

## Another FTC Challenge to the Settlement of a Brand Name Drug Patent Infringement Case Clarifies Matters – A Bit

On February 1, 2009, the Federal Trade Commission brought another in its series of challenges to settlements of patent infringement suits filed by manufacturers of brand name drugs against potential generic entrants.<sup>1</sup> This one, the second such suit in less than a year, followed in the pattern set with the Commission's March 2008 case against Cephalon, Inc.,<sup>2</sup> which focused on side deals between the parties that allegedly provided compensation to the generic in exchange for an agreement to defer entry. The suit, and the concurring statement of the Commission's likely new Chairman, make clear that it will take more than the increasing number of adverse decisions of courts of appeals to cause the FTC to reconsider its view of the law or its litigation strategy. But the outlines of that strategy may be becoming clearer, offering a welcome if modest measure of predictability to brand name drug companies looking for creative and lawful options to settle patent cases.

### The Complaint

The case involves AndroGel<sup>®</sup>, a branded synthetic testosterone replacement drug sold by Solvay Pharmaceutical, Inc. ("Solvay"). AndroGel<sup>®</sup> is the subject of a formulation patent licensed from Besins Healthcare, S.A. (with affiliates, "Besins") that expires in 2020. In May 2003, Abbreviated New Drug Applications ("ANDAs") to sell generic copies of AndroGel<sup>®</sup> were submitted first by Watson Pharmaceuticals, Inc. ("Watson") and then by Paddock Laboratories, Inc. ("Paddock"). Both Watson and Paddock submitted "Paragraph IV" certifications with their ANDAs, taking the position that their products would not infringe the Besins/Solvay patent, or that the patents were invalid.

Pursuant to the provisions of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, which govern the approval of generic drugs, Solvay and Besins initiated patent infringement lawsuits against Watson and Paddock in August 2003. The filing commenced automatic stays of FDA approvals of the Watson and Paddock ANDAs. In late January 2006, the FDA approved Watson's ANDA. Solvay did not seek a preliminary injunction, but instead engaged in settlement discussions with Watson and Paddock (and Paddock's partner, Par Pharmaceuticals, Inc., to which Paddock agreed to give a portion of its expected profits in exchange for financial support in the litigation). The discussions ultimately led to a settlement having the following principal terms:

- Watson and Solvay agreed that Watson could enter the market with its generic no later than 2015 — five years ahead of the expiration of the patent covering AndroGel<sup>®</sup>;
- Solvay entered into a co-promotion agreement with Watson pursuant to which Watson would promote AndroGel<sup>®</sup> to urologists and receive a share of the profits on the sale of the drug;
- Watson and Par/Paddock agreed that Par/Paddock could also enter the market with its generic no later than 2015;
- Solvay entered into a co-promotion agreement with Par pursuant to which Par would promote AndroGel<sup>®</sup> to primary care doctors and receive \$10 million per year for six years;
- Solvay also entered into a back-up manufacturing agreement with Par, the terms of which were not disclosed; and
- The patent infringement action would be dismissed with prejudice.

In a suit filed jointly in federal court in Los Angeles, the FTC and the State of California alleged that these terms essentially reflected an agreement by competitors not to compete in exchange for a division of the unlawful monopoly profits that would accrue from the continued sale of AndroGel<sup>®</sup> through 2015. The complaint alleges that Solvay was unlikely to prevail in its patent infringement suit, leaving the financial consideration provided in the agreements described above as the reason for the settlement. Moreover, the complaint alleges that Solvay planned a brand extension that would lure a substantial number of current users of AndroGel<sup>®</sup> away from the product set to receive generic competition to a new product that would continue to enjoy patent protection.

### Discussion

As in its complaint against Cephalon, the Commission has chosen to file suit in federal court, rather than in an administrative proceeding, and in a circuit (the Ninth) with no governing precedent regarding the lawfulness of “reverse payment” settlements of brand name drug patent infringement litigation. In the *Cephalon* case, Commissioner Leibowitz so much as said publicly that the action had been taken with hopes of provoking a circuit split and ultimate review by the Supreme Court;<sup>2</sup> here, that is left to one’s informed speculation as a reason for the suit. One difference between the cases is the addition of the State of California as a plaintiff, and claims under California’s antitrust statute, the Cartwright Act,<sup>4</sup> and its Unfair Competition Act.<sup>5</sup> This may well be an extension of the trend in which states, for whatever reason, join in what are clearly federal antitrust suits.<sup>6</sup>

For present purposes, we find of most interest the reasons why the plaintiffs allege that the side deals violate the law. The Complaint’s legal analysis proceeds under the heading, “Solvay paid Watson and Par/Paddock through business deals that made sense only when linked to deferred generic entry,”<sup>7</sup> suggesting, if only in conclusory form, that none of the deals reflected arm’s-length terms. By way of further explanation, the Complaint alleges (¶ 82) that the co-promotion deals between Solvay and Watson and Par are unlawful because they are not “independent business transactions” – a term that is not defined. In support of this characterization, however, the Complaint provides five grounds, only two of which are not completely redacted. The first expressly asserts that the payments made by Solvay “far exceed the value of the services provided” by Watson and Par. The other claims that terms of the deals “depart from industry standards.”

The Complaint (¶ 84) makes a similar allegation with respect to the back-up manufacturing deal between Solvay and Par. Again, the Complaint claims the deal is not an “independent business transaction” and provides three reasons in support, all of which are redacted.

A critical question posed by its continuing attack on settlements based on side deals is whether the FTC believes that illegality attaches only to side deals that *overpay* the generic – ones that are essentially shams used to funnel unearned compensation in exchange for a decision not to compete. The question has tremendous practical significance. Brand name drug manufacturers may have a wide range of arm’s-length transactions that they can choose to enter into with a generic as an inducement to settle a dispute. If it were clear that such actions would not in and of themselves create an unreasonable risk of attack or liability, litigation might be resolved sooner and with less cost, and companies committed to compliance with law might avoid the expense and disruption of defending against antitrust claims.

To date, all of the other patent settlements challenged by the FTC have likewise contained provisions alleged essentially to be shams.<sup>8</sup> *Cephalon* was notable in that one of the four side deals alleged to be unlawful did not contain such an express allegation.<sup>9</sup> But as an alternative ground for relief, that deal was of marginal significance. Despite the extensive redactions of the Complaint, it is clear that the case against Solvay is no exception to the observation that the FTC has only to date challenged settlements based on side deals alleged not to have reflected legitimate commercial terms.

### Conclusion

Perhaps we have reached a point where counsel may assume with a reasonable measure of confidence that the FTC will only choose to challenge patent settlements where either a cash payment is made to the generic, or a side deal is agreed to that provides compensation to the

generic alleged to be in excess of fair value. Whatever calculus was employed by the FTC in choosing the Solvay settlement to attack from among others,<sup>10</sup> it is a safe bet that the FTC has been choosing cases that it believes present the most favorable facts and that can be won at trial. Challenging arm's-length side deals would give the defendants very substantial defenses.

In his concurring statement, Commissioner Leibowitz, President Obama's nominee to be FTC Chairman, said that "[e]liminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today." This goes a long way to explaining the FTC's dogged pursuit of a legal theory that has now been rejected by several courts of appeal, and even by the Department of Justice. This approach may be considered noble or lawless, depending upon one's point of view. It is very much in keeping with that agency's view of itself, however, so clearly expressed in its criticism of DOJ's September 2008 report on Monopolization,<sup>11</sup> as answerable only to its own higher notions of a competitive marketplace. But none would argue that so much uncertainty in the law is a good thing; the absence of clear rules raises costs and pushes conduct towards the lowest common competitive denominator. With every indication that the FTC will maintain its view on this issue, it is hard to see the debate being resolved any time soon, and with anything less than intervention by the Supreme Court (or the legislative change that the FTC has also been advancing). Until then, brand name drug manufacturers might well consider whether the zone of risk has at last become well enough defined that a careful legal and factual analysis might allow them either to avoid the risk or fully appreciate it and take steps to be able to defend themselves.

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1. *Federal Trade Commission, et al. v. Watson Pharmaceuticals, Inc., et al.*, Case No. CV 09-598 (C.D. Cal. Complaint filed January 27, 2009).
  2. *Federal Trade Commission v. Cephalon, Inc.*, Civil Action No.: 08-cv-2141 (Complaint filed February 13, 2008).
  3. *Federal Trade Commission v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 30 n.5 (D.D.C. 2008).
  4. Cal. Bus. & Prof. Code §§ 16700, *et seq.*
  5. Cal. Bus. & Prof. Code §§ 17200, *et seq.*
  6. Another example is the Commission's recent suit against Ovation Pharmaceuticals, Inc. arising from the latter's acquisition of a drug from Abbott Laboratories. See *FTC v. Ovation Pharmaceuticals, Inc.*, 08-cv-6379 (JNE/JJG); *State of Minnesota v. Ovation Pharmaceuticals, Inc.*, 08-cv-6381 (JNE/JJG) (related cases).
  7. Complaint, Section VI.C (preceding ¶¶ 81-85).
  8. *FTC v. Schering-Plough Corp.*, 402 F.3d 1056, 1062 (11th Cir. 2005); *Cephalon*, Complaint for Injunctive Relief ¶¶ 60-76, available at <http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf>.
  9. *Cephalon*, Complaint for Injunctive Relief at ¶¶ 69-71 (as regards settlement with Mylan Pharmaceuticals Inc.).
  10. For fiscal year 2007, the FTC has stated that 14 of 32 final settlements of brand name/generic drug patent infringement suits provided for payments to be made to the generic and a restriction on the generic's entry. In 3 of the 14, such compensation was described as being provided by a side deal involving elements not directly related to the resolution of the patent dispute. See "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003/Summary of Agreements Filed in FY 2007/A Report by the Bureau of Competition" at 3, available at: <http://www1.ftc.gov/os/2008/05/mmaact.pdf>.
  11. See statement of Commissioners Harbour, Liebowitz, and Rosch, available at: <http://www.ftc.gov/os/2008/09/080908section2stmt.pdf>.

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