

Somerset Pharms., Inc. v. Dudas

No. 07-1447, Federal Circuit (Michel, Prost, Moore*)

Section 156(e)(2) . . . only gives the Director the authority to extend a patent's term beyond that provided for by section 154 when the patent for which a term extension is sought "would expire before a certificate of extension is . . . denied."

On October 4, 2007, the Federal Circuit, inter alia, affirmed the district court's denial of Somerset's motion for a preliminary injunction to compel an immediate grant by the USPTO Director of an interim extension of the term of the U.S. Reissue Patent No. 34,579, which related to depression treatment by a transdermal patch containing selegiline marketed as EMSAM®. The Federal Circuit stated:

Somerset filed a Patent Term Extension Application with the PTO on April 27, 2006, seeking to extend the term of the '579 patent under 35 U.S.C. § 156(d)(1). On February 21, 2007, Somerset filed a request for an interim extension under 35 U.S.C. § 156(e)(2). Shortly thereafter, Somerset filed suit in the United States District Court for the District of Delaware seeking to compel the Director of the PTO to act on, and grant, its request for interim extension. Somerset also filed a motion for a preliminary injunction in accordance with the prayer for relief made in its complaint. The district court denied that motion on June 29, 2007. Somerset filed a motion with this court on July 11, 2007 seeking to expedite the briefing schedule for its appeal, which we granted on July 12. That same day, the Director denied both Somerset's application for interim patent term extension and its application for term extension on the merits. . . .

Somerset was originally seeking an order compelling the Director to issue a decision on its request for interim extension under 35 U.S.C. § 156(e)(1). Because the Director issued his decision on July 12, 2007, Somerset has withdrawn the portion of its appeal that sought to compel the Director to act on its request for interim relief. Therefore, we dismiss that aspect of Somerset's appeal as moot.

Nonetheless, Somerset continues to press its appeal regarding the denial of injunctive relief compelling the Director to grant its request for an interim extension. We review the denial of a preliminary injunction for an abuse of discretion. To establish entitlement to a preliminary injunction a movant must establish a reasonable likelihood of success on the merits. Somerset cannot establish a reasonable likelihood of success on the merits in this case.

Section 156(e)(2) . . . only gives the Director the authority to extend a patent's term beyond that provided for by section 154 when the patent for which a term extension is sought "would expire before a certificate of extension is . . . denied." In this case, the Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks. Thus, Somerset has not demonstrated a reasonable likelihood of success on the merits. Because the district court did not abuse its discretion in denying Somerset's motion for a preliminary injunction, that denial is affirmed.

The previous statements are for information purposes only, and do not constitute legal advice. Questions regarding the matters discussed above, and any requests to be subscribed to the free electronic distribution of this publication, may be directed to Lawrence M. Sung, Ph.D., at +1 202.862.1025 or lsung@dl.com, or to any other Dewey & LeBoeuf LLP attorney with whom you regularly consult.

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