

Bristol-Myers, Sanofi Win Trial, Block Generic Plavix

By Lisa Rapaport and David Glovin

June 19 (Bloomberg) -- Bristol-Myers Squibb Co. and Sanofi- Aventis SA will continue to be the only marketers of the blood- thinner Plavix, the world's third-biggest-selling drug, after a U.S. judge upheld their patent today.

U.S. District Judge Sidney Stein in New York blocked generic competition from the Canadian drugmaker Apotex Inc., rejecting arguments the medicine's patent is invalid or unenforceable. Apotex said it will appeal immediately.

At stake for Sanofi and Bristol-Myers was \$6.1 billion in sales of a drug designed to prevent heart attacks. The Plavix ruling renewed speculation that Bristol-Myers might be a takeover target, with Sanofi, Pfizer Inc. and AstraZeneca Plc among potential suitors, analysts said.

``Today's decision will ignite speculation regarding the potential for a takeover now that the Plavix patent has been secured," said Joseph Tooley, an analyst with A.G. Edwards in St. Louis, in a telephone interview today. Bristol-Myers spokesman Tony Plohoros declined to comment on the speculation.

Sanofi might be a suitor because of the partnership on Plavix, analysts said. AstraZeneca and Pfizer also have alliances with Bristol-Myers. Pfizer agreed in April to pay as much \$1 billion to develop a blood thinner with Bristol-Myers, and AstraZeneca entered an accord in January to invest as much as \$1.35 billion in two diabetes drugs.

Cancer Drug Review

Bristol-Myers shares rose \$1.27, or 4.2 percent, to \$31.58 at 4:01 p.m. in New York Stock Exchange composite trading. They have gained 20 percent this year.

Sanofi shares rose 0.06 euros to 62.10 euros at 5:39 p.m. in Paris. The stock climbed as much as 1.71 euros, or 2.8 percent earlier.

Separately, Bristol-Myers won accelerated U.S. review today for its experimental breast-cancer drug ixabepilone, a new type of medicine for patients whose tumors have spread to other organs. The U.S. Food and Drug Administration may make an approval decision in October, the company said.

Stein said he will rule on cash compensation for the infringement at a later, unspecified date.

The former Bristol-Myers chief executive officer, Peter Dolan, tried to avoid a court ruling last year by signing an accord with Apotex to delay competition until 2011. The board ousted Dolan when the deal fell apart and Apotex started selling its generic versions.

Pass on Treble Damages

Dolan agreed not to seek the maximum legal damages from Apotex if the generics maker sold its cheaper copycat Plavix pills and later lost the patent case. Under

U.S. law, drugmakers can seek up to three times their lost profits.

`` In hindsight, it's easy to say Dolan made a terrible deal," A.G. Edwards's Tooley said. `` The penalties became so slim that Apotex faced no downside from launching its generic."

Plavix sales last year ranked behind Pfizer's cholesterol pill Lipitor, with \$13 billion in revenue, and GlaxoSmithKline Plc's asthma drug Advair, with \$6.13 billion. Revenue from Plavix plunged 53 percent in the fourth quarter after Apotex flooded the U.S. market with cheaper copies, before Stein ordered the sales halted.

Apotex Version

`` Apotex has failed to prove by clear and convincing evidence that the" Plavix `` patent is invalid or unenforceable," Stein wrote in an 82-page opinion. The judge found that Sanofi is entitled to a permanent injunction prohibiting Apotex from further infringement.

Bristol-Myers markets Plavix in the U.S. and the two companies share the profits. It is the biggest seller for Bristol-Myers and the second-biggest for Sanofi, behind the anti-clot treatment Lovenox.

Apotex, based in Weston, Ontario, said its generic version uses the same active ingredient, clopidogrel bisulfate, covered by the patent. The company claimed the compound was first covered by a patent that expired. Apotex also accused Sanofi of misleading the U.S. Patent and Trademark Office.

Sanofi maintained that the earlier patent covered an entire class of compounds and didn't direct scientists to select clopidogrel bisulfate. The company said it spent millions of dollars on dozens of tests to home in on clopidogrel and rejected allegations of withholding information from the patent office.

`` Clopidogrel bisulfate satisfied a long-felt need for a better anti-platelet medication with a better safety profile," Sanofi said in court documents. The earlier patent `` does not describe how to make clopidogrel bisulfate at all, let alone without undue experimentation."

The patent covers the main compound of the drug. Typically, such patents have weathered scrutiny by courts. Pfizer, the world's biggest drugmaker, fended off a challenge to the main patent on its biggest product, Lipitor. Eli Lilly & Co.'s patent on its biggest drug, the schizophrenia treatment Zyprexa, was also upheld.

The case is Sanofi-Synthelabo v. Apotex Inc., 02cv2255, U.S. District Court, Southern District of New York (Manhattan).

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