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# [***In re Namenda Direct Purchaser Antitrust Litig.***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=)

United States District Court for the Southern District of New York

May 23, 2017, Decided; May 23, 2017, Filed

No. 15 Civ. 7488 (CM)

**Reporter**

2017 U.S. Dist. LEXIS 83446 \*

IN RE NAMENDA DIRECT PURCHASER ***ANTITRUST*** LITIGATION

**Prior History:** [*Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC, 2016 U.S. Dist. LEXIS 128349 (S.D.N.Y., Sept. 13, 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=)

**Core Terms**

generic, patent, switch, manufacturer, brand-name, Competitors, exclusivity, patients, anticompetitive, Plaintiffs', expiration, memantine, injunction, merits, pediatric, partial summary judgment, announcement, drugs, collateral estoppel, settlement agreement, pharmaceutical, substitution, withdrawal, sales, preliminary injunction, procompetitive, Certification, patent infringement, monopolization, infringement

**Case Summary**

**Overview**

HOLDINGS: [1]-Because the elements of collateral estoppel as to the pharmaceutical manufacturer's violation of *§ 2 of the Sherman Act*, *15 U.S.C.S. § 2*, were met, the manufacturer was precluded from relitigating whether it possessed monopoly power over the U.S. Alzheimer drug market up until the entry of generic competition, whether its February 2014 announcement of the discontinuation of its twice-daily Alzheimer's medication was coercive and anticompetitive, and whether it had any non-pretextual procompetitive justification for its illegal conduct, but the direct drug purchasers were not entitled to summary judgment on its *§ 2* claim because outstanding questions of material fact remained regarding proof of an ***antitrust*** injury caused by the manufacturer's conduct; [2]-Summary judgment was denied on the purchaser's claims brought under *§ 1 of the Sherman Act*, *15 U.S.C.S. § 1*.

**Outcome**

Purchasers' motion for collateral estoppel and partial summary judgment on *§ 2 of Sherman Act* claims granted in part and denied in part. Cross-motions for partial summary judgment on *§ 1 of Sherman Act* claims denied.

**LexisNexis® Headnotes**

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN1***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc1)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



The [*Federal Food, Drug, and Cosmetic Act*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHK1-NRF4-42FV-00000-00&context=) (FDCA), [*21 U.S.C.S. § 301 et seq.*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GVH1-NRF4-425X-00000-00&context=), governs the manufacture, sale, and marketing of pharmaceuticals in the United States. Under the FDCA, a pharmaceutical company must submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) before it may bring a new drug to market. [*21 U.S.C.S. § 355*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). Because the NDA must provide the FDA with sufficient scientific data to demonstrate that the new drug is safe and effective, the testing and approval process is generally long, comprehensive, and costly.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN2***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc2)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



Once approved, though, a patented drug enjoys a period of market exclusivity. That period ends when the drug's patent expires and one or more low-cost generic versions of the drug enter the market and compete with the brand-name drug, what is referred to as going off the patent cliff. Generic versions of a drug, or generics, are copies of brand-name drugs and are the same as those brand-name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN3***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc3)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



The Drug Price Competition and Patent Term Restoration Act (the *Hatch-Waxman Act*), [*Pub. L. No. 98-417, 98 Stat. 1585*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CD7-HSN0-01XN-S4FK-00000-00&context=), to serve the dual purposes of incentivizing pharmaceutical innovation (by granting patent extensions to brand-name drug manufacturers) and lowering drug prices for consumers (by encouraging competition from generic drugs). To encourage innovation, the *Hatch-Waxman Act* provides brand-name drug manufacturers the opportunity to extend their exclusivity period beyond the standard 20-year patent term. To encourage competition from generics, the *Hatch-Waxman Act* makes it easier for generic manufacturers to get their drugs approved by the U.S. Food and Drug Administration.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN4***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc4)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



The *Hatch-Waxman Act* provides two methods by which a brand-name drug manufacturer can extend its period of market exclusivity. First, a manufacturer can seek an extension of its patent from the U.S. Patent and Trademark Office (PTO) to account for the time the manufacturer spent obtaining approval from the U.S. Food and Drug Administration (FDA) for its brand-name drug. *35 U.S.C.S. § 156*. That extension can last no more than five years. *§ 156(g)(6)*.Second, a brand-name drug manufacturer can obtain a six-month period of pediatric exclusivity if it conducts certain pediatric studies and the FDA determines that use of the drug in children may produce health benefits. [*21 U.S.C.S. § 355a*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=). A grant of pediatric exclusivity does not extend the length of the underlying patent, but can operate to exclude generic competition by delaying the date by which the FDA may approve generics for sale.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN5***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc5)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



Under the *Hatch-Waxman Act*, the manufacturer of a generic version of an U.S. Food and Drug Administration-approved drug may file an Abbreviated New Drug Application (ANDA), which allows the generic manufacturer to rely upon the studies submitted by the brand-name drug manufacturer in connection with the original New Drug Application to prove that the generic version of the drug is safe and effective. The ANDA filer must certify that its generic drug, among other things, has the same active ingredient as, and is bioequivalent to, the previously-approved drug. [*21 U.S.C.S. § 355(j)(2)(A)(ii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=), [*(iv)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). A generic drug is bioequivalent to the brand-name drug if it has the same rate and extent of absorption of the active ingredient as that of the brand-name drug. [*§ 355(j)(8)(B)(i)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN6***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc6)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



When a generic drug manufacturer files an Abbreviated New Drug Application (ANDA), it must certify one of four things: (1) that the brand-name drug is not patented; (2) that the brand-name drug's patent has expired;(3) that the brand-name drug's patent will expire prior to manufacture of the generic drug; or(4) that the brand-name drug's patent is invalid or will not be infringed by manufacture of the generic drug. [*21 U.S.C.S. § 355(j)(2)(A)(vii)(I)-(IV)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). This final route is called Paragraph IV Certification. The first manufacturer to file an ANDA with a Paragraph IV Certification may be granted a 180-day exclusive marketing period for its generic drug by the U.S. Food and Drug Administration. [*§ 355(j)(5)(B)(iv)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). This means that no other generic manufacturer's ANDA may become effective until 180 days after the date of the first commercial marketing of the drug by the first ANDA filer. [*§ 355(j)(5)(B)(iv)(I)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=).

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN7***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc7)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



Because the 180-day exclusivity period can be quite lucrative, generic manufacturers are incentivized to file an Abbreviated New Drug Application (ANDA) with a Paragraph IV Certification quickly, even if the brand-name drug's patent is ultimately found to be valid. However, the *Hatch-Waxman Act* provides that a Paragraph IV Certification is treated as an act of patent infringement and gives the holder of the brand-name drug patent the right to sue the prospective generic manufacturer within 45 days of being notified of the filing of a Paragraph IV Certification. [*21 U.S.C.S. § 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). If the brand-name manufacturer fails to bring suit during the 45-day period, the U.S. Food and Drug Administration's approval of the ANDA will become effective immediately. [*§ 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=).

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN8***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc8)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



If the brand-name manufacturer brings such suit within the 45 day period, the U.S. Food and Drug Administration (FDA) cannot make the Abbreviated New Drug Application (ANDA) approval effective until after a 30-month stay, unless a court first decides that the patent is invalid or not infringed by the generic manufacturer's drug, in which case the FDA will follow that determination and approve the ANDA. [*21 U.S.C.S. § 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). If the patent infringement litigation is not resolved by the conclusion of the 30-month stay, the FDA's approval of the ANDA becomes effective automatically unless the court handling the infringement litigation alters the length of the stay. [*§ 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=).

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN9***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc9)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



The pediatric exclusivity statute, [*21 U.S.C.S. § 355a*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=), provides that, if a brand-name manufacturer performs certain studies requested by the U.S. Food and Drug Administration (FDA) regarding the effects of the drug on children, the FDA may award the brand-name manufacturer a six-month period of market exclusivity following the date of the patent's expiration. During the six-month period, the FDA may not approve any new Abbreviated New Drug Application (ANDA), but the statute does not provide for automatic revocation of any already-approved ANDAs. [*§ 355a(c)(1)(B)(ii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=). However, if there is a pending ANDA with a Paragraph IV Certification, the six-month pediatric-exclusivity period only attaches if, in the patent infringement litigation resulting from the certification, the court determines that the patent is valid and would be infringed. [*§ 355a(c)(1)(B)(ii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=).

Civil Procedure > Judgments > Summary Judgment > Entitlement as Matter of Law

Civil Procedure > ... > Summary Judgment > Burdens of Proof > Movant Persuasion & Proof

Civil Procedure > Judgments > Summary Judgment > Evidentiary Considerations

[***HN10***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc10)[] **Summary Judgment, Entitlement as Matter of Law**



Summary judgment is appropriate where there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law. [*Fed. R. Civ. P. 56(c)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2421-6N19-F165-00000-00&context=). The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. A dispute concerning material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. A genuine issue for trial exists if, based on the record as a whole, a reasonable jury could find in favor of the non-movant. In making its determination, the court must resolve all ambiguities and draw all reasonable inferences in favor of the non-movant.

Civil Procedure > ... > Summary Judgment > Burdens of Proof > Nonmovant Persuasion & Proof

[***HN11***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc11)[] **Burdens of Proof, Nonmovant Persuasion & Proof**



To defeat summary judgment, it is not sufficient for the nonmoving party to present evidence that is conclusory or speculative, with no basis in fact. Instead, the nonmoving party must go beyond the pleadings and must do more than simply show that there is some metaphysical doubt as to the material facts. The nonmoving party must present specific facts showing that there is a genuine issue for trial. Summary judgment is designed to flush out those cases that are predestined to result in directed verdict.

Civil Procedure > ... > Preclusion of Judgments > Estoppel > Collateral Estoppel

[***HN12***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc12)[] **Estoppel, Collateral Estoppel**



Collateral estoppel, or issue preclusion, prevents the relitigation of an issue that was raised, litigated, and actually decided by a judgment in a prior proceeding. In order to establish that an issue was determined in a former adjudication, a party asserting collateral estoppel must establish four things: (1) the issues in the prior proceeding and the current proceeding are identical; (2) the issue raised in the current action was in fact actually decided in the prior proceeding; (3) there was full and fair opportunity to litigate the issue in the prior proceeding; and (4) the issue previously litigated and decided was necessary to support a valid and final judgment on the merits. In order to invoke collateral estoppel, the party asserting preclusion bears the burden of showing with clarity and certainty what was determined by the prior judgment.

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Actual Monopolization > Claims

[***HN13***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc13)[] **Actual Monopolization, Claims**



In order to establish a claim of monopolization in violation of *§ 2 of the Sherman Act*, a plaintiff must demonstrate that (1) the defendant possessed monopoly power in the relevant market and (2) the defendant willfully acquired or maintained that power through anticompetitive conduct. In order to establish attempted monopolization, the plaintiff must prove: (1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power. Attempted monopolization, unlike monopolization, requires a finding of specific intent. In short, a defendant violates *§ 2* only when it acquires or maintains, or attempts to acquire or maintain, a monopoly by engaging in exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Actual Monopolization > Claims

[***HN14***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc14)[] **Actual Monopolization, Claims**



The second prong of the monopolization claim whether the defendant willfully sought to maintain or attempted to maintain its monopoly in violation of *§ 2 of the Sherman Act*, is analyzed under the framework established by the D.C. Circuit in Microsoft. Under the Microsoft framework, once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer nonpretextual procompetitive justifications for its conduct. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit.

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Actual Monopolization > Anticompetitive & Predatory Practices

[***HN15***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc15)[] **Actual Monopolization, Anticompetitive & Predatory Practices**



A product redesign is anticompetitive or exclusionary when it coerces consumers and impedes competition.

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Actual Monopolization > Anticompetitive & Predatory Practices

[***HN16***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc16)[] **Actual Monopolization, Anticompetitive & Predatory Practices**



While neither product withdrawal nor product improvement alone is anticompetitive when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the *Sherman Act*.

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Actual Monopolization > Anticompetitive & Predatory Practices

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN17***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc17)[] **Actual Monopolization, Anticompetitive & Predatory Practices**



Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Actual Monopolization > Anticompetitive & Predatory Practices

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Attempts to Monopolize > Sherman Act

[***HN18***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc18)[] **Actual Monopolization, Anticompetitive & Predatory Practices**



The combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates *§ 2 of the Sherman Act*.

Civil Procedure > Remedies > Injunctions > Grounds for Injunctions

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

[***HN19***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc19)[] **Injunctions, Grounds for Injunctions**



Ordinarily, a decision granting a preliminary injunction is not considered a final judicial decision based on the actual merits of the controversy entitled to collateral estoppel effect. A plaintiff seeking a preliminary injunction need only establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest. A plaintiff need not show that success is an absolute certainty. As such, findings of fact and conclusions of law made in a preliminary injunction proceeding do not preclude reexamination of the merits at a subsequent trial.

Civil Procedure > Remedies > Injunctions > Permanent Injunctions

[***HN20***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc20)[] **Injunctions, Permanent Injunctions**



Entry of a permanent injunction is a final judgment on the merits. Likewise, in certain circumstances, a preliminary injunction decision may be rendered practically final, depending on factors such as the nature of the decision (i.e., that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review.

***Antitrust*** & Trade Law > ... > Monopolies & Monopolization > Actual Monopolization > Claims

***Antitrust*** & Trade Law > Sherman Act > Scope > Monopolization Offenses

[***HN21***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc21)[] **Actual Monopolization, Claims**



In order for a plaintiff to establish liability on a *Sherman Act* monopolization claim, it must also prove that the defendant's illegal conduct resulted in ***antitrust*** injury to the plaintiff. In order to meet this burden, the plaintiff need only show that the illegal conduct was a substantial or materially contributing factor to its injuries.

***Antitrust*** & Trade Law > ... > Price Fixing & Restraints of Trade > Per Se Rule & Rule of Reason > Per Se Violations

[***HN22***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc22)[] **Per Se Rule & Rule of Reason, Per Se Violations**



Agreements are deemed per se unlawful only when they have a predictable and pernicious anticompetitive effect.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN23***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc23)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



The pediatric exclusivity statute is [*21 U.S.C.S. § 355a(c)(1)(B)(ii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=), which states that, if the brand-name manufacturer's pediatric studies are accepted, then if the drug is the subject of a listed patent for which a Paragraph IV certification has been submitted, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under [*§ 355(j)(5)(B)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN24***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc24)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



Where the name-brand drug manufacturer being awarded the pediatric exclusivity period is faced with a Paragraph IV Certification (asserting that the name-brand drug's patent is invalid or will not be infringed by the generic competitor), if the name-brand manufacturer wins its patent infringement suit, the U.S. Food and Drug Administration may not approve any generic competitor until six months after the expiration of the patent's term.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN25***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc25)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



In the ordinary course, a Paragraph IV Certification gives the brand name manufacturer the right to sue the generic manufacturer within 45 days for patent infringement. [*21 U.S.C.S. § 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). Bringing suit triggers a 30-month stay during which the U.S. Food and Drug Administration may not approve the generic manufacturer's Abbreviated New Drug Application (ANDA) unless the brand-name manufacturer loses the infringement suit, in which case the ANDA is approved immediately. [*§ 355(j)(5)(B)(iii)(I)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). If the brand-name manufacturer wins the suit, the ANDA may not be approved until after the patent expires. [*§ 355(j)(5)(B)(iii)(II)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). If the suit is not resolved within the 30-month period, the ANDA is automatically approved at the end of the 30 months unless the court extends the stay. [*§ 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=).

***Antitrust*** & Trade Law > ... > Price Fixing & Restraints of Trade > Per Se Rule & Rule of Reason > Sherman Act

[***HN26***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc26)[] **Per Se Rule & Rule of Reason, Sherman Act**



A practice is considered per se anticompetitive when experience with a particular kind of restraint enables the court to predict with confidence that the rule of reason will condemn it. Conduct that is subject toper se analysis is invalid regardless of any procompetitive justification that may exist in a particular case. However, agreements to settle patent infringement litigation are not per se anticompetitive, because the court is required to evaluate the potential procompetitive effects of such agreements. In Actavis, the United States Supreme Court stated that, in general, settlement on terms permitting the patent challenger to enter the market before the patent expires brings about competition to the consumer's benefit. Evaluation of such procompetitive effects would be unnecessary if these agreements were subject toper se rules. Such settlements are, instead, reviewed under Actavis's rule-of-reason analysis.

Business & Corporate Compliance > ... > Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[***HN27***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=LNHNREFclscc27)[] **Agriculture & Food, Federal Food, Drug & Cosmetic Act**



Once an Abbreviated New Drug Application is approved, each generic competitor is no longer under an obligation to amend its patent certification, even after the patent expired.

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**Judges:** Colleen**[\*3]** McMahon, Chief Judge.

**Opinion by:** Colleen McMahon

**Opinion**

**MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR COLLATERAL ESTOPPEL AND PARTIAL SUMMARY JUDGMENT ON COUNT ONE; DENYING PLAINTIFFS' AND DEFENDANTS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT ON COUNT FIVE**

McMahon, C.J.:

This action is a sequel to a 2014 ***antitrust*** lawsuit brought by the State of New York against Defendants Actavis PLC (now known as Allergan PLC) and Forest Laboratories, LLC (collectively, "Forest"), a pharmaceutical manufacturer. In the earlier case, New York asserted that Forest was attempting to effectuate an illegal "hard switch" product hop by removing its twice-daily Alzheimer's medication, Namenda IR, from the market prior to the entry of generic competition in order to force patients and their physicians to switch to its once-daily version of the same drug, Namenda XR. New York alleged that this hard switch would permit Forest to extend its monopoly over a leading treatment for moderate-to-severe Alzheimer's disease through the end of Namenda XR's patent exclusivity period in 2029.

On December 11, 2014, my colleague the Hon. Robert Sweet issued a preliminary injunction in that prior action, blocking**[\*4]** Forest from restricting access to Namenda IR for the remainder of Namenda IR's patent exclusivity period and requiring Forest to affirmatively undo the effects of its announcement of the withdrawal. That ruling was upheld on appeal by the Second Circuit.

Plaintiffs J M Smith Corporation d/b/a Smith Drug Company ("Smith") and Rochester Drug Co-Operative, Inc. ("RDC," collectively with Smith, "Plaintiffs") are direct purchasers of Namenda, and allege that they (along with their proposed classes) were forced to pay supracompetitive prices due to Forest's anticompetitive conduct.

Before the Court are three motions: (1) Plaintiffs' motion for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134); (2) Plaintiffs' motion for partial summary judgment on Count Five (Dkt. No. 138); and (3) Defendants' cross-motion for partial summary judgment on Count Five (Dkt. No. 161).[[1]](#footnote-0)1

According to Plaintiffs, the anticompetitive nature of Forest's hard switch was thoroughly litigated in the prior action brought by New York, and the Court should apply the principles of offensive non-mutual collateral estoppel to avoid relitigating those issues again. If Forest is estopped from relitigating**[\*5]** the issues decided in Judge Sweet's opinion, they argue, Plaintiffs are entitled to summary judgment on the question of Forest's liability (but not causation or damages) with respect to Count One, which alleges a violation of *Section 2* of the *Sherman Act*, *15 U.S.C. § 2*. This motion is granted in part and denied in part.

In Plaintiffs' second motion, they assert that Forest, along with Defendants Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd. (collectively with Forest, "Defendants"), entered into settlement agreements with various generic drug manufacturers to, in effect, delay market entry of generic versions of Namenda IR until three months after Namenda IR's patent exclusivity period expired. These agreements, they argue, illegally extended Forest's patent license beyond the term of the patent and constituted a "naked restraint of trade" in violation of *Section 1* of the *Sherman Act*, *15 U.S.C. § 1*. Plaintiffs seek partial summary judgment on Count Five solely on the issue of whether the settlement agreements constitute a *per se* restraint of trade (and again, not on issues of causation or damages). Defendants cross-move on the same issue, arguing that the settlement agreements were not *per se* anticompetitive,**[\*6]** and seek summary judgment dismissing Count Five in its entirety. Both of these motions are denied.

**Background**

The basic facts of this case were thoroughly reviewed in Judge Sweet's opinion granting a preliminary injunction to New York, [*New York v. Actavis, PLC (Namenda I), No. 14 Civ. 7473, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*1 (S.D.N.Y. Dec. 11, 2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=),[[2]](#footnote-1)2 the Second Circuit's decision affirming Judge Sweet's opinion, [*New York ex rel. Schneiderman v. Actavis PLC (Namenda II), 787 F.3d 638 (2d Cir.)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=), *cert. dismissed*, *136 S. Ct. 581, 193 L. Ed. 2d 421 (2015)*, as well as in a prior decision of this Court denying Forest's motion to dismiss, [*Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC (Namenda III), Nos. 15 Civ. 6549, 15 Civ. 7488, 2016 U.S. Dist. LEXIS 128349, 2016 WL 4992690, at \*1-\*8 (S.D.N.Y. Sept. 13, 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=). The summary of facts in the following pages is drawn from *Namenda I, Namenda II*, and *Namenda III*, as well as from Plaintiffs' Rule 56.1 Statement of Material Facts on Count One ("Pls.' Count One 56.1"), Dkt. No. 137, and Defendants' Response ("Defs.' Count One 56.1"), Dkt. No. 158, and Plaintiffs' Rule 56.1 Statement of Material Facts on Count Five ("Pls.' Count Five 56.1"), Dkt. No. 141, and Defendants' Response and Counter-Statement ("Defs.' Count Five 56.1"), Dkt. No. 164. Unless otherwise noted, these facts are undisputed, and I summarize the factual and procedural history of this litigation only to the extent necessary to decide the instant motions.

**I. The Parties**

Forest manufactures**[\*7]** and sells brand-name pharmaceutical products, including the prescription pharmaceutical memantine hydrochloride ("memantine"), which is sold in the United States under the trade names "Namenda" (referred to here as "Namenda IR" to distinguish from Namenda XR) and "Namenda XR." (Defs.' Count Five 56.1 ¶ 1). Memantine is a treatment for moderate-to-severe forms of Alzheimer's disease. Forest developed Namenda IR pursuant to a license and cooperation agreement with Merz GmbH & Co. KGaA, Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, "Merz Entities"), which owned the relevant patent for a memantine-based drug.[[3]](#footnote-2)3

Plaintiff Smith is a South Carolina corporation that purchased Namenda IR directly from Forest and alleges that, during the class period, it paid prices higher than it would have absent Defendants' anticompetitive conduct. Plaintiff RDC is a New York corporation that also asserts that it purchased Namenda IR directly from Forest at supracompetitive prices.

**II. The *Regulatory* Scheme**

[***HN1***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc1)[] The [*Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq.*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GVH1-NRF4-425X-00000-00&context=), governs the manufacture, sale, and marketing of pharmaceuticals in the United States. Under the FDCA, a pharmaceutical company**[\*8]** must submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") before it may bring a new drug to market. *See generally* [*21 U.S.C. § 355*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). Because the NDA must provide the FDA with sufficient scientific data to demonstrate that the new drug is safe and effective, the testing and approval process is generally "long, comprehensive, and costly." [*FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228, 186 L. Ed. 2d 343 (2013)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=).



[***HN2***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc2)[] Once approved, though, a patented drug enjoys a period of market exclusivity. That period ends when the drug's patent expires and one or more low-cost generic versions of the drug enter the market and compete with the brand-name drug — what is referred to as going off the "patent cliff." [*Namenda II, 787 F.3d at 643*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Generic versions of a drug, or "generics," are "copies of brand-name drugs and are the same as those brand-name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." FDA, *Understanding Generic Drugs*, [*http://1.usa.gov/1SjEIso*](http://1.usa.gov/1SjEIso) (last visited May 22, 2017).



**A. The *Hatch-Waxman Act***

In 1984, Congress enacted [***HN3***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc3)[] the [*Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CD7-HSN0-01XN-S4FK-00000-00&context=), to serve the dual purposes of incentivizing pharmaceutical innovation (by granting patent extensions to brand-name drug**[\*9]** manufacturers) and lowering drug prices for consumers (by encouraging competition from generic drugs). [*Namenda II, 787 F.3d at 643-44*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). To encourage innovation, the *Hatch-Waxman Act* provides brand-name drug manufacturers the opportunity to extend their exclusivity period beyond the standard 20-year patent term. To encourage competition from generics, the *Hatch-Waxman Act* makes it easier for generic manufacturers to get their drugs approved by the FDA.



As relevant here, [***HN4***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc4)[] the *Hatch-Waxman Act* provides two methods by which a brand-name drug manufacturer can extend its period of market exclusivity.



First, a manufacturer can seek an extension of its patent from the U.S. Patent and Trademark Office ("PTO") to account for the time the manufacturer spent obtaining approval from the FDA for its brand-name drug. *35 U.S.C. § 156*. That extension can last no more than five years. *Id.* *§ 156(g)(6)*.

Second, a brand-name drug manufacturer can obtain a six-month period of "pediatric exclusivity" if it conducts certain pediatric studies and the FDA determines that use of the drug in children may produce health benefits. [*21 U.S.C. § 355a*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=). A grant of pediatric exclusivity does not extend the length of the underlying patent, but can operate to exclude generic competition by delaying**[\*10]** the date by which the FDA may approve generics for sale.

[***HN5***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc5)[] Under the *Hatch-Waxman Act*, the manufacturer of a generic version of an FDA-approved drug may file an Abbreviated New Drug Application ("ANDA"), which allows the generic manufacturer to rely upon the studies submitted by the brand-name drug manufacturer in connection with the original NDA to prove that the generic version of the drug is safe and effective. The ANDA filer must certify that its generic drug, among other things, has the same active ingredient as, and is "bioequivalent" to, the previously-approved drug. [*21 U.S.C. § 355(j)(2)(A)(ii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=), [*(iv)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=); [*Namenda II, 787 F.3d at 644*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). A generic drug is bioequivalent to the brand-name drug if it has the same "rate and extent of absorption" of the active ingredient as that of the brand-name drug. [*21 U.S.C. § 355(j)(8)(B)(i)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). "In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time." [*Namenda II, 787 F.3d at 644*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).



[***HN6***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc6)[] When a generic drug manufacturer files an ANDA, it must certify one of four things:



(1) that the brand-name drug is not patented; (2) that the brand-name drug's patent has expired;

(3) that the brand-name drug's patent will expire prior to manufacture of the generic drug; or

**[\*11]**(4) that the brand-name drug's patent is invalid or will not be infringed by manufacture of the generic drug. [*21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). This final route is called "Paragraph IV Certification."[*Namenda III, 2016 U.S. Dist. LEXIS 128349, 2016 WL 4992690, at \*4*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=).

The first manufacturer to file an ANDA with a Paragraph IV Certification may be granted a 180-day exclusive marketing period for its generic drug by the FDA. [*21 U.S.C. § 355(j)(5)(B)(iv)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). This means that no other generic manufacturer's ANDA may become effective until "180 days after the date of the first commercial marketing of the drug" by the first ANDA filer. *Id.* [*§ 355(j)(5)(B)(iv)(I)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=).

[***HN7***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc7)[] Because the 180-day exclusivity period can be quite lucrative, generic manufacturers are incentivized to file an ANDA with a Paragraph IV Certification quickly, even if the brand-name drug's patent is ultimately found to be valid. However, the *Hatch-Waxman Act* provides that a Paragraph IV Certification is treated as an act of patent infringement and gives the holder of the brand-name drug patent the right to sue the prospective generic manufacturer within forty-five days of being notified of the filing of a Paragraph IV Certification. *Id.* [*§ 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). If the brand-name manufacturer fails to bring suit during the forty-five-day period, the FDA's approval of the ANDA will become effective immediately. *Id.*



[***HN8***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc8)[] If the brand-name manufacturer brings such suit**[\*12]** within the forty-five day period, the FDA cannot make the ANDA approval effective until after a thirty-month stay, unless a court first decides that the patent is invalid or not infringed by the generic manufacturer's drug — in which case the FDA will follow that determination and approve the ANDA. *Id.* If the patent infringement litigation is not resolved by the conclusion of the thirty-month stay, the FDA's approval of the ANDA becomes effective automatically unless the court handling the infringement litigation alters the length of the stay. *Id.*



[***HN9***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc9)[] The pediatric exclusivity statute, [*21 U.S.C. § 355a*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=), provides that, if a brand-name manufacturer performs certain studies requested by the FDA regarding the effects of the drug on children, the FDA may award the brand-name manufacturer a six-month period of "market exclusivity" following the date of the patent's expiration. During the six-month period, the FDA may not approve any new ANDA, but the statute does not provide for automatic revocation of any already-approved ANDAs. *Id.* [*§ 355a(c)(1)(B)(ii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=). However, if there is a pending ANDA with a Paragraph IV Certification, the six-month pediatric-exclusivity period only attaches if, "in the patent infringement litigation resulting**[\*13]** from the certification[,] the court determines that the patent is valid and would be infringed." *Id.*



**B. State Drug Substitution Laws**

Various state laws seek to encourage competition from generics as well. All fifty states and the District of Columbia have drug substitution laws, which are laws that either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand-name drug unless the prescribing physician expressly directs that the prescription must be dispensed as written. [*Namenda II, 787 F.3d at 644*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Drug substitution laws give a preference to generic drugs because generics are generally cheaper than their brand-name counterparts. (Pls.' Count Five 56.1 ¶ 26.)

However, all substitution laws require the generic drug to be "therapeutically equivalent" to the brand-name drug for which it is substituted, and prohibit the substitution of drugs that are not therapeutic equivalents. Unfortunately, not all states define therapeutic equivalence in the same manner. Thirty states and the District of Columbia have adopted the FDA's definition of therapeutic equivalence and only allow generic substitution if the FDA designates the generic as therapeutically equivalent**[\*14]** in a publication commonly referred to as the "Orange Book." [*Namenda II, 787 F.3d at 645*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=); *see* [*N.Y. Educ. Law § 6816-a(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8P64-KJK2-D6RV-H4H8-00000-00&context=)); [*N.Y. Pub. Health Law § 206(1)(o)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8P64-C9F2-8T6X-7217-00000-00&context=); U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") (37th ed. 2017). Other states take other approaches, such as "develop[ing] formularies that list permissible or impermissible drug substitutes" or "giv[ing] discretion to individual pharmacists as long as the drugs are pharmaceutically equivalent." [*Namenda II, 787 F.3d at 645 n.9*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).

The FDA assigns a number of ratings to therapeutically-equivalent drugs. Drugs for which there are no known or suspected bioequivalence problems are assigned ratings of AA, AN, AO, AP, or AT, depending on the dosage form, and drugs for which "actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence" are given the rating AB. U.S. Food & Drug Admin., *Preface to Thirty Seventh Edition*, Orange Book, at xiii. Any of these therapeutically-equivalent ratings would appear to satisfy, for example, New York's requirements for generic substitution. N.Y. Ethic, Law [*§ 6816—a(1)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8P64-KJK2-D6RV-H4H8-00000-00&context=); [*N.Y. Pub. Health Law § 206(1)(o)(2)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8P64-C9F2-8T6X-7217-00000-00&context=).

According to the FDA, two drugs are considered therapeutic equivalents "only if they are pharmaceutical equivalents for which bioequivalence has been**[\*15]** demonstrated, and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." U.S. Food & Drug Admin., *Preface to Thirty Seventh Edition*, Orange Book, at vii. Two drugs are considered pharmaceutical equivalents if they "contain the same active ingredient(s), are of the same dosage form, route of administration and are formulated to contain the same amount of active ingredient, and to meet the same or compendial or other applicable standards (i.e., strength, quality, purity, and identity)." *Id.; see also* [*Namenda II, 787 F.3d at 645*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). The FDA considers two drugs to be bioequivalent when they display comparable bioavailability ("the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action") when studied under similar experimental conditions. U.S. Food & Drug Admin., *Preface to Thirty Seventh Edition*, Orange Book, at viii.

The requirement that substituted drugs meet therapeutic equivalence standards, although intended to protect patients, allows brand-name drug manufacturers to "game the system" through a practice known as "product hopping."**[\*16]** [*Namenda II, 787 F.3d at 645*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Before the patent on a brand-name drug expires and its manufacturer loses market share to cheaper generic competitors — the patent cliff — the manufacturer develops a follow-on version of the drug with a later patent expiration date and encourages patients and their physicians to switch to that version. Because the generic version of the follow-on drug is not "therapeutically equivalent" to the original brand-name drug, pharmacies cannot substitute a generic version of the original drug for the follow-on version — even if the pharmacological difference between the original and the follow-on drugs is negligible. [*Namenda III, 2016 U.S. Dist. LEXIS 128349, 2016 WL 4992690, at \*3*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=).

Brand-name drug manufacturers can use a variety of tactics to encourage patients and physicians to convert from the original brand-name drug to the follow-on version prior to the patent cliff. In what has been termed a "soft switch," a manufacturer may aggressively promote and market the follow-on drug to patients and doctors, or may reduce its price compared to the original drug, in order to incentivize voluntary conversions. [*2016 U.S. Dist. LEXIS 128349, [WL] at \*4*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=). In what has been termed a "hard switch" (sometimes called a "forced switch"), a manufacturer may stop selling the original drug prior to the expiration**[\*17]** of its patent term, in order to force patients and physicians to switch to the follow-on drug in order to ensure continuity of treatment. *Id.* If, after briefly switching from the original brand-name drug to the follow-on brand-name drug, a patient switches back to a generic version of the original drug, this process is known as "reverse commuting." [*Namenda II, 787 F.3d at 649*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).

**III. Factual History**

In June 2000, Forest entered into a license and cooperation agreement with the Merz Entities, German pharmaceutical companies, to give Forest the exclusive right to market a memantine-based drug in the United States under the Merz Entities' patent, U.S. Patent No. 5,061,703 (the "'703 Patent"). (Pls.' Count One 56.1 ¶¶ 3-4.) Pursuant to that agreement, Forest developed Namenda IR, a twice-daily immediate-release memantine-based tablet. [*Namenda III, 2016 U.S. Dist. LEXIS 128349, 2016 WL 4992690, at \*2*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=). In December 2002, Forest submitted an NDA to the FDA, seeking approval to market Namenda IR for the treatment of Alzheimer's disease. (Pls.' Count One 56.1 & 5.) The FDA approved that NDA on October 16, 2003, and Forest commercially launched Namenda IR in the United States in January 2004. (*Id.* ¶¶ 6-7.)

Forest then submitted an application to the PTO for a five-year extension to the '703 Patent (originally set to expire on April 11,**[\*18]** 2010), to account for the time Forest spent obtaining FDA approval for Namenda IR, as permitted by *35 U.S.C. § 156*. (*Id.* ¶¶ 9-10.) The PTO granted that request in March 2009, extending the term of the '703 Patent until April 11, 2015. (*Id.* ¶ 10.)

In January 2014, Forest sought six months of pediatric exclusivity for Namenda IR from the FDA, pursuant to [*21 U.S.C. § 355a*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=), and the FDA granted that request in June 2014. (*Id.* ¶ 11; Defs.' Count One 56.1 ¶ 11 (admitting same); *but see* Defs.' Count Five 56.1 && 13-15 (disputing that Forest "requested" the pediatric exclusivity period).) That six-month exclusivity period ran from the expiration of the term of the '703 Patent on April 11, 2015 to October 11, 2015. (Pls.' Count One 56.1 ¶ 12.)

Namenda IR was the first medication in the United States approved for individuals with moderate or severe forms of Alzheimer's disease and quickly became one of Forest's best-selling drugs. [*Namenda II, 787 F.3d at 647*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). It generated approximately $1.5 billion in annual sales in 2012 and 2013. *Id.*

At least seventeen generic drug manufacturers filed ANDAs seeking to market generic versions of Namenda IR. (*See* Solomon Decl. ¶ 2, Dkt. No. 146-11)[[4]](#footnote-3)4 At issue in this case are seven of those companies (the "Generic Competitors"): (1) Interpharm**[\*19]** Holdings, Inc. and Interpharm, Inc., which were acquired by a wholly-owned subsidiary of Amneal Pharmaceuticals, LLC (collectively, "Amneal"); (2) Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"); (3) Lupin Pharmaceuticals, Inc. ("Lupin"); (4) Mylan Pharmaceuticals, Inc. ("Mylan"); (5) Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"); (6) Sun India Pharmaceuticals Industries, Ltd. ("Sun"); and (7) Teva Pharmaceuticals USA, Inc. ("Teva"). (Pls.' Count Five 56.1 ¶ 16.)

In the fall of 2007, each of these seven Generic Competitors submitted its ANDA to the FDA along with a Paragraph IV Certification. (*Id.* && 17-20 (Amneal), 31-34 (Dr. Reddy's), 45-48 (Lupin), 59-62 (Mylan), 73-76 (Orchid), 86-89 (Sun), 100-103 (Teva).) Defendants timely brought suits for patent infringement against each Generic Competitor. (*Id.* ¶¶ 21-22 (Amneal), 35-36 (Dr. Reddy's), 49-50 (Lupin), 63-64 (Mylan), 77-78 (Orchid), 90-91 (Sun), 104-105 (Teva).) Between September 2009 and July 2010, Defendants reached settlement agreements with all seven manufacturers. (*Id.* && 23 (Amneal), 37 (Dr. Reddy's), 51 (Lupin),**[\*20]** 65 (Mylan), 79 (Orchid), 92 (Sun), 106 (Teva).)

Each settlement agreement contained a virtually identical provision that Plaintiffs assert was anticompetitive. In each case, Defendants granted the Generic Competitor a license to begin selling a generic version of Namenda IR beginning three months prior to the later of (1) the expiration of the '703 Patent or (2) the end of any pediatric exclusivity period attached to the '703 Patent. (*Id.* && 25-26 (Amneal), 39-40 (Dr. Reddy's), 53-54 (Lupin), 67-68 (Mylan), 81-82 (Orchid), 94-95 (Sun), 108-109 (Teva).) This meant that, under the settlements, had Forest not obtained the six-month pediatric exclusivity period under [*21 U.S.C. § 355a*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=), the seven Generic Competitors would have been able to begin selling generic versions of Namenda IR on January 11, 2015. However, because the FDA granted Forest the six-month pediatric exclusivity period after the settlement agreements were executed, the Generic Competitors could not begin selling their drugs until July 11, 2015. (*See* Pls.' Count One 56.1 ¶ 13; Defs.' Count One 56.1 ¶ 13.)

In June 2010, Forest obtained approval from the FDA for a second memantine drug, a once-daily extended-release memantine capsule called Namenda XR. [*Namenda II, 787 F.3d at 647*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Forest began**[\*21]** marketing Namenda XR in July 2013. *Id.* Namenda IR and Namenda XR contain the same active ingredient and have the same therapeutic effect, but Namenda IR is a tablet taken twice a day that releases directly into the bloodstream and Namenda XR is a capsule that is taken once a day and releases gradually. *Id.* Namenda IR and Namenda XR are not, therefore, "therapeutic equivalents" under the FDA's definition of that term, and so cannot be substituted for one another under any drug substitution law that requires substitutes to be certified by the FDA as "therapeutic equivalents." Likewise, generic drugs that are therapeutic equivalents of Namenda IR cannot be substituted for Namenda XR under the same standards. (Pls.' Count One 56.1 && 43-44; Defs,' Count One && 43-44.)

The key non-pharmacological difference between Namenda IR and Namenda XR relates to their patent protection. Namenda XR's period of patent exclusivity does not expire until 2029, while Namenda IR's expired in 2015. [*Namenda II, 787 F.3d at 647*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).

When Forest brought Namenda XR to market in 2013, it engaged in a variety of soft-switch tactics to encourage patients and physicians to convert from Namenda IR to Namenda XR before Namenda IR went off the patent**[\*22]** cliff in 2015. *See* [*id. at 647-48*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Forest priced Namenda XR below Namenda IR. (Defs.' Count One 56.1 ¶ 66.) Forest stopped actively marketing Namenda IR and heavily promoted the benefits of Namenda XR, including its lower price and once-daily dosage. (Pls.' Count One 56.1 && 66-68; Defs.' Count One 56.1 && 66-68.)

The parties disagree about whether Forest's soft-switch tactics were effective. (*See* Pls.' Count One 56.1 ¶¶ 69-71; Defs.' Count One 56.1 ¶¶ 69-71.) In *Namenda I*, Judge Sweet concluded that Forest executives were concerned that an insufficient number of patients would switch to Namenda XR before generic versions of Namenda IR entered the market, making a hard switch necessary. [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*18*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=).

It is undisputed that, on February 14, 2014, Forest announced (via a press release, notice to the FDA, and letters to physicians and patients) that it would discontinue sales of Namenda IR on August 15, 2014. (Pls.' Count One 56.1 ¶ 80; Defs.' Count One 56.1 ¶ 80.) In June of 2014, Forest announced that, due to manufacturing issues with Namenda XR, it would continue selling Namenda IR through the fall of 2014. (Pls.' Count One 56.1 ¶ 85; Defs.' Count One 56.1 ¶ 86.)

**IV. Procedural History**

On September 15, 2014, the**[\*23]** New York Attorney General filed an initial complaint against Forest in this court, alleging that the hard switch from Namenda IR to Namenda XR violated federal and state ***antitrust*** laws. *See* Complaint, [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (No. 14 Civ. 07473), Dkt. No. 1. Shortly thereafter, the Attorney General sought a preliminary injunction to block the discontinuation of Namenda IR sales. *See* Mot. for Prelim. Inj., [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (No. 14 Civ. 07473), Dkt. No. 27. Judge Sweet held a five-day evidentiary hearing on the preliminary injunction motion, during which time the court heard testimony from twenty-four witnesses and received over 1,400 exhibits. [*Namenda III, 2016 U.S. Dist. LEXIS 128349, 2016 WL 4992690, at \*6*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=). Based on this evidence, Judge Sweet made 167 factual findings and ultimately concluded that a preliminary injunction should issue. *See* [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*4-\*33*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=).

A few of Judge Sweet's key factual findings can be summarized here. Judge Sweet concluded that, prior to the entry of generic versions of Namenda IR, brand-name Namenda IR and Namenda XR were the only memantine therapies available to Alzheimer's patients. [*2014 U.S. Dist. LEXIS 172918, [WL] at \*5*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). He concluded that all other medications then-approved for the treatment of Alzheimer's disease were acetylcholinesterase inhibitors ("CIs"), which are not considered therapeutic equivalents for**[\*24]** memantine-based drugs but instead are considered complements (*i.e.*, memantine and Cis are often prescribed together). [*2014 U.S. Dist. LEXIS 172918, [WL] at \* 5, \*14-\*15*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=).

Judge Sweet concluded that, after various soft-switch tactics failed, Forest decided to pursue a hard switch in order to preserve its market share. [*2014 U.S. Dist. LEXIS 172918, [WL] at \*16-\*22*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). That hard switch began on February 14, 2014, when Forest publicly announced that it would discontinue sales of Namenda IR on August 15, 2014. [*2014 U.S. Dist. LEXIS 172918, [WL] at \*18*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Judge Sweet concluded that, for a variety of reasons, patients and physicians were reluctant to switch to Namenda XR absent being forced to do so by a hard switch — for instance, because most Alzheimer's patients are in long-term care facilities and take, on average, nine pills per day, moving from a twice-daily form of Namenda to a once-daily form is not particularly beneficial. [*2014 U.S. Dist. LEXIS 172918, [WL] at \*19*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Once converted, however, there was a relatively low risk that patients would reverse commute to generic versions of Namenda IR, because Alzheimer's patients are "especially vulnerable" and physicians are therefore reluctant to change their medications, even if it results in cost savings. [*2014 U.S. Dist. LEXIS 172918, [WL] at \*28-\*31*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=).

Judge Sweet concluded that Forest's hard switch would result in "dramatically higher drug costs for insurers and**[\*25]** patients." [*2014 U.S. Dist. LEXIS 172918, [WL] at \*31*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). He also found that Forest had presented no evidence of economic harm that would result from continuing sales of Namenda IR until the entry of generic competition — aside, of course, from the "harm" to Forest's bottom line. [*2014 U.S. Dist. LEXIS 172918, [WL] at \*32-\*33*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=).

Judge Sweet ultimately determined that New York had raised "substantial questions" regarding the merits of its ***antitrust*** claims because the court concluded that Forest's planned hard switch was anticompetitive, Forest's proposed justifications were pretextual, and any procompetitive effects were outweighed by the anticompetitive impact of the hard switch. [*2014 U.S. Dist. LEXIS 172918, [WL] at \*37-\*41*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Because New York also demonstrated the potential for irreparable harm, and equities favored an injunction, Judge Sweet entered the injunction on December 15, 2014. *See* Order, [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (No. 14 Civ. 07473), Dkt. No. 84. That injunction prevented Forest from halting sales of Namenda IR and required Forest to affirmatively undo the effects of its February 2014 announcement by informing patients and physicians that Namenda IR

In May 2015, the Second Circuit affirmed Judge Sweet's ruling on appeal. Significantly, the Circuit also characterized the hard switch as beginning on February 14, 2014 — the date of Forest's**[\*26]** public announcement of a planned withdrawal of Namenda IR — concluding that "announcing the imminent discontinuation of a drug is tantamount to withdrawal." [*Namenda II 787 F.3d at 648*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).

Pursuant to this decision, Forest kept Namenda IR on the market through July 2015.

On September 22, 2015, Smith filed its initial complaint in the instant case, alleging largely analogous ***antitrust*** claims as presented in the original litigation brought by New York. On December 28, 2015, RDC filed its complaint in a separate action, which was then consolidated with this action and recaptioned on January 26, 2016. (Dkt. No. 65). At least two other ***antitrust*** actions have been filed against Forest on the same grounds. *See A. F. of L. - Building Trades Welfare Plan v. Actavis, PLC*, No. 15 Civ. 4406; *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15 Civ. 6549.

On February 16, 2017, Plaintiffs moved for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134) and for partial summary judgment on Count Five (Dkt. No. 138). On March 16, 2017, Defendants cross-moved for partial summary judgment on Count Five (Dkt. No. 161).

**Applicable Legal Standard**

[***HN10***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc10)[] Summary judgment is appropriate where there are no genuine**[\*27]** issues of material fact and the movant is entitled to judgment as a matter of law. *See* [*Fed. R. Civ. P. 56(c)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2421-6N19-F165-00000-00&context=); [*Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-50, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6H80-0039-N37M-00000-00&context=). The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. [*Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6HC0-0039-N37R-00000-00&context=). A dispute concerning material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." [*Aldrich v. Randolph Cent. Sch. Dist., 963 F.2d 520, 523 (2d Cir. 1992)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4090-008H-V2TH-00000-00&context=) (quoting [*Anderson, 477 U.S. at 248*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6H80-0039-N37M-00000-00&context=)). A genuine issue for trial exists if, based on the record as a whole, a reasonable jury could find in favor of the non-movant. *See* [*Anderson, 477 U.S. at 248*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6H80-0039-N37M-00000-00&context=). In making its determination, the Court must resolve all ambiguities and draw all reasonable inferences in favor of the non-movant. *See* [*id. at 255*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6H80-0039-N37M-00000-00&context=).



[***HN11***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc11)[] To defeat summary judgment, it is not sufficient for the nonmoving party to present evidence that is conclusory or speculative, with no basis in fact. *See* [*Anderson, 477 U.S. at 249-50*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6H80-0039-N37M-00000-00&context=). Instead, the nonmoving party must go beyond the pleadings and "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, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-7P90-0039-N51W-00000-00&context=). The nonmoving party must present "specific facts showing that there is a genuine issue for trial." [*Beard v. Banks, 548 U.S. 521, 529, 126 S. Ct. 2572, 165 L. Ed. 2d 697 (2006)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4K8Y-05T0-004B-Y03X-00000-00&context=). "Summary judgment is designed . . . to flush out those cases that are predestined to result in directed verdict." [*Lightfoot v. Union Carbide Corp., 110 F.3d 898, 907 (2d Cir. 1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HP80-00B1-D34B-00000-00&context=).



**Discussion**

**I. Plaintiffs' Motion for Collateral [\*28]  Estoppel and Partial Summary Judgment on Count One Is Granted in Part and Denied in Part**

Plaintiffs seek a partial summary judgment of liability on Count One, which asserts that Forest's February 2014 announcement of the upcoming withdrawal of Namenda IR from the market constituted a violation of *Section 2* of the Sherman Act. Plaintiffs argue that Forest's ***antitrust*** liability for the February 2014 announcement was already determined in the prior *Namenda I* and *Namenda II* litigation and therefore Forest is collaterally estopped from relitigating the issue now. Even though Judge Sweet entered a preliminary injunction in *Namenda I*, Plaintiffs argue that the Second Circuit treated that injunction as permanent in *Namenda II*, and, therefore, that decision constitutes a "final judgment" entitled to collateral estoppel effect.

Plaintiffs' motion is granted in part and denied in part. While key facts regarding Forest's violation of *Section 2* were previously litigated and are entitled to preclusive effect, Plaintiffs' injury was not a subject of the prior litigation and therefore the Court cannot enter a "partial summary judgment of liability" in Plaintiffs' favor.

**A. Plaintiffs Have Satisfied the Elements of Collateral [\*29]  Estoppel as to Forest's Violation of *Section 2***

[***HN12***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc12)[] "Collateral estoppel, or issue preclusion, prevents the relitigation of an issue that was raised, litigated, and actually decided by a judgment in a prior proceeding." [*Jim Beam Brands Co. v. Beamish & Crawford Ltd, 937 F.2d 729, 734 (2d Cir. 1991)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-C440-008H-V4FS-00000-00&context=). In order to establish that an issue was determined in a former adjudication, a party asserting collateral estoppel must establish four things: (1) the issues in the prior proceeding and the current proceeding are identical; (2) the issue raised in the current action was in fact actually decided in the prior proceeding; (3) there was full and fair opportunity to litigate the issue in the prior proceeding; and (4) the issue previously litigated and decided was necessary to support a valid and final judgment on the merits. [*In re PCH Assocs., 949 F.2d 585, 593 (2d Cir. 1991)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-78P0-008H-V4K1-00000-00&context=). In order to invoke collateral estoppel, the party asserting preclusion "bears the burden of showing with clarity and certainty what was determined by the prior judgment." [*Clark v. Bear Stearns & Co., 966 F.2d 1318, 1321 (9th Cir. 1992)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-37J0-008H-V3D9-00000-00&context=).



**1. Forest's *Antitrust* Liability Was at Issue in the Prior Litigation**

The first element of collateral estoppel is identity of the issues. Forest argues that the theory of liability in the first litigation was different than the theory presented in the instant case, because *Namenda I* and *Namenda****[\*30]*** *II* only examined Forest's *prospective* potential ***antitrust*** liability *if* Forest were permitted to cease sales of Namenda IR. Because the injunction prevented Forest from halting its sales, Forest argues, that potentially anticompetitive scenario never actually occurred.

However, the Second Circuit made clear, in its *Namenda II* decision, that Forest's anticompetitive conduct began with its February 2014 announcement, and was not, therefore, purely prospective. The Circuit explicitly held that the February 2014 announcement was "tantamount to withdrawal" of Namenda IR from the market. [*Namenda II, 787 F.3d at 648*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). It concluded that, "Defendants' actions *effectively withdrew* Namenda IR from the market," starting with that announcement, *id.* (emphasis added), and that "Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—*forced* Alzheimer's patients who depend on memantine therapy to switch to XR," [*id. at 654*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=) (emphasis added). This Court previously characterized the *Namenda II* opinion as concluding, "in no uncertain terms, that the illegal hard switch began well before the date Forest intended to withdraw Namenda IR." [*Namenda III, 2016 U.S. Dist. LEXIS 128349, 2016 WL 4992690, at \*11*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=).

Therefore, by the plain language of the *Namenda****[\*31]*** *II* decision, Forest's ***antitrust*** liability for its actions beginning in February 2014 was at issue in the prior litigation.

**2. The Prior Litigation Actually Decided the Issue of Forest's *Antitrust* Liability**

Likewise, Forest's ***antitrust*** liability stemming from the February 2014 announcement was "actually decided" in the prior litigation, thereby satisfying the second element of collateral estoppel.

[***HN13***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc13)[] In order to establish a claim of monopolization in violation of *Section 2* of the Sherman Act, a plaintiff must demonstrate that (1) "the defendant possessed monopoly power in the relevant market" and (2) the defendant willfully acquired or maintained that power through anticompetitive conduct. [*Namenda II, 787 F.3d at 651*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). In order to establish attempted monopolization, "the plaintiff must prove: '(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power."' *Id.* (quoting [*Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456, 113 S. Ct. 884, 122 L. Ed. 2d 247 (1993))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S5B-0D20-003B-R505-00000-00&context=). "Attempted monopolization, unlike monopolization, requires a finding of specific intent." *Id.* In short, a defendant violates *Section 2* "only when it acquires or maintains, or attempts to acquire or maintain, a monopoly by engaging in exclusionary conduct**[\*32]** 'as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" [*United States v. Microsoft Corp., 253 F.3d 34, 58, 346 U.S. App. D.C. 330 (D.C. Cir. 2001)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=) (en banc) (quoting [*United States v. Grinnell Corp., 384 U.S. 563, 571, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (1966))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-G490-003B-S2W3-00000-00&context=).



**a. Forest Had Monopoly Power in the Relevant Market**

In *Namenda I*, Judge Sweet concluded that the relevant "geographic and product market for ***antitrust*** purposes in this case has been established as the memantine market in the United States." [*2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*35*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). He concluded that, prior to the upcoming entry of generics into the U.S. market, Forest was "the exclusive producer[] of all forms of memantine," meaning that Forest "[has] monopoly power." [*2014 U.S. Dist. LEXIS 172918, [WL] at \*36*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). On appeal, Forest did not dispute that it possessed monopoly power over the U.S. memantine drug market until the expiration of the '703 Patent on July 11, 2015. [*Namenda II, 787 F.3d at 651-52*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Therefore, the first element of a monopolization claim — monopoly power — was actually decided in the first litigation.

**b. Forest's Conduct Was Coercive and Anticompetitive**

[***HN14***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc14)[] The second prong of the monopolization claim whether Forest "willfully sought to maintain or attempted to maintain [its] monopoly in violation of *[Section 2*]" — is analyzed under the framework established by the D.C. Circuit in [*Microsoft, 253 F.3d 34, 346 U.S. App. D.C. 330*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=). [*Namenda II, 787 F.3d at 652*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). "Under the *Microsoft* framework, once a plaintiff establishes that a monopolist's**[\*33]** conduct is anticompetitive or exclusionary, the monopolist may proffer 'nonpretextual' procompetitive justifications for its conduct. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." *Id.* (internal citations omitted) (quoting [*Microsoft, 253 F.3d at 58-59*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=)).



[***HN15***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc15)[] A product redesign is anticompetitive or exclusionary "when it coerces consumers and impedes competition." *Id.* The leading case in this circuit examining the question of whether a product redesign is coercive or anticompetitive is [*Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir. 1979)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-VNM0-0039-M0S2-00000-00&context=). In *Berkey Photo*, Kodak, which held a lawful monopoly in film, introduced a new type of film — Kodacolor II — that was only compatible with its new camera, the Kodak 110. The plaintiff, Berkey Photo, a camera manufacturer, alleged that Kodak violated *Section 2* by introducing the Kodak 110 and Kodacolor II simultaneously. The Second Circuit concluded that the launch was not anticompetitive, but noted that "the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera." [*Berkey Photo, 603 F.2d at 287 n.39*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-VNM0-0039-M0S2-00000-00&context=). In *Namenda II*, the Second Circuit relied**[\*34]** on this dictum from *Berkey Photo* for the principle that, [***HN16***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc16)[] while "neither product withdrawal nor product improvement alone is anticompetitive . . . when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the *Sherman Act*." [*Namenda II, 787 F.3d at 653-54*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).



In the prior litigation, it was determined that Forest's actions, starting with the February 2014 announcement of the upcoming withdrawal of Namenda IR from the market, were both coercive and anticompetitive.

First, the Second Circuit found that, "The hard switch began on February 14, 2014 with the announcement of [Forest's] intention to withdraw Namenda IR and was suspended in September 2014" after New York instigated the first litigation. [*Namenda II, 787 F.3d at 648*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). [***HN17***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc17)[] "Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal." *Id.; see also* Merriam-Webster's Collegiate Dictionary 1277 (11th ed. 2003) (defining "tantamount" to mean "equivalent in value, significance, or effect").



Forest's February**[\*35]** 2014 announcement was multi-faceted. In addition to issuing a press release about the upcoming discontinuance of Namenda IR sales, Forest "published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR and urging caregivers to speak with their loved ones' healthcare provider[s] as soon as possible to discuss switching to Namenda XR.'" [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*18*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Judge Sweet found that, "Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR." *Id.* Forest also included the announcement in its fiscal year 2013 10-K filing with the Securities & Exchange Commission and sent a letter to the Centers for Medicare & Medicaid Services to remove Namenda IR from its Formulary Reference File — an unusual step that would make it more likely that health insurance plans would not cover Namenda IR starting in January 2015. *Id.*

Second, the Second Circuit concluded that Forest's hard switch "crosses the line from persuasion to coercion." [*Namenda II, 787 F.3d at 654*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Because Namenda IR and Namenda XR were the only non-CI forms of treatment for Alzheimer's disease approved by the FDA at the time of the hard switch, discontinuation of Namenda IR would leave only one**[\*36]** form of memantine available — Namenda XR. [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \* 5, \*14-\*15*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). "By effectively withdrawing Namenda IR prior to generic entry, Defendants *forced* patients to switch from Namenda IR to XR—the only other memantine drug on the market." *Namenda 11*, [*787 F.3d at 654*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=) (emphasis added). Absent the hard switch, patients and their doctors would have been able to freely choose between Namenda IR and Namenda XR (and, eventually generic versions of Namenda IR) based solely on the merits of those products. "By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice." [*Id. at 655*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).

Both Judge Sweet and the Second Circuit determined that the hard switch also impeded competition. The hard switch, Judge Sweet concluded, "limits access to Namenda IR in order to overcome what [Forest CEO Brenton] Saunders called the 'inertia' that causes most patients and physicians to resist changing medicines, with the goal of impeding lower-cost competition and the result of driving up the average price for memantine." [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*25*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Generic drug competition would be impeded because, by its nature, such competition relies almost exclusively upon "Price competition at the pharmacy, facilitated by state generic substitution**[\*37]** laws." [*2014 U.S. Dist. LEXIS 172918, [WL] at \*8*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Because most generic substitution laws (including New York's) would prevent a pharmacist from automatically substituting a prescription for Namenda XR with a generic version of Namenda IR (without first consulting the patient's physician), Judge Sweet concluded that "generics are unlikely to be able to make substantial sales." [*2014 U.S. Dist. LEXIS 172918, [WL] at \*26*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=); *see also* [*2014 U.S. Dist. LEXIS 172918, [WL] at \*27*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Even in the approximately twenty states that do not rely on the FDA's Orange Book to determine therapeutic equivalence, the Second Circuit determined that "pharmacists will not be permitted to substitute generic IR for XR" because of their different dosage and absorption rates. [*Namenda II, 787 F.3d at 657*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Because "competition through state drug substitution laws is the *only* cost-efficient means of competing available to generic manufacturers," [*id. at 655-56*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=) (emphasis added), other methods of generating sales, like advertising, are not feasible for generic drug manufacturers.

Both Judge Sweet and the Second Circuit concluded that the result of the hard switch would be that a "significantly higher" number of patients would convert from Namenda IR to Namenda XR than if Forest had not attempted to pull Namenda IR from the market. [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*28*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=); [*2014 U.S. Dist. LEXIS 172918, [WL] at \*39*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (hard switch would result in "inflation of [Namenda]**[\*38]** XR's share of the memantine market"); *see also* [*Namenda II, 787 F.3d at 655*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=) (holding that Forest's hard switch "has the effect of significantly reducing usage of rivals' products" (quoting [*Microsoft, 253 F.3d at 65*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=))). Forest's own internal projections estimated that, using only soft-switch tactics, [TEXT REDACTED BY THE COURT] of Namenda IR patients would voluntarily switch to Namenda XR.

*Namenda I*, Unredacted Op. at 80. Under a hard-switch strategy, that percentage [TEXT REDACTED BY THE COURT] *Id.* Judge Sweet determined that generic competition would only be able to capture [TEXT REDACTED BY THE COURT] of the memantine market, while Forest would continue to control [TEXT REDACTED BY THE COURT], if the hard switch were allowed to continue. [*Id. at 109-111*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=). Forest estimated that the hard switch would result in more than [TEXT REDACTED BY THE COURT] in additional sales of Namenda XR as compared to the soft switch. [*Id. at 80-81*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=).

Importantly, Judge Sweet found that Forest's hard-switch tactics had *already* resulted in more customers converting from Namenda IR to Namenda XR than Forest had estimated would convert voluntarily. At the time the preliminary injunction was entered, "about 50% of existing patients [had] converted from Namenda IR to Namenda XR in anticipation**[\*39]** of the lack of availability of Namenda IR." [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*29*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). This is significantly more than the [TEXT REDACTED BY THE COURT] that Forest had estimated would convert if only soft-switch tactics were employed.

Ultimately, if the hard switch continued, it "would likely have anticompetitive and exclusionary effects on competition in the memantine market, creating a 'dangerous probability' that [Forest] would maintain [its] monopoly power after generics enter[ed] the market." [*Namenda II, 787 F.3d at 655*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=) (quoting [*Spectrum Sports, 506 U.S. at 456*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S5B-0D20-003B-R505-00000-00&context=)). Judge Sweet noted that, in the past, market share of above 70% is usually considered strong evidence of monopoly power, while in some cases monopoly power has been found in cases where the monopolist controlled less than 50% of the relevant market. [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*36-\*37*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Here, Forest's own projections that it would continue to control more than [TEXT REDACTED BY THE COURT] of the memantine market if the hard switch was allowed to continue falls squarely in the category of "strong evidence of monopoly power."

**c. Forest's Procompetitive Justifications Were Rejected as Pretextual**

Both Judge Sweet and the Second Circuit determined that "All of [Forest's] procompetitive justifications for withdrawing [Namenda] IR are pretextual." [*Namenda II, 787 F.3d at 658*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). This conclusion was based,**[\*40]** in part, on statements made by one of Forest's own corporate officers, Brenton Saunders, who stated on an earnings call that the purpose of the hard switch was to impede generic competition. [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*40*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Judge Sweet accordingly rejected Forest's later-in-time justification that halting sales of Namenda IR would allow the company to more efficiently "focus" on Namenda XR, which he characterized as "not as specific, or as persuasive, as [Saunders'] earlier representations to shareholders." *Id.*

Furthermore, "by contending at the hearing that a preliminary injunction against the forced switch would require significant changes to [Forest's] operations as a result of the potential loss of [TEXT REDACTED BY THE COURT] in sales," Judge Sweet determined that Forest "essentially conceded that it is this expectation of [TEXT REDACTED BY THE COURT] increased sales of Namenda XR that is driving [its] business decision to engage in the forced switch." *Namenda I*, Unredacted Op. at 121. "No other non-pretex[t]ual pro-competitive purpose has been established, either at the hearing or by any contemporary Forest analysis." *Id.*

**d. Any Procompetitive Benefits Were Outweighed by Anticompetitive Harms**

Even though Forest had failed**[\*41]** to demonstrate the existence of any nonpretextual procompetitive justifications for the hard switch — meaning that New York had no burden to show that those justifications were outweighed by anticompetitive harms — both Judge Sweet and the Second Circuit expounded on the damage the hard switch would inflict if allowed to continue.

In *Namenda I*, Judge Sweet noted that any cost savings that could possibly result from the hard switch's "distribution efficiencies" (the only procompetitive justification that Forest attempted to quantify) would be "dwarfed" by the loss of revenue from Namenda IR sales within the first six months. [*2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*41*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). Furthermore, those same cost savings would also be outweighed "by the considerable anticompetitive harm: both to patients, who will pay [TEXT REDACTED BY THE COURT] in higher co-payments or have to switch medications twice, and to third party payors, who will pay more than [TEXT REDACTED BY THE COURT]." *Namenda I*, Unredacted Op. at 122.

In *Namenda II*, the Circuit noted that Forest's willingness to forsake short-term profits from sales of Namenda IR to achieve an anticompetitive end was "indicative of anticompetitive behavior," rather than evidence of the opposite.**[\*42]** [*787 F.3d at 659*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). The Circuit also flatly rejected Forest's argument that "***antitrust*** scrutiny of the pharmaceutical industry will meaningfully deter innovation," stating that Forest "presented no evidence" to support such a claim. *Id.* "To the contrary . . . immunizing product hopping from ***antitrust*** scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations." *Id.*

"In sum," the Second Circuit concluded, [***HN18***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc18)[] "the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates *§ 2* of the Sherman Act." [*Namenda II, 787 F.3d at 659*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). Because the Circuit also concluded that Forest "effectively withdrew" Namenda IR from the market starting in February 2014, [*id. at 648*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=), the prior litigation conclusively determined that Forest had violated *Section 2* of the Sherman Act.



**3. Forest Had a Full and Fair Opportunity to Litigate the Issue of Its *Antitrust* [\*43]  Liability in the Prior Litigation**

Forest had ample opportunity to litigate its ***antitrust*** liability in the first litigation, and does not argue otherwise in the face of Plaintiffs' motion.

Judge Sweet conducted a five-day hearing on New York's request for an injunction, during which the court received 1,416 exhibits (835 of which were from Forest) and heard live or written testimony from twenty-four witnesses. [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*3-\*4*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). In a meticulous 135-page decision granting the injunction, Judge Sweet made 167 findings of fact and dozens of conclusions of law regarding New York's ***antitrust*** claims, including New York's monopolization and attempted monopolization claims under *Section 2* of the Sherman Act. Forest was able to seek near-immediate review of Judge Sweet's decision by a panel of the Second Circuit, which unanimously rejected all of Forest's arguments regarding the monopolization and attempted monopolization claims. Forest petitioned for rehearing of the *Namenda II* decision and for rehearing *en banc*, both of which were denied.

**4. Forest's *Antitrust* Liability Was Necessary to a Valid and Final Judgment on the Merits**

The final questions in the collateral estoppel analysis are (1) whether the decision in *Namenda****[\*44]*** *II* resulted in a final judgment on the merits and (2) whether issue of Forest's ***antitrust*** liability was necessary to that decision. After a careful review of the record, the Court is convinced that the answer to both questions is "Yes."

**a. The Prior Litigation Resulted in a Valid and Final Judgment on the Merits**

[***HN19***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc19)[] Ordinarily, a decision granting a preliminary injunction is *not* considered "a final judicial decision based on the actual merits of the controversy" entitled to collateral estoppel effect. [*Univ. of Texas v. Camenisch, 451 U.S. 390, 395-96, 101 S. Ct. 1830, 68 L. Ed. 2d 175 (1981)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6JD0-003B-S1BN-00000-00&context=). A plaintiff seeking a preliminary injunction need only "establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." [*Winter v. NRDC, Inc., 555 U.S. 7, 20, 129 S. Ct. 365, 172 L. Ed. 2d 249 (2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TX2-8KV0-TXFX-13DV-00000-00&context=). A plaintiff "need not show that success is an absolute certainty." [*Abdul Wali v. Coughlin, 754 F.2d 1015, 1025 (2d Cir. 1985)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JK30-0039-P4X8-00000-00&context=). As such, "findings of fact and conclusions of law made in a preliminary injunction proceeding do not preclude reexamination of the merits at a subsequent trial." [*Irish Lesbian & Gay Org. v. Giuliani, 143 F.3d 638, 644 (2d Cir. 1998)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3SJ4-63F0-0038-X4RG-00000-00&context=).



[***HN20***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc20)[] Entry of a permanent injunction, by contrast, *is* a final judgment on the merits. [*Webb v. GAF Corp., 78 F.3d 53, 56 (2d Cir. 1996)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3CY0-006F-M0B6-00000-00&context=); *see also* [*Plummer v. AICPA, 97 F.3d 220, 229 (7th Cir. 1996)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0HP0-006F-M42Y-00000-00&context=). Likewise, in certain circumstances, a preliminary injunction decision may be**[\*45]** "rendered 'practically' final," [*Don King Prods., Inc. v. Douglas, 742 F. Supp. 741, 754 (S.D.N.Y.)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-8N40-0054-40NT-00000-00&context=), *on reargument*, [*742 F. Supp. 786 (S.D.N.Y. 1990)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-8880-0054-4308-00000-00&context=), depending on factors such as "the nature of the decision (i.e., that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review." *Lummus Co. v. Commonwealth Oil Ref Co., 297 F.2d 80, 89 (2d Cir. 1961)*.



All three of the *Lummus* factors — nature of the decision, adequacy of the hearing, and opportunity for review — were present here, making the injunction final for collateral estoppel purposes.

Here, Judge Sweet entered an injunction only after conducting an extensive hearing in which twenty-four witnesses testified and Forest was permitted to submit more than 800 exhibits into evidence. [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198, at \*3-\*4*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=). He concluded that New York had established "sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in [its] favor." [*2014 U.S. Dist. LEXIS 172918, [WL] at \*33*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=).[[5]](#footnote-4)5 The injunction required Forest to "continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)" and to "inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily**[\*46]** view the injunction) and the continued availability of Namenda IR in the same or substantially similar manner in which [it] informed them of [its] plan to discontinue Namenda IR in February 2014." Order, [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (No. 14 Civ. 07473), DM. No. 84 at 1-2.

After Judge Sweet entered the injunction, Forest was able to seek immediate review of that decision at the Second Circuit. The Second Circuit not only affirmed the decision in *Namenda I*, but did so under a far more stringent standard than Judge Sweet had applied. The Circuit concluded that, because the injunction barred removal of Namenda IR from the market until after the entry of generic competition, it "provide[d] the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." [*Namenda II, 787 F.3d at 650*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=). That meant the injunction, although nominally preliminary, "in effect," operated the same way "as if the injunction had been permanent." [*Id. at 651*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=) (quoting [*Eng v. Smith, 849 F.2d 80, 82 (2d Cir. 1988))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0MG0-001B-K29R-00000-00&context=). Therefore, "a trial on the merits [would be] largely or partly meaningless." *Id.* (quoting [*Tom Doherty Assocs., Inc. v. Saban Entm't, Inc., 60 F.3d 27, 35 (2d Cir. 1995))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-D5J0-001T-D1DX-00000-00&context=). This meant that New York had to demonstrate "a 'clear' or 'substantial' likelihood of success on the merits" for the injunction**[\*47]** to remain in place — a much more demanding standard than applied by Judge Sweet, [*Namenda II, 787 F.3d at 650*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=), and a more demanding standard than the Supreme Court articulated for preliminary injunctions in [*Winter v. NRDC, Inc., 555 U.S. 7, 20, 129 S. Ct. 365, 172 L. Ed. 2d 249 (2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TX2-8KV0-TXFX-13DV-00000-00&context=). That more demanding standard was met, the Circuit concluded, because New York demonstrated "a substantial likelihood of success on the merits of its monopolization and attempted monopolization claims under *§ 2* of the Sherman Act." [*Namenda II, 787 F.3d at 651*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G38-K6G1-F04K-J0G4-00000-00&context=).

Significantly, no trial on the merits was ever held in the prior litigation. By its terms, the injunction expired on August 10, 2015, thirty days after generic competition entered the memantine market on July 11, 2015. Order, [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (No. 14 Civ. 07473), Dkt. No. 84 at 2. After the expiration of the injunction, the parties stipulated to dismissal of the entire action, including Forest's pending petition for certiorari before the U.S. Supreme Court. *See* Stipulation of Voluntary Dismissal, [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (No. 14 Civ. 07473), Dkt. No. 96.

In its petition for certiorari, Forest described the Second Circuit's *Namenda II* decision as a final decision on the merits. While acknowledging that, "The propriety of a preliminary injunction is usually distinct from the final merits," Forest argued that, in this case,**[\*48]** "the two issues merged." Petition for a Writ of Certiorari at 32-33, *Allergan PLC v. New York, 136 S.Ct. 581, 193 L. Ed. 2d 421 (2015)* (No. 15-587), [*2017 U.S. Dist. LEXIS 83446, 2015 WL 6774554*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=). Forest further maintained that, "While nominally addressing the propriety of the district court's preliminary injunction, the [Second Circuit] left no doubt about the merits under *section 2* of the Sherman Act." [*2017 U.S. Dist. LEXIS 83446, [WL] at 8*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=). Because "the Second Circuit reached the merits of [New York's*] section 2* claim," [*2017 U.S. Dist. LEXIS 83446, [WL] at 32*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TX2-8KV0-TXFX-13DV-00000-00&context=), Forest asserted that New York "cannot seek any further relief under federal law," [*2017 U.S. Dist. LEXIS 83446, [WL] at 33*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=).

By Forest's own admission, the Second Circuit decided the merits of New York's ***antitrust*** claims in the first action. Forest was afforded ample opportunity to litigate those claims before Judge Sweet, and was able to have those claims reviewed on appeal. By acknowledging to the Supreme Court that New York could not seek "any further relief under federal law" for its claims, Forest admitted that New York had won on the merits. All of the *Lummus* factors — including Forest's own characterization of the *Namenda II* decision as final rather than tentative — support the conclusion that the first litigation constituted a final decision on the merits of New York's ***antitrust*** claims. *Lummus, 297 F.2d at 89*.

**b. Forest's *Antitrust* Liability Was Necessary to that Decision**

Finally, in**[\*49]** order for collateral estoppel to apply, the issue decided in the prior litigation must have been "necessary" to the final judgment. Forest argues that, because the prior litigation only prevented Forest from halting sales of Namenda IR, any comments from *Namenda I* or *Namenda II* about Forest's ***antitrust*** liability arising from the announcement of that upcoming withdrawal were purely dicta.

Forest is mistaken. The issue of Forest's ***antitrust*** liability was necessary to the decision in the first litigation because Judge Sweet's injunction did more than require Forest to continue making Namenda IR available to doctors and patients. It required Forest to affirmatively undo the effects of its February 2014 announcement of the upcoming withdrawal by "inform[ing] healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction . . . and the continued availability of Namenda IR in the same or substantially similar manner in which [it] informed them of [its] plan to discontinue Namenda IR in February 2014." Order, [*Namenda I, 2014 U.S. Dist. LEXIS 172918, 2014 WL 7015198*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5DV9-K971-F04F-04HS-00000-00&context=) (No. 14 Civ. 07473), Dkt. No. 84 at 1-2.

If the first litigation had only dealt with Forest's prospective ***antitrust*** liability, such affirmative steps would have been**[\*50]** unnecessary. Imposing this requirement was an acknowledgment that Forest had *already* caused anticompetitive injury to the memantine market that had to be rectified. Therefore, in order to affirm the terms of Judge Sweet's injunction, it was "necessary" for the Second Circuit to first determine that Forest (1) possessed monopoly power over the memantine market; (2) had engaged in conduct that was both coercive and anticompetitive; and (3) lacked any non-pretextual procompetitive justifications for its coercive and anticompetitive conduct.

**B. Although Forest Is Collaterally Estopped from Relitigating Questions About Its Illegal Conduct, Plaintiffs Are Not Entitled to Partial Summary Judgment on Count One**

Because of all of the elements of collateral estoppel are met, Forest is precluded from relitigating the questions of (1) whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition; (2) whether its February 2014 announcement of the upcoming discontinuation of Namenda IR was coercive and anticompetitive; and (3) whether Forest had any non-pretextual procompetitive justification for its illegal conduct. Plaintiffs' motion for collateral estoppel**[\*51]** on these issues of fact is GRANTED. They will be presented to the jury as already decided.

However, [***HN21***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc21)[] in order for a plaintiff to establish liability on a *Sherman Act* monopolization claim, it must also prove that the defendant's illegal conduct resulted in ***antitrust*** injury to the plaintiff. *See* [*Irvin Indus., Inc. v. Goodyear Aerospace Corp., 974 F.2d 241, 244 (2d Cir. 1992)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-21Y0-008H-V2K0-00000-00&context=) (quoting [*U.S. Football League v. NFL, 842 F.2d 1335, 1377 (2d Cir. 1988))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-2610-001B-K36J-00000-00&context=). In order to meet this burden, the plaintiff need only show that the illegal conduct "was a substantial or materially contributing factor" to its injuries. [*Litton Sys., Inc. v. Am. Tel. & Tel. Co., 700 F.2d 785, 823 n.49 (2d Cir. 1983)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0RR0-003B-G3K6-00000-00&context=).



Forest argues that, because questions of causation and injury to Plaintiffs were not adjudicated in the prior litigation — a fact that Plaintiffs do not dispute — the Court cannot grant partial summary judgment of liability in Plaintiffs' favor. In support, Forest points to two *Section 2* cases, [*Howard Hess Dental Labs., Inc. v. Dentsply Int'l, Inc., 516 F. Supp. 2d 324 (D. Del. 2007)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PS7-26F0-TXFP-J1SV-00000-00&context=), *aff'd*, [*602 F.3d 237 (3d Cir. 2010)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:7Y80-FTW0-YB0V-F0BS-00000-00&context=), and [*In re Microsoft Corp.* ***Antitrust*** *Litig., 232 F. Supp. 2d 534 (D. Md. 2002)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:475Y-3SD0-0038-Y38P-00000-00&context=), *rev'd*, [*355 F.3d 322 (4th Cir. 2004)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4BG9-THB0-0038-X1FG-00000-00&context=), in which courts declined to grant partial summary judgment to plaintiffs on the ground of collateral estoppel because the plaintiffs' injuries were not decided in the prior ***antitrust*** litigation.

In *Howard Hess*, the plaintiffs sought partial summary judgment on their ***antitrust*** claims solely on the ground of collateral estoppel, and asked the court to "infer" the existence of an ***antitrust*** injury based on a prior decision that**[\*52]** had not made a finding of injury to the plaintiffs. [*Howard Hess Dental Labs. Inc., 516 F. Supp. 2d at 334*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PS7-26F0-TXFP-J1SV-00000-00&context=). The court declined to grant that motion, but did note that the findings about the defendant's monopolization from the prior litigation "Certainly . . . are to be given preclusive effect." *Id.* The district court in *Microsoft* likewise denied the plaintiffs' motions for partial summary judgment solely on the ground that the previous litigation did not address their injuries, but did give preclusive effect to hundreds of findings of fact from the prior litigation regarding the defendant's monopolization efforts. [*In re Microsoft Corp.* ***Antitrust*** *Litig., 232 F. Supp. 2d at 538*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:475Y-3SD0-0038-Y38P-00000-00&context=).

Forest is correct that a necessary aspect of Plaintiffs' *Section 2* claim is proof of an ***antitrust*** injury to Plaintiffs caused by Forest's conduct, and that outstanding questions of material fact remain regarding that element of Plaintiffs' claim. Therefore, Plaintiffs' motion for partial summary judgment of liability on Count One is DENIED.

**II. Plaintiffs' Motion for Partial Summary Judgment on Count Five Is Denied; Defendants' Cross-Motion for Partial Summary Judgment Dismissing Count Five Is Also Denied**

In Count Five of their amended complaint, Plaintiffs assert that Defendants violated *Section 1* of the Sherman Act by entering into license agreements**[\*53]** with the seven Generic Competitors that unlawfully precluded the entry of generic competition until three months after the expiration of the '703 Patent's term. These agreements, Plaintiffs argue, were a *per se* restraint of trade because they prevented the Generic Competitors from entering the memantine market until "3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity." (*E.g.*, Pls.' Count Five 56.1 & 25 n.27 (Amneal settlement agreement).) This meant that, once Forest obtained six months of pediatric exclusivity, the Generic Competitors were unable to enter the market until July 11, 2015 — three months after the '703 Patent expired.

[***HN22***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc22)[] Agreements are deemed *per se* unlawful only when they have a "predictable and pernicious anticompetitive effect." [*State Oil Co. v. Khan, 522 U.S. 3, 10, 118 S. Ct. 275, 139 L. Ed. 2d 199 (1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RFP-CVB0-004C-3005-00000-00&context=). The problem with Plaintiffs' argument is that the settlement agreements permitted the Generic Competitors to enter the market *earlier* than they could have if Defendants had prevailed in their patent infringement litigation — a *generally procompetitive* result. Plaintiffs' characterization of the agreements as *per se* anticompetitive restraints relies on the assumption that Defendants would have lost the underlying**[\*54]** patent infringement suit — an assumption the Court cannot make on this pre-discovery motion. Likewise, the Court cannot assume that Defendants would have won their infringement suit, and therefore cannot grant summary judgment for Defendants on Count Five either.



**A. Plaintiffs' Motion Must Be Denied Because the Settlement Agreements Permitted the Generic Competitors to Enter the Memantine Market Earlier Than If Defendants Had Won Their Patent Infringement Suit**

The relevant provision of [***HN23***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc23)[] the pediatric exclusivity statute is [*21 U.S.C. § 355a(c)(1)(B)(ii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKB1-NRF4-448F-00000-00&context=), which states that, if the brand-name manufacturer's pediatric studies are accepted, then:



if the drug is the subject of a listed patent for which a [Paragraph IV] certification has been submitted . . . , **and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed**, the period during which an application may not be approved under . . . [[*21 U.S.C. § 355(j)(5)(B)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=)] shall be extended by a period of six months after the date the patent expires (including any patent extensions).

(Emphasis added.)

This means that, [***HN24***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc24)[] where the name-brand drug manufacturer being awarded the pediatric exclusivity period is faced with a Paragraph**[\*55]** IV Certification (asserting that the name-brand drug's patent is invalid or will not be infringed by the generic competitor), if the name-brand manufacturer *wins* its patent infringement suit, the FDA may not approve any generic competitor until six months after the expiration of the patent's term.



As discussed above, [***HN25***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc25)[] in the ordinary course, a Paragraph IV Certification gives the brandname manufacturer the right to sue the generic manufacturer within forty-five days for patent infringement. [*21 U.S.C. § 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). Bringing suit triggers a thirty-month stay during which the FDA may not approve the generic manufacturer's ANDA unless the brand-name manufacturer loses the infringement suit, in which case the ANDA is approved immediately. *Id.* [*§ 355(j)(5)(B)(iii)(I)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). If the brand-name manufacturer wins the suit, the ANDA may not be approved until after the patent expires. *Id.* [*§ 355(j)(5)(B)(iii)(II)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). If the suit is not resolved within the thirty-month period, the ANDA is automatically approved at the end of the thirty months unless the court extends the stay. *Id.* [*§ 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=); *see also* [*Actavis, 133 S. Ct. at 2228*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=).



The parties agree that, had Defendants prevailed in their patent infringement litigation against the Generic Competitors, no generic competitor would have been able to enter the memantine**[\*56]** market until April 11, 2015 (if Forest did not obtain pediatric exclusivity) or October 11, 2015 (if Forest obtained pediatric exclusivity). Had Defendants lost the litigation, the patent would have been declared invalid or not infringed and the Generic Competitors could have entered the market immediately, regardless of whether Forest obtained pediatric exclusivity or not. Had the litigation not resolved before the end of the thirty-month stay, the Generic Competitors' ANDAs would have become effective at the end of the thirty months unless the court extended the stay, again regardless of whether Forest obtained pediatric exclusivity.

Once Defendants settled with each Generic Competitor, the patent infringement litigation was dismissed, meaning that there was never a judicial determination about the validity or scope of the '703 Patent. Therefore, once the thirty-month stay period expired, the FDA proceeded to give final approval to each of the Generic Competitors' ANDAs. But for the terms of their settlement agreements with Defendants, each Generic Competitor would have been able to enter the memantine market as soon as the FDA gave final approval to its ANDA.

Plaintiffs argue that the settlement**[\*57]** agreements were a *per se* restraint of trade because, had the parties never settled, the ANDAs would have been automatically approved at the end of the thirty-month stay, and the Generic Competitors would have been able to enter the market as soon as they received approval from the FDA.

But Plaintiffs' position relies on several faulty assumptions. First, it assumes that the court handling the infringement action would not have extended the thirty-month stay, as it is empowered to do under the terms of [*Section 355(j)(5)(B)(iii)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GNC1-NRF4-4393-00000-00&context=). Second, it assumes that Defendants would not have *won* the infringement suit had they continued to pursue the action instead of agreeing to settle — a proposition for which it puts forward no evidence whatsoever. If Defendants had won, no ANDA would have been approved until after the expiration of the patent on April 11, 2015 (if Forest did not obtain pediatric exclusivity) or October 11, 2015 (if it did).

By settling with each of the Generic Competitors in the manner that they did, Defendants reduced the number of potential dates of the entry of generic competition down to two: (1) January 11, 2015 (if Forest did not obtain pediatric exclusivity) and (2) July 11, 2015 (if Forest obtained**[\*58]** pediatric exclusivity). Both of these dates were *earlier* than would have been the case if Defendants prevailed in their patent infringement action, and later than if Defendants lost the action or if the action failed to resolve before the expiration of the stay. They were, in the truest sense, a compromise. Defendants avoided the risk of the patent's being declared invalid, which would have allowed generic competition to start immediately after the lawsuit, and the Generic Competitors avoided the risk of Defendants winning the infringement action, which would have kept them out of the market until April 11, 2015, or possibly October 11, 2015.

Plaintiffs are correct that, once the FDA approved the Generic Competitors' ANDAs, nothing stopped them from entering the market other than their agreements with Defendants. But the FDA was only able to approve the ANDAs when it did *because* the parties had settled the infringement suit and allowed the thirty-month stay to elapse. If the court had extended the stay until the end of the litigation, or if Defendants had prevailed, the ANDAs could not have been approved until much later. Indeed, some of the letters approving the ANDAs explicitly state**[\*59]** that the settlement of the infringement litigation is what allowed the FDA to grant approval to the ANDA when it did: "You also notified the [FDA] that [the parties] agreed to the dismissal of this case, making your ANDA eligible for approval." (Litvin Decl. Ex. 4, Dkt. No. 149-3 (FDA Approval Letter to Dr. Reddy's).)

Because the settlement agreements allowed the Generic Competitors to enter the memantine market *earlier* than if Defendants had won their patent infringement action (regardless of whether Forest obtained pediatric exclusivity or not), the agreements were not *per se* restraints of trade in violation of the *Sherman Act*. Plaintiffs have cited no case where an agreement to potentially allow *greater* competition has been declared a *per se* restraint of trade in violation of *Section 1* of the Sherman Act.

[***HN26***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc26)[] A practice is considered *per se* anticompetitive when "experience with a particular kind of restraint enables the Court to predict with confidence that the rale of reason will condemn it." [*Arizona v. Maricopa Cty. Med. Soc., 457 U.S. 332, 344, 102 S. Ct. 2466, 73 L. Ed. 2d 48 (1982)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5GN0-003B-S4S3-00000-00&context=). Conduct that is subject *toper se* analysis is invalid *regardless* of any procompetitive justification that may exist in a particular case. [*Id. at 351*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5GN0-003B-S4S3-00000-00&context=).



However, agreements to settle patent infringement litigation like**[\*60]** those at issue here are not *per se* anticompetitive, because the Court is required to evaluate the potential procompetitive effects of such agreements. In *Actavis*, the Supreme Court stated that, in general, "settlement on terms permitting the patent challenger to enter the market *before* the patent expires . . . bring[s] about competition . . . to the consumer's benefit." [*133 S. Ct. at 2234*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=) (emphasis added). Evaluation of such procompetitive effects would be unnecessary if these agreements were subject *toper se* rules. Such settlements are, instead, reviewed under *Actavis's* rule-of-reason analysis. *See* [*id. at 2236*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=).

Plaintiffs' reliance on [*Brulotte v. Thys Co., 379 U.S. 29, 85 S. Ct. 176, 13 L. Ed. 2d 99 (1964)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-GS30-003B-S303-00000-00&context=), is, therefore, misplaced. *Brulotte* involved a royalty agreement that projected beyond the expiration of the patent term, which the Supreme Court concluded was an attempt to preserve the patent monopoly after expiration of the patent and thus a *per se* violation of the patent laws. [*Id. at 31-33*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-GS30-003B-S303-00000-00&context=). As discussed, in the event that Forest did not obtain pediatric exclusivity, the settlement agreements would not have delayed entry of generic competition beyond the end of the '703 Patent's term. Once Forest obtained pediatric exclusivity, the settlements delayed generic entry beyond the expiration of the patent but not**[\*61]** beyond what would have happened automatically under the *Hatch-Waxman Act* in the event Defendants had won their infringement suit. Neither scenario would result in a *per se* illegal extension of the '703 Patent's monopoly.

Whether the settlement agreements were anticompetitive or procompetitive will depend on several complex factual questions that cannot be decided on summary judgment. As the Court indicated in its earlier decision denying Defendants' motion to dismiss, Plaintiffs may have a viable *Section 1* claim under the theory that the settlements contained unlawful reverse payments to Defendants' Generic Competitors in exchange for dropping their challenges to the validity of the '703 Patent. *See* [*Namenda III, 2016 U.S. Dist. LEXIS 128349, 2016 WL 4992690, at \*12-\*15*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KRW-4Y01-F04F-00FJ-00000-00&context=). Such a claim, however, will depend on the presence of "evidence suggesting that the settlement agreements did, in fact, delay generic entry," which will presumably require proof that the '703 Patent would likely have been found invalid or not infringed by the Generic Competitors, or that the litigation would have continued past the expiration of the thirty-month stay, or that the reverse payment at issue was large or unexplained. [*Id. at \*15*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RFP-CVB0-004C-3005-00000-00&context=). Resolution of these questions under a rule-of-reason analysis will require significantly more factual**[\*62]** development than what is reflected in the present prediscovery record.

Plaintiffs' motion is, therefore, DENIED.

**B. Defendants' Cross-Motion Must Be Denied Because Plaintiffs May Have a Viable *Section 1* Claim Under *Actavis***

By the same token, Defendants' cross-motion seeking dismissal of Count Five's Section I claim must also be denied. Although Plaintiffs cannot proceed on a *per se* theory, Count Five also presents a viable *Section 1* claim under the rule-of-reason analysis set forth in *Actavis*, making summary judgment on that count inappropriate.

Defendants argue that, as a matter of law, their conduct was not anticompetitive under any standard because their settlement agreements with the Generic Competitors are not what prevented generics from entering the market. Defendants argue that the Generic Competitors' ANDAs were only "tentatively" approved by the FDA, and, because the '703 Patent was never declared invalid, it was the lack of "final" approval from the FDA that prevented the Generic Competitors from entering the market, not the operation of the settlement agreements. Defendants argue that, upon expiration of the '703 Patent, the still-unapproved ANDAs with their Paragraph IV Certifications automatically "converted as**[\*63]** a matter of law" to Paragraph II Certifications, or else had to be refiled as Paragraph II Certifications, citing [*Ranbaxy Labs. Ltd. v. FDA, 307 F. Supp. 2d 15 (D.D.C.)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4BX7-VMK0-0038-Y1P5-00000-00&context=), *aff'd*, [*96 F. App'x 1 (D.C. Cir. 2004)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4C87-YWG0-0038-X48T-00000-00&context=).

That argument is incorrect. There is nothing "tentative" about the FDA approval of the Generic Competitors' ANDAs. (*See, e.g.*, Litvin Decl. Ex. 6, Dkt. No. 149-5 (FDA Approval Letter to Amneal).) Each approval letter acknowledges the continued existence of the '703 Patent and notes that the patent infringement suit brought by Defendants had been dismissed. (*E.g., id.*) It then grants approval to the ANDA "effective on the date of this letter," with no indication that market entry must be delayed until the expiration of the patent or the pediatric exclusivity period. (*E.g., id.*)

As a matter of law, [***HN27***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NNX-X061-F04F-02KR-00000-00&context=&link=clscc27)[] once the ANDA was approved, each Generic Competitor was "no longer under an obligation to amend its patent certification," even after the '703 Patent expired. [*AstraZeneca AB v. Impax Labs., Inc., 490 F. Supp. 2d 368, 380 (S.D.N.Y. 2007)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4NVV-08P0-TVW3-P2XY-00000-00&context=). The Generic Competitors' existing Paragraph IV Certifications did not "convert" to anything upon expiration of the '703 Patent; their approvals were already final. Therefore, it was only through operation of the settlement agreements that the Generic Competitors were prevented from entering the memantine market immediately upon receipt of FDA**[\*64]** approval. As discussed, the settlement agreements also allowed the FDA to approve the ANDAs prior to the expiration of the patent.



Whether these settlements were ultimately procompetitive or anticompetitive is a question that will be determined at trial under the framework established in [*Actavis, 133 S. Ct. at 2234*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=). Therefore, Defendants' cross-motion is also DENIED.

**Conclusion**

For the foregoing reasons, Plaintiffs' motion for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134) is GRANTED IN PART AND DENIED IN PART. Plaintiffs' motion for partial summary judgment on Count Five (Dkt. No. 138) is DENIED. Defendants' cross-motion for partial summary judgment dismissing Count Five (Dkt. No. 161) is DENIED. Plaintiffs' motion for leave to file a sur-reply in support of its motion for partial summary judgment on Count Five (Dkt. No. 230) is DENIED.

The Clerk of the Court is directed to remove Dkt. Nos. 134, 138, 161, and 230 from the Court's list of pending motions.

Dated: May 23, 2017

/s/ Colleen McMahon

Chief Judge

**End of Document**

1. 1Plaintiffs' motion at Dkt. No. 138 and Forest's cross-motion at Dkt. No. 161 were initially styled as motions addressing Count Three. After an inquiry from the Court (Dkt. No. 187), the parties clarified that both motions were intended to address Count Five (Dkt. Nos. 188, 194), a representation that the Court accepted. (*See* Dkt. No. 195.) All references to "Count Five" in this opinion correspond to references to "Count Three" in the motion papers. [↑](#footnote-ref-0)
2. 2Unless otherwise noted, all references to the *Namenda I* opinion are to the public, redacted version. [↑](#footnote-ref-1)
3. 3The Merz Entities were originally named defendants to some of the counts in the amended complaint, but per a stipulation of the parties, the Merz Entities were terminated as defendants and replaced by Defendants Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd., which are named as defendants to Counts Three, Four, and Five of the amended complaint. (*See* Dkt. No. 207.) [↑](#footnote-ref-2)
4. 4Many of those generic manufacturers have been named defendants in a related suit before this Court, *Sergeants Benevolent Ass 'n Health & Welfare Fund v. Actavis, PLC*, No. 15 Civ. 6549, but none is a named defendant in the instant action. [↑](#footnote-ref-3)
5. 5Judge Sweet applied the standard for a preliminary injunction articulated in [*Oneida Nation of N.Y. v. Cuomo, 645 F.3d 154, 164 (2d Cir. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52TN-NJD1-F04K-J0TR-00000-00&context=). This standard appears at odds with the decision in [*Winter v. NRDC, Inc., 555 U.S. 7, 20, 129 S. Ct. 365, 172 L. Ed. 2d 249 (2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TX2-8KV0-TXFX-13DV-00000-00&context=), in which the Supreme Court said: "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." The *Oneida Nation* standard is less demanding than *Winter's*, since it does not require a showing of likelihood of success on the merits. However, in *Namenda II*, the Second Circuit applied a higher standard than in *Winter*, in view of the mandatory and permanent nature of the "preliminary" injunction. *See* [*infra at 30-31*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TX2-8KV0-TXFX-13DV-00000-00&context=). [↑](#footnote-ref-4)