO) treated Bayer's communication as a petition under 37 C.F.R. § 1.182. Decision, at 1. 37 C.F.R. § 1.182 (2002) states: "All situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Commissioner, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(h)."