FDA extends Plavix patent by 6 months to May 2012

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(AP) -- The makers of Plavix, the world's second best-selling medication, said Tuesday they will retain exclusive U.S. marketing rights to the blood thinner for an additional six months, under a decision by U.S. health regulators.

The marketing extension will help Bristol-Myers Squibb Co. and partner Sanofi-Aventis delay the financial crunch hitting nearly all drugmakers, as patents on a wave of blockbuster drugs from the 1990s begin to expire.

The companies announced that the Food and Drug Administration granted a six-month patent extension for Plavix after the companies conducted extra studies of the drug in infants. The FDA program is designed to reward companies for testing drugs in children, who are typically excluded from medical studies.

With the extension, the companies will be able to market the drug exclusively until May 17, 2012.

Plavix posted $9.1 billion in sales globally in 2009, according to health care data firm IMS Health. Only Pfizer's Lipitor had higher sales, at 13.3 billion. In the U.S., Plavix generated $5.6 billion.

New York-based Bristol-Myers faces one the starkest patent cliffs in the pharmaceutical industry, as four of its top five sellers lose patent protection between now and 2015. The company sells the schizophrenia

drug Abilify and blood pressure medication Avapro, among other prescription medications.

French drugmaker Sanofi is already weathering its own revenue decline, after the FDA unexpectedly approved a generic version of its drug Lovenox, an injectable medication for preventing life-threatening blood clots.

Bristol-Myers studied Plavix in more than 900 infants born with a rare heart defect to see if the drug would reduce dangerous clotting. The study failed to show any benefit.

Drug companies routinely conduct such tests, even when success is not expected, to receive the six-month patent extension.