UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MEIJER, INC., et al., Plaintiffs, Civil Action No. 05–2195 (CKK) v. BARR PHARMACEUTICALS, INC., Defendant. WALGREEN CO., et al., Plaintiffs, Civil Action No. 06–494 (CKK) v. BARR PHARMACEUTICALS, INC., Defendant. CVS PHARMACY, INC., et al., Plaintiffs, Civil Action No. 06–795 (CKK) v.

MEMORANDUM OPINION

BARR PHARMACEUTICALS, INC.,

Defendant.

(August 11, 2008)

Currently before the Court are three antitrust cases filed by the direct purchasers (and certain assignees of direct purchasers) of Ovcon 35 ("Ovcon"), a brand-name oral contraceptive

marketed by Warner Chilcott.¹ Plaintiffs allege that Defendant Barr Pharmaceuticals, Inc. ("Barr"), a manufacturer of Ovcon, entered into an illegal agreement with Warner Chilcott to delay the market entry of Barr's generic version of Ovcon in exchange for \$20 million.² According to Plaintiffs, this agreement violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by denying direct purchasers of Ovcon the benefits of generic competition and causing them to pay higher prices for Ovcon. Plaintiffs have moved for partial summary judgment on the issue of whether Barr's agreement with Warner Chilcott constituted a *per se* unreasonable restraint of trade. Barr has filed a cross-motion for summary judgment, arguing (among other things) that its agreement with Warner Chilcott should be examined under a rule of reason analysis, and that the procompetitive benefits of the agreement outweighed any of its alleged anticompetitive effects.

After a searching review of the parties' motions, including the mountainous attachments thereto, applicable statutory authority and case law, and the entire record herein, the Court holds that the agreement between Barr and Warner Chilcott must be evaluated under the rule of reason and cannot be condemned as a *per se* unlawful restraint of trade. The Court further holds that genuine issues of material fact exist with respect to the proper definition of the relevant product market in this case, and that these factual issues preclude entry of summary judgment.

Accordingly, the Court shall DENY Plaintiffs' Motion for Partial Summary Judgment, and shall

¹ "Warner Chilcott" refers to Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott (US) Inc., Warner Chilcott Company, Inc., and Galen (Chemicals), Ltd.

² On July 10, 2008, the Court approved a settlement between Plaintiffs and Warner Chilcott that dismissed Warner Chilcott as a Defendant in the above-captioned cases. *See Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, Civ. A. No. 05-2195, [181] Order and [182] Mem. Op. (July 10, 2008). Barr is the sole remaining Defendant.

GRANT-IN-PART and DENY-IN-PART Defendant's Motion for Summary Judgment, for the reasons that follow.

I. BACKGROUND

A. Factual Background

This case arises in the context of the manufacturing and sale of brand-name ("branded") and generic drugs.³ Warner Chilcott and Barr are pharmaceutical companies that develop, manufacture, market, and distribute drugs of varying application. Pls.' Stmt. ¶¶ 1, 2. In January 2000, Warner Chilcott purchased Ovcon, a branded oral contraceptive, from Bristol Myers Squibb ("BMS"). Def.'s Stmt. ¶ 6; Pls.' Stmt. ¶¶ 38. Because Warner Chilcott did not have the ability to manufacture Ovcon itself, it also entered into a supply agreement obligating BMS to supply Warner Chilcott with all of its requirements for Ovcon, as well as any line extensions

³ As the Court previously informed the parties, see, e.g., No. 05-2195, Order at 1 (Dec. 9, 2005), the Court strictly adheres to the text of Local Civil Rule 56.1 when resolving motions for summary judgment. See Burke v. Gould, 286 F.3d 513, 519 (D.C. Cir. 2002) (district courts need to invoke Local Civil Rule 56.1 before applying it to the case). Accordingly, the Court "assumes that facts identified by the moving party in its statement of material facts are admitted, unless such a fact is controverted in the statement of genuine issues filed in opposition to the motion." LCvR 56.1. Thus, in most instances the Court shall cite only to Plaintiffs' Statement of Material Facts ("Pls.' Stmt.") or Defendant's Statement of Material Facts ("Def.'s Stmt.") unless a statement is contradicted by the opposing party. Where a party objects to relevant aspects of an opposing party's proffered material fact, the Court shall cite to Plaintiffs' Response to Def.'s Stmt. ("Pls.' Resp. Stmt.") or Defendant's Response to Pls.' Stmt. ("Def.'s Resp. Stmt."), as necessary. Where a party objects to a proffered fact based on its materiality, or seeks to merely re-characterize a fact contained in the opposing party's Statement, the Court shall disregard the objection because it does not comport with the requirements of LCvR 56.1. The Court shall also cite directly to evidence in the record, where appropriate, to provide additional information not covered in either of the parties' Statements. Finally, the Court notes that Plaintiffs submitted a "counterstatement of material facts" that Barr argues should be disregarded because it contains facts that are voluminous and/or immaterial. See Def.'s Resp. Stmt. to Pls.' Counterstatement of Facts at 2. The Court finds that both Parties included voluminous and/or immaterial "facts" in their Statements, and that there is no basis to disregard Plaintiffs' factual counterstatement.

(i.e., additional Ovcon-related products).⁴ Def.'s Stmt. \P 7. Ovcon became one of Warner Chilcott's highest revenue-producing products while under agreement with BMS. Pls.' Stmt. \P 40. Nevertheless, Ovcon was not subject to patent protection, and in September 2001, Barr filed an application with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Ovcon.⁵ *Id.* \P 2.

The parties offer conflicting descriptions of the Warner Chilcott - BMS supply relationship. Barr maintains that Warner Chilcott was frustrated with BMS because its shipments of Ovcon were consistently delayed and inadequate, causing Warner Chilcott to "often [run] out of supply." Def.'s Stmt. ¶¶ 8-10. *See also* Def.'s Mot., Ex. 44 at 1 (2/6/01 Email from C. Yodice to T. Beer) ("the Ovcon schedules are at least 4 to 5 months overdue"); *id.*, Ex. 45 at 1 (8/21/01 Email from J. Nicol to I. Flores and R. Velez) ("We're looking for updates on the following issues so we can provide Warner Chilcott with the most recent information. They

⁴ Plaintiffs deny that BMS was obligated to supply Warner Chilcott with "line extension" products, citing section 2.10.1 of the agreement. *See* Pls.' Resp. Stmt. ¶ 7; Pls.' Stmt. ¶ 52; Def.'s Mot., Ex. 42 (1/26/00 Agreement). Plaintiffs' argument and citation are puzzling given that the very next section of the agreement states that "[o]nce [Warner Chilcott] has obtained any regulatory approvals that may be required, if any, to market a Line Extension Product in any country, such Line Extension Product shall be included as a Product under this Agreement" Def.'s Mot, Ex. 42 § 2.10.02. Plaintiffs' meritless objection is, in any event, irrelevant to the disposition of the instant motions.

⁵ A company seeking to market a new drug in the United States must first obtain approval by filing a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA"). Pls.' Stmt. ¶ 48; 21 U.S.C. § 355. The NDA must include reports and other materials showing that the drug is safe and effective for use. Pls.' Stmt. ¶ 48; 21 U.S.C. § 355(b)(1). A company seeking approval to market a generic drug may file an Abbreviated New Drug Application ("ANDA") with the FDA, which allows the company to rely on the FDA's prior determinations, made in the course of approving a new drug pursuant to an NDA, that the active ingredients of the proposed new generic drug are safe and effective. Pls.' Stmt. ¶ 48; 21 U.S.C. § 355(j)(2)(A).

continue to be concerned about significant delays and frequent changes in availability dates."); *id.*, Ex. 73 at 29:17 - 29:21 (Depo. Tr. of Leland Cross) ("Q: What is Warner Chilcott's judgment as to whether [BMS] was an adequate supplier of Ovcon? A: I could tell you my assessment, and they were the worst supplier that I have come across in 25 years in the industry"). Barr argues that these supply problems caused Warner Chilcott to seek out Barr as an alternative supplier of Ovcon. *See* Def.'s Opp'n at 6.

Plaintiffs advance a very different view concerning BMS's performance under its contract with Warner Chilcott, which Plaintiffs characterize as "adequate." Pls.' Resp. Stmt. ¶ 8. Plaintiffs argue that, "[o]n average, BMS provided Warner Chilcott with more than three months of Ovcon inventory." Id. Plaintiffs also argue that Warner Chilcott's supply problems were selfinduced because Warner Chilcott purposefully "bled down" its Ovcon inventory when it incorrectly anticipated FDA-approval (and a corresponding product launch) of a chewable version of Ovcon. Id. ¶ 10. Plaintiffs conclude that, based on evidence in the record, Warner Chilcott sought to enter into an agreement with Barr because it knew that the market entry of a generic version of Ovcon would substantially diminish its sales and profits. See, e.g., Pls.' Mot., Ex. 9 at 2 (5/13/03 Board Minutes) ("[t]he biggest risk to the Company is the introduction of a generic version of Ovcon"); Def.'s Resp. Stmt., Ex. C at 4, 201:23-25 (Depo. Tr. of Roger Boissonneault) (discussing the market entry of Barr's generic Ovcon and indicating that Warner Chilcott "would lose 50 percent of [its] business in the first year. That's the general metric for a generic coming into the marketplace for an oral contraceptive"); Pls.' Mot., Ex. 10 at 1 (1/20/03 Email from W. Poll to J. Smith) (estimating that Ovcon sales would increase from \$61 million in 2003 to \$78 million in 2005 if no generic were introduced, and would decrease to \$18 million if

a generic were launched in 2003).⁶

The parties' conflicting views are also reflected in their divergent characterizations of Warner Chilcott's plans to develop a chewable version of Ovcon. According to Plaintiffs, Warner Chilcott planned to convert Ovcon patients to a chewable version of Ovcon that would not have a generic equivalent as a way of protecting its Ovcon share. Pls.' Stmt. ¶ 63; Pls.' Opp'n, Ex. 12 at 2 (3/15/02 Report) (describing a strategy to "delay generic entry," "protect Ovcon," and indicating that "[p]hysicians will NOT be asked to write 'Ovcon Chewable' initially," but "[i]f generic becomes available, new strategy will ask physicians to write 'Chewable'"). See also Pls.' Opp'n, Ex. 27 at 3 (8/25/03 Brand Plan) ("The major threat this year to Ovcon is the inevitable launch of a generic by Barr Labs. The strategy is to launch Ovcon 35 chewable as soon as possible, keep regular Ovcon 35 on the market, and switch as much of the existing business to chewable as quick as possible . . ."). FDA approval of chewable Ovcon was delayed beyond what Warner Chilcott had projected, however, and Plaintiffs argue that Warner Chilcott viewed the combined unavailability of chewable Ovcon with Barr's generic entry as a "Total Disaster." Pls.' Mot., Ex. 19 at 3 (1/22/03 Ovcon Scenarios Spreadsheet). In response, Barr characterizes Plaintiffs' arguments as "untenable" because Warner Chilcott recognized that, even if chewable Ovcon were introduced, a "prescription [could] still be substituted if Ovcon generic [became] available," Def.'s Resp. Stmt. ¶ 61 (quoting Pls.' Opp'n, Ex. 12 at 2 (3/15/02 Report)), and that Warner Chilcott planned "to launch [its] line extension

⁶ Barr disputes the magnitude of Warner Chilcott's lost sales projections. *See* Def.'s Resp. Stmt. ¶ 6. For example, Barr contests the forecasts described by Mr. Poll, apparently on the basis that Mr. Poll was unsure of his projections. *Id.* The fact remains, however, that Warner Chilcott projected substantial lost sales and profits due to the entry of a generic version of Ovcon.

whether there [was] a generic or [not]," Def.'s Resp. Stmt. ¶ 63 (quoting Pls.' Opp'n, Ex. 61 at 3 (8/6/2003 Earnings Conference Call)).

Whether motivated by supply concerns (as Barr suggests) or generic entry concerns (as Plaintiffs suggest), on September 10, 2003, Warner Chilcott and Barr signed a Letter of Intent. Def.'s Stmt. ¶ 13. The Letter of Intent contemplated an agreement that would grant Warner Chilcott an option to acquire a five-year exclusive license to Barr's rights under its Abbreviated New Drug Application ("ANDA") for a generic version of Ovcon pending before the FDA, and obligate Barr to exclusively supply Warner Chilcott's requirements of Ovcon. *Id.* Barr subsequently submitted the Letter of Intent to the Federal Trade Commission ("FTC") for review. Def.'s Opp'n, Ex. 80 at 1 (4/30/03 Letter from M. Kovner to Pre-merger Notification Office and the Director of Operations and Civil Enforcement). Although Barr claims that the "letter of intent met with no objection from the FTC's Merger Division," Def.'s Opp'n at 8, the FTC Bureau of Competition sent a letter to Barr stating that

we [the FTC] are concerned that this transaction, if consummated, has the potential to significantly reduce competition by eliminating the only generic alternative to Ovcon. Accordingly, we intend to seek information relating to the Ovcon transaction.

Def.'s Opp'n, Ex. 84 at 1 (2/17/04 Letter from B. Albert to M. Kovner).

⁷ The FTC also submitted a statement to the Court to "correct misrepresentations" concerning how Defendants Barr and (at the time) Warner Chilcott were characterizing their interactions with the FTC during this period. *See State of Colorado v. Warner Chilcott Holdings Co. III, Ltd.*, No. 05-2182 (June 21, 2006), Docket No. [49]. According to the FTC, "more than a month before [Defendants] entered into the final agreement, they were aware that Commission staff had significant concerns about the defendants' agreement and was investigating the transaction." *Id.* at 1. The FTC characterizes "Defendants' efforts to make relevant to this litigation their interactions in 2003 with some FTC staff members—along with what they deem the Commission's lack of dispatch in issuing its complaint" as a "sideshow" that is "misleading." *Id.* at 2.

Notwithstanding the FTC's concerns, on March 24, 2004, Warner Chilicott and Barr executed the contemplated agreement, and according to its terms, Warner Chilcott made an initial \$1 million payment to Barr. Pls.' Stmt. \$3. Barr announced the Agreement in a press release dated March 25, 2004, Def.'s Stmt. \$17; Pls.' Resp. Stmt. \$17; Def.'s Mot., Ex. 87 at 1 (3/25/04 Press Release). On April 22, 2004, the FDA granted final approval of Barr's application for generic Ovcon, and the next day, Barr announced that it would begin marketing generic Ovcon under the name "Balziva" if Warner Chilcott chose not to exercise its option under the Agreement. Pls.' Stmt. \$4. On May 6, 2004, Warner Chilcott exercised its option under the licensing agreement and paid Barr an additional \$19 million for its rights to its ANDA. \$Id. Accordingly, Balziva was not introduced into the market, and Barr became obligated to supply its generic Ovcon tablets exclusively to Warner Chilcott in the United States for five years. \$9 Id. \$5.

In November 2005, various plaintiffs, including the FTC, a number of states, and the Plaintiffs in the above-captioned actions, filed Complaints against Warner Chilcott and Barr alleging that their Agreement violated the antitrust laws. *Id.* ¶ 7. On September 25, 2006, Warner Chilcott signed a waiver that terminated the exclusivity provisions of the Agreement. *Id.*

⁸ The agreement actually consists of two separate agreements that were simultaneously executed – an Option and License Agreement and a Finished Product Supply Agreement. *See* Def.'s Mot., Ex. 85 (3/24/04 Finished Product Supply Agreement), Ex. 86 (3/24/04 Option and License Agreement). Following the convention of the parties and unless otherwise specified, the Court shall refer to both agreements as Barr and Warner Chilcott's single "Agreement."

⁹ Barr did not begin purchasing Ovcon from Barr until May 2005 (approximately one year after execution of the licensing agreement) and continued to receive its supply from BMS until that time. Pls.' Stmt. ¶¶ 86-87. Barr explains that it was not in a position to immediately begin production of Ovcon once Warner Chilcott exercised its licensing option. Def.'s Resp. Stmt. ¶ 86.

As a result, Barr was able to market a generic version of Ovcon in the United States, and did so in October 2006 with the launch of Balziva, a lower-priced generic equivalent of Ovcon. *Id.* ¶ 8; Def.'s Resp. Stmt. ¶ 8.

Within months of Balziva's introduction, sales of Ovcon declined substantially, and Warner Chilcott reported that "OVCON net sales during the quarter declined \$19.4 million, or 80.7%, compared with the prior year quarter. The decline in OVCON revenue was due to the introduction of a generic version of OVCON 35 in late October 2006, which led to an 80.4% decline in filled prescriptions for OVCON 35 compared to the same quarter last year." Pls.' Stmt., Ex. 14 at 1 (5/11/07 News Release). Barr does not deny the accuracy or existence of Warner Chilcott's report, but argues that the report fails to describe other factors exacerbating the decline in Ovcon sales. Def.'s Resp. Stmt. ¶ 9. For example, Barr explains that Warner Chilcott terminated the widespread practice of "sampling" (the promotional practice of providing free samples of brand-name products to attract new patients) once Balziva was introduced into the market. Def.'s Resp. Stmt. ¶ 9; Def.'s Stmt. ¶¶ 25-27. In any event, Barr currently supplies Warner Chilcott (non-exclusively) with tablets that Warner Chilcott sells as Ovcon, and with tablets that Warner Chilcott sells to Watson Pharmaceuticals, Inc. that are marketed as "Zenchent," another generic form of Ovcon. Pls.' Stmt. ¶ 100.

¹⁰ Plaintiffs object to the relevance and description of Barr's sampling explanation, but do not object to the underlying premise that companies such as Warner Chilcott engage in the practice of sampling for their brand-name products, and that such practices are generally terminated once a generic equivalent of the branded drug is introduced into the market. Pls.' Resp. Stmt. ¶¶ 25-27.

Both parties include extensive "facts" related to market definition and competition in their factual statements that are far from undisputed. The Court shall address these areas in the context of the parties' summary judgment arguments, where they are more appropriately

B. Procedural Background

The above-captioned cases originally began with the filing of eight separate actions brought by direct purchasers of Ovcon (and assignees of direct purchasers). On April 14, 2006, six of those cases were consolidated into *Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, Civ. A. No. 05-2195. On October 22, 2007, the Court certified a plaintiffs' class in the consolidated action consisting of "[a]ll persons and entities in the United States who purchased Ovcon 35 directly from Defendants at any time during the period April 22, 2004 through December 31, 2006," with the exception of "Defendants and their officers, directors, subsidiaries or affiliates, and all governmental entities," as well as "hospitals, universities and clinics." *Meijer, Inc.*, [137] Order at 2 (Oct. 22, 2007). The other two above-captioned cases were not consolidated into the *Meijer* action, but are nevertheless also brought by assignees of direct purchasers.

Plaintiffs reached a settlement agreement with Warner Chilcott that was approved by the Court on July 10, 2008, which dismissed Warner Chilcott as a Defendant in these cases. *See Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, No. 05-2195, [180] Order and [181] Mem. Op. (July 10, 2008). After an extensive mediation period, Plaintiffs and Barr failed to reach a settlement agreement, and the parties proceeded to file and brief the instant Motions for Summary Judgment.

Plaintiffs filed a Motion for Partial Summary Judgment ("Pls.' Mot.") on November 14, 2007. *See Meijer, Inc. v. Barr Pharmaceuticals*, No. 05-2195, Docket No. [149]; *Walgreen Co. v. Barr Pharmaceuticals*, No. 06-494, Docket No. [88]; *CVS Pharmacy, Inc. v. Barr*

considered.

Pharmaceuticals, No. 06-795, Docket No. [95]. Barr filed a Motion for Summary Judgment ("Def.'s Mot") on November 28, 2007. *See Meijer, Inc.*, No. 05-2195, Docket No. [157]; *Walgreen Co.*, No. 06-494, Docket No. [96]; and *CVS Pharmacy, Inc.*, No. 06-795, Docket No. [103]. Plaintiffs filed their Opposition to Barr's Motion for Summary Judgment ("Pls.' Opp'n") on December 21, 2007, and Barr filed its Opposition to Plaintiffs' Motion for Partial Summary Judgment ("Def.'s Opp'n") on January 2, 2008. Plaintiffs replied to Barr's Opposition ("Pls.' Reply") on January 18, 2008, and Barr replied to Plaintiffs' Opposition ("Def.'s Reply") on February 1, 2008. Plaintiffs' Motions are fully briefed and ripe for resolution. 13

II. LEGAL STANDARD

A party is entitled to summary judgment if the pleadings, depositions, and affidavits demonstrate that there is no genuine issue of material fact in dispute and that the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Tao v. Freeh*, 27 F.3d 635, 638 (D.C. Cir. 1994). Under the summary judgment standard, the moving party bears the "initial responsibility of informing the district court of the basis for [its] motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits which [it] believe[s] demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The non-moving party, in response to

¹² The captions on these briefs include *State of Colorado v. Warner Chilcott Holdings Co. III., Ltd.*, No. 05-2182. The plaintiffs in that proceeding reached a settlement with Barr on February 25, 2008, after the above briefing had already been completed, and are therefore not parties to this opinion. *See* Civ. A. No. 05-2182, Docket No. [157] (Stipulated Final Order and Permanent Injunction).

¹³ The Court granted the Parties' requests for leave to file their pleadings and accompanying exhibits under seal, but required that they "file on the public docket a redacted copy of all documents filed under seal." Min. Order dated Nov. 28, 2007.

the motion, must "go beyond the pleadings and by [his] own affidavits, or depositions, answers to interrogatories, and admissions on file, 'designate' specific facts showing that there is a genuine issue for trial." *Id.* at 324 (internal citations omitted).

Although a court should draw all inferences from the supporting records submitted by the nonmoving party, the mere existence of a factual dispute, by itself, is not sufficient to bar summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). To be material, the factual assertion must be capable of affecting the substantive outcome of the litigation; to be genuine, the issue must be supported by sufficient admissible evidence that a reasonable trier-of-fact could find for the nonmoving party. Laningham v. U.S. Navy, 813 F.2d 1236, 1242-43 (D.C. Cir. 1987); *Liberty Lobby*, 477 U.S. at 251 (the court must determine "whether the evidence presents a sufficient disagreement to require submission to a [fact-finder] or whether it is so one-sided that one party must prevail as a matter of law"). "If the evidence is merely colorable, or is not sufficiently probative, summary judgment may be granted." *Liberty* Lobby, 477 U.S. at 249-50 (internal citations omitted). "Mere allegations or denials in the adverse party's pleadings are insufficient to defeat an otherwise proper motion for summary judgment." Williams v. Callaghan, 938 F. Supp. 46, 49 (D.D.C. 1996). The adverse party must do more than simply "show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Instead, while the movant bears the initial responsibility of identifying those portions of the record that demonstrate the absence of a genuine issue of material fact, the burden shifts to the non-movant to "come forward with 'specific facts showing that there is a genuine issue for trial." Id. at 587 (citing Fed. R. Civ. P. 56(e)) (emphasis in original).

III. DISCUSSION

The parties' motions require the Court to address three primary issues. First, the Court must determine whether Barr's agreement with Warner Chilcott is a *per se* unreasonable restraint of trade or whether the agreement should be reviewed under a rule of reason analysis. Second, assuming the rule of reason applies, the Court must determine whether Barr is entitled to prevail under that analysis as a matter of law. Third, the Court must consider Barr's three perfunctory arguments included at the end of its Motion that Plaintiffs lack standing to assert their claims. The Court shall address each of these issues in turn.

A. Per Se or Rule of Reason Standard

Plaintiffs allege that Barr's conduct violated Section 1 of the Sherman Act which prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States " 15 U.S.C. § 1. Although this language appears to prohibit every agreement "in restraint of trade," the Supreme Court has interpreted this Section to prohibit only "unreasonable restraints." *State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997). Courts have historically determined the reasonableness of a given restraint by performing a rule of reason analysis, pursuant to which "the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977). *See also Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 343 (1982) ("since *Standard Oil Co. of New Jersey v. United States* . . . we have analyzed most restraints under the so-called 'rule of reason'"). The reasonableness of a particular restraint depends on a broad range of considerations, including specific information about the relevant

product market, the history, nature, and effect of the particular restraint, and whether the companies involved have market or monopoly power. *See Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.*, 127 S. Ct. 2705, 2712-13 (2007).

Even though the rule of reason "is the accepted standard for testing whether a practice restrains trade in violation of § 1 [of the Sherman Act]," *Leegin*, 127 S. Ct. at 2712, some restraints are so pernicious in all or almost all cases that courts forego a rule of reason inquiry and condemn the restraints as *per se* illegal. *See Maricopa County*, 457 U.S. at 344. This *per se* rule is "reserved for only those agreements that are 'so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality," *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006) (quoting *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 692 (1978)), and there is thus no need "to study the reasonableness of an individual restraint in light of the real market forces at work." *Leegin*, 127 S. Ct. at 2713 (citing *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988)). The application of the *per se* rule is only appropriate where a court first determines that "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output" *Broadcast Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 19-20 (1979).

In the present case, the parties dispute whether the rule of reason or the *per se* rule applies to the Agreement between Barr and Warner Chilcott. Under the terms of the Agreement, Warner Chilcott exercised an option that prevented Barr from selling generic Ovcon products (itself or through a third-party) in the United States for five years, and obligated Barr to supply Warner Chilcott with Ovcon during the same period:

Exclusivity. During the First License Term, except as provided in the Supply

Agreement, neither Barr nor its Affiliates shall, either itself or with or through a Third Party, (a) market, commercialize, distribute or sell a Licensed Product [defined to include the contemplated generic version of Ovcon] in the Territory [defined to include the United States] or (b) import or export a Licensed Product for the purposes of clause (a).

Def.'s Mot., Ex. 86 § 3.3 (3/24/04 Option and Option and License Agreement).

Commitment to Supply. During the term of this Agreement . . . Barr shall use Commercially Reasonable Efforts to supply [Warner Chilcott], and [Warner Chilcott] shall purchase from Barr, all of [Warner Chilcott's] requirements for Finished Product [defined to include the contemplated generic version of Ovcon] pursuant to purchase orders delivered from time to time . . . neither Barr nor any of its Affiliates shall have the right to manufacture or supply any Licensed Product for or to any other Person.

Id., Ex. 85 § 2.1 (3/24/04 Finished Product Supply Agreement).

Plaintiffs characterize the prohibition on Barr's ability to compete with Warner Chilcott as a horizontal market allocation agreement because the provision "(i) was horizontal, i.e., between actual or potential competitors [] and (ii) allocated all sales of Ovcon 35 Products in the United States to Warner Chilcott for five years." Pls.' Reply at 2. Plaintiffs argue that "[a]s a result of the Agreement, customers were forced to purchase [Ovcon] only from Warner Chilcott, and Warner Chilcott earned artificially inflated profits from sales of Ovcon that it would not have made in the absence of the Agreement." Pls.' Mot. at 11. In contrast, Barr refers to the Agreement as a "mixed vertical and horizontal commercial arrangement[]" with predominantly vertical supply provisions, Def.'s Opp'n at 34, and argues that the Agreement is not "manifestly anti-competitive" or a 'naked restraint' for which no analysis is required to determine the economic impact." *Id.* at 26. Further, Barr argues that the Agreement produced procompetitive benefits, such as increasing the output of Ovcon 35 products or A-B rated generics plus branded Ovcon 35, *see* Def.'s Opp'n at 29 n.16, and led to substantial discounting of Ovcon 35 that

would not have existed but for the agreement, id. at 29.

Both parties cite extensive case law supporting their characterizations of the Agreement. Plaintiffs cite cases for the proposition that horizontal market allocation agreements are per se illegal under well-established Supreme Court precedent. See, e.g., Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49-50 (1990) (applying per se rule to market allocation agreement among bar review course providers). Plaintiffs also place considerable reliance on lower court decisions that have applied the per se rule to certain patent settlements between manufacturers of branded and generic drugs. For example, in In re Cardizem CD Antitrust Litigation, the Sixth Circuit considered a patent settlement between Hoechst Marion Roussel ("HMR"), the manufacturer of a branded drug called Cardizem CD, and Andrx, an applicant to sell generic Cardizem CD. 332 F.3d 896, 907-909 (6th Cir. 2003). Under this agreement, HMR paid Andrx not to sell its FDAapproved generic drug until the conclusion of their pending patent litigation. The Sixth Circuit affirmed the district court's application of the per se rule to this arrangement, holding that "[t]here is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade." Id. at 908. See also Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1305 (11th Cir. 2003) (explaining that patent settlements delaying the launch of generic drugs beyond the scope of a drug manufacturer's patents may be per se illegal).

In contrast, Barr cites cases standing for the proposition that exclusive supply relationships are consistently analyzed under a rule of reason, and that such agreements often produce procompetitive benefits. *See, e.g., Jefferson Parish Hospital District No. 2 v. Hyde*, 466

U.S. 2, 45 (1984) (O'Connor, J., concurring) (explaining that exclusive dealing relationships "may, in some circumstances, create or extend market power of a supplier or the purchaser . . . and may thus restrain horizontal competition," but that such agreements may also be "substantially procompetitive by ensuring stable markets and encouraging long-term, [and] mutually advantageous business relationships"), *overruled on other grounds by Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006); *Standard Oil Co. v. United States*, 337 U.S. 293, 306 (U.S. 1949) (finding that exclusive supply contracts "may assure supply, afford protection against rises in price, enable long-term planning on the basis of known costs, and obviate the expense and risk of storage in the quantity necessary for a commodity having a fluctuating demand"); *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 393 (7th Cir. 1984) (holding that exclusive dealing agreements are "judged under the Rule of Reason, and [are] thus condemned only if found to restrain trade unreasonably").

Notwithstanding Plaintiffs' desire to characterize the Agreement between Barr and Warner Chilcott as a horizontal market allocation agreement, the law does not allow a party to simply isolate one particular provision or restraint within an overall agreement and argue, in isolation, that the restraint is subject to *per se* condemnation. That improvident approach has been foreclosed by Supreme Court cases admonishing lower courts to avoid forcing conduct into a particular "category" and applying the *per se* rule. *See Broadcast Music, Inc.*, 441 U.S. at 8-9, 20 (rejecting application of *per se* rule even though entities may have price-fixed "in the literal sense" because "literalness is overly simplistic and often overbroad," and the relevant inquiry must focus on the effects of the restraint at issue); *FTC v. Indiana Fed n of Dentists*, 476 U.S. 447, 458 (1986) ("[a]]though this Court has in the past stated that group boycotts are unlawful

per se, we decline to resolve this case by forcing the [defendant's] policy into the 'boycott' pigeonhole and invoking the per se rule"). See also Valley Drug Co., 344 F.3d at 1313 n.31 ("[A]greements that are anti-competitive when considered in isolation . . . can still be lawful if they are ancillary to another agreement and, when viewed in combination, will have the overall effect of enhancing competition."). The D.C. Circuit has also recently explained that "[t]he Supreme Court's approach to evaluating a § 1 claim has gone though a transition over the last twenty-five years, from a dichotomous categorical approach to a more nuanced and case-specific inquiry." Polygram Holding, Inc. v. FTC, 416 F.3d 29, 33-34 (D.C. Cir. 2005). Accordingly, this Court must focus on market realities associated with the entire Agreement to determine whether it should be condemned as a per se unlawful restraint of trade, not facial characterizations of the Agreement's constituent parts. See Leegin, 127 S. Ct. at 2713 ("a departure from the rule-of-reason standard must be based upon demonstrable economic effect rather than . . . upon formalistic line drawing") (quoting Continental T.V., Inc., 433 U.S. at 58); While the Court need not undertake the in-depth analysis associated with a rule of reason inquiry to determine whether the per se rule is applicable to Barr's Agreement (and, indeed, such an approach would undermine the efficiencies that the per se rule is designed to achieve), "[t]he Supreme Court has made it clear for some time now that [courts] should not throw labels like per se around loosely, without some appreciation for the economic arrangement [they] are evaluating." Generac Corp. v. Caterpillar, Inc., 172 F.3d 971, 977 (7th Cir. 1999).¹⁴

¹⁴ For this reason, the Court rejects as legally inaccurate Plaintiffs' argument that "a decision to apply the *per se* rule does not depend on any inquiry into market definition or market power . . . [because that inquiry] is made only *after* a court has decided *not* to apply the *per se* rule." Pls.' Reply at 8 (emphasis in original). Even a cursory examination of the precedents in the text above reveals that courts must evaluate relevant market dynamics prior to condemning a

In the present matter, the Agreement created an exclusive supply arrangement whereby a supplier and potential competitor, Barr, agreed not to compete with a buyer, Warner Chilcott, for the duration of their agreement. Considering that arrangement as a whole, it is apparent that the Agreement's resulting economic effects largely depend on the definition of the relevant market. Specifically, Plaintiffs argue that the relevant market in this case consists only of Ovcon and its generic equivalents. See Pls.' Opp'n at 3. If that is correct, the economic effects of Barr's Agreement are readily identifiable – the Agreement would have prevented the introduction of a lower-priced alternative product to consumers so that Warner Chilcott could continue as the only supplier of a higher-priced product. See Valley Drug Co., 344 F.3d at 1304 ("[w]hen a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced"). Barr, however, argues that the relevant market is much broader and includes other branded and generic contraceptives, some of which contain active ingredients that are chemically identical to Ovcon. See Def.'s Mot. at 9, 11. Barr also argues that the Agreement did not prevent other drug manufacturers from becoming potential Ovcon competitors, see Def.'s Mot., Ex. 14 at 242:14 - 242:18 (Depo. Tr. of Keith Leffler) ("Q: [T]here's nothing in the license and supply agreement between Barr and Warner Chilcott that prevents another generic entering, is there? A: No"), and that courts have consistently "recognized that the mere filing of an ANDA [application to sell a generic equivalent of a branded drug] is sufficient evidence that generic drug companies are competitors

restraint as a *per se* violation of the antitrust laws. *See, e.g., Indiana Fed'n of Dentists*, 476 U.S. at 459 (discussing group boycotts and explaining that "the *per se* approach has generally been limited to cases in which firms with market power boycott suppliers or customers in order to discourage them from doing business with a competitor," thereby necessitating an inquiry into market power *prior* to application of the *per se* rule).

of brand-name manufacturers." *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1315 n.34 (S.D. Fla. 2005). If Barr's explanation of the broader relevant market is accepted, the anticompetitive effects of the Agreement are far less clear. *See, e.g., Jefferson Parish*, 466 U.S. at 45 (O'Connor, J., concurring) ("[w]hen the sellers of services are numerous and mobile, and the number of buyers is large, exclusive-dealing arrangements of narrow scope pose no threat of adverse economic consequences").

Because the economic effects of the Agreement depend on the proper definition of the market (and the competitive effects therein), the Agreement cannot be condemned as a per se unreasonable restraint of trade. The *per se* rule is reserved for restraints that are anticompetitive in all or nearly all instances, not those that are anticompetitive depending on particular market dynamics. See Broadcast Music, Inc., 441 U.S. at 19-20 (holding that per se condemnation is only appropriate for a restraint that "facially appears to be one that would always or almost always tend to restrict competition and decrease output"). Plaintiffs themselves acknowledge this legal principle. See Pls.' Opp'n at 9 ("The per se rule is based on the premise that particular restraints are unreasonable as a class.") (emphasis in original) (quoting XI Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1910b at 281 (2d ed. 2005)). The per se rule is also inappropriate where the effects of a particular restraint are unclear, even where aspects of the restraint may appear to be facially anticompetitive. See, e.g., United States v. Microsoft, 253 F.3d 34, 94 (D.C. Cir. 2001) ("we cannot comfortably say that bundling in platform software markets has so little redeeming virtue, and that there would be so very little loss to society from its ban, that an inquiry into its costs in the individual case [can be] considered [] unnecessary. We do not have enough empirical evidence . . . to exercise sensible judgment regarding that

entire class of behavior") (internal citations and punctuation omitted); *Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696, 709 (4th Cir. 1991) (applying the rule of reason to a restraint where its anticompetitive effects were "far from clear"). In this case, Daniel Rubinfeld even testified on behalf of Plaintiffs that delayed generic entry is not necessarily anticompetitive in every instance. *See* Def.'s Opp'n, Ex. 17 at 66:14 - 66:19 ("I take your questions to be asking me whether I think that delayed [generic] entry is somehow, per se, anti-competitive. I'll just make it clear that I don't believe that's the case. I think there are cases where delayed entry could be on balance procompetitive."). Finally, whether a restraint produces anticompetitive effects is often unclear where, as here, it arises in the context of an exclusive supply relationship. *See Jefferson Parish*, 466 U.S. at 45 (O'Connor, J., concurring) ("[i]n determining whether an exclusive-dealing contract is unreasonable, the proper focus is on the structure of the market . . ."). 16

For these reasons, the Court cannot conclude that the Agreement between Barr and Warner Chilcott produced the presumptive anticompetitive effects necessary to condemn the agreement as a *per se* restraint of trade. The Court is not persuaded otherwise by *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), or *Valley Drug Co. v. Geneva*

¹⁵ Plaintiffs attempt to diminish the significance of Dr. Rubinfeld's concession by characterizing it as testimony relating to a "legal standard." *See* Pls.' Reply at 5 n.9. While Plaintiffs are correct that Dr. Rubinfeld's testimony as to whether the Agreement should be analyzed under the rule of reason or the *per se* rule would have no bearing on the Court's determination of the same, Dr. Rubinfeld's analysis concerning the economic effects of delayed generic entry is an appropriate area for expert testimony and is a relevant consideration in the Court's analysis.

¹⁶ Plaintiffs argue that "there is ample evidence . . . that the supply relationship [between Barr and Warner Chilcott] was merely a pretext to disguise the Agreement's actual purpose" Pls.' Reply at 4. As Plaintiffs concede, however, whether the supply relationship was pretextual "must be determined by the trier of fact and cannot be resolved on summary judgment." Pls.' Opp'n at 12 n.11.

Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir. 2003), the cases on which Plaintiffs rely. Those cases are distinguishable because each involved an accepted definition of the relevant market, allowing the courts to draw conclusions about the anticompetitive effects produced by the particular agreements. See In re Cardizem, 332 F.3d at 900 (referring to a "market for Cardizem CD and its generic equivalents"); In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1319 n. 40 (opinion following remand from Valley Drug Co., 344 F.3d 1294) (referring to a "market for Hytrin and its generic bioequivalent forms of terazosin hydrochloride"). For reasons explained in greater detail below, the Court cannot resolve the parties' disagreements concerning the proper definition of the market in this case on summary judgment. See section III.B., infra. In addition, those cases involved patent litigation settlements whereby generic drug manufacturers agreed not to market drugs (including non-infringing drugs that were not subject to the parties' patent litigation) for varying durations. See In re Cardizem, 332 F.3d at 908 & n.13; In re Terazosin Hydrocholoride, 352 F. Supp. 2d at 1315. While those courts were able to conclude that the agreements created naked restraints of trade, this case involves a supply relationship where the supplier agreed not to compete with the buyer for the duration of the agreement. The Court cannot conclude, without an inquiry into the relevant market and the competitive dynamics therein, that this arrangement produced a naked or even unreasonable restraint of trade.¹⁷

¹⁷ Plaintiffs' reliance on *Engine Specialities, Inc. v. Bombardier Ltd.* is also unpersuasive. 605 F.2d 1 (1st Cir. 1979). In that case, two companies entered into a horizontal agreement to allocate certain markets pursuant to an envisioned joint venture. *Id.* at 8. Even though the parties implemented their agreement, the joint venture "never materialized," resulting in a naked restraint on competition without the procompetitive benefits of the joint venture. *Id.* at 11. *Cf. Texaco Inc. v. Dagher*, 547 U.S. 1, 6 (2006) ("though [a joint venture's] pricing policy may be price fixing in a literal sense, it is not price fixing in the antitrust sense," and joint venture pricing

Nor is the Court impressed by Plaintiffs' other legal argument, relegated to a footnote in Plaintiffs' Reply brief, that "[a]n exclusive supply agreement is evaluated under the rule of reason only when the parties to the agreement are not actual or potential competitors." Pls.' Reply at 4 n.6 (emphasis in original). Setting aside that the cases cited by Plaintiffs offer no support for this cursory argument, Plaintiffs' analysis fails to recognize that exclusive dealing agreements are analyzed under the rule of reason precisely because they occur in a variety of contexts (between potential competitors or not) and produce both anticompetitive or procompetitive effects depending on case-specific facts. As a result, although the relationship between the buyer and seller as parties to an agreement may be one relevant consideration in a court's analysis of an exclusive supply relationship, a court must apply a rule of reason inquiry that focuses on a broad range of considerations. See Jefferson Parish, 466 U.S. at 45 (O'Connor, J., concurring) (examining exclusive dealing relationship under rule of reason inquiry and focusing on "the structure of the market for the products or services in question – the number of sellers and buyers in the market, the volume of their business, and the ease with which buyers and sellers can redirect their purchases or sales to others").

For all of these reasons, the Court finds that Barr's Agreement with Warner Chilcott is appropriately reviewed under a rule of reason analysis.¹⁸ The Court shall therefore deny

decisions "do not fall within the narrow category of activity that is *per se* unlawful under § 1 of the Sherman Act"). Unlike *Engine Specialities*, Barr and Warner Chilcott *did* execute their exclusive supply relationship, and its resulting effects are unclear for the reasons described in the text above.

¹⁸ The Court notes that Barr raised two other arguments on which the Court expressly does *not* rely. First, Barr argues that the *per se* rule is inappropriate in instances where a party marshals evidence of procompetitive effects. The Court rejects this argument because the Supreme Court "has consistently rejected the notion that naked restraints of trade are to be

Plaintiffs' Motion for Partial Summary Judgment, and grant-in-part Defendant's Motion for Summary Judgment as to Barr's claim that the Court should apply a rule of reason analysis to its Agreement with Warner Chilcott. The Court shall now proceed to address the remainder of Barr's Motion for Summary Judgment.

B. Rule of Reason Analysis

1. Whether Proof of a Relevant Antitrust Market Is Necessary

A rule of reason analysis almost always begins with the definition of the relevant market, without which there is little context to discuss competition, anticompetitive effects, or procompetitive benefits. *See Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (explaining that an inquiry into market definition is "useful for analyzing [] § 1 allegations because a market definition provides the context against which to measure the competitive effects of an agreement"); *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 81 (D.D.C. 2006) ("[t]o prove that the restraint of trade [is] unreasonable, Plaintiffs [have] to prove by a preponderance of the evidence . . . what the relevant market is," among several other elements). Before turning to the parties' dispute concerning the relevant market

tolerated because they are well intentioned or because they are allegedly developed to increase competition." *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972). Thus, if the Court were to find that the Agreement were subject to the *per se* rule as a naked restraint of trade, Barr's proffered procompetitive benefits would not alter that finding. Second, Barr repeatedly emphasizes that it submitted its Letter of Intent with Warner Chilcott to the FTC before finalizing the contemplated Agreement. *See* Def.'s Opp'n, Ex. 80 at 1 (4/30/03 Letter from M. Kovner to Pre-merger Notification Office and the Director of Operations and Civil Enforcement). Barr argues that the Agreement could not constitute a naked restraint of trade because the FTC waited approximately two years to bring suit against Barr. *See*, *e.g.*, Def.'s Opp'n at 3. The Court rejects the idea that the FTC's investigation and ultimate filing of charges against Barr for a *per se* violation of the antitrust laws somehow *belies* Barr's alleged anticompetitive conduct simply because the FTC did not move with the dispatch that Barr would expect.

definition in this case, the Court shall address Plaintiffs' antecedent arguments that their claims do not require proof of a properly defined antitrust market.

Relying on the Supreme Court's decision in *Federal Trade Commission v. Indiana*Federation of Dentists, 476 U.S. 447 (1986), Plaintiffs first argue that a market definition is unnecessary in this case because Plaintiffs have offered evidence that Barr delayed generic competition, thereby giving rise to anticompetitive effects that are apparent without resorting to a market analysis. See Pls.' Opp'n at 18. In *Indiana Federation of Dentists*, the Supreme Court explained that a properly defined market is not required as part of a rule of reason analysis where the actual anticompetitive effects of a restraint are clear:

the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, [so] 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'

Areeda, Antitrust Law ¶ 1511 at 429 (1986)). Accord Nat'l Collegiate Athletic Assoc. v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 106-07 (1984) (foregoing a full market analysis because "[t]he anticompetitive consequences of [the subject] arrangement are apparent. Individual competitors lose their freedom to compete. Price is higher and output is lower than they would otherwise be, and both are unresponsive to consumer preference."). Plaintiffs also place extensive reliance on In re Schering-Plough Corporation, 2003 FTC LEXIS 187 (F.T.C. Dec. 8, 2003), an administrative decision that Plaintiffs characterize as having "facts virtually identical to those at bar." Pls.' Opp'n at 17-18. In that case, the FTC condemned a patent litigation settlement as anticompetitive by relying on the Supreme Court's Indiana Federation of Dentists decision and foregoing a full market

analysis. *Id.* at *33-*35.

Plaintiffs' arguments are unavailing. The Court first expresses its disbelief that Plaintiffs would rely on In re Schering-Plough Corporation even though that decision was overruled and vacated by the Eleventh Circuit precisely because of its erroneous application of *Indiana* Federation of Dentists – a fact that Plaintiffs failed to raise in its briefing. See Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1065 (11th Cir. 2005) (finding that "the Commission clearly made its decision [about anticompetitive effects] before it considered any contrary conclusion" by simply assuming that the agreement was anticompetitive). In any event, the Court finds that the *Indiana Federation of Dentists* analysis does not apply in this case because the consequences of Barr's Agreement with Warner Chilcott are unclear in the absence of a defined market in which Ovcon competes. There are over 80 branded and generic oral contraceptive products that a physician may prescribe to a patient for prevention of pregnancy, at least a dozen of which contain active ingredients identical to Ovcon. See Def.'s Mot., Ex. 2 ¶ 14 (Expert Report of Richard P. Dickey) ("[a]s of September 2006, there were 83 oral contraceptive products available for physicians to prescribe in the United States . . . "). Ovcon is not subject to patent protection, and other drug manufacturers may potentially enter the market by filing an application with the FDA to produce a generic equivalent of Ovcon. See In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d at 1315 n.34 ("courts have recognized that the mere filing of an ANDA is sufficient evidence that generic drug companies are competitors of brand-name manufacturers"). The Agreement between Barr and Warner Chilcott did not block, or attempt to block, any manufacturer from introducing a generic equivalent of Ovcon. Def.'s Mot., Ex. 14 at 242:14 - 242:18 (Depo. Tr. of Keith Leffler) ("Q: [T]here's nothing in the license and supply agreement between Barr and Warner Chilcott that prevents another generic entering, is there? A: No"). Accordingly, the Court cannot determine, in the absence of an inquiry into the relevant market and the competition therein, that the Agreement resulted in an obvious restraint of trade that harmed competition. *See Klickads, Inc. v. Real Estate Board of New York, Inc.*, No. 04-8042, 2007 U.S. Dist. LEXIS 57305 at *16 (S.D.N.Y. Aug. 6, 2007) ("[P]laintiff cannot sidestep its obligation to identify and prove the relevant antitrust market. Without knowing the relevant market, the Court cannot assess defendants' market power or [aspects of competition] in the relevant market.").

Plaintiffs next argue that proof of a relevant market is unnecessary in this case based on Warner Chilcott's alleged market power, offering the following syllogism: "Warner Chilcott had market power in selling Ovcon 35; that prevention of generic competition maintained that market power; and (equivalently) that Ovcon 35 Products constitute a relevant product market." Pls.' Opp'n at 23. This reasoning is a somewhat novel application of antitrust principles. Antitrust plaintiffs generally prove a defendant's market power by defining a relevant market and indicating the percentage share of the market possessed by the defendant. *See, e.g., Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 221 (D.C. Cir. 1986). Plaintiffs are certainly correct that this method of proof is not required, and that plaintiffs may offer direct evidence of a defendant's market power by showing that the defendant has the ability to "profitably raise prices substantially above the competitive level." *Microsoft Corp.*, 253 F.3d at 51; *Re/Max Intern. v. Realty One, Inc.*, 173 F.3d 995, 1018 (6th Cir. 1999) ("an antitrust plaintiff is not required to rely on indirect evidence of a defendant's monopoly power, such as high market share within a defined market, when there is direct evidence that the defendant has

actually set prices or excluded competition"). Nevertheless, Plaintiffs fail to cite a single case (and the Court is aware of none) where a court has allowed the use of direct evidence of market power to define a product market. At least one other court has been confronted with, and rejected, the same argument. *See In re Remeron Direct Purchaser Litig.*, 367 F. Supp. 2d 675, 680 n.8 (D.N.J. 2005) ("none of [the cases cited by the plaintiffs] use direct evidence to define the antitrust product market"). It is difficult to imagine such an approach working where, as here, the definition of the relevant product market greatly informs whether Warner Chilcott exercised market power. *See* Section III.B.2, *infra*.

Assuming Plaintiffs' approach is even cognizable, the two sources of evidence that Plaintiffs' proffer in support of their argument are insufficient: (1) "evidence showing the likely and actual effects that unimpeded generic Ovcon 35 competition would (and ultimately did) have on the average prices for Ovcon 35 products . . ." and (2) evidence that "the Agreement, by delaying the entry of generic Ovcon 35, maintained Warner Chilcott's ability to charge substantially above marginal cost for Ovcon 35 Products without losing substantial sales." Pls.' Opp'n at 21. The mere showing that the *average* price of Ovcon (combined with Ovcon generics) was lower after generic entry says little about Warner Chilcott's market power.

Generic drugs normally enter the market at a price lower than their branded equivalents. *See* Def.'s Mot., Ex. 8 ¶ 30 (Expert Report of Daniel L. Rubinfeld) ("[t]o successfully sell their products, generic suppliers generally must offer prices that are lower than their brand-name counterparts"); *In re Remeron*, 367 F. Supp. 2d at 683 ("[g]enerics normally enter the market with prices significantly lower than that of the first brand name manufacturers"). Manufacturers of generic drugs also do not engage in the substantial marketing and promotional activities

undertaken by manufacturers of branded drugs, resulting in lower costs associated with their products. *See* Def.'s Mot., Ex. 8 ¶ 31 (Expert Report of Daniel L. Rubinfeld) ("branded products compete to some degree along price dimensions, [but] they also compete along non-price dimensions, such as product sampling, promotions, and marketing that emphasizes superior product characteristics . . . [but] [p]roducers of generic products compete primarily by offering discounts off the price of the corresponding brand-name drugs"). Without a showing that Warner Chilcott's higher prices were the result of restricted output—an inquiry that requires a showing as to the scope of the relevant market—Plaintiffs' sources of evidence cannot unambiguously establish Warner Chilcott's market power.

Further, the Court agrees with Barr that Plaintiffs' argument, if accepted, would lead to the anomalous result that every branded drug manufacturer would necessarily have market power simply by virtue of pricing their product above the price of any hypothetical or actual generic equivalents. *See* Def.'s Reply at 22 (arguing that Plaintiffs' argument would imply that "any agreement among pharmaceutical manufacturers could be condemned as 'anticompetitive' simply by demonstrating that the market price exceeded the so-called marginal cost of producing that product"). The Court rejects that result just as other courts have:

pricing proof may of course be indicative of monopoly power. However, absent from plaintiffs' proffer is any analysis of Barr's costs. Hence, we do not know whether the allegedly elevated prices led to an abnormally high price-cost margin. Nor do plaintiffs present direct evidence that defendants restricted output, asking us to infer the basis for the higher prices.

Geneva Pharms. Tech. Corp. v. Barr Labs., Inc., 386 F.3d 485, 500 (internal citation omitted).

Plaintiffs here provide no evidence of excessive price-cost margins or restricted output but merely rely on the fact that later generic manufacturers could enter the market more cheaply than Remeron's price in order to establish monopoly power

. . . Plaintiffs provide no evidence that Organon reduced the price of Remeron after generic entry in order to compete with the cheaper generic price.

In re Remeron, 367 F. Supp. 2d at 682. Accordingly, the Court holds that the application of the rule of reason in this case requires Plaintiffs to proffer evidence of the relevant antitrust market.¹⁹

2. The Relevant Antitrust Market

A relevant antitrust market is defined as all "commodities reasonably interchangeable by consumers for the same purposes," *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956), because "the ability of consumers to switch to a substitute [product] restrains a firm's ability to raise prices above the competitive level." *In re Lorazepam & Clorazepate*, 467 F. Supp. 2d at 81. The criteria used to evaluate interchangeability include "industry or public recognition . . ., the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962).

Plaintiffs argue that the relevant market in this case consists only of Ovcon and its generic equivalents. *See* Pls.' Opp'n at 23. Barr, in contrast, argues the market is much broader, and

¹⁹ Plaintiffs argue that Barr's counterclaim filed in *Celgene Corp. v. Barr Laboratories, Inc.*, No. 07-286 (D. N.J.), a case concerning a different branded drug, contains statements that support Plaintiffs' position in this case. *See* Pls.' Opp'n at 22-23. While this argument may reflect the researching adeptness of Plaintiffs' counsel, the Court cannot make a finding as to the relevant market or scope of competition in this case by relying on arguments raised in a different case involving a different product market–particularly where Barr disputes the similarities of the markets between that case and the one at present. *See* Def.'s Reply at 22 n.14 ("[t]he product at issue in that case, thalidomide, was a highly controlled substance with highly specialized therapeutic uses . . . unlike the market for oral contraceptives in which there are over 80 products available on the market that are prescribed for precisely the same purpose").

includes "a variety of oral contraceptive products." Def.'s Mot. at 32-33. The instant question is whether the Court may determine that one party's definition of the relevant market is correct as a matter of law. After reviewing the parties' arguments and the record evidence in this case, the Court finds that both parties have proffered evidence supporting their respective market definitions, creating a genuine issue of material fact that precludes entry of summary judgment.

As a starting point, Barr asserts that Ovcon products are functionally interchangeable with non-Ovcon oral contraceptives; that is, Ovcon and non-Ovcon oral contraceptives are "roughly equivalent." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437 (3d Cir. 1997). Functional interchangeability is a relevant consideration because it is probative of whether "consumers of one product might be willing to switch to the other in the face of a non-trivial price increase." *Geneva Pharms. Tech. Corp.*, 386 F.3d at 496. Barr's argument is based on four areas of evidence, largely derived from the reports and deposition testimony of Plaintiffs' experts. First, all approved oral contraceptives effectively prevent contraception. *See, e.g.*, Def.'s Mot., Ex. 1 ¶ 30 (Expert Report of Richard J. Derman) (hereinafter "Derman Report") ("[a]]ll approved oral contraceptives effectively prevent conception . . ."); *id.*, Ex. 14 at 27:15 - 27:19 (Depo. Tr. of Keith Leffler) (Q: Isn't it true that oral contraceptives work in roughly the same way? . . . A: That's my understanding"). Second, most oral contraceptives have similar active ingredients and FDA labeling. *Id.*, Ex. 2 ¶ 4 (Expert Report of Richard P. Dickey) (hereinafter "Dickey Report") ("[i]t is correct that, broadly speaking, most oral contraceptives

The parties do not appear to dispute that Ovcon and its generic equivalents are in the same market; they dispute whether the market also consists of other oral contraceptives. *See* Pls.' Opp'n at 26 n.39. Thus, the Court's references to "Ovcon" (as opposed to "non-Ovcon oral contraceptives") throughout this section are meant to denote both Ovcon and generic equivalents of Ovcon unless otherwise specified.

have similar active ingredients (typically being composed of some ratio of one of a number of different progestins and an estrogen) and similar FDA labels . . . "); *id.*, Ex. 66 ¶ 10 (Expert Report of Daniel R. Mishell) (hereinafter "Mishell Report") ("the Food and Drug Administration (FDA) mandates that each oral contraceptive's labeling and package inserts contain identical disclosures and/or warnings . . . In other words, the FDA has determined that all oral contraceptive formulations should be considered to be similar in terms of safety and effectiveness absent specific scientific evidence to the contrary"). Third, physicians have a variety of oral contraceptives from which to choose in order to prescribe an appropriate product. *See, e.g.*, Dickey Report ¶ 14 ("[a]s of September 2006, there were 83 oral contraceptive products available for physicians to prescribe in the United States . . . "). Fourth, several branded and generic oral contraceptive products contain identical active ingredients as Ovcon:

Ovcon 35 (containing 35ug ethinyl estradiol and 0.4 mg norethindrone) is not unique among oral contraceptive products. It is one of many oral contraceptives with similar dosages of active ingredients, ethinyl estradiol and norethindrone. Furthermore, there is no evidence demonstrating any clinical (e.g., side-effects or patient tolerance) or pharmacological differences between Ovcon 35 and the numerous other oral contraceptive products available . . . Ovcon 35 is thus medically interchangeable or substitutable for a host of other oral contraceptive products.

Mishell Report ¶ 24. Based on the above, Barr argues that Plaintiffs' attempt to limit the relevant antitrust market to "the sale and purchase of Ovcon 35 and any A-B rated generic," Def.'s Mot. at 35 (quoting Def.'s Mot., Ex. 1¶ 7A (Expert Report of Keith Leffler)), is untenable and simply inconsistent with commercial realities. *See* Def.'s Mot. at 34; *see also United States v. Grinnell*, 384 U.S. 563, 572 (1966) ("[w]e see no barrier to combining in a single market a number of different products or services where that combination reflects commercial realities").

Plaintiffs do not dispute that there are other oral contraceptives that perform similar functions, but their experts argue that Ovcon is "not treated as interchangeable by practicing physicians." Derman Report ¶ 8A. In particular, Richard Derman explains that some formulations of oral contraceptives

have higher failure rates in certain classes of women, and they differ widely in their safety and side-effect profiles . . . The differing efficacy, safety and side effect profiles of different oral contraceptives play a critical role in the process of selecting the most appropriate oral contraceptive for a particular patient.

Derman Report ¶ 30. *See also* Def.'s Mot., Ex. 8 ¶ 35 (Expert Report of Daniel L. Rubinfeld) (hereinafter "Rubinfeld Report") ("In addition to Ovcon, there are numerous other related oral contraceptive and other combined hormonal contraceptive products . . . While these products may be chemically similar to Ovcon, and they all have a common indication (i.e., the prevention of pregnancy), the FDA does not consider these products bioequivalent, and there is variation in the dosage of the active ingredients"). Even with these clinical variations, however, Plaintiffs' own experts concede that physicians *may* choose to prescribe non-Ovcon oral contraceptives based on price or promotional differences, suggesting that the drugs can be substituted for each other despite their variations:

Consider specifically the case of oral contraceptives and Ovcon 35. All the possible therapeutical alternatives are apparently effective, but they are differentiated in side effect profiles. Given the differences in the alternatives, promotion and sampling can play an important role in the physicians' selection of product. Ovcon 35, with its heavy sampling, has been successful in getting many physicians to select it . . . However, absent Ovcon 35 sampling, physicians may have selected an alternative, perhaps a comparably priced, sampled brand name [oral contraceptive] or perhaps a less expensive generic.

Def.'s Mot., Ex. 6 ¶¶29, 60 (Expert Report of Keith Leffler) (hereinafter "Leffler Report").

Because Ovcon and non-Ovcon oral contraceptives *may* be substituted for each other despite

their variations, Barr is correct to argue that they are functionally interchangeable.

While a finding of functional interchangeability may be probative of whether different products are in the same relevant market, it is certainly not dispositive. See FTC v. Swedish Match N. Am., Inc., 131 F. Supp. 2d 151, 158-60 (D.D.C. 2000) ("[f]inding two products to be functionally interchangeable . . . does not end the analysis"); In re Lorazepam & Clorazepate, 467 F. Supp. 2d at 81 (the "fact that products are just functionally interchangeable does not compel a finding that they belong in the same market"). Instead, the essential inquiry is whether the amount of actual or potential substitution between oral contraceptives acted to constrain the pricing behavior of Warner Chilcott, regardless of any functional interchangeability that may have existed between Ovcon and non-Ovcon oral contraceptives. See In re Lorazepam & Clorazepate Antitrust Litig., 467 F. Supp. 2d at 82 ("the purpose of defining the relevant market is to identify the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output"); FTC v. Staples, Inc., 970 F. Supp. 1066, 1074 (D.D.C. 1997) (finding that products were not in the same relevant market despite their functional interchangeability based on a cross-elasticity of demand analysis). In this respect, the parties each offer substantial evidence supporting their opposing views.

Plaintiffs introduce evidence from which a jury could find that Warner Chilcott "was able to profitably keep the average prices of Ovcon at least 5% higher than the average price reached for Ovcon and its generic equivalents once generic competition was introduced into the market." Pls.' Stmt. ¶ 111. Plaintiffs' expert, Jeffrey Leitzinger, explains that

prior to the entry of Barr's generic Ovcon 35 product, Warner Chilcott's average net price of its branded Ovcon 35 Product sold to Class members was approximately \$39 per monthly dose. Upon the entry of Barr's Ovcon 35 Product,

Barr's average net price to Class members was approximately \$32 per monthly dose. Once Watson entered with the second generic Ovcon 35 Product, the average net price of its generic Ovcon 35 Product was approximately \$20 per monthly dose.

Pls.' Opp'n, Ex. 73 at 27 (Expert Report of Jeffrey J. Leitzinger) (hereinafter "Leitzinger Report"). *See also* Leffler Report ¶ 66 (explaining that the market entry of two generic alternatives to Ovcon caused "the generic price to fall between \$.61 and \$.56 per pill, or a discount of about 57% to 61% of the pre-generic entry Ovcon 35 price").

Plaintiffs' experts also explain that Warner Chilcott was able to maintain prices that were higher than its generic equivalents because there is an economically "insignificant" amount of switching among oral contraceptives:

Switching among [oral contraceptives], while common, is insignificant in magnitude. When a low priced generic enters the market, it captures a trivial share of the sales of the branded products that are not A-B rated. Such minimal switching indicates the absence of significant economic substitution . . . The patterns of sales and prices of Ovcon 35 when other branded oral contraceptives enter the marketplace and when generics enter with lower prices also show the absence of price competition and economic substitution among the drugs in the oral contraceptive therapeutic category. A number of significant [oral contraceptive] products have entered the market since 2000 . . . If alternative contraceptives were significant economic substitutes for Ovcon 35, Ovcon 35 would be expected to lose significant sales in response to their entry. This simply did not occur.

Leffler Report ¶¶ 34-36. *See also* Rubinfeld Report ¶ 61 ("entry by generic alternatives to other branded oral contraceptives has not affected the growth of Ovcon's sales").

Barr's experts disagree. In particular, Gregory Bell explains that the amount of switching, as determined by his analysis, is substantial enough to suggest that the relevant market is comprised of Ovcon and at least several other oral contraceptives. *See* Def.'s Mot., Ex. 61 ¶ 31 (Expert Report of Gregory K. Bell) (hereinafter "Bell Report"). Barr also submits evidence

that Warner Chilcott and other oral contraceptive manufacturers viewed other oral contraceptives as competition that constrained their pricing behaviors:

Q: When Ortho makes pricing decisions regarding . . . Ortho Tri-Cyclen Lo, do you consider the prices of other branded oral contraceptives?

A: Yes.

Q: Why do you consider those other prices?

A: We consider the prices at the absolute price level and we also consider the magnitude and frequency of their price actions.

Q: So Ortho's pricing decisions are based at least in part on the price movements of other oral contraceptives?

A: Yes. We evaluate the pricing actions of the competitive set when making ours.

Def.'s Mot., Ex. 41 at 94:25 - 95:12 (Depo. Tr. of David Lin).

Q: In the time that you were responsible for marketing Ovcon 35, did you ever try to differentiate Ovcon from other oral contraceptives on the basis of price?

A: No.

Q: Why not?

A: Well, because we didn't have much to say. In fact, . . . our pricing strategy with Ovcon was to be a fast follower. So, we tracked Ovcon's price pretty much against whatever Ortho's major pill was . . . once Ortho switched their strategy, and so when they would take a price increase, we would fast follow with a price increase . . . there were other products in the market that had a lower price, Yasmin, for example, so we wouldn't have wanted to go out and make a big deal that Ovcon was less expensive, because then our other competitor, Yasmin, could come right in behind us and have gone there.

Def.'s Mot., Ex. 75 at 53:2 - 52:23 (Depo. Tr. of Katie MacFarlane). Consistent with these views, Barr's experts explain that Warner Chilcott's internal documents support a market definition that includes oral contraceptives besides Ovcon and its generic equivalents. *See, e.g.*, Def.'s Mot., Ex. 63 ¶ 13 (Expert Report of Jerry A. Hausman) (hereinafter "Hausman Report") (describing a "Warner Chilcott internal document that provides background on the 'OC Market,'" which it characterizes as "very crowded and fragmented."); Bell Report at 20 n. 70 (describing Warner Chilcott's internal documents that "viewed the market in which Ovcon 35

competes as much broader than Ovcon 35 itself . . . [and] defined its key competitors as Tri-Cyclen, Tri-Cyclen Lo, Evra, Yasmin, NuvaRing, and Cyclessa"). Warner Chilcott even initiated a bonus program for its sales representatives "based on how much they increase[d] the market share of Warner Chilcott products, where the market share '[was] based on the major oral contraceptives in the market in [an employee's] territory." Hausman Report ¶ 19 (quoting Warner Chilcott internal document). The views of individuals in the industry, and particularly the internal documents of Warner Chilcott, are all probative areas of inquiry for determining the outer boundaries of the relevant product market. *See Spirit Airlines, Inc. v. Northwest Airlines, Inc.*, 431 F.3d 917, 929, 933 (6th Cir. 2005) (considering the defendant's internal documents and the views of its marketing representatives for purposes of defining the relevant market); *Geneva Pharms. Tech. Corp.*, 386 F.3d at 498 (holding that employee testimony that pricing decisions were based on generic competition was relevant to market definition).²¹

To be sure, Plaintiffs' experts acknowledge some amount of competition among oral contraceptives, but argue that the competition is limited to the physician's initial decision as to which oral contraceptive to prescribe to a patient. *See* Def.'s Mot., Ex. 9 ¶ 31 (Rebuttal of Daniel L. Rubinfeld) ("there is no dispute that, prior to the entry of Barr's A-rated generic version of Ovcon, there was competition between Ovcon and the other CHCs that were available at the time at which oral contraceptives were initially prescribed"); *id.*, Ex. 14 at 140:16 - 140:20

²¹ Plaintiffs counter that *Barr* 's internal documents suggest that Barr considered the relevant market to be limited to Ovcon and its generic equivalents. *See* Rubinfeld Rebuttal Report ¶ 33 ("in its various sales forecasts for generic Ovcon, Barr identifies the price of generic Ovcon as a percentage of the branded Ovcon price. Barr then calculates the expected market share of generic Ovcon as a percentage of a market consisting only of branded Ovcon and it's Arated generics.").

(Depo. Tr. of Keith Leffler) ("Q: Is it fair to say that . . . Warner Chilcott viewed other branded products as competitors to Ovcon 35? A: In the marketing sense, yes. At its current price, yes."). Because of this competition, Barr argues that manufacturers have to expend substantial funds to market and promote their products or risk losing market share to manufacturers of other oral contraceptives. *See* Hausman Report ¶ 29 ("[t]he contraceptive marketplace is promotionally sensitive, which means that declines in promotion lead to declines in sales"); Def.'s Mot., Ex. 72 at 41:4 - 41:18 (Depo. Tr. of Roger Boissonneault) ("Q: What is the purpose of marketing a pharmaceutical product? . . . A: Well, the idea is to market the product so that the product will increase in market share, and we go out and distinguish our product and tell physicians why they should be writing our product perhaps versus somebody else's product "); *id.*, Ex. 17 at 203:1 (Depo. Tr. of Daniel Rubinfeld) ("when doctors are initially prescribing an oral contraceptive to a patient, and it's the first time that doctor is making such a prescription that the availability of sampling is very important. The doctors are much more likely to prescribe a product that is sampled than one that is not"). ²²

Plaintiffs, in turn, emphasize that a physician's initial prescription choice is not based on price, and that once an initial determination has been made as to which oral contraceptive to prescribe, patients continue to use the same oral contraceptive regardless of price:

the physician typically will write the prescription for the oral contraceptive pill that the woman is already using because of the risk that switching to any other

²² Plaintiffs seek to diminish the importance of promotional activities such as sampling by arguing that "Warner Chilcott did not react by increasing sampling during periods when entry of other branded and less expensive generic non-Ovcon oral contraceptives occurred." Pls.' Opp'n at 28; Def's Mot., Ex. 7 ¶ 27 (Rebuttal Report of Keith Leffler) ("the sampling of Ovcon 35 was relatively constant from April 2002 through 2005, a period of substantial entry of both branded and generic oral contraceptives").

product could result in side effects. Consequently, even though there may be a number of different oral contraceptive pills a physician could have started a patient on, or in theory could switch a patient to, once the physician and patient find one that is well-tolerated, it is very unlikely that the patient will switch to a different oral contraceptive.

Dickey Report ¶ 29. *See also* Pls.' Opp'n, Ex. 104 at 207:16 - 207:19 (Depo. Tr. of Mitchell Lazar) ("[i]f a patient is doing well on a pill, the doctor is going to keep the patient on that pill"); *id.*, Ex. 77 at 37:9 - 37:13 (Depo. Tr. of Richard Dickey) ("Q: So you don't take into account your patients' sensitivities to the pricing of oral contraceptives in prescribing oral contraceptives? A: I do take that into account, but I would never make the decision based on the cost"); Derman Report ¶ 8B ("[p]hysicians generally select an oral contraceptive for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price . . ."). This inattention to price differences, according to Plaintiffs, "allows pharmaceutical manufacturers to avoid price competition and maintain monopoly prices so long as AB-rated generic alternatives to their drugs are not available"
Pls.' Opp'n at 28.

The Court cannot resolve the parties' disputed market definition on summary judgment. As reflected above, Plaintiffs have marshaled evidence from which a jury could find that Warner Chilcott was not price-constrained prior to the entry of generic competition because physicians do not prescribe oral contraceptives based on price, patients do not switch oral contraceptives based on price, and there is an insignificant amount of actual switching between oral contraceptives. Barr has marshaled competing evidence from which a jury could find that Ovcon is functionally interchangeable with non-Ovcon oral contraceptives, and that Warner Chilcott was price-constrained by competition from other manufacturers' oral contraceptives, both in

terms of setting the price of Ovcon and also having to expend significant funds for marketing and promotional efforts.²³ In the face of this conflicting evidence, the finder of fact must determine the proper scope of the relevant product market, not the Court. *See Coastal Fuels Inc. v.*Caribbean Petroleum Corp., 79 F.3d 182, 197 (1st Cir. 1996) ("the question of market definition is one of fact for the jury"); Reazin v. Blue Cross & Blue Shield, Inc., 899 F.2d 951, 975 (10th Cir. 1990) ("[m]arket definition is a question of fact").

3. Balancing Procompetitive Benefits with Anticompetitive Effects

The balancing of competitive harms and/or benefits associated with Barr's Agreement turns almost entirely on the contested market definition – a result that is not uncommon in antitrust cases. *See, e.g., FTC v. Whole Foods Market, Inc.*, No. 07-5276, Slip. Op. at 4 (D.C. Cir. July 29, 2008) (Tatel, J., concurring) ("I agree with the district court that this case hinges—almost entirely—on the proper definition of the relevant product market, for if a separate natural and organic market exists, there can be little doubt that the acquisition of the second largest firm in the market by the largest firm in the market will tend to harm competition in that market") (internal quotations omitted); *Microsoft Corp.*, 253 F.3d at 69 (describing an antitrust challenge to various exclusive contracts and explaining that "the plaintiff must both define the relevant market and prove the degree of foreclosure"). For example, Plaintiffs allege that Barr entered into the Agreement with Warner Chilcott that prevented the introduction of a lower-priced alternative product to consumers so that Warner Chilcott could continue as the only

²³ Defendants also quote from a book that Dr. Rubinfeld co-authored that stated "[i]in the pharmaceutical industry . . . [m]arkets are usually defined in terms of therapeutic classes of drugs." Def.'s Mot. at 31 (quoting Pindyck, Robert S. and Rubinfeld, Daniel L., Microeconomics (6th ed. 2005) at 10). The Court is unpersuaded that the general statements contained in this book have any application to the particular market at issue in this case.

supplier of a higher-priced product. *See* Pls.' Opp'n at 30 (describing anticompetitive harms such as reduced output, higher prices, and reduced consumer choice, all of which are cognizable anticompetitive effects). If the relevant market consists of Ovcon and its generic equivalents, the anticompetitive effects of the agreement are readily identifiable. *See Valley Drug Co.*, 344 F.3d at 1304 ("[w]hen a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced"). If, however, the relevant market is broader and includes other branded and generic oral contraceptives, consumers could switch to alternative products to avoid excessive pricing of Ovcon, thereby making the competitive effects of the Agreement much less clear. *See, e.g., Swedish Match*, 131 F. Supp. 2d at 157 (explaining that if moist snuff and loose leaf tobacco are in the same market, the existence of one would have the ability to constrain prices and maintain a competitive marketplace based on the existence of the other).

Barr proffers, in turn, six procompetitive benefits:

- (1) the agreement ensured a safe, stable, and reliable supply of Ovcon 35 for consumers;
- (2) the agreement ensured continued, substantial sampling of Ovcon 35 by Warner Chilcott, resulting in low net prices to consumers;
- (3) the agreement enabled Ovcon 35 to aggressively compete against the numerous other hormonal contraceptives in the marketplace;
- (4) the agreement enabled Barr to produce Ovcon 35 in the face of a possible line extension contemplated by Warner Chilcott that would have moved patients away from the Ovcon tablet Barr was able to produce;
- (5) the agreement removed the potential that Ovcon 35 would exit from the market altogether; and
- (6) the agreement resulted in an overall increase in market share for Ovcon, i.e.,

output, for Ovcon products.

Def.'s Mot. at 3-4. Some of these benefits depend almost entirely on market definition. For example, a finding that the relevant market consists of Ovcon and its generic equivalents would eviscerate Barr's argument that the Agreement allowed Ovcon to compete against other hormonal contraceptives in the marketplace. In the absence of a defined market, however, the Court shall decline to opine on the parties' proffered procompetitive benefits or anticompetitive effects—or the balancing of the same—which shall be considered by the finder of fact at trial.²⁴

C. Direct Purchaser Standing

As a final matter, Barr includes a few perfunctory standing arguments in its Motion that do not require extended discussion. First, Barr argues that numerous Plaintiffs have brought suit based on assignment contracts from the wholesalers McKesson and Cardinal, but that Warner Chilcott's distribution agreements with those wholesalers bar the assignment of any claims without Warner Chilcott's written consent (which Warner Chilcott has not provided). Def.'s Mot. at 41-42 & n.21. Barr argues that "[b]ecause McKesson is contractually barred from assigning any claims arising from its purchases of Ovcon 35 from Warner Chilcott, its assignment of claims" to Plaintiffs is void and Plaintiffs lack standing. *Id.* at 42; *id.* at 42 n.21 (asserting the same argument as to Cardinal). The Court notes that it is highly doubtful that Barr, as a stranger to the Warner Chilcott agreements, would itself have standing to challenge the

²⁴ Although the Court does not reach the merits of Barr's proffered procompetitive benefits, the Court notes that "benefits" are only procompetitive when they promote and protect competition, not competitors, *see Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993), and when they do not rely on "the assumption that competition itself is unreasonable," *National Society of Professional Engineers v. United States*, 435 U.S. 679, 696 (1978).

assignments at issue, particularly after Warner Chilcott has already settled the claims brought against it pursuant to those assignments. In any event, Barr's argument would only have merit if the Court ignored the actual language of the assignment provisions at issue, which state that "[n]either party may assign *this Agreement* without the prior written consent of the other party." *Id.* at 42 & n.21. While such a provision may prevent an assignment of the parties' contractual duties, it cannot be read to prevent the assignment of the parties' statutorily-based antitrust claims. *See Cedar Point Apartments v. Cedar Point Inv. Corp.*, 693 F.2d 748, 753 (8th Cir. 1982) (interpreting a contractual prohibition against "assignment of the contract" as only preventing a delegation of the parties' contractual duties). Accordingly, the Court finds that Barr's argument lacks merit.²⁵

Next, Barr argues that Plaintiffs Meijer and Meijer Distribution lack standing to sue because they received an assignment from wholesaler Kerr "nearly two years before their complaint was filed." Def.'s Mot. at 42 (emphasis in original omitted). Barr further argues that, although Meijer and Meijer Distribution acquired another assignment "one year after they filed suit," such an "after the fact" assignment is insufficient because plaintiffs must show standing at the time they file a complaint. *Id.* at 43 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 569 n.4 (1992)) (emphasis in original omitted). Once again, Barr's argument simply ignores the relevant language of the assignment, which includes and incorporates subsequent transactions, and that contemplates the execution of a subsequent assignment of claims as further evidence of

²⁵ Barr cites to *In re Ditropan XL Antitrust Litigation* for support, but it has no relevance to the present matter. 529 F. Supp. 2d 1098 (N.D. Cal. 2007). In that case, the court merely held that the plaintiff had *failed to allege in its complaint* that it had received an assignment from the wholesaler Cardinal. *Id.* at 1100. The court therefore dismissed the plaintiff's antitrust claim with leave to amend. *Id.*

the same:

Kerr hereby conveys, assigns and transfers to Meijer all rights, title and interest in and to all causes of action and any resulting proceeds Kerr may have under the antitrust laws . . . relating to Kerr's purchases of any pharmaceutical products which were subsequently resold to Meijer during the period of January 1, 1987 to the Effective Date of this Agreement.

All sales transactions between Meijer and Kerr pertaining to pharmaceutical products occurring after the date of this Agreement shall incorporate, without further action of the parties, an assignment to Meijer by Kerr of all causes of action described in paragraph 2 above. Kerr agrees that, upon Meijer's request, Kerr shall execute an assignment of claims containing language substantially similar to the language contained in Paragraph 2 above as further evidence of such assignment.

Pls.' Opp'n at 42 n. 63; Pls.' Opp'n, Ex. 47 (10/4/02 Assignment). Therefore, Meijer and Meijer Distribution had standing at the time they filed their claims. In Reply, Barr argues that a party cannot assign claims that it does not possess at the time of an assignment, *see* Def.'s Reply at 34, but that argument is legally deficient. *See, e.g., King & King v. Harbert Int'l, Inc.*, 503 F.3d 153, 155 (D.C. Cir. 2007) (finding no fault with an assignment of all "pending and future claims" under various contracts); *Pollice v. Nat'l Tax Funding, L.P.*, 225 F.3d 379, 386 (3d Cir. 2000) (finding no fault with an assignment of "not only existing claims but also future claims").

Finally, Barr argues that one or more wholesalers may lack standing because possible "overcharges" were "passed on" through the use of "cost plus" contracts, and therefore, the assignees of the wholesalers would also lack standing. Def.'s Mot. at 43-44. Barr's five-sentence argument is based on *Hanover Shoe, Inc. v. United Shoe Machinery Corporation*, a case where the Supreme Court held that, in general, only direct purchasers (as opposed to indirect purchasers) have standing to assert antitrust injury. 392 U.S. 481, 494 (1968). The Court recognized a possible exception for instances when "an overcharged buyer has a pre-existing

'cost-plus' contract, thus making it easy to prove that he has not been damaged." *Id.* The Court reaffirmed this ruling in *Illinois Brick Co. v. Illinois*, but emphasized its narrowness and explained that it was intended only for situations where

the purchaser is insulated from any decrease in its sales as a result of attempting to pass on the overcharge[] because its customer is committed to buying a fixed quantity regardless of price. The effect of the overcharge is essentially determined in advance, without reference to the interaction of supply and demand that complicates the determination in the general case.

431 U.S. 720, 735-36 (1977).

Barr fails to cite to a single decision where this exception has ever been satisfied, and the Third Circuit has characterized its vitality as "doubtful." *McCarthy v. Recordex Svc., Inc.*, 80 F.3d 842, 855 (3d Cir. 1996). In any event, Barr's cursory analysis fails to even allege that the referenced contracts are for a fixed quantity, and Barr fails to explain how the contracts operate so as to make the effect of any overcharge "preordained." *See In re Lorazepam & Clorazepate Antitrust Litig.*, 202 F.R.D. at 19-20 (citing *Kansas v. Utilicorp. United, Inc.*, 497 U.S. 199, 216-17 (1990)). Accordingly, the Court finds that Barr's final argument is without merit.

IV. CONCLUSION

For the reasons set forth above, the Court shall DENY Plaintiffs' Motion for Partial Summary Judgment, and shall GRANT-IN-PART and DENY-IN-PART Defendant's Motion for Summary Judgment. The Court holds that the agreement between Barr and Warner Chilcott must be evaluated under the rule of reason and cannot be condemned as a *per se* unlawful restraint of trade. The Court further holds that genuine issues of material fact exist with respect to the proper definition of the relevant product market in this case, and that these factual issues

preclude entry of summary judgment. An appropriate Order accompanies this Memorandum Opinion.

Date: August 11, 2008

<u>/s/</u> COLLEEN KOLLAR-KOTELLY

United States District Judge