UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	)	CIVIL ACTION NO. 12-md-02409-WGY

YOUNG, D.J. September 4, 2014

MEMORANDUM AND ORDER

I. INTRODUCTION

This case, arising under the federal antitrust laws and state analogues, presents a challenge to the use of reverse payment settlements in patent litigation. Reverse payment settlements are agreements to settle patent infringement litigation under which the patent holder pays the claimed infringer handsomely to refrain from competing with the patent holder until the patent or patents in suit expire. The arrangement preserves the patent holder's monopoly and the full term of its patents, while compensating the claimed infringer with at least some of the money it would have earned had it successfully challenged the patents. In a key ruling last year, the Supreme Court held that these kinds of "pay for delay" agreements can, under certain circumstances, violate the federal antitrust laws. Federal Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013). The case at bar, now a multidistrict

class action, asks this Court to put the Supreme Court's holding into practice.

This action is brought by a class of wholesale drug distributors (the "Direct Purchasers"), a class of individual consumers, third-party payors, union plan sponsors, and certain insurance companies (the "End-Payors") (collectively, with the Direct Purchasers, the "Class Plaintiffs"), and a number of pharmaceutical retail outlets: Eckerd Corporation, Giant Eagle, Inc., HEB Grocery Company L.P., JCG (PJC) USA, LLC, The Kroger Co., Maxi Drug, Inc. d/b/a Brooks Pharmacy, Rite Aid Corporation, Rite Aid Headquarters Corp., Safeway Inc., Supervalu, Inc., and Walgreen Co. (collectively, the "Retailer Plaintiffs") (collectively, with the Direct Purchasers and the End-Payors, the "Plaintiffs"). The Plaintiffs have brought claims for alleged violations of federal and state antitrust laws involving the heartburn medication, Nexium, referred to in its generic form as esomeprazole magnesium, against AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP (collectively, "AstraZeneca"), Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., and Ranbaxy Laboratories, Ltd. (collectively, "Ranbaxy"), Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"), and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL")

(collectively, with Ranbaxy and Teva, the "Generic Defendants") (collectively, with AstraZeneca, the "Defendants").

Beginning in December 2013, the Defendants filed a plethora of motions for summary judgment which the Court decided in January and February of this year. As promised in those summary orders -- and as urged by Fed. R. Civ. P. 56(a), see Securities Exch. Comm'n v. Eagle Eye Asset Mgmt., LLC, 975 F. Supp. 2d 151 (D. Mass. 2013) -- the Court now sets out in full the reasoning for its rulings.

A. Procedural Posture

This case has had an extensive and tortuous procedural history. Out of necessity, the developments and filings in this case will be reviewed here with a primary focus on the motions for summary judgment being addressed in this opinion.

1. Initial Proceedings and Class Certification

On December 7, 2012, six actions pending in the District of Massachusetts, the District of New Jersey, and the Eastern District of Pennsylvania were consolidated into the present multidistrict litigation and assigned to this Court, pursuant to 28 U.S.C. § 1407. See Elec. Notice, Dec. 7, 2012, ECF No. 1; Transfer Order, MDL No. 2409, ECF No. 2. Representatives for the End-Payors filed a consolidated complaint on February 1, 2013, Corrected Consol. Am. Class Action Compl. & Demand Jury Trial ("End-Payors' Compl."), ECF No. 114, and representatives

for the Direct Purchasers filed their consolidated complaint on February 21, 2013, Consol. Am. Compl. & Demand Jury Trial ("Direct Purchasers' Compl."), ECF No. 131. The Defendants filed a number of motions to dismiss these complaints, and the Court denied all of them at a motion hearing held on April 18, 2013. See Elec. Clerk's Notes, Apr. 18, 2013, ECF No. 218; see also In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367 (D. Mass. 2013).

Several months later, the Court granted two motions certifying an End-Payor damages class,[1] Mem. & Order, Nov. 14, 2013, ECF No. 519, and a Direct Purchaser class, Mem. & Order, Dec. 11, 2013, ECF No. 660. During this time, the Retailer Plaintiffs individually entered this litigation when they collectively filed three amended complaints against the Defendants on November 14, 2013. See Am. Compl. & Demand Jury Trial ("Walgreen Compl."), ECF No. 515; Am. Compl. & Demand Jury Trial ("Rite Aid Compl."), ECF No. 516; Am. Compl. & Demand Jury Trial ("Giant Eagle Compl."), ECF No. 517.

2. Motions for Summary Judgment

On December 10, 2013, the Defendants collectively filed eleven motions for summary judgment. See DRL's Mot. Summ. J. All Claims, ECF No. 594; Teva Defs.' Mot. Summ. J. Based Absence

[1] The Court's End-Payor class certification is currently under appellate review by the First Circuit. See United States Ct. Appeals First Circuit, Judgment, May 14, 2014, ECF No. 924.

Reverse Payment Teva, ECF No. 600; Teva Defs.' Mot. Summ. J. Based Lack Causation, ECF No. 606; Def. Ranbaxy's Mot. Summ. J. Lack Causation, ECF No. 641; AstraZeneca & Ranbaxy Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlement Agreement Ranbaxy, ECF No. 642; AstraZeneca Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlements Teva & DRL, ECF No. 644; AstraZeneca Defs.' Mot. Summ. J. Basis Causation, ECF No. 645; AstraZeneca, Ranbaxy, & Teva Defs.' Mot. Partial Summ. J. Overarching Conspiracy, ECF No. 647; AstraZeneca Defs.' Mot. Summ. J. Direct Purchaser Pls. Lack Actual Injury & Exclude Direct Purchaser Pls.' Experts' Damages Opinions, ECF No. 648; AstraZeneca Defs.' Mot. Partial Summ. J. Basis Statute Limitations, ECF No. 649; AstraZeneca Defs.' Mot. Summ. J. Barring Assigned Claims, ECF No. 650.

The Plaintiffs' responses came on January 9, 2014. See Direct Purchaser Class Pls.' Opp'n AstraZeneca Defs.' Mots. Summ. J. Direct Purchaser Pls.' & Associated Daubert Mot. Relating "Actual Injury" (ECF No. 648), ECF No. 735; Direct Purchaser Class Pls.' Opp'n AstraZeneca Defs.' Mot. Summ. J. Barring Non-Class Direct Purchasers' Assigned Claims (Dkt. 650), ECF No. 738; Retailer Pls.' Mem. Opp'n AstraZeneca's, Ranbaxy's, & Teva's Mot. Partial Summ. J. Pls.' Overall Conspiracy Claim, ECF No. 746; Retailer Pls.' Mem. Opp'n AstraZeneca & Ranbaxy's Mot. Summ. J., ECF No. 747; Retailer Pls.' Mem. Opp'n Teva's

Mot. Summ. J., ECF No. 748; Retailer Pls.' Mem. Opp'n Dr. Reddy's' Mot. Summ. J., ECF No. 749; Retailer Pls.' Mem. Opp'n AstraZeneca's Mot. Summ. J. Respect Teva & Dr. Reddy's Settlements, ECF No. 750; Opp'n Retailer Pls. AstraZeneca's Mot. Summ. J. Barring Assigned Claims, ECF No. 753; Opp'n Retailer Pls. AstraZeneca's Mot. Summ. J. Direct Purchaser Pls. Lack Actual Injury & Exclude Direct Purchaser Pls.' Expert Damages Opinions, ECF No. 761; Retailer Pls.' Mem. Opp'n Teva's Mot. Summ. J. Based Lack Causation, ECF No. 762; Retailer Pls.' Opp'n AstraZeneca Defs.' Mot. Summ. J. Statute Limitations, ECF No. 765; Direct Purchaser & End-Payor Class Pls.' Mem. Opp'n Teva Defs.' Mot. Summ. J. Based Absence Reverse Payment (ECF No. 600), ECF No. 770; Direct Purchaser & End-Payor Class Pls.' Opp'n AstraZeneca's Mot. Summ. J. All Claims Arising AstraZeneca's Settlements Teva & DRL (ECF No. 644), ECF No. 771; Direct Purchaser & End-Payor Class Pls.' Opp'n DRL's Mot. Summ. J. (ECF No. 594), ECF No. 772; Retailer Pls.' Mem. Opp'n Ranbaxy's Mot. Summ. J. Based Causation, ECF No. 773; Direct Purchaser & End-Payor Class Pls.' Opp'n AstraZeneca & Ranbaxy Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settelement Agreement Ranbaxy, ECF No. 779; Retailer Pls.' Mem. Opp'n AstraZeneca Defs.' Mot. Summ. J. Basis Causation, ECF No. 781; Direct Purchaser & End-Payor Class Pls.' Opp'n AstraZeneca, Ranbaxy & Teva Defs.' Mot. Partial Summ. J. Overarching

Conspiracy (ECF No. 647) & Portion DRL's Mot. Summ. J. (ECF No. 594), ECF No. 784; Direct Purchaser & End-Payor Class Pls.' Opp'n [606] Teva's Mot. Summ. J. Based Lack Causation, ECF No. 789; Direct Purchaser & End-Payor Class Pls.' Opp'n AstraZeneca's Mot. Summ. J. Causation, ECF No. 790; Direct Purchaser Class & End Payor Class Pls.' Opp'n Ranbaxy's Mot. Summ. J. Due Lack Causation, ECF No. 791.

On January 13, 2014, the Court denied AstraZeneca's ECF No. 648 motion seeking summary judgment against the Direct Purchasers and Retailer Plaintiffs for lack of actual injury and seeking exclusion of testimony from two experts. Elec. Order, Jan. 13, 2014, ECF No. 801. The Court also denied AstraZeneca's ECF No. 649 motion for partial summary judgment seeking to bar the Retailer Plaintiffs on the basis of statute of limitations. Elec. Order, Jan. 13, 2014, ECF No. 802.

Shortly thereafter, on January 16 and 17, 2014, the Defendants filed replies in further support of their surviving motions. See Teva Defs.' Reply Supp. Mot. Summ. J. [ECF No. 600] Based Absence Reverse Payment Teva, ECF No. 814; Teva Defs.' Reply Supp. Mot. [ECF No. 606] Summ. J. Based Lack Causation, ECF No. 815; Reply Supp. AstraZeneca, Ranbaxy, & Teva Defs.' Mot. Partial Summ. J. Overarching Conspiracy, ECF No. 816; Reply Mem. Supp. AstraZeneca Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlements Teva & DRL, ECF No.

817; AstraZeneca's Reply Mem. Further Supp. Mot. Summ. J. Barring Assigned Claims [Docket No. 650], ECF No. 818; Reply Mem. Supp. DRL's Mot. Summ. J., ECF No. 819; Reply Mem. Supp. AstraZeneca & Ranbaxy Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlement Agreement Ranbaxy, ECF No. 820; Reply Mem. Supp. AstraZeneca Defs.' Mot. Summ. J. Basis Causation, ECF No. 821; Def. Ranbaxy's Reply Supp. Mot. Summ. J. Due Lack Causation, ECF No. 823.

The Court heard oral argument on five of the Defendants' motions on January 21, 2014. Elec. Clerk's Notes, Jan. 21, 2014, ECF No. 846. The five motions argued were: (1) DRL's ECF No. 594 motion seeking summary judgment on all claims, (2) Teva's ECF No. 600 motion seeking summary judgment because of the purported absence of a reverse payment made to Teva, (3) Ranbaxy's ECF No. 641 motion seeking summary judgment due to a purported lack of causation, (4) AstraZeneca's ECF No. 642 motion seeking summary judgment on claims arising from its settlement with Ranbaxy, and (5) AstraZeneca, Ranbaxy, and Teva's ECF No. 647 motion seeking partial summary judgment on the issue of overall conspiracy. Id. At that hearing, the Court denied from the bench the final of these five motions, regarding the existence of an overall conspiracy, and took all remaining motions under advisement. Id.

On February 12, 2014, the Court issued an order laying out its rulings on all eleven motions for summary judgment. See Order, Feb. 12, 2014, ECF No. 857. In light of the aggregate effect of these rulings on the Plaintiffs' claims, the Court administratively closed this case until the publication of this written opinion explaining its reasoning. Id.

3. Motions for Reconsideration

The case was reopened, however, upon the filing of a number of motions for reconsideration on February 28, 2014. See Pls.' Mot. Rule 6(b)(1)(B) & (2) Reconsideration Teva's Mot. Summ. J. Based Absence Reverse Payment Teva (ECF No. 600) & AstraZeneca's Mot. Summ. J. All Claims Arising AstraZeneca's Settlements Teva & DRL (ECF No. 644); & Pls.' Opp'n Teva's Supplemental Br. Based New McGuire Report (ECF No. 855), ECF No. 864; Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation (ECF # 641, 645) Based New Evidence, ECF No. 867; Direct Purchaser Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation (ECF # 641, 645) Based Payment-Free Settlement, ECF No. 870; End-Payor Pls.' Joinder Direct Purchaser Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation, ECF No. 872.

The Court entered an order on March 7, 2014, denying all but two of the motions for reconsideration and scheduling oral

argument on (1) the Plaintiffs' ECF No. 864 motion to reconsider the Court's grant of summary judgment to Teva based on the absence of a reverse payment and the Court's grant of summary judgment to AstraZeneca on claims arising from its settlements with Teva and DRL, and (2) the Plaintiffs' ECF No. 867 motion to reconsider the Court's grant of summary judgment to AstraZeneca and Ranbaxy due to a lack of causation. Order, Mar. 7, 2014, ECF No. 874.

Oppositions to the two surviving motions for reconsideration followed on March 20, 2014. See Teva's Opp'n Pls.' Mot. Reconsideration Court's Grant Summ. J. Based Absence Reverse Payment Teva, ECF No. 877; AstraZeneca's Opp'n Pls.' Mot. Reconsideration AstraZeneca & Ranbaxy's Mots. Summ. J. Due Lack Causation (ECF # 641, 645) Based New Evidence, ECF No. 879; AstraZeneca's Opp'n Pls.' Mot. Reconsideration AstraZeneca & Ranbaxy's Mots. Summ. J. Due Lack Causation (ECF # 641, 645) Based New Evidence, ECF No. 881; Ranbaxy's Opp'n Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation Based New Evidence, ECF No. 882. The Plaintiffs filed reply briefs in further support of their motions for reconsideration on March 27, 2014. Pls.' Reply Ranbaxy's Opp'n Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation Based New Evidence, ECF No. 889; Pls.' Reply AstraZeneca's Opp'n Pls.' Mot. Reconsideration

AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation Based New Evidence, ECF No. 890.

On March 4, 2014, the Court heard oral argument on the two motions for reconsideration and took them under advisement. Elec. Clerk's Notes, Apr. 4, 2014, ECF No. 896. At an interim pretrial conference held on April 16, 2014, the Court announced its rulings (1) granting the Plaintiffs' ECF No. 864 motion for reconsideration of summary judgment regarding the absence of a reverse payment to Teva, (2) granting in part the Plaintiffs' ECF No. 864 motion for reconsideration of AstraZeneca's motion for summary judgment on claims arising from its settlements with Teva and DRL, with the Court's reconsideration being limited to AstraZeneca's settlement with Teva, and (3) denying the Plaintiffs' ECF No. 867 motion for reconsideration of summary judgment to AstraZeneca and Ranbaxy for lack of causation. See Elec. Clerk's Notes, Apr. 16, 2014, ECF No. 902; Elec. Endorsement, June 4, 2014, ECF No. 940. Accordingly, the case was reopened and set for trial in October 2014, with a final pretrial conference set to take place in September 2014. Elec. Clerk's Notes, Apr. 16, 2014; see also Case Reopened, Apr. 17, 2014, ECF No. 903.

A final flurry of activity relating to the issue of overarching conspiracy has occurred since the case reopened. On April 22, 2014, DRL filed a motion for reconsideration of the

Court's denial of summary judgment as to overarching conspiracy. DRL's Mot. Reconsideration, ECF No. 905. The Plaintiffs opposed on May 6, 2014. Pls. Mem. Opp'n DRL's Mot. Reconsideration (ECF 905), ECF No. 914. The Court denied DRL's motion on May 9, 2014. Elec. Order, May 9, 2014, ECF No. 916. The Defendants have most recently filed supplemental authority for their argument that the overarching conspiracy claims must fail: a recently published opinion by Judge Mitchell S. Goldberg of the Eastern District of Pennsylvania on issues similar to those before this Court. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., Civil Action Nos. 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2014 WL 2813312 (E.D. Pa. June 23, 2014); see also Defs.' Submission Supplemental Authority Relating Pls.' Overarching Conspiracy Claims, ECF No. 955. The Plaintiffs' response was filed on July 2, 2014. Direct Purchaser Class Pls.' Response Defs.' Submission Supp. Authority Relating Pls.' Overarching Conspiracy Claims, ECF No. 960.

B. Regulatory and Factual Background

In addition to having a complicated procedural history, this case implicates a large and complex body of facts. Although some of this background has been laid out in the Court's opinion dealing with the Defendants' prior motions to dismiss, see In re Nexium, 968 F. Supp. 2d at 376-78, further review of the regulatory and factual background is required

here. Where appropriate, additional facts pertinent to the Court's analysis will be set out within the relevant sections.

1. Regulatory Framework

When a pharmaceutical manufacturer seeks to introduce a new brand-name prescription drug to the U.S. market, it must file a New Drug Application with the United States Food and Drug Administration ("FDA") and undergo a long and expensive review process to gain agency approval. See Actavis, 133 S. Ct. at 2228; see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012). When a generic pharmaceutical manufacturer seeks to market a generic version of a brand-name drug, the approval process is considerably less burdensome. The Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, 21 U.S.C. § 355, "was passed with the express purpose of expediting the entry of noninfringing generic competitors into pharmaceutical drug markets in order to decrease healthcare costs for consumers." In re Nexium, 968 F. Supp. 2d at 378.

To launch a generic version of a brand-name drug, a pharmaceutical manufacturer is required to file an Abbreviated New Drug Application ("ANDA") showing that the proposed generic product is suitably equivalent to the targeted brand drug. See 21 U.S.C. § 355(j)(2)(A)(ii)-(iv). The Hatch-Waxman Act encourages generic competition by rewarding the manufacturer

that is first to file an ANDA for a brand drug. A first filer has the right, once final FDA approval is secured, to enter the generic market first and exclusively market its product for 180 days, during which time the FDA will not grant final approval to any other generic manufacturer's version of the drug. See 21 U.S.C. § 355(j)(5)(B)(iv). The potential rewards of being a first filer are considerable. See Ralph B. Kalfayan & Vic A. Merjanian, Ensuring Access to Affordable Medication: The Supreme Court's Opinion in F.T.C. v. Actavis, Inc., 22 Competition 120, 121 (2013) ("This 180-day exclusivity period provides a potentially powerful incentive to become the first manufacturer to file an ANDA -- by some estimates, millions and perhaps billions in profits.").

Any manufacturer seeking ANDA approval, however, must "assure the FDA that its proposed generic product will not infringe" any patents related to the targeted brand drug. Novo Nordisk, 132 S. Ct. at 1676. This ostensibly is straightforward if there are no patents related to the targeted brand drug, or if those patents have or will be expired. See 21 U.S.C. § 355(j)(2)(A)(vii)(I-III). But the Hatch-Waxman Act also sets out a process by which a manufacturer can obtain approval to market the generic version of a brand drug before the brand drug's underlying patents have expired. See id. § 355(j)(2)(A)(vii)(IV). To do so, a generic manufacturer's ANDA

must make so-called "Paragraph IV" certifications, which assert that all active patents related to the targeted brand drug are "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale" of the applicant's generic product. 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

Paragraph IV certifications usually provoke the patent-holding brand manufacturer to sue the generic ANDA filer for patent infringement. See Novo Nordisk, 132 S. Ct. at 1677 (noting that "[t]he patent statute treats [a Paragraph IV] filing as itself an act of infringement, which gives the brand [manufacturer] an immediate right to sue" (citing 35 U.S.C. § 271(e)(2)(A))). When such a lawsuit is timely filed, it triggers a 30-month stay of the generic manufacturer defendant's ANDA, during which time it cannot receive final FDA approval of its product. See 21 U.S.C. § 355(j)(5)(B)(iii).

At the end of the 30-month stay, however, the FDA may approve an ANDA even if final judgment or settlement has not been reached in the related patent lawsuit. Cf. id. If this happens, the generic manufacturer may choose to launch its generic product "at risk" -- that is, with the risk of losing the infringement case against it hanging over its head. Losing an infringement case after launching at risk can result in significant liability for the generic manufacturer, as damages typically are calibrated by the amount of its at-risk sales.

See 35 U.S.C. § 271(e)(4)(C) (providing that damages may be awarded "only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug"); 35 U.S.C. § 284 (providing for "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer"); see also, e.g., AstraZeneca AB v. Apotex Corp., 985 F. Supp. 2d 452 (S.D.N.Y. 2013) (awarding AstraZeneca more than $76,000,000 in damages for a generic manufacturer's at-risk sales of a product infringing AstraZeneca's patents).

Alternately, as is the case in all civil litigation, the brand manufacturer and generic manufacturer may settle their patent infringement case before final judgment or even final FDA approval is rendered. Such a settlement can have consequences for the entire generic market, particularly when the settling generic manufacturer is the first filer and agrees to delay its generic launch. Because no other manufacturer may launch a product until 180 days after the first filer has done so, a first filer's delay effectively delays all of its competitors' entries, creating a bottleneck in the market that postpones the date on which any generic product will become available.

To ameliorate the risk of bottleneck, the Hatch-Waxman Act contains provisions directed to triggering the start of a first

filer's 180-day exclusivity period, and to forfeiture of the privilege entirely. Generally, the exclusivity period is triggered "either on the date that the first . . . filer begins marketing its generic drug, or on the date of a final court decision finding the relevant . . . patents invalid or not infringed, whichever comes first." Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1283 (Fed. Cir. 2008) (citing 21 U.S.C. § 355(j)(5)(B)(iv)). In 2003, however, Congress enacted the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066, which amended the Hatch-Waxman Act to create several ways for a first filer to forfeit its marketing exclusivity period. See 21 U.S.C. § 355(j)(5)(D); see also Forest Labs., 527 F.3d at 1283 n.2.

Under the post-MMA regime, the first filers of ANDAs submitted after December 2003 lose their exclusivity privilege if they do not timely come to market after the occurrence of certain forfeiture events. Forest Labs., 527 F.3d at 1283 n.2. One is particularly relevant to the facts of this case. The exclusivity privilege can be forfeited if the first filer does not come to market within 75 days of a final, nonappealable court judgment ruling that the first filer's product does not infringe any of the targeted brand drug's patents. Id. § 355(j)(5)(D)(i)(I)(bb). Moreover, "a 'court decision' for

purposes of triggering the exclusivity period . . . is not limited to actions involving the first ANDA filer." Minnesota Mining & Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775, 785 (Fed. Cir. 2002) (concurring with FDA policy and Teva Pharm. v. Food & Drug Admin., 182 F.3d 1003, 1009 (D.C. Cir. 1999)). It is not uncommon for generic manufacturers who submitted ANDAs after the first filer to seek declaratory judgment that the specific patents challenged in the lawsuit against the first filer are invalid or not infringed by the first filer's product. See generally id. at 789-92. For the second (or third or subsequent) filer, winning a declaratory judgment as to the first filer means triggering or causing the forfeiture of the first filer's exclusivity period, moving up the date on which subsequent filers can in turn enter the market. This is one way subsequent filers can break a bottleneck formed by a first filer's agreement to delay its market entry.

2. Undisputed Factual Background

Nexium is the brand name of a proton pump inhibitor which contains esomeprazole magnesium as its active ingredient and which is prescribed to treat heartburn.[2] In re Nexium, 968 F. Supp. 2d at 375, 380. In 2001, the FDA approved a New Drug Application granting exclusive rights to market branded Nexium

[2] Although Nexium is referred to in its generic form as esomeprazole or esomeprazole magnesium, this opinion will typically refer to the generic product as generic Nexium.

to the pharmaceutical manufacturer AstraZeneca, then the holder of fourteen active patents related to the drug. Id. at 380. Four years later, the generic drug manufacturer Ranbaxy was the first to file an ANDA, containing Paragraph IV certifications, to market a generic version of Nexium. Id. AstraZeneca responded to this development by filing a patent infringement lawsuit against Ranbaxy in the District of New Jersey, contending that Ranbaxy's version of generic Nexium would infringe several of AstraZeneca's patents. Id. In the following months, generic manufacturers Teva and DRL each filed Paragraph IV ANDAs seeking to market generic Nexium, and AstraZeneca responded again by suing each of them for patent infringement in the United States District Court for the District of New Jersey. Id. at 381. All three cases were drawn to Judge Joel A. Pisano. DRL's Statement Undisputed Facts Regarding Mot. Summ. J. ¶¶ 70-71, ECF No. 673.

Before judgment entered in any of these cases, AstraZeneca entered into settlement agreements with each generic manufacturer which ended all three lawsuits and suspended the entry of generic Nexium into the market. First, on April 14, 2008, AstraZeneca agreed to drop its lawsuit against Ranbaxy in exchange for Ranbaxy's agreement (1) to admit that certain of AstraZeneca's Nexium-related patents were enforceable and valid, (2) to admit that Ranbaxy's generic Nexium would infringe these

patents, and (3) to delay launching a generic version of Nexium until May 27, 2014. Id. at 381-82; see Decl. James H. Weingarten, Esq. Supp. Mots. Summ. J. ("Weingarten Decl."), Settlement Agreement ("Ranbaxy Agreement") 1, ECF No. 676-1. Ranbaxy allegedly also received consideration for the agreement in the form of lucrative manufacturing and distribution agreements and prospective future revenue under an exclusive marketing privilege. In re Nexium, 968 F. Supp. 2d at 382.

Ranbaxy's agreement created a bottleneck in the generic Nexium market until May 27, 2014. Id. Teva and DRL each attempted to break that bottleneck by filing declaratory judgment actions seeking a ruling that Ranbaxy's generic product did not infringe any Nexium patents, but ultimately both Teva and DRL settled their lawsuits with AstraZeneca as well. Id. at 382-83. On January 7, 2010, Teva agreed to make similar admissions as Ranbaxy had regarding AstraZeneca's patents and to delay its entry into the generic Nexium market until May 27, 2014. Id. at 383; see Weingarten Decl., Settlement Agreement ("Teva Agreement") 1, ECF No. 676-2. In exchange, AstraZeneca agreed to drop its lawsuit. In re Nexium, 968 F. Supp. 2d at 383. On the same day, AstraZeneca also agreed to settle a contingent liability owed by Teva to AstraZeneca in connection with Teva's prior at-risk sales of a generic drug infringing on AstraZeneca's brand drug, Prilosec. Id. The following year, on

January 28, 2011, AstraZeneca concluded a similar agreement with DRL, under the terms of which DRL agreed to refrain from challenging AstraZeneca's Nexium patents and to defer entering the generic Nexium market until May 27, 2014. Id. at 384; see Weingarten Decl., Settlement Agreement ("DRL Agreement") 1, ECF No. 676-3. In exchange, AstraZeneca dropped its litigation and on the same day, agreed to drop its appeal of a lawsuit arising from DRL's sales of a generic version of another AstraZeneca drug, Accolate. In re Nexium, 968 F. Supp. 2d at 384.

II. STANDARD OF REVIEW

All of the motions before the Court in this opinion are ones for summary judgment, and the same familiar standard controls them all. Summary judgment is proper when, based on the materials in the record, "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). An issue of material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1985). Whether a fact is material or not depends on the substantive law of the case, and only factual disputes that might affect the outcome of the suit can properly preclude summary judgment. Id. When deciding a motion for summary judgment, the Court views the record "in

the light most favorable to the non-moving party" and draws all reasonable inferences in favor of the respondent. Pineda v. Toomey, 533 F.3d 50, 53 (1st Cir. 2008).

Save as to facts admitted by both parties, the Court must disregard all evidence upon which the moving party bears the burden of proof. Reeves v. Sanderson Plumbing Products, Inc., 530 U.S. 133, 151 (2000). Moreover, the moving party bears the initial burden of production, and then the nonmoving party who bears the ultimate burden of proof must provide some evidence in favor of its case. That evidence must be admissible at trial, and "[p]roof based on arrant speculation, optimistic surmise or farfetched inference will not suffice." Kelley v. United States, 924 F.2d 355, 357 (1st Cir. 1991). Nor can the evidence be "merely colorable." Anderson, 477 U.S. at 249-50.

Finally, though the Court properly may consider expert testimony at the summary judgment stage, "expert testimony without . . . a factual foundation cannot defeat a motion for summary judgment." Virgin Atl. Airways Ltd. v. British Airways PLC, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999) (quoting Advo, Inc. v. Phila. Newspapers, Inc., 51 F.3d 1191, 1198 (3d Cir. 1995) (alteration in original)); see also Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242 (1993) (holding that an expert opinion cannot support a jury verdict when it "is not supported by sufficient facts to validate it in the eyes of the

law, or where indisputable record facts contradict or otherwise render the opinion unreasonable"). Similarly, summary judgment must be granted if the opposition thereto "rest[s] solely on an expert's 'bottom line' conclusion, without some underlying facts and reasons, or a logical inference process to support the expert's opinion." Sullivan v. Nat'l Football League, 34 F.3d 1091, 1105 (1st Cir. 1994).

III. MOTIONS FOR SUMMARY JUDGMENT AS TO OVERARCHING CONSPIRACY [ECF Nos. 594, 647, 905]

The Court begins its analysis by focusing on the issue which most broadly affects all of the Defendants. The Defendants sought partial summary judgment last December on the issue of whether an overarching antitrust conspiracy exists among them. See DRL's Mot. Summ. J. All Claims, ECF No. 594; AstraZeneca, Ranbaxy, & Teva Defs.' Mot. Partial Summ. J. Overarching Conspiracy, ECF No. 647. According to the Plaintiffs, the three bilateral settlement agreements made between AstraZeneca and each of the Generic Defendants not only constitute separate illegal reverse payment agreements, but they also effect a single overarching conspiracy illegally to restrain trade in the market for generic Nexium. This would mean that the antitrust liability of just one Defendant is attributable to all of its co-Defendants as co-conspirators. If

no such conspiracy can be reasonably inferred from the evidence, however, the Defendants are no longer yoked together by the Plaintiffs' claims, leaving them more flexibility to litigate the antitrust issues in this case on facts specific to each individual Defendant. For the reasons set out below, the Court ruled that the Plaintiffs have met their burden of establishing a reasonable inference of overarching conspiracy. Order, Feb. 12, 2014, ¶ 3, ECF No. 857.

A. Undisputed Facts Germane to These Motions

As has been reviewed, AstraZeneca was the plaintiff in three Nexium-related patent infringement lawsuits against Ranbaxy, Teva, and DRL. See AstraZeneca, Ranbaxy, & Teva Defs.' Statement Undisputed Facts Relating Mot. Partial Summ. J. Overarching Conspiracy ("Defs.' Conspiracy SOF") ¶¶ 1, 2, 9, ECF No. 687; DRL's Statement Undisputed Facts Regarding Motion Summ. J. ("DRL's Conspiracy SOF") ¶ 52, ECF No. 673. AstraZeneca ultimately settled all three lawsuits over the course of three years: Ranbaxy settled on April 14, 2008, Defs.' Conspiracy SOF ¶ 6, Teva settled on January 6, 2010, id. ¶ 22, and DRL settled on January 18, 2011, id. ¶ 26. See Ranbaxy Agreement 1; Teva Agreement 1; DRL Agreement 1.

Several elements were common to all three agreements. Each Generic Defendant, for example, acknowledged the validity of and agreed to refrain from challenging AstraZeneca's patents related

to Nexium. See Ranbaxy Agreement ¶¶ 4.1-4.2; Teva Agreement ¶¶ 4.1-4.2; DRL Agreement ¶¶ 4.1-4.2. Each Generic Defendant also agreed to delay launching generic Nexium in the United States until a certain agreed-upon entry date. See Ranbaxy Agreement ¶ 6.1; Teva Agreement ¶ 6.1; DRL Agreement ¶ 6.1. Each agreement defined that entry date in nearly identical contingent terms, as

> the earliest of: (a) May 27, 2014; (b) the date on which a Third Party launches a Generic Esomeprazole product in the United States following a final court decision from which no appeal has been or can be taken holding that all claims of the AstraZeneca Patents asserted in that litigation are invalid, unenforceable, or not infringed by the Generic Esomeprazole product at issue in that litigation; or (c) the date prior to May 27, 2014 on which any Third Party is authorized, under a license granted by AstraZeneca . . . to commence manufacturing, using, selling, offering to sell, importing or distributing Generic Esomeprazole in and for the United States pursuant to an ANDA or application pursuant to 21 U.S.C. § 355(b)(2).

Ranbaxy Agreement ¶ 5.2; see also Teva Agreement ¶ 5.2 (containing substantially similar language); DRL Agreement ¶ 5.2 (containing substantially similar language). The effect of this contingent launch provision was to commit each signing Generic Defendant to refrain from launching generic Nexium until May 27, 2014, unless another generic manufacturer found a way to legally enter the market on an earlier date.

Although the terms of these agreements were all publicized shortly after their signing, there is no evidence that any of the Generic Defendants communicated with each other, directly or

indirectly, when brokering their own agreements with AstraZeneca.

B. Legal Standard: Antitrust Conspiracy

To prevail on a conspiracy claim under Section 1 of the Sherman Act, 15 U.S.C. § 1, the Plaintiffs must prove the existence of a single agreement, tacit or express, in restraint of trade. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 553 (2007); White v. R.M. Packer Co., Inc., 635 F.3d 571, 575 (1st Cir. 2011). Independent decisions by individual firms, even if they constitute parallel business behavior and "lead to the same anticompetitive result as an actual agreement among market actors," are not prohibited by the federal antitrust laws. White, 635 F.3d at 575; see also Twombly, 550 U.S. at 553.

To that end, the Supreme Court has ruled that the phenomenon of conscious parallelism is not per se illegal. See Brooke Grp., Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 227 (1993). Conscious parallelism occurs when "firms in a concentrated market might in effect share monopoly power, setting their prices at a profit-maximizing, supracompetitive level by recognizing their shared interests and their interdependence with respect to price and output decisions." Id. "Each producer may independently decide that it can maximize its profits by matching one or more other producers' price, on the hope that the market will be able to maintain high

prices if the producers do not undercut one another." White, 635 F.3d at 576.

Gas stations in a geographically isolated region, for example, are likely to engage in parallel supracompetitive pricing behavior because each gas station understands that matching the highest price in the region encourages prices to stay uniformly high without hurting demand, and that all local competitors are likely to independently reach the same conclusion. See id. at 581-82 (ruling that evidence of such parallel pricing among gas stations on Martha's Vineyard did not support any inference beyond conscious parallelism). "One does not need an agreement to bring about this kind of follow-the-leader effect in a concentrated industry." Clamp-All Corp. v. Cast Iron Soil Pipe Inst., 851 F.2d 478, 484 (1st Cir. 1988) (citing 6 P. Areeda & D. Turner, Antitrust Law ¶¶ 1432-33 (1978)). In contrast, a tacit agreement to conspire may be characterized by "uniform behavior among competitors, preceded by conversations implying that later uniformity might prove desirable or accompanied by other conduct that in context suggests that each competitor failed to make an independent decision." White, 635 F.3d at 576 (quoting Brown v. Pro Football, Inc., 518 U.S. 231, 241 (1996)).

At the summary judgment stage, antitrust law "limit[s] the range of permissible inferences from ambiguous evidence in a

[Section 1 conspiracy] case," id. at 577, because the risk of mistaking independent, parallel decisionmaking for a conspiracy could "chill the very conduct the antitrust laws are designed to protect," Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 594 (1986). Accordingly, "conduct as consistent with permissible competition as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy." Id. (quoting Monsanto Co. v. Spray-Rite Service Corp., 465 U.S. 752, 764 (1984) (internal quotation marks omitted)).

Here, the Plaintiffs "must show that the inference of conspiracy is reasonable in light of the competing inferences of independent action or collusive action." Id. This requires "direct or circumstantial evidence that is not only consistent with conspiracy, but 'tends to exclude the possibility of independent action.'" White, 635 F.3d at 577 (quoting Monsanto Co., 465 U.S. at 764). Circumstantial evidence meeting this standard may demonstrate, for example, "parallel behavior that would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties." Twombly, 550 U.S. at 556 n.4 (quoting 6 Areeda & Hovenkamp, Antitrust Law ¶ 1425, at 167 (2d ed. 2003)). Pieces of evidence pointing toward conspiracy are sometimes called "plus factors." See White, 635

F.3d at 577 (citing Twombly, 550 U.S. at 556 & n.4; In re Flat Glass Antitrust Litig., 385 F.3d 350, 360 (3d Cir. 2004)).

C. The Parties' Arguments

According to the Defendants, the Plaintiffs have failed to meet their evidentiary burden under this standard. First, the Defendants argue, the discovery process has yielded no direct evidence of discussions among AstraZeneca and the Generic Defendants suggesting a single agreement or conspiracy. Mem. Supp. AstraZeneca, Ranbaxy, & Teva Defs.' Mot. Partial Summ. J. Overarching Conspiracy ("Defs.' Conspiracy Mem.") 6-7, ECF No. 654; see also Mem. Supp. DRL's Mot. Summ. J. ("DRL Mem.") 18-19, ECF No. 633; Reply Supp. AstraZeneca, Ranbaxy, & Teva Defs.' Mot. Partial Summ. J. Overarching Conspiracy ("Defs.' Conspiracy Reply Mem.") 3, ECF No. 816; Reply Mem. Supp. DRL's Mot. Summ. J. ("DRL Reply Mem.") 12-17, ECF No. 819. Second, regarding potential circumstantial evidence, the Defendants point out that "[t]he existence of discrete, bilateral agreements between companies does not support an inference of an overarching agreement." Defs.' Conspiracy Mem. 8. They emphasize that their agreements, which were concluded "many months apart from one another and at different stages of the individual lawsuits," id., were negotiated at arms' length and based on the interests of the parties involved in each settlement, not on a common goal shared by the Defendants, id. at 9. They deny that

"similarities" among the three agreements, or the fact that AstraZeneca was a party to all three settlements, make out a reasonable inference of interdependence. Id.

The Plaintiffs, for their part, read the record quite differently. The Plaintiffs argue that at least three sets of undisputed facts constitute either direct or sufficient circumstantial evidence of a conspiracy: (1) the May 27, 2014 market entry date and "virtually identical" contingent launch clauses common to all three agreements, (2) the provisions authorizing disclosure of settlement terms to the Generic Defendants still in the midst of their own settlement negotiations, and (3) the Generic Defendants' knowledge that delayed generic entry was anticompetitive. See Direct Purchaser & End-Payor Class Pls.' Opp'n AstraZeneca, Ranbaxy & Teva Defs.' Mot. Partial Summ. J. Overarching Conspiracy (ECF No. 647) & Portion DRL's Mot. Summ. J. (ECF No. 594) ("Class Pls.' Conspiracy Opp'n") 3-4, 11, ECF No. 784; see also Retailer Pls.' Mem. Opp'n AstraZeneca's, Ranbaxy's, & Teva's Mot. Partial Summ. J. Pls.' Overall Conspiracy Claim ("Retailer Pls.' Conspiracy Opp'n") 8, 10-11, ECF No. 746 (similarly relying on the above facts).[3]

[3] The Retailer Plaintiffs also refer in their brief to evidence of a July 2007 settlement conference convened by Judge Pisano and "attended by three of the four conspirators (AstraZeneca, Ranbaxy and Teva)." Retailer Pls.' Conspiracy

D. Direct Evidence

To start, the Court will not construe the facts offered by the Plaintiffs as direct evidence of a conspiracy. These pieces of evidence are not analogous to the types of express threats or communications that other courts have treated as direct evidence. See, e.g., Monsanto, 465 U.S. at 765 (regarding a supplier's advice to distributors that they would be terminated if they did not maintain suggested price levels); Mayor & City Council of Baltimore v. Citigroup, Inc., 709 F.3d 129, 136 (2d Cir. 2013) ("[Direct] evidence would consist, for example, of a recorded phone call in which two competitors agreed to fix prices at a certain level."); InterVest, Inc. v. Bloomberg, L.P., 340 F.3d 144, 163 (3d Cir. 2003) (listing examples of direct evidence, including "a direct threat to the plaintiff from a competitor that if he went into business his competitors would do anything they could to stop him," "a memorandum . . . detailing the discussions from a meeting of a group of alleged conspirators," and "a public resolution by a professional association recommending that its members withdraw their affiliation with an insurer" (quoting Intervest Fin. Servs. v.

Opp'n 7. No party has offered substantive evidence, however, that the Defendants used the conference to coordinate with each other. The Court gives no weight to the Retailer Plaintiffs' mention of the conference, because without more, the Defendants' compulsory attendance at a court-ordered conference ought not be construed even as weak evidence of concerted action.

S.G. Cowen Sec. Corp., 206 F. Supp. 2d 702, 713 (E.D. Pa. 2002)).

The Court's conclusions are informed by the Third Circuit's persuasive reasoning that "[d]irect evidence in [an antitrust] conspiracy must be evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted." In re Baby Food Antitrust Litig., 166 F.3d 112, 118 (3d Cir. 1999). By this logic, the evidence offered by the Plaintiffs is not direct evidence, because it does not establish, on its own, concerted action among the Defendants. Evidence of close similarities among the Defendants' three settlements, of the Defendants' opportunities to conform their settlements to the others, and of the Defendants' motives to cooperate still requires the Court to infer that illegal coordination occurred.

E. Circumstantial Evidence

The Plaintiffs' evidence, particularly the settlement agreements themselves, fares much better when evaluated as circumstantial evidence of a conspiracy.

1. Interstate Circuit and Toys "R" Us

While the Defendants are correct to state that "discrete, bilateral agreements" are not necessarily evidence of an overarching conspiracy, Defs.' Conspiracy Mem. 8, courts do treat separate bilateral agreements as evidence of a single

conspiracy when the agreements are sufficiently interdependent and made in the context of other plus factors suggesting coordination.

In Interstate Circuit, Inc. v. United States, 306 U.S. 208 (1939), the Supreme Court considered whether a set of eight bilateral agreements between a movie exhibitor and eight movie distribution companies could constitute an illegal conspiracy. The manager of the exhibitor, Interstate, had sent a letter to all the distributors, "each letter naming all of them as addressees, in which he asked compliance with two demands as a condition of Interstate's continued exhibition of the distributors' films." Id. at 215-16. All the distributors agreed to the demands. Id. at 218-19. The Supreme Court inferred not only that the exhibitor and distributors had engaged in an unlawful conspiracy, but also that no evidence of agreement among the distributors was required to sustain such an inference:

> It was enough that, knowing that concerted action was contemplated and invited, the distributors gave their adherence to the scheme and participated in it. Each distributor was advised that the others were asked to participate; each knew that cooperation was essential to successful operation of the plan. They knew that the plan, if carried out, would result in a restraint of commerce . . . .

Id. at 226.

A more recent case affirming the Interstate Circuit

approach to conspiracy hews even closer to the facts before this Court. In Toys "R" Us, Inc. v. Fed. Trade Comm'n, 221 F.3d 928 (7th Cir. 2000), the toy retailer Toys "R" Us executed a series of agreements with individual toy manufacturers, "in each of which the manufacturer promised to restrict the distribution of its products to lowpriced warehouse club stores, on the condition that other manufacturers would do the same." Id. at 930 (emphasis added). The Seventh Circuit, reviewing a decision of the Federal Trade Commission ("F.T.C.") under a relatively deferential substantial evidence standard, affirmed the F.T.C.'s ruling that Toys "R" Us had brokered "a network of vertical agreements," id., constituting a horizontal agreement. Id. at 935-36.

In both of these cases, interdependence was not the sole basis for an inference of conspiracy; the presiding courts also relied on the presence of plus factors suggesting that the parties were tacitly cooperating. In Interstate Circuit, the distributors knew that while lone action created "risk of a substantial loss of . . . business and good will," collective action offered "the prospect of increased profits," creating "strong motive for concerted action." 306 U.S. at 222. Further, their compliance with Interstate's demands "involved a radical departure from the previous business practices of the industry." Id. The Seventh Circuit observed these

characteristics in Toys "R" Us as well, citing evidence that Toys "R" Us's demands were against the toy manufacturers' interests and that each manufacturer resisted committing to an agreement unless all its competitors did so. See Toys "R" Us, 221 F.3d at 936.

It does not escape the Court's notice that these cases involve a series of vertical agreements between parties at different points in the distribution chain, whereas the instant case presents a series of horizontal agreements between direct competitors. This distinction does not convince the Court that the cases are inapposite, however. The Supreme Court has affirmed that the logic of Interstate Circuit can apply to a conspiracy made up only of horizontal competitors. See United States v. Masonite Corp., 316 U.S. 265, 274-76 (1942) (quoting Interstate Circuit, 306 U.S. at 226) (holding that a series of independent bilateral contracts made between a hardboard manufacturer/distributor and its competitors comprised an illegal price-fixing competition).

Moreover, the vertical nature of the Interstate Circuit and Toys "R" Us agreements had little bearing on the substantive reasoning of either decision. If anything, those decisions required only that the parties acquiescing to the proposed arrangement -- the movie distributors and toy manufacturers -- be direct competitors in a horizontal relationship with each

other. See Interstate Circuit, 306 U.S. at 227 (referring to "[a]cceptance by competitors . . . of an invitation to participate in a plan"); Toys "R" Us, 221 F.3d at 936 ("[Toys "R" Us] accomplished [its] goal by inducing the suppliers to collude, rather than to compete independently . . . ."). This element is satisfied in the instant litigation, as all the Generic Defendants accepting AstraZeneca's settlement were direct competitors.

2. Interdependence

Like the agreements at issue in Interstate Circuit and Toys "R" Us, AstraZeneca's agreements with the Generic Defendants demonstrate a degree of interdependence suggesting a single agreement, even if no such agreement was expressly made between the Generic Defendants.

The core concession that AstraZeneca extracted from each Generic Defendant in this part of each settlement was an agreement not to enter the market until May 27, 2014. Especially in light of the significant consideration being offered by AstraZeneca through various side agreements, as well as AstraZeneca's interest in negotiating the same entry date for all Generic Defendants, it is not difficult to understand their agreements to delay entry as being driven by separate business decisions that happened to coincide because of "independent responses to common stimuli." Twombly, 550 U.S. at 556 n.4.

These concessions are, alone, as consistent with conspiracy as they are with independent action.

But when the concessions are contingent on the actions of others, they are not so clearly discrete. Each Generic Defendant may have made an independent decision to sign its agreement with AstraZeneca, but it did not enter into an arrangement independent of its generic competitors. Each agreed to delay its market entry on the express condition that every other Generic Defendant do the same. See, e.g., Ranbaxy Agreement § 5.2.

The Defendants attempt to frame this conditional agreement as evidence that no conspiracy existed, since the participants in a bona fide conspiracy to delay market entry would have no need for contingency provisions protecting each participant from the actions of its co-conspirators. See Defs.' Conspiracy Reply 5. This argument seems to assume that the Plaintiffs imagine the existence of a secret, back room deal to delay market entry, which was then memorialized in three separate settlement agreements. While the Defendants are correct that such an arrangement cannot be reasonably inferred from the evidence, this is not the inference the Plaintiffs ask the Court to draw. Rather, the Court infers -- as commanded by Fed. R. Civ. P. 56 -- that the contingent launch clauses themselves were the mechanism of a single agreement, the means by which individual

market delay concessions knit together into a network of related agreements.

The interdependence of these provisions is self-evident. Without contingent launch provisions, each Generic Defendant's agreement to delay entry until May 27, 2014 is a genuinely independent concession, setting a date that holds firm regardless of the actions of competitors. With contingent launch provisions, each Generic Defendant's May 2014 commitment only holds firm if in concert with its competitors. There is no independence in agreeing to terms that depend on the actions of third parties in order to operate.

The Court is not dissuaded by evidence that each agreement was independently negotiated and apparently settled without consultation between any other Generic Defendant. The Defendants rely on these facts to argue that the three settlements cannot be considered a single overarching agreement. See, e.g., Defs.' Conspiracy Mem. 8-10. In fact, no evidence of such communication among the Generic Defendants is necessary to form a Sherman Act conspiracy, nor is it even necessary for the agreements to have occurred close in time:

> It is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators. Acceptance by competitors, without previous agreement, of an invitation to participate in a plan [restraining interstate commerce] is sufficient to establish an unlawful conspiracy under the Sherman Act.

Interstate Circuit, 306 U.S. at 227 (internal citations omitted); see also Masonite, 316 U.S. at 275 (holding a combination among Masonite and its fellow appellees to be illegal even though "each appellee, other than Masonite, acted independently of the others, negotiated only with Masonite, desired the agreement regardless of the action that might be taken by any of the others, did not require as a condition of its acceptance that Masonite make such an agreement with any of the others, and had no discussions with any of the others").[4]

DRL makes a similar argument, arguing that the lack of agreement among the Generic Defendants is fatal to the Plaintiffs' conspiracy claims because the Plaintiffs have alleged a "rimless wheel" conspiracy, in which AstraZeneca is the hub and the Generic Defendants are the spokes of a wheel. See DRL Mem. 18; see, e.g., Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield, 552 F.3d 430, 435 n.3 (6th

[4] In a case very similar to this one, discussed infra, Judge Goldberg of the Eastern District of Pennsylvania has ruled this language mere dicta and thus inapposite, because the Masonite conspiracy was proven by direct evidence. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., Civil Action Nos. 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2014 WL 2813312, at *13 (E.D. Pa. June 23, 2014). The Court sees no reason so to downplay this reasoning. The Supreme Court's language quoted here simply establishes that an illegal conspiracy can exist under the described conditions. Whether the Masonite Court also observed the presence of direct evidence of conspiracy does not affect the controlling nature of the principle it endorsed in this part of its opinion.

Cir. 2008). Courts in the First Circuit do not appear commonly to employ this mode of analysis in antitrust cases, but persuasive authority from other circuits holds that in order to establish such a conspiracy, the "wheel" of the alleged conspiracy must have a rim -- in other words, evidence of agreement or connection between the spokes. See, e.g., In re Insurance Brokerage Antitrust Litig., 618 F.3d 300, 327 (3d Cir. 2010); Total Benefits, 552 F.3d at 435-36; Dickson v. Microsoft Corp., 309 F.3d 193, 203 (4th Cir. 2002); Impro Products, Inc. v. Herrick, 715 F.2d 1267, 1279-80 (8th Cir. 1983).

To the extent it is necessary to do so, the Court is able reasonably to infer such connections between Generic Defendants in this case. At least one court has expressly distinguished both Interstate Circuit and Toys "R" Us from rimless wheel conspiracies on grounds that are equally applicable to the Nexium agreements. In In re Insurance Brokerage Antitrust Litigation, 618 F.3d at 300, the Third Circuit reasoned that there was a rim connecting the spokes in the Interstate Circuit and Toys "R" Us arrangements because "[i]n both cases, the evidence clearly indicated that the defendants would not have undertaken their common action without reasonable assurances that all would act in concert." Id. at 332; see also Total Benefits Planning Agency, 552 F.3d at 435-36 (asserting that the "wheel" in the Toys "R" Us arrangement had a rim). In the

instant case, such assurances that market delay would not unduly disadvantage any one Generic Defendant were memorialized in the form of contingent launch clauses. For the purposes of the hub-and-spoke analogy, keeping in mind the presumptions required at the summary judgment stage, the Court treats the intrinsic interdependence of the contingent launch clauses as sufficient evidence of connection between the Generic Defendant "spokes."

3. Plus Factors Pointing to Conspiracy

Moreover, the types of plus factors that supported the rulings in Interstate Circuit and Toys "R" Us are present here. The protracted litigation between each Generic Defendant and AstraZeneca leading up to each settlement demonstrates that the Generic Defendants wanted to come to market years before May 2014. There is evidence that agreeing to delay market entry is contrary to a generic competitor's interests, because of the potentially lucrative market for generic Nexium and the risk that by the time the generic competitor enters, the brand manufacturer will have transferred its monopoly power to a slightly reformulated product, shrinking the market for generic Nexium. See Retailer Pls.' Conspiracy Opp'n 11; see also AstraZeneca AB v. Apotex Corp., 985 F. Supp. 2d 452, 465-467 (discussing AstraZeneca's efforts to transfer its lucrative sales of Prilosec, a branded proton pump inhibitor medication for heartburn, to Nexium, a distinct and newer branded proton

pump inhibitor medication for heartburn, just before the expiration of the Prilosec patents). The record -- and common sense -- also shows that each Generic Defendant would be reluctant to agree to delay its entry unless AstraZeneca could secure the same guarantee of delay from all its generic competitors, lest a competitor capture the generic market before May 27, 2014. See Class Pls.' Conspiracy Opp'n 11-12. The Defendants possessed strong motives to coordinate the actions they took. In conjunction with the interdependence of the agreements themselves, these factors are consistent with the existence of a single agreement, tend to exclude the possibility of independent action, and adequately support a reasonable inference of conspiracy.

F. The In re Modafinil Litigation

Since the Court's denial of this motion in January, another court has considered these same issues and reached a different conclusion. In the consolidated litigation currently before Judge Mitchell S. Goldberg in the Eastern District of Pennsylvania, putative classes of direct purchasers, end-payors, and individual direct pharmaceutical retailers are among the plaintiffs suing a brand drug manufacturer and several generic manufacturers (including Ranbaxy and Teva), for alleged conspiracy to restrain trade in the market for a generic drug. King Drug Co. of Florence, Inc. v. Cephalon, Inc. ("In re

Modafinil Litig."), Civil Action Nos. 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2014 WL 2813312, at *1-2 (E.D. Pa. June 23, 2014). At the heart of the case are four reverse payment agreements, made between a brand manufacturer and four generic manufacturers, that settled the brand manufacturer's pending patent infringement lawsuits relating to the brand drug Provigil. Id. at *1-3. Each generic manufacturer agreed to delay its entry into the generic Provigil market until an identical future date, unless a third party legally entered the market first. Id. at *4. As is evident and as all parties here agree, the case presents overarching conspiracy questions indistinguishable from those before this Court. See Defs.' Submission Supp. Authority Relating Pls.' Overarching Conspiracy Claims ("Defs.' Modafinil Mem.") 1, ECF No. 955; Direct Purchaser Class Pls.' Resp. Defs.' Submission Supp. Authority Relating Pls.' Overarching Conspiracy Claims ("Direct Purchasers' Modafinil Mem.") 1, ECF No. 960.

In In re Modafinil, the court ruled that the defendant pharmaceutical companies' agreements did not constitute evidence of an illegal conspiracy and granted the defendants' motion for summary judgment. 2014 WL 2813312, at *14. Key to Judge Goldberg's reasoning was the conclusion that cases like Toys "R" Us" and United States v. Apple, Inc., 952 F. Supp. 2d 638 (S.D.N.Y. 2013) (holding that individual agreements between book

publishers and Apple, Inc. to raise the retail price of e-books constituted an illegal antitrust conspiracy), are distinguishable from the Modafinil agreement. He reasoned that unlike the toy manufacturers in Toys "R" Us and the book publishers in Apple (and, indeed, the movie distributors in Interstate Circuit), the Modafinil generic defendants entered into agreements that were in their economic interest regardless of what their competitors did. See In re Modafinil Litig., 2014 WL 2813312, at *11-12. The court commented that "the [Modafinil] settlements seemed to offer the best of both worlds: an end to costly litigation, combined with lucrative business deals and an assurance that each Generic Defendant would not be disadvantaged regarding the entry of generic Provigil." Id. at *12. Thus, with "no evidence that the bilateral settlements contravened the Generic Defendants' self-interest, and significant evidence that the settlements were in line with their economic self-interests, . . . a fact-finder cannot draw an inference of conspiracy." Id. at *13. The Defendants in the instant case have urged this Court to adopt identical reasoning. See Defs.' Conspiracy Reply 13-14 (discussing Toys "R" Us); Defs.' Modafinil Mem. 3-4.

Although Judge Goldberg's analysis is thorough and thoughtful, this Court respectfully disagrees with his understanding of the nature of these settlements. The issue is

not whether it was economically rational for the Generic Defendants to include contingent launch clauses in their agreements -- it is obvious that such clauses are beneficial, because they prevent a settling generic manufacturer from being locked out of the market while its competitors take over. Rather, the issue is whether it was rational for each generic manufacturer to agree to delay entering the generic market until May 27, 2014. Delayed entry, not contingent launch, is the substance of this part of each settlement agreement, and the actual concession for which AstraZeneca allegedly paid valuable consideration.

It is conceivable that AstraZeneca's consideration could have been so valuable that it was financially attractive for a generic manufacturer to forego the generic market for a multi-year period without protection from the actions of its competitors. If that were the case, it would be straightforward to conclude that each Generic Defendant made a purely independent decision in its own self-interest. But that does not appear to have been the case here. The Defendants themselves have conceded that the Generic Defendants "needed" protection from the actions of their competitors to justify agreeing to delayed entry. Mot. Hr'g Tr. 41:18, Jan. 21, 2014, ECF No. 833. This is sufficient, for the purposes of summary judgment, to give rise to a reasonable inference that delayed

entry on its own was not an economically beneficial proposition for any of the Generic Defendants. The unattractiveness of being "stuck on the sidelines," id. at 41:19, until May 27, 2014, meant that to each Generic Defendant, delayed entry on its own was not a viable proposition unless it could be assured of its position vis-à-vis its competitors.

This dilemma sets up a clear incentive for the Defendants to cooperate with each other, and they did so by providing for contingent launch clauses that would coordinate the Generic Defendants' entries into the market. This is no different than the situation faced by the parties in Toys "R" Us". Toys "R" Us asked individual toy manufacturers to restrict their business in exchange for the consideration of continuing to retail that manufacturer's toys -- an unattractive deal for the manufacturer worried about its competition's freedom to do broader business with other retail outlets. See Toys "R" Us, 221 F.3d at 932-33. Each manufacturer's calculus changed, however, when it received assurance that it would only have to restrict its business if its competitors did the same.[5] The Seventh Circuit has held that individual decisions to join such an arrangement can constitute a single overarching conspiracy, and this Court agrees. From

[5] Contrary to Judge Goldberg's characterization, In re Modafinil Litig., 2014 WL 2813312, at *12-13, joining such an arrangement must have, at that point, been an economically rational proposition, because the toy manufacturers would not otherwise have agreed to it.

the fact that the Nexium settlement agreements were not in the Generic Defendants' self-interest unless their agreements contained provisions aligning their behavior, a reasonable fact-finder could draw an inference of conspiracy. This is enough. The issue of conspiracy vel non is one for a jury to decide -- not a judge. Cf. Securities & Exch. Comm'n v. EagleEye Asset Mgmt., 975 F. Supp. 2d. 151, 161 (D. Mass. 2013).

G. DRL's Motion for Reconsideration [ECF No. 905]

On April 22, 2014, DRL moved for reconsideration of this Court's denial of its motion for summary judgment as to overarching conspiracy, and the Court subsequently denied its motion. See DRL's Mot. Reconsideration, ECF No. 905; Elec. Order, May 9, 2014, ECF No. 916. Although DRL raised arguments which the Court already has declined to adopt, it also advanced arguments underscoring the proposition that it is differently situated from its co-Defendants as to the issue of overarching conspiracy. See Mem. Supp. DRL's Mot. Reconsideration ("DRL's Conspiracy Reconsideration Mem."), ECF No. 906. Those arguments merit further consideration.

As is explicated in greater detail later in this opinion, evidence in the record shows that at the time of its settlement with AstraZeneca, DRL was experiencing problems developing a generic Nexium product that could obtain FDA approval in time for a May 2014 launch. See id. at 4. DRL asserts that because

of these problems, it signed its settlement agreement believing that it likely lacked the capacity to come to market before May 2014 under any circumstance. Id. Understandably, this made DRL indifferent to the fact that it agreed to delay market entry until May 2014 as a part of its settlement with AstraZeneca. Id. at 5.

DRL relies on these largely undisputed facts to argue that to the extent a conspiracy exists in this case, it ought not be considered a co-conspirator. Two compelling propositions underpin its arguments: (1) that DRL's settlement agreement did nothing to advance a conspiracy to delay generic entry, and (2) that DRL had no motive to join such a conspiracy because the scheme conferred no benefit on DRL. For the reasons explained below, neither proposition justifies reversing the Court's denial of summary judgment.

First, DRL contends that because it could not have come to market before May 2014 even had it been free to do so, agreeing to delay its market entry did nothing to further the alleged conspiracy to delay generic competition. Id. at 5-7. DRL reasons that its settlement agreement had no effect on the alleged conspiracy because it merely agreed to refrain from doing what it lacked the capacity to do anyway. See id. at 7.

These arguments presume that elements of the conspiracy allegation are requisite when they simply do not exist. DRL's

status as an alleged co-conspirator does not turn on whether it actually contributed to the delayed market entry of generic Nexium as a result of its settlement. The essence of conspiracy is agreement, and a party may be a co-conspirator even if he does nothing to further the accomplishment of the conspiracy's goals. See United States v. Paramount Pictures, 334 U.S. 131, 161 (1948) ("[A]cquiescence in an illegal scheme is as much a violation of the Sherman Act as the creation and promotion of one."). DRL is not aided by arguing that it failed to contribute to the alleged conspiracy because it lacked the capacity to do so. See United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 224 n.59 (1940) ("[I]t is well established that a person may be guilty of conspiring, although incapable of committing the objective offense.") (internal quotation marks and citations omitted).

Nor is the Court persuaded to disregard DRL's settlement because it agreed only to do what it would have done anyway. "[C]onspiracies under the Sherman Act are not dependent on any overt act other than the act of conspiring," and participants in an illegal conspiracy have never been required to have altered their behavior as a result of the conspiracy to be treated as co-conspirators. Id. DRL, like its co-Defendants, signed an agreement to stay out of the generic Nexium market as long as its competitors did the same. This continues to be compelling

evidence of acquiescence to a common scheme to delay generic competition. That DRL's purported acquiescence may not have had any effect on the state of generic competition is irrelevant.

Second, DRL argues that a reasonable factfinder cannot infer that it acquiesced to a conspiracy, because it had no motive to join such a scheme. See DRL's Conspiracy Reconsideration Mem. 11-13. DRL's inability to come to market before May 2014, regardless of the terms of its settlement, meant that it had nothing to gain from a conspiracy to delay generic competition. This purportedly made it indifferent to the concession it made to delay its generic launch. Id. The Court recognizes that in this regard, DRL appears differently situated from its Generic co-Defendants. The Court also recognizes that its ruling that a reasonable jury could infer that the Generic Defendants acted against their interests in agreeing to delay generic launch does not apply so neatly to DRL. But these distinctions still do not absolve DRL of potential liability.

DRL's inability to come to market notwithstanding, the Court is not persuaded that it lacked sufficient motive to acquiesce to the alleged conspiracy. It is not difficult to infer that DRL agreed to delay market entry not because the provision was important to DRL, but because it was important to AstraZeneca and a condition of settlement. By making that

concession, DRL obtained benefits in return, including an end to two lawsuits brought by AstraZeneca. That it was not a costly concession for DRL to make would only strengthen DRL's incentive to agree to such terms. In this light, it seems absurd to posit that DRL obtained no benefit from its agreement to delay market entry. DRL only stood to gain from agreeing to the same terms as Ranbaxy and Teva.

Further, evidence in the record supports the inference that DRL knew it was agreeing to the same terms as its generic competitors, and that it understood generic delay to be anticompetitive. See Pls.' Mem. Opp'n DRL's Mot. Reconsideration (ECF 905) 7-8, ECF No. 914. Even if DRL was differently situated from its generic competitors, a reasonable fact-finder could infer that DRL's acceptance of identical delayed entry terms constituted knowing acquiescence in the other Defendants' "unity of purpose" -- that is, their common goal to delay generic competition in the Nexium market until May 2014. American Tobacco Co. v. United States, 328 U.S. 781, 810 (1946).

The Court cannot, in light of these plausible and reasonable inferences, rule that summary judgment is warranted as to DRL's role in a purported conspiracy.

The net effect of these various rulings concerning overarching conspiracy is that if any one of the Defendants is

subject to antitrust liability, all the Defendants may be liable as co-conspirators.

IV. MOTIONS FOR SUMMARY JUDGMENT AS TO THE RANBAXY SETTLEMENT [ECF Nos. 642, 641, 645, 867]

In addition to their motions challenging the notion that an overarching conspiracy exists, the Defendants filed several motions for summary judgment on the grounds that specific elements of the Plaintiffs' case have not been established as to every Generic Defendant. First, the Defendants argue that their settlement agreements were not illegal reverse payments under the standards set out by the Supreme Court. Second and in the alternative, they claim that because none of the Generic Defendants would have come to market before May 27, 2014, even absent settlement, the Plaintiffs cannot show that the Nexium settlements were the cause of any delay in the availability of generic Nexium.

Determining whether these assertions are true requires due consideration of the facts specific to each of the three Nexium settlements. In this section, the Court explains its analysis of the issues with respect to AstraZeneca's settlement with Ranbaxy (the "Ranbaxy Settlement").

First, this Court examines the issue of whether the Ranbaxy Settlement and related agreements made on the same day arranged a "large and unjustified" reverse payment to Ranbaxy. Actavis,

133 S. Ct. at 2237 ("In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects . . . ."). Upon AstraZeneca and Ranbaxy's joint motion for summary judgment, AstraZeneca & Ranbaxy Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlement Agreement Ranbaxy, ECF No. 642, the Court ruled that the Plaintiffs have established a reasonable inference that Ranbaxy received a reverse payment that ought be subject to antitrust scrutiny. Order, Feb. 12, 2014, ¶ 8.

Next, the Court addresses whether the Plaintiffs have adequately shown a causal nexus between the Ranbaxy Settlement and their alleged antitrust injury. Finding that the Plaintiffs have failed sufficiently to demonstrate causation, this Court granted Ranbaxy's motion for summary judgment on that issue, Def. Ranbaxy's Mot. Summ. J. Lack Causation, ECF No. 641. Order, Feb. 12, 2014, ¶ 9. The Court also denied the Plaintiffs' subsequent motion for reconsideration, Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation (ECF # 641, 645) Based New Evidence, ECF No. 867. Elec. Clerk's Notes, Apr. 16, 2014, ECF No. 902.

Finally, this Court extends its antitrust causation analysis to AstraZeneca's derivative motion for summary judgment, AstraZeneca Defs.' Mot. Summ. J. Basis Causation, ECF

No. 645. The Court partially granted this motion as to the Ranbaxy Settlement. Order, Feb. 12, 2014, ¶ 10.

A. AstraZeneca and Ranbaxy Defendants' Motion for Summary Judgment on All Claims Arising From AstraZeneca's Settlement with Ranbaxy [ECF No. 642]

AstraZeneca and Ranbaxy jointly filed a motion for summary judgment on all claims arising from the Ranbaxy Settlement, arguing that AstraZeneca made no illegal reverse payment to Ranbaxy as part of their settlement. AstraZeneca & Ranbaxy Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlement Agreement Ranbaxy, ECF No. 642. The Court denied this motion on the basis that the Plaintiffs were able to support an inference of a "large and unjustified payment," evincing the proper economic valuation and factual support to suggest that Ranbaxy was induced to delay its generic launch in exchange for certain lucrative side business arrangements with AstraZeneca. Order, Feb. 12, 2014, ¶ 8, ECF No. 857 (quoting Actavis, 133 S. Ct. at 2237). A reasonable jury would be able to find that these side arrangements amounted to an illegal reverse payment to Ranbaxy. This decision warrants explanation, and it is provided here.

1. Undisputed Factual Background Germane to This Motion

In addition to the facts which have been outlined earlier in this opinion, it is necessary to review in some further depth the particular character of the Ranbaxy Settlement. Recall that

AstraZeneca's initiation of a patent infringement lawsuit against Ranbaxy triggered a 30-month litigation stay under the Hatch-Waxman Act, during which time no final approval of Ranbaxy's tentatively-approved generic Nexium product could be granted. See 21 U.S.C. § 355 (j)(5)(B)(iii); see also Direct Purchaser & End-Payor Class Pls.' Local R. 56.1 Resp. AstraZeneca & Ranbaxy Statement Undisputed Facts Relating Mot. Summ. J. Claims Arising AstraZeneca's Settlement Ranbaxy (ECF No. 684) & Statement Additional Material Facts ("Pls.' Ranbaxy Reverse Payment Facts") ¶ 1, ECF No. 778; Direct Purchaser & End-Payor Class Pls.' Opp'n AstraZeneca & Ranbaxy Defs.' Summ. J. All Claims Arising AstraZeneca's Settlement Agreement Ranbaxy ("Pls.' Ranbaxy Reverse Payment Opp'n") 4, ECF No. 787. Anticipating the expiration of the stay in April 2008 and the possibility that Ranbaxy might choose to launch generic Nexium at risk after that time, AstraZeneca began an effort in 2007 and 2008 to launch its own authorized generic version of Nexium, in order to maintain revenue that it would otherwise lose upon Ranbaxy's entry into the market. See Pls.' Ranbaxy Reverse Payment Opp'n 4 n.8.

AstraZeneca changed its plans, however, when it settled with Ranbaxy on April 14, 2008. As was the case in all of the Nexium settlements, AstraZeneca agreed to end its patent infringement lawsuit against Ranbaxy in exchange for certain

legal admissions and an agreement to delay launch of Ranbaxy's generic product until May 27, 2014. See In re Nexium, 968 F. Supp. 2d at 381-82. As part of the Ranbaxy Settlement, however, AstraZeneca also "agree[d] to refrain from producing its own authorized generic version of Nexium during [Ranbaxy's] 180-day exclusivity period." Id. at 382. Further, on the same day the parties signed their settlement, they also entered into a series of other business agreements ("the Side Agreements"). AstraZeneca & Ranbaxy Statement Undisputed Facts Relating Mot. Summ. J. Claims Arising AstraZeneca's Settlement Ranbaxy ("Defs.' Ranbaxy Reverse Payment Facts") ¶ 4, ECF No. 684. These Side Agreements included (1) two agreements under which Ranbaxy would distribute authorized generic versions of AstraZeneca's brand drugs, Plendil and 40 mg Prilosec ("the Distribution Agreements"), (2) an agreement under which Ranbaxy would store AstraZeneca's products for a nominal fee, (3) an agreement ("the API Supply Agreement") under which Ranbaxy would supply AstraZeneca with significant amounts of esomeprazole magnesium, the active pharmaceutical ingredient in Nexium, for sale in the United States, and (4) an agreement ("the Tolling Agreement") under which Ranbaxy would supply AstraZeneca with branded Nexium capsules for sale in the United States. Defs.' Ranbaxy Reverse Payment Facts ¶ 4, ECF No. 684.

Following the execution of these agreements with Ranbaxy, AstraZeneca abandoned its efforts to produce its own authorized generic Nexium pills. See Pls.' Ranbaxy Reverse Payment Opp'n 7.

2. Legal Standard: Illegal Reverse Payments

The Supreme Court has held that the existence of a reverse payment is neither presumptively lawful nor unlawful, see Actavis, 133 S. Ct. at 2237, and deciding whether such a payment is unlawful requires consideration of multiple factors to determine whether a large reverse payment "can bring with it the risk of significant anticompetitive effects," id. To that end, "large and unjustified" reverse payments must be analyzed under the rule of reason, giving weight to "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification," as well as the particularities of the parties' industry. Id. As this Court held in denying the Defendants' motion to dismiss, unlawful reverse payments are not limited to monetary payments. In re Nexium, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("This Court does not see fit to read into the [Actavis] opinion a strict limitation of its principles to monetary-based arrangements alone. Adopting a broader

interpretation of the word 'payment,' . . . serves the purpose of aligning the law with modern-day realities.").

The initial burden of proof lies with the Plaintiffs, who must present evidence of these factors to show that the accused brand manufacturer made a payment to a generic manufacturer that exceeded anticipated future litigation costs, exceeded the costs of other services, and lacked "any other convincing justification." Actavis, 133 S. Ct. at 2237. The size and scale of such a payment, for example, can be an indicator of anticompetitive intent, because "[a] large payment would be an irrational act unless the patentee believed that generic production would cut into its profits." Herbert Hovenkamp, Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision, 15 Minn. J.L. Sci. & Tech. 3, 25 (2013). Once this showing is made, the burden then shifts to the Defendants to show that a challenged payment was justified by some precompetitive objective. For example, "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." Actavis, 133 S. Ct. at 2236.

If the Defendants can demonstrate a precompetitive justification, the burden shifts back to the Plaintiffs to

establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance. See Sullivan, 34 F.3d at 1111 ("[T]he rule of reason analysis requires a weighing of the injury and the benefits to competition attributable to a practice that allegedly violates the antitrust laws.") (citation omitted). At summary judgment, this requires a "showing of harm to competition, either directly or by reasonable inference." Benjamin v. Aroostook Med. Ctr., Inc., 113 F.3d 1, 2 (1st Cir. 1997); see also Addamax Corp. v. Open Software Found., Inc., 888 F. Supp. 274, 283 (D. Mass. 1995) (Tauro, J.) ("To state a Sherman Act claim under the rule of reason, [the Plaintiff] bears the initial burden of establishing that [the Defendant's] actions have 'an actual adverse effect on competition as a whole in the relevant market.'") (quoting Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc., 996 F.2d 537, 543 (2d Cir. 1993)). "If the [D]efendant then comes forward with a legitimate justification for the conduct, the [P]laintiff must show that the same legitimate purpose could have been obtained through less restrictive means." Id. (citing Capital Imaging, 996 F.2d at 543).

3. Analysis

a. The Side Agreements

AstraZeneca and Ranbaxy assert that their Side Agreements cannot be considered a form of reverse payment to Ranbaxy,

because the Plaintiffs have failed to show evidence that the Side Agreements were anything other than a fair market exchange of value for services. Mem. Supp. AstraZeneca & Ranbaxy Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlement Agreement Ranbaxy ("Defs.' Ranbaxy Reverse Payment Mem.") 5, ECF No. 656. The Defendants insist that without such evidence, their Side Agreements are "per se lawful" under Actavis. Id. The Court takes a different view.

The Plaintiffs proffer evidence that the Side Agreements had the potential to be highly lucrative for Ranbaxy. They argue that the Supply and Tolling Agreements, under which Ranbaxy would provide esomeprazole magnesium and branded Nexium capsules to AstraZeneca, "provided Ranbaxy a steady stream of profits in the millions of dollars," and that "Ranbaxy would not have received these agreements in the absence of the Nexium settlement." Pls.' Ranbaxy Reverse Payment Facts ¶ 12. The Plaintiffs also point out that the Distribution Agreements, under which Ranbaxy would distribute authorized generic versions of Plendil and Prilosec, allowed Ranbaxy to retain 20 percent of its profits from sales. This, the Plaintiffs contend, "provided a continuous stream of revenue to Ranbaxy." Pls.' Ranbaxy Reverse Payment Opp'n 10.

The Defendants counter that such evidence is of no avail without evidence that Ranbaxy gained greater than fair market

value for its services. See Defs.' Ranbaxy Reverse Payment Mem. 6-8 (pointing out that very little assessment of fair market value has been shown by the Plaintiffs, and challenging the ability of Plaintiffs' experts to conduct such an assessment at all), see also id. at 11 (asserting that absent such evidence, their agreements cannot trigger antitrust concerns). The Court does not agree, however, that Actavis counsels such a narrow view of fair market value as a dispositive issue. The Actavis opinion makes it clear that evidence of a fair value exchange can "redeem[]" an otherwise suspicious reverse payment. 133 S. Ct. at 2236. The Court understands this to mean that establishing fair market value is just one of many possible defenses available to a Defendant seeking to demonstrate procompetitive justifications for a reverse payment. Nowhere in Actavis does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny. Neither does the opinion place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something other than fair market value.

What the Plaintiffs have established is a reasonable inference that the Side Agreements were lucrative for Ranbaxy and that they were negotiated in conjunction with the Ranbaxy Settlement. It is notable that these agreements were formally extraneous to the Nexium patent litigation, falling into a

category of non-traditional settlement forms which logically trigger heightened antitrust scrutiny. Cf. Actavis, 133 S. Ct. at 2236 ("Where a reverse payment reflects traditional settlement considerations, . . . there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."). It is also notable that the Side Agreements essentially provided a steady flow of revenue to Ranbaxy, based on use of AstraZeneca's intellectual property, in the precise time period during which it agreed to refrain from marketing its generic Nexium product. The Plaintiffs point out that even if Ranbaxy had won its litigation instead of settling, it would not have secured such favorable arrangements. Pls.' Ranbaxy Reverse Payment Facts ¶ 12. The evidence as a whole, notwithstanding the lack of fair market value evidence, raises enough suspicions to support a reasonable inference that the Side Agreements were improper reverse payments to induce Ranbaxy to delay its generic launch.

b. The "Exclusive License"

The Defendants also contest the notion that AstraZeneca made additional reverse payments to Ranbaxy by agreeing to refrain from selling its own authorized generic version of Nexium during Ranbaxy's 180-day exclusivity period. They argue that the concession was an "exclusive license" exempt from

antitrust scrutiny under Actavis and federal patent laws, and further that the license was a reasonable business decision in light of the regulatory atmosphere around authorized generics in early 2008. See Defs.' Ranbaxy Reverse Payment Mem. 11-12.

Because exclusive licenses are authorized by patent law, the Defendants posit that their exclusive license cannot be considered a reverse payment under Actavis. See id. at 13. They draw the Court's attention, for example, to the fact that even the F.T.C. expressly differentiated license agreements from reverse payments in its arguments before the Actavis Court. Id. at 12 (referencing the F.T.C.'s arguments that licensors and licensees stand in a "vertical relationship," unlike brand and generic manufacturers, and that licensing agreements "are generally procompetitive") (citing Reply Br. Pet'r, Actavis, 133 S. Ct. at 2223, 2013 WL 1099171, at *21).

This does not end the Court's inquiry, however. "Patents give no protection from the prohibitions of the Sherman Act . . . when the licenses are used . . . in [a] scheme to restrain." United States v. New Wrinkle, Inc., 342 U.S. 371, 378 (1952). The Plaintiffs' citation to Moraine Products v. ICI America, Inc., 538 F.2d 134 (7th Cir. 1976), is compelling:

> Where a patent license is used to protect the licensee in addition to the patentee or is used to allow the licensees to divide a market among themselves, thus enabling them jointly to regiment an industry under

> the guise of a patent license, there is good reason to declare such a restrictive scheme illegal.

Id. at 145. There is little reason to think this rationale has been abrogated by Actavis. In fact, the Supreme Court rejected the "near-automatic antitrust immunity" the Eleventh Circuit afforded to reverse payment settlements, 133 S. Ct. at 2237, suggesting that formally classifying an agreement a "license" ought not halt further inquiry into the actual nature of the underlying arrangement.

In this case, while AstraZeneca may have granted an exclusive license for generic Nexium, it retained the right to continue to sell brand Nexium -- providing itself with the kind of economic self-protection that Moraine Products suggests warrants suspicion. The Defendants cannot shield themselves with the argument that patent licenses are common and authorized, if such licenses disguise unlawful reverse payments. In view of this consideration, the Court rules that AstraZeneca's agreement to refrain from marketing generic Nexium during Ranbaxy's exclusivity period may be considered part of an illegal reverse payment.

The Defendants make one last attempt to exempt this license agreement from scrutiny by arguing that the arrangement was an eminently prudent one in light of the regulatory atmosphere at the time of the Ranbaxy Settlement. Defs.' Ranbaxy Reverse

Payment Mem. 15. They attempt to show that as of early 2008, Congress and the F.T.C. were hostile to authorized generics and believed such practices to be anticompetitive. See id. at 15-16 (citing to an F.T.C. study on the anticompetitive effects of authorized generics, and the statement of U.S. Representative Henry Waxman that authorized generics were an "unfair practice").

This is a weak argument. As a preliminary matter, the Plaintiffs offer contrary evidence that, at the time of the Ranbaxy settlement, authorized generics were actually considered procompetitive. See Pls.' Ranbaxy Reverse Payment Opp'n 14 (citing, inter alia, an FDA pronouncement that authorized generics promote pharmaceutical competition). Moreover, the evidence proffered by the Defendants -- amounting to the personal opinions of members of Congress and isolated statements of the F.T.C. -- simply is not sufficient on its own to win summary judgment for the Defendants.

The Plaintiffs present some of their stronger arguments in service of this particular motion for summary judgment. A reasonable jury can determine on the evidence in the record that under the rule of reason, an unlawful reverse payment was made from AstraZeneca to Ranbaxy in exchange for generic delay. Accordingly, the Court DENIED AstraZeneca and Ranbaxy's motion

for summary judgment on all claims arising from the Ranbaxy settlement, ECF No. 642.

B. Ranbaxy's Motion for Summary Judgment on the Basis of Causation [ECF No. 641]

The Court now turns to issues of antitrust causation. Ranbaxy moved for summary judgment on the claims against it based on a purported lack of causation. Under the rule of reason, the Plaintiffs are responsible for demonstrating that AstraZeneca, as the brand manufacturer of Nexium, held sufficient market power "to warrant a conclusion of plausible competitive harm" as well as proof of antitrust injury in the form of "higher consumer prices or reduced output." Hovenkamp, supra, at 23, 25. Central to this analysis is a determination as to whether the Plaintiffs can establish a causal link between any alleged reverse payment and their antitrust injuries, as required under the federal antitrust laws. See 15 U.S.C. § 15(a) (providing a private right of action to plaintiffs "by reason of" an antitrust violation). In other words, even if an illegal reverse payment was made, the Plaintiffs cannot prevail unless the Ranbaxy Settlement is proved to have caused Ranbaxy's delayed entry.

Ranbaxy argues that under any possible circumstance, regulatory hurdles would have prevented Ranbaxy from launching a generic version of Nexium before May 27, 2014, the agreed-upon

entry date. Here, the Court, mindful of the presumptions necessitated at summary judgment, must determine whether the Plaintiffs have adequately shown otherwise. This motion rests at the fulcrum of two opposing considerations: on one hand, a legal framework strongly favors sending causality questions to the jury, and on the other hand, the Plaintiffs have offered little evidence in support of their complicated, multi-step proposition that the FDA would have approved Ranbaxy's generic Nexium any earlier than May 2014 in the absence of this settlement agreement.

1. Undisputed Facts Germane to This Motion

a. The Ranbaxy Settlement

Ranbaxy and AstraZeneca representatives began to negotiate settlement of their Nexium lawsuit in July 2007. Class Pls.' Opp'n [641] Ranbaxy's Statement Undisputed Facts Relating Causation ("Pls.' Ranbaxy Causation SOF") ¶¶ 7-8, ECF No. 791-1. In August 2007, Ranbaxy proposed a May 2012 date for it to enter the generic Nexium market; in November 2007, AstraZeneca countered with a date of May 27, 2014. Id. ¶¶ 8-9. The eventual settlement and its accompanying Side Agreements were finalized on April 14, 2008. After entering into this agreement, "Ranbaxy changed its projections to commercially market its generic Nexium to May 2014." Id.

In the context of the parties' Supply and Tolling Agreements, Ranbaxy warranted that it "had the 'ability and desire to custom manufacture and formulate' Nexium out of its Ohm [New Jersey] facility." Id. ¶ 13 (internal citation omitted). To enable Ranbaxy to produce branded Nexium capsules for AstraZeneca under the Tolling Agreement, the FDA approved the site transfer of relevant AstraZeneca technology from India to New Jersey. Id.

b. Ranbaxy's Nexium ANDA

Ranbaxy's pending ANDA for generic Nexium was filed out of its Paonta Sahib, India, facility. Id. ¶ 3. This means that any FDA approval to market generic Nexium only extended to production at the Paonta Sahib facility. Id. To move production to another facility, Ranbaxy is required to file and gain approval of a site transfer amendment to its ANDA. Id.

The Paonta Sahib site has experienced serious quality control problems since Ranbaxy filed its generic Nexium ANDA in 2005. On February 25, 2009, after issuing several warnings, id. ¶¶ 14-16, 21-24, the FDA invoked its Application Integrity Policy ("AIP") against Paonta Sahib, which "halted FDA's substantive review and approval of all pending ANDAs, including amendments and post-approval supplements that relied on supporting data from the Paonta Sahib site" -- including the generic Nexium ANDA. Id. ¶¶ 26-27. The FDA subsequently

rejected Ranbaxy's proposed Corrective Action Operating Plan, designed to remedy the problems, as well as a request to continue the approval process for Nexium under a public health exception. Id. ¶¶ 27, 29, 30 (denying a public health exception request for generic Nexium but granting it as to generic Lipitor, another product produced out of Paonta Sahib).

Finally, in 2010, Ranbaxy and the FDA began to negotiate a consent decree to resolve enforcement issues against the company. Id. ¶ 31. The parties dickered over various terms, including whether Ranbaxy would have to relinquish its right to 180-day marketing exclusivity for generic Nexium, id. ¶¶ 32-34, and the final decree was filed on January 25, 2012, id. ¶ 35. It states that the "FDA will not resume review of Ranbaxy's [Nexium ANDA] . . . until Ranbaxy achieves certain milestones set out in the Consent Decree." Def. Ranbaxy's Statement Undisputed Facts Supp. Mot. Summ. J. Due To Lack Of Causation ("Ranbaxy Causation SOF") ¶ 36, ECF No. 646; see also Decl. Sarah Choi Supp. Ranbaxy Def.'s Mot. Summ. J., Ex. 58, Consent Decree Permanent Inj. ("Consent Decree") ¶¶ XIV, XV, ECF No. 693-45.

The decree set out certain milestones that had to be met before review of Ranbaxy's Nexium ANDA would continue. Ranbaxy Causation SOF ¶ 36. The first of these milestones was met on May 4, 2012, when the FDA deemed that the Nexium ANDA was

"substantially complete when filed," triggering an audit process of the ANDA filing. Id. ¶ 40. At this time, Ranbaxy began working on a site transfer amendment to move production from Paonta Sahib to a plant in Ohm, New Jersey, see id. ¶ 50, which was submitted to the FDA on November 15, 2013, id. ¶ 51.

The decree also set in place significant data integrity review protocols for evaluating applications from the Paonta Sahib facility. See Consent Decree ¶ XVII (requiring the development and submission of internal review protocols, an internal review and audit plan, and an approved corrective action operating plan). If Ranbaxy has not completed these protocols by September 30, 2014, it will waive its 180-day generic Nexium marketing exclusivity. Id. ¶ XIII; see also Blume Report ¶ 64. To date, these protocols have not been completed. See Ranbaxy Causation Mem. 18-19.

2. Legal Standard: Antitrust Causation

In order for judgment to be entered in his or her favor, "[a]n antitrust plaintiff must prove that he or she suffered damages from an antitrust violation and that there is a causal connection between the illegal practice and the injury." Sullivan, 34 F.3d at 1103. The "Plaintiffs need not prove that the antitrust violation was the sole cause of their injury, but only that it was a material cause." Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1, 14 (1st Cir. 1979) (citing Zenith

Radio Corp. v. Hazeltine Research Inc., 395 U.S. 100, 114 n.9 (1969)). This "material" connection has been interpreted as a proximate cause requirement. See In re Neurontin Marketing & Sales Practices Litig., 712 F.3d 21, 35 (1st Cir. 2013).

Complicating matters is the fact that in disputes like this one, an injury can have multiple independent causes -- some stemming from, as alleged in this case, FDA regulatory actions, some from manufacturing problems, and some from anticompetitive behaviors. Judge Anita Brody of the Eastern District of Pennsylvania has articulated this analytical challenge well:

> An antitrust violation can be the proximate cause of a plaintiff's injury even if there are additional independent causes of the injury. On occasion, however, an independent cause fully accounts for the plaintiff's alleged injury and breaks the causal connection between the alleged antitrust violation and the plaintiff's injury. When a defendant relies upon the existence of an independent cause, however, such cause must be examined closely to make sure that it is the independent cause, rather than the illegal antitrust action, that gives rise to the plaintiff's injury.

In re Flonase Antitrust Litig., 798 F. Supp. 2d 619, 627-28 (E.D. Pa. 2011) (internal citations and quotation marks omitted).

In determining whether the act of a third party is an independent act of causation, courts are oriented by several key guideposts. First, drawing from the common law principles of proximate cause, courts have held that intervening conduct "does

not sever the chain of causation where that [third-party] conduct was a foreseeable consequence of the original antitrust violation." Id. at 619. Second, injuries that are caused almost exclusively by the actions of government regulators do not give rise to antitrust liability. See RSA Media, Inc. v. AK Media Grp., Inc., 260 F.3d 10, 12-15 (1st Cir. 2001) (holding that there was no antitrust liability because "[the Plaintiff] was not excluded from the market for outdoor billboards because of [the Defendant's] threats; it was excluded because of the Massachusetts regulatory scheme that prevents new billboards from being built"); see also In re Canadian Import Antitrust Litig., 470 F.3d 785, 791 (10th Cir. 2006) (concluding that "[t]he absence of competition from Canadian sources in the domestic prescription drug market, therefore, is caused by the federal statutory scheme adopted by the United States government, not by the conduct of the [D]efendants").

In cases where governmental influence is not so pervasive, however, and the intervening governmental act followed from a defendant's conduct in some way, liability may still attach. See In re Flonase, 798 F. Supp. 2d at 629-30; see also Spear Pharms., Inc. v. William Blair & Co., LLC, 610 F. Supp. 2d 278, 287 (D. Del. 2009) (holding that the Defendant's filing of a citizen petition with the FDA, which led to a delay in the approval of the Plaintiff's ANDA, was not so "highly

unforeseeable" as to be a superseding cause); In re Dr. Reddy's Labs., Ltd., No. 01 Civ. 10102(LAP), 2002 WL 31059289, at *11 (S.D.N.Y. Sept. 13, 2002) (holding that allegations that the Defendant submitted data to the FDA, knowing that the FDA would use that data to delay ANDA review, satisfied proximate cause requirements for purposes of motion to dismiss).

Turning from general principles to a specific example, the causality question at issue here is whether a government agency would have approved a product earlier in time, but for certain allegedly anticompetitive events. The most on-point examination comes from Judge James Robertson of the United States District Court for the District of Columbia. In Twin Cities Bakery Workers Health and Welfare Fund v. Biovail Corporation, No. Civ.A. 01-2197(JR), Civ. A. 03-2075(JR), 2005 WL 3675999 (D.D.C. Mar. 31, 2005), aff'd sub nom., Meijer, Inc. v. Biovail Corp., 533 F.3d 857 (D.C. Cir. 2008), Judge Robertson acknowledged that although a defendant can be held liable notwithstanding the independent gatekeeping actions of a government regulator, certain evidentiary thresholds must be met before a claim can be brought:

> The subject matter of [the Plaintiff's experts'] declarations is whether or not, and when, the Food and Drug Administration would have made complex, discretionary, multi-layered, case-specific decisions relating to the initial approval and subsequent need to recall a prescription drug. [The expert's] opinion is that the FDA would have approved Andrx's ANDA on or

> about February 14, 2011 if Biovail had not listed the '463 patent in the Orange Book in January 2001 . . . . These opinions are unaccompanied by data that demonstrate their reliability -- no examples of the time lines by which the FDA has approved the ANDAs of other drug manufacturers, no personal experience of predicting what the FDA might do that proved to be correct. . . . The experts' declarations are too speculative to forge the chain of causation plaintiffs' proof of damages requires.

Id. at *4-5. Such evidentiary sufficiency is particularly important, he observed, when the jury must believe chains of inferences in order to find damages. See id. at *5 ("[W]hat plaintiffs have offered on the critical question of what Andrx would have done is either a broken link in the chain of causation, or a very weak one. It takes more than a scintilla of evidence to survive summary judgment. 'The greater number of uncertain links in a causal chain, the less likely it is that the entire chain will hold true.'") (internal citation omitted) (quoting Florida Audubon Soc'y v. Bentsen, 94 F.3d 658, 670 (D.C. Cir. 1996) (en banc)). If there are "fatal gaps" in the evidence introduced to prove the plaintiff's causal chain, summary judgment is appropriate. Kearney v. Phillip Morris, Inc., 916 F. Supp. 61, 66 (D. Mass. 1996) (Keeton, J.).

Particularly at the summary judgment stage, however, these principles must be tempered by a final consideration: that "[t]he issues of proximate causation and superseding cause involve application of law to fact, which is left to the

factfinder, subject to limited review." Exxon Co., U.S.A., v. Sofec, Inc., 517 U.S. 830, 840-41 (1996). Indeed, the First Circuit has held that "[c]ausation questions of this sort are normally grist for the jury's mill." Peckham v. Continental Cas. Ins. Co., 895 F.2d 830, 837 (1st Cir. 1990); see also Wortley v. Camplin, 333 F.3d 284, 295 (1st Cir. 2003) ("Proximate causation and intervening cause are usually issues for the jury to resolve.").

Thus, to distill these cases, summary judgment on questions of causality is not appropriate where the plaintiff was injured by intervening conduct proximately caused by the defendant's antitrust action, or where such intervening conduct was a foreseeable consequence of the defendant's antitrust action. Summary judgment is appropriate, however, where there is insufficient proof of causation, or where the intervening conduct was independently caused by a government actor.

3. Analysis

At its core, Ranbaxy's argument is simple: because Ranbaxy would not, under any circumstance, have been able to launch a generic version of Nexium before May 27, 2014, its settlement agreement with AstraZeneca (and the allegedly anticompetitive consequences) cannot have been a proximate cause of the Plaintiffs' injuries. In so arguing, Ranbaxy points to FDA approval and litigation barriers that would have delayed its

generic launch. See Def. Ranbaxy's Mem. Law. Supp. Mot. Summ. J. Due Lack Causation ("Ranbaxy Causation Mem.") 10-13, ECF No. 643. The Plaintiffs, in turn, argue that Ranbaxy's settlement caused it to purposely delay addressing the regulatory issues that would have paved the way to generic launch. See Direct Purchaser Class & End-Payor Class Pls.' Opp'n Ranbaxy's Mot. Summ. J. Due To Lack Of Causation ("Pls.' Ranbaxy Causation Opp'n") 2, ECF No. 791.

The Court must determine whether a reasonable jury could find that Ranbaxy would have overcome regulatory and other hurdles to enter the market before May 27, 2014, if it had not entered its settlement with AstraZeneca. If Ranbaxy would not have overcome such hurdles, then these obstacles were independent causes of Ranbaxy's delayed launch and thus break the causal chain between the Ranbaxy Settlement and the Plaintiffs' injuries. Analyzing this issue requires looking at two separate questions: absent the Ranbaxy Settlement, did Ranbaxy have the "will" to enter the market before 2014, and was there a "way" for it to enter had the agreement allowed for earlier entry, considering both manufacturing and FDA approval requirements? The Court discusses these two issues in turn.

a. Ranbaxy's Willingness to Launch Generic Nexium Before May 27, 2014

According to the Plaintiffs, while Ranbaxy wanted to launch a generic Nexium product before May 2014, it deliberately slowed or stopped its efforts in response to its settlement with AstraZeneca. First, the Plaintiffs point to the fact that during settlement negotiations, Ranbaxy initially proposed a market entry date of 2012, indicating its desire to come to market earlier than 2014. Id. at 8. The Plaintiffs further posit that Ranbaxy ultimately ceded to AstraZeneca's May 27, 2014, entry date in exchange for AstraZeneca's agreement to refrain from selling its own authorized generic during Ranbaxy's exclusivity period and the various Side Agreements explained earlier in this opinion. Id. at 8-9. Second, the Plaintiffs point to evidence showing that Ranbaxy responded to its settlement with AstraZeneca by slowing its efforts to launch its generic product. For example, deposition testimony given by Ranbaxy's Director of North American Operations showed that after the settlement, because Ranbaxy believed it would "be getting an approval in 2014," it saw no need to proceed with generic Nexium preparatory strategies at an earlier time. See Pls.' Ranbaxy Causation SOF ¶ 13.

While this evidence is far from conclusive, it supports a reasonable inference that Ranbaxy curtailed its activities in light of the entry date it had negotiated with AstraZeneca, as well as a reasonable inference that had the agreement not been

in place, Ranbaxy would have had the will to enter the market sooner.

b. Ranbaxy's Ability to Enter the Generic Market Before May 27, 2014

The harder question is, even if Ranbaxy had the "will," did it have the "way"?

Ranbaxy says no, relying on the basic uncontroverted fact that in the years leading up to May 2014, quality control problems at its Paonta Sahib facility made it impossible to lawfully market generic Nexium manufactured at that site. See generally id. ¶¶ 15-27. Ranbaxy maintains that it could never have obtained FDA approval to transfer production to another facility before 2008, and that it was "highly unlikely" that it would have been able to do so before May 27, 2014. Ranbaxy Causation Mem. 3. The Plaintiffs contend that not only did Ranbaxy have capacity at its Ohm, New Jersey plant to manufacture generic Nexium, but also that it could have received approval to site transfer its production facilities well before 2014. See generally Pls.' Ranbaxy Causation Opp'n 10-12.

Regarding Ranbaxy's capacity to produce generic Nexium outside of Paonta Sahib, the Plaintiffs look to Ranbaxy and AstraZeneca's Supply and Tolling Agreements, under which Ranbaxy agreed to supply AstraZeneca with esomeprazole magnesium and capsules for branded Nexium. In 2008, at the time of

settlement, Ranbaxy warranted to AstraZeneca that it had "'the ability and desire to custom manufacture and formulate' [branded] Nexium out of its Ohm facility and 'there is no matter or impediment which would prevent Ohm from performing, or would restrict or hinder Ohm in the performance of its obligations.'" Pls.' Ranbaxy Causation SOF ¶ 13. To make good on its agreement, Ranbaxy "ramp[ed] up" its manufacturing processes and obtained FDA approval to transfer AstraZeneca's technology to Ranbaxy's facilities. Id. The Plaintiffs argue that because branded and generic Nexium "[b]oth have the same active ingredient, the same milligram strength, and the same route of administration, and are bioequivalent," Pls.' Ranbaxy Causation Opp'n 12 n.48, Ranbaxy's ability to supply AstraZeneca with brand Nexium materials meant that Ranbaxy also had the technical capacity to manufacture generic Nexium in its Ohm-based plant prior to 2014. See id. at 12.

This evidence is far from conclusive. But the demonstrated ability of Ranbaxy to manufacture a nearly identical product to generic Nexium as early as 2008 is more than a "scintilla of evidence" in the Plaintiffs' favor. Twin Cities Bakery, 2005 WL 3675999, at *5. The Plaintiffs, therefore, meet the summary judgment threshold on the prerequisite question of whether Ranbaxy physically could have manufactured the product at the Ohm plant before 2014. See Anderson, 477 U.S. at 252.

The more complicated and contentious question is whether Ranbaxy could have received final FDA approval of its generic Nexium ANDA in time to launch before May 27, 2014. Ranbaxy maintains that it could not have done so under any circumstance, while the Plaintiffs present three counterfactual scenarios, each of which purportedly would have led to Ranbaxy's generic launch before May 27, 2014: (1) Ranbaxy declines to settle, gains final FDA approval before February 2009, and launches generic Nexium at risk while its litigation pends, (2) Ranbaxy enters into a settlement agreement with AstraZeneca for an earlier negotiated entry date and wins final FDA approval at some time between February 2009 and January 2012, and (3) Ranbaxy enters into a settlement agreement with AstraZeneca for an earlier negotiated entry date and wins FDA approval after January 2012, but before May 2014.[6] Under any of these purportedly likely scenarios, the Plaintiffs argue, Ranbaxy would have come to market well before May 27, 2014.

i. First Scenario: No Settlement Agreement

The Plaintiffs posit that if Ranbaxy had never settled its litigation with AstraZeneca, it would have obtained FDA approval to transfer generic Nexium production away from Paonta Sahib

[6] These three scenarios do not represent all possible timelines under which Ranbaxy allegedly could have come to market, but they are the only possibilities meaningfully discussed by the Plaintiffs. Other variations, the Court presumes, are so unlikely as to be completely unrealistic.

before February 2009, when the FDA's February 2009 AIP froze the ANDA approval process. The Plaintiffs further assert that the company would have then launched generic Nexium at risk -- that is, in spite of the possibility of losing its pending patent infringement case to AstraZeneca. Pls.' Ranbaxy Causation SOF ¶ 7.

The Plaintiffs point out that by November 19, 2007, Ranbaxy knew that it could not win final approval to produce generic Nexium at Paonta Sahib. See Pls.' Ranbaxy Causation SOF ¶ 18. They also suggest that it would have taken six months for Ranbaxy to prepare and submit a site transfer amendment request, extrapolating from the fact that Ranbaxy actually did take six months to prepare such a request in 2013. Pls.' Ranbaxy Causation Opp'n 14; see also Ranbaxy Causation Mem. 12. This implies that the FDA would have received Ranbaxy's application as early as mid-May 2008.

More importantly, this timeline also implies that the agency would have granted approval for a site transfer within nine months. The Plaintiffs' expert, Dr. Blume, estimates that "it would have taken approximately six months from submission of the amendment" for the FDA to approve the site transfer. Pls.' Ranbaxy Causation SOF ¶ 43. To support that conclusion, she notes that in actuality, Ranbaxy submitted its amendment in November 2013 and expected FDA approval by May 2014, a period of

approximately six months. Id. The Plaintiffs analogize more generally to examples of other Ranbaxy ANDA site transfers from Paonta Sahib to Ohm, see Blume Report ¶ 81 (referencing pravastatin sodium, where a site-transfer amendment was approved six months after submission, and generic Lipitor, where a site-transfer amendment was approved two years after submission), and to examples of site transfers between other Ranbaxy facilities, id. ¶¶ 82-84 (referencing Valtrex, 25 and 50 mg Imitrex, and 100 mg Imitrex, where site transfer approvals were granted between three and nine months from submission).

What is missing here is direct evidence that the FDA was likely to grant final approval to Ranbaxy's generic Nexium product within the proposed timeline. The Plaintiffs' argument is limited to referencing Ranbaxy's 2013 site transfer amendment process. This is not an unreasonable comparator, but the Plaintiffs do not discuss, for example, whether changes at Paonta Sahib or changes to the FDA's site transfer review process between 2008 and 2013 might account for differences in the speed of agency approval. Such context is crucial to understanding how reasonable it would be to infer that site transfer approval would have taken the same time in 2008 as it did in 2013. Moreover, while Dr. Blume's report does provide examples of other speedy approval timelines, see Blume Report ¶ 81, these examples are of limited value, because Dr. Blume does

not analyze how they are similar to, or differ from, the case of generic Nexium. See, e.g., British Telecomm'ns PLC v. Coxcom, Inc., Nos. 10-658-SLR, 11-8430SLR, 2014 WL 119077 (D. Del. Jan. 13, 2014) (giving little weight at summary judgment to an expert report which "contain[s] conclusory opinions, without analysis or reliance on evidence"), vacated on other grounds, 2014 WL 1364853. This hypothetical timeline comes perilously close to the kind of "improbable inferences or unsupported speculation" which cannot support a nonmovant's opposition to summary judgment. Travers v. Flight Services & Systems, Inc., 737 F.3d 144, 145 (1st Cir. 2013).

Moreover, even if the Plaintiffs' evidence is sufficient on this point, they must meet their evidentiary burden as to a second key proposition -- that, absent settlement, Ranbaxy would have launched generic Nexium at risk. This premise is almost entirely unsupported by evidence, and indeed, there is direct, undisputed evidence stating the opposite.

For its part, Ranbaxy offers evidence that it "never" would have launched generic Nexium at risk. Ranbaxy Causation SOF ¶ 53 (quoting the deposition testimony of a Ranbaxy executive that generic Nexium is so valuable that the potential liability damages of launching at risk "could wash away the company"). It also points to contemporaneous industry reports concluding "that

an at risk launch was 'unlikely' and 'extremely risky.'" Id. ¶ 55.

The Plaintiffs do not rebut this statement directly, instead stating in general terms that Ranbaxy would have had an incentive to proceed at risk "[b]ecause of the enormous financial incentives attached to a generic Nexium launch."[7] Blume Report ¶ 67. They also point to internal projections showing that Ranbaxy had, at one point, plans to market generic Nexium in the second or third quarter of 2008. Pls.' Ranbaxy Causation SOF ¶ 7. That period marks the earliest time Ranbaxy could have launched at risk, as it approximates the April 2008 end of the Hatch-Waxman 30-month litigation stay on final FDA approval. Id.; see 21 U.S.C. § 355(j)(5)(B)(iii). This, the Plaintiffs argue, is evidence that the company would have been willing to launch at risk. Ranbaxy responds that these forecasts were "placeholder date[s]" that do not represent plans to launch at risk, Ranbaxy Causation SOF ¶ 54 -- a fact the Plaintiffs deny without explanation, Pls.' Ranbaxy Causation SOF ¶ 54, leaving their case largely to rest on the type of "conclusory allegations, improbable inferences, and unsupported speculation," that the First Circuit directs this Court to ignore. Travers, 737 F.3d at 146. Given these weaknesses, the

[7] The Court notes, however, that this report does not offer primary evidence (e.g., sales data) to support this conclusion.

Court cannot conclude that the Plaintiffs have met their burden under this potential scenario.

ii. Second Scenario: Entry Between February 2009 and January 2012[8]

The Plaintiffs posit in the alternative that even if Ranbaxy and AstraZeneca had settled, Ranbaxy would have found a way to overcome regulatory hurdles and come to market earlier than May 27, 2014, if it had negotiated an earlier entry date. The Plaintiffs state that under an earlier entry date permitting entry after the February 2009 AIP but before January 2012, when the FDA issued its formalized consent decree setting out milestones for Ranbaxy to achieve ANDA approval, Ranbaxy would have come to market as early as December 2010. See Blume Report ¶ 33. In this world, Ranbaxy would not have had to worry about launching at risk, but it would have had to overcome the significant hurdle presented by the FDA's AIP.

According to the Plaintiffs, the FDA likely would have granted Ranbaxy an exception to the Paonta Sahib AIP "in the interests of public health," paving the way for final FDA approval of Ranbaxy's generic Nexium product. Pls.' Ranbaxy Causation SOF ¶ 30. Ranbaxy counters that "the grant of [such]

[8] Note that under this scenario, Ranbaxy still would have had to receive approval for a site transfer by 2012, so the considerations discussed supra apply, albeit with significantly more time for the transfer to be approved.

an exception is extremely rare," Ranbaxy Causation Mem. 17, and points out that in fact, the FDA still has not granted an AIP exception to its generic Nexium ANDA, nor has the agency granted any of Ranbaxy's ten other AIP exception requests, Ranbaxy Causation SOF ¶ 30.

To support their proposed counterfactual scenario, the Plaintiffs rely heavily on the fact that the FDA granted an AIP exception for Ranbaxy's generic Lipitor product, which they purport is analogous to generic Nexium. Pls.' Ranbaxy Causation SOF ¶ 27. They lay out some similarities, like that generic Nexium and Lipitor are produced in the same facilities, and that the drugs present similar first-to-file pressures. The Plaintiffs assert that the primary difference between the two drugs is that in the case of generic Lipitor, which had an agreed-upon launch date of November 30, 2011, the FDA and Ranbaxy negotiated a regulatory compromise that would allow Ranbaxy to launch generic Lipitor if it took corrective actions by a certain deadline, and force Ranbaxy to relinquish its first filer status if it missed that deadline. Pls.' Mem. 18 & n.75; see Pls.' Ranbaxy Causation SOF ¶ 27. The Plaintiffs posit that if generic Nexium had been subject to an earlier entry date than May 27, 2014, the FDA and Ranbaxy would have negotiated a similar compromise.

The Plaintiffs do not, however, discuss the similarities and differences between Nexium and Lipitor in any depth, and no further primary evidence was offered at this stage showing why generic Nexium independently would have satisfied the public health exception to the AIP. Nor do the Plaintiffs discuss what steps would have been required to satisfy the exception, and how Ranbaxy could have taken them. Without evidence to support their expert's opinions, the Plaintiffs' claim that generic Nexium would have received an AIP exception is conclusory.

iii. Third Scenario: Entry Between January 2012 and May 27, 2014[9]

The Plaintiffs lastly propose that even if Ranbaxy had negotiated an entry date after the issue of the FDA's January 2012 consent decree, it would have come to market earlier than May 27, 2014. To do so, Ranbaxy would have had to achieve all the milestones to final FDA approval set out in the consent decree in a timely fashion.

Recall that the consent decree contains a key relinquishment date, September 30, 2014, on which Ranbaxy will lose its rights to any 180-day exclusivity period if it has not completed certain review protocols by that time. Consent Decree

[9] Note that under this scenario, Ranbaxy still would have had to both receive approval for an AIP and then a site transfer by 2014. Thus, the considerations discussed supra apply, albeit with more time for the regulatory approvals to be secured.

¶ XIII; see also Blume Report ¶ 64. The Plaintiffs present a sufficient argument at the summary judgment stage that this date was chosen with the Ranbaxy Settlement's May 27, 2014, entry date in mind, and that if Ranbaxy had negotiated an early entry date with AstraZeneca, the consent decree's relinquishment date also would have been correspondingly earlier. See Pls.' Ranbaxy Causation Opp'n 16; Blume Report ¶ 64 ("[I]t is clear that the regulatory milestones for the [generic Nexium] product were set based on Ranbaxy's agreed upon entry date with AstraZeneca.").

The Plaintiffs are unable to point to any specific evidence, however, indicating that Ranbaxy could have met an earlier deadline. Instead, they again make an argument by inference, stating that because Ranbaxy was able to meet similar requirements for generic Lipitor, it would have been able to meet the requirements for generic Nexium. See Pls.' Ranbaxy Causation Opp'n 16. These assumptions are not discussed in depth, and there is no analysis of, for example, what steps would have been required to pass muster under the Nexium consent decree. See ZF Meritor LLC v. Eaton Corp., 646 F. Supp. 2d 663, 667 (D. Del. 2009) (holding that experts looking at but-for worlds must qualify and discuss data in support of conclusions).

The Plaintiffs point out that even if Ranbaxy could not have met an earlier deadline, Ranbaxy would have lost its marketing exclusivity on the relinquishment date, opening the

door for another firm, like Teva, to come to market before May 2014. See Pls.' Ranbaxy Causation SOF ¶ 27. This assumes, of course, that another generic manufacturer would have timely gathered the technical competency and FDA approval necessary for such a launch. While the Plaintiffs spend some time discussing Teva's technical capabilities, see Blume Rebuttal ¶¶ 30-42, they do not thoroughly consider whether the FDA would have granted Teva timely approval. Instead, they conclude in more general terms that "Teva would have been highly motivated to pursue final approval and launch at the earliest opportunity given the vast economic opportunities available to it by and through this generic drug product." Blume Report ¶ 121.

Their support for this proposition does not amount to more than an assertion that Teva would have received faster approval had it started trying on an earlier date. They do not discuss when Ranbaxy would have recognized that it could not have met an earlier relinquishment deadline, which would prompt subsequent ANDA filers like Teva to speed up their own application efforts, nor do the Plaintiffs discuss how long that application process would take. Such an argument layers hypothetical scenario upon hypothetical scenario, and as this Court routinely charges the jury, there must be no "pack[ing] [of] inference upon inference." See, e.g., United States v. O'Brien, No. 12-cr-

40026-WGY, Excerpt Tr.: Jury Charge 20, July 15, 2014, ECF No. 560.

Thus, as with the AIP, the Plaintiffs offer no direct evidence that Ranbaxy would have been capable of meeting an accelerated consent decree deadline, that it would have lost or relinquished its exclusivity period, or that another pharmaceutical company could have been prepared to come to market before May 2014.

It was for these reasons that, on February 12, 2014, this Court GRANTED Ranbaxy's motion for summary judgment due to lack of causation. Order, Feb. 12, 2014, ECF No. 857.

C. Motion for Reconsideration as to Causation [ECF No. 867]

The Plaintiffs asked the Court to reconsider its grant of Ranbaxy's summary judgment motion based on causation. Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation (ECF # 641, 645) Based New Evidence, ECF No. 867. To support their motion, they introduced several new FDA documents shedding light on the agency's approval of Ranbaxy's generic Lipitor ANDA. These documents indicate that the FDA was motivated to accelerate approval of Ranbaxy's Lipitor ANDA by concerns that delayed approval would create a regulatory bottleneck, wherein Ranbaxy's first-filer status would prevent the entry of any other generic product in the market. This

evidence, the Plaintiffs say, strengthens their analogy between the Lipitor ANDA and the Nexium ANDA, further demonstrating that in a but-for world, the FDA would have accelerated approval of generic Nexium in time for a launch earlier than May 27, 2014. Ranbaxy disagreed, maintaining that the two ANDAs are too factually dissimilar to justify such an inference.

1. New Evidence

The Plaintiffs produced three FDA internal memoranda regarding the agency's approval of Ranbaxy's generic Lipitor ANDA: (1) a May 11, 2011, memorandum from the Director of the Office of Compliance to the Director of the Center for Drug Evaluation and Research, Decl. A. Luke Smith ("Smith Decl."), Ex. 1, Mem. Director, May 11, 2011, Proposal Review Ranbaxy's Atorvastatin ANDA ("May Memo"), ECF No. 869-1, (2) a July 29, 2011, memorandum from the Branch Chief of the Regulatory Support Branch of the FDA's Office of Generic Drugs, Smith Decl., Ex. 2, Mem. Re-examination ANDA 076477 Substantial/Sufficient Completeness, July 29, 2011 ("July Memo"), ECF No. 869-2, and (3) a November 30, 2011, memorandum from the Deputy Director of the FDA's Office of Pharmaceutical Science's Center for Drug Evaluation and Research, Smith Decl., Ex. 6, Concerns Gave Rise Application Integrity Policy; OGD's Review of ANDA 076477, Nov. 30, 2011 ("Nov. Memo") 1, ECF No. 869-6.

The May 2011 memorandum examined the circumstances of Ranbaxy's generic Lipitor ANDA and recommended that the agency grant the ANDA an AIP exception. See May Memo 1. Among other factors, the memorandum observed that Ranbaxy's original ANDA, submitted in 2002, contained data collected at Paonta Sahib before problems began to arise at the facility, and that none of Ranbaxy's subsequent Lipitor ANDA amendments relied on Paonta Sahib data. May Memo 4. The document also reflects a serious concern with the possibility of regulatory bottleneck and set an internal goal of completing review by November 30, 2011. See id. at 5. This specifically referenced the generic entry date Ranbaxy had negotiated with Lipitor's brand manufacturer, Pfizer, in an earlier settlement agreement. See id. The document also set out specific criteria for evaluating Ranbaxy's amended Lipitor ANDA submissions to ensure that any concerns related to the AIP do not apply. Id. at 4-5.

In the July 2011 memorandum, the agency took the "extremely unusual" step of reexamining the Lipitor ANDA to determine whether it had been substantially complete at the time of its 2002 filing. July Memo 1. A finding that the ANDA was not substantially complete would have led to forfeiture of Ranbaxy's first-filer status, thus relieving any possibility of a regulatory bottleneck in the Lipitor market. The agency concluded that the application had been substantially complete,

id. at 2, 6-7, and that there was no evidence that data in the ANDA had been falsified.

The November 2011 memorandum documented the FDA's conclusion that the data submitted as part of Ranbaxy's amended Lipitor ANDA was reliable, overcoming concerns that the ANDA was still compromised by the problems that gave rise to the AIP. Nov. Memo 1. The FDA discussed Ranbaxy's newly submitted amendments and studies and determined that Ranbaxy had addressed outstanding concerns regarding manufacturing processes and data integrity. See id. at 2-4.

2. Analysis

The Plaintiffs contend these memoranda bolster the inference that if Ranbaxy had settled on an earlier negotiated entry date with AstraZeneca, the FDA would have granted expedited approval to Ranbaxy's Nexium ANDA in time for a launch before May 2014. The issue for this Court to determine is whether the similarities between Lipitor and Nexium sufficiently support such an inference. See Pls.' Mem. Supp. Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation (ECF # 641, 645) Based New Evidence ("Pls.' Ranbaxy Causation Reconsideration Mem.") 1, ECF No. 868. This inquiry primarily bears on the second but-for scenario proffered by the Plaintiffs in their original motion, under which Ranbaxy settles with AstraZeneca and negotiates a generic entry date

after the February 2009 AIP but before the January 2012 consent decree.[10]

First, the Plaintiffs argue that the FDA's evident concern about the prospect of a regulatory bottleneck in the generic Lipitor market shows that the agency would have had the same concerns about generic Nexium. See id. at 11-12. Ranbaxy does not seriously dispute that the FDA expedited its approval of generic Lipitor to avoid a regulatory bottleneck, but it relies on the fact that unlike generic Nexium, generic Lipitor was a "pre-MMA" drug, having been submitted for ANDA approval before the passage of the MMA in 2003. See Ranbaxy's Opp'n Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mots. Summ. J. Due Lack Causation Based New Evidence ("Ranbaxy Causation Reconsideration Opp'n") 11, ECF No. 882. As a "post-MMA" drug, generic Nexium was subject to new forfeiture provisions added to the Hatch-Waxman Act. Thus, according to Ranbaxy, the FDA would not have been as concerned about a bottleneck in the generic Nexium market, because there were more avenues for Ranbaxy to

[10] The Plaintiffs do not supply evidence that would warrant reconsideration of the first and third counterfactual scenarios proposed in their original motion. The evidence does not touch on the possibility that Ranbaxy could have come to market before February 2009. The evidence also does not clearly address the January 2012 consent decree, nor does it offer further insight into how Ranbaxy would have been able to comply with it in time to launch before May 2014.

lose its first-filer exclusivity and allow other firms to enter the market. Ranbaxy Causation Reconsideration Opp'n 12.

The Plaintiffs reasonably point out, however, that in reality, the Lipitor and Nexium ANDAs were subject to effectively the same risk of forfeiture. See Pls.' Ranbaxy Causation Reconsideration Mem. 16. For one thing, some of the MMA's forfeiture provisions were not relevant to generic Nexium in the time period at issue.[11] More importantly, the provisions which were relevant had, in practice, also applied to generic Lipitor at the time of the FDA's Lipitor ANDA review. The Plaintiffs sufficiently demonstrate that the FDA's concern with regulatory bottlenecks led it to insist that Ranbaxy agree to forfeit its exclusivity if it did not come to market by a certain time. See May Memo 3-4. This agreement was similar in effect to those provisions which are now required by the MMA. Compare id., with 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa), (bb)(AA).

Accordingly, the fact that the MMA took effect between the two Ranbaxy ANDAs does not, by itself, necessitate summary

[11] For example, the MMA provides for first-filer exclusivity forfeiture if the first filer does not timely obtain tentative ANDA approval, or if the first filer does not timely come to market after a final court judgment that the underlying patents are invalid, unenforceable, or not infringed. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa), (bb)(AA). As is well-established in the record by now, Ranbaxy received timely tentative approval, and its settlement with AstraZeneca ensured that there would be no final judgment of patent invalidity, unenforceability, or lack of infringement.

judgment. A reasonable jury could infer that the FDA would have been as concerned about the possibility of a regulatory bottleneck for generic Nexium as it was for generic Lipitor.

It still need not follow, however, that the FDA would have granted final approval to generic Nexium in time for a pre-May 2014 launch.

The Plaintiffs argue that new evidence, showing why the FDA granted an exception to its AIP for Ranbaxy's generic Lipitor ANDA, strengthens the inference that the FDA would have granted the same exception to generic Nexium in a but-for world. See Pls.' Ranbaxy Casuation Reconsideration Mem. 12-14. This presumes that because the FDA's reasons for granting an AIP exception to generic Lipitor apply equally to generic Nexium, an earlier agreed-upon generic Nexium entry date would have motivated the FDA to avoid a regulatory bottleneck by granting a speedy exception, as it did for Lipitor.

The newly-submitted evidence does not convincingly show that the FDA's basis for granting Lipitor an exception applies equally to Nexium. Ranbaxy notes that its generic Lipitor ANDA was based on Paonta Sahib data collected, at the latest, in 2002, while its generic Nexium ANDA was based on Paonta Sahib data from 2005. See Ranbaxy Causation Reconsideration Opp'n 11. This is crucial, because quality control problems at the facility do not appear to have arisen until after 2002. See May

Memo 4 (citing findings "that the [Paonta Sahib] practices at issue arose during a time period after 2002"). Indeed, several of the FDA's justifications for granting an AIP exception to the generic Lipitor ANDA were based on the fact that all the underlying data were collected before problems arose at Paonta Sahib or from other, more reliable facilities. See May Memo 4.

In contrast, the generic Nexium ANDA relied on Paonta Sahib data collected in the midst of the facility's regulatory troubles. Ranbaxy Causation Reconsideration Opp'n 11. Presumably, Ranbaxy would have had to completely repopulate its Nexium ANDA with clean data to receive an AIP exception under the standards the FDA applied to Lipitor. While it is reasonable to infer that Ranbaxy would have done this, there is no evidence in the record about what new data the FDA would have required, how much data would have to be collected, or how long it would have taken to produce this data. Such gaps in the factual record make it difficult to infer that the FDA would have approved an AIP exemption here. Cf. Florida Audubon, 94 F.3d at 670 ("The greater the number of uncertain links in a causal chain, the less likely it is that the entire chain will hold true.").

The Court does not overlook the fact that the FDA did cite the risk of regulatory bottleneck as a reason for granting an AIP exception to Lipitor; this concern likely would have counted

in Nexium's favor as well. See May Memo 4-5. But the FDA ultimately ruled that "the overall circumstances [around the Lipitor ANDA] are such that the agency believes it will be able to determine whether the data and information as amended are reliable and whether the ANDA meets the requirements for approval." Id. at 5. The summary judgment record continues to lack evidence of whether a Nexium ANDA would have met these requirements, and there is weak support for finding that the FDA would have granted Ranbaxy an AIP exception for its Nexium ANDA.

Even assuming, however, that the FDA would have granted an AIP exception and reviewed the Nexium ANDA, there is still little evidence that the agency would have given final approval to the Nexium ANDA. The evidence shows that even after granting an AIP exception to the generic Lipitor ANDA, the FDA examined Ranbaxy's subsequent submissions carefully to ensure that they "were free of the concerns which gave rise to the AIP." May Memo 3. The FDA ultimately concluded that they were, noting that Ranbaxy had substituted all Paonta Sahib data with new data from Ohm, and that Ranbaxy had changed the chemical structure of its generic Lipitor product's active pharmaceutical ingredient. Nov. Memo 4.

It is unclear from the record as presented whether making comparable changes to the generic Nexium application would have been as straightforward, and whether they would have allayed the

FDA's concerns after granting an AIP exception. The Plaintiffs fail to indicate how long it would take to produce new data at the Ohm site, whether pharmacological changes similar to generic Lipitor's would be required, and if so, how long they would take to implement. Neither is there evidence comparing the technical challenges Ranbaxy faced in getting generic Lipitor approved to the kinds of challenges Ranbaxy would have faced vis-à-vis Nexium. The fact-intensive nature of the FDA approval process requires this kind of evidence before the Plaintiffs' proposed inferences can be considered reasonable.

Finally, Ranbaxy would have had to satisfy the FDA's criteria for final approval separate and apart from the AIP issues. The Plaintiffs implicitly argue that because the ANDA received tentative approval in 2008, final approval would not have been difficult to obtain. That is not so clear. Responding to the AIP likely would have required Ranbaxy to produce new data to support an amended ANDA. See Pls.' Reply Ranbaxy's Opp'n Pls.' Mot. Reconsideration AstraZeneca's & Ranbaxy's Mot. Summ. J. Due To Lack of Causation Based on New Evidence 9, ECF No. 889. It is conceivable that preparing such data to meet the standards that were met at the tentative approval stage might require considerable effort. See 21 U.S.C. § 355(j)(2)(A)(iii)-(iv) (requiring ANDAs to demonstrate, for example, that the brand drug and proposed generic drug have the

same "route of administration," "dosage form," and strength, and that they are bioequivalent); id. at § 355(j)(5)(B)(iv)(II)(dd) (providing that tentative approval cannot be granted unless these requirements are met).

While evidence that the FDA would have granted timely approval of generic Nexium need not be conclusive at the summary judgment stage, the causality inquiry does require that there is some evidence to support all the causal links. See Twin Cities Bakery, 2005 WL 3675999, at *5. The Plaintiffs ably describe how Ranbaxy could have navigated the approval process, and their new evidence does bolster the inference that Nexium and Lipitor are apt analogues. See Pls.' Reply 13-14. But the Plaintiffs' logical chain still requires some evidence that generic Nexium would have successfully followed each major step of Lipitor's path to FDA approval. Here, there is insufficient evidence that it would have done so.

For these reasons, this Court DENIED the Plaintiffs' motion for reconsideration, ECF No. 867, on April 16, 2004. Elec. Clerk's Notes, Apr. 16, 2014, ECF No. 902.

D. AstraZeneca's Motion for Summary Judgment on the Basis of Causation [ECF No. 645]

AstraZeneca also moved for summary judgment on all of the Plaintiffs' complaints on the basis that the Plaintiffs are unable to establish antitrust causation. AstraZeneca Defs.'

Mot. Summ. J. Basis Causation, ECF No. 645. Noting that they "incorporate[d] by reference the arguments on this issue made by Ranbaxy . . . by Teva . . . and by DRL," AstraZeneca provided only highlights of the main arguments in support of summary judgment in their favor. Mem. Supp. AstraZeneca Defs.' Mot. Summ. J. Basis Causation 1, ECF No. 655. For the sake of avoiding repetition, this Court's explanation in regards to the Ranbaxy agreement has been addressed above, and its explanation in regards to Teva and DRL will be addressed in the succeeding sections. The ruling on this particular motion was as follows: AstraZeneca's Motion for Summary Judgment on the Basis of Causation is GRANTED in regards to Ranbaxy, DENIED in regards to Teva, and GRANTED in regards to DRL.

The net effect of these rulings is that the Ranbaxy Settlement is not a basis for imposing antitrust liability.

V. MOTIONS FOR SUMMARY JUDGMENT AS TO THE TEVA SETTLEMENT [ECF NOS. 600, 606, 644, 864]

The Court turns next to the settlement made between AstraZeneca and Teva (the "Teva Settlement"). This settlement is the focus of two motions for summary judgment brought by Teva, one for lack of a "large and unjustified" reverse payment, Teva Defs.' Mot. Summ. J. Based Absence Reverse Payment Teva,

ECF No. 600, and another based on a lack of causation, Teva Defs.' Mot. Summ. J. Based Lack Causation, ECF No. 606.

Teva's reverse payment motion is like Ranbaxy's, in that it disputes the valuation of an agreement ancillary to the Teva Settlement. But whereas Ranbaxy's motion turned on how much it stood to gain from its side agreements with AstraZeneca, Teva's motion focused on how much it saved by settling the Nexium lawsuit and a case involving another AstraZeneca drug at the same time. Litigation of this motion turned into a battle of the experts. The Court initially granted Teva's motion, Order, Feb. 12, 2014, ¶ 4, but upon a motion for reconsideration and the belated presentation of new expert analysis, Pls.' Mot. (1) Under Rule 6(b)(1)(B) & (2) For Reconsideration Teva's Mot. Summ. J. Based Absence Reverse Payment Teva (ECF No. 600) & AstraZeneca's Mot. Summ. J. All Claims Arising AstraZeneca's Settlements Teva & DRL (ECF No. 644); & Pls.' Opp'n Teva's Supplemental Brief Based New McGuire Rpt. (ECF No. 855) ("Pls.' Mot. Reconsideration"), ECF No. 864, the Court reversed its decision. Elec. Clerk's Notes, Apr. 16, 2014; see also Elec. Endorsement, June 2, 2014, ECF No. 940.

Teva's causation motion differs from the one brought by Ranbaxy as well, in that it relies heavily on the proposition that because Teva was not a first filer for generic Nexium, the bottleneck created by Ranbaxy's marketing exclusivity period was

an intervening proximate cause of the Plaintiffs' alleged antitrust injuries. The Court denied summary judgment, however, ruling that the Plaintiffs have provided enough evidence to support a reasonable inference that, but for the Teva Settlement, Teva would have found a way to overcome Ranbaxy's first filer privilege and enter the generic Nexium market before May 27, 2014. Order, Feb. 12, 2014, ¶ 5. For the same reasons, the Court also partially denied AstraZeneca's derivative motion for summary judgment based on causation, AstraZeneca Defs.' Mot. Summ. J. Basis Causation, ECF No. 645, as to the Teva Settlement. Order, Feb. 12, 2014, ¶ 10.

A. Teva's Motion for Summary Judgment Based on the Absence of a Reverse Payment [ECF No. 600] and the Plaintiffs' Motion for Reconsideration [ECF No. 864]

A bit of procedural history is warranted here. When this Court heard oral arguments on Teva's motion for summary judgment based on the absence of a reverse payment on January 21, 2014, it also addressed the admissibility of several of the Plaintiffs' expert reports. See Elec. Clerk's Notes, Jan. 21, 2014, ECF No. 846. At this hearing, the Court granted the Defendants' motion to exclude the testimony of Shashank Upadye and John Thomas. Id.; see Mot. Exclude Expert Testimony Thomas McGuire, Shashank Upadhye and John Thomas Relating Prilosec Litig., ECF No. 604. The Court also ruled that although Dr. Thomas McGuire is qualified to provide expert testimony for the

Plaintiffs on what royalty rate Teva and AstraZeneca reasonably would have negotiated for use of certain patents, any admissible report by him would have to be based on a judicially-acceptable analytical method for calculating a reasonable royalty rate. See Elec. Clerk's Notes, Jan. 21, 2014. The Court accordingly requested from the Plaintiffs a new report containing a so-called Georgia-Pacific analysis, named for the case which set out a fifteen-factor test for calculating reasonable royalty rates between pharmaceutical companies. See Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970).

Although the Plaintiffs responded by timely submitting a new expert opinion by Dr. McGuire to the Defendants, the Plaintiffs neglected to file a copy of Dr. McGuire's supplemental analysis with the Court. Having no admissible Plaintiffs' expert report before it, on February 12, 2014, this Court granted Teva's motion for summary judgment based on the absence of a reverse payment, Teva Defs.' Mot. Summ. J. Based Absence Reverse Payment Teva, ECF No. 600, and administratively closed this case -- an event that no doubt caught the attention of Plaintiffs' counsel. Order, Feb. 12, 2014, ECF No. 857.

The Plaintiffs, acknowledging their oversight, filed Dr. McGuire's supplemental report with the Court and moved for reconsideration of Teva's motion. Pls.' Mot. Reconsideration. Crediting counsel's explanation that failure to timely file with

the Court was inadvertent and that all other service deadlines were met, see Decl. Thomas M. Sobol, ECF No. 861; Decl. John D. Radice, 2-3, ECF No. 866, the Court accepted this supplemental report for consideration alongside the Plaintiffs' motion for reconsideration.

In choosing to review their new report, the Court provided a second opportunity for the Plaintiffs to demonstrate that Teva and AstraZeneca's settlement of a contingent liability related to AstraZeneca's brand drug, Prilosec, executed simultaneously with their Nexium settlement agreement, amounted to an illegal reverse payment under the Actavis standard. Upon review of the new expert report and following oral arguments heard on April 4, 2014, this Court granted the Plaintiffs' motion for reconsideration and denied Teva's motion for summary judgment based on the absence of a reverse payment. See Order, Apr. 17, 2014, ECF No. 902; see also Elec. Endorsement, June 2, 2014, ECF No. 940. Here, the Court explains its analysis of the various motions related to the existence of a reverse payment to Teva.

1. Undisputed Factual Background Germane to These Motions

Since 1989, AstraZeneca has been the brand manufacturer of Prilosec, a heartburn medication sold today in its generic form as omeprazole. Teva Defs.' Rule 56.1 Statement Undisputed Facts Supp. Mot. Summ. J. Based on Absence Reverse Payment Teva,

("Teva Reverse Payment Facts") ¶ 7, ECF No. 602. In 1999, a generic manufacturer, Impax, filed for FDA approval to market a generic version of Prilosec, prompting AstraZeneca to sue for patent infringement. Id. ¶ 8. In September 2004, Teva partnered with Impax to enter the generic Prilosec market at risk, selling omeprazole manufactured by Impax before the resolution of AstraZeneca's patent infringement lawsuit. Id. ¶ 9.

AstraZeneca, however, won its case. On May 31, 2007, a district court held that two of AstraZeneca's Prilosec patents were valid and infringed by the omeprazole manufactured by Impax and marketed by Teva. Id. ¶ 13. The Federal Circuit affirmed in August 2008, and the case was remanded to district court for an assessment of damages owed to AstraZeneca. Id.; see In re Omeprazole Patent Litig., 536 F.3d 1361, 1382 (Fed. Cir. 2008).

The parties settled, however, before a court judgment of damages was entered. AstraZeneca and Teva agreed that Teva would pay AstraZeneca $9,000,000 for Teva and Impax's infringement of the Prilosec patents. Id. ¶ 15. This agreement was entered into on January 6, 2010, the same day AstraZeneca and Teva signed their settlement agreement related to Nexium. Id. The Plaintiffs have evinced evidence that the two agreements were negotiated simultaneously: both cases were discussed during the same settlement meetings, and drafts of

both agreements were circulated on the same dates. Direct Purchaser & End-Payor Class Pls.' Local Rule 56.1 Response Teva Defs.' Mot. Summ. J. Based Absence Reverse Payment (ECF No. 600), Statement Additional Mat. Facts ("Pls.' Add'l Reverse Payment Facts") ¶¶ 108-111, ECF No. 775.

2. Legal Standard: Reasonable Royalty Damages

The Plaintiffs seek to prove that the $9,000,000 settlement paid by Teva to AstraZeneca for the Prilosec patent infringement lawsuit was so far below what it would have been required to pay had damages been assessed in litigation, a reasonable jury could find that it constituted a reverse payment to Teva to induce it into delaying its generic Nexium product. Direct Purchaser & End-Payor Pls.' Mem. Opp'n Teva Defs.' Mot. Summ. J. Based Absence Reverse Payment (ECF No. 600), ECF No. 770.

Under federal patent law, an infringer liable for damages must compensate the patent holder either for lost profits or at least for reasonable royalty damages, along with interests and costs as fixed by the deciding court. 35 U.S.C. § 284. Reasonable royalty damages measure the amount in royalties that the infringer would have paid to the patent holder if the technology had been properly licensed during the period of infringement. Teva Reverse Payment Facts ¶ 14.
Evidence in the record shows that prior to settlement, AstraZeneca forewent lost profits damages and specifically

sought reasonable royalty damages. See Teva Defs.' Mem. Supp. Mot. Exclude Proposed Expert Testimony Thomas McGuire, Shashank Upadhye & John Thomas Relating Prilosec Litig. ("Teva Mem. Exclude") 2, ECF No. 605.

The most commonly accepted methodology for the calculation of reasonable royalty damages is the Georgia-Pacific "hypothetical negotiation" approach, which is based on the premise of a negotiation between a "willing licensor" and "willing licensee" at the time the infringement began. See Rite-Hite Corp. v. Kelley Co., Inc., 56 F. 3d 1538, 1554 (Fed. Cir. 1995). In the seminal case, the district court identified fifteen factors to be considered in determining an appropriate percentage royalty rate, which is then multiplied by a royalty base, representing the amount of infringing sales earned, to yield a reasonable royalty damages calculation. See Georgia-Pacific Corp., 318 F. Supp. at 1120, 1143; see also id. at 1120 (including in its list of "pertinent" evidentiary factors "the rates paid by the licensee for the use of other patents comparable to the patent in suit"). As the Court has done on previous occasions, this approach is adopted as the accepted methodology for this case.

3. The Parties' Expert Reports

To prove that the damages Teva paid for its infringement of AstraZeneca's Prilosec patents were significantly discounted,

the Plaintiffs rely on expert testimony purporting to estimate the amount of Prilosec damages Teva actually owed. The Defendants counter with their own expert testimony offering a much lower damages valuation. A brief overview of their reasonable royalty calculations is provided here.

In his initial expert report for the Plaintiffs, Dr. McGuire's key conclusion was his calculation that Teva owed AstraZeneca at least $34,000,000 in damages, a significantly greater amount than the $9,000,000 Teva actually paid. Direct Purchaser & End-Payor Class Pls.' Mem. Opp'n Teva Defs.' Mot. Summ. J. Based Absence Reverse Payment ("Pls.' Mem. Reverse Payment"), 1, 5, 6, ECF No. 770. Dr. McGuire's calculations, however, relied on an "80 percent fee" method, which approximates the profit-sharing rate that AstraZeneca and Teva may have reached on the basis of other agreements AstraZeneca had brokered. Teva Mem. Exclude 6, 19. Because this is not an accepted method for calculating reasonable royalty damages, the Court cannot accord any weight to Dr. McGuire's initial conclusions and ruled as such last January. Order, Feb, 12, 2014, ECF No. 857.

In contrast, Teva's expert, Philip Green, an intellectual property consultant with experience in license negotiations and valuations, conducted a Georgia-Pacific analysis and estimated that Teva and AstraZeneca would have negotiated a reasonable

royalty rate between 10 and 20 percent of sales for use of the Prilosec patents. Decl. Laurence A. Schoen, Ex. 13, Expert Rpt. Philip Green ("Green Rpt.") 20, ECF No. 671. Green determined that the appropriate royalty base for purposes of a royalty calculation would have been $41,068,000, the amount of Teva's net sales of omeprazole during the period of infringement. Id. at 22. From this, he calculated that absent settlement, Teva would have negotiated a reasonable royalty rate between 10-20 percent, paying damages to AstraZeneca between $4,110,000 and $8,220,000. Id. Green's conclusion, therefore, was that Teva's $9,000,000 damages payment, falling slightly above this upper range, was "consistent with the amount that AstraZeneca reasonably would have recovered in the Prilosec litigation." Id. at 30.

Faced with the prospect of leaving Green's conclusions unrebutted, the Plaintiffs have since submitted a supplemental report by Dr. McGuire which utilizes a comprehensive Georgia-Pacific analysis. In it, Dr. McGuire estimates that a hypothetical negotiation between Teva and AstraZeneca would have yielded a 60 percent royalty rate. Notice Filing Supp. Rpt. Thomas G. McGuire, Ex. 1, Supplemental Rpt. Thomas G. McGuire Reas. Royalty Analysis AstraZeneca & Teva Patent Settlement ("McGuire Supp. Rpt.") 1-2, ECF No. 860-1. He also determines that the appropriate royalty base on which to base a royalty

calculation is $43,000,000,000, representing an estimate of Teva's profits from omeprazole during the period of infringement. Id. at 18-19. Accounting for prejudgment interest, these inputs yield a total hypothetical damages payment of $33,100,000. Id. at 1-2. Dr. McGuire also proposes that AstraZeneca saved $2,000,000 in litigation costs by settling with Teva instead of litigating damages in court. Id. at 23 tbl. 3. Although somewhat different from his initial estimates, Dr. McGuire's calculations are starkly different from Green's and suggest a reverse payment of approximately $22,100,000 to Teva in consideration of its delay in launching generic Nexium. Id. at 3.

4. Teva's Opposition to the Supplemental McGuire Report

Teva complains bitterly (and with considerable merit) that the Court's consideration of Dr. McGuire's supplemental report does violence to the case management order and allows an unfair supplementation of the evidentiary record after the Court's original ruling that the Plaintiffs' original evidence was legally insufficient. Order, Feb. 12, 2014, ECF No. 857. The Court is not troubled.

Trials are not sublimated "Hunger Games." Trial experts are not the source of primary evidence. They merely provide the jury with a potential means for analyzing that evidence. Here

the primary evidence is what it is. The Court's recognized procedure for dealing with such experts adequately protects Teva from prejudice. First, as is always the case for every expert proffered pursuant to Fed. R. Evid. 702, Dr. McGuire's report must be to the level of exquisite detail of a patent claim. Order, Jan. 8, 2014, ECF No. 724. Second, no expert will give any testimony not in that expert's report. Third, in this Court, the basis for the expert's opinion must be laid out in testimony before the ultimate opinion is adduced, as is permitted by Fed. R. Evid. 703. This will provide for a fair trial.[12]

Pursuant to Fed. R. Civ. P. 54(b), the Court can revise an interlocutory order at any time prior to entry of a judgment adjudicating all claims. The First Circuit has outlined the circumstances warranting a motion for reconsideration: "if the moving party presents newly discovered evidence, if there has been an intervening change in the law, or if the movant can demonstrate that the original decision was based on a manifest

[12] That said, it is true that had the Court been able to adhere to its original March trial date (it was not due to the unexpected obligation to try a massive criminal case, United States v. O'Brien, 4:12-cr-40026-WGY), the Plaintiffs would have been caught short and their carefully constructed theory would have collapsed, as McGuire's originally flawed methodology was (and is) unacceptable to the Court. It is only the unavoidable continuance of the case to the October running trial list that has permitted the Plaintiffs to cobble together this theoretically acceptable analysis.

error of law or was clearly unjust." United States v. Allen, 573 F.3d 42, 53 (1st Cir. 2009). Similarly, a motion for reconsideration can be granted if the court has "patently misunderstood" a party or made an error "not of reasoning but of apprehension." Ruiz Rivera v. Pfizer Pharm., LLC, 521 F.3d 76, 82 (1st Cir. 2008). Here, because the primary reason for the Court's grant of Teva's motion for summary judgment was based on its "understandable misimpression" that McGuire had failed to provide an acceptable reasonable royalty analysis, the Court reconsiders its order as an error "not of reasoning but of apprehension." Pls.' Mem. Law Supp. (1) Mot. Rule 6(b)(1)(B) & (2) Mot. Reconsideration Teva's Mot. Summ. J. Based Absence Reverse Payment Teva (ECF No. 600) & AstraZeneca's Mot. Summ. J. All Claims Arising AstraZeneca's Settlements Teva & DRL (ECF No. 644); & Pls.' Opp'n Teva's Supplemental Br. Based New McGuire Rpt. (ECF No. 855) ("Pls.' McGuire Reconsideration Mem.") 10, ECF No. 865.

Balked at getting the Court to ignore Dr. McGuire's late filed report altogether, Teva mounts a frontal attack on it. Upon being served with Dr. McGuire's new report and following a second deposition, Teva filed a supplemental brief seeking to exclude Dr. McGuire's testimony at trial. See Teva's Supplemental Br. Based New McGuire Expert Rpt. Supp. Mot.

Exclude McGuire's Testimony [ECF No. 604] & Mot. Summ. J. [ECF No. 600] ("Teva Opp'n New McGuire Rpt."), ECF No. 855.

Specifically, Teva contests: (1) Dr. McGuire's reliance on generic drug distribution agreements entered into between AstraZeneca and Ranbaxy, rather than patent license agreements, as comparative royalty benchmarks, id. at 4, (2) Dr. McGuire's proposed royalty base, id. at 11, and (3) the lack of explanation for Dr. McGuire's estimate that AstraZeneca saved $2,000,000 in litigation costs by settling both the Prilosec and Nexium litigations with Teva in 2010, id. at 12. Generally, Teva argues that because its $9,000,000 payment to AstraZeneca falls within the range of reasonable royalty estimates offered by Green and Dr. McGuire, the Court is bound by Supreme Court precedent to conclude "that the Prilosec settlement was within the range of reasonableness under any standard." Teva Opp'n New McGuire Rpt. 13 (positing that the Actavis Court "rejected" the second-guessing of patents damages settlements and provided a safe harbor for discounted settlements as long as they are "commonplace").

The Plaintiffs have responded to Teva's arguments with varying degrees of success. For example, Dr. McGuire sufficiently justifies his use of distribution agreements as comparators by explaining that "the Georgia-Pacific [test] . . . involves a kind of bargaining which is also the domain of

economics," making it "natural . . . to look to evidence of business arrangements between the parties regarding the products that were at issue here and to examine the kind of business relationships they had." Pls.' McGuire Reconsideration Mem. 14.

On the other hand, the Court agrees with Teva that the Plaintiffs have failed to provide any real evidence of AstraZeneca's actual or estimated litigation costs amounting to $2,000,000. The Plaintiffs assert that they sought discovery on Teva to bolster this specific claim and were met with resistance. See id. at 18. As a result, they may well be protected from surprise evidence being introduced at trial that contradicts Dr. McGuire's estimated savings. See Elec. Clerk's Notes, July 11, 2014, ECF No. 966 (setting out the Court's order barring any party from proffering evidence on subjects as to which that party has asserted the attorney-client privilege). This does not change the fact that Dr. McGuire's explanation of saved litigation costs is so lacking in analysis that it cannot be useful to any jury.

Even Teva's strongest criticisms, however, appear to go more to the weight of Dr. McGuire's opinions, rather than their admissibility. Dr. McGuire's estimated litigation savings, for example, do not affect his conclusion that Teva and AstraZeneca would have negotiated a 60 percent royalty rate for the use of the Prilosec patents absent settlement. Teva also does not

challenge the fact that Dr. McGuire was able to produce damage calculations far exceeding Teva's $9,000,000 actual payment under a variety of royalty rates, even under Green's lower proposed royalty base. See McGuire Supp. Rpt. 22.

More generally, Teva boldly proclaims that even if Dr. McGuire's new report is admissible, a reverse payment of $22,100,000 is "per se" lawful under the supposed safe harbor provisions in Actavis. Teva Opp'n New McGuire Rpt. 14-15. But the Supreme Court has rather explicitly prohibited settlements that delay generic entry:

> In the traditional examples cited above, a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim. In reverse payment settlements, in contrast, a party with no claim for damages (something that is usually true of a [patent] litigation defendant) walks away with money simply so it will stay away from the patentee's market. That, we think, is something quite different.

Actavis, 133 S. Ct. at 2233. Teva's attempts to characterize its settlements as free from antitrust scrutiny, just because one side obtained less than it demanded in negotiation, simply cannot stand.

The central question presented by these motions is whether a savings of $22,100,000 (or any of the various proposed savings amounts) constituted a significant forgiveness of debt intended to induce Teva to delay its entry into the market for generic Nexium. The Court is faced with determining whether this is an

appropriate question to put to a jury. Ultimately, Dr. McGuire has dutifully provided a thorough Georgia-Pacific analysis supporting his royalty rate determination. Since at summary judgment, the Court must draw all reasonable inferences in the Plaintiffs' favor, his conclusions sufficiently demonstrate a significant forgiveness of debt to support a reasonable inference that Teva received a reverse payment to delay its generic Nexium launch. As a result, this Court GRANTED the Plaintiffs' motion for reconsideration regarding Teva's motion for summary judgment on the absence of a reverse payment. The evidence in the record appears to warrant a jury trial, if the Plaintiffs can sufficiently meet their burden of proof as to antitrust causation, the matter to which the Court now turns.

B. Teva's Motion for Summary Judgment on the Basis of Causation [ECF No. 606]

In its motion for summary judgment based on causation, Teva sought disposition of all claims against it on the ground that the Plaintiffs have failed to meet their burden of proving that the Teva Settlement caused their antitrust injuries. Teva Defs.' Mot. Summ. J. Based Lack Causation, ECF No. 606. The Plaintiffs' theory of causation hinges on the proposition that Teva was willing and ready to launch a generic version of Nexium as early as 2009, but that it reversed course upon entering a settlement agreement with AstraZeneca in 2010. Direct Purchaser

& End-Payor Class Pls.' Opp'n [606] Teva's Mot. Summ. J. Based Lack Causation ("Pls.' Mem. Causation") 2-3, ECF No. 789. The Plaintiffs argue that this settlement injured them because it effectively postponed Teva's generic Nexium launch date until May 27, 2014, because Teva would have entered the market at an earlier date but for entering into the settlement. Id.

Teva attacks this theory on two fronts. Its primary argument for summary judgment is that the proximate cause of the Plaintiffs' alleged injuries was actually the intervening fact of Ranbaxy's 180-day period of marketing exclusivity, not Teva's settlement with AstraZeneca. Teva Defs.' Mem. Supp. Mot. Summ. J. Based Lack Causation ("Teva Mem. Causation") 9, ECF No. 607. Teva also argues that the Plaintiffs cannot prove their contention that absent its AstraZeneca settlement agreement, Teva would have entered the market earlier than May 27, 2014. Id. at 12.

1. Burden of Proof

As a preliminary matter, the parties starkly disagree as to who bears what burden of proof at this stage of the litigation. The Plaintiffs argue that Teva bears the burden of proving its affirmative defense that Ranbaxy's exclusivity period was the superseding cause of the Plaintiffs' injury. Pls.' Mem. Causation 5. According to the Plaintiffs, Teva "is entitled to summary judgment only if it offers conclusive proof that its

sloth in pursuing approval was not a cause." Id. at 5, n.24 (citing Ritch v. AM Gen. Corp., No. Civ. 93-451-SD, 1997 WL 834214, at *5 (D.N.H. Nov. 17, 1997); and Flight Int'l, Inc. v. Allied Signal, Inc., No. 94-55289, 59 F.3d 175, slip op. at *4 (9th Cir. June 20, 1995) ("Comparative negligence and superseding causation are, however, affirmative defenses on which the defendant has the burden of proof . . . ."). Teva counters that the Plaintiffs must first meet their burden of proving but-for causation. It further protests that the Plaintiffs are attempting to "re-cast longstanding causation requirements as an affirmative defense." Teva Defs.' Reply Supp. Their Mot. [ECF No. 606] Summ. J. Based Lack Causation ("Teva Reply") 2, ECF No. 815.

The legal standard is clear to the Court. Although the Plaintiffs attempt to shift their burden of proof to the Defendants, this Court rules that at the summary judgment stage, the Plaintiffs are required to demonstrate sufficient evidence to support a reasonable jury verdict in their favor. This means that the Plaintiffs bear the burden of evincing evidence that would enable a reasonable jury to find each core element of an antitrust claim -- including causation. See Sullivan, 34 F.3d at 1099; see also Hovenkamp, supra, at 23-24 ("What the Actavis majority stated was that the presumptions continue to lie with the defendant, thus giving the plaintiff the burden of proof. .

. . . Here the Court was clear that more abbreviated proof than ordinarily attends the full rule of reason was available for both power and anticompetitive effects.").

2. Analysis

Beyond the issue of burden of proof, the merits of the parties' arguments as to causation turn on questions of fact.

Teva argues that it is beyond dispute that Ranbaxy's first-filer status was the actual proximate cause of the Plaintiffs' antitrust injuries. Teva Mem. Causation 9. Such a finding would not only absolve Teva, but also its co-Defendants, since, as has been explicated, no antitrust injury exists where a regulatory or statutory scheme lawfully forecloses market entry. See RSA Media, Inc., 260 F.3d at 15.

To make out its argument, Teva points to two major undisputed facts and treats them as dispositive: (1) Teva still does not have tentative or final FDA approval of its generic Nexium product, and (2) Teva was not the first ANDA filer for generic Nexium, meaning that it could not obtain final approval of its product until the end of Ranbaxy's 180-day exclusivity period. Teva Reply 1. According to Teva, the inquiry begins and ends here, because it purports that these facts are the sole and direct cause of Teva's failure to enter the generic Nexium market before May 27, 2014. See id. at 3 (citing Bristol-Myers Squibb Co. v. Copley Pharm., Inc., 144 F. Supp. 2d 21, 23 (D.

Mass. 2000) (Tauro, J.); and RSA Media Inc., 260 F.3d at 13); see also id. at 5 ("The undisputed fact that Teva lacks tentative approval is enough for summary judgment.").

The Court declines to adopt such a cursory approach to this subject. If Teva could have gone to market and deliberately stalled that opportunity as a result of its settlement with AstraZeneca, the Teva Settlement could have been at least a significant cause of Teva's delayed market entry, irrespective of other hurdles. The Court's duty is to decide whether it is reasonable to infer that the Plaintiffs' assumptions regarding Teva's ability to come to market are true. Since the Plaintiffs bear the burden of proving antitrust causation, the Court reaches its decision by considering the facts and theories they have presented.

Their argument has two key elements. First, the Plaintiffs contend that Teva could have obtained tentative FDA approval of its generic Nexium product well before May 2014, and that the company abruptly changed course as a result of AstraZeneca's Nexium settlements. Second, the Plaintiffs attack Teva's contention that Ranbaxy's first-filer status is the actual cause of their injuries, outlining two specific ways Teva could have entered the market before or simultaneously with Ranbaxy. Direct Purchaser & End-Payor Class Pls.' Opp'n [606] Teva's Mot. Summ. J. Based Lack Causation, Ex. 1, Class Pls.' Opp'n [608]

Teva's Statement Undisputed Facts Relating Causation ("Pls.' Causation Facts.") ¶ 18, ECF No. 789-1. Together, these elements construct a but-for scenario under which Teva would have obtained FDA approval of its Nexium ANDA and overcome Ranbaxy's first-filer marketing exclusivity rights, coming to market significantly earlier than May 2014.

Finding the Plaintiffs' evidence and legal arguments to be far more crystallized and grounded here than in their oppositions to the Ranbaxy and DRL motions for summary judgment, the Court denies Teva's motion for summary judgment based on causation.

a. Teva's Ability to Obtain FDA Approval

The Plaintiffs proffer a theory that Teva was close to obtaining tentative FDA approval for its generic Nexium product, but that it changed course in response to AstraZeneca's settlements by diverting its efforts to other projects. See Pls.' Mem. Causation 18. They point to evidence suggesting that before the settlements, Teva appears to have placed a high priority on its Nexium ANDA. A February 2007 e-mail stated that Teva was "initiating launch planning activities for Esomeprazole DR Capsules," and the message was accompanied by an attachment titled, "Launch Readiness date: July 2008." Pls.' Causation Facts 11 n.23. In a March 2008 e-mail to Teva's manufacturing partner Cipla, regarding pending chemistry analysis results

required for FDA approval, a Teva regulatory affairs director stated: "We need [chemistry data] today -- we cannot wait until tomorrow. Kindly pull whatever resources you have to pull in order to provide these documents to us today." Id.

In contrast with this sense of urgency, notes and messages apparently written after AstraZeneca's April 2008 settlement with Ranbaxy indicate that Teva's efforts to obtain FDA approval were put "on hold" and that its projected generic Nexium launch had been "[m]oved out to [May] 2014." Id. at 11 n. 23. These communications are consistent with directions Teva gave Cipla in September 2010 to "hold off [on] manufacturing" preparatory batches of generic Nexium. Id. The Plaintiffs also point out that it took the company nearly three years to deliver a straightforward response to an August 2008 letter from the FDA commenting on Teva's Nexium ANDA. Id. at 11.

As the Plaintiffs frame it, this change in course is even more striking given how close Teva was to obtaining tentative approval. As of 2009, Teva had passed FDA review in two out of three categories necessary for tentative approval and needed only to satisfy requirements in the third category, chemistry analysis, to complete its ANDA process. Id. at 10 nn. 19, 22. In mid-2009, Teva described its ANDA status as being "in an approvable state" when it met with Ranbaxy and another

manufacturer, Daiichi, to discuss potential generic Nexium launch partnerships. Id. at 10 n. 19.

Whether Teva actually was close to obtaining approval is hotly disputed by the parties. For instance, the FDA questioned Teva's chemical formulation of the active ingredient in its proposed drug, and the parties disagree as to whether this is a significant hurdle or a minor one. See Teva Mem. Causation 7; Pls.' Causation Facts 13-14. Teva also asserts that any progress it could have made towards obtaining approval has been hindered by business conflicts with Cipla in 2012 and 2013, while the Plaintiffs respond that Teva and Cipla's positive and efficient working relationship in the preceding years could easily have yielded a generic Nexium launch years ago. See Teva Mem. Causation 7-8; Pls.' Causation Facts 14-15. The parties further dispute whether a 2012 request from the FDA for further tests presents a meaningful or minor obstacle to approval. See Teva Mem. Causation 8; Pls.' Causation Facts 15.

These factual issues going to Teva's readiness for launch, however, are not appropriately resolved at the summary judgment stage. The Plaintiffs have marshaled sufficient evidence in the record to demonstrate genuine and material factual disputes on this point. The timing and content of the change in tone of Teva's internal communications and documents, as well as Teva's agreement to set May 27, 2014 as a new proposed launch date,

provide ample grounds for a reasonable juror to conclude that Teva was well on its way to obtaining tentative approval as of early 2008, and that it has since slowed its progress in response to the terms of its settlement with AstraZeneca. Teva is free to combat these premises with evidence that other, more meaningful hurdles account for its delay in obtaining approval, but it must do so at trial.

b. Two "Scenarios" Which Would Allow for Earlier Market Entry: One May Work, the Other Does Not

The Plaintiffs' burden to prove causation, however, is not fully met by showing that Teva could have gained timely tentative FDA approval. The record must also support a reasonable inference that Teva could have entered the market before May 2014 in spite of Ranbaxy's 180-day marketing exclusivity period -- in other words, that Ranbaxy's exclusivity period was not a superseding cause of the Plaintiffs' antitrust injuries. To accomplish this, the Plaintiffs have presented two possible scenarios under which they claim Teva could have come to market before or with Ranbaxy.

The first scenario posits that Ranbaxy could have voluntarily relinquished its exclusivity rights and entered into a strategic partnership with Teva in jointly launching generic Nexium. Pls.' Mem. Causation 8. This is not unprecedented. The Plaintiffs point out that Teva has entered into such "share

in exclusivity" partnerships with Ranbaxy on at least two previous occasions where Ranbaxy was a first filer for the generic version of a drug. Pls.' Facts 16 n.35 (partnering in the launches of generic Accupril and generic Lipitor). Teva appears to have been interested in a similar partnership with regard to Nexium; there is evidence in the record of meetings between Teva and Ranbaxy in which Teva expresses a keen interest in partnering with Ranbaxy on any of Ranbaxy's first-to-file products, including Nexium. See Pls.' Mem. Causation 8 n.40. Standing alone, this evidence likely could not ward off summary judgment. But in conjunction with the genuine issues of material fact the Plaintiffs have already demonstrated, it is certainly relevant and further tips the scale in favor of denying summary judgment as to causation.

The Plaintiffs also posit an alternative scenario, arguing that a reasonable jury could find that if Teva had decided not to settle with AstraZeneca, Teva would ultimately have prevailed in its litigation and obtained final, non-appealable judgments that AstraZeneca's Nexium patents were invalid or not infringed. See Pls.' Mem. Causation 8. This would have triggered a regulatory provision under the Hatch-Waxman Act giving Ranbaxy a mere 75 days from the date of Teva's final judgment to either launch a generic Nexium product or lose its marketing exclusivity period. See 21 U.S.C. § 355(j)(5)(B), (D).

Conceivably, either choice would have led to an earlier availability of generic Nexium to consumers than the present reality.

This second scenario, however, is sheer speculation, and the Court pays it no mind. It is too speculative as matter of law to assume that Teva would have prevailed in all its actions and seen those rulings affirmed by the Federal Circuit.[13] Cf. Watson Pharm. Inc., 677 F.3d at 1313 ("[A] chance is only a chance, not a certainty."). Moreover, the Plaintiffs are unable to offer a reasonable timeline for when these lawsuits could have been won,[14] making it difficult to conclude that this scenario would have yielded a market entry date before May 2014.

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[13] Many commentators have pointed out the high reversal rate of patent decisions appealed to the Federal Circuit, particularly when claim construction issues are under review. See, Ted L. Field, "Judicial Hyperactivity" in the Federal Circuit: An Empirical Study, 46 U.S.F. L. Rev. 721, 722-23 (2012) (reviewing literature). Further, empirical studies have found that the Federal Circuit reverses claim construction decisions as much as 44 percent of the time. Id at 722. In patent cases overall, the Federal Circuit reversed 28.8 percent of decisions in the first half of 2010, while the Second, Fifth, Seventh, and Ninth Circuits' combined average reversal rate in January and February 2010 was 14.0 percent. Id. at 759 tbl. 9. The study concluded that, "the reversal rates of the Federal Circuit in patent cases were significantly greater than the reversal rates of the regional circuits." Id. at 776.

[14] Patent litigation in the federal courts frequently has been criticized for being slow and inefficient, due to unusually high reversal rates and problems with forum shopping. See Jeanne C. Fromer, Patentography, 85 N.Y.U. L. Rev. 1444, 1446,

Although some of these theories are weaker than others, the Plaintiffs are able to provide significant pieces of primary evidence, in the form of relevant emails, communications, business agreements, and FDA letters, which are enough for this Court to rule that the Plaintiffs can establish antitrust causation and survive summary judgment. The Court, thus, DENIED Teva's motion for summary judgment based on the lack of causation.

C. AstraZeneca's Motion for Summary Judgment on All Claims Arising From AstraZeneca's Settlements with Teva and DRL [ECF No. 644]

In the first wave of summary judgment motions last December, AstraZeneca filed a derivative motion for summary judgment on all claims arising from the Teva and DRL settlements, incorporating the reverse payment arguments presented by Teva and DRL in their respective motions for summary judgment.[15] AstraZeneca Defs.' Mot. Summ. J. All Claims

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1463 (2010); see also id. at 1465 ("[F]orum shopping can be economically inefficient because it can waste resources when litigants fight over the appropriate forum or when one litigant is severely inconvenienced by a remote forum choice."). One empirical study has found that the median time-to-trial for patent cases is around three years, although this varies across jurisdictions. PricewaterhouseCoopers, 2013 Patent Litigation Study 20-22, available at http://www.pwc.com/en_us/us/forensic-services/publications/assets/2013-patent-litigation-study.pdf.

[15] With regard to whether a reverse payment was made in these settlements, Teva and DRL are similarly situated. Both settlements, unlike the Ranbaxy settlement, involved the forgiveness of contingent liabilities. Also, as non-first-

Arising From AstraZeneca's Settlements Teva & DRL, ECF No. 644; see Mem. Supp. AstraZeneca Defs.' Mot. Summ. J. All Claims Arising AstraZeneca's Settlements Teva & DRL, ECF No. 657.

This Court originally ruled that this motion ought be granted, on the basis that the Plaintiffs had failed to demonstrate that Teva and DRL's settlements provided for "large and unjustified payment[s]" under Actavis. See Order, Feb. 12, 2014, ECF No. 857. The Court changed its decision, however, after it granted the Plaintiffs' motion for reconsideration as to Teva's motion for summary judgment based on the absence of a reverse payment. See Order, Apr. 16, 2014, ECF No. 902; Elec. Endorsement, June 4, 2014, ECF No. 940. Accordingly, the Court DENIED AstraZeneca's motion for summary judgment in regards to the claims arising from the Teva Settlement.

The resulting effect of the Court's rulings on these motions is that the Plaintiffs may pursue at trial antitrust claims based on the Teva Settlement.

VI. MOTION FOR SUMMARY JUDGMENT AS TO THE DRL SETTLEMENT [ECF NO. 594]

This leaves the Court to consider the specifics of the third Nexium settlement, made between AstraZeneca and DRL (the

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filers, both Teva and DRL faced the additional barrier to generic entry of being subject to Ranbaxy's 180-day marketing exclusivity period.

"DRL Settlement"). Unlike its Generic co-Defendants, DRL brought one motion for summary judgment that addressed issues of overarching conspiracy, reverse payment, and causation together. DRL's Mot. Summ. J. All Claims, ECF No. 594. The Court set out in full its analysis of overarching conspiracy and DRL's related motion for reconsideration supra, and so it will address only DRL's reverse payment and causation arguments in this section.

On the matter of whether a "large and unjustified" reverse payment was made to DRL, the discussion focused yet again on a separate agreement signed on the same day as DRL's Nexium settlement agreement. Like Teva, DRL simultaneously settled two AstraZeneca patent infringement lawsuits by entering said agreements. The Plaintiffs have not put forth the same quality of evidence, however, to show that the litigation costs DRL saved by settling constituted a suspicious reverse payment under Actavis. Accordingly, the Court granted DRL's motion for summary judgment as to the issue of a reverse payment. Order, Feb. 12, 2014, ¶ 6.

DRL's arguments as to causation prevail for similar reasons. The Plaintiffs' claims that the DRL Settlement caused their injuries founder for lack of support for the proposition that DRL would have been able to enter the generic market before May 27, 2014. No inferences can be drawn in the Plaintiffs' favor when there is a lack of a counterargument in a summary

judgment proceeding. The Court had no choice but to grant DRL's motion for summary judgment as to the issue of causation as well. Id.

A. Undisputed Factual Background Germane to This Motion

1. DRL's Accolate Litigation

AstraZeneca is the brand manufacturer of Accolate, an asthma medication. DRL's Statement Undisputed Facts Regarding Mot. Summ. J. ("DRL's SOF") ¶ 80, ECF No. 673. In 2008, DRL filed an ANDA seeking to market a generic version of Accolate, prompting AstraZeneca to sue for patent infringement. Id. In that lawsuit, AstraZeneca pursued a theory of infringement exclusively under the doctrine of equivalents. Id. ¶ 82. On November 15, 2010, the presiding district court ruled that AstraZeneca was estopped by Accolate's patent prosecution history from asserting the doctrine of equivalents, resulting in summary judgment for DRL. Id. ¶ 83. DRL launched generic Accolate at risk, and proceeded to earn between $10,000,000 and $14,000,000 annually from sales of the drug. Direct Purchaser & End-Payor Class Pls.' Local 56.1 Response DRL's Motion Summ. J. (ECF No. 594), & Statement Additional Material Facts ("Class Pls.' DRL SOF") ¶¶ 170-72, ECF No. 778. Instead of attempting to enjoin DRL, DRL's SOF ¶ 84, AstraZeneca quickly launched its own authorized generic Accolate, id. ¶ 47.

Later, on December 13, 2010, AstraZeneca filed a notice of appeal seeking review of the district court's Accolate decision. Id. ¶ 48. It entered an agreement to drop its appeal (the "Accolate Agreement") on January 18, 2011, the same day it settled its Nexium lawsuit with DRL. Id. ¶ 16.

2. DRL's Nexium Litigation

DRL was the third and last manufacturer among the Generic Defendants to file an ANDA for generic Nexium, submitting its application on April 25, 2006. See DRL's SOF ¶ 52. It was sued by AstraZeneca for patent infringement in January 2008. Id. ¶ 36. The Ranbaxy Settlement was signed a few months later, and DRL responded by filing a declaratory judgment action seeking a ruling that Ranbaxy's product did not infringe the Nexium patents. Class Pls.' DRL SOF ¶ 137. AstraZeneca's lawsuit against DRL and DRL's declaratory judgment action both were filed in the District of New Jersey and assigned to Judge Pisano, who ruled that he would not construct claims or hold trial in the latter case until the resolution of the former. DRL's SOF ¶¶ 70-71. In the course of seeking declaratory judgment, DRL took a clear position that the Ranbaxy Settlement was anticompetitive. See Class Pls.' DRL SOF ¶ 139.

In the meantime, DRL continued its efforts to obtain FDA approval of its generic Nexium product, but was plagued by setbacks. The FDA rejected DRL's first ANDA as deficient, and

DRL's amended ANDA continued to fall short of agency standards. DRL'S SOF ¶¶ 53-55. As of the date of the DRL Settlement in 2010, the FDA had issued more than eleven deficiency letters detailing problems with DRL's application and seeking, among other things, more scientific information, more tests, and even reformulation of DRL's proposed product. Id. ¶¶ 55-56. In July 2009, the FDA suspended review of DRL's ANDA because of a "major deficiency" in the formulation of the active ingredient in DRL's product. Id. ¶ 60. DRL made significant manufacturing changes and submitted a new active ingredient for review, but that formulation failed pharmacological stability tests in December 2010. Id. ¶ 64.

By that time, DRL had been engaged in Nexium patent infringement litigation with AstraZeneca for nearly two years, id. ¶ 36, and the stability failure of DRL's reformulated product had significant consequences for that case and related litigation, see id. ¶ 71. Because DRL did not actually have a generic Nexium product that could move forward in the ANDA process, DRL could not comply with a discovery order to produce samples of its product, nor could it effectively litigate the question of whether its product infringed AstraZeneca's patents. Id. ¶¶ 40-41. This was, in the words of a DRL executive, "the final straw on the camel's back," id. ¶ 74, and DRL contacted AstraZeneca to discuss settlement "[i]mmediately" after learning

of the stability failure, id. ¶ 77 (indicating DRL's willingness to accept the May 27, 2014 generic entry date proposed by AstraZeneca). To date, DRL has yet to obtain even tentative approval for its generic Nexium product. Class Pls.' SOF ¶ 4.

B. Analysis

1. Existence of a Reverse Payment

The Plaintiffs' reverse payment case against DRL proposes that AstraZeneca made a large and unjustified payment to DRL, in the form of the Accolate Agreement, to delay its generic Nexium launch. Direct Purchaser & End-Payor Class Pls.' Opp'n DRL's Mot. Summ. J. (ECF No. 594) ("Class Pls.' DRL Opp'n") 7, ECF No. 772. According to the Plaintiffs, the Accolate Agreement was valuable to DRL because it eliminated any risk that AstraZeneca's appeal would eventually lead to a judgment of infringement and damages liability. Id. at 14. DRL disagrees, asserting that no reasonable jury could infer that the Accolate Agreement was a payment worthy of scrutiny under the Actavis criteria. See Mem. Supp. DRL's Mot. Summ. J. ("DRL Mem.") 3, ECF No. 672.

To support their allegation of a suspicious reverse payment, the Plaintiffs marshal evidence suggesting that settlement of the Accolate lawsuit was valuable to DRL. According to the Plaintiffs, DRL viewed the Accolate lawsuit as a means to "extract" additional consideration from AstraZeneca

in exchange for generic Nexium delay. Class Pls.' DRL Opp'n 4 (citing the statement of a DRL executive that the manufacturer's "entire objective" was to tie the Nexium settlement to "another business deal which could bring value to" DRL). At one point, DRL is said to have sent AstraZeneca a "brainstorming" list of the generic manufacturer's priorities (by the Plaintiffs' terms, a "wish list"), which included settlement of the Accolate lawsuit as a top discussion point. Class Pls.' DRL SOF ¶¶ 145-46; see also id. (noting that the list additionally indicated DRL's interest in negotiating royalty-free licensing of the esomeprazole patents).

The Plaintiffs also construct an inverse version of their argument, asserting that because DRL made concessions in its Nexium settlement that "starkly changed its position" as to AstraZeneca's patents, it follows that DRL must have been induced to do so by some valuable consideration -- i.e., the Accolate Agreement. Class Pls.' DRL Opp'n 7; see id. at 6-7 (contrasting DRL's "vociferous[]" attempts to obtain a judgment against the Nexium patents and to break the bottleneck created by the Ranbaxy Settlement, with DRL's subsequent admission at settlement that AstraZeneca's Nexium patents were valid and infringed by DRL's generic product). This arrangement, the Plaintiffs say, must be carefully scrutinized because the Accolate Agreement did not "reflect[] traditional settlement

considerations," Actavis, 133 S. Ct. at 2237, and because DRL never would have been able to obtain resolution of the Accolate litigation by continuing to litigate the Nexium lawsuit. Class Pls.' DRL Opp'n 7-8.

Variations on these arguments helped the Plaintiffs survive summary judgment as to a reverse payment to Teva. The Court observes a key difference, however, between Teva and DRL's respective arrangements: Teva agreed to the amount of damages it owed in a case it lost, whereas DRL agreed to the dismissal of an appeal in a case it won. The latter hardly seems to qualify as a large and unjustified payment as imagined by the Actavis Court -- to realize the full extent of the risk that AstraZeneca's appeal posed to DRL, AstraZeneca would have had to win its appeal and then win a judgment of patent infringement on remand. The speculation required to presume that this would have come to pass makes it difficult to conclude that DRL believed it was saving anything more than some litigation costs by entering the Accolate Agreement.

The Court is also concerned that the Plaintiffs have made little attempt to quantify the extent of the alleged reverse payment to DRL. Actavis tasks this Court with evaluating, among other things, the DRL Settlement's size and "its scale in relation to [DRL's] anticipated future litigation costs" to determine whether the agreement is suspect. 133 S. Ct. at 2237;

see also Aaron Edlin et al., Activating Actavis, Antitrust, Fall 2013, at 16 (modeling the economic reasoning underlying the Supreme Court's inference of competitive harm from a large reverse payment, incorporating as factors the parties' prospective litigation costs and the value of other goods and services in the agreement). It is surprising, then, that the Plaintiffs have provided virtually no economic assessment of the value DRL received from its arrangement, save for abstracted references to litigation costs savings and legal analysis. See, e.g., DRL's SOF, Ex. 24, Expert Report John R. Thomas, Behalf Walgreen Co. & Giant Eagle, Inc. ¶¶ 72-73 (asserting, without development, that "AstraZeneca had a significant chance" of winning its Accolate appeal and discussing weaknesses in the lower court's summary judgment decision). Without a more concrete estimate of what DRL would have spent on further litigation or paid in damages absent the Accolate Agreement, there is little factual basis for a jury to properly engage in a rule-of-reason analysis of the alleged reverse payment.

The Supreme Court has made it clear that reverse payments are not presumptively unlawful and must be evaluated for anticompetitive harm under a holistic rule-of-reason approach. The Plaintiffs bear the burden of making an initial showing that a reverse payment is suspect. But even under the generous slant of the summary judgment standard, the Plaintiffs fail to provide

much more than conclusory statements that the Accolate Agreement was illegal. Summary judgment in favor of DRL is, therefore, appropriate here.

2. Proof of Antitrust Causation

DRL also seeks summary judgment as to whether the Plaintiffs have established a causal link between their injuries and the DRL Settlement. See DRL Mem. 10. Like its co-Defendants, DRL claims there is insufficient evidence that it would have been able to enter the generic Nexium market before May 27, 2014, in the absence of the DRL Settlement. Id.

This argument is compelling in light of the challenges DRL has faced in seeking ANDA approval. Internal communications from around the time of the DRL Settlement indicate that DRL had little hope of prevailing in litigation in time to launch a generic product before May 2014, see DRL's SOF ¶¶ 73, 76, and it is easy to see why. DRL would have had to do more than any other Generic Defendant to come to market in that time: formulate a new product, gain tentative and final agency approval, and win a final court judgment either triggering or eliminating Ranbaxy's marketing exclusivity period.

The Plaintiffs have provided little evidence that DRL could have accomplished these goals before 2014. The Retailer Plaintiffs hypothesize that in a but-for world in which both Ranbaxy and Teva fail to obtain final FDA approval and settle

their Nexium lawsuits, DRL would have had an opportunity to enter the generic Nexium market first, making it "highly motivated" to resolve the technical problems standing in the way of its ANDA approval. Retailer Pls.' Mem. Opp'n Dr. Reddy's Mot. Summ. J. ("Retailer Pls.' DRL Opp'n") 6, ECF No. 749. To enter first, DRL would have had to cause the forfeiture of Ranbaxy's first filer exclusivity privileges, which the Retailer Plaintiffs say DRL could have achieved by litigating a point of fact that, if it is true, has been strangely ignored throughout this litigation: Ranbaxy obtained tentative approval of its generic Nexium product 30 months and one day after filing its ANDA. Id. at 7. Because the MMA provides that a first filer loses its privileges if it does not obtain tentative approval within 30 months of filing its ANDA, 21 U.S.C. § 355(j)(5)(D)(i)(IV), the Retailer Plaintiffs assert that DRL could have pressed the issue with the FDA and in court to force a waiver of Ranbaxy's exclusivity period. Id. While such a scenario is plausible and has some basis in expert testimony, the Retailer Plaintiffs' suggestion is speculative and undeveloped, and the Court is not persuaded to deny summary judgment on this basis.

The Class Plaintiffs offer even less in the way of evidence or explanation. In fact, the Court observes that while the Class Plaintiffs' expert, Dr. Cheryl Blume, attests that Ranbaxy

and Teva "would have been ready, able, and incentivized" to launch early, she has not offered the same conclusion about DRL. DRL's SOF, Ex. 5, Blume Dep. 243:4-6, Dec. 3, 2013; see also id. at 242:11-18. Given this evidentiary record, the Court is unable to draw any inference suggesting that DRL's market entry was delayed by the DRL Settlement. As a result, DRL's motion for summary judgment was GRANTED, and on this basis, the Court also GRANTED the part of AstraZeneca's derivative causation motion, AstraZeneca Defs.' Mot. Summ. J. Basis Causation, ECF No. 645, that relates to the DRL Settlement. Order, Feb. 12, 2014, ¶ 10.

VII. ASTRAZENECA'S REMAINING MOTIONS FOR SUMMARY JUDGMENT [ECF NOS. 648, 649, 650]

In addition to the motions that have already been addressed in this opinion, AstraZeneca filed three motions for summary judgment on other grounds which merit discussion here. These motions go to whether the Direct Purchasers and Retailer Plaintiffs have standing to bring their claims.

A. AstraZeneca's Motion for Summary Judgment Against Direct Purchaser Plaintiffs for Lack of Actual Injury and to Exclude Direct Purchaser Plaintiffs Experts Damages Opinions [ECF No. 648]

AstraZeneca sought summary judgment on the grounds that the Direct Purchasers have failed to demonstrate actual injury under Article III of the Constitution and federal antitrust law. See

Mem. Supp. AstraZeneca Defs.' Mot. Summ. J. Against Direct Purchaser Pls.' Lack Actual Injury & Exclude Direct Purchaser Pls.' Experts' Damages Opinions ("AstraZeneca Mem. Actual Injury") 6-7, ECF No. 653. Specifically, AstraZeneca challenged the Direct Purchasers' theory of damages, which posits that they were overcharged for branded Nexium when they purportedly should have had access to the drug at lower prices.

The general legal standards for demonstrating cognizable injury in an antitrust action are not contested here. "Article III of the Constitution . . . entail[s] as an 'irreducible minimum' that there be (1) an injury in fact, (2) a causal relationship between the injury and the challenged conduct, and (3) a likelihood that the injury will be redressed by a favorable decision." United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc., 517 U.S. 544, 551 (1996) (citations omitted). Further, to recover treble damages under the Clayton Act, 15 U.S.C. § 15, as the Plaintiffs seek to, they "must make some showing of actual injury attributable to something the antitrust laws were designed to prevent." J. Truett Payne Co., Inc. v. Chrysler Motors Corp., 451 U.S. 557, 562 (1981) (citing Perkins v. Standard Oil Co., 395 U.S. 642, 648 (1969)).

To demonstrate such injury, the Direct Purchasers have proffered evidence that from the time of the 2008 Ranbaxy

Settlement through 2012, the wholesale acquisition price paid by Direct Purchasers for branded Nexium rose from $4.82 to $6.27. Direct Purchaser Class Pls.' Opp'n AstraZeneca Defs.' Mots. Summ. J. Against Direct Purchaser Pls. & Associated Daubert Mot. Relating "Actual Injury" (ECF No. 648) ("Direct Purchaser Actual Injury Opp'n") 4, ECF No. 735. They also submitted an expert report by Dr. Raymond S. Hartman, concluding that "all or virtually all" members of their class would have switched to a less costly generic product and also would have been able to purchase brand Nexium at a lower price, if generic entry had occurred earlier. Id. The Plaintiffs theorize that their damages manifest in the amount they were overcharged -- that is, the difference between (1) the actual wholesale prices of branded Nexium during the relevant time period, and (2) the but-for prices that would have been charged in the absence of the Nexium settlements delaying generic entry. Id. at 4-5 (estimating "aggregate overcharges of between $4.1 billion to $19.9 billion (depending on when generic competition would have begun)").

AstraZeneca contends that this overcharge model is insufficient to show injury, because it fails to account for the

possibility that earlier generic entry actually might have hurt, rather than helped, the Direct Purchasers' overall profits.[16] AstraZeneca points out that the earlier introduction of a generic product could have caused the price of branded Nexium to increase, and that generic bypass would likely have driven down the Direct Purchasers' total sales volume.[17] See AstraZeneca Mem. Actual Injury 1. Because these factors might have caused the wholesaler Direct Purchasers to lose profits overall upon generic launch, AstraZeneca contends that the Direct Purchasers must provide evidence ruling out that possibility before they can establish injury sufficient to survive summary judgment. Id. at 5. AstraZeneca also moved to strike the expert opinions of Hartman and Dr. Keith Leffler, an expert for the Retailer Plaintiffs, on the same grounds. Id. at 15.

As it did in In re Relafen Antitrust Litig., 218 F.R.D. 337, 344-45 (D. Mass. 2003) and in granting class certification to the Direct Purchasers, In re Nexium, 296 F.R.D. at 55, this

[16] More specifically, AstraZeneca points out that the proposed overcharge model fails to account for inflation in the price of brand Nexium, the Direct Purchasers' profit margins on the resale of brand and generic Nexium, and their expected generic Nexium sales volumes in the relevant time period. AstraZeneca Mem. Actual Injury 2, 9, 10.

[17] As this Court has explained in previous opinions, generic bypass describes a common market dynamic whereby retailers typically purchase branded drugs from wholesalers like the Direct Purchasers, but then switch to purchasing drugs directly from the manufacturer once a generic version becomes available. See In re Relafen Antitrust Litig., 346 F. Supp. 2d 349, 368-69 (D. Mass. 2004); see also In re Nexium, 296 F.R.D. at 56-57.

Court discerns no requirement that antitrust damages be demonstrated only by "lost profit" methodologies. See Hanover Shoe v. United Shoe Mach. Corp., 392 U.S. 481, 489 (holding that damages can be established even "[t]hough [the buyer] may manage to maintain his profit level," as "he would have made more if his purchases from the defendant had cost him less"); In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 190 (1st Cir. 2009) (ruling that overpayments constituted sufficient evidence of damages in a case involving the deceptive pricing of physician-administered drugs). Moreover, the Court has already ruled in the course of this litigation that generic bypass cannot be a defense that precludes the Plaintiffs from recovering damages based on overcharge calculations. In re Nexium, 296 F.R.D. at 5556 (citing Hanover Shoe, 392 U.S. at 489).

For the purposes of summary judgment, the Direct Purchasers have sufficiently demonstrated proof of antitrust injury in the form of overcharges. The Court further ruled that Hartman and Leffler's expert opinions, based on legal standards which accept overcharges as sufficient evidence of antitrust injury, are admissible. AstraZeneca's motion for summary judgment on this ground was, therefore, DENIED.

B. AstraZeneca's Motion for Summary Judgment Barring Assigned Claims [ECF No. 650]

AstraZeneca also filed for summary judgment against the Retailer Plaintiffs, asking this Court to disallow the assignments of claims which are the basis of the Retailer Plaintiffs' direct participation in this case. See AstraZeneca Defs.' Mot. Summ. J. Barring Assigned Claims, ECF No. 650. AstraZeneca's primary concern is that allowing the Retailer Plaintiffs to litigate their claims alongside the Direct Purchasers is needlessly complicated and risks "multiple recoveries for the same purchase" at the liability phase of trial. Mem. Supp. AstraZeneca Defs.' Mot. Summ. J. Barring Assigned Claims ("AstraZeneca Assigned Claims Mem.") 1-2, ECF No. 658.

A brief exposition of the Retailer Plaintiffs' posture is appropriate here. The Retailer Plaintiffs are eight large retail pharmacy chains that purchased brand Nexium from three wholesaler members of the Direct Purchaser class (the "Assigning Wholesalers"). See Direct Purchaser Class Pls.' Opp'n AstraZeneca Defs.' Mot. Summ. J. Barring Non-Class Direct Purchasers' Assigned Claims (Dkt. 650) 2, ECF No. 738. The Assigning Wholesalers have partially assigned their claims to the Retailer Plaintiffs, so that the Retailer Plaintiffs can directly seek recovery in this litigation for the portions of those claims which are attributable to their Nexium purchases. Id. at 3-4; see Decl. Barry L. Refsin Supp. Retailer Pls.'

Response Opp'n AstraZeneca's Mot. Summ. J. Barring Assigned Claims, Exs. A-H, Assignment Agreements ("Assignment Agreements"), ECF No. 755-1 through 755-8. The Assigning Wholesalers retain, however, the portions of their claims which are attributable to direct purchases of Nexium resold to other buyers. AstraZeneca Assigned Claims Mem. 1. The Retailer Plaintiffs have declined the opportunity to opt out of the Direct Purchaser Class,[18] and they have not indicated any desire to litigate their claims in a separate proceeding. They describe themselves as "absent members of [the Direct Purchaser] class." Retailer Pls.' Opp'n AstraZeneca Defs.' Mot. Summ. J. Statute Limitations, ECF No. 765.

AstraZeneca argues that the Assigning Wholesalers ought be required to litigate the full extent of their own claims as part of the Direct Purchaser Class, and to apportion any recovered damages to the Retailer Plaintiffs after the fact. AstraZeneca Assigned Claims Mem. 2. To do otherwise, AstraZeneca says, would run counter to "the policy concerns animating the Supreme Court's ruling in" Illinois Brick Co. v. Illinois, 431 U.S. 720

[18] When the Court considered AstraZeneca's motion in February 2014, it denied summary judgment partially on the basis that AstraZeneca's arguments were not yet ripe; at the time, the Retailer Plaintiffs still had an opportunity to file for exclusion from the Direct Purchaser class. See Order, Feb. 12, 2014, ECF No. 857. As that window has closed, the Court focuses its discussion here on the merits.

(1977) -- namely, "the difficulty of apportioning damage overcharges between direct and indirect purchasers, the increase in complexity in already complicated treble damage suits, and the risk of multiple recoveries." AstraZeneca Assigned Claims Mem. 6.

Both Illinois Brick and its predecessor, Hanover Shoe, address the question of how damages ought be apportioned when overcharges have been passed on from the direct purchaser to others in the sales chain. The "passing on" theory of damages posits that direct purchasers who incur antitrust injury as a result of illegal overcharges sometimes pass on their harms to indirect purchasers (i.e., the customers of direct purchasers and other subsequent buyers), instead of absorbing losses. See Hanover Shoe, 392 U.S. at 488-89. In Hanover Shoe, the Supreme Court ruled that antitrust defendants cannot use the "passing on" theory as a defense against direct purchaser claims of injury. Id. at 493-94 (noting that permitting such a defense "would often require additional long and complicated proceedings involving massive evidence and complicated theories"). In Illinois Brick, the Supreme Court extended this rule to hold that indirect purchasers cannot use the "passing on" theory as an offensive tactic to join direct purchaser antitrust actions and recover their own treble damages. 431 U.S. at 741 ("We are no more inclined than we were in Hanover Shoe to ignore the

burdens that [tracing the effect of overcharges to each would-be indirect purchaser plaintiff] would impose on the effective enforcement of the antitrust laws.").

These policy concerns are not necessarily implicated, however, when indirect purchasers have received express assignments and pursue claims in a single proceeding with direct purchasers. As a preliminary matter, several circuits have ruled that antitrust claims like those presented here can be expressly assigned. See Gulfstream III Associates, Inc. v. Gulfstream Aerospace Corp., 995 F.2d 425, 437 (3d Cir. 1993) (concurring with rulings from the Second and Ninth Circuits). Moreover, at least one circuit has held that when assignees of partial claims litigate alongside class members in the same proceeding, there is little risk of added complexity or duplicative recovery. See In re Fine Paper Litig., 632 F.2d 1081, 1090 (3d Cir. 1980) (holding that consolidation of the claims actually assures defendants against multiple liability, because each claim can be readily monitored). Indeed, this Court has allowed such claims to proceed in the past without difficulty. See In re Relafen, 346 F. Supp. 2d at 368.

This is not to say that apportionment is never a problem. Courts have invalidated assignments to plaintiffs who sought to litigate complicated multi-party antitrust claims, citing for good reason the reasoning of Illinois Brick. See In re Wyoming

Tight Sands Antitrust Cases, No. 85-2349, 1990 WL 155542, at *9 (D. Kan. Sept. 6, 1990) (invalidating assignments that would have required apportionment of damages among consumers in four states, where there were also overlapping claims held by different plaintiffs). The Court is not convinced, however, that the instant case presents the same challenges.

As has been mentioned to the parties on several occasions, the Court takes no issue with allowing the Retailer Plaintiffs to litigate their claims alongside the End-Payor and Direct Purchaser Classes against all Defendants at trial, although it remains the Plaintiffs' burden to agree on their lead counsel, experts, and witnesses, as well as to present to the Court a definitive plan for the liability phase of trial. See Mot. Hr'g Tr. 37:4-9, Dec. 30, 2013, ECF No. 716; Mot. Hr'g Tr. 92:17-19, Jan. 21, 2014, ECF No. 833. The Retailer Plaintiffs also ought bear in mind that they each may only litigate issues relating to their specific assignment from the Assigning Wholesalers. With that said, the Court has reviewed the submitted copies of the assignment agreements between the Assigning Wholesalers and the Retailer Plaintiffs, Assignment Agreements, and it assumes these assignments to be valid.[19] The Retailer Plaintiffs also assure

[19] AstraZeneca briefly has raised the argument that these agreements violate "non-assignment" clauses in AstraZeneca's distribution contracts with the Assigning Wholesalers. AstraZeneca Assigned Claims Mem. 6 n.4. No evidence of said

the Court that they have detailed records enabling them to trace the recovery they seek to specific purchases under their assigned claims. Opp'n Retailer Plaintiffs AstraZeneca's Mot. Summ. J. Barring Assigned Claims 7, ECF No. 753.

Upon these assurances, the Court concludes that if liability can be established at trial, calculating the damages due to the eight Retailer Plaintiffs will be a straightforward process. Assuming that the three plaintiff groups are able to come to a mutual agreement as to a streamlined trial plan, agreeing on experts, witnesses, and counsel alike, this Court anticipates little risk of multiple recovery against the Defendants. Lastly, while the Retailer Plaintiffs have raised the possibility of joinder under Fed. R. Civ. P. 19, this Court sees no need for movement towards mandatory joinder -- again, there seems to be little risk of incurring inconsistent results or unfair duplicative recovery against the Defendants.

Understanding that the Retailer Plaintiffs have not sought voluntary joinder, nor seek to be members of the Direct Purchaser class, it is this Court's intention to allow them to continue litigating alongside the plaintiff classes at trial. AstraZeneca's motion for summary judgment on the basis of barring assigned claims is, therefore, DENIED.

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distribution contracts or even specific contractual language has been introduced, however, to support AstraZeneca's assertion. The Court therefore dismisses this argument.

C. AstraZeneca's Motion for Summary Judgment on the Basis of Statute of Limitations [ECF No. 649]

Finally, AstraZeneca filed a motion for partial summary judgment against the Retailer Plaintiffs, arguing that all of their claims related to the Ranbaxy Settlement are time-barred. AstraZeneca Defs.' Mot. Partial Summ. J. Basis Statute Limitations, ECF No. 649; see Mem. Supp. AstraZeneca Defs.' Mot. Partial Summ. J. Basis Statute Limitations ("AstraZeneca Time-Barred Mem.") 2, ECF No. 652. Federal antitrust law requires plaintiffs to bring their claims "within four years after [their] cause of action [has] accrued," 15 U.S.C. § 15b, and the laws of twenty-three states impose a similar statute of limitations of four years or less. See Order, Nov. 27, 2013, at 1, ECF No. 546; see also Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 338 (1971) ("Generally, a cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business.").

AstraZeneca's motion against the Retailer Plaintiffs repurposes the arguments it has made in previous motions against the Direct Purchaser and End-Payor classes. See, e.g., Order, Nov. 27, 2013 (ruling on a motion for summary judgment against the Direct Purchasers and End-Payors on the basis that their claims based on the Ranbaxy Settlement are time-barred). AstraZeneca argued that because the Direct Purchasers' and End-

Payors' claims were filed on August 24 and 27, 2012, more than four years after the signing of the Ranbaxy Settlement on April 14, 2008, any claims related to that settlement ought be precluded. See id. at 1, 3. The Court rejected this argument as to the Class Plaintiffs, ruling that the Direct Purchasers and End-Payors have sufficiently demonstrated that their cause of action accrued in August 2008, on the theory that Ranbaxy would have come to market in August 2008 but for its settlement agreement. Id. at 3-4.

The Court's holding, however, did not apply to the Retailer Plaintiffs or their later-filed complaint, allowing AstraZeneca an opportunity to revisit its time-barred arguments as to this plaintiff subset. Although AstraZeneca maintains that the operable date on which the Plaintiffs' harms accrued is the April 2008 date of the Ranbaxy Settlement, it contends that even under the Class Plaintiffs' theory that their harms accrued in August 2008, the Retailer Plaintiffs ought be precluded because their separate complaint was filed more than four years after August 2008. AstraZeneca Time-Barred Mem. 1.

The Court does not conclude that the Retailer Plaintiffs are so differently situated. As has been established supra, the Court regards the Retailer Plaintiffs as valid and express assignees of the Direct Purchasers for the purposes of this motion, notwithstanding the fact that the Retailer Plaintiffs

will have to demonstrate at trial that their assignments were valid and based on identifiable purchases of Nexium from the Assigning Wholesalers. As such, the Court attributes the filing date of the Direct Purchasers' complaint to the Retailer Plaintiffs. See American Pipe & Const. Co. v. Utah, 414 U.S. 538, 554 (1974) ("[T]he commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the suit been permitted to continue as a class action."); see also Crown, Cork & Seal Co., Inc. v. Parker, 462 U.S. 345, 353-54 (1983). That complaint was filed on August 24, 2012, coming within four years of all proposed but-for entry dates[20] and tolling the applicable statute of limitations. On this basis, the motion for partial summary judgment was DENIED.

VIII. CONCLUSION

And so, as the dust settles on these various motions, it appears that the Plaintiffs will get their six-week trial on liability as to a single one of their several theories, viz. that the AstraZeneca-Teva settlement caused, and was intended to

[20] The Retailer Plaintiffs allege in their amended complaint that Ranbaxy's but-for generic entry date would have been "on or about December 1, 2008." Am. Compl. & Demand Jury Trial ¶ 2, ECF No. 515. Although this is obviously different from the Direct Purchasers' allegation that but-for generic entry would have occurred in August 2008, the discrepancy does not bear on the Court's disposition of this motion.

cause, actionable antitrust injury, and that both Ranbaxy and DRL conspired with AstraZeneca to accomplish this result.

Of course, even now the Plaintiffs are far from out of the woods. Their sole remaining theory depends on Dr. McGuire's Georgia-Pacific analysis, and it appears Dr. McGuire has no real world experience whatsoever in negotiating patent licenses and royalties. This Court has routinely excluded such testimony on the ground that such a witness is not qualified to render such an opinion. See, e.g., NewRiver, Inc. v. Newkirk Products, Inc., 674 F. Supp. 2d 320, 331 (D. Mass. 2009); Read Corp. v. Friday, No. 92-cv-12085 (D. Mass. Aug. 3, 1994), vacated on other grounds sub nom. Read Corp. v. Freiday, No. 94-1504, 1995 WL 515227 (Fed. Cir. Aug 30, 1995). Indeed, apparently fearing such a ruling -- which would effectively bring this case to an end -- the Plaintiffs have produced yet another expert, this time one who has actual experience in patent royalty negotiation, and he has rendered another Georgia-Pacific analysis which largely tracks Dr. McGuire's. See Notice Service Expert Op. W. Shannon McCool, ECF No. 958. Since this Court will permit testimony from only one expert per discipline, it is unclear how this will all work out at the final pre-trial conference.

The Court is confident, however, that -- once a final pre-trial conference is held pursuant to Fed. R. Civ. P. 16 and a

detailed pre-trial order is entered -- a jury can handle the factual issues here presented fairly and impartially.

> [E]mpirical studies . . . establish that jurors are sufficiently educated, take their responsibilities seriously, and seem to arrive at the "correct" decision as frequently as judges do. Academic critiques -- largely outdated in this new era -- should not lessen America's faith in its jury system that, so far, has lived up to its task.

Andrew J. Wilhelm, Complex Litigation in the New Era of the iJury, 41 Pepp. L. Rev. 817, 858-59 (2014).[21]

In any event, the Court hopes the exposition set forth above will aid the parties in their trial preparation.

By the Court,

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE

[21] See Lisa S. Meyer, Note, Taking the "Complexity" Out of Complex Litigation: Preserving the Constitutional Right to a Civil Jury Trial, 28 Val. U. L. Rev. 337, 359, 372 (1993); see also David J.F. Gross et al., You're Still Killing Me: How to Prevent Your Expert Witness from Destroying Your Patent Case at Trial, in Patent Litigation 2012, at 296, 296 (PLI Pats., Copyrights, Trademarks & Literary Prop., Course Handbook Ser. No. 34279, 2012); Roger W. Kirst, The Jury's Historic Domain in Complex Cases, 58 Wash. L. Rev. 1, 8-9 (1982); Keith Broyles, Note, Taking the Courtroom into the Classroom: A Proposal for Educating the Lay Juror in Complex Litigation Cases, 64 Geo. Wash. L. Rev. 714, 723 (1996); Development in the Law -- The Jury's Capacity to Decide Complex Civil Cases, 110 Harv. L. Rev. 1489, 1498 (1997).