Generic drug firms fight patent loophole

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WASHINGTON -- With the new Democratic Congress promising to lower health care costs, makers of inexpensive generic drugs sense a unique opportunity to level the playing field with their brand-name rivals.

Generic manufacturers such as Woodcliff Lake-based Barr Pharmaceuticals and Mylan Laboratories know, however, that sympathy on Capitol Hill will go only so far. So lobbyists are using a Bush administration threat of new regulatory fees to the industry's advantage, arguing that Congress must first fix a patent-law loophole that favors brand-name competitors.

The legislative gambit is driven by rising financial concerns: U.S. generic drug companies are facing shrinking profit margins as global competition accelerates in the roughly $60 billion market for discounted pills to treat everything from impotence to high cholesterol.

With patents on drugs selling $16 billion worth annually scheduled to expire this year alone, brand-name manufacturers such as Pfizer Inc. and Merck & Co. are increasingly competing head-to-head with generic companies.

"As a lot of the big blockbuster drugs from the '90s have come off patent, it has created an opportunity for generics," said Herman Saftlas, analyst with Standard & Poor's.

"To counter that opportunity, the branded companies have come up with new ways to salvage as much of their business as possible."

Among the blockbuster drug patents scheduled to expire in the next two years are Schering Plough's allergy treatment Clarinex, Merck's osteoporosis drug Fosamax and Pfizer's hypertension drug Norvasc.

Generic companies argue this direct competition is only possible because of a legal loophole that allows their branded rivals to launch cheaper versions of drugs just as they lose patent protection -- a loophole they hope to close with help from lawmakers.

Three senior Senate Democrats and a bipartisan group of House members have introduced bills that would put an end to this practice.

Promoting generic drugs is seen as one way to keep government spending in check because they can typically cost up to 60 percent less than brand-name drugs.

Still, policy analysts say generic drug makers face long odds in changing the patent law, and that they must prepare for a fight on another front: proposed regulatory fees for their drug applications.

Under the president's budget released this month, generic drug makers would pay a fee each time they submit a new product for review. The Food and Drug Administration hopes to raise nearly $16 million through the program in fiscal 2008.

Backlog of requests

Given that the FDA has a backlog of more than 1,200 generic drug applications, policymakers say user fees are worth considering.

Lobbyists for the generic manufacturers are using the proposed fees to draw attention back to the patent-law loophole they say must be fixed.

The FDA approves generic versions of drugs when either the patent of the original drug has expired or a generic company has shown the patent to be invalid. Because the first company to bring out a generic version of a blockbuster drug can expect massive profits, generic firms spend considerable time and money

challenging patents.

More importantly, the first company to successfully challenge a patent can market the generic exclusively for six months.

But the law can't stop the original patent holder from launching an "authorized generic" through a subsidiary or a third party.

Sales of an authorized generic during the exclusivity period can cut the generic maker's profits by 59 percent, according to research by Merrill Lynch analyst Greg Gilbert.

"While we're open to discussing options that get affordable generics to consumers faster, user fees will not improve access as long as market barriers like authorized generics exist," said Kathleen Jaeger, president of the Generic Pharmaceutical Association.

Talks with lawmakers

While this is not the first time generic drug makers have pushed for a ban on authorized generics -- a similar measure failed to pass last year -- industry leaders are expecting this year's legislation to find a more receptive audience.

"The difference between the chances of success for the legislation last year and this year is very simple: Congress now gets it," said Mylan Chief Executive Robert Coury. In the past year representatives from Mylan and Barr have met with lawmakers on Capitol Hill to educate them on authorized generics.

Original drug makers argue that authorized generics benefit consumers by spurring competition, which drives drug prices down. The presence of authorized generics decreased health care spending by an average of $23 million across nine drug case studies, according to IMS Health statistics cited by the Pharmaceutical Research and Manufacturers of America.

However, Barr's chief executive, Bruce Downey, said their overall effect goes beyond pricing to influence how generic companies make strategic decisions. A generic company would be less likely to challenge a patent if its drug launch is likely to face a brand-name rival, and as a result fewer generic drugs will make it to consumers, Downey said.

Woodcliff Lakes-based Barr Pharmaceuticals is the world's third-largest maker of generic drugs after its acquisition last year of Croatia-based Pliva. The combined company reaches 30 markets worldwide, employs more than 8,000 people and is expected to generate annual revenue of $2.4 billion. In addition to generic drugs, Barr also makes the so-called "morning after pill," a birth-control option that received federal approval last year for over-the-counter sales to women 18 years old and older.

Feeling the heat

Generic firms are already feeling global competitive pressures more than before. While overall generic drug sales in the U.S. are steadily increasing, year-over-year growth of the sector has decreased from more than 10 percent at the beginning of the decade to an estimated 6 percent in 2007, according to figures by UBS health care director Tommy Erdei.

The slower growth is mostly due to smaller profit margins as the generic drug space becomes increasingly crowded. And many newcomers, such as India-based Ranbaxy Laboratories and Dr. Reddy's Ltd., have lower production costs than their Western counterparts.

Against this backdrop, a law curtailing brand manufacturers' competitive practices here in the U.S. would be major coup.