UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM AND ORDER

YOUNG, D.J. July 30, 2015

I. INTRODUCTION

I did not try this case very well. I did try it fairly. As the Supreme Court has recognized, "a litigant is entitled to a fair trial but not a perfect one." McDonough Power Equip., Inc. v. Greenwood, 464 U.S. 548, 553 (1984) (internal quotation marks and alterations omitted); see also Kyle v. United States, 297 F.2d 507, 514 (2d Cir. 1961) (Friendly, J.) (noting that "the interest in obtaining an ideal trial . . . may be outweighed by the interest in avoiding a retrial unlikely to have a different outcome"). The question now before this Court in considering these post-trial motions is thus whether the trial proceedings here were sufficiently fair that one can have a strong degree of confidence in the outcome. The answer to that question is that they were.

This multi-district litigation case is one of a spate of antitrust claims that turns on the Supreme Court's

decision in Federal Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223 (2013).[1] This case arises as a result of alleged reverse payment settlements between the brand manufacturer of a heartburn medication called Nexium, referred to in its generic form as esomeprazole magnesium ("generic Nexium"), and other pharmaceutical companies.

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 re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 240 (D. Mass. 2014)("In re Nexium Summary Judgment 2014").

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[1] E.g. In re Aggrenox Antitrust Litig., No. 14-MD-2516, 2015 WL 1311352 (D. Conn. Mar. 23, 2015); In re Effexor XR Antitrust Litig., No. 11-5479, 2014 WL 4988410 (D.N.J. Oct. 6, 2014); Time Ins. Co. v. Astrazeneca AB, 52 F. Supp. 3d 705 (E.D. Pa. 2014); In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523 (D.N.J. 2014); In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735 (E.D. Pa. 2014); see Sheri Qualters, An Antitrust Litigation 'Explosion', THE NATIONAL LAW JOURNAL, July 20, 2015, at 1. See also Michael A. Carrier, Payment After Actavis, 100 Iowa L. Rev. 7 (2014); Joshua P. Davis & Ryan J. McEwan, Deactivating Actavis: The Clash Between the Supreme Court and (Some) Lower Courts, 67 Rutgers U.L. Rev. 557 (2015); Murat C. Mungan, Reverse Payments, Perverse Incentives, 27 Harv. J.L. & Tech. 1 (2013). This case is the first post-Actavis case to be tried to a jury.

The action is brought by a class of wholesale drug distributors (the "Direct Purchasers"), and another 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[2] (collectively, the "Retailer Plaintiffs") (collectively, with the Direct Purchasers and the End–Payors, the "Plaintiffs"). In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 240. The Plaintiffs brought claims 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.

[2] 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. In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 240. CVS Pharmacy, Inc. is also one of the retailer Plaintiffs since it entered the litigation by filing an independent action on April, 11 2014, case 14-cv-11788, Compl., ECF No. 1, consolidated with the leading case a few days later. Case 14-cv-11788, Order of Consolidation, ECF No. 5.

(collectively, "DRL") (collectively, with Ranbaxy and Teva, the "Initial Defendants"). Id.

Trial commenced before a jury on October 21, 2014. Elec. Clerk's Notes, Oct. 21, 2014, ECF No. 1151. The Plaintiffs settled first with DRL and then with Teva[3] during the course of the trial. The special questions that went to the jury thus concerned only the dispute between the Plaintiffs and AstraZeneca and Ranbaxy (collectively, the "Defendants"). The jury returned its verdict, answering the special questions, on December 5, 2014. Elec. Clerk's Notes, Dec. 5, 2014, ECF. 1382. The answers mandate the entry of judgment for the Defendants.

The Plaintiffs filed timely motions for a new trial along with supporting memoranda, Class Pls.' Mot. New Trial Fed. R. Civ. Proc. 59 ("Class Pls. Mot. New Trial"), ECF No. 1450; Mem. Support Class Pls.' Mot. New Trial Pursuant Fed. R. Civ. P. 59 ("Class Pls. Mem. New Trial"), ECF No. 1451; Ind. Pls.' Mot. New Trial ("Retailers Pls. Mot. New Trial"), ECF No. 1453; Ind. Pls.' Mem. Support Mot. New Trial, ECF No. 1454, and supplemental submissions in connection with these motions, Pls.' Supp. Submission

[3] DRL's Consent Mot. Approval Settlement Agreements, ECF No. 1474; Elec. Order, ECF No. 1478; Elec. Clerk's Notes, ECF No. 1376.

Connection Pending New Trial Mots. ("Pls. Supp. Mem."), ECF No. 1515. The Retailer Plaintiffs also filed a motion for permanent injunction. Mot. Permanent Inj., ECF No. 1457; American Sales Co., LLC's Joinder Mot. Permanent Inj., ECF No. 1464.

These motions are best analyzed by considering the run-up to trial (where a major misconception crept into this Court's understanding of this case), and the trial itself (where the misconception was corrected). Along the way a few comments on the class certification issues may be helpful.

II. THE RUN-UP TO TRIAL: A CAUTIONARY TALE

"Well now they file their libels
And they cite Sir William Scott.
The sailors say the French must pay
Their Counsel argues not."[4]

On December 7, 2012, the Judicial Panel on Multi District Litigation consolidated six actions pending in the District of Massachusetts, the District of New Jersey, and the Eastern District of Pennsylvania into the present multidistrict litigation and assigned it to this Session of the Court pursuant to 28 U.S.C. § 1407. Elec. Notice, ECF No. 1; Transfer Order, ECF No. 2.

[4] Arthur E. Sutherland, The Ship Blaireux (1954).

On February 1, 2013, representatives for the End–Payors filed a consolidated complaint, 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.

By any standard, this is a "big" case and the Court has treated it as such.[5] The Initial 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. In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 376 (D. Mass. 2013) ("In re Nexium Motions to Dismiss 2013").

Six months later, this Court granted two motions certifying a Direct Purchase Class and an End–Payor class.[6]

[5] Throughout the run-up to trial, I deployed three of my six law clerks to work on this case. Technically, I deployed two law clerks and an unpaid volunteer lawyer. I call such volunteer lawyers "judicial counsellors" as we're now not supposed to refer to them as law clerks. Report of the Proceedings of the Judicial Conference of the United States 23 (September 16, 2014), http://www.uscourts.gov/about-federal-courts/reports-proceedings-judicial-conference-us. This bit of sophistry has no place in a judicial opinion, however, and so I call them what they are.

[6] Pursuant to Fed. R. Civ. P. 23(f), the Defendants took an interlocutory appeal of this Court's End-Payor

In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D. 168, 184 (2013); In re Nexium (Esomeprazole) Antitrust Litig., 296 F.R.D. 43 (D. Mass 2013); In re Nexium (Esomeprazole) Antitrust Litig., 296 F.R.D. 47, 60 (D. Mass. 2013). During this period, the Retailer Plaintiffs individually entered this litigation when they collectively filed three amended complaints against the Initial Defendants. Am. Compl. & Demand Jury Trial, ECF No. 515; Am. Compl. & Demand Jury Trial, ECF No. 516; Am. Compl., ECF No. 517.

In late 2013, the Initial Defendants collectively filed eleven motions for summary judgment, to which the Plaintiffs responded. In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 241.

So far so good. The case had been set at the initial case management scheduling conference for a February 2014 trial, and we were on track. Jan 22, 2013 Scheduling Conference Tr. 20:11-12, ECF No. 90.

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class certification to the First Circuit, which accepted the appeal as it presented substantial unanswered questions of law. United States Ct. Appeals First Circuit, Judgments, May 15, 2014, ECF Nos. 926-29. See also Daniel Jacobs, Comcast Corp. v. Behrend: Common Questions versus Individual Answers – Which Will Predominate?, 47 Loy. L. A. L. Rev. 505 (2014). More of this anon.

To understand how this Court initially lost its way, it is worth remembering how the case appeared at this juncture. Necessarily, the consolidated complaint here is somewhat kaleidoscopic as the Plaintiffs, post-Actavis, were seeking to explore terrain where no court had gone before. The legal contours, however, were ascertainable.

First, and perhaps foremost, this antitrust action cannot be maintained unless the Plaintiffs prove an "antitrust injury" -- a real-world impact on the relevant market from the alleged monopolistic practice or practices. Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990) (noting that a "plaintiff must prove the existence of antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful") (quotation marks omitted).

Second, one must understand and thread the morass of the governing statutory law (the Hatch-Waxman Act) and its attendant regulations:

> 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. 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 ["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., AztraZeneca 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. Circ. 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.

In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 244-46.[7]

On January 13, 2014, the Court denied two summary judgment motions submitted by AstraZeneca. Id. at 242.[8]

[7] Today, all of this is history as the Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010), has largely superseded the Hatch-Waxman Act with a new statutory framework which Congress believes (and certainly hopes) will better balance the need for patent protection to encourage the research necessary to bring new and beneficial drugs to market with the equally important need for competition to make those drugs affordable.

[8] The Court denied AstraZeneca's motion seeking summary judgment against the Direct Purchasers and Retailer Plaintiffs, ECF No. 648, 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

The Court heard oral argument on five of the Initial Defendants' motions for summary judgment on January 21, 2014. Elec. Clerk's Notes, Jan. 21, 2014, ECF No. 846; In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 242.[9] 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. In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 242-43.

I well remember the course of analysis I took in addressing these several intricate motions for summary judgment. First, there was not much time since this case was scheduled to be trial ready the first Monday in March,

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AstraZeneca's motion for partial summary judgment, ECF No. 649, seeking to bar the Retailer Plaintiffs on the basis of statute of limitations. Elec. Order, Jan. 13, 2014, ECF No. 802.

[9] 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. Elec. Clerk's Notes, Jan. 21, 2014, ECF No. 846.

2014, and that date was sacrosanct.[10] Second, as matter of constitutional law, an antitrust case is a jury case. See Puretest Ice Cream, Inc. v. Kraft, Inc., 614 F. Supp. 994, 997 (D. Mass. 1985) (Skinner, J.) (noting that plaintiffs in antitrust claims are undoubtedly entitled to a jury trial). It is thus the constitutional right of an American jury to hear and decide the factual disputes here. See In re Gutierrez, No. 15-mc-91076, April 30, 2015 Tr. 79:20-24; William G. Young, United States District Court Judge, Address at MCLE Conference: In Celebration of the American Jury Trial (October 2, 2014).

Accordingly, any motion for summary judgment must be approached with a high degree of skepticism, as granting such a motion runs the risk of improperly displacing the constitutional officers (jurors) to whom the Seventh Amendment assigns the sole authority to make factual determinations. All too often today, courts appear to stretch to grant summary judgment where the reverse ought be the case. Unless the factual record as to material

[10] Virtually on the eve of trial, a major trial-ready criminal case was re-drawn to this Session, see United States v. O'Brien, case 12-cr-40026, which was tried to a jury from May 8, 2014 to July 15, 2014, with deliberations continuing until July 24, 2014. We thus did not get the Nexium case going until October 21, 2014.

issues is clear beyond peradventure, summary judgment ought be denied.[11]

It is against this substantive and procedural background that analysis proceeded apace. Given the conscious parallelism, the similar contingent launch provisions, and the suspect "no authorized generic" clauses ("no-AG clauses")[12] in each of the settlement agreements

[11] In her article titled Why Summary Judgment is Unconstitutional, 93 Va. L. Rev. 139 (2007), Professor Suja Thomas perhaps goes too far, but not by much. Courts ought be especially wary of granting summary judgment upon the rationale "no jury could possibly find…" In all too many cases, this is a thinly disguised form of judicial factfinding, forbidden by the Constitution in a jury case. U.S. Const. amend. VII ("In Suits at common law . . . the right of trial by jury shall be preserved."). Moreover, absent binding admission by the non-moving party, it ought be well-nigh impossible for a party bearing the burden of proof to obtain summary judgment. This is so because a court, while it must "draw all reasonable inferences in favor of the nonmoving party [at summary judgment], it may not make credibility determinations or weigh the evidence" because such tasks "'are jury functions, not those of a judge.'" Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 151 (2000) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)). Thus the many local rules adopting a point-counterpoint system which converts a failure to adduce affirmative contradictive evidence into an admission of the point advanced is simply contrary to Reeves when the moving party bears the burden of proof. United States v. Massachusetts, 781 F. Supp. 2d 1, 10 n.18 (D. Mass. 2011). This point is now widely recognized. E.g., Romag Fasteners, Inc. v. Fossil, Inc., 979 F. Supp. 2d 264, 273 n.5 (D. Conn. 2013); Delano v. Abbott Labs., 908 F. Supp. 2d 888, 897 n.4 (W.D. Tenn. 2012); Seitz v. DeQuarto, 777 F. Supp. 2d 492, 495 n.2 (S.D.N.Y. 2011).

[12] Authorized generics are drugs manufactured by the brand-name company to the brand's specifications, but

AstraZeneca made with Ranbaxy, Teva and DRL, see Decl. James H. Weingarten, Esq. Supp. Mots. Summ. J. ("Weingarten Decl."), Ex. 1, Settlement Agreement ("AstraZeneca-Ranbaxy Settlement Agreement"), ECF No. 676-1; Weingarten Decl., Ex. 2, Settlement Agreement ("Teva Settlement Agreement"), ECF No. 676-2; Weingarten Decl., Ex. 3, Settlement Agreement ("DRL Settlement Agreement"), ECF No. 676-3, it appeared the Plaintiffs would be able to make out their general civil conspiracy case.[13] All the Defendants would, therefore, apparently remain in the case through trial.

The Plaintiffs' evidence of a large and unjustified non-cash reverse payment[14] appeared strongest with respect

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marketed as generic. Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, Federal Trade Commission, August 2011 Report i.

[13] In retrospect, after trial it appears this is a bit too sweeping. At trial, the evidence warranted, at most, a finding that AstraZeneca was the hub of a hub-and-spoke conspiracy with the three generic manufacturers acting as competitors vis-à-vis each other, not conspirators.

[14] Post-Actavis decisions and scholarship are largely in accord with this Court's view that reverse payments need not be in cash to be anticompetitive. See In re Nexium Motions to Dismiss 2013, 968 F. Supp. 2d at 392. Accord King Drug Co. of Florence v. Smithkline Beecham Corp., No. 14-1243, 2015 WL 3967112, at *2 (3d Cir. June 26, 2015); In re Aggrenox Antitrust Litig., 2015 WL 1311352, at *11; United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Teikoku Pharma USA, Inc., No. 14-md-02521, 2014 WL 6465235, at *11-12 (N.D. Cal. Nov. 17, 2014); In re Effexor XR Antitrust Litig., 2014 WL 4988410, at *20-22; In re Lipitor Antitrust

to Ranbaxy, less so as to Teva, and virtually non-existent as to DRL. Analysis thus focused on antitrust causation – the ability of Ranbaxy to bring its generic Nexium to market absent the payment from AstraZeneca to Ranbaxy. Here, the Plaintiffs came a cropper. Despite all my huffing and puffing about granting summary judgment only in the last extremity, there was simply no way, on the record before me, that Ranbaxy was going to get to market with a generic version of Nexium prior to the expiry date in the AstraZeneca-Ranbaxy Settlement Agreement.[15] Thus, the AstraZeneca-Ranbaxy Settlement Agreement apparently could not be the source of antitrust damages.[16]

Litig., 46 F. Supp. 3d at 543-46. See also Michael A. Carrier, Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment, 67 Rutgers U.L. Rev. 697 (2015); Davis, supra note 1. But see In re Loestrin 24 FE Antitrust Litig., 45 F. Supp. 3d 180, 192 (D.R.I. 2014) ("Actavis should be applied only to cash settlements, or to their very close analogues."); In re Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560, 567 (declining to extend Actavis to the non-monetary facts of the case).

[15] Indeed, notwithstanding that Ranbaxy has now lost its blocking position in a scathing opinion that faults both the FDA and Ranbaxy, Ranbaxy Labs., Ltd. v. Burwell, 2015 WL 1218933, at *31 (D.D.C. March 11, 2015), only Teva has come to market with an FDA-approved generic version of Nexium.

[16] This was the Court's mistaken assumption.

The Court's focus next turned to the Teva Settlement Agreement. Teva, the largest generic drug manufacturer in the world, appeared capable of bringing a generic version of Nexium to market within a reasonably short period around the time of its agreement with AstraZeneca. But the evidence of a large and unjustified reverse payment to it was wanting and, believing – erroneously – that the key to calculating the existence of a large and unjustified reverse payment lay in figuring out the royalty agreement that would otherwise have resulted from an AstraZeneca-Teva settlement which would not have been anticompetitive, the Court was of opinion that adequate evidence of such calculation was not forthcoming.[17]

The Court, on February 12, 2014, issued an order laying out its rulings on all eleven motions for summary judgment, and administratively closed this case pending the issuance of a full written opinion as suggested by Fed. R. Civ. P. 56(a). Order, Feb. 12, 2014, ECF No. 857.

[17] At this stage in the litigation, the Court was having trouble figuring out what has come to be known as the "Actavis Inference," which refers to a "large and otherwise unexplained payment, combined with delayed entry, [which] supports a reasonable inference of harm to consumers from lessened competition." Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, The Actavis Inference: Theory and Practice, 67 Rutgers U. L. Rev. 585, 585 (2015).

The Court reopened the case on February 28, 2014 upon the filing of a number of motions for reconsideration. In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 243.[18] On March 7, 2014, the Court denied all but two of the motions for reconsideration and scheduled oral argument on the remainder. Order, Mar. 7, 2014, ECF No. 874.[19]

The Court heard oral argument on the two motions for reconsideration, 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' motion for reconsideration of summary judgment

[18] 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 Supp. 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.

[19] These motions were (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.

regarding the absence of a reverse payment to Teva, (2) granting in part the Plaintiffs' 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' motion for reconsideration of summary judgment to AstraZeneca and Ranbaxy for lack of causation. Elec. Clerk's Notes, Apr. 16, 2014, ECF No. 902; Elec. Endorsement, June 4, 2014, ECF No. 940.

The Court set the case for trial in October 2014, with a final pretrial conference set to take place in September 2014. Elec. Clerk's Notes, Apr. 16, 2014, ECF No. 902.

Despite the Court's numerous rulings on the motions for reconsideration, DRL was not done. On April 22, 2014, it filed a motion for reconsideration of the Court's denial of summary judgment as to overarching conspiracy, DRL's Mot. Reconsideration, ECF No. 905, and supported its position with 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., Nos. 2:06–cv–1797, 2:06–cv–1833, 2:06–cv–2768, 2014 WL 2813312 (E.D.Pa. June 23, 2014).

On September 4, 2014, the Court delivered its opinion setting out in full its reasoning for its rulings on the eleven motions for summary judgment, on the Plaintiffs' motions for reconsideration, ECF Nos. 864 and 867, and on DRL's motion for reconsideration, ECF No. 905. Mem. & Order, ECF No. 977.

The opinion makes clear that the Court, believing that if the Actavis inference was to be found anywhere, it had to arise out of the AstraZeneca-Teva interactions, thought that the Plaintiffs' case was hanging by a thread. In any event, we were headed for trial.[20]

[20] There followed the usual blizzard of motions in limine. I like motions in limine. They are better than a trial brief in highlighting contentious issues that may arise at trial. The problem is that they can delay the proceedings and beget still more such motions.

Accordingly, I make it a practice rarely to entertain such motions pre-trial unless they clearly impact a party's opening or, as in the case of prior convictions under Fed. R. Evid. 609, they affect a criminal defendant's decision to testify. Trials are living things; motions in limine are best decided during the course of trial proceedings upon an actual evidentiary record. All too often pre-trial motions in limine arise from hopes or fears that have little relation to the practicalities of putting on or defending an actual case. As George Bernard Shaw said of second marriages, they are the "triumph of hope over experience," or are simply expressions of the "Jellicoe Syndrome" – the fear of losing the war in an afternoon.

So here. Many of these motions reflected the "instinct for the capillaries," In re Relafen Antitrust Litig., 231 F.R.D. 52, 87 (D. Mass. 2005), were of little moment, and were unlikely to occur. The Court largely ignored them.

The Court held a final pre-trial conference, pursuant to Fed. R. Civ. P. 16, on September 30, 2014. Elec. Clerk's Notes, Sept. 30, 2014, ECF No. 1136. Reflecting my continuing unease as to whether any reasonable jury could draw the Actavis inference from the AstraZeneca-Teva interactions, I directed all evidence supportive of that inference be introduced first, before the Plaintiffs put on other evidence. DRL settled and dropped out of the case on the eve of trial. ECF Nos. 1092, 1093, 1098, 1102, 1103, and 1140. Jury selection took place on Monday, October 20, 2014, Elec. Clerk's Notes, Oct. 20, 2014, ECF No. 1138, and the trial commenced.

III. THE TRIAL ITSELF

A. The Value of a Trial Generally

ELEVEN YEARS AGO…

Litigation management
is our primary job, and,
even with fewer trials,
there is a lot of litigation
to be managed.

President, Federal Judges' Association, Conference Represents Federal Trial Judges, THIRD BRANCH, June 2003.

Litigation management: hardly a shining vision is it?
Once divorced from daily interaction with jurors,
our written opinions subtly mock the very idea that
democratic institutions might be made to
serve the cause of justice.

Hon. William G. Young, U.S. District Judge, Address at the Judicial Luncheon, Florida Bar's Annual Convention in Orlando (June 28, 2007).

Having set themselves adrift from their constitutional partner--the American Jury--federal trial judges now find themselves bereft of the central wellspring of their moral authority. Public disparagement and Congressional disdain follow in the wake of this trend.

Honorable William G. Young, Vanishing Trials, Vanishing Juries, Vanishing Constitution, 40 Suffolk U. L. Rev. 67, 81 (2006).

> **TODAY….**
>
> **In three quarters of a century, we have moved from a culture of trial to a culture of settlement and dismissal. Cases are terminated earlier based on less information about the claim, the evidence, or the merits. And the values of efficiency and cost reduction have been privileged over other systemic values, particularly the dignitary notion that every litigant deserves his or her day in court…**
>
> **In such a world, who loses? Plaintiffs and under-resourced litigants lose, juries almost never sit to decide cases, and novel claims lose. Perhaps the greatest loss is that judges give up their traditional function as adjudicators and become "terminators." As Judge William Young said at this Symposium, judges sit to close cases; they are increasingly seen and see themselves as gatekeepers, managers who administer techniques of settlement and dismissal. When you cannot measure what is important, you tend to make important what you can measure. And so like anyone else in the workplace, judges tend to do what is measured, and what is measured and valued in today's courthouses is how many cases are closed, not how justly they are decided.**

Dean Harold Hongju Koh, "The Just, Speedy, and Inexpensive Determination of Every Action?", 162 U. Pa. L. Rev. 1525, 1529 (2014).

> **Adjudication has a special purchase on the public fisc because of its distinctive character as a**

> **specific kind of social ordering. In contrast, through case management, judicial efforts at settlement, and mandatory ADR in or through courts; through devolution to administrative agencies; and through enforcement of waivers of rights to court, the framework of "due process procedure," with its independent judges and open courts, is replaced by what can fairly be called "contract procedure." As judges press to alter juridical modes and reconfigure courts as but one of many places for dispute resolution, as judges embrace management and settlement, and as judges stop working before the public eye, judges lose the argument for their independence and for expansive public subsidies.**

Judith Resnik, The Privatization of Process: Requiem for and Celebration of the Federal Rules of Civil Procedure at 75, 162 U. Pa. L. Rev. 1793, 1837 (2014).

> **Are judges content with the profound evolution of their role from trial judges to business managers? They should consider why the public--including Congress--should show them great respect and provide ample financial support if they are largely business executives at the pyramid of a huge bureaucracy that is somewhat disinterested in, or antagonistic to whether ordinary Americans can go to court with a realistic opportunity of having their rights vindicated**

Stephen N. Subrin & Thomas O. Main, The Fourth Era of American Civil Procedure, 162 U. Pa. L. Rev. 1839, 1891 (2014).

B. The Nexium Trial

A rip-roaring six-week trial to verdict followed jury empanelment. In every respect, this case was tried with civility and consummate professional skill by counsel for

each party.[21] Throughout, the jury was attentive and asked intelligent questions.

The claims that survived to trial were Section 1 claims and their state law equivalents against all of the Defendants, except for DRL who settled before the trial.[22] The trial was initially structured to begin with the Teva Settlement Agreement, which was the logical starting point in the aftermath of the Court's summary judgment rulings. In those rulings, the Plaintiffs had sufficient evidence in support of a large reverse payment made to Ranbaxy but failed to adequately demonstrate antitrust causation, allowing the Court to grant summary judgment to Ranbaxy on substantive antitrust claims. See In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 275.

[21] The entire proceeding gives the lie to Judge Posner's sour and jaundiced view of our federal trial bar. See Reserve Hotels PTY Ltd. v. Mavrakis, No. 14-2990, 2015 WL 3852645, at *6 (7th Cir. June 23, 2015) (Posner, J., dissenting).

[22] The motion to enter final judgment in favor of the Defendants is in regard to "(i) all counts of Plaintiffs' Complaints regarding any claims for an overarching conspiracy or agreement in restraint of trade among all Defendants, and (ii) all counts . . . arising from the settlement agreement between AstraZeneca and Ranbaxy." AstraZeneca & Ranbaxy Defs.' Mot. Entry Rule 54(b) Final J. Claims Resolved Trial Favor AstraZeneca & Ranbaxy Defs., Ex. 1, Rule 54(b) Final J. Claims Resolved Trial Favor AstraZeneca & Ranbaxy Defs., ECF No. 1447-1.

Two weeks into trial, the FDA decided to rescind its previously granted tentative approval of Ranbaxy's ANDA for generic Nexium. Pls. Supp. Mem. 2. A few days later, Ranbaxy sued the FDA in the United States District Court for the District of Columbia, seeking declaratory and injunctive relief including, inter alia, a ruling compelling the "FDA to rescind and declare null nunc pro tunc any action that interferes with Ranbaxy's statutory rights to 180-day exclusivity for [its generic esomeprazole]" (the "Ranbaxy-FDA litigation"). Id. at 2-3.

Obedient to this Court's directive and mindful of its fixation on deriving a "fair settlement" with a reasonable royalty rate for licensing AstraZeneca's patented Nexium, the Plaintiffs, on November 5, 2014, called Professor W. Shannon McCool ("McCool"). Elec. Clerk's Notes, Nov, 5, 2014, ECF No. 1179. McCool was well qualified to derive such a hypothetical royalty, but candidly admitted that such a calculus was simply not very germane to the conduct of rational parties in the Hatch-Waxman context. Nov. 5, 2014 Tr. 31:21-33:9, ECF No. 1405. The Court wound up striking most of his testimony, Elec. Clerk's Notes, Nov. 12, 2014, ECF No. 1312, and was left wondering why the case seemed to be going awry.

On November 7, 2014, the Plaintiffs called what proved to be – in the Court's eyes anyway – their star witness, Thomas McGuire ("McGuire"). Elec. Clerk's Notes, Nov. 7, 2014, ECF No. 1182. McGuire's life's work has been the economics of the pharmaceutical industry and, over strenuous objection, he gave compelling testimony as to the enormous financial stakes that turned on the entry date of a lower cost generic into a market hitherto dominated by a patented, more expensive brand name drug. He also detailed how the benefits AstraZeneca conferred on Teva through their mutual settlement exceeded the litigation costs the parties thereby avoided. Along the way, the Plaintiffs persuaded the Court, again over strenuous objection, to allow McGuire to testify "for context" to the far greater reverse payment made by AstraZeneca to Ranbaxy to induce it to forego its challenge to AstraZeneca's Nexium patents. McGuire proved largely impervious to cross examination.

The sockdolager came on November 18, 2014, seventeen days into the trial. As more recently described in the Actavis Inference,

> Real-world evidence [of the concretely high value placed on no-AG provisions by both branded and generic firms] recently emerged in the first reverse payment trial after Actavis. At trial, purchasers and end-payors for Nexium, a blockbuster heartburn drug, argued that AstraZeneca paid first-filer Ranbaxy to delay

> entry by agreeing to a no-AG provision. In particular, plaintiffs offered a short memorandum prepared by outside counsel describing Ranbaxy's anticipated bargaining position and AstraZeneca's strategy in response. The strategy centered on offering a no-AG provision. As counsel candidly explained, "Ranbaxy likely will want a settlement that preserves its 180-day period of exclusivity against other generics and also guarantees that exclusivity against authorized generic competition, and it may be willing to agree to a relatively late entry date in a settlement that provides it with sole exclusivity.

Edlin, supra note 17, at 596-97 (referring to Nexium trial exhibit 140).[23]

[23] Exhibit 140, Nexium Settlement Considerations, is, of course, a privileged document within the ambit of the attorney-client relationship. How then did it find its way in evidence? The Defendants at first proposed to have "expert" attorneys testify as to why these settlement agreements occurred. The Court would have none of it, ruling that no such "expert" could testify absent a full recitation of the actual factual bases of such opinion, Fed. R. Evid. 703, and perhaps not even then, since, in the absence of those who actually negotiated such settlements, such second-hand opinions probably would not be "relevant to the task at hand." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 597 (1993); Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) (same). Faced with the potential loss of evidence justifying the settlements, the Defendants raised no objection to the testimony of the negotiating attorneys themselves. This in turn waived the privilege as to a penumbra of documents used during the negotiations of the AstraZeneca-Ranbaxy Settlement Agreement. Nov. 10, 2014 Motion Tr. 10:10-11:16, ECF No. 1413. See also In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.), 348 F.3d 16, 25 (1st Cir. 2003). AstraZeneca raised no privilege objection to the admission of Exhibit 140. Nov. 10, 2014 Motion Tr. 10:10-11:16.

That did it. The Court promptly corrected course, charging the jury that I had misapplied the Plaintiffs' theory to focus on Teva when in fact their main theory was actually that AstraZeneca and Ranbaxy had conspired via the AstraZeneca-Ranbaxy Settlement Agreement to use Ranbaxy's blocking position under the Hatch-Waxman regulatory scheme artificially to maintain the higher branded Nexium price. The Defendants – especially Ranbaxy – howled, and immediately moved for a mistrial. Ranbaxy's Mot. Mistrial, ECF No. 1243; AstraZeneca Defs.' Mot. Mistrial, ECF No. 1265. Significantly, the Plaintiffs did not (and in fact, opposed the Defendants' motions for mistrial), desiring to press on with this, their most viable theory. The Court denied the motions for mistrial. Elec. Clerk's Notes, Nov. 20, 2014, ECF No. 1318. Thereafter, the case went swimmingly (in the sense that I understood what the lawyers were doing and why).

The Plaintiffs still faced a daunting task, and they knew it. In order to prove antitrust damages, they would have to prove that, had it not been for the AstraZeneca-Ranbaxy Settlement Agreement, Ranbaxy would have teamed with Teva to launch a generic version of Nexium. There was no direct evidence of any such planning; the idea was merely theoretical.

Now that the Plaintiffs had their case back on track, and no doubt sensing the power of McGuire's testimony, they moved to recall him to the stand. Having given the Plaintiffs a fair amount of latitude during McGuire's first outing, the Court refused.[24]

Unwilling to give up, the Plaintiffs proffered "new evidence," a so-called "Event Study" analysis which purported to show "that it is possible to use econometric analysis of the stock market's reaction to the actual settlement reached by AstraZeneca and Ranbaxy to estimate an objective entry date without such a payment." Ind. Pls.' Mem. Support Mot. New Trial (Ind. Pl.'s Mem.) 11, ECF No. 1454. Reasoning that the Event Study would have no bearing on whether Ranbaxy and Teva would have partnered to produce a generic form of Nexium in the absence of the AstraZeneca-Ranbaxy Settlement Agreement, the Court refused this study. Nov. 20, 2014 Tr. 83:7-20, ECF No. 1424.

The Plaintiffs' lead witness on the issue of the crucial "but for entry date," i.e., the hypothetical date on which Ranbaxy-Teva would have launched generic Nexium but for the AstraZeneca-Ranbaxy Settlement Agreement, was Cheryl Blume. Blume started to testify before the jury on

[24] This is probably the closest judgment call the Court made during the course of this case.

November 18, 2014, Elec. Clerk's Notes, Nov. 18, 2014, ECF No. 1315, and continued to testify on November 19 and 20, 2014. Elec. Clerk's Notes, Nov. 19, 2014, ECF No. 1316; Elec. Clerk's Notes, Nov. 20, 2014, ECF No. 1317. Blume did not fare very well, especially under the searching cross-examination by Teva's counsel. The Court was left with the distinct impression that much of her testimony was a priori rationalization.

Once the Defendants had presented their case, Teva settling out along the way on November 24, 2014, Elec. Clerk's Notes, Nov. 24, 2014, ECF No. 1376, the Plaintiffs made one last attempt to recall McGuire to the witness stand. This time, they called him a "rebuttal" witness and, for the first time, argued that he had testimony to present concerning the but-for entry date of generic Nexium. Pls.' Mot. Permit Dr. McGuire Testify Concerning Entry Date & Request Oral Argument, ECF No. 1325. Putting aside the Plaintiffs' now rather protean view of McGuire's expertise, this was hardly true rebuttal testimony because establishing that date was an essential part of the Plaintiffs' prima facie case. The Court refused the Plaintiffs' renewed proffer of McGuire. Dec 1. 2014 Tr. 81:15-19, ECF No. 1436.

Both sides having rested, the two remaining Defendants came within an ace of convincing me to grant them a directed verdict on the issue of whether their conduct caused antitrust damages. Like many judges, I reasoned that, since we were but a day away from submitting the case to the jury, the better part of valor lay in going to verdict and then unwinding it should I become convinced that the Defendants were entitled to judgment as matter of law.[25] Fed. R. Civ. P. 50.

C. The Plaintiffs' Remaining Claims Against The Defendants

A brief recapitulation of the Plaintiffs' claims that were resolved before and during trial is below:

End Payor Class Complaint [ECF No. 114]	**Claim for Relief**	**Defendant(s)**	**Result**

[25] Many judges in this situation recount – after the verdict – that "the jury saved me." I try to eschew thinking along those lines when ruling on motions for directed verdict at the close of all the evidence lest the thought morph subtly into influencing the charge.

The situation arises, of course, when the evidence strongly favors the defense. In those cases where the jury verdict is for the plaintiff, however, I strive mightily to sustain it, whatever my earlier impression. Here, the Plaintiffs' truly superb closing gave me reason to ponder.

Claim 1	Monopolization Under State Law	AZ	Voluntarily dismissed before trial[26]
Claim 2	Attempted Monopolization Under State Law	AZ	Voluntarily dismissed before trial
Claim 3	Conspiracy to Monopolize Under State Law	AZ/R, AZ/T, AZ/DRL, All Defendants	Voluntarily dismissed before trial
Claim 4	Conspiracy & Combination in Restraint of Trade Under State Law	AZ/R, AZ/T, AZ/DRL, All Defendants	**TRIAL (AZ and R)**
Claim 5	Declaratory/Injunctive Relief Under Section 16 of Clayton Act for Violations of Section 1 and 2 of Sherman Act	All Defendants	Injunctive class was not certified, but claim for relief survived
Direct Purchaser Class Complaint	**Claim for Relief**	**Defendant(s)**	**Result**

[26] The Class Plaintiffs agreed to dismiss their Section 2 claims under the Sherman Act, and their parallel state law monopolization claims, against all Defendants on October 14, 2014. See Stip. Regarding Certain Claims, ECF No. 1048 (End-Payors dismiss Claims 1-3 and strike Section 2 from Claim 5). The Retailer Plaintiffs followed suit on October 17, 2014. See Stip. Regarding Section 2 Claims, ECF No. 1070 (Rite Aid and CVS); Notice Regarding Section 2 Claims, ECF No. 1074 (Walgreen); Notice Regarding Section 2 Claims, ECF No. 1075 (Giant Eagle).

[ECF No. 131][27]			
Claim 1	Conspiracy to Monopolize, Section 2 of Sherman Act	AZ/R	Voluntarily dismissed before trial[28]
Claim 2	Conspiracy to Monopolize, Section 2 of Sherman Act	AZ/T	Voluntarily dismissed before trial
Claim 3	Conspiracy to Monopolize, Section 2 of Sherman Act	AZ/DRL	Voluntarily dismissed before trial
Claim 4	Agreement in Restraint of Trade, Section 1 of Sherman Act	AZ/R	**TRIAL (AZ & R)**
Claim 5	Agreement in Restraint of Trade, Section 1 of Sherman Act	AZ/T	Teva settled on 11/24/2014
Claim 6	Agreement in Restraint of Trade, Section 1 of Sherman Act	AZ/DRL	DRL settled on 10/17/2014
Claim 7	Monopolization, Section 2 of Sherman Act	AZ	Voluntarily dismissed before trial
Claim 8	Attempt to Monopolize, Section 2 of Sherman Act	AZ	Voluntarily dismissed before trial
Claim 9	Agreement in Restraint of Trade, Section 1 of Sherman Act	All Defendants	**TRIAL (AZ & R)**

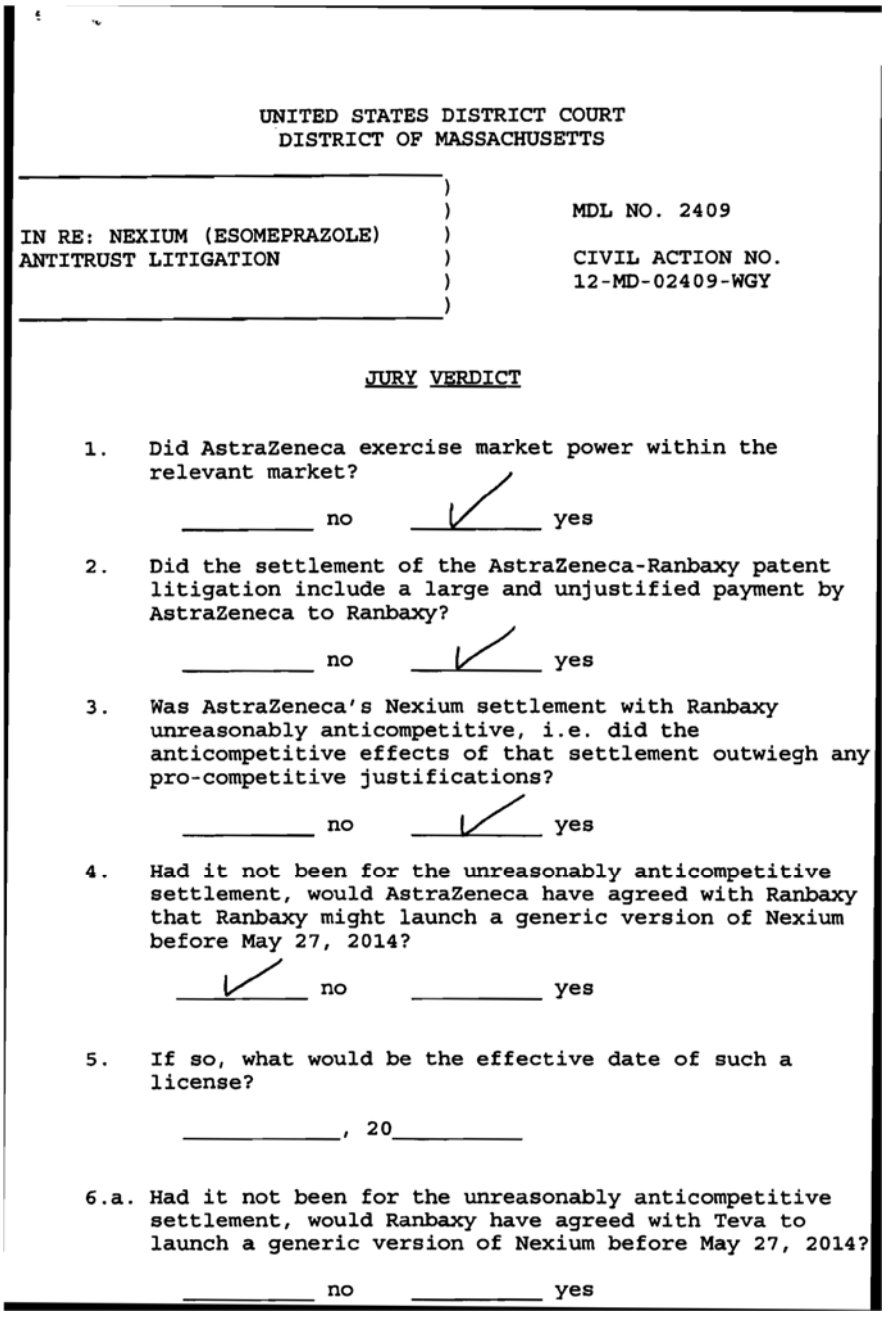
[27] Retailer Plaintiffs' complaints were left out of this table, as they essentially mirror the Direct Purchasers' complaint. The Retailer Plaintiffs, CVS, Rite Aid, Giant Eagle, and Walgreen Corp., are opt-outs from the Direct Purchaser Class and are assignees of individual Direct Purchasers.

[28] Direct Purchasers dismissed all claims arising under Section 2 of the Sherman Act. Stip. Regarding Section 2 Claims, ECF No. 1047.

Claim 10	Conspiracy to Monopolize, Section 2 of Sherman Act	All Defendants	Voluntarily dismissed before trial

The case then proceeded to conclusion. On December 3, 2014, the Court charged the jury on the theory that but for the AstraZeneca-Ranbaxy Settlement Agreement, Ranbaxy would have agreed to an earlier generic launch date, which would have allowed Teva, the more launch-prepared generic, to work out an agreement with Ranbaxy to take over the generic launch as they had done on previous occasions. Dec. 3 Tr. 50:21-51:10, ECF No. 1439. Whether this scenario could have come to fruition was posed in Questions 4 through 6b in the verdict slip. Id. By instructing the jury that their deliberations would end as soon as they checked "no" to any question, id. at 13:13-20, the verdict form set up each necessary step of what it would take to prove whether AstraZeneca and Ranbaxy conspired to violate the antitrust laws. After thirteen hours of deliberation over three

days, the jury returned the following verdict:[29]



UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	)	MDL NO. 2409 CIVIL ACTION NO. 12-MD-02409-WGY

JURY VERDICT

1. Did AstraZeneca exercise market power within the relevant market?

   _____ no ___✓___ yes

2. Did the settlement of the AstraZeneca-Ranbaxy patent litigation include a large and unjustified payment by AstraZeneca to Ranbaxy?

   _____ no ___✓___ yes

3. Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, i.e. did the anticompetitive effects of that settlement outwiegh any pro-competitive justifications?

   _____ no ___✓___ yes

4. Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?

   ___✓___ no _____ yes

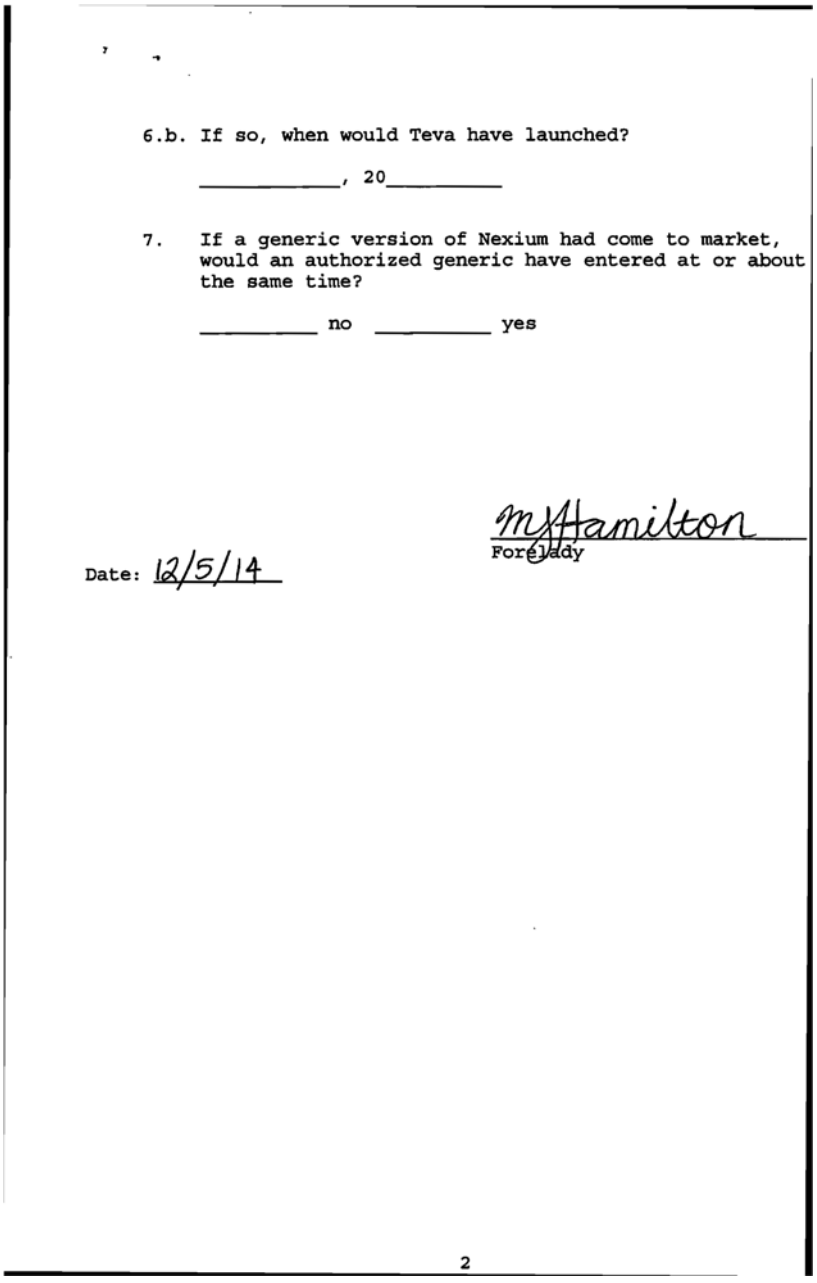
5. If so, what would be the effective date of such a license?

   _____, 20_____

6.a. Had it not been for the unreasonably anticompetitive settlement, would Ranbaxy have agreed with Teva to launch a generic version of Nexium before May 27, 2014?

   _____ no _____ yes

[29] Building upon the charge conference and the actual charge in this case, two of the lawyers for the End-Payor Plaintiffs in this case have prepared a very creditable proposal for suggested instructions in pay-for-delay antitrust cases. David F. Sorensen & Steve D. Shadowen,



6.b. If so, when would Teva have launched?

_____, 20_____

7. If a generic version of Nexium had come to market, would an authorized generic have entered at or about the same time?

_____ no _____ yes

M Hamilton
Forelady

Date: 12/5/14

2

By checking "yes" to Questions 1, 2, and 3, the jury indicated that they were convinced that the AstraZeneca-Ranbaxy Settlement Agreement was unreasonably

Model Jury Instructions: Trial by Actavis, 67 Rutgers U.L. Rev. 637 (2015).

anticompetitive under a rule of reason standard. But by checking "no" at Question 4, the jury indicated they could not conclude that Ranbaxy would have agreed to an earlier launch date but for their reverse payment settlement agreement. There may have been intent to violate the antitrust laws, and certainly anticompetitive "effect" from the AstraZeneca-Ranbaxy Settlement Agreement, but the jury could not establish that this materially caused the overcharges the Plaintiffs allegedly had suffered as consumers of Nexium. While ultimately, the verdict came out in favor of the Defendants, it was certainly tainted with the jury's holding that the AstraZeneca-Ranbaxy Settlement Agreement was, in fact, anticompetitive in nature.

Absent further proceedings, the jury verdict mandates the entry of judgment for the two remaining Defendants.

D. Was the Trial Worth It?

Was it worth it? The question is worth asking when one considers that, for all intents and purposes, the Court's initial rulings on February 12, 2014 mandated the entry of judgment for all the Defendants. Then, after the Court partially reconsidered, this twenty-six day trial ensued at a cost to the taxpayers conservatively estimated at $780,000.00 ($30,000 per day). See Chappee v. Com. of

Mass., 659 F. Supp. 1220, 1226 n.9 (D. Mass. 1987) rev'd on other grounds Chappee v. Vose, 843 F.2d 25 (1st Cir. 1988) (estimating a per day cost for federal courts of $10,000-$15,000 in 1987 and explains the methodology). See also Specialized Plating, Inc. v. Fed. Envtl. Servs., Inc., 975 F. Supp. 397, 398-401 (D. Mass. 1997) (citing to Chappee and estimating a per trial day cost of $17,500.00 in 1997); Judith Resnik, Managerial Judges, 96 Harv. L. Rev. 374 (1982). All this, only to have the jury **find** on December 5, 2014 essentially what this Court had **ruled** as matter of law eleven months earlier.[30]

Was the trial that valuable? To answer that question, one must look to the resolution of the post-trial motions to see whether it all must be done again.

E. Developments Post-Trial

On January 21, 2015, the First Circuit affirmed this Court's grant of class certification over a vigorous

[30] Of course, as has been explained, this Court's rulings on February 12, 2014 were, at least in part, wrong. The Court did not get things straightened out until mid-trial. It is not at all clear, however, that reversal of the Court's summary judgment ruling would necessarily have followed. In the real world, the Plaintiffs – rebuffed at the summary judgment stage – might not have appealed, or even had they done so, had this Court not permitted them to supplement the record to demonstrate the genuine issue of fact, the Court of Appeals could well have affirmed despite this Court's imperfect understanding of the actual facts.

dissent. In re Nexium Antitrust Litig., 777 F.3d 9, 32 (1st Cir. 2015).

On January 26, 2015, the FDA notified Ranbaxy "that [it] had forfeited its eligibility for 180-day exclusivity for [its Nexium generic] because it failed to obtain tentative approval of its ANDA within 30 months after the date on which the ANDA was submitted and that failure was not caused by a change in or a review of the requirements for approval." Pls. Supp. Mem. 3. On the same day, the FDA separately approved Teva's ANDA for its generic Nexium, id., which was launched on February 17, 2015. Id. at 4. Ranbaxy filed a judicial notice in the D.C. District Court on the same day regarding this launch. Defs.' Notice Admin. Action, 14-cv-01923, ECF No. 67 (D.C. District Court) (filed Jan. 26, 2015).

On February 27, 2015, the D.C. District Court granted the FDA's motions for summary judgment and denied Ranbaxy's motion for a preliminary injunction in the case before it. Id. at 4. Ranbaxy appealed this order and, a few days later, the D.C. District Court unsealed a redacted version of its opinion, a scathing criticism of both Ranbaxy's conduct and the FDA's oversight. Ranbaxy Labs., Ltd. v. Burwell, 2015 WL 1218933, at *31 (D.D.C. March 11, 2015).

IV. THE MOTION FOR A NEW TRIAL

A. The New Trial Rule and its Interpretation

Under Rule 59 of the Federal Rules of Civil Procedure, "[t]he court may, on motion, grant a new trial on all or some of the issues—and to any party . . . after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A).

New trials are, however, most assuredly the exception. "[N]o error in admitting or excluding evidence — or any other error by the court or a party — is ground for granting a new trial, for setting aside a verdict, or for vacating, modifying, or otherwise disturbing a judgment or order." Fed. R. Civ. P. 61. The First Circuit has held that "[a] district court may set aside the jury's verdict and order a new trial only if the verdict is against the law, against the weight of the credible evidence, or tantamount to a miscarriage of justice." Casillas-Diaz v. Palau, 463 F.3d 77, 81 (1st Cir. 2006); see also Boston Gas Co. v. Century Indem. Co., 708 F.3d 254, 260 (1st Cir. 2013) (quoting Mayo v. Schooner Capital Corp., 825 F.2d 566, 570 (1st Cir.1987)). "A motion for a new trial is not to be taken lightly. Such an expensive, burdensome option should be exercised only when an error occurred in the

conduct of the trial that was so grievous as to have rendered the trial unfair." MacNeill Eng'g Co., Inc. v. Trisport, Ltd., 126 F. Supp. 2d 51, 63 (D. Mass. 2001) (quotation marks omitted).

Still, whenever I have "botched the charge," I have not hesitated to order a new trial. Suboh v. Borgioli, 298 F. Supp. 2d 192, 206 (D. Mass. 2004); see also DiFiore v. Am. Airlines, Inc., 561 F. Supp. 2d 131, 138 (D. Mass. 2008) certified question answered, 454 Mass. 486 (2009).[31]

B. Analysis

1. Background

The Plaintiffs' major argument[32] is that at trial the Court improperly allowed them to proffer only one causation theory as to Ranbaxy, i.e., that "'but for' AstraZeneca's unlawful payments to Ranbaxy to delay the entry of generic

[31] Ironically, in both of these cases, my attempt to be fair and accurate only increased the litigants' cost and delay because I had botched issues more fundamental than the charge. In Suboh, I should have granted the defendant qualified immunity, Suboh v. Dist. Attorney's Office of Suffolk Dist., 298 F.3d 81, 95 (1st Cir. 2002), and in DiFiore, I should have recognized that federal law preempted the entire cause of action. DiFiore v. Am. Airlines, Inc., 646 F.3d 81, 90 (1st Cir. 2011).

[32] The Plaintiffs raise other objections and make other arguments as to why a new trial ought be granted. These are all dealt with adequately in the trial record and further exegesis defending my approach will not be particularly helpful.

Nexium . . . [the Defendants] would have agreed to a significantly earlier entry date, and Ranbaxy would have voluntarily relinquished its statutory first-filer exclusivity as part of a deal with Teva once Ranbaxy discovered that it was unable to come to market by the negotiated date." Pls. Supp. Mem. 1-2.

The Plaintiffs thus presented three scenarios which would have led to Ranbaxy's winning FDA approval and launching its generic drug before May 27, 2014: (1) Ranbaxy declines to settle with AztraZeneca, gains final FDA approval before February 2009, and launches generic Nexium at-risk while its litigation with AztraZenenca 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, or (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. In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 271. This Court rejected the three scenarios and granted Ranbaxy's motion for summary judgment due to lack of causation. Id. at 275.[33]

[33] The Plaintiffs subsequently moved the Court to reconsider this ruling, offering FDA documents for the

As to the causation, the Court approved only one scenario submitted by the Plaintiffs as demonstrating that an earlier market entry of a generic Nexium would have been possible. Id. at 289-90. This theory, submitted with respect to Teva, "posits that Ranbaxy could have voluntarily relinquished its exclusivity rights and entered into a strategic partnership with Teva in jointly launching generic Nexium" before May 27, 2014. Id. at 289.

Later, at the final preconference trial held on September 30, 2014, the Court confirmed that this causation theory presented by the Plaintiffs was the one that could be presented to the jury. Sept 30, 2014 Final Pretrial Tr. 4:8-5:13, ECF No. 1030.

First, it ought be noted that the Plaintiffs now take a position in their supplemental submissions opposite those advanced in their opposition to the Defendants' motions for summary judgment and in their motion for reconsideration. The Plaintiffs now argue that Ranbaxy would have

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purpose of shedding light on the approval of another of Ranbaxy's ANDA generics, Lipitor. The Plaintiffs argued that the documents demonstrated FDA concerns about the creation of a regulatory bottleneck in case of delayed approval, and demonstrated that the FDA would have accelerated approval of a generic Nexium ANDA in time for a launch earlier than May 27, 2014. The Court denied the motion to reconsider, holding that the documents were not sufficient evidence of any of the three proffered theories of causation. Id. at 279.

involuntarily lost its first-filer exclusivity before May 27, 2014 while before they defended just as rigorously that Ranbaxy could have won FDA's approval before that date. Compare Pls. Supp. Mem. 7, with, e.g., Retailer Pls.' Mem. Opp'n Ranbaxy's Mot. Summ. J. Based Causation 3, ECF No. 773. Indeed, in their motions for summary judgment, the Defendants argued as to causation that under no circumstance would Ranbaxy have been able to launch a generic version of Nexium before May 27, 2014 (as proved to be the case). In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 269. The Plaintiffs countered that the AstraZeneca-Ranbaxy Settlement Agreement "caused it to purposely delay addressing the regulatory issues that would have paved the way to generic launch," id., and that Ranbaxy "deliberately slowed or stopped its efforts in response to its settlement with AztraZeneca." Id. at 270.

The Plaintiffs contend that during the trial, they could not have shown that Ranbaxy would involuntarily have lost its exclusivity, while the events occurring at the end of 2014 and start of 2015 proved precisely that. Pls. Supp. Mem. 1-2. According to the Plaintiffs, had there been no large and unexplained anticompetitive reverse payment, AstraZeneca and Ranbaxy would have agreed to an earlier entry date and, when it became clear that Ranbaxy

could not meet that date, "the FDA would have stepped in and found Ranbaxy to have forfeited its exclusivity . . . ." Id. at 2. For support, the Plaintiffs cite the FDA's November 4, 2014 decision to rescind the previously granted tentative approval of Ranbaxy's Generic Nexium ANDA, id., its January 26, 2015 notification to Ranbaxy that Ranbaxy had forfeited its first-filer exclusivity, id. at 3, and the approval, on the same day, of Teva's ANDA for generic Nexium, id., which was eventually brought to market on February 17, 2015, id. at 4. The Plaintiffs argue that the FDA forfeited Ranbaxy's exclusivity as late as January 2015 because Teva, as the Plaintiffs say, "slowed its efforts to get approval of its ANDA" once AztraZeneca paid Ranbaxy to delay its entry date. Id. at 3. In the Plaintiffs' view, these facts support an "alternate non-speculative theory of causation that Ranbaxy would have involuntarily lost its exclusivity" at an earlier date, and Teva would have entered the market, absent the Ranbaxy Agreement. Id. at 4.

This is a serious argument and the Court regards it as such. Two points, however, must be made at the outset. First, in no sense did this Court "prevent" the Plaintiffs from advancing their present involuntary forfeiture

argument at trial.[34] Simply put, the Plaintiffs had no such argument until the FDA finally acted. One can search the pre-trial and trial record in this case in vain for any such argument presented with any cogency. Second, this Court never made any finding that Teva ever "slowed its efforts to get approval of its ANDA." Id. at 3. How could it? This is a jury case and, under the Seventh Amendment, only the jury makes findings. Beacon Theatres, Inc. v. Westover, 359 U.S. 500, 501 (1959). At most, the Court recognized prior to trial that the record presented a genuine issue as to this aspect of the case. Indeed, at trial, the overwhelming evidence was that Teva pressed forward relentlessly to develop its generic version of Nexium. Oct 30, 2014 Tr. 42:14-18, ECF No. 1398.

[34] It ought be noted that the present theory of involuntary relinquishment differs from the one presented by the Plaintiffs in their pre-trial submissions that, had AztraZeneca and Ranbaxy agreed to an earlier entry date, then the FDA would earlier have retroactively revoked Ranbaxy's tentative approval and determined that Ranbaxy forfeited its exclusivity. See Class Pls.' Opp'n [641] Ranbaxy's Statement Undisputed Facts Relating Causation ¶ 27 n. 41, ECF No. 791-1 (referring to the rebuttal report of Martha Bennett, at ¶ 45, stating "For reasons explained below, it is my opinion that if the launch date for Ranbaxy's generic Nexium product was prior to May 2014 but after finalization of the Consent Decree on January 25, 2012, FDA would have implemented earlier dates for Ranbaxy to satisfy the pertinent regulatory milestones under the Decree or else face FTF [180-day exclusivity] relinquishment").

2. Judicial Estoppel

The Defendants argue that the Court ought pay no attention to any of this as the Plaintiffs are judicially estopped from arguing that anything that happened after May 27, 2014 is relevant. As grounds, the Defendants point out that the Plaintiffs fought during the trial to preclude evidence of activities after this date and successfully moved in limine for an order precluding the Defendants from introducing evidence "post May 27, 2014." AstraZeneca's Opp'n Pls.' Motion Leave File Pls.' Supp. Submission Connection Pending New Trial Motions 3-4, ECF No. 1507; Ranbaxy's Opp'n Pls.' Supp. Submission Support Mot. New Trial 6-7, ECF No. 1508.

Under the doctrine of judicial estoppel, "where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him." New Hampshire v. Maine, 532 U.S. 742, 749 (2001) (alterations omitted). This rule "generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase." Id. The purpose of

the doctrine of judicial estoppel is "to protect the integrity of the judicial process by prohibiting parties from deliberately changing positions according to the exigencies of the moment." Id. at 749-50 (internal citations and quotation marks omitted).

When deciding whether to judicially estop a party from asserting a position, courts consider the following factors: whether the party's later position is "clearly inconsistent" with its earlier position, "whether the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create the perception that either the first or second court was misled," and "whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped." Id. at 750-751 (internal quotation marks omitted). "Absent success in a prior proceeding, a party's later inconsistent position introduces no risk of inconsistent court determinations, and thus poses little threat to judicial integrity." Id. at 751 (internal citations and quotations omitted).

Judicial estoppel is not appropriate here. True, the Plaintiffs moved in limine to prevent the Defendants from

introducing evidence post-dating May 27, 2014. Pls.' Mot. In Limine Preclude Defs. Introducing Evid. Events Occurring On or After May 27, 2014, ECF No. 1071. The Plaintiffs, however, did not succeed in their motion in limine; the Court denied it without prejudice. Elec. Order, Oct. 20, 2014, ECF No. 1105. To the extent the Court enforced the May 27, 2014 date as the limit of relevant evidence,[35] it made its rulings in light of the matters then at issue in the trial.

More to the point, the Plaintiffs simply are not now taking a position contrary to that which they took earlier in the judicial process. They are simply arguing that Ranbaxy's involuntary forfeiture (which post-dated the motion in limine) is relevant, where earlier in the trial, and prior to the involuntary forfeiture occurring, they argued that the Defendants' post-May 27, 2014 evidence was not. There is nothing inconsistent about this. Allowing the Plaintiffs to rely on the post-May 27, 2014 evidence of Ranbaxy's involuntary forfeiture does not impair the

[35] Oct. 30, 2014 Tr. 140:6-7, ECF No. 1399 (where the Court held "[w]e're going up to May 27, 2014, that's what the issue is"); see also Oct. 31, 2014 Tr. 114:6-8, ECF No. 1401 (where the Court held "let's go to [May 27, 2014]. I'm not counting more recent than that. But you can go to that date.").

integrity of the judicial process, nor does it confer any unfair advantage or impose any unfair detriment. Consequently, the Plaintiffs are not judicially estopped from arguing that this post-May 27, 2014 evidence is relevant and necessitates a new trial.

3. A Miscarriage of Justice?

The Plaintiffs allege that Ranbaxy's evidence in its litigation against the FDA before the D.C. District Court directly contradicts the evidence Ranbaxy presented to the jury in this case, since "[a]t the trial of this case, Ranbaxy took the position that it never would have entered into a deal to voluntarily relinquish its first to file exclusivity on Nexium, but, in its litigation with the FDA, Ranbaxy suggested that it could take precisely such action to monetize its first-to-file exclusivity." Pls. Supp. Mem. 10.

The Plaintiffs argue specifically that at the jury trial, on December 1, 2014, Venkatachalam Krishnan, Ranbaxy Regional Director of North America testified as follows:

> Q. Did Ranbaxy, in your entire tenure as Regional Director, from '06 to 2014, ever voluntarily relinquish its first-filer exclusivity on any product?
>
> A. No. Never.
>
> Q. Why is that?

A. You work very hard to earn exclusivity under the Hatch-Waxman Act and the company invests a lot of money and effort and people putting in a lot of effort, so it's not a good business sense to give up such a valuable asset.

Q. . . . during your 9 years as the Regional Director of North America [for Ranbaxy], from 2006 to October of 2014, at any point did Ranbaxy ever consider doing a deal with Teva regarding generic Nexium?

A. Never.

Q. Never?

A. Never.

Q. Why not?

A. There was no need for us to that because, um, (A) I think we had put in a lot of effort in getting exclusivity, so there was a lot of effort by our people, and (B) we were always confident that we'll be putting the product into the marketplace irrespective of all the issues that we faced with FDA. So there was absolutely no need for us to consider that --

Dec. 1, 2014 Tr. 14:3-12; 8:1-16, ECF No. 1435.

Krishnan was employed by Ranbaxy from June 1993 to October 31, 2014 and occupied the position of Regional Director from 2006 to 2014. Id. at 5:12-6:7. As a Regional Director, he was in charge of the business operations of Ranbaxy in North America and participated in the "consideration and evaluation of all settlements of cases involving Ranbaxy." Id. at 6:8-7:6.

The Plaintiffs argue that, on the contrary, before the D.C. District Court, Dan Schober, Vice President – Trade Sales for Ranbaxy Pharmaceuticals, declared in an affidavit:

> My experience also has shown that even when an exclusivity-entitled generic applicant is unable to market its own product due to manufacturing or other issues, it can still take advantage of its exclusivity right by waiving or relinquishing that right to another company which can market its product in exchange for valuable consideration. Moreover, the first applicant can execute a "file merger," under which it acquires the rights to use another company's product in its exclusivity-entitled ANDA in exchange for a share of the proceeds from selling the product. Based on my past experience and my understanding of the projected markets for generic Nexium® and Valcyte® specifically, I estimate that Ranbaxy would earn tens, if not hundreds, of millions of dollars during the first year of anticipated product sales following the effectuation of a waiver or relinquishment of its exclusivity or from consummating a file merger [for Nexium and Valcyte].

Pls. Supp. Mem., Ex. J., Second Am. Decl. Dan Schober ¶ 13-14 ("Schober Decl."), ECF No. 1515-11.

First, based on a review of the record, it appears that Krishnan correctly testified that, during his nine years as Ranbaxy Regional Director of North America, Ranbaxy never voluntarily relinquished its first-filer exclusivity on any product.[36]

[36] It is true that Ranbaxy and Teva entered into strategic partnerships as to generic Lipitor and generic

Second, upon this record, Ranbaxy and Teva never entered into any agreement as to generic Nexium.[37]

Third, Krishnan's testimony was also consistent with the affidavit later filed in the D.C. District Court in which Schober emphasized the value of keeping exclusivity whenever possible rather than entering a partnership agreement with another generic company in order for a generic to come to market.[38] Krishnan never denied

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Accupril. Yet for generic Accupril, Teva, and not Ranbaxy, voluntarily relinquished its first-filer exclusivity. See Deshmukh's testimony as to Accupril, Nov. 19, 2014 Tr. 52-55, ECF No. 1423. For Lipitor, since Teva had an earlier entry date than Ranbaxy resulting from a settlement agreement with the brand company of Lipitor, Pfizer, when Ranbaxy got the FDA approval, it entered into an agreement with Teva to ensure a timely launch of Lipitor. Again, this agreement did not involve Ranbaxy forfeiting its exclusivity. See Blume testimony as to Lipitor, November 20, 2014 Tr. 113:14-115:25, 117:14-16, ECF No. 1425.

[37] Krishnan testified that Ranbaxy never considered doing a deal with Teva as to generic Nexium from 2006 to 2014. Tr. Dec. 1, 2014, 8:1-16, ECF No. 1435. He also testified that Teva asked Ranbaxy for a meeting "to discuss a potential deal regarding Nexium," but that Ranbaxy was "not keen" for it. Dec. 1, 2014 Tr. 10:13-11:25, ECF No. 1435; see also Oct. 31, 2014 Tr. 23:14-20, ECF No. 1400. The absence of agreement as to generic Nexium between Teva and Ranbaxy was confirmed by Blume, see Blume testimony, Nov. 20, 2014 Tr. 112:19-113:13, ECF No. 1425; Oct. 31, 2014 Tr. 24:8-10, ECF No. 1400.

[38] Both Ranbaxy executives recognized that it is more valuable to get the first-filer exclusivity than voluntarily to relinquish exclusivity by entering into a partnership agreement with another generic company because generic companies put forth a great deal of effort to develop generics and put them into the marketplace.

the general possibility of a partnership agreement when a company has first-filer exclusivity.[39] Krishnan simply denied that Ranbaxy had an interest in such a partnership for generic Nexium prior to May 27, 2014. According to him, since Ranbaxy thought it would be able to get final approval in 2014, it did not take any steps to enter into

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December 1, 2014 Tr. 8:10-9:7, ECF No. 1435; Schober Decl. ¶ 11 (stating that "180-day generic marketing exclusivity plays a vital role in ensuring that generic drug applicants like Ranbaxy continue to undertake the efforts and invest the resources necessary to develop generic drugs, challenge patents, and subject themselves to the risk of patent infringement litigation. Any action by FDA that decreases the certainty of receiving 180-day exclusivity reduces the incentive for companies like Ranbaxy to undertake the risks associated with filing Paragraph IV certifications and invest the resources necessary to do so successfully.").

[39] Krishnan testified as follows:

> A. "Voluntary relinquishment" means that Ranbaxy, or the company that has the exclusivity, would give up the exclusivity to the public. That means just give it up.
>
> Q. Okay. Now, you said "to the public," "give it up to the public," could you explain to the jury what that means?
>
> A. That means that Ranbaxy would no longer hold exclusivity and it would be free for all the people who have filed the product and launched the product.
>
> So it would be not be specific exclusivity for anybody else, there would be a gate open for all the players in the marketplace.

Dec. 1, 2014 Tr. 12:20-13:6, ECF No. 1435.

such an agreement with Teva. Dec. 1, 2014 Tr. 9:8-21, ECF No. 1435

At most, the Ranbaxy affidavit in the D.C. District Court was useful impeachment of Krishnan's testimony. There has been no miscarriage of justice here.

As a consequence, and notwithstanding the question whether Schober's declaration in the Ranbaxy-FDA litigation before the D.C. District Court constitutes impeachment material, there is no contradiction between his declaration in the Ranbaxy-FDA litigation and Krishnan's testimony in this jury trial.

4. Newly Discovered Evidence?

The First Circuit has held that

> [a]n order for new trial on the ground of newly discovered evidence requires proof of the following elements: (1) The evidence has been discovered since the trial; (2) The evidence could not by due diligence have been discovered earlier by movant; (3) The evidence is not merely cumulative or impeaching; and (4) The evidence is of such nature that it would probably change the result if a new trial is granted.

Raymond v. Raymond Corp., 938 F.2d 1518, 1527 (1st Cir. 1991); see also In Re Neurontin Mktg. & Sales Practices Litig., 799 F. Supp. 2d 110, 113 (D. Mass. 2011) (Saris, J.). The same four-factor test for determining whether a new trial should be granted on the grounds of newly discovered evidence applies regardless of whether a motion

for new trial is brought under Rule 59 – the rule governing new trials - or Rule 60(b)(2) – the rule governing relief from judgment based on newly discovered evidence. Kettenbach v. Demoulas, 901 F. Supp. 486, 493 (D. Mass. 1995) (Saris, J.).

As to the first requirement of "newly discovered evidence," the First Circuit has held that "'newly discovered evidence' normally refers to 'evidence of facts in existence at the time of trial of which the aggrieved party was excusably ignorant.'" Rivera v. M/T Fossarina, 840 F.2d 152, 156 (1st Cir. 1988) (quoting Brown v. Pa. R. Co., 282 F.2d 522, 526-27 (3d Cir. 1960)); see also In Re Neurontin, 799 F. Supp. 2d at 114-15 (holding that scholarly article regarding efficacy of pharmaceutical manufacturers' prescription anticonvulsant drug for off-label uses was not newly discovered evidence, since it provided meta-analysis of studies that were available during trial and which manufacturers could have similarly analyzed before trial). "A motion for new trial on the ground of newly discovered evidence will generally be granted only where the movant was excusably ignorant of the facts despite exercising due diligence to uncover them." Jay Edwards, Inc. v. New Eng. Toyota Distrib., Inc., 708 F. 2d 814, 825 (1st Cir. 1983). In addition, even if created

after trial, evidence can be considered as "newly discovered" within the meaning of Rule 60(b)(2) when the events that it purports to describe took place long before judgment. Kettenbach, 901 F. Supp. at 494 (a recorded conversation occurred after the trial, but purported to describe an alleged wiretap of Demoulas Super Markets, Inc., which took place long before judgment).

Still, "[a] trial can be no more than a resolution of an immediate dispute on the basis of present knowledge." In re Neurontin, 799 F. Supp. 2d at 116 (quoting Merrell Dow Pharms., Inc. v. Oxendine, 649 A.2d 825, 831 (D.C. 1994)). The requirement that facts must exist at the time of trial is important. "'If it were ground for a new trial that facts occurring subsequent to the trial have shown that the expert witnesses made an inaccurate prophecy of the prospective disability of the plaintiff, the litigation would never come to an end.'" Colyer v. Consol. Rail Corp., 114 F. App'x 473, 481 (3d Cir. 2004) (quoting Campbell v. Am. Foreign S.S. Corp., 116 F.2d 926, 928 (2d Cir. 1941)) (alterations omitted).

The fourth requirement is a "materiality" test. Kettenbach, 901 F. Supp. at 497. Rule 60(b)(2) is aimed at "correcting erroneous judgments based on the unobtainability of evidence," meaning that "the burden is

on the party presenting the new evidence to demonstrate that the missing evidence was of such a material and controlling nature as would probably have changed the outcome." Id. (internal quotations omitted); see also In Re Neurontin, 799 F. Supp. 2d at 116-17 (concluding that the scholarly article regarding efficacy of pharmaceutical manufacturers' prescription anticonvulsant drug for off-label uses was not likely to change result of trial).

Here, the most significant facts and evidence which occurred after the jury trial – the FDA's decision to revoke Ranbaxy's exclusivity, the FDA's approval of Teva's generic Nexium, and Teva's launch of generic Nexium in early 2015 – cannot be considered "newly discovered evidence" under Rules 59 and 60(b)(2). Even though these important decisions are the results of a long process of ANDA review before the FDA, that is not enough to consider them as "based" upon facts that were in existence at the time of trial or as merely describing events that took place before or during the jury trial.

Some evidence submitted by or referred to by the Plaintiffs in their supplemental submissions, however, was in existence at the time of the trial. This is the case for the complaint filed in the Ranbaxy-FDA litigation before the end of the jury trial and the FDA's decisions

attached to it, in particular the ones decided November 4, 2014 as to Ranbaxy's generic Nexium, Decl. Thomas M. Sobol ("Sobol Decl."), Ex. A, Ranbaxy Labs., LTD. & Ranbaxy, Inc.'s Compl. Decl. & Inj Relief, ECF No. 1515-2, as well as the administrative record referred to in that complaint which the Plaintiffs argue reflects the actions that the FDA took with respect to the Ranbaxy ANDA. Likewise, Schober's affidavit filed in the D.C. District Court in the Ranbaxy-FDA litigation purports to describe events and facts which were in existence before or during the trial, Schober Decl., and thus should be considered "newly discovered evidence." See Kettenbach, 901 F. Supp. at 494. For the purposes of this opinion only, the Court will excuse the Plaintiffs' failure to become aware of these matters before the conclusion of the trial. The question is, therefore, are any of these matters material?

5. Materiality

What then is one to make of the Plaintiffs' new theory of involuntary forfeiture? Upon all the evidence of record, including the so-called "new" evidence, and in light of the indisputable post-trial developments, ought this Court grant a new trial?

Suppose the Court were to grant the Plaintiffs' motion for a new trial and do it all over again, this time with

the Plaintiffs completely reversing field and advancing their involuntary forfeiture theory. Here is what the Plaintiffs would be attempting to prove:

But for AstraZeneca's large, unjustified, and anti-competitive reverse payment to Ranbaxy, Ranbaxy would have forged ahead vigorously in trying to bring generic Nexium to market. **If** Ranbaxy had forged ahead vigorously, it would have run into difficulty much sooner than it actually did. **If** Ranbaxy had run into these development and production difficulties sooner, then the FDA aggressively would have earlier established production milestones. **If** the FDA had established these earlier milestones, Ranbaxy would have failed to meet them earlier than actually happened. **If** Ranbaxy had earlier failed to meet the requisite milestones, the FDA would earlier have involuntarily forfeited Ranbaxy's 180-day exclusivity period. **If** the FDA had earlier involuntarily forfeited Ranbaxy's exclusivity, then Teva was ready, willing, and able to bring its own version of generic Nexium to market. **If** Teva had been earlier ready, willing, and able to bring its own version of generic Nexium to market, the FDA would earlier have approved Teva's product. **If** the FDA had earlier approved Teva's version of generic Nexium, Teva would have launched "at risk" appreciably earlier than it

actually did. **If** Teva had launched "at risk," it would have warded off AstraZeneca's patent-based motion for an injunction and successfully marketed its generic version of Nexium – all this well before May 27, 2014 – thus the inflated price for Nexium and its generic equivalents would naturally have tanked due to appropriate competition and this would establish antitrust damages as of that earlier date (whenever it was).

There are two obvious (and insurmountable) difficulties with this theory.

First, it stretches any reasonable inference from the evidence of record at least a couple of bridges too far. See CORNELIUS RYAN, A BRIDGE TOO FAR: THE CLASSIC HISTORY OF THE GREATEST BATTLE OF WORLD WAR II, Reprint edition. 1995 (monumental history of the disastrous Arnhem campaign in World War II).[40] This Court instructs jurors with a consistency that borders on monotony (at least for the Court) that they may neither guess nor speculate and may not "pack inference upon inference." See, e.g., United States v. O'Brien, No. 12-cr-40026-WGY, July 15, 2014 Excerpt Tr. 19:25-20:10, ECF No. 560.

[40] For the Hollywood version, see A Bridge Too Far (Joseph E. Levine Productions 1977).

Second, there is simply no evidence that the events that played out in the latter half of 2014 and early 2015 can simply be transposed entire to an earlier point in history. True, it is now clear that AstraZeneca did make a large, unjustified, and anticompetitive reverse payment to Ranbaxy and one supposes the Plaintiffs could prove it yet again. Moreover, in 2010, Ranbaxy and the FDA began to negotiate a consent decree to resolve enforcement issues against the company. The parties dickered over various terms, including whether Ranbaxy would have to relinquish its right to 180-day marketing exclusivity for generic Nexium, and the final decree was filed on January 25, 2012. 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." In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 267.

The decree set out certain milestones that had to be met before review of Ranbaxy's Nexium ANDA would continue. 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. At this time, Ranbaxy began working on a site transfer amendment to move production from Paonta Sahib,

India to a plant in Ohm, New Jersey, which was submitted to the FDA on November 15, 2013. Id.

The decree also set in place significant data integrity review protocols for evaluating applications from the Paonta Sahib facility. If Ranbaxy had not completed these protocols by September 30, 2014, it waived its 180-day generic Nexium marketing exclusivity. Id.

Still, there is no evidence whatsoever as to the FDA's funding, investigative resources, or policies during the period at issue and the one judge who has looked into this matter has flayed the FDA for its lax enforcement. Burwell, 2015 WL 1218933, at *31 (Howell, J.). Nor do the Plaintiffs suggest any evidence sufficient to prove that Teva would have been able to come to the market with its generic Nexium earlier than May 27, 2014. Indeed, in the Ranbaxy-FDA litigation, the FDA argued that at that date, the "FDA has not yet even tentatively approved any other [Generic Nexium ANDA]." Sobol Decl., Ex. C, Defs.' Mem. Opp'n Pls.' Mot. Preliminary Inj. & Supp. Mot. Summ. J. 20, ECF No. 1515-4.

More specifically, in reference to another case involving Teva, the FDA stated in the Ranbaxy-FDA litigation:

> As the Court also held, Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010), is distinguishable from the facts of this case. TRO Tr. at 100:21-23. The outcome in Teva was compelled by the "absence of any colorable factual dispute," and there was "no suggestion that any possible deficiency or uncertainty in Teva's ANDA could thwart final approval." 595 F.3d at 1309. The scenario that Teva sued to resolve was, for all intents and purposes, inevitable, and "the prospect of impending harm was effectively certain." Id. at 1314. Here, in contrast, significant factual uncertainty remains. Ranbaxy has made no showing that it will be in a position to get final approval of, or otherwise capitalize on, its esomeprazole ANDA anytime soon, and FDA has not yet even tentatively approved any other generic esomeprazole ANDAs. Cf. 595 F.3d at 1311 (noting that, "as of April 6, 2010, [Teva] will be entitled" to market its product and "would almost certainly face competition" absent judicial intervention). And unlike in Teva, where the application of another forfeiture event was "virtually inconceivable," id. at 1309-10, it remains possible in this case that the relevant patents could expire or that the "failure to market" forfeiture trigger could apply before either Ranbaxy or another applicant is eligible for final approval. See 21 U.S.C. §§ 355(j)(5)(D)(i)(I), (VI). Because of the possibility that FDA's rescission of the esomeprazole tentative approval letter ultimately may not affect the landscape for approval of ANDAs for generic esomeprazole, it is clear that "consideration of the issue would benefit from a more concrete setting." Id. at 1308.
>
> Id.

For all these reasons, and the proper resolution of issues in the trial record, the Plaintiffs' motions for a new trial, ECF Nos. 1450, 1453, ought be, and hereby are, DENIED.

V. CLASS ACTION CONSIDERATIONS

On January 21, 2015, the Court of Appeals for the First Circuit affirmed this Court's certification of the End-Payor class over a vigorous dissent. In re Nexium Antitrust Litig., 777 F.3d at 32. The dissent aptly and succinctly framed the appellate issue:

> The chief difficulty we confront in this case arises from the fact that some of the members of the class have not suffered the antitrust injury upon which this entire case is predicated. This percentage, while small, could constitute as many as 24,000 consumers who would have no valid claim against the defendants under the state antitrust laws even if the named plaintiffs win on the merits.
>
> The majority correctly recognizes that certification of a class that includes uninjured consumers hinges on there being a method of identifying and removing those consumers prior to entry of judgment, and that any such method must be both administratively feasible and protective of the defendants' Seventh Amendment and due process rights. Op. at 19–20. The majority also correctly recognizes that the district court has not identified-much less rigorously analyzed-any method for identifying and excluding these thousands of consumers prior to entry of judgment. Op. at 20. Rather, the district court certified the class because it considered the Rule 23 predominance inquiry satisfied by the fact that the vast majority of consumers in the class had been injured. As for the uninjured, the court simply kicked the can down the road by noting that the court "preserve[d] the Defendants' right to challenge individual damage claims at trial." In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D. 168, 179 (2013).

Id. at 32-33 (1st Cir. 2015) (Kayatta, J., dissenting).

I suppose it behooves me to be grateful for the affirmance – the majority opinion breaks important new ground – and otherwise remain silent. Yet this was an interlocutory appeal and much has happened since. The full appeal has yet to occur and is well-nigh inevitable. Moreover, there is the distinct possibility that further proceedings may be ordered, either before me or before another judge.[41]

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[41] The Massachusetts Local Rules make clear that a case remanded for further proceedings after a trial has taken place before one judge is to be re-tried before another judge. LR, D. Mass. 40.1(K)(1). This case, however, was assigned to this Session not by our Court's random draw procedures, LR, D. Mass. 40.1(A)(3), but by the Judicial Panel on Multi District Litigation acting pursuant to 28 U.S.C. § 1407. In such circumstances, I am uncertain who ought handle a remand given my intimate familiarity with the case.

As the Judicial Panel for Multi District Litigation now holds the case assignment power over more than one-third of the civil cases presently pending in the nation's federal district courts, Jaime L. Dodge, Wrangling the Beast, 99 Judicature 32 (2015); see also Thomas Metzloff, The MDL Vortex Revisited, 99 Judicature 36 (2015), its exercise of that power can have drastic, real-world consequences, not all of them beneficent. Report of the Proceedings of the Judicial Conference of the United States 20 (Mar. 10, 2015), http://www.uscourts.gov/about-federal-courts/reports-proceedings-judicial-conference-us (recommending to the President and the Senate not to fill the next judgeship vacancy in the District of Wyoming due to low caseload); see also In re Am. Cont'l Corp./Lincoln Sav. & Loan Sec. Litig., 102 F.3d 1524, 1547 (9th Cir. 1996) rev'd sub nom. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 118 (1998) (Kozinski, J., dissenting) (noting that "[t]he simple reality is that once a case is sucked into the MDL vortex, it seldom comes back" to the transferor

In such circumstances – like the moth to the flame – it is my duty briefly to articulate the method I had devised for culling the uninjured from the injured class members if ever we had gotten to the damages phase of the litigation. Had antitrust liability been established, my idea was to shift to the Defendants the burden of going forward with evidence of lack of injury to particular class members, while leaving the End-Payor Plaintiffs with the ultimate burden of persuasion as to the damages suffered by particular claimants.

This accords well with the common law practices of the several states in which the individual class members in the End-Payor Plaintiffs' class reside: one who bears the affirmative position on a legal issue (here, the Defendants claiming non-injury due to brand loyalty, discounts, and the like) ought come forward with evidence of that circumstance. Moreover, it is the Defendants who possess this data. Only they know how deeply they have discounted their product and to whom; they possess what studies may

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court to proceed to trial, as was originally intended by Congress); DeLaventura v. Columbia Acorn Trust, 417 F. Supp. 2d 147, 150-53 (D. Mass. 2006); Patrick Higginbotham, Bureaucratizing the Courts?, 99 Judicature 44, 45-46 (2015). Fortunately, the Supreme Court has put limits on the tendency to sweep cases far from the courts where they were filed, never to return. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 40 (1998).

exist as to brand loyalty and its effects and, I reasoned, by that stage the Defendants would have been adjudicated antitrust violators, so making them come forward with evidence to mitigate the damages seemed only logical.

While I mistakenly had not included these thoughts in the class certification opinion, I had communicated them to the parties during the run-up to the trial. Dec. 11, 2013 Pretrial Conf. Tr. 10:21-11:14; 32:3-33:9; 34:3-22, ECF No. 668. Not surprisingly, no hint of any of this appears in the appellate record. Why should it? All the parties hated these suggestions. The End-Payor Plaintiffs were dismayed that the Court seemed intent on forcing them to prove the actual damages of individual class members (I was) – they were talking about nothing more nuanced than state-wide aggregate damages. The Defendants loathed the idea that they might have to disclose closely held corporate data.

Is this the "figure-it-out-as-we-go-along approach" condemned in Madison v. Chalmette Ref., L.L.C., 637 F.3d 551, 557 (5th Cir. 2011)? Perhaps. I prefer to think of it as deciding only what needs to be decided,[42] and then

[42] In re One Star Class Sloop Sailboat Built in 1930 with Hull No. 721, Named ""Flash II'', 517 F. Supp. 2d 546, 556 n.5 (D. Mass. 2007) aff'd United States v. One Star Class Sloop Sailboat built in 1930 with hull no. 721, named

where the issue is squarely presented and briefed. I speak here only to aid a likely appeal. In the future – in light of the majority and dissenting opinions in the First Circuit's affirmation of class certification here – I shall be careful to explicate an approach to assessing damages even when certifying only a liability class.

VI. THE MOTION FOR PERMANENT INJUNCTION

A. Introduction

Following the close of the trial, the Individual Plaintiffs filed a motion for permanent injunction under Section 16 of the Clayton Act, and a memorandum of support thereof. Mot. Permanent Inj. ("Mot. Perm. Inj."), ECF No. 1457; Mem. Supp. Pls.' Mot. Permanent Inj. ("Pls.' Mem. Inj."), ECF No. 1458. This motion reflects a fundamental disagreement between the parties as to whether the jury's verdict at trial established the existence of an antitrust violation.

""Flash II'', 546 F.3d 26 (1st Cir. 2008) (recalling the sage advice given to me by Judge Owen Panner: "There's not too much to this judging business, Bill. You find out what cases you have. You get them to trial as soon as you reasonably can. You try cases the best you know how. You decide what you need to decide as fairly as you can — and you keep moving on.").

Section 16 of the Clayton Act provides injunctive relief for violations of the antitrust laws, with broad discretionary power to the courts. 15 U.S.C. § 26.

> An injunction-seeker must show either that some past unlawful conduct has continuing impact into the future . . . or else he must show a likelihood of future unlawful conduct on the defendant's part . . . . To gain a permanent injunction in the former case, the plaintiff must actually succeed on the merits of his claim by proving that the past conduct violated his rights.

Lopez v. Garriga, 917 F.2d 63, 67-68 (1st Cir. 1990)) (internal citations omitted).

The Plaintiffs argue that the jury's affirmative answers to questions 1-3 of the verdict slip establish a violation of Section 1 of the Sherman Act – that the Ranbaxy-AstraZeneca Settlement Agreement was "in restraint of trade." Pls.' Mem. Inj. 4. AstraZeneca and Ranbaxy counter that no antitrust liability was established by the special verdict because in question 4 of the verdict slip, the jury did not find that Ranbaxy could have entered the generic market before May 2014. As a result, they argue, no Section 16 relief is possible. AstraZeneca's Opp'n Pls.' Mot. Permanent Inj. ("AstraZeneca Opp'n Mot. Permanent Inj.") 9-11, ECF No. 1473; Ranbaxy's Opp'n Pls.' Mot. Permamemt Inj. ("Ranbaxy Opp'n Mot. Permanent Inj.") 1, ECF No. 1475.

B. Standing to Sue for Injunctive Relief

1. Section 16 of the Clayton Act

Section 16 of the Clayton Act provides injunctive relief to "[a]ny person, firm, corporation, or association . . . against threatened loss or damage by a violation of the antitrust laws." 15 U.S.C. § 26. Under a plain language reading of this provision, Section 16 standing requires a showing of "'threatened' loss or damage," Cargill, Inc. v. Monfort of Colo., Inc., 479 U.S. 104, 111 (1986), and that "the injury in question is 'injury of the type the antitrust laws were intended to prevent.'" In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 399 (3d Cir. 2000) (quoting Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc., 429 U.S. 477, 489 (1977)). Unlike claims arising under Section 4 of the Clayton Act, which require proof of antitrust harm, Section 16 only requires proof of a threat of antitrust harm. Id. Courts have broad equitable discretion to grant permanent injunctions pursuant to Section 16. See Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 131 (1969) ("Section 16 should be construed and applied . . . with the knowledge that the remedy it affords . . . is flexible and capable of nice adjustment and reconciliation between the public interest and private needs as well as between competing private

claims.") (internal quotation marks omitted). Injunctions should be granted "not merely to provide private relief, but . . . to serve as well the high purpose of enforcing the antitrust laws." Id. at 130-31.

Once a private party has shown threatened harm stemming from a violation of the antitrust laws, a four-step test for permanent injunctive relief applies. Under "well-established principles of equity," a private party must demonstrate:

> 1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).[43]

2. End Payors and Retailer Plaintiffs' Standing to Sue for Injunctive Relief

This motion for injunctive relief was brought by individual End Payors as well as the Retailer Plaintiffs, which are comprised of Walgreen, Rite Aid, CVS, and Giant

[43] "We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." eBay Inc., 547 U.S. at 394.

Eagle. Mot. Perm. Inj. On November 14, 2013, this Court certified a class of End Payors for damages claims only, ruling that an injunctive class was improper because the End Payors primarily sought monetary damages and the May 2014 delay date was set to expire soon after the scheduled March 2014 trial. In re Nexium, 297 F.R.D. 168, 174, 183 (D. Mass. 2013), aff'd, 777 F.3d 9 (1st Cir. 2015).

After the classes were certified, the initially scheduled March 2014 trial was postponed to September due to a criminal trial, and May 2014 came and went without the introduction of a generic Nexium on the market. In hindsight, these developments affect the Court's initial reasoning that:

> [e]njoining the reverse payment agreements at the conclusion of a March 2014 trial (the scheduled month for trial) provides but little relief when the reverse payment agreements are set to expire just three months later, in May 2014. With such limited injunctive relief, especially where the primary relief sought is monetary damages, the Court rules that class certification under Rule 23(b)(2) is inappropriate under the governing law.

Id. at 174. As discussed above, Ranbaxy did not come to market in May 2014, and is no longer slated to be the first generic entrant. Nevertheless, the Court did not dismiss or grant summary judgment on the End Payor and Retailer Plaintiffs' injunctive relief claims, and the parties do

not seriously dispute that the Plaintiffs can now assert this claim for an injunction.

AstraZeneca raises issue only with ACS's attempt to join the motion for permanent injunction, arguing that ASC, as a Direct Purchaser Plaintiff, has no standing to file a "joinder" when it never raised claims for injunctive relief to begin with. AstraZeneca Opp'n Mot. Permanent Inj. 1 n.1.

3. ASC's Motion for Joinder

ASC, a Direct Purchaser Plaintiff and a class representative, filed a joinder to this motion on January 12, 2015 (filed by Tom Sobol, lead counsel for the Direct Purchasers). Am. Sales Co., LLC's Joinder Mot. Permanent Inj. (ECF No. 1457) ("ASC Joinder"), ECF No. 1464. True, the Direct Purchasers' Complaint, ECF No. 131, did not contain a claim for injunctive relief, but it nevertheless seems plausible that they may be able to join the motion under Fed. R. Civ. P. 20, which allows for Permissive Joinder of Parties. Rule 20 provides that plaintiffs may join an action if:

> (A) they assert any right to relief jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences; and
> (B) any question of law or fact common to all plaintiffs will arise in the action.

Fed. R. Civ. P. 20(a)(1). ASC essentially argues the same points as the End Payors and asks for the same relief, to enjoin the Defendants from using no-AG clauses in their settlement agreements. ASC Joinder 3-5. It is undisputed that ASC asserts this right to relief "arising out of the same transaction" as the End Payors, namely, the Ranbaxy-AstraZeneca Settlement Agreement, and there are questions of law and fact common to all of the Plaintiffs. Neither ASC nor the Defendants discuss Rule 20 in their briefs, and it can be assumed that ASC's qualifications for permissive joinder are easily met.

Realistically, understanding that this joinder was filed solely by ASC and lead counsel Tom Sobol, this filing can be read as Mr. Sobol's addendum to the End Payors' briefs in support of a motion for permanent injunction. Mr. Sobol makes clear his discontent with the Defendants' post-trial statements about their jury "win" and points out their "failure to even recognize, let alone grapple with, the reality that the jury found they broke the antitrust laws." Id. at 4. His recidivism arguments against Ranbaxy and AstraZeneca would make an impact should the Court's inquiry move past determining whether there was an antitrust violation allowing for injunctive relief. Accordingly, permissive joinder is allowed.

C. Analysis

1. The Plaintiffs' Case for Injunctive Relief

The Plaintiffs argue that the jury's answers to Questions 1 through 3 constitute a finding of an antitrust violation. Pls.' Mem. Inj. 4. They posit that the no-AG clause present in the AstraZeneca-Ranbaxy Settlement Agreement ought be enjoined, and that AstraZeneca and Ranbaxy generally ought be enjoined from utilizing such clauses for a period of ten years. Id. at 2. Their argument has respectable academic support. Edlin, supra note 17, at 597-98.

2. The FTC's Views on No-AG Provisions

A brief aside guides this Court on the issue of authorized generics in pay-for-delay settlement agreements. The Federal Trade Commission ("FTC") takes the view that no-AG clauses have de facto anticompetitive effects on the pharmaceutical market. In August 2011, the FTC issued a study on the short-term and long-term effects of authorized generic drugs. Authorized Generic Drugs: Short-Term Effects and Long-Term Impact ("FTC Study"), Federal Trade Commission, August 2011 Report.

This study found that authorized generics significantly lower the revenue of first-filer generics during the 180-day exclusivity period by taking about half

of the generic market share. Id. at 139. For instance, an authorized generic during an exclusivity period lowers retail generic prices by four to eight percent, and lowers wholesale generic prices by seven to fourteen percent. Id. at ii. In the thirty months following exclusivity, the presence of an authorized generic causes first-filers to lose an additional fifty-three to sixty-two percent in overall revenues. Id. at iii.

The past decade has shown noteworthy trends in patent challenges, which is unsurprising in light of the 2003 MMA Amendments incentivizing generic challenges to brand patent holders. The FTC found that the number of drugs receiving Paragraph IV certification doubled between 2003 and 2008, and observed that generic companies were not deterred from filing Paragraph IV ANDAs even with the likelihood of shared exclusivity with an authorized generic. Id. at v. The FTC also tracked the rise of the use of no-AG agreements, which became more common around 2006, perhaps reflecting brand companies' emerging strategies in preserving brand monopolies against generic challenges. Id. at 26. Between 2004 and 2010, about a quarter of final patent settlement agreements contained explicit no-AG clauses and pay-for-delay provisions. Id. at vi (totaling 39 patent settlement agreements, with an average length of

generic delay of 37.9 months after the settlement date. For comparison, Ranbaxy agreed to delay market entry for 6 years, or 72 months, in its Nexium settlement.). Over this period, the size of the market affected by these no-AG, pay-for-delay agreements exceeded $23,000,000,000. Id. at 140.

The FTC points out two ways consumers are harmed by no-AG clauses: (1) higher prescription drug costs due to the "few additional months without generic competition in a large market," and (2) the loss of competitive pricing on the generic drug in the absence of an authorized generic competing with a first-filer during the exclusivity period. Id. at 139. This is economically and legally undisputed and supports the position that no-AG provisions, like the one in the AstraZeneca-Ranbaxy Settlement Agreement, are likely to harm consumers.[44] Id. at 141 (noting that "'pay-for-delay' settlements[] thwart the goal of the Hatch-

[44] There is also an argument that no-AG clauses provide consideration to generic infringers that cannot be obtained by winning a patent infringement suit. If a generic defendant prevails in a patent infringement suit, it can immediately launch its product on the market under the determination that the brand's patent was invalid or non-infringed. One author argues that the prevailing generic would not have the power to prevent the entry of an AG during its launch, and that the value of a no-AG agreement can only be realized in a pay-for-delay settlement agreement. See Carrier, supra note 14 at 712-13.

Waxman Amendments to encourage generic companies to challenge questionable patents and promptly 'make available more low cost generic drugs,' while simultaneously protecting legitimate patent claims."). The FTC goes on to explain that antitrust concerns are raised when patent settlements delay generic entry beyond a "simple compromise date," which is a negotiated date based off of the patents' strengths and weaknesses as well as each parties' "respective tolerances for risk." Id. at 140.[45]

As this Court realized during the trial, patent strength is not the sole driving factor for negotiating these lucrative settlement agreements. Rather, these settlements primarily are designed to maximize revenue to both brand and generic by pushing the irreversible "generic waterfall" as far out in the future and as close to patent expiration as possible, by making sure the generic is provided sufficient compensation during the wait and during the exclusivity period. The reality, as shown in the

[45] This Court, too, instructed the jury at trial that "you can't take care of the risk of the litigation by taking part of your monopoly profits and spilling them off to a . . . generic attacker. You can settle it, but the settlement should reflect traditional settlement considerations and those settlement considerations are the money you save, the litigation costs you save, and a fair value for services." Dec. 3, 2014 Tr. 47:17-24, ECF No. 1439.

rising use of no-AG clauses in patent settlements, is that brand companies have successfully been able creatively to structure patent settlement agreements within FDA regulations, preserving revenue for themselves, and also for first-filer generics.

Critics have pointed out that loopholes in the MMA allow first-filers to "park" their 180-day exclusivity by entering into delayed entry settlement agreements. This also reveals the shortcomings of the FDA in enforcing their own regulations on generic drugs. See Chad A. Landmon and Jay B. Sitlani, FDA Removes Teeth From Exclusivity Forfeiture (January 24, 2008), http://www.axinn.com/media/article/101_CALJBS- ip360-FDA%20Removes%20Teeth.pdf (describing how the FDA issued a letter ruling that Teva did not have to forfeit exclusivity even though it failed to come to market within thirty months of filing its ANDA); see also AG Jepsen to FDA: End Bottleneck Preventing Generic Nexium from Entering the Market, OFFICE OF THE ATTORNEY GENERAL OF CONNECTICUT (Sept. 4, 2014), http://www.ct.gov/ag/cwp/view.asp?Q=552410&A=2341 (petitioning the FDA to remove Ranbaxy's first-filer bottleneck which has "stalled FDA approval of any other generic drug alternatives to AstraZeneca's Nexium.").

It is concerning that the FDA only removed Ranbaxy's first-filer exclusivity rights in January 2015, which shows, first, that the MMA forfeiture provisions only kick in when the FDA wants them to, and second, that it took Teva's efforts to obtain final FDA approval to remove Ranbaxy's exclusivity (raising many questions as to what negotiations were made between Ranbaxy and Teva in order for Teva to have made the decision to move forward with obtaining FDA approval as a non-first filer generic).

The FDA could have revoked exclusivity in November 2014, when it revoked Ranbaxy's tentative approval. It could also have responded to the Citizen Petition filed by Attorney General George Jepsen asking the FDA to "exercise its discretion to immediately waive the 180-day waiting period and approve the sale" of generic Nexium. Jepsen, supra at 81. Regardless, this Court's impact in this reverse payment world is limited to interpreting the narrower issues that arise from the case before it. It will be interesting, however, to see how the FDA and FTC respond to the growing chorus of criticism of no-AG clauses in the coming years.

3. Did Questions 1 through 3 establish an Antitrust violation under Section 16?

The jury's findings on December 5, 2014 answered yes to the first three of seven questions, which asked them: (1) whether AstraZeneca had market power, (2) whether the AstraZeneca-Ranbaxy Settlement Agreement contained a large and unjustified payment from AstraZeneca, and (3) whether this settlement was unreasonably anticompetitive. Jury Verdict, ECF No. 1383. The Plaintiffs argue these findings establish all elements of a Sherman Act Section 1 violation, which prohibits specific means of anticompetitive conduct in restraint of trade or commerce.[46] 15 U.S.C. § 1. They rely on Sullivan v. Nat'l Football League, 34 F.3d 1091 (1st Cir. 1994), which explains:

> To establish an antitrust violation under § 1 of the Sherman Act, Sullivan must prove that the NFL's public ownership policy is "in restraint of trade." Under antitrust law's "rule of reason," the NFL's policy is in restraint of trade if the anticompetitive effects of the policy outweigh the policy's legitimate business justifications. Anticompetitive effects, more

[46] The Sherman Act, Section 1, provides: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court." 15 U.S.C. § 1.

> commonly referred to as "injury to competition" or "harm to the competitive process," are usually measured by a reduction in output and an increase in prices in the relevant market.

Id. at 1096-97 (internal citations omitted). Applied here, the Plaintiffs argue that Question 3 answered affirmatively establishes a Section 1 violation because the jury found that anticompetitive effects of the AstraZeneca-Ranbaxy Settlement Agreement outweighed procompetitive justifications. Pls.' Mem. Inj. 4. Anticompetitive "effect" thereby establishes a right to injunctive relief.

The Plaintiffs, however, seem to forget that the First Circuit in Sullivan also imposed a causation requirement on every private antitrust plaintiff. In Sullivan, the First Circuit wrote: "An 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." Id. at 1103 (emphasis added). They also affirmed a District of Rhode Island case which listed the three elements a Plaintiff must allege to state a valid claim under Section 1 of the Sherman Act: "(1) the existence of a contract, combination or conspiracy; (2) that the agreement unreasonably restrained trade under the per se or rule of reason analysis; and (3) that the restraint affected interstate commerce." Lee v. Life Ins.

Co. of N. Am., 829 F. Supp. 529, 535 (D.R.I. 1993) aff'd, 23 F.3d 14 (1st Cir. 1994) (emphasis added). This case law on causation, as this Court carefully applied in its summary judgment order, is very clear that private plaintiffs bear the burden of establishing causation. In re Nexium Summary Judgment 2014, 42 F. Supp. 3d at 267 ("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.'") (quoting Sullivan, 34 F.3d at 1003); see also Zenith Radio Corp. v. Hazeltine Research Inc., 395 U.S. 100, 114 n.9 (1969) (the illegality must be shown to be "a material cause of the injury"); Out Front Prods., Inc. v. Magid, 748 F.2d 166, 169 (3d Cir. 1984) ("Although the burden is not a heavy one, since 'a plaintiff need not exhaust all possible alternative sources of injury', Zenith Radio Corp., 395 U.S. at 114 n. 9, 89 S.Ct. at 1571 n. 9, if plaintiff fails to establish a causal relationship between its financial difficulties and defendants' antitrust violations, its case must fail."); Foremost-McKesson, Inc. v. Instrumentation Lab., Inc., 527 F.2d 417, 418 (5th Cir. 1976) ("The necessity for proof of causation in a private antitrust action is likewise clear.). This is

to be distinguished from actions filed by the Federal Trade Commission under the FTC Act, which requires "only that the government prove that a defendant's action is 'likely to cause' injury." Ian Simmons, Kenneth R. O'Rourke, & Scott Schaeffer, Viewing FTC v. Actavis Through the Lens of Clayton Act Section 4, Antitrust, Vol. 28, No. 1 (2013) (quoting 15 U.S.C. § 45(n)).

Reviewing the Plaintiffs' motion for a new trial suggests that the Plaintiffs are fully aware of the burden of proving antitrust causation, as demonstrated by their efforts to show that it was judicial error and misdirection that caused the jury erroneously to check "no" to Question 4. Class Pls. Mem. New Trial 14-16. Their approach in the motion for a permanent injunction, by contrast, appears instead to try an alternative argument seeking to convince the Court that an antitrust violation was established by pointing to the obvious and "extant" anticompetitive effects of the AstraZeneca-Ranbaxy Settlement Agreement. Pls.' Mem. Inj. 6. While the Defendants vehemently deny this position, it is apparent that the jury answers on Questions 1 through 3 sent a message that these types of reverse payment deals are understood as anticompetitive in intent and effect. What is missing in this case, as mentioned previously, is the causal link between this

suspicious agreement and the overcharge harms the Plaintiffs allege. Although surface-level analysis of the verdict slip reflects a pro-plaintiff outcome ("the unlawful payment had actual anticompetitive effects"), id., this does not equate to a final determination of antitrust liability.[47]

In short, affirmative answers to Questions 1 through 3 do not support a finding of an antitrust violation by

[47] The Plaintiffs' failure to establish causation in this case renders the Plaintiffs' supplemental authorities to this motion unhelpful. Notice Supp. Authority Support Pls.' Mot. Permanent Inj., ECF No. 1532 (drawing the Court's attention to New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015)); Notice Supp. Authority Support Pls.' Motions New Trial & Motion Permanent Inj., ECF No. 1542 (drawing the Court's attention to King Drug, 2015 WL 3967112). In Schneiderman, the Second Circuit affirmed the trial court's grant of a preliminary injunction in a pharmaceutical antitrust case based, in part, on the trial court's finding that the Defendants' "hard switch" between branded products "ha[d] the effect of significantly reducing usage of [generic] products," and would cause consumers irreparable and quantifiable, economic harm. Schneiderman, 787 F.3d 638, 655, 660-61. No such effect was proved here. Although more factually analogous to this case because it addressed no-AG clauses, King Drug is equally unavailing. In discussing the rule-of-reason analysis, the Third Circuit stated that a factfinder must "prove[] the existence of actual anticompetitive effects, such as reduction of output, increase in price, or deterioration in quality of goods or services." King Drug, 2015 WL 3967112, at *16. Because the jury found that Ranbaxy could not have brought generic Nexium to market before May 2014, even in the absence of the AstraZeneca-Ranbaxy Settlement Agreement, King Drug also fails to come to the Plaintiffs' rescue.

AstraZeneca and Ranbaxy. Question 4, or any version of Question 4, would still ask the jury whether causation was proven. The jury's answer showed that it was not persuaded by the evidence presented in favor of the Plaintiffs' sole theory of liability, that Ranbaxy would have agreed to an earlier entry date and would have subsequently negotiated a partnered launch with Teva. On this basis, the Court cannot find that the Plaintiffs have shown the prerequisite antitrust violation underlying their Section 16 claim for relief and therefore must **DENY** the motion for permanent injunction for this reason.

4. The No-AG Clause in the AstraZeneca-Ranbaxy Settlement Agreement After the Loss of First Filer Exclusivity

The motion for a permanent injunction, filed at the end of December, preceded the FDA's January 2015 declaration that Ranbaxy lost its Nexium first-filer exclusivity rights. The Court notes that the parties have not filed briefs or addenda to their motions discussing this significant development. The only such addendum came on the same day Ranbaxy lost its exclusivity, when Ranbaxy filed a Judicial Notice with the Court regarding Amneal's launch of generic esomeprazole strontium,[48] which is another

[48] As far as the Court can tell, this is the first mention in this litigation of esomeprazole strontium. It

proton pump inhibitor (as one can guess from the name of the compound). Ranbaxy's Request Judicial Notice Amneal's Launch Esomeprazole Strontium, ECF No. 1477. The purpose of the filing was to argue that this launch extinguished any rights of exclusivity Ranbaxy had in the AstraZeneca-Ranbaxy Settlement Agreement due to the agreement's clause allowing AstraZeneca to launch an authorized generic "if another Third Party launches any Generic Esomeprazole in the United States before the Entry Date without a license." Ranbaxy Opp'n Mot. Permanent Inj. 13-14 (thus mooting the Plaintiffs' request for an injunction).

Interpreting whether "any generic esomeprazole" incorporates esomeprazole strontium is a red herring, however, when in fact the real event of interest in this case is the FDA's determination that Ranbaxy lost its first filer exclusivity under the MMA, which provides multiple forfeiture provisions, including the failure to obtain tentative approval within thirty months of filing an ANDA. 21 U.S.C. § 355; see also Defs.' Notice Admin. Action, 14-cv-01923, ECF No. 67 (D.C. District Court) (filed Jan. 26, 2015) (notifying the court of the FDA's determination that

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was not part of the group of PPIs discussed during the trial as competitors of Nexium, nor was it discussed during expert testimony on the superiority of Nexium as compared to Prilosec.

Ranbaxy forfeited its exclusivity and grant of approval for Teva/Ivax's Nexium ANDA). This directly affects the no-AG clause in the Ranbaxy-AstraZeneca Settlement Agreement, which ensures that AstraZeneca will not offer a generic that competes with Ranbaxy during its 180-day exclusivity period (effectively a promise that Ranbaxy would keep 100 percent of the generic market during that period). Without this 180-day exclusivity period, the key condition underlying the no-AG clause no longer exists, and so the no-AG clause itself is extinguished and unenforceable.

As a result, the Plaintiffs' request to enjoin the no-AG clause in the AstraZeneca-Ranbaxy Settlement Agreement must be denied as moot, due to the fact that this clause can no longer be enforced by the parties. See Pls.' Mem. Inj. 8 ("An injunction is required here because AstraZeneca's No-AG promise is still executory – Astrazeneca has promised not to launch an authorized generic whenever Ranbaxy finally enters with Hatch-Waxman exclusivity."). Although both AstraZeneca and Ranbaxy fully brief other reasons why this motion ought be denied as to the AstraZeneca-Ranbaxy Settlement Agreement, their arguments are best read in regard to the parties' overall positions in light of the motion for a new trial and the Court's present action thereon.

a. Request to Enjoin Future No-AG Clauses

The Plaintiffs also ask this Court to enjoin AstraZeneca and Ranbaxy from utilizing no-AG clauses in future patent settlements. Id. at 10. This relief is premised on the argument that the Nexium jury established that the Defendants committed an antitrust violation, and that the Court ought "prevent similar violations from recurring in the future." Id. Noting the frequency of past violations by AstraZeneca and Ranbaxy ("serial antitrust violators with respect to No-AG clauses in agreements to settle Hatch-Waxman cases"), id. at 11, they argue that the Defendants are recidivists, especially in light of public post-trial statements denying any sort of illegal wrongdoing. Id. at 10-13.

The inquiry focuses on whether the threatened harm arises from an antitrust violation. 15 U.S.C. § 26 (allowing private parties to sue "against threatened loss or damage by a violation of the antitrust laws"). If no such antitrust violation can be established from the jury's verdict, as is the case here, see supra Section VI.C.3, the Plaintiffs' rights to Section 16 injunctive relief against future no-AG clauses effectively are foreclosed.

VII. ORDER FOR JUDGMENT

As discussed above, the motions for a new trial, ECF Nos. 1450, 1453, must be, and hereby are, DENIED.

When viewed through a certain lens, the jury's finding that the AstraZeneca-Ranbaxy Settlement Agreement is "anticompetitive" in nature supports an argument that the Court enjoin whatever negative effects are stemming from it. Having determined, however, that (1) the AstraZeneca no-AG clause is effectively dismantled as of January 26, 2015 and (2) that the jury was unable to find that Ranbaxy could actually have launched before May 2014 through a Teva partnership, a **DENIAL** of the motion for permanent injunction, ECF. No. 1457, must logically follow. Judgment will enter for AstraZeneca and Ranbaxy.

VIII. WAS IT WORTH IT? – YES, TRIALS MATTER

"The faces of the United States district courts are fading," laments Judge Patrick Higginbotham as judges retreat from their core function as trial judges to become unseen government administrators. Patrick E. Higginbotham, The Present Plight of the United States District Courts, 60 Duke L.J. 745 (2010).[49] Year by year, federal district

[49] Indeed, it was Judge Higginbotham who first commented on this phenomenon in his seminal article, "So Why Do We Call Them Trial Courts?" Patrick E. Higginbotham, Judge Robert A. Ainsworth, Jr. Memorial Lecture, Loyola

judges spend less and less time out on the bench, Jordan M. Singer & Hon. William G. Young, Bench Presence 2014: An Updated Look at Federal District Court Productivity, 48 New Eng. L. Rev. 565 (2014),[50] even though it is their presence in the courtroom that best affords principled adjudication to America's most underserved litigants. See Hon. William G. Young, Keynote: Mustering Holmes' "Regiments", 48 New Eng. L. Rev. 451 (2014). The fact that actual trials are so scarce leads distinguished commentators to conclude that the federal courts are in decline. See Koh, supra at 23. One even goes so far as to suggest that the civil jury trial has outlived its usefulness and that the Seventh Amendment ought be repealed. Renee Lettow Lerner, The

University School of Law: So Why Do We Call Them Trial Courts?, 55 SMU L. Rev. 1405 (2002). Today, the marginalization of our trial processes is so well documented as to need no extensive argumentation. See D. Brock Hornby, The Business of the U.S. District Courts, 10 Green Bag 2d 453 (2007).

[50] "After reviewing statistics gathered by the Administrative Office of the U.S. Courts, researchers reported a steady year-over-year decline in total courtroom hours from 2008 to 2012 that continued into 2013. Federal judges spent less than two hours a day on average in the courtroom, or about 423 hours of open court proceedings per active district judge." Judith Resnik, Diffusing Disputes: The Public in the Private of Arbitration, the Private in Courts, and the Erasure of Rights, 124 Yale L.J. 2804, 2935 (2015) (footnotes and quotation marks omitted).

Uncivil Jury: Part 5: What to do Now – Repeal and Redesign, THE VOLOKH CONSPIRACY (May 29, 2015), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2015/05/29/the-uncivil-jury-part-5-what-to-do-now-repeal-and-redesign/.

The remarkable unanimity of opinion as to the present marginalization of our trial processes requires brief comment on the continuing vitality and social utility of jury trials in general[51] and this trial in particular, as well as an even briefer look at some of the alternatives such marginalization has allowed to flourish.

There are, of course, "islands of resistance" to the ominous trend depicted above. Marc Galanter, The Hundred-Year Decline of Trials and the Thirty Years War, 57 Stan. L. Rev. 1255, 1273, n.63 (2005). Jury trials and judicial bench presence have their advocates.[52] See, e.g., Harry T.

[51] That jury trials enhance civil engagement today just as they did in De Tocqueville's time is so well documented as to need no further exposition here. John Gastil, E. Pierre Deess, Philip J. Weiser & Cindy Simmons, The Jury and Democracy: How Jury Deliberation Promotes Civil Engagement and Political Participation, New York, Oxford Univ. Press (2010); Valerie P. Hans, John Gastil, & Traci Feller, Deliberative Democracy and the American Civil Jury, 11 J. Empirical Legal Studies 697 (2014).

[52] "I trace the reawakening of our interest in traditional trial processes to a moving speech given by the Hon. Joseph F. Anderson, Jr., of the District of South Carolina at the 2003 annual meeting of the chief district

Edwards, Alternative Dispute Resolution: Panacea or Anathema?, 99 Harv. L. Rev. 668 (1986); Steven S. Gensler & Lee H. Rosenthal, The Reappearing Judge, 61 U. Kan. L. Rev. 849 (2013); Alex Kozinski, Criminal Law 2.0, 44 Geo. L.J. Ann. Rev. Crim. Proc. iii, xx-xxi (2015);[53] Arthur R. Miller, The Pretrial Rush to Judgment: Are the "Litigation Explosion," "Liability Crisis," and Efficiency Clichés Eroding Our Day in Court and Jury Trial Commitments?, 78 N.Y.U. L. Rev. 982 (2003); Arthur Miller, Awards Luncheon

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court judges on April 26, 2003. In his speech, Chief Judge Anderson called upon trial judges to devote themselves to the core function of the judicial office, namely the fair and impartial trial of cases. Echoing a similar theme, Alex Sanders, one of America's foremost jurists, minces no words: '[t]rial judges should return to being trial judges, instead of docket managers. They should start treating jury trials as a vindication of the justice system rather than a failure of the justice system. They should revere and respect the jury trial as the centerpiece of American democracy.'" Hon. William G. Young, Vanishing Trials, Vanishing Juries, Vanishing Constitution, 40 Suffolk U. L. Rev. 67, 84-85 (2006).

[53] Judge Rosenthal and Professor Gensler's article offers eminently sensible advice for managing one's docket from the bench. I try hard to follow it. Most of Judge Kozinski's "suggestions for reform" of our jury system are not new and have long been staples of jury practice in this Court, including giving the jury a say in sentencing. See United States v. Kandirakis, 441 F. Supp. 2d 282, 303 (D. Mass. 2006); United States v. Gurley, 860 F. Supp. 2d 95 (D. Mass. 2012). In this case, I used all of his applicable suggestions in order to have an informed and empowered jury. I always do.

Speech, AAJ 2012 Annual Conference, Chicago (July 31, 2012); J. Harvie Wilkinson III, In Defense of American Criminal Justice, 67 Vand. L. Rev. 1099, 1157 (2014).

Even more important than academic advocacy are those real world federal district courts most productive in trials and bench presence. The top five between 2009 and 2014 are (in order) the Southern District of Florida, the Eastern District of New York, the District of Colorado, the Eastern District of California, and the District of Idaho. Young, supra at 93, at 465-74.[54] How can we learn from these courts' efficient use of judicial time to try cases and remain out on the bench? We should, for trials (especially jury trials) still remain, as Thomas Jefferson put it, "'the only anchor, ever yet imagined by man, by which a government can be held to the principles of its constitution.' Letter from Thomas Jefferson to Thomas Paine (July 11, 1789), in 15 The Papers of Thomas Jefferson 266, 269 (Julian P. Boyd ed., 1958)." United States v. Orthofix, Inc., 956 F. Supp. 2d 316, 336 n.31 (D. Mass. 2013).

[54] As one might expect, the judges of these courts are strong advocates of our jury trial system. See, e.g., B. Lynn Winmill, Chief Judge of the United States District Court for the District of Idaho, Address at the Idaho State Bar Convention: The Wisdom of the Crowd: Why The American Jury Trial System Works (July 23, 2015).

> [T]oday's courts serve . . . as a site of democratic practices. Courts model the democratic precepts of equal treatment, demonstrate that the state itself is subject to democratic constraints, and facilitate democratic revisions of governing norms. Adjudication is an odd moment in which individuals can oblige others to treat them as equals as they argue in public about their disagreements, misbehavior, wrongdoing, and obligations. Courts are the great leveler, as the goals of participatory parity and reciprocal respect require that all participants, including the government, act as their opponents' equals.
>
> Litigation forces dialogue upon the unwilling and temporarily alters configurations of authority. The public facets either make good on egalitarian promises or prompt inquiries (such as the gender, race, and ethnic bias task forces of the 1980s and 1990s) into the failures to live up to them. Moreover, rights of audience divest the litigants and the government of exclusive control over conflicts and their resolution. The public and the immediate participants see that law varies by contexts, decisionmakers, litigants, and facts. Through democratic iterations--the backs-and-forths of courts, legislatures, and the public--norms can be reconfigured.
>
> As in other democratic processes, such as majoritarian voting, the outputs are widely varied. Public awareness can generate new rights, such as freedom from domestic violence, and new limitations, such as caps on monetary damages for malpractice . . . .
>
> [C]ourt-based publicity . . . enable[s] debate about norms, and the ascent of participatory rights in public judicial processes prompted significant investments in the courts. The shift towards ADR represents the decline of adjudication, and, with it, the role of the federal courts. . . . The current solutions privatize procedures, and those put at risk are not only litigants or members of the potential audience but the judges themselves.

Judith Resnik, supra at 24 at 1836-37.

So it was here: public adjudication aptly and ably aired the grievances of the parties to this case. Witnesses with actual knowledge testified forthrightly through able and searching direct and cross examination. What emerged was a richly detailed picture of how these questioned settlement agreements actually came into being against the real world economic incentives and realities. It is a picture with focus and precision that the pallid affidavits submitted in aid of summary judgment motions could not approach, much less equal.[55]

And what was learned?

First, the wisdom of Justice Breyer's observation in Actavis that arcane questions of patent law need not dominate a pay-for-delay case was unequivocally and irrefutably confirmed. See Actavis, 133 S. Ct. 2223, 2230-31 (noting that "to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question").

[55] "The affidavit is the Potemkin Village of today's litigation landscape. Purported adjudication by affidavit is like walking down a street between two movie sets, all lawyer-painted façade and no interior architecture." Massachusetts, 781 F. Supp. 2d at 22, n.25.

Second, the jury verdict – amply supported by the evidence – put paid to the Plaintiffs' largely speculative claims of antitrust injury. Tested against the common sense of actual jurors, the Plaintiffs' evidence fell short. Far short. The message is clear – the plaintiffs' bar will need far more detailed evidence of events in the "but-for" world before a jury will find actual antitrust damages.

Most important, here the jury has **found as fact** that the "no-AG" clause central to the AstraZeneca-Ranbaxy Settlement Agreement was a large and unjustified reverse payment with anticompetitive effects outweighing any procompetitive justifications. This real-world **finding** is of surpassing importance. It is as much "a development in the law" as it would be were I to have made this same finding in the context of a jury-waived proceeding, for

> [j]urors are as much constitutional officers as are [judges], U.S. Const., art. III, § 2, cl. 3 (criminal cases), id., Amend. VII (civil cases). Indeed, when applying the law to the facts they have found, jurors are supreme. Their verdicts are an even more important indicia of legal development as they come from the people themselves, a transparent expression of direct democracy.

S.E.C. v. EagleEye Asset Mgmt., 975 F. Supp. 2d 151, 161 n.12 (D. Mass. 2013). No longer can the pharmaceutical industry simply assume that no antitrust liability can

attach to the use of no-AG clauses simply because the FTC cannot, or has not, barred them. Why? An American jury has said so.

To make the point, here are just a handful of important jury findings, each signaling an important development in the law:

- Ciulla v. Rigny, 89 F. Supp. 2d 97, 98 (D. Mass. 2000) (search of a female detainee by matron in a holding cell involving minimal disarray of outerwear nevertheless violated detainee's civil rights where cell had an observation window accessible to male officers);
- United States v. Gurley, 860 F. Supp. 2d 95, 116 (D. Mass. 2012) (jury finding as to drug quantity requires lesser sentence – presaging Alleyne v. United States, 133 S. Ct. 2151 (2013)). See also United States v. Newton, 13-cr-10164, Jury Verdict, ECF No. 418;
- EagleEye Asset Mgmt., 975 F. Supp. 2d at 160-61 (financial advisor violated Securities Exchange Act of 1934 by fraudulently failing to disclose his foreign exchange trading record to his clients notwithstanding the absence of an SEC regulation addressing the issue);
- United States v. O'Brien, No. 12-cr-40026-WGY, Jury Verdict, ECF No. 579, appeal docketed, Nos. 14-2313; 14-2314; 14-2315 (1st Cir. Dec. 9, 2014) (giving state lawmaker patronage power to hire state employee constitutes an illegal gratuity under Mass. Gen. Laws ch. 268A, § 3(a));
- United States v. Wairi, 14-cr-10143-WGY, Jury Verdict, ECF No. 91 (child pornographer's surreptitious videos of young boys showering and changing into swim suits, though a gross invasion of privacy, not "lascivious" as that term is used in 18 U.S.C. § 2256(2)(A));
- Denault et al. v. Town of Chelmsford et al., 14-cv-13687-WGY, Jury Verdict, ECF No. 121 (police officer who ignored town's regulations about return of property liable for conversion notwithstanding that property had been seized lawfully from criminal).

It is well and truly said that "where a jury sits, there burns the lamp of liberty." Hon. William G. Young, U.S. District Judge, Address at the Judicial Luncheon, Florida Bar's Annual Convention in Orlando (June 28, 2007). Another approach to assessing the value of jury trials is to consider what happens wherever the people's jury is excluded. Here are but a few examples, as fresh as today's headlines:

A. Fact-Finding is Debased

It must never be forgotten that for seventeen years under the oxymoronic mandatory sentencing guidelines system, every single federal criminal defendant received a sentence that is today unconstitutional. United States v. Booker, 543 U.S. 220, 245 (2005). Fortunately, today the Supreme Court has made clear the constitutional command: "This Court has repeatedly held that, under the Sixth Amendment, any fact that exposes a defendant to a greater potential sentence must be found by a jury, not a judge, and established beyond a reasonable doubt, not merely by a preponderance of the evidence." Cunningham v. California, 549 U.S. 270, 281 (2007).

Even so, under today's advisory guideline system, we judges continue to enhance criminal sentences without juries and without any evidence at all, piously talking

about “preponderance of the evidence” when all we have before us is a presentence report reiterating multiple hearsay. It need not be this way. The jury appropriately can have a role in sentencing. United States v. Kandirakis, 441 F. Supp. 2d 282, 315 (D. Mass. 2006). See also Kozinski, supra at 95; A Jury Draws a Line, N.Y. TIMES, June 2, 2012, at A20.

B. Forced Arbitration[56] Destroys Individual Rights

Today, forced arbitration bestrides the legal landscape like a colossus, effectively stamping out the individual’s statutory rights wherever inconvenient to the businesses which impose them. What is striking is that, other than the majority of the Supreme Court whose questionable jurisprudence erected this legal monolith, e.g. AT&T Mobility LLC v. Concepcion, 131 S. Ct. 1740, 1753 (2011); Moses H. Cone Mem'l Hosp. v. Mercury Const. Corp., 460 U.S. 1, 24-25 (1983), no one thinks they got it right – no one, not the inferior federal courts, e.g. In re Am. Exp. Merchants' Litig., 667 F.3d 204, 206 (2d Cir. 2012) rev'd, Am. Exp. Co. v. Italian Colors Rest., 133 S. Ct.

[56] Forced arbitration arises from arbitration clauses imposed on consumers as a cost of engaging in many of the routine aspects of daily living, e.g. making telephone calls and using the nation’s wireless network.

2304 (2013); Jackson v. Rent-A-Ctr. W., Inc., 581 F.3d 912, 916 (9th Cir. 2009) rev'd, 561 U.S. 63 (2010), not the state courts, e.g. Allied-Bruce Terminix Cos., Inc. v. Dobson, 628 So. 2d 354, 357 (Ala. 1993) rev'd, 513 U.S. 265 (1995); Casarotto v. Lombardi, 274 Mont. 3 (1995) rev'd, Doctor's Assocs., Inc. v. Casarotto, 517 U.S. 681 (1996), not the Equal Employment Opportunity Commission, Cole v. Burns Int'l Sec. Servs., 105 F.3d 1465, 1479 (D.C. Cir. 1997) (collecting cases),[57] and certainly not the academic community.[58] Indeed, even the respected American

[57] See also EEOC Notice Number 915.002 (July 10, 1997), http://www.eeoc.gov/policy/docs/mandarb.html.

[58] See generally Ronald G. Aronovsky, The Supreme Court and the Future of Arbitration: Towards A Preemptive Federal Arbitration Procedural Paradigm?, 42 Sw. L. Rev. 131 (2012); Stuart M. Boyarsky, Not What They Bargained for: Directing the Arbitration of Statutory Antidiscrimination Rights, 18 Harv. Negot. L. Rev. 221 (2013); Dustin Charters, Uphill Battle or Insurmountable Peak? The Pursuit to Uphold Provisions Within Arbitration Agreements, 47 Idaho L. Rev. 679 (2011); Carolyn L. Dessin, Arbitrability and Vulnerability, 21 Temp. Pol. & Civ. Rts. L. Rev. 349 (2012); Christopher R. Drahozal, Why Arbitrate? Substantive Versus Procedural Theories of Private Judging, 22 Am. Rev. Int'l Arb. 163, 163 (2011); Joel L. Fishbein, Not Inherently Unfair: Arbitration in the Long-Term Care Setting, 54 No. 8 DRI For Def. 8 (2012); David Horton, Federal Arbitration Act Preemption, Purposivism, and State Public Policy, 101 Geo. L.J. 1217 (2013); Roger J. Perlstadt, Article III Judicial Power and the Federal Arbitration Act, 62 Am. U. L. Rev. 201 (2012); Larry J. Pittman, Mandatory Arbitration: Due Process and Other Constitutional Concerns, 39 Cap. U. L. Rev. 853 (2011); Ankita Ritwik, Tobacco Packaging Arbitration and the State's Ability to Legislate, 54 Harv. Int'l L.J. 523

Arbitration Association withdrew from consumer debt collection arbitration because of "fairness and due process concerns." Press Release, American Arbitration Association, The American Arbitration Association Calls for Reform of Debt Collection Arbitration (July 23, 2009) (on file at https://www.nclc.org/images/pdf/arbitration/testimonysept09-exhibit3.pdf).

> From 1925 until the mid-1980s, obligations to arbitrate rested on consent. Thereafter, the U.S. Supreme Court shifted course and enforced court and class action waivers mandated when consumers purchased goods and employees applied for jobs. To explain the legitimacy of precluding court access for federal and state claims, the Court developed new rationales -- that arbitration had procedural advantages over adjudication, and that arbitration was an effective enforcement mechanism to "vindicate" public rights.
>
> The result has been the mass production of arbitration clauses without a mass of arbitrations. Although hundreds of millions of consumers and employees are obliged to use arbitration as their remedy, almost none do so -- rendering arbitration not a vindication but an unconstitutional evisceration of statutory and common law rights. The diffusion of disputes to a range of private, unknowable alternative adjudicators also violates the constitutional protections accorded to the public -- endowed with the right to observe state-empowered decision makers as they impose binding outcomes on disputants. Closed processes preclude

(2013); Nantiya Ruan, What's Left to Remedy Wage Theft? How Arbitration Mandates That Bar Class Actions Impact Low-Wage Workers, 2012 Mich. St. L. Rev. 1103 (2012).

> the public from assessing the qualities of what gains the force of law and debating what law ought to require. The cumulative effect of the Supreme Court's jurisprudence on arbitration has been to produce an unconstitutional system that undermines both the legitimacy of arbitration and the functions of courts.

Resnik, supra note 50, at 2804; see also Jessica Silver-Greenberg & Michael Corkery, Failed by Law and Courts, Troops Come Home to Repossessions, N.Y. TIMES, Mar. 17, 2015, at A1.

C. The Government's Executive Power can Effectively Crush an Individual Who has Committed No Crime

The Seventh Amendment provides unequivocally, "[i]n suits at common law . . . the right of trial by jury shall be preserved." U.S. Const. amend. VII. Properly read, this means **all** suits that historically were beyond the court's equitable and admiralty jurisdiction. See, e.g., Tull v. United States, 481 U.S. 412, 420-21 (1987); Joseph Czerwien, Preserving the Civil Jury Right: Reconsidering the Scope of the Seventh Amendment, 65 Case W. Res. L. Rev. 429 (2014).

Still, the Supreme Court has recognized a limited "public right" exception to trial by jury to allow for administrative tribunals to implement the congressional purposes in creating the administrative state. Granfinanciera, S.A. v. Nordberg, 492 U.S. 33, 53 (1989).

The exception is, however, strictly limited. Northern Pipeline Const. Co. v. Marathon Pipe Line Co., 458 U.S. 50, 70 (1982); see also Stern v. Marshall, 131 S. Ct. 2594, 2610 (2011).

Or is it?

> Andrew J. Ceresney, the S.E.C.'s enforcement director, outlined the agency's plans to bring more regulatory lawsuits to its in-house judges . . . [T]he S.E.C.'s promise to expand the use of its internal tribunals has generated intense opposition. Perhaps even more crucially, so has its filing of highly complex cases there.

Gretchen Morgenson, Crying Foul on In-House S.E.C. Courts, N.Y. TIMES, June 28, 2015, at BU1.

Doesn't it seem odd that an officer of the executive branch can decide whether a citizen can seek a jury? And how is it working out? Consider Hopkins v. S.E.C., No. 15-1117 (1st Cir. filed January 16, 2015); Flannery v. S.E.C., No. 15-1080 (1st Cir. filed January 14, 2015), presently pending in the First Circuit. The quasi-independent hearing officer who first examined this enforcement action found against the S.E.C. Dissatisfied with that "trial," the S.E.C. itself went ahead and suspended one offender, fining him $65,000, and now asks the Court of Appeals to defer to its judgment. Ed Beeson, SEC Urges 1st Circ. To Deny Ex-State Street Exec's Appeals, Law 360, July 15,

2015,

http://www.law360.com/securities/articles/679512.

Expressing no opinion whatsoever on the merits (that's the business of the Court of Appeals), I note that if the power to tax is the power to destroy, see McCulloch v. State, 17 U.S. 316, 327 (1819), how much more so is the power to fine, to levy a monetary sanction? Indeed, this is a criminal sanction imposed for non-criminal conduct. Calling it a "civil" fine hardly diminishes its burden. As Lincoln famously said, "[h]ow many legs does a dog have if you call the tail a leg?" The answer is, of course, "four" because "calling a tail a leg doesn't make it a leg." United States v. Bowen, 527 F.3d 1065, 1077 n.9 (10th Cir. 2008). Indeed, I always thought that one of the central purposes of our jury trial right is to "prevent oppression by the Government." Williams v. Florida, 399 U.S. 78, 100 (1970).

D. "The Eclipse of Fact Finding Foreshadows the Twilight of Judicial Independence."[59]

Article III of our Constitution begins, "[t]he judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress

[59] DeLaventura v. Columbia Acorn Trust, 417 F. Supp. 2d 147, 153 n.7 (D. Mass. 2006).

may from time to time ordain and establish." U.S. Const. art III, § 1. At the very epicenter of judicial power is the power to resolve disputed factual claims and apply the legal framework to the result. Under the Seventh Amendment to the United States Constitution, save for equity and admiralty cases, this power is reserved to the American people themselves, sitting as jurors. What then is one to think of the supra national arbitration tribunals established by the Investor-State Dispute Settlement ("ISDS") procedures of the North American Free Trade Agreement who, free from any judicial review whatsoever, can hand down monetary awards directly against the United States upon claims by foreign investors that enactments passed in America impair the value of their investments? North American Free Trade Agreement, U.S.-Can.-Mex., Arts. 1101-1138.2, Dec. 17, 1992, 2010 WL 2960052 (INS). The matter is of current interest because it is feared that the proposed Trans Pacific Partnership ("TPP") may include similar provisions. See Senator Elizabeth Warren & Representative Rosa DeLauro, Who is writing the TPP?, BOSTON GLOBE, May 11, 2015; Professor Alan Morrison, Is the Trans-Pacific Partnership Unconstitutional?, The Atlantic, June 23, 2015. In essence, these authorities are arguing "surely we have not fallen so low as to dismantle our

democracy in order to trade with China, have we?" The answer remains to be seen.

Small wonder that, over the past eight years, the average American has seen his or her chance of serving on the nation's juries diminish by nearly a third (32.54% to be exact). Statistics maintained by the Administrative Office of the United States Courts show that the percentage likelihood of being selected for federal petit jury service has been steadily declining over the past decade. EagleEye Asset Mgmt., 975 F. Supp. 2d at 155 n.5.[60]

[60] Compare Admin. Office U.S. Courts, 2011 Annual Report of the Director: Judicial Business of the United States Courts 326 tbl. J–2 (2012), available at http://www.uscourts.gov/uscourts/Statistics/JudicialBusiness/2011/JudicialBusiness2011.pdf with Admin. Office U.S. Courts, 2004 Annual Report of the Director: Judicial

Even so, every Monday, potential jurors are summoned to the three courthouses in Massachusetts where this Court sits. They are welcomed and told that their service is as important today as at any time in the long history of our Republic. It ends like this: "Every single jury trial is both a test and a celebration of the right of a free people to govern themselves. Go now and do justice."[61]

Do you care about any of this?

Does it concern you?

It should.

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

Business of the United States Courts 325 tbl.J–2 (2005), available at http://www.uscourts.gov/uscourts/Statistics/JudicialBusiness/2004/appendices/j2.pdf. This Court calculated an average American's chance of serving on a federal petit jury by taking the number of individuals who gave jury service, and dividing that number by the number of individuals in the United States who are over the age of eighteen. The former number was gleaned from the Administrative Conference reports cited above, the latter from the Census Bureau. EagleEye Asset Mgmt., 975 F. Supp. 2d at 155 n.5.

[61] Juror Welcome Address, District of Massachusetts, Eastern Division, most recently delivered July 27, 2015. See also video tapes: Jury Impanelment (10-11117 Miranda v. Hurley); Charge to Jury (12-10326 Lu v. Boston College) (on file at http://www.mad.uscourts.gov/boston/young.htm).