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EXHIBIT
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Unimed, Inc. and Theodor Petrzilka, Plaintiffs-appellees, v. Donald J. Quigg, Commissioner of Patents and Trademarks, defendant-appellant, 888 F.2d 826 (Fed. Cir. 1989)

US Court of Appeals for the Federal Circuit - 888 F.2d 826 (Fed. Cir. 1989) Oct. 23, 1989

Harold D. Steinberg, Steinberg & Raskin, New York City, argued for plaintiffs-appellees. With him on the brief was Martin W. Schiffmiller, Kirschstein, Ottinger, Israel & Schiffmiller, P.C.

Fred E. McKelvey, Sol., Office of the Sol., of Arlington, Va., argued for defendant-appellant. With him on the brief were Stuart E. Schiffer, Acting Asst. Atty. Gen., Jay B. Stephens, U.S. Atty., Charles E. Van Horn, Deputy Sol. and Linda M. Skoro, Asst. Sol.

Donald O. Beers, Stuart J. Land, Peter T. Grossi, Jr., William W. Vodra and David E. Korn, Arnold & Porter, of Washington, D.C., were on the brief for amicus curiae Hoffmann-La Roche Inc. Also on the brief were David A. Seligman and George W. Johnston, Hoffmann-La Roche Inc., Nutley, N.J., of counsel.

Before ARCHER, Circuit Judge, SKELTON, Senior Circuit Judge, and MAYER, Circuit Judge.

MAYER, Circuit Judge.

This is an appeal of the judgment of the United States District Court for the District of Columbia, 707 F. Supp. 17, 10 USPQ2d 1698 (1989), setting aside the Commissioner's denial of Theodor Petrzilka's application for extension of the term of U.S. Patent 3,668,224 pursuant to 35 U.S.C. § 156 (Supp. II 1984) because the application was untimely. Unimed, Inc., is the exclusive licensee of the patent, and the appellees will be referred to jointly as "Unimed". The district court remanded the application to the Patent and Trademark Office for consideration on the merits and ordered it to grant an interim extension pending its final decision. We reverse.

Background

U.S. Patent 3,668,224 describes and claims a process for making a dibenzo-pyran, which has the trade name Marinol. Marinol is the synthetic equivalent of an isomer of delta-9-

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Background

U.S. Patent 3,668,224 describes and claims a process for making a dibenzo-pyran, which has the trade name Marinol. Marinol is the synthetic equivalent of an isomer of delta-9-

tetrahydrocannabinol or THC, which is the principal psychoactive substance in Cannabis sativa L. marijuana. As exclusive licensee of the patent, Unimed submitted a New Drug Application (NDA) to the Food and Drug Administration on June 24, 1981 pursuant to section 505(b) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 355, requesting approval of Marinol capsules for use as an antiemetic and antinauseant. By letter dated May 31, 1985, the FDA approved the NDA. The approval letter also stated, "We wish to remind you that MARINOL may not be legally marketed until the Drug Enforcement Administration has completed rescheduling activities as required by the Controlled Substances Act."

On May 13, 1986, the Drug Enforcement Administration finalized the removal of Marinol from Schedule I to Schedule II of the Controlled Substances Act, 21 U.S.C. § 812, clearing the way for commercial marketing of the drug. Unimed's application for extension of the patent term pursuant to 35 U.S.C. § 156 was filed in the PTO fourteen days after DEA rescheduled the drug, but more than a year after the FDA's final approval letter.

The PTO denied Unimed's application for extension of the patent term because it was not timely filed under 35 U.S.C. § 156(d) (1). After an unsuccessful request for reconsideration, Unimed filed this suit, and the district court granted its motion for summary judgment.

Discussion

Title II of the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156, permits the term of a patent claiming a human drug product or method of using or manufacturing such a product to be extended for a period of time related to the time the drug was subject to regulatory review. As a condition for extension of the patent term, the patent owner must submit an application to the Commissioner of Patents and Trademarks in accordance with section 156(d). 35 U.S.C. § 156(a) (3). Section 156(d) provides:

(1) ... Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use.

The "regulatory review period" for human drug products is defined in section 156(g) (1) (B):

The regulatory review period for a human drug product is the sum of--

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

Sections 505 and 507 are from the FFDCA, 21 U.S.C. §§ 355 and 357, and section 351 is from the Public Health Service Act, 42 U.S.C. § 262. See 35 U.S.C. § 156(f) (4).

The timeliness issue boils down to whether the sixty-day period specified in section 156(d) (1) began, as the Commissioner argues, when the FDA sent its approval letter, on May 31, 1985 or, as Unimed argues, when the DEA rescheduled Marinol nearly a year later. By Unimed's reckoning, because Marinol could not legally have been marketed until DEA rescheduling was complete, the sixty-day period under section 156(d) (1) did not begin until then. Unimed also tells us the FDA regarded DEA rescheduling as a precondition to marketing; indeed it goes a step further and argues that, from a practical standpoint, the FDA's approval of the NDA was contingent on DEA rescheduling.

We look first to the language of the statute. Unless it is ambiguous, the language Congress chose is conclusive of its meaning absent a clearly stated contrary intention. Burlington N. R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461, 107 S. Ct. 1855, 1860, 95 L. Ed. 2d 404 (1987).

According to section 156(d) (1), the sixty-day period begins "on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." Read in light of the definition of the "regulatory review period" in section 156(g) (1) (B), this language is crystal clear. In this case, "the provision of law under which the applicable regulatory review period occurred" is section 505 of the FFDCA, which governs the approval of new drugs by the FDA. There is no mention of DEA rescheduling or of 21 U.S.C. § 811(a), the statute under which rescheduling takes place. Therefore, section 156(d) (1) admits of no other meaning than that the sixty-day period begins on the FDA approval date.

According to the FDA, the date of marketing approval for all new drugs is the date appearing on its approval letters. Two circuit courts of appeals have confirmed this, holding that, for purposes of the transitional provisions of Title I of the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355(j) (4) (D) (i) (Supp. II 1984), the date when a new drug is "approved" by the FDA is the date of the FDA approval letter, even where the applicant still needs to submit final printed labeling to the FDA. Mead Johnson Pharmaceutical Group v. Bowen, 838 F.2d 1332, 1337, 6 USPQ2d 1565, 1569 (D.C. Cir. 1988); Norwich Eaton Pharmaceuticals, Inc. v. Bowen, 808 F.2d 486, 491 (6th Cir. 1987).

Unimed thinks Mead Johnson and Norwich Eaton are different from this case because, as of the date of the FDA approval letters there, no "governmental" barrier to marketing the new drugs remained, whereas here, Unimed could not market the drug until the DEA had completed rescheduling. This distinction is impermissible because the Patent Term Restoration Act takes into account only the regulatory review carried out by the FDA and no other government obstacles to marketing new drugs. The May 31, 1985 letter to Unimed gave notice of the FDA's final approval to market Marinol; nothing more from the FDA was needed. DEA rescheduling was a legal prerequisite to Unimed's "commercial marketing or use" of Marinol, but "permission under the provision of law under which the applicable regulatory review period occurred" per section 156(d) (1) did not comprehend it.

Unimed's argument that the May 31, 1985 FDA letter was conditional is also unsound. The letter reminded Unimed that DEA rescheduling was necessary before the drug could be marketed. But this was not a condition on FDA approval, which declares only that the drug is safe and effective, not whether it should remain classified as a controlled substance. Acceptance of Unimed's view that, by the terms of the FDA approval letter, the new drug had not received "permission ... for commercial marketing or use" would read important language out of the law. But we "must give effect, if possible, to every word of the statute." Bowsher v. Merck & Co., 460 U.S. 824, 833, 103 S. Ct. 1587, 1593, 75 L. Ed. 2d 580 (1983).

Because subsections 156(d) (1) and 156(g) (1) (B) are clear and unambiguous, resort to the legislative history of the Patent Term Restoration Act is unnecessary to determine their meaning. Even if the history were contrary to the statutory language employed and passed, we would be bound by what the law says, not by what it "should" have said. Happily, the construction of these provisions which we confirm is nevertheless consistent with that record. Before the enactment of the present section 156, much broader coverage was rejected by the House of Representatives. The Senate bill would have allowed patent term extension for regulatory review under a variety of statutes besides the FFDCA and the Public Health Service Act. See S.Rep. No. 138, 97th Cong. 1st Sess. (1981). What became law was much more circumscribed and limited the extension only to the period of FDA review. See H.R.Rep. No. 857, 98th Cong., 2d Sess., Part II, 11 (1984), reprinted in 1984 U.S.Code Cong. & Admin.News 2647, 2686, 2695. For our purposes it does not matter why.

Contrary to Unimed, our resolution does not contravene the purpose of the Patent Term Restoration Act. The act was intended to ameliorate the loss incurred when patent terms tick away while the patented product is awaiting regulatory approval for marketing, but the scope of the relief was explicitly and precisely limited. And we can find no implication that the approval date that commences the running of the sixty-day application period under subsection (d) should be different from the approval date that marks the end of the regulatory review period under subsection (g) (1) (B) (ii).

Finally, this is purely a case of statutory interpretation, so the equitable considerations raised by Unimed are inappropriate. It may appear incongruous, at least in a case like this, that the operative review period would not include activities by other governmental entities that forestall marketing as effectively as FDA's, but it is not for us to distort the statute to "fix" what Congress either intentionally or inadvertently failed to anticipate. TVA v. Hill, 437 U.S. 153, 194, 98 S. Ct. 2279, 2301, 57 L. Ed. 2d 117 (1978). The sixty-day period specified in section 156(d) (1) commenced on May 31, 1985, the date of the FDA's letter to Unimed giving notice of its final approval of Marinol and Unimed's application for extension of the patent term was untimely.

Conclusion

Accordingly, the judgment of the district court is reversed.

REVERSED.

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