

FTC Challenges Post-Closing Deal Too Small to Be Subject to the HSR Act

December 22, 2008

The Federal Trade Commission (FTC) has filed a complaint against Ovation Pharmaceuticals, Inc. (Ovation) in connection with its 2006 acquisition of a drug nearing FDA approval (NeoProfen). The FTC alleged that NeoProfen was the only potential competitor to Ovation's own marketed product (Indocin) used to treat a potentially life-threatening heart defect in premature babies called *patent ductus arteriosus* (PDA). According to the FTC complaint, after acquiring the rights to NeoProfen, Ovation raised the price of Indocin nearly 1300% from \$36 per vial to \$500 per vial and soon thereafter introduced NeoProfen at approximately the same price.

The FTC alleges that Ovation's acquisition of NeoProfen violates Section 7 of the Clayton Act and Section 5 of the FTC Act by *inter alia* eliminating the only price constraint on Indocin, to the detriment of hospitals, state Medicaid agencies, and other purchasers. The FTC seeks a divestiture of one of the products to restore the competition that was allegedly lost when Ovation acquired NeoProfen. The complaint also requests other equitable relief, including disgorgement of "all unlawfully obtained profits."

Within a day of the FTC filing its complaint, at least one class action has been filed against the parties raising similar claims. Such actions carry the risk of treble damages. If Ovation is ultimately found liable, the potential damages will likely exceed significantly the approximately \$45 million in annual sales attributable to these PDA products.

Noteworthy Lessons and Future FTC Enforcement Guide

Review of Non-HSR Reportable Deals. This case again demonstrates that the government can and does bring enforcement actions with respect to transactions that are too small to satisfy the above \$63.1 million size-of-transaction HSR Act test. Accordingly, antitrust counsel needs to assess the antitrust risks of such transactions pre-signing.

Review of Closed Transactions and Possible Rescission. The government can and will, under the appropriate circumstances, seek to unwind consummated transactions. The acquisition of NeoProfen took place nearly three years ago. Here the government is seeking divestiture of one of the two PDA products but also *rescission*, meaning the disposition of NeoProfen to Abbott Laboratories, the original owner.

Sellers and Not Just Buyers Are at Risk. Abbott Laboratories faces potential class action liability and the risk of rescission.

No Market Too Small. According to the complaint, there are 30,000 cases of PDA each year. The highest price that Ovation allegedly charged for its PDA therapies is \$500 per vial or \$1,500 for a full regimen. This suggests that PDA drug therapy is a \$45 million market and shows that the size of the relevant market generally does *not* matter, whereas the possibility of consumers being harmed, does.

Potential Competition Still Relevant. When Ovation acquired NeoProfen, the drug was not on the market, but was close to FDA approval. Although the success rate for bringing drugs to market is fairly low, this case shows that potential competition from drugs in development, especially when close to regulatory approval, must be considered in a substantive merger analysis. In sum, counsel must explore with the parties what is in the “pipeline.”

Notable Commissioner Commentary and Future FTC Enforcement Guide. The aggressive enforcement policies exhibited by the FTC in this case and over the last couple of years are likely to continue with the arrival of the Obama administration, which will be able to fill the current Commissioner vacancy and select a new chair. It is anticipated that the three most aggressive current Commissioners (Leibowitz, Rosch, Jones Harbour) will continue at the FTC at least until the end of Harbour’s term in September 2009. Assuming an activist Commissioner is selected to fill the remaining vacancy, four of the five Commissioners will have pro-enforcement leanings.

Two FTC Commissioners who will remain with the Commission wrote separate concurring statements that shed light on where the FTC is likely to head in the new administration. Commissioner Leibowitz, one candidate to chair the Commission, said that protecting competition in the healthcare industry “will continue to be a priority” for the FTC. Combined with statements that President-elect Obama made as a presidential candidate, it is clear that the new administration, with the FTC’s help, will be more active in reviewing antitrust issues in the healthcare industry. Commissioner Leibowitz also said that the FTC should use disgorgement of profits as a remedy more often.

Commissioner Rosch’s statement indicated that he was willing to challenge Ovation’s original acquisition of Indocin despite the stubborn fact that Ovation owned no competing drug at the time. The Commissioner stated that Merck, the original owner of Indocin, may have had reputational reasons (i.e., not offending purchasers of its numerous other products) for not raising the price of Indocin to a monopoly price even though it was the only product on the market. Ovation, according to the Commissioner, had no such reputational constraints. Therefore, according to Commissioner Rosch, “there is reason to believe” that the sale of Indocin to Ovation—which did not own a competing product—had the effect of eliminating the reputational constraints on Merck and thereby “had the effect of enabling Ovation to exercise monopoly power in its pricing of Indocin.” In support for his novel position, Commissioner Rosch cited cases from the 1960s which, although not overturned, belie fifty years of Chicago School economic theory and related antitrust legal precedent.

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