

Pfizer painkiller gets longer patent protection (Update)

March 5 2013, by Linda A. Johnson

Drugmaker Pfizer Inc. said Tuesday that a new patent on one of its top drugs, anti-inflammatory painkiller Celebrex, extends its U.S. patent protection by 18 months, potentially bringing the company a few billion dollars in additional revenue.

Shares of New York-based Pfizer jumped nearly 2 percent on the news before giving up part of that gain. Pfizer also filed a lawsuit against five generic drugmakers to try to prevent them from selling generic versions of Celebrex before the new patent runs out in December 2015.

Pfizer said the U.S. Patent & Trademark Office has granted what's called a "reissue patent" that replaces an older patent a federal appeals court had ruled invalid in 2008 during a prior round of litigation.

The reissue patent corrects what Pfizer called technical deficiencies in the original patent covering the diseases treated by the drug's active ingredient, celecoxib. Those include acute and menstrual pain, osteoarthritis, the immune disorder rheumatoid arthritis and a painful spinal joint disorder called ankylosing spondylitis.

The new patent will run until Dec. 2, 2015, about 18 months after the May 30, 2014 expiration of the two basic patents for Celebrex, which cover aspects of the drug's chemical composition.

The suit, filed Tuesday in federal court in Norfolk, Virginia, names as defendants the generic drugmakers Teva Pharmaceuticals USA Inc.,

Mylan Pharmaceuticals Inc., Lupin Pharmaceuticals USA Inc., Apotex Inc. and Watson Laboratories Inc., which recently became Actavis Inc. after a merger.

All five companies previously had applied to the U.S. Food and Drug Administration years ago for approval to begin selling generic versions of Celebrex as of May 30, 2014. Three of the companies—Teva, Mylan and Actavis—already have been granted tentative approval by the FDA to sell capsules of celecoxib in strengths from 50 milligrams to 400 milligrams.

If Pfizer's lawsuit is not resolved before May 2014, Pfizer noted in the suit that it would have to seek a preliminary injunction blocking all sales of generic Celebrex, to prevent "irreparable and irreversible harm" while the litigation continues.

Celebrex is Pfizer's fifth-best-selling drug. It had annual sales of \$2.72 billion last year, with \$1.75 billion of that coming from U.S. sales. Capsules of the drug, generally taken twice a day, range in price from about \$90 to \$160 a month, depending on the strength.

In trading Tuesday, Pfizer shares rose 38 cents to \$38.07.

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