

Bill revision could mean money for NJ drug company

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(AP) -- A billion-dollar "technical revision" added to a patent bill passed by the House last week could provide huge financial benefits to one pharmaceutical company and a law firm.

On the surface, the barely noticed amendment simply clarifies a process by which the [Food and Drug Administration](#) approves a [patent](#) for a brand-name drug, and gives the manufacturer 60 days to apply for an extension with the U.S. Patent and Trade Office.

In reality, the measure could give a New Jersey drugmaker, The Medicines Co., 2 1/2 more years of [patent protection](#) for its lucrative blood thinner Angiomax. It would also save the law firm WilmerHale \$214 million it would owe the drug company under a malpractice lawsuit if a generic alternative is sold in the United States before June 15, 2015.

The amendment barely won House approval and it is not a part of the Senate version of the [patent system](#) overhaul bill, so it is questionable whether it will ever become law. The amendment would write into law a court decision in favor of the drug company and would pre-empt any appeal.

It shows how, hidden behind the lines of obtuse legislative language, huge fortunes can be at stake, sometimes for specific companies.

The chairman and CEO of The Medicines Co., Clive Meanwell, said in an interview with The Associated Press that while "we have been the

poster child for this problem for some years now," the congressional action was not a favor bestowed on a single company. "This is a systematic problem that needs fixing for lots of people, not just us."

The company's troubles began late on a Friday in December 2000 when the FDA approved Angiomax, a hospital drug used for [heart patients](#). Under law, makers of brand-name drugs are allowed to ask for patent extensions to compensate for the time it takes to win [FDA approval](#). The company, thinking the 60-day window for applying for an extension began the next business day, on Monday, filed a day late in February, and the Patent and Trade Office rejected the extension, which would have prolonged the patent from March 2010 to December 2014.

The company sued, and last August a federal district court ruled in its favor, ordering the patent office to recognize The Medicines Co.'s application as timely and saying the FDA and the patent office need to better coordinate their rules. APP Pharmaceuticals LLC of Illinois, which wants to market a generic brand of Angiomax, has appealed that ruling. APP Pharmaceuticals officials declined to comment on the issue, saying the litigation is ongoing.

The Medicines Co.'s sales of Angiomax exceed \$400 million a year. A company spokesman said the typical cost is about \$600 of the \$11,000 to \$14,000 it costs to treat a heart attack patient in the hospital.

In February this year, The Medicines Co. reached a settlement with WilmerHale, its legal representative in the patent case. The law firm agreed to pay The Medicines Co. \$18 million up front for past expenses and \$214 million if the district court's decision is overturned and a generic drug enters the market early. Of that, \$99 million would be provided by malpractice insurance. Loss of the patent could cost The Medicines Co. hundreds of millions of dollars a year in revenue.

"This amendment provides the certainty necessary to encourage costly investments in lifesaving medical research," Rep. John Conyers, D-Mich., said in defending the legislation on the House floor. He noted that the same amendment, which some referred to as "The Dog-Ate-My-Homework Act," had passed the House several times before.

But Judiciary Committee Chairman Lamar Smith, R-Texas, said that the amendment was a "special fix for one company" and that Congress shouldn't be interfering in a case that was still being litigated. He added that if The Medicines Co. eventually loses and generics are allowed into the market early, it could potentially save billions of dollars in health care expenses.

The Medicines Co. pointed to a June 2009 report in the journal *Nature Biotechnology*, which found that of the last 100 patent term extensions granted, 78 had incorrectly identified the 60th day of the filing period. It said that among the applicants that filed on the 60th day, mistakenly thinking they were filing a day early, were the makers of the cholesterol drug Crestor, which had global sales of \$3.6 billion in 2008.

Meanwell acknowledged that his company has actively lobbied on the issue, spending about \$8 million in 2009 and 2010, but he rejected the notion that it was a case of a big pharmaceutical company pushing its weight around. He said that after the one-day filing error blocked the patent extension on its only significant revenue source, the company laid off 100 of its 500 workers and shut down research in new uses for Angiomax and other drugs.

The company, he said, is being depicted as "the big, wicked drug baron. It just doesn't fit with who we are."

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