

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

In re: Nifedipine Antitrust
Litigation

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Master Docket No. 03-MS-223
MDL DOCKET NO. 1515
ALL CASES

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NANCY MAYER WHITTINGTON, CLERK
U.S. DISTRICT COURT

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MEMORANDUM OPINION & ORDER

(September 1, 2004)[Dkt #20, 22, 24]

Before the Court are the Joint Motion of Elan and Biovail to Dismiss the Complaints and Teva's Motions to Dismiss the Consolidated Class Action Complaints. Upon consideration of the defendants' motions, the plaintiffs' oppositions, the defendants' replies, the various supplemental filings of both parties and the entire record herein, the Court GRANTS IN PART and DENIES IN PART the defendants' motions to dismiss. Specifically, the Court grants the motion to dismiss the claims for injunctive relief for lack of subject matter jurisdiction. Because the Court lacks jurisdiction over the End-Payor Plaintiffs' sole federal claims, the Court likewise lacks jurisdiction over, and must dismiss, the End-Payor Plaintiffs' state law claims.

I. BACKGROUND

A. *The Parties*

The defendants in this case, Biovail Corporation, Elan Corporation, and Teva Pharmaceutical Industries (collectively "the defendants"), are pharmaceutical companies

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involved in the manufacture and distribution of generic Adalat CC, a once-a-day prescription drug used in the treatment of hypertension. Sherman Act Second Consolidated Amended Class Action Complaint (“SACC”) ¶¶ 13-15; End-Payor Consolidated Amended Class Action Complaint (“EPCC”) ¶¶ 15-21. The plaintiffs in this case fall into three general categories. The Sherman Act Class Plaintiffs are comprised of companies, such as retail and wholesale drug stores and distributors, that bought generic Adalat CC from the defendants.¹ SACC ¶¶ 7-12. The Sherman Act Non-Class Plaintiffs include major national drug store chains that purchased generic Adalat CC from the defendants.² The End-Payor Plaintiffs include health and benefit funds for unions, an HMO, a consumer advocacy group, and one individual user of generic Adalat CC.³ EPCC ¶¶ 7-14. Although the End-Payor Plaintiffs purchased generic Adalat CC, they did not purchase it directly from any of the defendants. *Id.* The plaintiffs bring this antitrust action alleging that Biovail, Elan, and Teva conspired to allocate the sales of generic Adalat CC so as to reduce competition among the generics and the branded drug

¹ The Sherman Act Class Plaintiffs include SAJ Distributors, Inc., Stephen L. LaFrance Holdings, Inc., Meijer, Inc., Meijer Distribution, Inc., Rochester Drug Cooperative, and Independent Drug Company. SACC ¶¶ 7-12.

² The Sherman Act Non-Class Plaintiffs include CVS Meridian, Walgreen Company, and Rite Aid Corporation.

³ The End-Payor Class Plaintiffs include A.F. of L. - A.G.C. Building Trades Welfare Plan, United Food and Commercial Workers Local 56 Health & Welfare Fund, Vista Healthplan, Inc., Alvin Shiggs, Health Care for All, American Federation of State, County and Municipal Employees, AFL-CIO, American Federation of State, County and Municipal Employees 47 Health and Welfare Fund, and Sidney Hillman Health Center of Rochester, Inc. EPCC ¶¶ 7-14

and to artificially, and illegally, inflate prices for both. SACC ¶ 2. The plaintiffs seek treble damages and injunctive relief.

B. Regulatory History of Generic Adalat CC and the Agreement Between Biovail and Elan

Nifedipine, the drug at the center of this litigation, is a coronary vasodilator used for the treatment of hypertension. SACC ¶ 31; EPCC ¶ 48. Bayer Corporation holds an approved New Drug Application (“NDA”)⁴ for an extended release formulation of nifedipine that it sells under the name Adalat CC®.⁵ SACC ¶ 34; EPCC ¶ 52. Adalat CC is marketed in the United States in 30 mg, 60 mg, and 90 mg dosages.⁶ EPCC ¶ 57. Bayer’s Adalat CC extended release tablets are subject to two United States patents. *Id.*

On April 30, 1997, Elan filed the first Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”), seeking approval to

⁴ Drug manufacturers must obtain approval from the Food and Drug Administration (“FDA”) for new drugs by filing an NDA which requires the submission of data on the safety and effectiveness of the drug and information on any applicable patents. When a drug manufacturer seeks to produce a generic version of a drug, the manufacturer only has to file an Abbreviated New Drug Application (“ANDA”), which can rely upon the safety and effectiveness findings in the NDA. The ANDA application must also indicate whether the original drug is protected by any patents, and if so, how the patent will affect the production of the generic. SACC ¶¶ 25-27.

⁵ The extended release version of nifedipine offers the principle advantage of increased patient compliance. Because hypertension is a asymptomatic, patients frequently neglect to take their prescribed medication. A once-a-day prescription is easier to remember, and thus, is more successfully administered. EPCC ¶ 51.

⁶ In 2000, over 5.9 million prescriptions for Adalat CC were filled, making it the 70th most prescribed drug in the U.S. Biovail reported that in 2000, U.S. sales for generic and branded Adalat were approximately \$441 million. SACC ¶ 35; EPCC ¶ 56.

produce a generic version of 30 mg Adalat CC. SACC ¶ 37; EPCC ¶ 58. In its ANDA, Elan certified that its manufacture, use, sale, or importation of the 30 mg generic Adalat CC either would not infringe on any of Bayer's patents or that the patents were invalid.⁷ SACC ¶¶ 28, 37; EPCC ¶ 63. On August 22, 1997, Bayer filed a patent infringement suit against Elan.⁸⁹ SACC ¶ 38; EPCC ¶ 64. Under FDA regulations, Elan's ANDA was put on hold pending the resolution of the patent suit. SACC ¶ 38; EPCC ¶ 64. With that suit pending, Biovail filed on ANDA on December 9, 1997 for generic versions of 30 mg and 60mg Adalat CC. SACC ¶ 39; EPCC ¶ 65. Six days later, on December 15, 1997, it entered into an exclusive agreement with Teva for the marketing and distribution of its products in the United States ("the Biovail/Teva Agreement").

On March 16, 1999, the United States District Court for the Northern District of Georgia found that Elan's 30 mg generic product did not infringe Bayer's patent. SACC ¶ 40. Two months later, the FDA, on May 28, 1999, notified Elan that it had tentatively approved Elan's ANDA for 30 mg generic Adalat CC. SACC ¶ 43; EPCC ¶ 68. A month later, on June 29, 1999, the FDA tentatively approved Biovail's ANDA for 30mg

⁷ This is referred to a "Paragraph IV Certification." Alternatively, an applicant may represent that there is no relevant patent, that the relevant patent has expired, or that the ANDA applicant will not produce the generic drug until after the relevant patent expires. 21 U.S.C. §355(j)(5)(B)(vii).

⁸ *Bayer AG and Bayer Corporation v. Elan Pharmaceutical Research Corporation and Elan Corporation, Plc.*, No. 97-cv-143 (N.D. Ga.).

⁹ Under FDA regulations, the NDA holder has 45 days to bring a patent suit after receiving notice of the ANDA applicant's position on potential infringement in order to stay the FDA's approval process. SACC ¶ 38.

and 60 mg Adalat CC generics. SACC ¶ 43; EPCC ¶ 69. The next day, June 30, 1999, Elan filed an ANDA to produce a 60mg generic for Adalat CC. SACC ¶ 44; EPCC ¶ 70. However, on October 4, 1999, while still awaiting final approval on its 30 mg generic, Biovail entered into an exclusive agreement to market and distribute Elan's 30 mg generic ("the Distribution Agreement"), which had only been tentatively approved by the FDA four weeks earlier than Biovail's 30 mg generic. SACC ¶ 45; EPCC ¶ 71. In exchange for the marketing and distribution rights, Biovail agreed to pay Elan at least \$73.5 million over a six-year period. *Id.*

On March 10, 2000, the FDA granted a final approval of Elan's 30mg generic. SACC ¶ 48; EPCC ¶¶ 58, 60, 72. Three days later, on March 13, 2000, Biovail announced that, pursuant to a Distribution Agreement with Elan, it would launch Elan's 30 mg generic Adalat CC, using Teva as the exclusive U.S. Distributor.¹⁰ SACC ¶ 49; EPCC ¶ 73. Under FDA regulations, Elan received a 180-day period of market exclusivity because it was the first ANDA filer to receive approval for the 30mg generic. SACC ¶ 29.

On December 4, 2000, the FDA granted final approval to Biovail for its 30 mg and 60 mg generic Adalat. SACC ¶ 53; EPCC ¶¶ 59, 77. Immediately thereafter, Biovail

¹⁰ After the launch of the 30 mg generic, Bayer sued Elan, Biovail and Teva on May 8, 2000. SACC ¶ 50. Judge O'Kelley, U.S. District Judge for the Northern District of Georgia, ultimately dismissed this case on collateral estoppel grounds. SACC ¶ 58. Bayer had previously sued Biovail for patent infringement in the United States District Court for the District of Puerto Rico (Civ. Action No. 98-1282) and the United States District Court for the District of Columbia (Civ. Action No. 98-1681). SACC ¶ 39; EPCC ¶ 59.

launched a 60 mg generic version of Adalat CC. SACC ¶ 53; EPCC ¶ 77. As the first filer on the 60 mg generic, Biovail qualified for the 180-day period of exclusivity, which ran until approximately June 4, 2001. SACC ¶ 59. Although Elan's period of market exclusivity for the 30 mg generic had expired by that point in time, Biovail chose not to launch its own 30 mg generic, continuing to distribute Elan's 30 mg generic product. SACC ¶ 53.

On March 20, 2001, the FDA tentatively approved Elan's 60 mg generic. SACC ¶ 56. Final approval was granted October 26, 2001, more than four months after Biovail's period of market exclusivity on the 60 mg dosage had expired. SACC ¶ 60; EPCC ¶ 84. However, Elan chose not to launch a 60 mg product at that time. SACC ¶ 60. Indeed, although both Biovail and Elan were legally entitled to produce a generic version of 60 mg Adalat CC by October 26, 2001, and both companies were similarly legally able to produce a generic version of 30 mg Adalat CC by December 4, 2000, neither did. SACC ¶¶ 61, 63; EPCC ¶¶ 84, 87. Biovail only produced a 60 mg product and Elan only produced a 30 mg product, which Biovail exclusively distributed. According to the plaintiffs, neither product had any direct competition and both products were exclusively distributed through Teva. SACC ¶ 63.

The plaintiffs allege that the exclusive Distribution Agreement between the parties entered into on October 4, 1999 precluded Elan from selling generic Adalat products in competition with Biovail and Teva. SACC ¶ 45; EPCC ¶ 71. The plaintiffs also allege

that Teva participated in the negotiations with Biovail and Elan and that, as a result of the Biovail/Teva Agreement, Teva became the exclusive marketing and distribution agent for Elan in the United States. SACC ¶ 47.

The plaintiffs further allege that, but for the Distribution Agreement among the defendants, Biovail would have introduced a 30 mg generic as of December 4, 2000, when the FDA approved Biovail's ANDA. SACC ¶ 54. Similarly, plaintiffs allege that Elan would have introduced a 60 mg generic as of October 26, 2001, when the FDA approved Elan's ANDA. SACC ¶ 60. In either case, had either company that received the second approval brought a product to market, the new competition would have resulted in lower prices to consumers. Thus, the alleged effect of the agreement among the defendants was to maintain supra-competitive prices on both the 30 mg and 60 mg dosages of generic Adalat CC.¹¹ SACC ¶¶ 55, 60; EPCC ¶ 79.

C. The FTC Consent Order

On June 27, 2002, the Federal Trade Commission ("FTC") filed an administrative complaint alleging that Biovail and Elan had "unreasonably restrained competition" in the market for generic Adalat CC. SACC ¶ 65. On the same date, the FTC announced that it had entered into a proposed Consent Order with the two companies. *Id.* The Consent

¹¹ The plaintiffs also allege that, as a result of the lack of competition and supra-competitive pricing, Bayer was able to maintain a higher market share and higher prices for a longer period of time than otherwise would have been possible in a competitive market. SACC ¶ 64.

Order, which was finally approved on August 15, 2002, requires Elan and Biovail to terminate the Distribution Agreement and prohibits each company from entering anti-competitive price, output or distribution agreements with another generic competitor. SACC ¶¶ 65-66. In addition, the Consent Order prohibits Elan from distributing its generic Adalat CC through Teva, and requires it to use its best efforts to sell its 30 mg and 60 mg generic Adalat CC through another distributor as promptly as possible. SACC ¶¶ 66, 67. Biovail was required to use its best efforts to bring a 30 mg product to market as soon as possible and to continue marketing its 60 mg product. SACC ¶ 67. As a temporary remedy, Elan was required to supply Biovail with its 30 mg generic Adalat CC at cost until Biovail launched its own 30 mg product or until May 31, 2003, whichever came first. SACC ¶ 68. This would ensure that the supply of 30 mg generic Adalat CC would continue uninterrupted while Elan sought a new distributor and that consumers would have two competing 30 mg products as soon as possible. EPCC ¶ 98. In August 2002, Watson Pharmaceuticals, Inc. acquired the U.S. rights to Elan's 30 mg and 60 mg dosages of generic Adalat CC. SACC ¶ 69; EPCC ¶ 99. Watson thereafter began selling generic Adalat CC in both dosages. *Id.* The plaintiffs allege that since the implementation of the Consent Order, prices of Adalat have begun to decrease and that, but for the Distribution Agreement, that decrease would have occurred much earlier. SACC ¶ 69.

D. The Instant Lawsuit

The Sherman Act Plaintiffs¹² allege that the Distribution Agreement between Elan and Biovail was an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. SACC ¶¶ 74, 75. Each of the Sherman Act Plaintiffs seek monetary damages under Section 4 of the Clayton Act and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. §§ 15, 26.¹³ SACC ¶ 5. The End-Payor Plaintiffs also allege that the Distribution Agreement was an unreasonable restraint of trade in violation of Section 1 of the Sherman Act.¹⁴ EPCC Count I. However, they only seek declaratory and injunctive relief on their federal claim. EPCC Prayer for Relief ¶¶ D, E. They additionally allege damage claims under the antitrust statutes, consumer protection statutes, and the common law of unjust enrichment under the laws of numerous individual states. EPCC Counts II-IV. The End-Payor Plaintiffs argue that this Court should exercise supplemental jurisdiction over their state law claims because they are closely related to the federal claim and are part of the same case or controversy. End-Payor

¹² Collectively, the Sherman Act Class Plaintiffs and the Sherman Act Non-Class Plaintiffs.

¹³ The Walgreen Complaint expressly requests Section 16 injunctive relief. Walgreen Complaint, Prayer for Relief ¶ C. However, the other Sherman Act Plaintiffs merely ask for injunctive relief generally or any other relief that the Court may deem proper, which may be construed to include injunctive relief. CVS Complaint ¶¶ 1, 5, Prayer for Relief ¶ (d); SACC ¶ 1, Prayer for Relief (v). In addition, CVS seeks damages pursuant to Section 2 of the Sherman Act, but does not allege a monopolization claim in its complaint.

¹⁴ Although their Prayer for Relief seeks a declaration that the Distribution Agreement violated Sections 1 and 2 of the Sherman Act, the End-Payor Plaintiffs' Complaint does not include a count articulating a Section 2 monopolization claim.

Purchaser Plaintiff's Mem. of P&A in Opp. to Def. Joint Mot. to Dismiss ("EPP Opp.") at 16.

The defendants base their motions to dismiss on various theories, three of which are discussed more fully below. First, the defendants argue that the Section 1 claims brought by the Sherman Act Plaintiffs should be dismissed for failure to state a claim for damages under Section 4 of the Clayton Act. Fed. R. Civ. P. 12(b)(6). Joint Mot. to Dismiss ¶ 9; Teva's Mot. to Dismiss the SACC ¶¶ 3-9. Second, the defendants argue that all of the plaintiffs' claims for injunctive relief should be dismissed for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(1), (b)(6); Joint Mot. to Dismiss ¶ 10; Teva's Mot. to Dismiss the EPCC. Finally, for purposes of this opinion, the defendants argue that the Court should decline to exercise supplemental jurisdiction over the End-Payor Plaintiffs' state law claims if their federal claims are dismissed. 28 U.S.C. § 1367(c); Joint Mot. to Dismiss ¶ 11.

II. STANDARD OF REVIEW

Federal district courts are courts of limited jurisdiction and "possess only that power conferred by [the] Constitution and [by] statute." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). There is a presumption against federal court jurisdiction and the burden is on the plaintiff to establish that the Court has subject matter jurisdiction over the action. *McNutt v. Gen. Motors Acceptance Corp. of Ind.*, 298 U.S.

178, 182-83 (1936). Federal Rule of Civil Procedure 12(b)(1) imposes on the Court “an affirmative obligation to insure that it is acting within the scope of its jurisdictional authority.” *Jones v. Ashcroft*, 321 F.Supp.2d 1, 5 (D.D.C. 2004) (citing *Uberoi v. EEOC*, 180 F.Supp.2d 42, 44 (D.D.C. 2001)). Thus, upon a motion to dismiss for lack of jurisdiction, the Court need not limit itself to the allegations of the complaint. *Hohri v. United States*, 782 F.2d 227, 241 (D.C.Cir.1986), *vacated on other grounds*, 482 U.S. 64, 107 S.Ct. 2246, 96 L.Ed.2d 51 (1987). In determining whether it has jurisdiction over the case, the Court may consider the complaint, any undisputed facts, and its resolution of any disputed facts. *Herbert v. Nat'l Acad. of Sciences*, 974 F.2d 192, 197 (D.C. Cir.1992).

The Court will only dismiss a complaint under Rule 12(b)(6) for failure to state a claim if “it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957); *Kowal v. MCI Communications Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994). However, while the Court accepts as true all of the factual allegations set forth in the complaint, *Doe v. United States Dept. of Justice*, 753 F.2d 1092, 1102 (D.C. Cir. 1985), and construes the complaint liberally in favor of the plaintiff, *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979), it “need not accept inferences drawn by [the] plaintiffs if such inferences are unsupported by the facts set out in the complaint.” *Kowal*, 16 F.3d at 1276.

III. DISCUSSION

A. *Sherman Act Damage Claims*

The Sherman Act Plaintiffs seek damages pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15, for alleged violations of Section 1 of the Sherman Act, 15 U.S.C. § 1. SACC ¶ 5; CVS Compl. ¶ 5; Walgreen Compl. ¶ 5. Biovail and Elan move to dismiss these claims under Rule 12(b)(6) on the grounds that the Sherman Act Plaintiffs lack standing because Teva, a named co-defendant and alleged co-conspirator, is the direct purchaser and the only proper plaintiff under the Supreme Court's decision in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) ("*Illinois Brick*"). Teva also moves for dismissal of the plaintiffs' Section 1 claims on the grounds that Teva was not a party to the allegedly anticompetitive agreement and any allegations regarding Teva's involvement are "simply conclusory." Teva Mot. to Dismiss the SACC 3.

In an antitrust case, as in other cases under the Federal Rules, the plaintiffs need only provide "[a] short plain statement of a claim for relief which gives notice to the opposing party..." *In re Vitamins Antitrust Litigation*, 2000 WL 1475705, at *8 (D.D.C. May 9, 2000) ("*Vitamins*") (citing *Nagler v. Admiral Corp.*, 248 F.3d 319, 322-23 (2d Cir. 1957)). While the plaintiffs may not "simply paraphrase the language of the federal antitrust laws" in conclusory terms, if their complaint sets forth direct or inferential allegations with respect to the material elements necessary for recovery under a viable

legal theory, it should survive a motion to dismiss. *Jung v. Association of Medical Colleges*, 300 F.Supp.2d 119, 157 (D.D.C. 2004). Moreover, as discovery is usually critical to securing proof, or disproof, of an alleged antitrust conspiracy, the Court will grant dismissal prior to the discovery stage sparingly. Applying these standards, as set forth below, the Court finds that the Sherman Act Class Plaintiffs' have sufficiently pled their allegations of conspiracy against the three defendants in this case. The Court thus denies the defendants' motions as to the claims for damages based on a violation of Section 1 of the Sherman Act.

1. *Biovail and Elan's Motion to Dismiss under the Direct-Purchaser Rule of Illinois Brick*

In *Illinois Brick*, the Supreme Court held that the "overcharged direct purchaser, and not others in the chain of manufacture or distribution" is the proper plaintiff in an action for damages under federal antitrust laws. 431 U.S. at 727-28; *see also California v. ARC Am. Corp.*, 490 U.S. 93, 100 (1989). The Supreme Court reasoned that permitting indirect purchasers to collect damages would subject defendants to the risk of multiple liability and would also lead to complex damage apportionment if successive suits were brought based on the same alleged antitrust violation. *Illinois Brick*, 431 U.S. at 730, 731-32. The Court did, however, leave open the possibility of two exceptions to this direct-purchaser rule. First, indirect purchasers might be able to maintain a damage action if they could show that "the direct purchaser is owned or controlled by its

customer.” *Id.* at 736 n. 16. Second, a “pass-on” defense might be available where an overcharged indirect purchaser has a pre-existing cost-plus contract, which would insulate the direct purchaser from any decrease in sales as a result of passing on an overcharge to its customer, a circumstance clearly not present here. *Id.* at 735-36.

Several federal Circuit courts have recognized a variant of the “control” exception through a so-called “co-conspirator” exception, under which an indirect purchaser could maintain a damage action upon a showing that there was a conspiracy between the manufacturers and the direct purchaser middleman. *See In re Brand Name Prescription Drugs Antitrust Litigation*, 123 F.3d 599, 604-05 (7th Cir. 1997); *see also Lowell v. American Cyanamid Co.*, 177 F.3d 1228, 1233 (11th Cir. 1999); *Arizona v. Shamrock Foods Co.*, 729 F.2d 1208, 1212-14 (9th Cir. 1984); *In re Beef Antitrust Litigation*, 600 F.2d 1148, 1163 (5th Cir. 1979). *But see Link v. Mercedes-Benz of North America*, 788 F.2d 918, 931-33 (3d Cir. 1986) (declining to recognize the co-conspirator exception where the alleged co-conspirators were not joined as co-defendants). Under this “co-conspirator” theory, the party who purchases from a co-conspirator middleman is treated as a “direct purchaser” because the manufacturers and the middleman direct purchaser are viewed as one entity.

In this case, the defendants assert that the damage claims of the Sherman Act Plaintiffs must fail because these plaintiffs did not purchase nifedipine directly from Biovail or Elan, or from any party owned or controlled by these entities. Joint Mot. to

Dismiss 19. Moreover, the defendants argue that the Sherman Act Plaintiffs cannot proceed under a “co-conspirator” theory because the D.C. Circuit has not yet recognized the “co-conspirator” exception. *Id.* at 34. Finally, the defendants argue that recognizing a “co-conspirator” exception would be inconsistent with the Supreme Court’s decision in *Perma-Life Mufflers, Inc. v. International Parts Corp.*, 392 U.S. 134 (1968), which rejected the use of the *in pari delicto* defense in antitrust actions, unless Teva was alleged to be an “equal, voluntary and complete” co-conspirator. *Id.* at 139-40.

The Sherman Act Plaintiffs respond that their damage claims are not barred because *Illinois Brick*, as interpreted by the lower federal courts, provides that the first purchaser from the alleged conspiracy is a proper plaintiff. SAP Opp. 10. Moreover, the plaintiffs assert that *Perma-Life* does not bar their suit because they have alleged that Teva was an essential, voluntary, and active participant in the illegal conspiracy and that Teva and Biovail entered into a joint venture relationship. *Id.* at 8-9, 17-19.

In light of the Sherman Act Plaintiffs’ allegations regarding the active role of Teva in the alleged conspiracy, which the Court must accept as true, the Court will deny Biovail and Elan’s motion to dismiss with regard to their *Illinois Brick* challenge. In the Court’s view, it would be premature to dismiss the plaintiffs’ claims when their allegations raise factual issues yet to be explored in discovery with regard to Teva’s relationship to Biovail and Elan, and the extent to which the plaintiffs may have been prevented from purchasing nifedipine from parties other than Teva as a result of the

alleged conspiracy. While the D.C. Circuit has neither rejected a “co-conspirator” exception to the *Illinois Brick* direct-purchaser rule, nor ruled that *Perma-Life* prevents a plaintiff from asserting such an exception, the Court need not, at this point, rule on the viability of this legal theory since there is at least one other theory of recovery alleged by the plaintiffs (*i.e.*, the existence of a joint venture between Biovail and Teva). As such, the Court finds that under the existing state of the facts and law in this case, the Sherman Act Plaintiffs have pled a viable legal theory for recovery.¹⁵

2. *Teva’s Motion to Dismiss for Failure to State a Conspiracy Claim*

In a separate motion to dismiss, Teva moves for dismissal of the Sherman Act Plaintiffs’ damage claims on the grounds that Teva was not a party to the allegedly anticompetitive agreement between Biovail and Elan and all other allegations regarding Teva’s participation in the conspiracy are too conclusory to state a claim for relief. Section 1 of the Sherman Act provides the “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several

¹⁵ The Court fully appreciates that to the extent that it might have to rule on the viability of the “co-conspirator” exception, it is in the interest of justice to have as complete a factual record as possible on the existence of a conspiracy prior to any such ruling. *See, e.g., In re Brand Name Prescription Drugs Antitrust Litigation*, 123 F.3d 599, 604 (7th Cir. 1997) (recognizing co-conspirator exception following detailed discussion of defendants’ alleged “chargeback” system); *Arizona v. Shamrock Foods Co.*, 729 F.2d 1208, 1212-14 (9th Cir. 1984) (upholding complaint against remote sellers where extensive discovery supported the plaintiffs’ initial allegation of a retail conspiracy, even though the action previously focused on the existence of a retail conspiracy).

States, or with foreign nations, is declared to be illegal.” 15 U.S.C. § 1. Thus, to withstand a motion to dismiss a Section 1 conspiracy claim, the plaintiffs must allege concerted action by two or more persons that unreasonably restrains interstate or foreign trade or commerce. *Vitamins*, 2000 WL 1475705, at *9. With regard to the existence of concerted action, an claim of antitrust conspiracy is adequate so long as “there are allegations ‘from which an inference of an unlawful agreement can be drawn.’” *Id.* at *10. *Accord In re Linerboard Antitrust Litigation*, 2000 WL 1475559, at *6 (E.D. Pa. Oct. 4, 2000). The plaintiffs need not plead an overt act on the part of each defendant because “a single overt act by just one of the conspirators is enough to sustain a conspiracy even on the merits.” *Vitamins*, 2000 WL 1475705, at *11 (citing *In re Nasdaq Market-Makers Antitrust Litigation*, 894 F.Supp. 703, 712 (S.D.N.Y. 1995)).

Among the Sherman Act Plaintiffs’ allegations with regard to Teva are that:

(1) Teva “participated in negotiating” the unlawful agreement between Biovail and Elan, which allocated all sales of generic Adalat CC to Biovail/Teva, SACC ¶¶ 1, 47; (2) that as result of Teva’s marketing agreement with Biovail and the Distribution Agreement between Biovail and Elan, Teva became “the agent of and/or joint venturer with Biovail and Elan” as the exclusive distributor of generic versions of Adalat CC in the United States, SACC ¶ 47; and (3) that Teva shared in unlawful profits flowing from the agreement between Biovail and Elan. SACC ¶ 47. Furthermore, the plaintiffs assert that “[w]ithout Teva, neither Biovail nor Elan could have sold generic Adalat CC in the

United States because neither company distributed generic drugs in the United States.” SAP Opp. 17-18. The Court finds that the Sherman Act Plaintiffs have sufficiently pled a claim of conspiracy against Teva in their complaint, even though they do not allege that Teva was a party to the Biovail/Elan Distribution Agreement. Simply stated: “It is not necessary to find an express agreement in order to find a conspiracy. It is enough that a concert of action is contemplated and that the defendants conformed to this arrangement.” *Ambook Enterprises v. Time, Inc.*, 612 F.2d 604, 614 (2d Cir. 1979). Accordingly, the Court will also deny Teva’s motion to dismiss the Sherman Act Plaintiffs’ Section 1 conspiracy claim.

B. Claims for Injunctive Relief

All of the plaintiffs seek injunctive relief pursuant to Section 16 of the Clayton Act.¹⁶ The defendants move to dismiss¹⁷ on the grounds that plaintiffs lack standing to bring these claims because there is no threat of future violations or injuries, and therefore, this Court lacks subject matter jurisdiction over the claims for injunctive relief. Fed. R. Civ. P. 12(b)(1); Joint Mot. to Dismiss ¶ 10. To establish that they have standing, the plaintiffs must demonstrate that they have suffered an injury-in-fact, that the injury is

¹⁶ The plaintiffs frame their injunctive relief with varying levels of specificity. See section I.D., and note 13, *supra*.

¹⁷ Biovail and Elan filed a Joint Motion to Dismiss the Consolidated Complaints. Teva adopted the portions of that motion pertaining to injunctive relief without making any additional arguments. Teva’s Mot. to Dismiss the EPCC.

fairly traceable to the challenged conduct, and that the injury is redressable by the relief sought from the Court. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-1 (1992). Because the FTC Consent Order disbanded the Distribution Agreement between the defendants and required the companies to take various steps to introduce competition to the market, the defendants argue that there is no threat of future injury and that any hypothetical injury is redressable only by money damages, and not injunctive relief. In short, they argue that there is nothing to enjoin, and as a result, the plaintiffs lack standing to bring claims for injunctive relief. The Court agrees that the plaintiffs have failed to allege a real and immediate threat of future injury and that, as a result, this Court lacks jurisdiction over any claims for injunctive relief in this case.¹⁸

The defendants also argue that the Court should decline to exercise supplemental jurisdiction over the End-Payor Plaintiffs' state law claims if their federal claims are dismissed. 28 U.S.C. § 1367; Joint Mot. to Dismiss ¶ 11. For the following reasons, the Court agrees, and dismisses the End-Payor Plaintiffs' state law claims for lack of jurisdiction.

¹⁸ Alternatively, the defendants argue that the plaintiffs have failed to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); Joint Mot. to Dismiss ¶ 10. Because the Court concludes that it lacks jurisdiction over these claims, it does not reach the defendants remaining arguments.

1. *Injury-in-Fact*

When seeking injunctive relief to prevent a future injury, the plaintiff must show that he “is immediately in danger of sustaining some direct injury” and that the threat of injury is “real and immediate,” and not “conjectural” or “hypothetical.” *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983) (internal citations omitted). “Abstract injury is not enough.” *O’Shea v. Littleton*, 414 U.S. 488, 494 (1974). Moreover, “[p]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief ... if unaccompanied by any continuing, present adverse effects.” *Lyons*, 461 U.S. at 102 (quoting *O’Shea*, 414 U.S. at 495-96). The plaintiffs¹⁹ make several arguments in support of their contention that they have alleged a real and immediate threat of future injury such that they have standing to request injunctive relief. None of their arguments, however, bear this out.

First, the plaintiffs point out, and the Court agrees, that the mere existence of the Consent Order does not preclude private injunctive relief. *See Sam Fox Publishing Co. v. United States*, 366 U.S. 683, 689 (1961). Indeed, in antitrust cases, private and governmental claims for injunctive relief “were designed to be cumulative, not mutually exclusive.” EPP Opp. at 10 (quoting *United States v. Borden Co.*, 347 U.S. 514, 518 (1954)). However, the party seeking the injunction nonetheless has the burden of

¹⁹ Only the End-Payor Plaintiffs argue this issue in their opposition. The Sherman Act Plaintiffs appear to concede the issue by focusing solely on the 12(b)(6) challenge to the Section 1 claims. However, to the extent that their claims for injunctive relief are analogous, this section ascribes the End-Payor Plaintiffs’ arguments to all of the plaintiffs.

establishing that such cumulative relief is needed. Although the existence of the Consent Order in this case is not dispositive, it is relevant to the determination of whether “there exists some cognizable danger of [a] recurrent violation.” *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)). In short, the plaintiff must still satisfy the injury-in-fact requirement of the standing doctrine while taking the effect of the Consent Order into account.

The plaintiffs insist that they meet this requirement because the relief they seek exceeds the scope of the FTC Consent Order. EPP Opp. at 11. The only differences that the plaintiffs are able to point to, however, are that they seek a *permanent* injunction, whereas the Consent Order expires in ten years, and they lack standing to enforce the Consent Order in the event that it is violated. EPP Opp. at 11-13. The plaintiffs do not articulate any specific action that they seek to enjoin that is not already prohibited by the Order or identify any action taken by defendants in violation of the Order.²⁰ Neither of the distinctions relied upon by the plaintiffs bears on the inquiry of whether there exists a real and immediate danger of recurrent violations. Moreover, a review of the facts, as laid out by the plaintiffs, simply does not support the existence of a real and immediate threat of injury.

The Distribution Agreement, which is at the center of the plaintiffs’ claim that an

²⁰ The End-Payor Plaintiffs assert that “the precise contours of appropriate injunctive relief should be decided only after a determination on the merits.” EPP Opp. at 12. However, the plaintiffs appear to be conflating the threshold issue of whether a sufficient threat of future injury exists with the ultimate determination of liability and scope of relief.

illegal agreement existed, has already been terminated by the Consent Order. SACC ¶ 65; EPCC ¶ 96. The Order further prohibits Elan from selling generic Adalat CC to a generic competitor, and specifically prohibits Elan from selling generic Adalat CC through Teva. SACC ¶ 66. Indeed, the plaintiffs acknowledge that Watson purchased the rights to Elan's 30 mg and 60 mg generic versions of Adalat CC, that Watson is currently selling them, and that neither product is being sold to either Biovail or Teva. SACC ¶ 68; EPCC ¶ 99. At this point, Biovail has also launched a 30 mg version in competition with Elan's 30 mg generic.²¹ Hr'g Tr. 72:1-6. The plaintiffs have neither alleged that the Consent Order is inadequate nor have they identified any specific conduct that should be enjoined over and above the conduct prohibited by the Consent Order. In short, none of the allegedly illegal conduct is currently occurring and, more importantly, none seems likely to resume in light of the Consent Order and the Watson agreement.

Finally, the plaintiffs generally allege, without providing any factual basis, that the defendants have continued their allegedly unlawful conduct after the entry of the Consent Order.²² EPP Opp. at 15; *see e.g.*, EPCC ¶ 110 ("Defendants are presently engaged in illegal conduct to prevent competition in the U.S. marketplace of generic versions of 30

²¹ The parties' briefs are unclear on this point. However, the Consent Order does obligate Biovail to use best efforts to launch a 30 mg generic and there is no indication that potential disincentives to competition that operated under the Distribution Agreement currently exist.

²² At the motions hearing, Counsel for Elan indicated that the End-Payor Plaintiffs had actually withdrawn these allegations. However, without a stipulation to that effect from plaintiffs, the Court must address them. Hr'g Tr. at 69:2-13.

mg and 60 mg Adalat CC. The illegal combination continues.”); and EPCC ¶ 115 (“The Plaintiffs and the Class will continue to be injured in their person and property by Biovail’s and Elan’s continuing conduct in violation of the antitrust laws of the United States.”). The plaintiffs further argue that, even if the defendants’ allegedly illegal conduct had ended,²³ they would still be entitled to seek a “reparative injunction,” designed to “prevent[] the future harmful effects of past acts” by “requir[ing] the defendant to restore the plaintiff to a pre-existing condition to which plaintiff was entitled.” EPP Opp. at 15 (quoting *Lampkin v. District of Columbia*, 886 F.Supp.56, 62 (D.D.C. 1995)). Both of these theories fail. The Court is not required to accept the plaintiffs’ conclusions and inferences if they are unsupported by facts, and indeed, the plaintiffs have provided no factual basis for their claims that there is any kind of continuing violation on the part of the defendants. Moreover, notwithstanding the fact that a reparative injunction does not appear to be appropriate because the plaintiffs have not identified a “pre-existing condition to which [they were] entitled,” the plaintiffs have

²³ The plaintiffs also make the argument that voluntary cessation of illegal conduct does not render a case moot. EPP Opp. at 13. However, the defendants are not arguing that the case is moot as a result of the entry of the Consent Order. Def. Reply at 33. Rather, the defendants are only challenging the plaintiffs’ standing to seek injunctive relief. Although the doctrines of standing and mootness overlap to a certain extent, they are nonetheless distinct principles of Article III jurisdiction, both of which must be satisfied. Because the Court finds that the plaintiffs lack standing, it need not address any potential mootness argument in this case. *See also W.T. Grant Co.*, 345 U.S. at 633 (holding that the case was not moot simply because the illegal conduct has ceased, but that the plaintiffs still had to establish “that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive.”).

failed to establish that there is any ongoing injury to justify such a remedy. *See O'Shea*, 414 U.S. at 495-96 ("Past exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief, however, if unaccompanied by any continuing, present adverse effects."). Although the plaintiffs make a passing observation that prices may remain artificially inflated after a conspiracy ends, they stop short of actually alleging that the prices are currently inflated in this case.²⁴ EPP Opp. at 16 n.9. Indeed, the Court would agree that lingering price inflation would be a natural factor in damages calculations. In the context of injunctive relief, however, lingering monetary injury, without any ongoing threat of recurrent violations, is not sufficient to confer standing to seek an injunction.²⁵ Thus, the Court concludes, based on the absence of facts alleged in the Complaints and the speculative nature of the plaintiffs' remaining arguments regarding present and future damages, that the plaintiffs have simply not established that there remains any "threatened conduct that will cause loss or damage" such that they have standing to seek injunctive relief. 15 U.S.C. § 26. Accordingly, this

²⁴ The plaintiffs make no specific allegation in their complaints or in their briefs. A possible implication of footnote nine is that prices have not come down as much as they expected, however, the Court is not required to accept as true the conclusory allegations, let alone possible implications, in a footnote in a brief. Moreover, the case cited by the plaintiffs for this economic proposition is inapposite as it applies the principle in the context of calculating damages, not granting injunctive relief. *See In re Cardizem CD Antitrust Litigation*, 2003 WL 22407160, at *14 n.12 (E.D. Mich. Oct. 10, 2003).

²⁵ Damages would be the more appropriate remedy when the only injury is monetary and there is no conduct to enjoin. Thus, the plaintiffs would also lack standing to seek an injunction on these claims because the relief they seek would not be reasonably likely to redress their injury. For example, an injunction ordering Elan and Biovail not to conspire to restrict competition would not affect current prices if it didn't require them to change their current behavior.

Court lacks jurisdiction over the claims for injunctive relief.

C. *State Law Claims*

Under 28 U.S.C. § 1367, which governs supplemental jurisdiction, the District Court may generally decline, in its discretion, to entertain supplemental jurisdiction after it “has dismissed all claims over which it has original jurisdiction.” 28 U.S.C. § 1367(c)(3). However, if the underlying claim is dismissed on jurisdictional grounds, then the Court does not have available to it the option of maintaining supplemental jurisdiction over pendant state law claims. *Saksenasingh v. Sec’y of Educ.*, 126 F.3d 347, 351 (D.C. Cir. 1997). Because the Court lacks jurisdiction over the End-Payor Plaintiffs’ sole federal claim, it also necessarily lacks supplemental jurisdiction over the End-Payor Plaintiffs’ state law claims. Accordingly, the End-Payor Plaintiffs’ case is dismissed in its entirety.

ORDER

It is, this 1st day of September, 2004, hereby

ORDERED that the Joint Motion of Elan and Biovail to Dismiss the Complaints [#20] and Teva's Motion to Dismiss the Sherman Act Plaintiffs' Complaint [#22] are **GRANTED** as to plaintiffs' claims for injunctive relief, and are otherwise **DENIED** as to any remaining claims; and it is further

ORDERED that Teva's Motion to Dismiss the End-Payor Plaintiffs' Complaint [#24] is **GRANTED**; and it is further

ORDERED that the End-Payor Plaintiffs' Amended Complaint [Dkt #10] be dismissed with prejudice (Case Nos. 02-cv01343, 02cv1377, 02cv01777, and 02cv02121).

SO ORDERED.



RICHARD J. LEON
United States District Judge