

Pfizer Faces Patent Woes

AUG 22, 2007

BY: [GEORGE KORONEOS](#)

PHARMEEXEC DIRECT

Pfizer hit a stumbling block last week as the United States Patent and Trademark Office (USPTO) initially rejected the request that would have extended market exclusivity of the company's cholesterol-reducing drug Lipitor (atorvastatin) for another year.

Last year, a federal appeals court ruling in a suit launched by Ranbaxy, found Pfizer's US Patent No. 5,273,995 to be invalid due to a technical error. (Specifically, the company linked its claim covering the hemicalcium salt of atorvastatin acid to a claim that cited the acid form of the compound rather than to a separate claim referring to its salts.) Pfizer sought to correct the error in an effort to use the patent to block competition. If reissued, the patent would allow Pfizer to maintain control over Lipitor through 2011 rather than 2010, when Pfizer's US Patent No. 4,681,893 expires.

The good news for Pfizer: USPTO ruled that the defective claim, contrary to Ranbaxy's opinion, could indeed be corrected by reissuing the patent. The bad news: All 14 of Pfizer's claims in the patent were rejected on the grounds of obviousness or double-patenting.

"An initial rejection is not uncommon in reissue application proceedings. Pfizer will now review the communication from the patent office and respond as appropriate to address the issues raised by the examiner," Pfizer stated in a release. "It is important to note, however, that Lipitor continues to be protected by its basic patent until March 2010, including pediatric exclusivity. The decision has no impact on the basic patent."

According to Pfizer, the average time for obtaining a reissue patent is about two years from the date the application is filed. Pfizer filed its reissue application on Lipitor's calcium salt patent in January 2007.

"With almost all patent applications--whether a reissue or a regular application--99 percent of the time you'll get an office action rejecting the claims on some statutory grounds," said John Iwanicki, senior partner at Banner & Witcoff. "This isn't necessarily good news for Pfizer, but it certainly isn't something that is insurmountable. They do have an opportunity to argue with the patent and trademark office that the claims are, in fact, patentable and should not be rejected."

If the rejection does hold, this will be good news for drug manufacturer Ranbaxy Laboratories, which plans to release a generic version of Lipitor in the United States by 2010. Ranbaxy is vying to lock up a 180-day exclusive-rights period to market its generic version when Pfizer's patent expires.

The two companies have been embroiled in legal battles over patent rights for the last few years. Last year, Ranbaxy Laboratories challenged two of Pfizer's atorvastatin patents and succeeded in getting the US Court of Appeals for the Federal Circuit to overthrow US Patent No. 5,273,995. However, the court confirmed Ranbaxy's atorvastatin infringes on Pfizer's US Patent No. 4,681,893.