FTC probes drug patents

Suspect book listings are allegedly created to stall generic versions

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NEW YORK — The drug industry's bible, known as the orange book, might not make great reading but it's pretty good at inflaming passions.

With its official title, Approved Drug Products for Therapeutic Equivalents Evaluation, it's a stretch to even call it a book. It is a list of patents.

But those patents are at the heart of pharmaceutical profits, and company executives lean on it heavily — too heavily, according to generic manufacturers who accuse them of filling the book with invalid entries.

The Federal Trade Commission, investigating allegations of anticompetitive practices in the industry, is looking with particular interest into whether companies are improperly tagging new patents on existing medicines to keep generic brands off the market longer.

Earlier this month, the FTC inserted itself into a court case where two generic firms, 29 states and a coalition of consumer groups are accusing Bristol-Myers Squibb Co. of antitrust violations by listing a patent on its antianxiety drug BuSpar just before generic versions of the medicine were to be launched.

Also this month, the FTC deepened its inquiry into patent issues surrounding Prilosec, the world's best-selling ulcer medication made by AstraZeneca PLC.

The commission asked Kremers Urban Development Corp. for documents related to charges it has made that AstraZeneca improperly listed patents and is abusing the system, according to the company's lawyer, Nic Cerrito. AstraZeneca spokeswoman Rachel Bloom said the FTC also has asked the company for documents regarding Prilosec.

Kremers and three other generic companies are in a court battle with AstraZeneca over some of Prilosec's patents.

While acknowledging it has been investigating anticompetitive practices in the drug industry, the FTC won't comment on specifics. However, many of those familiar with the investigation say the commission's focus has shifted to studying whether drug companies are listing patents improperly to lengthen their products' life cycle by keeping generics at bay.

Previously, the inquiry seemed to focus on possible collusion between drug company and generic firms engaged in patent disputes that were settled through a licensing agreement or cash payout.

The FTC had filed complaints over three different deals where patent disputes were ended by the drug company paying a generic firm. Two were settled but a charge that Schering-Plough Corp. paid Upsher-Smith Laboratories and American Home Products Inc. to keep generic versions of K-Dur20, a potassium supplement, off the market is still pending. All three companies have denied wrongdoing.

Those types of agreements are said to have stopped.

"Those deals were easy for the FTC to target. The payments were easy to find," said Cerrito. "Nobody is really doing those anymore because they just look suspicious."

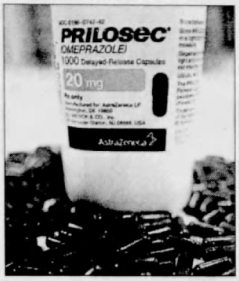
There are numerous lawsuits over whether drug companies are listing patents improperly and experts contend the multiple listings reflect a large wave of patent expirations that threaten profits.

About a third of prescription medicines in the United States, worth more than $30 billion in sales, will lose existing patent protection between 2000 and 2005, according to a study by UBS Warburg. Drugs under development won't provide enough income to make up for the loss, it said.

Listing new patents for existing drugs "is not new, but the drug companies are hitting the limit on it so the FTC is interested," said David Balto, a lawyer who worked for the FTC.

Experts say investigating patent listing is difficult because it is an arcane world made more complicated by the conflicting opinions of the drug companies.

The U.S. Patent Office approves drug patents which then are listed in the Food and Drug Administration's orange book. A generic manufacturer must wait for a patent to expire or provide evidence that its formulation of the medicine doesn't infringe on the innovator's patent. The pharmaceutical company can challenge that evidence and automatically block the generic substitute from the market for 30 months.



AP photo

AstraZeneca PLC, the maker of Prilosec, is being questioned by the FTC on patent issues about the medication.

The FTC filed a brief in the BuSpar case asserting that the antitrust charges against Bristol-Myers should not be dropped as the company requested.

The BuSpar case exemplifies the complications of patent listing and challenges. Last October, a U.S. Court of Appeals in Washington reversed the decision of a lower court that ended BuSpar's patent protection. The generic drug is already on the market and Bristol-Myers is exploring its legal options.

In its legal brief, the FTC pointed out that, in allowing patents to be listed in the orange book, "the FDA does not purport to evaluate the propriety of patent listings."

The FTC rarely enters lawsuits in this fashion, signalling how serious it considers the issue. "They realize there is a lot at stake," said Balto.

There are at least two orange book patent investigations the FTC has acknowledged. One is over patents listed on Paxil, an anti-depressant made by GlaxoSmithKline.

The other concerns Taxol, a breast cancer drug made by Bristol-Myers. According to the National Post in Canada, the FTC is also looking at Ontario-based Biovail Corp.'s patents on Tiazac, a hypertension treatment.