UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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| FEDERAL TRADE COMMISSION,<br><br>Plaintiff,<br><br>v.<br><br>WARNER CHILCOTT HOLDINGS COMPANY III, LTD., *et al.*,<br><br>Defendants. | Civil Action No. 05-2179 (CKK) |

**MEMORANDUM OPINION**
(January 22, 2007)

Currently before the Court is Defendant Barr Pharmaceuticals, Inc.'s ("Barr") motion to dismiss as moot the First Amended Complaint in this action, brought by Plaintiff, the Federal Trade Commission ("FTC"). The FTC's First Amended Complaint alleges that Barr and Defendant Warner Chilcott[1] entered into an anticompetitive agreement (hereinafter the "Final Agreement") whereby Barr granted Warner Chilcott an exclusive license to Barr's Abbreviated New Drug Application for a generic version of Warner Chilcott's Ovcon 35 oral contraceptive product. The First Amended Complaint seeks to enjoin Barr and Warner Chilcott from operating under that exclusive license, and further seeks to enjoin Barr and Warner Chilcott from engaging in similar and related conduct in the future. Subsequent to the filing of the First Amended Complaint, a number of events occurred: (1) Warner Chilcott launched a chewable version of Ovcon 35 and irrevocably waived all exclusivity provisions in the Final Agreement with Barr; (2)

[1] The Court shall collectively refer to Defendants Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott (US) Inc., and Warner Chilcott Company, Inc., as "Warner Chilcott".

Barr launched a generic version of Ovcon 35; and (3) Warner Chilcott entered into a Settlement Agreement with the FTC and the Court entered a Final Order and Stipulated Permanent Injunction in this action, which bars Warner Chilcott from entering into any agreements of the same type as the Final Agreement with Barr or any other company. Barr argues that these events render the FTC's case moot because there is no justiciable case or controversy for this Court to address and no relief that can be granted.

Upon a searching review of Barr's motion to dismiss, the FTC's opposition, Barr's reply, the relevant statutes and case law, and the entire record herein, the Court shall deny Barr's motion to dismiss, concluding that this action is not rendered moot by the events described above.

## I: BACKGROUND

### *A. Allegations Contained in the FTC's First Amended Complaint*

The FTC filed its First Amended Complaint against Defendants Barr and Warner Chilcott on December 2, 2005. According to the FTC, Defendant Barr's business, among other things, includes developing, manufacturing, marketing, and distributing generic oral contraceptive products. First Am. Compl. (hereinafter "Compl.") ¶ 18. Defendant Warner Chilcott Holdings Company III, Ltd., through its direct and indirect subsidiaries (including the three named as Defendants in this action), discovers, develops, manufactures, and distributes pharmaceutical products in the United States, including the oral contraceptive product Ovcon 35 (hereinafter "Ovcon"). *Id.* ¶¶ 11-16.

Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman

Act) and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) (2005), a company seeking to market a new branded drug must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product. Compl. ¶¶ 19-20 (citing 21 U.S.C. § 355(b) (2005)). An "AB-rated" generic drug is one that the Food and Drug Administration ("FDA") has determined to be bioequivalent to a branded drug, and a company seeking to market an AB-rated generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. *Id.* ¶¶ 21-22 (citing 21 U.S.C. §§ 355 (j) and 355 (j)(8)(B) (2005)). According to the FTC, almost all states and the District of Columbia encourage generic competition through laws and policies that facilitate pharmacies' substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs. *Id.* ¶¶ 24-25. Furthermore, the FTC maintains, as a result of lower prices and the ease of substitution, many consumers switch from a branded drug to an AB-rated generic drug when a generic is introduced, such that AB-rated generic drugs typically promptly capture a significant share of their branded counterparts' sales, and competition from generic drugs results in large savings for consumers *Id.* ¶¶ 26-27.

Ovcon was originally approved by the FDA in 1976 and is not currently subject to patent protection. *Id.* ¶ 28. Warner Chilcott acquired Ovcon from Bristol-Myers Squibb Company on January 26, 2000, at which point Bristol-Myers Squibb Company agreed to supply Ovcon to Warner Chilcott. *Id.* According to the FTC, Ovcon is, and has been, one of Warner Chilcott's highest revenue-producing products, with net sales for the twelve months ending September 30, 2004 of approximately $71.5 million. *Id.* ¶ 32. The FTC further alleges that Warner Chilcott sells Ovcon at a price substantially above Warner Chilcott's cost of acquiring the product, and

that Ovcon's net dollar sales have more than doubled since 2000, even as Warner Chilcott has raised Ovcon's price. *Id.* ¶¶ 29-31.

Barr filed an ANDA with the FDA for approval to manufacture and sell an AB-rated generic version of Ovcon in September 2001 and, in January 2003, publicly announced its intention to market a generic version of Ovcon by the end of 2003. *Id.* ¶¶ 33-34. According to the FTC, Barr planned to price generic Ovcon at approximately 30 percent less than the price that Warner Chilcott then charged for branded Ovcon, and Barr projected that generic Ovcon would capture approximately 50 percent of Warner Chilcott's branded Ovcon sales within the first year of introduction. *Id.* ¶¶ 35-36. The FTC alleges that Warner Chilcott calculated that, as a result of Barr's generic Ovcon, Warner Chilcott's net revenues from the sale of branded Ovcon would decline by at least $100 million over a three year period. *Id.* ¶ 37. The FTC claims that in response, Warner Chilcott planned to introduce a chewable form of Ovcon ("Ovcon Chewable") before Barr introduced its generic Ovcon, to convert Warner Chilcott's Ovcon customers to Ovcon Chewable, and to stop selling branded Ovcon. *Id.* ¶ 38. However, the FTC alleges, by mid-2003 Barr's generic Ovcon entry appeared imminent, Ovcon Chewable had not obtained FDA approval, and Warner Chilcott's chief financial officer warned the company's Board of Directors that generic Ovcon entry was "the biggest risk to the company." *Id.* ¶¶ 40-41.

The FTC further alleges that in "August 2003, Warner Chilcott and Barr discussed a possible business arrangement under which Barr would agree to refrain from competing in the United States with its generic Ovcon product." *Id.* ¶ 43. According to the FTC, on September 10, 2003, Warner Chilcott and Barr executed a letter of intent, which provided that Warner Chilcott would pay Barr $20 million and that Barr would agree not to compete in the United

States with its generic Ovcon for five years after receiving final FDA approval of its ANDA, but instead would agree to be available as a second supplier of Ovcon to Warner Chilcott upon request. *Id.* ¶ 44. The FTC alleges that in February 2004, the FTC notified Defendants that it intended to investigate the agreement outlined in the letter of intent "because of its potential to significantly reduce competition by eliminating the only generic alternative to Ovcon." *Id.* ¶ 45. Thereafter, on March 24, 2004, Warner Chilcott and Barr signed a Final Agreement, which implemented the letter of intent. *Id.* ¶ 46. Warner Chilcott paid Barr $1 million upon the signing of the Final Agreement and, within 45 days of the FDA's approval of Barr's generic Ovcon ANDA, Warner Chilcott could elect to pay the remaining $19 million to secure the exclusive license to Barr's ANDA for generic Ovcon for five years. *Id.* ¶¶ 46-48. In addition, according to the FTC, the Final Agreement gave Warner Chilcott the ability to purchase Ovcon supply from Barr, pursuant to specified payment terms. *Id.* ¶ 48. The FTC alleges that both Defendants "understood that if, upon receiving FDA approval, Barr went ahead and entered the market with its generic Ovcon product, Warner Chilcott's Ovcon supply needs would immediately be drastically reduced." *Id.*

The FDA approved Barr's ANDA for generic Ovcon on April 22, 2004 and, as of the date of the FTC's First Amended Complaint, Barr remained the only company that had received approval from the FDA to make an AB-rated generic version of Ovcon. *Id.* ¶¶ 49, 57. The FTC alleges that, upon receiving FDA approval for its ANDA for generic Ovcon, "Barr had the desire, intent, and capability to market generic Ovcon in the United States." Indeed, the FTC asserts, Barr publicly announced on April 23, 2004 that it intended to market generic Ovcon if Warner Chilcott did not exercise its exclusive license option. *Id.* ¶¶ 50-51. On May 6, 2004, Warner

Chilcott exercised the exclusive license option and paid Barr $19 million. *Id.* ¶ 52. Thereafter, according to the FTC, Warner Chilcott continued to purchase Ovcon solely from Bristol-Myers Squibb Co., until about May 2005. *Id.* ¶ 53.

The FTC alleges that, under the terms of the Final Agreement, Barr cannot sell generic Ovcon in the United States until approximately May 2009, but that, absent the Final Agreement, "Barr would have started selling generic Ovcon shortly after receiving final FDA approval in April 2004." *Id.* ¶ 54. The FTC asserts that the introduction of Barr's generic Ovcon into the United States "would have quickly and significantly reduced the sales of Warner Chilcott's branded Ovcon, and led to a significant reduction in the average price purchasers paid for Ovcon," and that Defendants' Final Agreement deprives consumers of the choice of purchasing lower-priced generic Ovcon instead of higher-priced branded Ovcon. *Id.* ¶¶ 55, 60. The FTC describes the Final Agreement as a "horizontal agreement not to compete," which "on its face eliminates competition and has no plausible procompetitive justification," and is therefore "a naked restraint of trade." *Id.* ¶ 62. The FTC asserts that the Final Agreement is not ancillary to any procompetitive undertaking and that any purported procompetitive benefits of the Final Agreement could have been achieved "through means appreciably less restrictive of competition than preventing competition from Barr's generic Ovcon for five years." *Id.* ¶ 65. The FTC further alleges that the Final Agreement is anticompetitive because its "purpose and effect" is to prevent Barr, the only maker of an FDA-approved generic Ovcon product, from offering its product to consumers, and that many purchasers are paying higher prices in the market for Ovcon than would otherwise prevail absent the Final Agreement. *Id.* ¶ 66.

The FTC thus claims that "by entering into this illegal horizontal agreement not to

compete, defendants Warner Chilcott and Barr have engaged, and are engaging, in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act." *Id.* ¶ 67 (citing 15 U.S.C. § 45 (2005)). As relief for this alleged violation, the FTC seeks (1) a declaration that the Final Agreement violates Section 5 of the FTC Act, 15 U.S.C. § 45(a); (2) a permanent injunction preventing Warner Chilcott and Barr "from maintaining or enforcing their agreement not to compete . . . and from engaging in similar and related conduct;" and (3) "such other equitable relief as the Court finds necessary to redress and prevent recurrence of defendants' violation of Section 5(a) of the FTC Act." *Id.*, Section X, ¶¶ 2-3.

*B. Events Subsequent to the Filing of the FTC's First Amended Complaint*

On September 25, 2006, after learning that Warner Chilcott had told customers that it planned to replace regular Ovcon with Ovcon Chewable, the FTC filed a motion for a preliminary injunction seeking to keep regular Ovcon on the market. FTC Opp'n to Def. Barr's Mot. to Dismiss FTC Compl. as Moot (hereinafter "FTC Opp'n") at 1. Also on September 25, 2006, Warner Chilcott executed a waiver terminating the exclusivity provisions of the Final Agreement. *Id.*; Ex. A (9/26/06 Press Release, Warner Chilcott, *The FTC Files a New Motion in Connection with Ongoing Ovcon Litigation*). On September 26, 2006, Barr announced that it would introduce its generic version of Ovcon in October 2006. Barr Mot. to Dismiss FTC Compl. as Moot (hereinafter "Barr Mot. to Dismiss"); Ex. B (9/26/06 Press Release, Barr Pharmaceuticals, Inc., *Barr Announces Warner Chilcott Waives Exclusive License for OVCON®) 35*).

As a result, on October 5, 2006, Barr filed the instant motion to dismiss. In that motion to dismiss, Barr argues that Warner Chilcott's waiver of exclusivity moots the FTC's case

because the FTC's First Amended Complaint "alleges that the Defendants' [Final Agreement] was anticompetitive ***because*** Barr granted an ***exclusive*** license (to its ANDA for generic Ovcon) to Defendant Warner Chilcott" and seeks "a Court order rendering the Defendants' [Final Agreement] ***non-***exclusive." Barr Mot. to Dismiss at 1 (emphasis in original). Barr argues that there remains no relief that can be granted by the Court and the FTC's case must therefore be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1). *Id.* at 2. The FTC filed its Opposition to Barr's motion to dismiss on October 20, 2006, arguing that a live controversy remains because the FTC "has asked the Court not only to enjoin the defendants from maintaining their agreement not to compete with regard to Ovcon, but also to prevent them from engaging in 'similar and related conduct,' and to provide other necessary equitable relief to prevent recurrence of the defendants' violation of law." FTC Opp'n at 2 (citing Compl., Section X, ¶¶ 2-3). The FTC further argues that Barr has not met its "heavy burden" of demonstrating that Barr's voluntary cessation of allegedly illegal conduct moots this case. *Id.* at 3.

On October 23, 2006, the Court approved a Settlement Agreement between the FTC and Warner Chilcott and entered a Final Order and Stipulated Permanent Injunction. The Final Order and Stipulated Permanent Injunction describes the nature of the Final Agreement, provides that Warner Chilcott has waived the exclusivity provisions of the Final Agreement, and "requires Defendant Warner Chilcott to refrain from entering into similar agreements in the future." *Federal Trade Commission v. Warner Chilcott Holdings Company III, Ltd., et al.*, Civil Action No. 05-2179, Final Order and Stipulated Permanent Injunction, October 23, 2006. Thereafter, on October 30, 2006, Barr filed its Reply in Support of its Motion to Dismiss (hereinafter "Barr Reply"), in which it argues that the Court's approval of the Settlement Agreement and entry of

the Final Order and Stipulated Injunction provides further support for Barr's claim that the FTC's case is moot, and further argues that the FTC's request that this Court enjoin Defendants from engaging in "similar and related conduct" is not sufficient to sustain a live controversy. Barr Reply at 1-2.

## II: LEGAL STANDARDS

A court must dismiss a case when it lacks subject matter jurisdiction pursuant to Rule 12(b)(1). In general, a motion to dismiss under Federal Rule of Civil Procedure 12(b) should not prevail "unless plaintiffs can prove no set of facts in support of their claim that would entitle them to relief." *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994) (citing *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)). A court may appropriately dispose of a case under 12(b)(1) for standing, and may "consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Coalition for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003) (citations omitted); *see also Artis v. Greenspan*, 223 F. Supp. 2d 139, 152 n.1 (D.D.C. 2002) ("A court may consider material outside of the pleadings in ruling on a motion to dismiss for lack of venue, personal jurisdiction or subject matter jurisdiction."); *Vanover v. Hantman*, 77 F. Supp. 2d 91, 98 (D.D.C. 1999) ("where a document is referred to in the complaint and is central to plaintiff's claim, such a document attached to the motion papers may be considered without converting the motion to one for summary judgment") (citing *Greenberg v. The Life Ins. Co. of Virginia*, 177 F.3d 507, 515 (6th Cir. 1999)). At the stage in litigation when dismissal is sought, the plaintiff's complaint must be construed liberally, and the plaintiff should receive the benefit of all favorable inferences that can be drawn from the alleged facts.

*EEOC v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997). In spite of the favorable inferences that a plaintiff receives on a motion to dismiss, it remains the plaintiff's burden to prove subject matter jurisdiction by a preponderance of the evidence. *Am. Farm Bureau v. Envtl. Prot. Agency*, 121 F. Supp. 2d 84, 90 (D.D.C. 2000).

**III: DISCUSSION**

Barr argues that the FTC's case has been rendered moot by (1) Warner Chilcott's waiver of the exclusivity provisions of the Final Agreement that Barr asserts "formed the sole basis for the FTC's action;" (2) Barr's introduction of its generic version of Ovcon; and (3) this Court's approval of the Settlement Agreement and entry of the Final Order and Stipulated Permanent Injunction, which prevents Warner Chilcott from entering into similar agreements with Barr in the future. Barr Reply at 1. The FTC responds by asserting that its case is not moot because the First Amended Complaint seeks not only to enjoin Defendants from maintaining the exclusivity provisions of the Final Agreement, but also seeks to prevent Barr from engaging in "similar and related conduct." The FTC further asserts that Barr has not carried its heavy burden of demonstrating that Barr's voluntary cessation of its allegedly illegal activities moots this case. FTC Opp'n at 2-3.

"It is well settled that federal courts may act only in the context of a justiciable case or controversy" and that this Court's "lack of jurisdiction to review moot cases derives from . . . Article III of the Constitution." *Sec. and Exch. Comm'n v. Med. Comm. for Human Rights*, 404 U.S. 403, 407, 92 S. Ct. 577, 30 L. Ed. 2d 560 (1972) (citations omitted). "Simply stated, a case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *County of Los Angeles v. Davis*, 440 U.S. 625, 631, 99 S. Ct. 1379, 59

L. Ed. 2d 642 (1979) (citing *Powell v. McCormack*, 395 U.S. 486, 496, 89 S. Ct. 1944, 23 L. Ed. 2d 491 (1969)). Thus, when two conditions are satisfied: (1) "it can be said with assurance that there is no reasonable expectation that the alleged violation will recur;" and (2) "interim relief or events have completely and irrevocably eradicated the effects of the alleged violation" – a case is moot "because neither party has a legally cognizable interest in the final determination of the underlying questions of fact and law." *Id.*

However, "voluntary cessation of allegedly illegal conduct" does not moot a case because it leaves the defendant "free to return to his old ways." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633, 73 S. Ct. 894, 97 L. Ed. 1303 (1953); *see also Friends of the Earth, Inc. v. Laidlaw Envtl. Servs*, 528 U.S. 167, 189, 120 S. Ct. 693, 145 L. Ed. 2d 610 (2000). Moreover, finding a case to be moot entitles the defendant to a dismissal as of right, and as a result, courts have been reluctant "to grant defendants such a powerful weapon against public law enforcement" because there is "a public interest in having the legality of . . . practices settled." *W.T. Grant Co.*, 345 U.S. at 632-33, 73 S. Ct. 894. Indeed, the burden of demonstrating mootness "is a heavy one" and the standard "for determining whether a case has been mooted by the defendant's voluntary conduct is stringent: 'A case might become moot if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Friends of the Earth v. Laidlaw*, 528 U.S. at 189, 120 S. Ct. 693 (citing *United States v. Concentrated Phosphate Export Assn.*, 393 U.S. 199, 203, 89 S. Ct. 361, 21 L. Ed. 2d 344 (1968)).

Here, Barr first argues that "the FTC's complaint only seeks to enjoin Barr and Warner Chilcott from operating under an ***exclusive***" Final Agreement, and that the FTC's case is now

moot because "the conduct of which the FTC complained (the exclusivity of the license) has ceased and the relief sought (an order rendering the license non-exclusive) can no longer be granted." Barr Mot. to Dismiss at 5 (emphasis in original). However, as the FTC points out, the First Amended Complaint seeks not only an injunction against the maintenance of the exclusivity provisions of the Final Agreement, but also seeks to prevent Barr and Warner Chilcott from engaging in "similar and related conduct." FTC Opp'n at 2 (citing Compl., Section X, ¶¶ 2-3). Indeed, a review of the First Amended Complaint reveals that the FTC brought this action "to undo *and prevent*" Barr and Warner Chilcott's allegedly unfair methods of competition, and that the FTC's prayer for relief asks this Court to enter a permanent injunction to prevent Defendants from engaging in "similar and related conduct" and to "grant such other equitable relief as the Court finds necessary to redress *and prevent recurrence* of defendants' violation of Section 5(a) of the FTC Act." Compl. at 2, Section X, ¶¶ 2-3 (emphasis added).

Moreover, the First Amended Complaint contains substantial detailed explanations of the regulatory system governing pharmaceuticals, including generic drugs, in the United States, the consumer benefits of generic drugs, the impact of generic drug entry on the market for branded drugs, and the nature and alleged effects of the agreement between Warner Chilcott and Barr. Thus, in addition to specific factual allegations concerning the Final Agreement between Warner Chilcott and Barr, the First Amended Complaint contains sufficient generalized allegations from which the Court can discern the nature of the "similar and related conduct" that the FTC would have this Court find violative of Section 5(a) of the FTC Act. The Court therefore disagrees with Barr both that there is no relief remaining for the Court to grant in this action, *see* Barr Mot. to Dismiss at 2, and also that adjudication of this action cannot "have a more-than-speculative

chance of affecting" the parties in the future, *see* Bar Reply at 4.

In addition, the Court notes that the notice form of pleading employed in all federal courts requires only a "short and plain statement of the claim showing that the pleader is entitled to relief" and a demand for the judgment sought. Fed. R. Civ. P. 8. While it might be a stretch to describe Plaintiff's Complaint as "short and plain," Federal Rule of Civil Procedure 8 makes clear that the First Amended Complaint adequately pleads a claim for relief beyond an injunction directed at terminating the exclusivity provisions of the Final Agreement. The Court therefore rejects Barr's argument that the First Amended Complaint contains nothing more than a "vague, speculative allegation of possible future injury paired with a general request for equitable relief," which cannot serve as a basis for jurisdiction in light of "Article III's stringent requirements." Barr Reply at 8.

Having concluded that the First Amended Complaint challenges conduct beyond the particular exclusivity provisions of the Final Agreement, and seeks relief beyond an injunction against the maintenance of those provisions, the Court continues to address whether the instant case is nevertheless mooted by events subsequent to the filing of the First Amended Complaint. Of particular significance to the case at hand, "[i]t is well settled that 'a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice.'" *Friends of the Earth v. Laidlaw*, 528 U.S. at 189, 120 S. Ct. 693 (citing *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289, 102 S. Ct. 1070, 71 L. Ed. 2d. 152 (1982)). Thus, voluntary cessation of allegedly illegal conduct will not moot a case unless "subsequent events [have] made it absolutely clear that the allegedly wrongful behavior could not reasonable be expected to recur." *Id.* The Court therefore turns to Barr's argument that, as a

result of Warner Chilcott's voluntary waiver of the exclusivity provisions of the Final Agreement, Barr's introduction of its generic version of Ovcon, and the Court's approval of the Settlement Agreement between Warner Chilcott and the FTC and entry of the Final Order and Stipulated Permanent Injunction, "there can be no reasonable expectation that the conduct at issue will be repeated." Barr Mot. to Dismiss at 6.

Barr's argument in this respect focuses solely on the likelihood that the exclusivity provisions of the Final Agreement will recur. However, as noted above, the scope of the FTC's First Amended Complaint goes beyond the Final Agreement between Barr and Warner Chilcott to encompass "similar and related conduct" – other agreements of the nature described in the First Amended Complaint. In determining whether a case is moot, "the concern is with repeated violations of the same law, and not merely with repetition of the same offensive conduct." *TRW, Inc. v. Fed. Trade Comm'n*, 647 F.2d 942, 953 (9th Cir. 1981); *see also W.T. Grant Co.*, 345 U.S. at 632 n.5, 73 S. Ct. 894 ("When defendants are shown to have . . . entered into a conspiracy violative of antitrust laws, courts will not assume that it has been abandoned without clear proof. It is the duty of the courts to beware of efforts to defeat injunctive relief by protestations of repentance and reform, especially when abandonment seems timed to anticipate suit, and there is probability of resumption.") (citing *United States v. Oregon Med. Soc'y*, 343 U.S. 326, 333, 72 S. Ct. 690, 96 L. Ed. 2d 978 (1952)). Thus, Barr's arguments regarding the recurrence of the exclusivity provisions of the Final Agreement do not convince the Court that the "conduct at issue," inclusive of "similar and related conduct," cannot reasonably be expected to recur.

First, Barr asserts that the "alleged violation at issue here cannot recur for a simple reason: this Court has approved and entered an Order approving the FTC's settlement with Warner

Chilcott," which prevents Warner Chilcott from entering into the type of agreement described in the First Amended Complaint with Barr or any other company. Barr Reply at 5. Thus, Barr argues, where "allegedly wrongful conduct is prohibited as a matter of law, no reasonable expectation can exist that the conduct will recur." *Id.* at 6 (citing *County of Los Angeles v. Davis*, 440 U.S. 625, 99 S. Ct. 1379). The Court agrees that Warner Chilcott has waived the exclusivity provisions of the Final Agreement and that Warner Chilcott has agreed not to enter similar agreements in the future. However, while Warner Chilcott may be enjoined from entering into similar agreements in the future, Barr – who did not enter into a settlement agreement with the FTC and is not bound by the Final Order and Stipulated Permanent Injunction – faces no such constraint. *Cf. Douglas v. Donovan*, 704 F.2d 1276, 1279 (case mooted where comprehensive settlement agreement between plaintiff and third-party wife made it "virtually impossible" for alleged violation to recur). Barr thus remains free to enter into the very type of agreement that the FTC would seek to enjoin through a permanent injunction.

Barr also argues that "current economic and market realities" demonstrate that there is no reasonable expectation that Barr's allegedly illegal conduct will recur. Barr Mot. to Dismiss at 7-8; Barr Reply at 6-7. Barr maintains that it would not make business sense for Barr to enter into an exclusive license with Warner Chilcott in the future because it began selling its generic version of Ovcon, "Balziva," in mid-October 2006. Barr Mot. to Dismiss at 7; Barr Reply at 7. As a result, Barr argues, reviving the exclusivity provisions of the Final Agreement "would require Barr to pull Balziva from the market, thereby forfeiting its investment in marketing, distribution, and all potential profits" as well as "draw[ing] the ire of Barr's customers and patients and result[ing] in incalculable harm to Barr's goodwill and reputation." Barr Reply at 7. However,

while this argument might be convincing with respect to the exclusivity provisions of the Final Agreement between Warner Chilcott and Barr, it bears no relation to whether Barr will have economic incentives to enter into similar agreements in the future. Indeed, in its Opposition to Barr's motion to dismiss, the FTC asserts that "the circumstances that gave rise to Barr's unlawful agreement with Warner Chilcott . . . are not unique to Ovcon" and that "Barr currently has pending applications seeking FDA approval to market generic versions of branded products where patent protection has expired." FTC Opp'n at 7 (citing FTC Opp'n Ex. B (filed under seal)).

As a result, the Court concludes that Barr has failed to carry its "heavy burden" of demonstrating that the "conduct at issue" – broadly defined – cannot reasonably be expected to recur. To the contrary, the Court notes that Barr has thus far maintained that the exclusivity provisions of the Final Agreement are entirely lawful, and that courts have found cases not to be moot where, as here, defendants have insisted upon the legality of the challenged practices. *See, e.g.*, *Donovan v. Cunningham*, 716 F.2d 1455, 1461-62 (5th Cir. 1983) (defendants' "bare assurances" that they did not intend to serve as ERISA fiduciaries in the future were "insufficient to meet their burden of persuasion" "in the face of [their] continuing insistence that their discontinued activities were legal"); *cf. Am. Fed'n of Gov't Employees, AFL-CIO v. Brown*, 886 F. Supp. 16, 19 (1994) (case mooted where defendants had "adopted entirely plaintiffs' view of [the] dispute"). In light of Barr's belief that the exclusivity provisions of the Final Agreement are lawful and Barr's absolute freedom to enter similar agreements in the future (with any counterparty other than Warner Chilcott), the Court does not believe it to be "absolutely clear" that the challenged conduct will not repeat itself.

The Court thus determines that the instant case is not moot as a result of Warner Chilcott's

waiver of the exclusivity provisions of the Final Agreement, Barr's introduction of its generic version of Ovcon, and the Settlement Agreement between Warner Chilcott and Barr. The Court does not, however, reach the entirely separate question of whether, as this case progresses, the FTC will be able to demonstrate an entitlement to injunctive relief aimed at conduct "similar and related" to the exclusivity provisions of the Final Agreement. *See W.T. Grant Co.*, 345 U.S. at 633, 73 S. Ct. 894 ("Along with its power to hear the case, the court's power to grant injunctive relief survives discontinuance of the illegal conduct;" however, "the moving party must satisfy the court that relief is needed" by showing "that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive.").

**CONCLUSION**

For the reasons set forth above, the Court shall deny Barr's motion to dismiss, concluding that the instant case is not moot as a result of Warner Chilcott's waiver of the exclusivity provisions of the Final Agreement, Barr's introduction of its generic version of Ovcon, or the Settlement Agreement between Warner Chilcott and the FTC. An appropriate Order accompanies this Memorandum Opinion.

Date: January 22, 2007

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COLLEEN KOLLAR-KOTELLY
United States District Judge