

2008 FTC Actions in the Drug Industry: An Annotated Summary

As much as any one or even series of court decisions, actions by the U.S. Federal Trade Commission shape the guidance given to brand-name drug manufacturers to ensure their compliance with antitrust law. What follows below are summaries of six FTC actions taken by the FTC so far in 2008, with brief discussions that seek to highlight their relevance to the industry.

I. Enforcement Actions

1. ***In the Matter of Sun Pharmaceutical Industries Ltd., File No. 071-0193; consent order relating to the acquisition of Taro Pharmaceutical Industries Ltd. ("Taro") by Sun Pharmaceutical Industries Ltd. ("Sun")***

On September 8, 2008, the FTC announced an enforcement action against Sun, and a vote to accept a consent order, that would call for the divestiture of three generic drugs in order to address alleged competitive concerns arising out of Sun's acquisition of Taro. At issue are immediate-release, chewable, and extended-release forms of carbamazepine, an anti-convulsant principally used in connection with the treatment of epilepsy. With respect to the first two dosage forms, Taro and Sun are two of the three and four approved manufacturers, respectively. Taro and Sun are also allegedly the only two manufacturers that the FTC's statement announcing acceptance of the consent order describes as "expected to enter the market" for the extended-release form pursuant to FDA approval of their ANDAs. The consent order, which was published for a thirty-day comment period, tentatively identifies Torrent Pharmaceutical Limited (like Sun and Toro, a foreign manufacturer) as an acceptable purchaser of the products.

The Commission's materials provide a good summary of the current economic orthodoxy applied by the agency regarding competition in generic drug markets. Specifically, the cornerstone of the Commission's analysis is the categorical assertion that generic drug pricing is directly related to the number of competitors in the market up to a rather large number of competitors. This conclusion followed from analyses conducted by FDA as well as the FTC itself,¹ one suspects precisely to be able to respond to arguments by respondents that deterring generic entry in one situation or another would not affect competition because some number of generics were already in the market. In addition, the FTC repeats its view that greenfield generic entry cannot be counted upon to remedy the alleged anticompetitive effects of an action, since drug development and approval could not be expected within the two-year horizon typically used for considering whether new entry will defeat anticompetitive concerns. Finally, reflecting its continuing interest in the development of the different theoretical bases for enforcement actions, the Commission asserts that the acquisition would raise both "coordinated" competitive concerns (that the remaining small number of firms would coordinate their pricing) and "unilateral" competitive concerns (that the merging parties would have been first and second choices in bidding situations).

For a more thorough description of the FTC's action, please see the Analysis of Agreement Containing Consent Orders To Aid Public Comment, the link to which may be found at: <http://www.ftc.gov/os/caselist/0710193/index.shtm>. We note that, as in any matter

involving a consent order, the theories relied upon will not have been tested in court, nor necessarily even much challenged by the parties, for which a divestiture (presumably at or near fair value) may be far less important than securing approval for the rest of the deal.

2. *In the Matter of Fresenius Medical Care Ag & Co. KgaA ("Fresenius")* FTC File No. 081-0146; consent order relating to the proposed acquisition of an exclusive sublicense from a wholly owned U.S. subsidiary of Daiichi Sankyo Company, Ltd. ("Daiichi")

Fresenius operates independent kidney dialysis centers in the United States. One drug used by such centers in substantial quantities is an intravenous iron sucrose preparation, currently sold in this country by Daiichi and Watson Pharmaceuticals Inc. The vertical license in question would grant to Fresenius the exclusive right to manufacture and sell Daiichi's product to independent dialysis centers (such as the ones Fresenius itself operates), leaving the rest of the market (hospitals, doctors' offices, and the like) still served by Daiichi. The Commission's complaint does not allege that competition, as such, would be injured in any way as to any purchaser of the Daiichi product as a result of the vertical agreement. Rather, it alleges as within the scope of Section 7 of the Clayton Act and Section 5 of the FTC Act that Fresenius, as a consequence of its dialysis centers not making open-market purchases, would have the ability and incentive to manipulate the reported purchase price to the Centers for Medicare and Medicaid Services ("CMS"), the effect of which would be to increase in the amount of the reimbursement that Medicare pays to the centers for dialysis services pursuant to formula based upon acquisition cost. (The FTC alleges no plan on the part of Fresenius to engage in such conduct.) The FTC states that approximately 80% of outpatient services are subject to reimbursement under Medicare Part B, and that intravenous iron, specifically, results in Medicare payments of \$400 million. By way of relief, the consent order would impose alternative mechanisms that would limit the acquisition cost for the drug that Fresenius could report to CMS.

Two aspects of the FTC's complaint and the proposed consent order warrant special notice. First, the complaint is not based upon an injury to competition in any conventional sense. Rather, it proceeds on the assumption that Fresenius' alleged ability (and incentive) to inflate the transfer price of the drug as among its subsidiaries, and thereby, through the operation of law, cause the drug's Medicare reimbursement to rise, causes an injury within the scope of the antitrust laws. There is, in other words, no aggrieved buyer suddenly without choices it previously had — usually as good a rough marker as one needs for an injury to competition. Indeed, the FTC notes that CMS regulations do not themselves provide for any relief on the facts as presented, certainly not the relief set out in the consent order.

Second, it is impossible to understand this decision without reference to the industry-wide litigation brought by federal and state governmental entities and private parties alleging fraud in connection with the Average Wholesale Price ("AWP") reported for medicines. The central allegation of the governmental cases is that Medicare and Medicaid authorities provided greater reimbursements as a result of misrepresentations about AWP and manipulative conduct allegedly engaged in by literally scores of drug manufacturers, essentially comprising the entire industry. The FTC specifically acknowledges the assistance of the CMS staff in helping it assess the "competitive implications" of the acquisition and the proposed remedy, and it is impossible to think that the undeniably aggressive jurisdictional approach taken by the FTC does not have least some roots in the larger fight being played out in courtrooms across the country.

For a more thorough description of the FTC's action, please see the Analysis of Agreement Containing Consent Orders To Aid Public Comment, the link to which may be found at: <http://www.ftc.gov/os/caselist/0810146/index.shtm>.

3. *FTC v. Cephalon, Inc. ("Cephalon"); complaint challenging settlements of patent infringement litigation.*

On February 13, 2008, the FTC sued Cephalon in U.S. District Court for the District of Columbia alleging that the drug manufacturer had entered into improper agreements with four potential generic competitors that had challenged Cephalon's patent for Provigil®, an \$800 million drug used in connection with the treatment of sleep apnea. The case was the latest salvo in the FTC's ongoing attack on patent infringement settlements in the drug area (see item II.2 below), and comes against the background of a number of unfavorable decisions having been reached from the FTC's standpoint, including in the Commission's own case against Schering-Plough.²

Two points warrant special mention. First, and somewhat unusually, the FTC brought the case not as an administrative action but in federal court, in the District of Columbia. The purpose of the move appeared to be to invite a conflict among the circuits in the event of a favorable (or even unfavorable) outcome, supporting a request for review by the U.S. Supreme Court. Even this purpose was frustrated in June, however, when the court in Washington ordered that the case be transferred to the Eastern District of Pennsylvania, where private litigation arising out of the same facts has been pending for more than two years. In his order transferring the case, Judge Bates specifically noted (at 16) that Commission was "rather openly shopping for a circuit split," and that it was "both odd and unreasonable" to seek one at the expense of exposing a defendant to the risk of inconsistent judgments."³

Second, the Commission's complaint elaborates upon the kinds of agreements that the agency believes violate the law. Since its subsequently-reversed decision in the *Schering-Plough* case, the Commission has taken the view that any patent settlement that results in a payment to the generic manufacturer in exchange for the manufacturer's agreement to defer the introduction of its product violates the law, and that in connection with this inquiry it was necessary to look not merely to the terms of the settlement but of any side agreements that were entered into by the parties in connection with the settlements. Such agreements — dealing with matters such as supply agreements and R&D ventures — were identified in the *Cephalon* complaint with respect to each of the potential generic entrants. With respect to three of the potential entrants the complaint alleges that the agreements did not reflect an arm's length transaction, so that their effect was essentially that of a payment. Significantly, however, no such allegation was expressly made with respect to a fourth payment, which was merely described as having been entered into as a means of providing additional compensation to the generic manufacturer. The FTC, at least so far as this complaint is concerned, has thus apparently left open for itself the argument that side deals that bring money to a generic manufacturer in settlement of patent litigation may be unlawful even where the deals reflect legitimate commercial terms. Whether this step was taken to be a message to industry, as a low-risk shot at winning a broad ruling, or just as filler in a complaint in which far more serious allegations were made, remains to be seen.

For copies of the complaint, the District of Columbia's order on transfer, and other materials, please visit this link: <http://www.ftc.gov/os/caselist/0610182/index.shtm>.

4. *In the Matter of Schering-Plough Corporation, File No.*

On January 4, 2008, the FTC made final a consent order that followed Schering-Plough's acquisition of Organon Biosciences N.V. from Akzo-Nobel N.V. The order required the divestiture of three live vaccines administered to poultry, and related technical support. The acquisition would allegedly leave Schering-Plough with 100%, 85%, and 72% of the sales of each vaccine, respectively. The Commission has preliminarily approved Wyeth as a purchaser of the vaccines, and appointed an "Interim Monitor Trustee" to oversee implementation of the orders' provisions. The Analysis to Aid Public Comment identifies the competitive concerns as solely unilateral.

For copies of materials relating to this action, please visit the following link:
<http://www.ftc.gov/os/caselist/0710132/index.shtm>.

II. Other Actions

1. DOJ Report on Monopolization Claims Under Section 2 of the Sherman Act, and Related FTC Responses

On September 8, 2008, the Department of Justice issued a 213-page report entitled “Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act,” which followed on joint hearings conducted by DOJ and the FTC in 2006 and 2007. The report was expected to reflect a joint statement of the two antitrust enforcement agencies, but the FTC pointedly failed to join in its issuance, with three commissioners publishing a strong critique of what they thought was a pro-monopolist report that did not fairly take into account the proper goals of Section 2 or accurately reflect governing law. Chairman Kovacic issued a separate statement that sought to put modern antitrust enforcement in an historical context, and to get beyond a debate over specific rules to address the larger social and economic forces that shape antitrust law, especially at the Supreme Court level.

The fact of the intra-familial dispute that underlies the competing DOJ and FTC statements has, unfortunately to some extent, taken the focus away from the content of the various documents. Together, those statements provide as good a snapshot of Section 2 issues as may be found, even if the reader must bring his or her own judgments to bear as to the likely resolution of disputed principles.

The DOJ report and the FTC statements may be found at these links:
<http://www.usdoj.gov/atr/public/reports/236681.htm> (DOJ report);
<http://www.ftc.gov/os/2008/09/080908section2stmt.pdf>
(statement of Commissioners Harbour, Liebowitz, and Rosch);
<http://www.ftc.gov/os/2008/09/080908section2stmtkovacic.pdf>
(statement of Chairman Kovacic).

2. Bureau of Competition Summary of Pharmaceutical Company Settlement Agreements.

On May 21, 2008, the FTC’s Bureau of Competition issued its Fiscal Year 2007 summary of agreements settling patent infringement litigation that had been filed pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. These annual reports have been a fascinating window on the changing ways in which the research-based drug industry has responded to the uncertainty regarding the lawfulness of settlements of patent challenges by generic drug manufacturers.

The report, which reflects settlements filed in the year ending September 30, 2007, describes thirty-three final settlements. In fourteen of those settlements, the FTC states that the generic company received compensation and was also limited in its ability to enter the market with its product. Whereas the FTC characterized most of the compensation paid to generics in its FY 2006 report as stemming from “side deals” of the type at issue in the *Cephalon* case discussed above, more recently the Commission identified the principal source of “compensation” (present in eleven of the fourteen settlements) as an agreement by the branded firm not to launch or sponsor an authorized generic. Only three of the final settlements assertedly contained side deals unrelated to the specific issues involved in the settlement.

The FTC press release describing the report, with a link to the report itself, may be found here: <http://www.ftc.gov/opa/2008/05/drug.shtm>.

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- ¹ The FTC's 2002 report by the Bureau of Economics, "Generic Drug Industry Dynamics," asserts that generic drug pricing will generally continue to decline with the number of generic entrants. Significantly, the report states (at 4) that beneficial competition may continue to occur even with the addition of an eighth generic entrant; "Generic prices decline with the number of producers and begin to approach long-run marginal cost when there are 8 or more competitors."
 - ² See *FTC v. Schering-Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006).
 - ³ The full text of the court's opinion can be found at the link set forth at the end of this section.