IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)	MDL DOCKET NO. 2084 ALL CASES 1:09-MD-2084-TWT
FEDERAL TRADE COMMISSION, Plaintiff, v. ACTAVIS, INC., et al., Defendants.	CIVIL ACTION FILE NO. 1:09-CV-955-TWT

OPINION AND ORDER

This is an antitrust action. It is before the Court on the Defendant Actavis Holdco U.S., Inc.'s ("Actavis Holdco") Motion for Summary Judgment [Doc. 541]. For the following reasons, the Defendant Actavis Holdco's Motion for Summary Judgment [Doc. 541] is DENIED.

I. Background

In 2003, Actavis, Inc. ("Actavis")[1] filed an Abbreviated New Drug Application with the Food and Drug Administration seeking approval for a generic version of a popular testosterone product, AndroGel. A few years later, Solvay Pharmaceuticals, Inc.,[2] the manufacturer of AndroGel, sued Actavis for patent infringement over Actavis' generic version of AndroGel. The parties settled the litigation in September 2006. As part of the settlement agreement, Actavis agreed to delay the launch of its generic version of AndroGel until 2015. In exchange, Solvay shared some of AndroGel's profits with Actavis. The FTC considers this to be a "reverse payment" that is forbidden by antitrust law.

During this time, Teva Pharmaceutical Industries Ltd., along with its wholly-owned subsidiary Teva Pharmaceuticals USA, Inc. (together, "Teva"), had also engaged in a similar agreement with another company. The FTC brought suit over that agreement, and the parties settled. As part of the settlement, Teva agreed to be subject to a permanent injunction. Among other things, the Teva Injunction prohibits Teva from "entering into any Brand/Generic Settlement that includes: (1) Payment by the

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[1] Then known as Watson Pharmaceuticals, Inc.

[2] Through Solvay's subsidiary, Unimed Pharmaceuticals, LLC.

[brand manufacturer] to the [generic manufacturer]..."[3] The order defines "payment" as a "transfer of value by the [brand manufacturer] to the [generic manufacturer] (including, but not limited to, money, goods or services)...where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 60 day period" centered on the execution of the settlement.[4] Importantly, however, the Teva Injunction expressly carves out what are commonly known as "no authorized generic," or "no-AG agreements."[5] No-AG agreements are essentially a promise by the brand manufacturer to refrain from marketing a generic version of its own drug, thereby reducing competition with the generic manufacturer.

In January 2009, the FTC brought suit against Actavis, alleging that the 2006 settlement agreement violated federal antitrust law. The FTC's Complaint asked for broad injunctive relief, including: (1) an order requiring Actavis to launch its generic earlier, (2) an injunction prohibiting Actavis "from engaging in similar and related conduct in the future," and (3) "[t]hat the Court grant such other equitable relief as the

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[3] Stipulated Order for Permanent Injunction and Equitable Relief, FTC v. Cephalon, No. 2:08-cv-2141 (E.D. Pa. June 17, 2015), at 9 [Doc. 564-7].

[4] Id. at 4.

[5] Id. at 5 ("c. provisions in a Brand/Generic Settlement Agreement through which the NDA Holder provides the ANDA Filer an exclusive license to the Subject Drug Product...").

Court finds necessary to redress and prevent recurrence of Defendants' violations."[6] In August 2016, during the pendency of this litigation, Teva acquired the movant, Actavis Holdco, from Allergan plc, Actavis' corporate parent. In connection with the acquisition, Allergan reassigned certain assets and liabilities related to its generics business, including liability for this litigation, to Actavis Holdco. As a result, when Teva acquired Actavis Holdco, it also acquired a significant portion of Allergan's generics business. Also as a result, Actavis Holdco became subject to the Teva Injunction. Actavis Holdco argues that because it is now subject to the Teva Injunction, which prohibits most forms of reverse payment agreements, and because a generic version of AndroGel has since entered the market, there is no more relief to be granted to the FTC. Consequently, Actavis Holdco now moves for summary judgment on the grounds that the action is moot.

II. Legal Standard

Summary judgment is appropriate only when the pleadings, depositions, and affidavits submitted by the parties show no genuine issue of material fact exists and that the movant is entitled to judgment as a matter of law.[7] The court should view the

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[6] FTC's Second Amended Compl., Prayer for Relief ¶¶ 4-5 at 44 [Doc. 114].

[7] FED. R. CIV. P. 56(a).

evidence and any inferences that may be drawn in the light most favorable to the nonmovant.[8] The party seeking summary judgment must first identify grounds to show the absence of a genuine issue of material fact.[9] The burden then shifts to the nonmovant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of material fact does exist.[10] "A mere 'scintilla' of evidence supporting the opposing party's position will not suffice; there must be a sufficient showing that the jury could reasonably find for that party."[11]

III. Discussion

Federal judicial power is restricted by the Constitution to actual cases or controversies.[12] "The doctrine of mootness derives directly from the case-or-controversy limitation because an action that is moot cannot be characterized as an active case or controversy."[13] A case becomes moot when " it no longer presents

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8 Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970).

9 Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986).

10 Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986).

11 Walker v. Darby, 911 F.2d 1573, 1577 (11th Cir. 1990).

12 Spokeo, Inc. v. Robins, 136 S.Ct. 1540, 1547 (2016).

13 Al Najjar v. Ashcroft, 273 F.3d 1330, 1335 (11th Cir. 2001) (quotations omitted).

a live controversy with respect to which the court can give meaningful relief."[14] However, the mootness doctrine inquires into a court's authority to order a remedy, not the likelihood or appropriateness of that remedy under particular circumstances.[15] Therefore, as long as a court has the ability to fashion some form of meaningful relief, a case is not moot.[16]

Federal courts have broad authority to order equitable relief in antitrust cases.[17] The goal of an equitable antitrust suit is not to simply punish past behavior, "nor is it merely to end specific illegal practices."[18] The goal is to "effectively pry open to competition a market that has been closed by defendants' illegal restraints."[19] In other

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[14] Ethredge v. Hail, 996 F.2d 1173, 1175 (11th Cir. 1993).

[15] See Decker v. Nw. Envtl. Def. Ctr., 133 S. Ct. 1326, 1335-36 (2013) ("The District Court, it is true, might rule that...arguments lack merit, or that the relief it seeks is not warranted on the facts of these cases. That possibility, however, does not make the cases moot.").

[16] See Cook v. Bennett, 792 F.3d 1294, 1299 (11th Cir. 2015) ("Generally, a case becomes moot only when it is impossible for a court to grant *any effectual relief whatever* to the prevailing party.") (quotations omitted) (emphasis added).

[17] Int'l Salt Co. v. United States, 332 U.S. 392, 400–01 (1947) abrogated by Illinois Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006) (District Courts "are invested with large discretion to model their judgments to fit the exigencies of the particular case.").

[18] Id. at 401.

[19] Id.

words, the goal is to prevent anti-competitive activity in the future, and the courts have a wide range of means at their disposal to do so.[20] "[I]it is not necessary that all of the untraveled roads to that end be left open and that only the worn one be closed."[21] Oftentimes, this may even mean that otherwise legal activity may have to be enjoined.[22] "The standard against which the order must be judged is whether the relief represents a reasonable method of eliminating the consequences of the illegal conduct."[23]

Turning to the case at hand, the Defendant argues that the case is now moot because it has since become covered by the Teva Injunction and any additional relief sought by the FTC is merely redundant. The Court disagrees. The FTC has outlined three potential types of relief it seeks in addition to the activities enjoined in the Teva Injunction: (1) a ban on no-AG agreements, (2) an advance notice provision, and (3) an extended injunction period beyond the expiration of the Teva Injunction. Contrary

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[20] Fed. Trade Comm'n v. Nat'l Lead Co., 352 U.S. 419, 430 (1957) (Courts are "obliged not only to suppress the unlawful practice but to take such reasonable action as is calculated to preclude the revival of the illegal practices.").

[21] Int'l Salt Co., 332 U.S. at 400.

[22] Nat'l Lead Co., 352 U.S. at 430 ("...decrees often suppress a lawful device when it is used to carry out an unlawful purpose.").

[23] Nat'l Soc. of Prof'l Engineers v. United States, 435 U.S. 679, 698 (1978).

to the Defendant's argument, none of these remedies are redundant, and all three are well within the Court's authority to grant.

The FTC is concerned that any transfers of value between brand name manufacturers and generic manufacturers in exchange for delayed market entry for generic competitors is anti-competitive and violates the antitrust statutes. The Teva Injunction, which Actavis Holdco is now subject to, prohibits these transfers of value. However, there is an important exception: no-AG agreements are not covered by the Teva Injunction. There is significant debate about whether no-AG agreements are unlawful reverse payments under recent Supreme Court jurisprudence, a debate in which the FTC and Actavis Holdco are squarely opposed.[24] But the Court does not need to take a stance on this issue to enjoin Actavis Holdco from entering into no-AG agreements. The Court has the power to reasonably restrain lawful conduct if it is necessary to prevent anti-competitive actions in the future. Because no-AG agreements clearly hold significant value to the parties involved, and could serve as an alternative to cash-only reverse payment agreements, an injunction against such

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[24] See, e.g., Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co. (In re Loestrin 24 Fe Antitrust Litig.), 814 F.3d 538, 550 (1st Cir. 2016) ("the key word used throughout the [Supreme Court's Actavis] opinion is 'payment,' which connotes a much broader category of consideration than cash alone."); King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 403 (3d Cir. 2015), ("We do not believe Actavis's holding can be limited to reverse payments of cash.").

behavior in the future is certainly considered to be within the realm of possible remedies.[25]

Likewise, modifications of the timing requirements, the length of the injunction, and the addition of an advance notice requirement are also well within this Court's power. The Teva Injunction will likely be nearly halfway through its course by the time this case is finished. Should this Court feel that more time is needed to prevent anti-competitive conduct by Actavis Holdco, it is within its power to grant an injunction that extends past the expiration of the Teva Injunction.[26] Alternatively, should this Court feel it is necessary, it could also impose an advance notice requirement for all transfers of value, including no-AG agreements. Currently, under the Teva Injunction, Actavis Holdco is not required to seek the FTC's approval prior to entering into patent litigation settlements that involve certain forms of payment

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[25] Nor is this remedy speculative or designed to address merely hypothetical behavior, despite the Defendant's arguments to the contrary. Indeed, a no-AG settlement was expressly considered by Actavis Holdco as one potential form of payment. See Brau Decl. Ex. E at 5 [Doc. 564-8] (presentation discussing "Watson/Par Options - Potential Settlement Features" including "Agreement by Solvay with Watson to Not Launch an Authorized Generic for Androgel.").

[26] This would not necessarily be a modification of the Teva Injunction. The Teva Injunction applies to Teva and its subsidiaries. Actavis Holdco could be sold and cease to be a subsidiary of Teva at any time. Thus, an injunction against Actavis Holdco would ensure that Actavis Holdco's anti-competitive conduct would be prevented no matter its ownership.

agreements. By requiring Actavis Holdco to seek prior approval for all patent litigation settlements that involve reverse payment agreements, including no-AG agreements, the potential anti-competitive consequences of such agreements could be addressed proactively rather than reactively.[27]

This is not to say that the Court will eventually grant any of these proposed remedies. But they are all available to the Court. As stated above, the mootness doctrine inquires into a court's authority to order a remedy, not the likelihood or appropriateness of that remedy under particular circumstances. Because the Court still has the ability to grant meaningful relief to the Plaintiff, the case is not moot.[28]

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[27] Contrary to the Defendant's contention, an advance notice requirement would not necessarily be redundant. The advance notice requirement contained in the Teva Injunction only applies to agreements prohibited by the Teva Injunction. Since no-AG agreements are not prohibited by the Teva Injunction, a new advance notice requirement covering such agreements would not be duplicative.

[28] As an aside, the Defendant briefly argued that the FTC was inappropriately seeking a declaratory judgment against conduct that had happened in the past. Though Actavis Holdco seems to have abandoned this argument in its reply brief, the Court will briefly address it here. The FTC is not seeking a declaratory judgment; it is asking the Court to hold that the agreement was unlawful, and therefore grant an injunction. The Defendant's argument is inapposite.

IV. Conclusion

For the reasons stated above, the Defendant Actavis Holdco's Motion for Summary Judgment [Doc. 541] is DENIED.

SO ORDERED, this 1 day of June, 2017.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge