Keywords: patent term extension; terminal disclaimer; FDA review; Hatch-Waxman

General: A term of a patent subject to a terminal disclaimer may be extended, pursuant to 35 U.S.C. § 156, to compensate for delays that occur during regulatory review.

Merck and Co., Inc. v. Hi-Tech Pharmacal Co., Inc.
No. 06-1401 (Fed. Cir. 2007),
available at http://fedcir.gov/opinions/06-1401.pdf
Decided March 29, 2007

I. Facts

Merck and Co., Inc ("Merck") produces TRUSOPT®, a drug used to treat glaucoma. TRUSOPT® includes the active ingredient dorzolamide, which is covered by U.S. Patent No. 4,797,413 (the "413 patent"). During prosecution, the '413 patent was rejected for obviousness-type double patenting over the claims of an earlier Merck patent, U.S. Patent No. 4,677,115 (the "115 patent"). To overcome the rejection, Merck filed a terminal disclaimer under 35 U.S.C. § 253. The terminal disclaimer disavowed any term of the '413 patent that would extend beyond June 30, 2004, the original term of the '115 patent. In 1994, the term of the '115 patent was extended to December 12, 2004, under changes made to patent term calculation under the 1994 Uruguay Round Agreements Act, whereby patents in force were given the later of 17 years from issue or 20 years from the earliest effective filing date. The term of the '413 patent was also reset to December 12, 2004.

Under 35 U.S.C. § 156, a patent term may be extended to allow for time spent in regulatory review by the FDA. In 1997, at the request of Merck, the PTO extended the term of the '413 patent pursuant to 35 U.S.C. § 156 for a period of 1233 days, calculated from the effective date of the terminal disclaimer, December 12, 2004. The new expiration date of the '413 patent became April 28, 2008.

In August 2005, Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") filed an Abbreviated New Drug Application ("ANDA") for a generic version of TRUSOPT®. In response, Merck sued Hi-tech for infringement of the '413 patent. Hi-Tech's sole defense against infringement was that the '413 patent was foreclosed from any term extension under 35 U.S.C. § 156, because any term subsequent to the expiration date of the '115 patent had been disclaimed. Thus, the '413 patent had expired on December 12, 2004, and was not enforceable after that date. On April 25, 2006, the district court entered a judgment in favor of Merck and enjoined Hi-Tech from commercializing their generic drug until the end of the extended patent term of the '413 patent. The district court adopted the reasoning of an earlier case with a similar fact pattern, *King Pharmaceuticals, Inc. v. Teva Pharmaceuticals, Inc*., 409 F. Supp. 2d 609 (D.N.J. 2006).

II. Issue

Did the district court err in holding that patents subject to terminal disclaimer are not foreclosed from Hatch-Waxman term extension?

III. Discussion

No. The Federal Circuit held that a terminal disclaimer does not negate patent term extension under Section 156.

Section 156 was enacted as part of the Hatch-Waxman Act in 1984 to allow restoration of up to five years of a pharmaceutical patent's term due to lengthy FDA review of a new drug application. At issue in this case was the proper interpretation of Section 156. In finding for Merck, the Federal Circuit relied primarily on the language of the statue.

Section 156 provides that:

> a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if– (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension; (2) the term of the patent has never been extended under subsection (e)(1) of this section; (3) an application for extension is submitted by the owner of record of the patent . . . ; (4) the product has been subject to a regulatory review period before its commercial marketing or use; (5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; . . . .

The Federal Circuit noted that the statute is unambiguous because it states that a patent "shall be extended" if the enumerated requirements are met. While Section 156 is silent as to terminally disclaimed patents, other sections of statute provide expressly for dealing with patent term extensions for terminally disclaimed patents. Namely, the Federal Circuit noted that Section 154(b)(2)(B) explicitly prohibits patent term adjustment (for U.S.P.T.O. delay) for a terminally-disclaimed patent. The lack of a similar explicit prohibition in Section 156, coupled with a reference in Section 156 to Section 154(b), further supported its conclusion that eligibility for a patent term extension is not foreclosed by a terminal disclaimer.

Additionally, the Court explained why Section 156 and Section 253 are compatible. Section 253 allows the filing of a terminal disclaimer to overcome obviousness-type double patenting rejections made by the Patent Office. The Section 156 extension may be computed from the terminally disclaimed date. Thus, a patent may simultaneously have part of its term disclaimed and part of its term extended. In response to Hi-Tech's argument that the '413 patent, as a result of the patent term extension, is now improperly "uncoupled" from the earlier parent patent, the Federal Circuit noted that the expiration date set by the terminal disclaimer remains in place. Because the extension is added onto this expiration date, rather than onto the expiration date calculated without the terminal disclaimer (which would be later), the purpose of the terminal disclaimer remains fulfilled.

Finally, the Federal Circuit rejected Hi-Tech's arguments that 37 C.F.R. § 1.775, which expressly authorizes extensions under Section 156 for terminally disclaimed patents, was invalid.