

NOTE: This disposition is nonprecedential.

## United States Court of Appeals for the Federal Circuit

2007-1447

SOMERSET PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

JON W. DUDAS,

in his official capacity as Under Secretary of Commerce for Intellectual Property  
and Director of the United States Patent and Trademark Office,

Defendant-Appellee.

John M. Faust, Vinson & Elkins L.L.P. of Washington, DC, for plaintiff-appellant.  
With him on the brief were Tracey B. Davies and Margaret J. Sampson, of Austin,  
Texas.

Stephen Walsh, Acting Solicitor, Solicitor's Office, United States Patent and  
Trademark Office, of Arlington, Virginia for defendant-appellee. With him on the brief  
were Nathan K. Kelley, Janet Gongola, and William LaMarca, Associate Solicitors.

Appealed from: United States District Court for the District of Delaware

Chief Judge Gregory M. Sleet

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DECIDED: July 31, 2007

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Before MICHEL, Chief Judge, PROST, and MOORE, Circuit Judges.

MOORE, Circuit Judge.

Somerset Pharmaceuticals, Incorporated (Somerset) appeals from an order by the United States District Court for the District of Delaware denying Somerset's request for a preliminary injunction. See Somerset Pharms., Inc. v. Dudas, No. 07-279 (D. Del. Jun. 29, 2007). We dismiss Somerset's request to compel the United States Patent and Trademark Office (PTO) to issue a decision as moot, otherwise we affirm.

## BACKGROUND

Somerset is owner of United States Reissue Patent No. RE 34,579 (the '579 patent). That patent is currently set to expire on August 18, 2007. Somerset obtained marketing approval from the Food and Drug Administration (FDA) for its drug product

EMSAM®, a transdermal pharmaceutical patch that includes selegiline as the active ingredient. A method of treating depression using that patch is allegedly covered by the '579 patent. 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. See Compl. at 8-9, Somerset Pharms., No. 07-279 (D. Del. May 22, 2007) (prayer for “an order compelling the Director to immediately grant an interim extension of the term of the '579 patent for a period of one year . . . or until a final, non-appealable judicial decision . . . is obtained . . .”). 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. Briefing was completed in this matter on July 27, 2007. We have jurisdiction under 28 U.S.C. § 1292(c)(1) (2006).

## DISCUSSION

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. Ranbaxy Pharms., Inc. v. Apotex, Inc., 350 F.3d 1235, 1239 (Fed. Cir. 2003). To establish entitlement to a preliminary injunction a movant must establish a reasonable likelihood of success on the merits. Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.3d 1319, 1325 (Fed. Cir. 2004) (“[A] movant is not entitled to a preliminary injunction if he fails to demonstrate a likelihood of success on the merits.”). Somerset cannot establish a reasonable likelihood of success on the merits in this case.

Section 156(e)(2) provides

If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2). This section 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.” Id. at § 156(e)(2).

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.<sup>1</sup> Because the district court did not abuse its discretion in denying Somerset's motion for a preliminary injunction that denial is affirmed.

#### COSTS

Each party shall bear its own costs.

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<sup>1</sup> Nothing in this opinion is intended to address any claim that Somerset may have on the underlying merits of the Director's July 12, 2007 denial of its request for patent term extension under 35 U.S.C. § 156(e)(1).