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## Big Money at Stake

Typically, generics take away about half of the U.S. sales of a branded drug during the first six months of competition. If Schering-Plough's metabolite defense can postpone generics for half a year, the company could gain as much as \$650 million in U.S. Claritin sales—most of which is profit.

The brand-name companies say that all they are doing is legitimately protecting their intellectual property and patients. But their maneuvering is one reason why the FDA typically takes longer to approve generic-drug applications than it does to certify more-complicated brand-name applications. Agency records show that last year, the median time for reviewing a generic drug was 18.2 months, or 63% longer than the 11.2 months it took for a brand-name to gain approval.

Brand-name companies file thick citizen petitions under 1977 federal regulations designed to allow anyone to raise concerns about the safety of a drug or other items the FDA is reviewing. A petition doesn't prevent the FDA from approving a new drug. But in practice, the agency tends to delay generic approvals, sometimes for six months or more, to scrutinize objections raised by brand-name companies. "We don't want to put a product out with some cloud hanging over it," says Mr. Buehler.

When brand-name companies go to court to impede the introduction of

copy-cat competitors, their key weapon is a federal statute that commands the FDA to delay for up to 30 months the approval of any generic if there is a dispute over a patent.

The 1984 law was intended to protect branded drugs during what were

An hour later, Bristol-Myers hand-delivered its new patent to the FDA, according to records later filed with the federal district court in Washington. The company informed the agency that it intended to use the metabolite patent to try to block the generics and requested that the FDA

### Delayed Reaction

Drug Manufacturers Step Up Legal Attacks  
That Slow Generics

That's One Reason It Takes The FDA Longer to Approve  
Knock-Offs Than Brands The "Metabolite Defense"

By Gardiner Haris and Chris Adams

Staff Reporters of THE WALL STREET JOURNAL

expected to be relatively unusual intellectual-property spats. But as name-brand makers have devised a broadening array of antigeneric legal theories, the number of disputes has increased sharply. (The FDA says it doesn't track how frequently it grants the 30 month delays)

### How Far Companies Will Go

On June 6, 2000, Bristol-Myers tried again. It told the patent office that it sought protection only for swallowing the metabolite, not BuSpar, to relieve anxiety. On Nov. 21 - the last day of BuSpar's monopoly - the patent office issued a patent for 6-hydroxy-buspirone. The timing, says Stephen Kunin, deputy patent commissioner, was pure chance.

delay approval of generic competitors for up to 30 months. The FDA agreed.

### A Contradiction

Bristol-Myers executives deny the company made any contradictory statements to the government or exaggerated the scope of any of its patents. "I really don't want to leave you with the thought that we told the patent office we wouldn't do something and then we went to the FDA with the opposite, because that did not happen," says Dr. Bodnar, the Bristol-Myers Vice President. He stresses that Bristol-Myers sent a letter to the patent office, stating that in the company's view, the metabolite patent application still covered swallowing BuSpar, even if those words didn't appear in the patent that was approved.