Competition Cops Zero In on Drug Makers

By Paul M. Rivard

With brand name drugs that account for combined U.S. sales of about $20 billion coming off patent within the next four years, the Federal Trade Commission has recently taken a highly visible role in examining the actions of drug manufacturers for anti-competitive conduct.

On April 23, the FTC announced its first complaint against and consent order with an innovator drug manufacturer for wrongfully listing a patent in the Food and Drug Administration's "Orange Book" in order to block generic competition. The complaint charges that to protect its market for Tiazac, a drug used to treat high blood pressure and chest pain, the Biovail Corp. acquired an exclusive patent license in violation of federal antitrust law and wrongfully caused the FDA to list that patent in the Orange Book.

The FTC's announcement was made by chairman Timothy Muris at a hearing on generic drug competition before the Senate Committee on Commerce, Science, and Transportation. At the hearing, Muris commended the overall success of the 1984 Hatch-Waxman Act, which has fostered both innovation in new drugs and competition by generic drugs. But he warned that some brand name manufacturers have abused the regulatory framework to secure greater profits for themselves while delaying the entry of generic drugs into the market.

Under the Hatch-Waxman Act, a generic manufacturer can obtain a 180-day period of generic-market exclusivity by filing a so-called Paragraph IV certification with its Abbreviated New Drug Application (ANDA). A Paragraph IV certification asserts that any patent listed in the Orange Book as covering the drug is invalid or not infringed by the generic. The patent holder, in turn, has 45 days to bring an infringement suit against the generic manufacturer. If a suit is not brought in this time frame, the FDA must approve the ANDA immediately. If the patent holder files suit, however, an automatic 30-month stay of FDA approval is triggered, and the generic manufacturer may not enter the market during this period unless the litigation is resolved in its favor.

These provisions of the Hatch-Waxman Act create a unique set of incentives for the innovator and generic drug manufacturer in reaching settlement agreements. In the FTC's view, they also create fertile soil for collusion.

While recognizing that such settlement agreements must be individually examined for anti-competitive effect, Muris has articulated three types of provisions that, in the FTC's judgment, raise red flags under the antitrust laws.

The first type involves "reverse" payments from the patent holder to the generic manufacturer. The FTC has characterized such payments as a potential "anticompetitive division of monopoly profits."

The second category of questionable provisions restricts the generic manufacturer's ability to introduce non-infringing products. According to the FTC, this improperly extends the boundaries of the original patent monopoly.

The third type restricts the generic manufacturer's ability to assign or waive its 180-day market exclusivity rights. The FTC's concern is that such agreements can further delay generic market entry and the resulting benefit of competitive drug pricing.

Joseph Simmons, director of the FTC's Bureau of Competition, said the Biovail consent order should be seen as evidence that the FTC is "concerned with the use of questionable Orange Book listings and subsequent patent infringement lawsuits to unfairly delay generic entry, as well as other tactics such as obtaining exclusive rights to another company's patent for anti-competitive use."

The FTC is conducting an industry-wide study of generic drug competition to assess industry practices under the Hatch-Waxman Act. (A broader ongoing series of joint hearings by the FTC and Justice Department on competition and intellectual property should continue through June.) The study is expected to be completed this summer and the results published in a report later this year.

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