

Federal Trade Commission v. Warner Chilcott Holdings Company III

22 January 2007

United States District Court for the District of Columbia
Civil Action No. 05-2179 (CKK) (D.D.C. Jan. 22, 2007)

Prepared by UNCTAD's Intellectual Property Unit

Summary

The case concerns liability of parties for anticompetitive behavior, more specifically for pay-for-delay agreements. Even though Barr's anticompetitive agreement with Warner Chilcott was later dissolved, the District Court upheld the FTC's complaint, which sought to prevent Barr from engaging in similar conduct in the future.

The facts

The defendants, Barr Pharmaceuticals and Warner Chilcott, entered into an agreement in which Barr agreed not to sell the generic version of Warner Chilcott's oral contraceptive, Ovcon 35, in the United States during five years for \$20 million. The plaintiff, the Federal Trade Commission (hereinafter 'FTC'), filed a complaint in a federal district court, claiming that this horizontal agreement was anticompetitive. The FTC sought to not only enjoin the defendants from operating under their agreement, but also to enjoin them from engaging in similar and related conduct in the future. Subsequent to the filing of the FTC's complaint, a number of events occurred: (1) Warner Chilcott launched a chewable version of the contraceptive and irrevocably waived all exclusivity provisions in the agreement with Barr; (2) Barr launched a generic version of Ovcon 35; and (3) Warner Chilcott entered into a settlement agreement with the FTC prohibiting it from entering into any agreements of the same type as the one concluded with Barr. Following these events, Barr filed a motion to dismiss the FTC's complaint, arguing that the action was moot.

The legal issues

The District Court examined by referring to case law whether the FTC's case had been rendered moot by the events subsequent to the filing of the FTC's complaint. The District Court found that:

- A case is moot when two conditions are met: (1) there is no reasonable expectation that the violation will recur; (2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation.¹ In other words, this means that all the issues in a case are no longer 'live' or that the parties lack a legally cognizable interest in the outcome.² However, voluntary cessation of allegedly illegal conduct does not moot a case because it leaves the defendant free to return to his old ways.³ Moreover, courts are generally reluctant to find a case moot because there is a public interest in having the legality of practices settled.⁴

¹ *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979).

² *Ibidem*.

³ *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953).

⁴ *Idem*, 632, 633.

- A case might become moot if a *subsequent event* made it absolutely clear that the allegedly wrongful behavior *could not reasonably be expected to recur*.⁵ However, the test for mootness in such cases is stringent and the heavy burden of demonstrating mootness lies with the party asserting it.⁶
- In the present case, there was no doubt that Barr would not enter into the same type of agreement again with Warner Chilcott. Warner Chilcott waived the exclusivity provisions of the agreement with Barr and agreed not to enter into similar agreements in the future while Barr introduced its generic version of Ovcon 35. However, the FTC’s complaint was going beyond the agreement between Barr and Warner Chilcott. It encompassed *similar and related conduct*, i.e. other agreements of the same nature as the one concluded between Barr and Warner Chilcott.
- In determining whether a case is moot or not, the concern is with repeated violations of the same law and not only the repetition of the same offensive conduct.⁷ Unlike Warner Chilcott, Barr did not enter into a settlement agreement with the FTC preventing it from engaging in ‘similar and related conduct’. Barr thus remained free to enter into this type of agreement in the future with other companies. Furthermore, the context that gave rise to Barr’s agreement with Warner Chilcott is not unique to Ovcon 35. In fact, Barr had at that particular time pending applications seeking Food and Drug Administration (“FDA”) approval to market generic versions of branded products where patent protection had expired.
- As a consequence, Barr failed to carry its heavy burden of demonstrating that the conduct at issue could not reasonably be expected to recur. On the contrary, Barr maintained that the agreement with Warner Chilcott was entirely lawful. Based on Barr’s belief that the agreement was lawful together with its freedom to enter into similar agreements in the future, it was not ‘absolutely clear’ that the challenged conduct would not repeat itself.

The District Court concluded that the case was not mooted by the events subsequent to the filing of the FTC’s complaint. It therefore denied Barr’s motion to dismiss.

Points of significance

- The agreement between Warner Chilcott and Barr constitutes an example of ‘product hopping’, also called ‘evergreening’: while Warner Chilcott entered into an agreement with Barr to delay the generic entry of Ovcon 35, Warner Chilcott planned in parallel to introduce a chewable form of Ovcon 35 and to stop selling regular Ovcon 35 in order to convert its customers to the new product. This strategy could have prevented generic substitution since regular Ovcon 35 would no longer have been available at the pharmacy.
- This case demonstrates the difficulties that pharmaceutical undertakings face when attempting to get rid of a horizontal agreement that prevents generic competition. One of the parties entered into a settlement agreement with the FTC prohibiting it from entering these types of agreement, and therefore escaped liability. The other party that did not settle with the FTC could not escape liability by relying on the mootness of the case due to the

⁵ United States v. Concentrated Phosphate Export Assn., 393 U.S. 199, 203 (1968).

⁶ Friends of the Earth, Inc. v. Laidlaw Env’tl. Servs, 528 U.S. 167, 189 (2000).

⁷ TRW, Inc. v. Fed. Trade Comm’n, 647 F.2d 942, 953 (9th Cir. 1981).

other party's settlement agreement with the FTC, for the termination of the anticompetitive agreement at stake or for having launched generic version of the product at stake.

- Courts are reluctant to find a case moot, but they can do so when there is no reasonable expectation that the violation will recur, or if the events have completely and irrevocably eradicated the effects of the alleged violation.
- A substantive opinion on the relationship between pay-for-delay agreements and competition law was provided by the US Supreme Court in the *Actavis* case (see case summary, *Federal Trade Commission v Actavis*, 570 U.S 2013)

Key words:

Antitrust, generic competition, FTC's settlement agreement, moot, horizontal agreement, product hopping.

Available at:

http://www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_05-cv-02179/pdf/USCOURTS-dcd-1_05-cv-02179-0.pdf