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Drug patent profit extended



June 28, 2001: 7:34 a.m. ET

Generic approval time grows, giving patent holders longer to reap earnings

NEW YORK (CNNfn) - Pharmaceutical stocks are usually a safe haven for investors in times of economic trouble, according to experts. After all, even during a slowdown consumers still need to buy medication.

But when Merck & Co. stock [tumbled](#) after warning on second-quarter revenue and earnings on June 22, pulling the entire drug sector down with it, things looked a little more shaky.

[Merck](#) (MRK: down \$0.15 to \$65.49, [Research](#), [Estimates](#)) cited disappointing sales of its arthritis drug Vioxx, which was expected to make up for a shortfall in sales of hypertension treatment Vasotec, ulcer medicine Pepcid, and Mevacor, a cholesterol fighter; all of whose patents expired this year.

Once a company loses its patent and generic alternatives become available, drugmakers can see revenue for the product fall as much as 80 percent. But new data, suggesting the time for generic drug approval is on the rise, could mean a little more time for pharmaceutical companies to squeeze profits from top-selling drugs and provide a little more bottom-line stability.

Generic approval time increases

According to statistics released by the FDA, in 2000 the mean average time for generic drug approval increased for the first time in five years.

For the 232 generic drug approvals in fiscal 2000 the average approval time was 22.3 months, up 2.4 months from average time of the 198 approvals in 1999.

GENERIC APPROVALS BY FISCAL YEAR

Average approval time for generic drugs according to the FDA.

- 1995 - 35.3 months
- 1996 - 33.2 months
- 1997 - 25.6 months
- 1998 - 22.5 months
- 1999 - 19.9 months
- 2000 - 22.3 months

Since 1995, when the FDA averaged 35.3 months for generic approval, the time has decreased steadily. Preliminary data for fiscal 2001 are not yet available.

According to Jeffrey Kraws, pharmaceutical analyst with Gruntal & Co., a continued increase in approval time will have more of an impact, with a record number of drugs losing patents during the next

three years.

"If the generic doesn't get out there then the pharmaceutical company (with the patent) obviously benefits," Kraws said.

But he did not see any current effect on the drug sector and said the companies are doing the right thing by investing in their drug pipelines to have replacement drugs at the ready when patents expire.

The FDA said during fiscal 2000 the median approval time for new drugs was 11.6 months, down 3 percent from the previous fiscal year.

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Take them to court

Analysts said one reason for the increased approval time could be patent-holders prolonging court battles against proposed generic alternatives. And those battles could get even nastier with some of the top-selling drugs up for expiration.

Earlier this month [Mylan Laboratories Inc.](#) (MYL: up \$0.69 to \$29.00, [Research, Estimates](#)) won FDA approval of cholesterol-lowering agent lovastatin – the generic version of Merck's Mevacor – and Merck immediately acquired a temporary restraining order for a fuller hearing.

In May, [Eli Lilly & Co.](#) (LLY: down \$0.39 to \$73.63, [Research, Estimates](#)) lost an appeal on the approval of its top-selling anti-depressant Prozac, which had sales of \$2.5 billion last year.

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Lilly is still considering a rehearing or taking the matter to the Supreme Court, but is running out of time as [Barr Laboratories Inc.](#) (BRL: up \$1.07 to \$70.02, [Research, Estimates](#)) intends to launch its generic version on Aug. 2.

And AstraZeneca PLC is still in court battling for the patent to remain on the world's best-selling drug, ulcer treatment Prilosec, which had sales of \$6.5 billion last year.

But AstraZeneca also has a backup plan and has already put a successor to Prilosec, Nexium, on the shelves.

Pharmaceutical firms develop new versions of successful drugs – either chemical cousins that may be more potent or produce fewer side effects than the original, or combination therapies that use their product in conjunction with another compound to treat a different type of illness or that offer more effective treatment. The new products can't prevent the introduction of generic competition to the original brands, but they can help the companies retain patients who might be looking for the cheaper generic alternative.

[Schering-Plough Corp.](#) (SGP: down \$0.54 to \$36.44, [Research, Estimates](#)) is also trying to get ahead of the game with a successor to No. 1 allergy medicine Claritin, which is scheduled for patent expiry in 2002. The company put its hopes on a non-sedating antihistamine known as desloratadine to keep customers. ■

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