United States Court of Appeals
For the First Circuit

Nos. 15-2005, 15-2006, 15-2007

IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; VALUE DRUG COMPANY; BURLINGTON DRUG COMPANY INC.; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and others similarly situated; MEIJER, INC.; MEIJER DISTRIBUTION, INC.; ALLIED SERVICES DIVISION WELFARE FUND; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 17 HEALTH CARE FUND; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND; A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN; FRATERNAL ORDER OF POLICE MIAMI LODGE 20 INSURANCE TRUST FUND; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOC. OF NEW YORK CITY, INC. HEALTH BENEFITS FUND; UNITED FOOD & COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND; MICHIGAN REGIONAL COUNCIL OF CARPENTERS EMPLOYEE BENEFITS FUND; INTERNATIONAL UNION OF MACHINISTS AND AEROSPACE WORKERS DISTRICT NO. 15 HEALTH FUND; INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS LOCAL 595 HEALTH AND WELFARE FUND; WALGREEN CO.; THE KROGER COMPANY; SAFEWAY INCORPORATED; SUPERVALU, INC.; HEB GROCERY CO. LP; GIANT EAGLE, INC.; RITE AID CORPORATION; RITE AID HEADQUARTERS CORPORATION; JCG (PJC) USA, LLC; MAXI DRUG, INC., d/b/a BROOKS PHARMACY; ECKERD CORPORATION; CVS, INC.,

Plaintiffs, Appellants,

v.

ASTRAZENECA LP; ASTRAZENECA AB; AKTIEBOLAGET HASSLE; RANBAXY PHARMACEUTICALS INC.; RANBAXY INC.; RANBAXY LABORATORIES LTD.,

Defendants, Appellees.

APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. William G. Young, U.S. District Judge]

Before

Lynch, Stahl, and Thompson,
Circuit Judges.

Thomas M. Sobol, with whom David S. Nalven, Kristen A. Johnson, James J. Nicklaus, Kristie A. LaSalle, Hagens Berman Sobol Shapiro LLP, Bruce E. Gerstein, Joseph Opper, Elena K. Chan, Ephraim R. Gerstein, Garwin Gerstein & Fisher, LLP, David F. Sorensen, Ellen Noteware, Daniel C. Simons, Caitlin G. Coslett, Berger & Montague, P.C., Linda P. Nussbaum, Nussbaum Law Group, P.C., Steve D. Shadowen, Hilliard & Shadowen LLP, Kenneth A. Wexler, Bethany R. Turke, Justin N. Boley, Wexler Wallace LLP, J. Douglas Richards, Sharon K. Robertson, Donna M. Evans, Cohen Milstein Sellers & Toll, PLLC, Jayne A. Goldstein, Pomerantz LLP, Matthew Wessler, and Gupta Wessler PLLC were on brief, for direct purchaser and end-payor class appellants.

Barry L. Refsin, Monica L. Rebuck, Maureen S. Lawrence, Hangley Aronchick Segal Pudlin & Schiller, Bernard D. Marcus, Moira Cain-Mannix, Marcus & Shapira LLP, Richard A. Arnold, Scott E. Perwin, Lauren C. Ravkind, Anna T. Neill, and Kenny Nachwalter, P.A. on brief for individual retailer appellants.

Kannon K. Shanmugam, with whom Dane H. Butswinkas, Paul B. Gaffney, John E. Schmidtlein, and Williams & Connolly LLP were on brief, for appellees AstraZeneca LP, AstraZeneca AB, and Aktiebolaget Hassle.

Jay P. Lefkowitz, P.C., with whom Steven J. Menashi, Amanda Elbogen, Jonathan D. Janow, Kirkland & Ellis LLP, James Douglas Baldridge, Lisa Jose Fales, Danielle R. Foley, Vincent E. Verrocchio, and Venable LLP were on brief, for appellees Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd.

Mark S. Hegedus, Attorney, Office of the General Counsel, Federal Trade Commission, Deborah L. Feinstein, Director, Markus H. Meier, Acting Deputy Director, Bradley S. Albert, Deputy Assistant Director, Elizabeth R. Hilder, Attorney, Bureau of Competition, Daniel W. Butrymowicz, Attorney, Bureau of Competition, Jonathan E. Nuechterlein, General Counsel, and Joel Marcus, Director of Litigation, on brief for Federal Trade Commission, amicus curiae.

November 21, 2016

LYNCH, **Circuit Judge**. This appeal arises from the first pharmaceutical-settlement antitrust action tried before a jury since the Supreme Court's decision in FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013). The jury found that although the plaintiffs had proved an antitrust violation in the form of a large and unjustified reverse payment from AstraZeneca to Ranbaxy, the plaintiffs had not shown that they had suffered an antitrust injury that entitled them to damages.

Defendant AstraZeneca is a brand-name drug manufacturer that owns the patents covering Nexium, a prescription heartburn medication that has grossed billions of dollars in annual sales. After defendant Ranbaxy notified the Food and Drug Administration ("FDA") that it sought to market a generic version of Nexium, AstraZeneca sued Ranbaxy for patent infringement. The two companies reached a settlement agreement, under which Ranbaxy agreed to delay the launch of its generic until a certain date in return for various promises from AstraZeneca. AstraZeneca similarly sued and subsequently settled two patent infringement suits with generic manufacturers Teva and Dr. Reddy's, who were (but no longer remain) defendants in this case. The plaintiffs -- various pharmaceutical retail outlets and certified classes of direct purchasers and end payors -- brought suit, arguing that the terms of these settlement agreements violated federal antitrust laws and state analogues.

After summary judgment proceedings that winnowed down the number of causal mechanisms through which the plaintiffs could attempt to prove antitrust violation and injury, the case proceeded to a jury, which found as we have described. Following the verdict, the district court denied the plaintiffs' motions for a permanent injunction and for a new trial.

The plaintiffs appeal, raising four categories of claims. First, they challenge various evidentiary rulings. Second, they argue that the district court erroneously granted judgment as a matter of law in the defendants' favor on the issue of overarching conspiracy. Third, they argue that the special verdict form and jury instructions contained reversible error. The final argument, which lies at the heart of this appeal, is that the district court, at summary judgment, impermissibly cut down the number of causal mechanisms through which the plaintiffs could make their case to the jury. See In re Nexium (Esomeprazole) Antitrust Litig. ("In re Nexium [Summary Judgment]"), 42 F. Supp. 3d 231 (D. Mass. 2014). This error at summary judgment pervaded the entire trial, the plaintiffs argue, and constitutes grounds to vacate the jury verdict and award a new trial.

We find no reversible error in the district court's evidentiary rulings, the formulation of the special verdict form and jury instructions, or its judgment as a matter of law on overarching conspiracy. In fact, many of the plaintiffs'

objections have been forfeited or mooted by the jury's findings. We further hold that the jury verdict, finding an antitrust violation but not an antitrust injury, coupled with developments at trial on the issue of patent invalidity, renders harmless any error that may have occurred during the summary judgment proceedings. Accordingly, we need not, and indeed should not, review the summary judgment order for error. We affirm.

I. REGULATORY FRAMEWORK

An overview of the intricate pharmaceutical regulatory framework is necessary to understand the issues presented. A manufacturer that seeks to market a new brand-name drug must file a New Drug Application ("NDA") with the FDA and "undergo a long, comprehensive, and costly testing process." Actavis, 133 S. Ct. at 2228. Generic-drug manufacturers formerly underwent similarly rigorous processes to obtain FDA approval to market generic versions of the brand-name drug. In order to accelerate the entry of generic competitors into the market and decrease healthcare costs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act has three regulatory components that are relevant here.

First, the Act permits generic manufacturers to file the notably less costly Abbreviated New Drug Application ("ANDA"), "specifying that the generic has the 'same active ingredients as,'

and is 'biologically equivalent' to, the already-approved brand-name drug." Actavis, 133 S. Ct. at 2228 (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012)). "[B]y allowing the generic to piggy-back on the pioneer's approval efforts, [the Hatch-Waxman Act] 'speed[s] the introduction of low-cost generic drugs to market,' thereby furthering drug competition." Id. (third alteration in original) (quoting Caraco, 132 S. Ct. at 1676).

Second, the Act requires brand-name manufacturers to list the numbers and expiration dates of all relevant patents in their NDAs, which are then published in the FDA's "Orange Book," an annual publication of all approved drugs and the reported patents or statutory exclusivities that cover those drugs. In turn, generic manufacturers filing ANDAs must "'assure the FDA' that the generic 'will not infringe' the brand-name's patents," and may provide this assurance in one of four ways. Id. (quoting Caraco, 132 S. Ct. at 1676). The generic manufacturer may (1) certify that the brand-name manufacturer has failed to list any relevant patents; (2) certify that any relevant patents have expired; (3) request the FDA's approval to market its generic upon the expiration of any still active patents covering the brand name; or (4) certify that "any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale' of the

drug described in the [ANDA]." Id. (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

This last route, known as a "paragraph IV certification," usually triggers an immediate patent infringement suit from the brand-name manufacturer. If that suit is brought within 45 days of the paragraph IV certification, the FDA must withhold approval of the generic ANDA, usually for a 30-month period, during the course of litigation on patent validity or infringement. Id. If the court decides the patent matter within 30 months, the FDA follows the court's determination. But if the court does not, the FDA may approve an ANDA before a court rules on patent validity or infringement. Id. (citing 21 U.S.C. § 355(j)(5)(B)(iii)). This pre-ruling approval, in turn, allows the generic manufacturer to launch its 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." In re Nexium [Summary Judgment], 42 F. Supp. 3d at 245.

The final relevant component of the Hatch-Waxman Act is that it rewards the first generic manufacturer to file an ANDA with a paragraph IV certification by granting that first filer a 180-day period of exclusivity. Actavis, 133 S. Ct. at 2228–29.

During that 180-day window, the FDA cannot approve ANDAs from competing manufacturers for the same generic, leaving only the first filer with the ability to market its generic. Accordingly, this period of exclusivity can be "worth several hundred million dollars." Id. at 2229 (quoting Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). In fact, the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." Id. From the market perspective, however, the first filer may create a bottleneck, as all other generic manufacturers must wait for the exclusivity period to end before launching their own generics.

Significantly, this lucrative 180-day exclusivity period is not absolute. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, a first filer may forfeit its exclusivity period if it fails to come to market within 75 days of a final, nonappealable court judgment that the first filer's product does not infringe the brand-name's patents. 21 U.S.C. §§ 355(j)(5)(D)(i)(I)(bb), (D)(ii). Alternatively, first-filer exclusivity can be forfeited if another generic manufacturer successfully challenges the brand-name patents at issue and if the first filer fails to market its generic within 75 days of a final,

nonappealable judgment in that other manufacturer's suit. Id.; see also In re Nexium [Summary Judgment], 42 F. Supp. 3d at 246.

In 2013, the Supreme Court held that reverse payment settlements in paragraph IV litigation "can sometimes violate the antitrust laws." Actavis, 133 S. Ct. at 2227. A reverse payment refers to an arrangement in which the brand-name manufacturer and patent holder compensates the generic manufacturer and alleged patent infringer to settle the paragraph IV litigation and delay the generic's market entry. Id. at 2229. When a brand-name manufacturer pays to delay the first filer's generic launch, that reverse payment postpones not only the first filer's product but also those of all other generic manufacturers, who must wait out the 180-day exclusivity period before going to market. Given that "a reverse payment, where large and unjustified, can bring with it th[is] risk of significant anticompetitive effects," the Supreme Court held that the potential anticompetitive effects of a reverse payment are subject to the antitrust "rule of reason" test. Id. at 2237.

Earlier this year, in In re Loestrin 24 Fe Antitrust Litigation, 814 F.3d 538 (1st Cir. 2016), this circuit ruled that improper reverse payments may take the form of "non-monetary" advantages. Id. at 549. The language and logic of Actavis dictated that outcome. See id. ("[T]he Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer

effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court's decision to pure cash payments."). Under this functional approach, "no-AG" provisions -- in which the brand-name manufacturer agrees not to market an "authorized generic" version of the drug for a certain period of time -- and other settlement provisions in which some advantage is transferred from the patent holder to the alleged infringer may constitute a reverse payment subject to antitrust scrutiny.

II. FACTS

Nexium is a proton-pump inhibitor whose active ingredient is esomeprazole magnesium. The FDA approved AstraZeneca's NDA to market Nexium in 2001. Between 2008 and 2014, Nexium grossed at least $3 billion annually in U.S. sales and joined the ranks of "blockbuster" drugs -- those that generate annual sales of at least $1 billion. In 2001, AstraZeneca held fourteen active patents covering Nexium. As relevant here, two medical patents expired on May 27, 2014, two other patents expired in February 2015 and July 2015, and two more are set to expire in May 2018.

In August 2005, Ranbaxy first filed an ANDA with a paragraph IV certification in order to market a generic version of Nexium. The filing stated that Ranbaxy's launch would await the

2007 expiration of some of AstraZeneca's Nexium patents, but certified that other patents were either not infringed or invalid. As to patent invalidity, Ranbaxy contended that there was "nothing new" about Nexium, as the active compound in Nexium was effectively "one-half" of the compound in Prilosec, another blockbuster drug for stomach-acid treatment that AstraZeneca had marketed prior to Nexium.

AstraZeneca promptly brought suit, alleging that Ranbaxy had violated six of its patents: two that would expire on May 27, 2014, two that would expire in 2015, and two that would expire in May 2018. The suit stayed FDA approval of Ranbaxy's ANDA until April 2008. Meanwhile, Teva filed its ANDA for generic Nexium in November 2005, and Dr. Reddy's filed in December 2007. AstraZeneca sued Teva and Dr. Reddy's as well, and all three patent infringement suits were consolidated in the U.S. District Court for the District of New Jersey.

A. Settlement Agreements

Ranbaxy was the first defendant to settle after reaching an agreement with AstraZeneca in April 2008. Under the settlement agreement, Ranbaxy received a license to all relevant Nexium patents starting on May 27, 2014. The settlement also contained a no-AG clause, under which AstraZeneca agreed not to market an authorized generic version of Nexium during Ranbaxy's 180-day period of exclusivity. The clause thus ensured that Ranbaxy's

generic would be the only one on the market if it could launch in time to avoid triggering the statutory forfeiture provisions. AstraZeneca could still continue to market its brand-name drug during that period. In return, Ranbaxy stipulated to patent validity and infringement and consented to the entry of an injunction against the sale of its generic before the license took effect on May 27, 2014.

AstraZeneca and Ranbaxy also executed three other agreements, under which Ranbaxy would serve as AstraZeneca's subcontractor and manufacture certain quantities of branded Nexium, and would also serve as AstraZeneca's distributor for authorized generic versions of two other AstraZeneca drugs, Prilosec and Plendil. For the distribution agreement, Ranbaxy would receive 20% of AstraZeneca's profits.

After litigating for a few more years, Teva settled with AstraZeneca in January 2010. Like Ranbaxy, Teva received a license to the Nexium patents starting on May 27, 2014 and also consented to an injunction barring the sale of its generic before that license took effect. Simultaneously, AstraZeneca and Teva agreed to settle another pending patent infringement lawsuit regarding Prilosec. In that multiyear litigation, AstraZeneca had succeeded in establishing Teva's liability, but Teva had been contesting the damages amount based on its past infringing sales. Teva paid AstraZeneca $9 million to resolve that suit.

Dr. Reddy's settled with AstraZeneca in January 2011. Like Ranbaxy and Teva, Dr. Reddy's received a license for the Nexium patents starting on May 27, 2014 and also consented to an injunction barring sales before that date. Simultaneously, AstraZeneca and Dr. Reddy's settled another pending patent infringement lawsuit in which AstraZeneca agreed to drop its appeal of the entry of summary judgment in Dr. Reddy's favor.

The three settlement agreements contained parallel contingent launch provisions under which each generic manufacturer agreed to delay launching its generic in the United States until (1) May 27, 2014; (2) a hypothetical date prior to May 27, 2014 on which any third party launched generic Nexium pursuant to a final, nonappealable court order that AstraZeneca's Nexium patents were invalid, unenforceable, or not infringed by the generic; or (3) a hypothetical date prior to May 27, 2014 on which AstraZeneca authorized any third party to manufacture a generic Nexium. In re Nexium [Summary Judgment], 42 F. Supp. 3d at 249 (citing ¶ 5.2 in the three settlement agreements).

B. Ranbaxy's Regulatory Troubles

Throughout Ranbaxy's paragraph IV litigation challenging AstraZeneca's Nexium patents, Ranbaxy faced serious issues with the FDA. Specifically, Ranbaxy had filed its ANDA for generic Nexium out of its manufacturing facility in Paonta Sahib, India, which meant that any FDA approval to launch generic Nexium would

extend only to that facility. In February 2009, after issuing several warnings about quality control problems with the India facility, the FDA ultimately invoked its Application Integrity Policy ("AIP") against Paonta Sahib. The AIP "halted FDA's substantive review and approval of all pending ANDAs, including amendments and post-approval supplements that relied on supporting data from the Paonta Sahib site -- including the generic Nexium ANDA." Id. at 266. The agency then rejected Ranbaxy's proposed Corrective Action Operating Plan and further turned down Ranbaxy's request that it grant a public health exception to the AIP and continue the approval process for the generic Nexium ANDA. Meanwhile, the FDA granted a public health exception for generic Lipitor, another Ranbaxy product manufactured out of the Paonta Sahib facility.

In 2010, Ranbaxy and the FDA began negotiating a Consent Decree, which they finalized on January 25, 2012. Under its terms, Ranbaxy could meet "several onerous and time-consuming milestones" to obtain potential FDA approval for generic Nexium or to obtain a site-transfer amendment to change the manufacturing site for the drug. The Consent Decree also contained a "key relinquishment date" of September 30, 2014. Id. at 274. If Ranbaxy could not meet the requisite milestones before that date, it would forfeit its 180-day exclusivity period. Id. Ranbaxy took over two and a half years to prepare a site-transfer amendment, and the

manufacturer failed to receive final FDA approval for its generic Nexium ANDA prior to May 27, 2014.

On November 4, 2014, the FDA rescinded its tentative approval of Ranbaxy's generic Nexium ANDA, and Ranbaxy promptly sued the FDA in the U.S. District Court for the District of Columbia. See Ranbaxy Labs, Ltd. v. Burwell, 82 F. Supp. 3d 159, 163 (D.D.C. 2015). Subsequently, in January 2015, the FDA notified Ranbaxy that it had forfeited its first-filer exclusivity period by failing to obtain approval for its generic within 30 months of submitting its ANDA. The FDA simultaneously approved Teva's ANDA for generic Nexium, which launched on February 17, 2015.

C. Dispute over Teva's Readiness to Launch Generic Nexium

The plaintiffs' evidence at summary judgment and at trial showed that Teva was closer than Ranbaxy to obtaining FDA approval and launching generic Nexium before May 27, 2014. An internal Teva email from February 2007 approximated Teva's "Launch Readiness date" as July 2008. And by 2009, Teva had passed FDA review in two out of the three categories necessary for tentative approval of its generic Nexium.

The parties vehemently disagreed at summary judgment on whether the third remaining category for FDA approval was "a significant hurdle or a minor one," an issue material to determine whether Teva was indeed close to FDA approval. In re Nexium

[Summary Judgment], 42 F. Supp. 3d at 288–89. The jury heard evidence from both sides on this issue.

III. PROCEDURAL HISTORY

A. Pretrial Proceedings

Plaintiffs commenced six different actions in three different federal district courts, alleging that AstraZeneca made improper reverse payments to Ranbaxy, Teva, and Dr. Reddy's in order to delay the market entry of generic Nexium. On December 7, 2012, the U.S. Judicial Panel on Multidistrict Litigation consolidated and assigned the six pending actions to the U.S. District Court for the District of Massachusetts. See 28 U.S.C. § 1407. This appeal arises from that consolidated case.

On appeal, plaintiffs are a class of wholesale drug distributors (the "Direct Purchasers"); a class of individual consumers, third-party payors, union plan sponsors, and certain insurance companies (the "End Payors"); and numerous pharmaceutical retail outlets.[1] In January 2015, a panel of this circuit affirmed the certification of the End Payors damages class over a dissent. See In re Nexium Antitrust Litig., 777 F.3d 9 (1st Cir. 2015). The original defendants in this litigation were

[1] The pharmaceutical retail outlets are CVS, Inc.; Eckerd Corporation; Giant Eagle, Inc.; HEB Grocery Co. LP; JCG (PJC) USA, LLC; the Kroger Company; Maxi Drug, Inc. d/b/a Brooks Pharmacy; Rite Aid Corporation; Rite Aid Headquarters Corporation; Safeway Incorporated; Supervalu, Inc.; and Walgreen Co.

AstraZeneca, Ranbaxy, Teva, and Dr. Reddy's. Teva and Dr. Reddy's have settled, leaving only AstraZeneca and Ranbaxy as defendants on appeal.

Consistent with In re Loestrin 24 Fe, the plaintiffs' complaints identified aspects of AstraZeneca's settlements with each of the three generic manufacturers that allegedly were reverse payments in violation of the antitrust laws. In the Ranbaxy settlement, the plaintiffs pointed to the no-AG clause, as well as the side manufacturing and distribution agreements. In the Teva settlement, the plaintiffs argued that Teva's payment of only $9 million to settle the Prilosec lawsuit, rather than the higher amount that Teva actually owed AstraZeneca, constituted the reverse payment. In the Dr. Reddy's settlement, the plaintiffs cited AstraZeneca's agreement to drop its appeal challenging Dr. Reddy's summary judgment win in another patent infringement lawsuit.

In December 2013, the defendants collectively filed eleven motions for summary judgment. Following the court's initial rulings from the bench, both parties filed various motions for reconsideration. In a September 4, 2014 opinion, the district court memorialized its rationale as to each summary judgment motion that it decided. See In re Nexium [Summary Judgment], 42 F. Supp. 3d 231. This opinion grouped the motions into five categories:

First, the district court denied the defendants' motions for partial summary judgment on the existence of an overarching antitrust conspiracy, among all four original defendants, to restrain trade in the market for generic Nexium. Id. at 248–60. At the pretrial stage, the court found that the plaintiffs had "met their burden of establishing a reasonable inference of overarching conspiracy," id. at 249, as the evidence demonstrated that each generic "manufacturer's calculus [on its entry date into the generic Nexium market] changed . . . when it received assurance that it would only have to restrict its business if its competitors did the same," id. at 258. The denial of summary judgment to the defendants imposed no restrictions on the plaintiffs' ability to produce evidence at trial. Following the plaintiffs' case in chief, the district court granted judgment as a matter of law in the defendants' favor on this overarching conspiracy claim.

Second, although the district court denied the defendants' motion for summary judgment as to the existence of an improper reverse payment from AstraZeneca to Ranbaxy, the court granted the motion as to the argument that such a reverse payment caused the plaintiffs' injury. Id. at 260. The court elaborated that the no-AG clause in the AstraZeneca–Ranbaxy settlement agreement "may be considered part of an illegal reverse payment," id. at 265, while the lucrative "side" agreements granting Ranbaxy supply and distribution contracts likewise "raise[] enough

suspicions to support a reasonable inference [of] improper reverse payments to induce Ranbaxy to delay its generic launch," id. at 264.

Nonetheless, in light of the quality control issues that Ranbaxy's Paonta Sahib facility had experienced, the court found that the plaintiffs did not show how Ranbaxy could still have obtained final FDA approval and launched its generic before May 27, 2014. Id. at 270-75. The court was skeptical of the plaintiffs' analogy to generic Lipitor, which had been manufactured out of Paonta Sahib and had faced similar regulatory issues but had nonetheless launched after Ranbaxy reached a compromise with the FDA. Id. at 273-74.

"The net effect of these rulings [wa]s that the Ranbaxy Settlement [could] not [be] a basis for imposing antitrust liability." Id. at 279. However, later at trial, the court acknowledged its error as to this ruling and reversed course.

Third, the court denied the defendants' motions for summary judgment based on the Teva settlement. The court found that the plaintiffs' evidence -- that Teva's $9 million payment to AstraZeneca to settle the Prilosec lawsuit was so low a sum that it "constituted a significant forgiveness of debt" by AstraZeneca to delay the launch of Teva's generic -- was sufficient to proceed to trial. Id. at 286. The court next found that the plaintiffs had also met their burden as to, what it called, antitrust

causation because they showed (1) that Teva was close to obtaining tentative FDA approval but slowed down its efforts toward that goal after settling with AstraZeneca, and (2) that Teva could have entered the market before May 2014, notwithstanding Ranbaxy's first-filer exclusivity period, by partnering with Ranbaxy on a joint launch. Id. at 288–89.[2] In sum, the plaintiffs could pursue the Teva settlement as a basis for antitrust liability at trial.

Fourth, the district court granted the defendants' motion for summary judgment based on the Dr. Reddy's settlement, finding that the plaintiffs had proffered insufficient evidence both on the existence of an improper reverse payment and on "antitrust causation." Id. at 291–95.

Finally, the district court denied three miscellaneous motions for summary judgment that AstraZeneca had filed: (1) a motion against the Direct Purchaser and Individual Retailer plaintiffs for lack of actual injury and seeking exclusion of testimony from two experts; (2) a motion barring assigned claims; and (3) a motion on the basis of the statute of limitations. Id. at 295–300.

[2] The court rejected as too speculative another causal mechanism -- namely, that Teva could have won its paragraph IV suit and obtained a final, nonappealable judgment that AstraZeneca's Nexium patents were invalid or not infringed. That theoretical victory could, in turn, have triggered the regulatory 75-day window within which Ranbaxy had to launch its generic or forfeit its first-filer exclusivity. Id. at 289–90.

In sum, after the summary judgment proceedings, the plaintiffs were allowed to present evidence on AstraZeneca's improper reverse payment to Teva and any antitrust liability flowing from that payment, as well as the existence of an overarching antitrust conspiracy among AstraZeneca, Ranbaxy, Teva, and Dr. Reddy's. That evidence would include testimony from the plaintiffs' expert, Dr. Thomas McGuire. The court further directed the plaintiffs to present all evidence supporting an antitrust violation arising out of the Teva settlement first, before presenting any other evidence.

After summary judgment, at a January 21, 2014 pretrial motion hearing, the district court granted the defendants' motion in limine to exclude testimony from Shashank Upadhye, a former in-house lawyer at a nondefendant generic manufacturer. The plaintiffs sought Upadhye's testimony to "augment Dr. McGuire's economic testimony with a real world business perspective on settlement negotiations for drug patent lawsuits." The court reasoned that Upadhye, along with another proposed expert witness (John Thomas), could not testify because they were "lawyers, not economists, and . . . they d[id] not have the requisite qualifications to testify." At an October 15, 2014 charge conference, the court reminded both parties that its decisions regarding motions in limine were "not rulings" and that the parties

"must make [their] objections known during the course of the trial."

Dr. Reddy's settled and dropped out of the lawsuit shortly before trial.

B. Trial

A six-week trial commenced on October 20, 2014. The trial transcript, exhibits, and filings comprise thousands of pages in the record. We summarize only the aspects of trial that are relevant to the arguments on appeal.

1. Plaintiffs' Statement on Patent Invalidity and Evidence Introduced During Their Case in Chief

At a conference on the second day of trial, the plaintiffs described their case in chief to the district court:

> [In order to show that Teva could have gotten to market before May 27, 2014, the district court said that the plaintiffs] would need to prove that Teva would have won its litigation [against AstraZeneca]. And then . . . [the court] also indicated though that we could also perhaps prove that Teva would have done a deal with Ranbaxy in order to have the 180 days lifted.
>
> . . . We plan to do the latter, primarily in our case in chief . . . . We don't plan on proving a patent case inside of an antitrust case [by pursuing the former]. . . . [W]e do not plan to be proving that Teva would have won the litigation.

This choice by the plaintiffs was not mandated by the district court's ruling. At trial, consistent with the district court's order, the plaintiffs first presented evidence on the existence of a reverse payment from AstraZeneca to Teva.

Dr. McGuire, an economist and one of the plaintiffs' key expert witnesses, testified twice during the plaintiffs' case in chief. McGuire first testified 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." In re Nexium (Esomeprazole) Antitrust Litig. ("In re Nexium [Post-Trial Opinion]"), 309 F.R.D. 107, 119 (D. Mass. 2015). He further "detailed how the benefits AstraZeneca conferred on Teva through their mutual settlement exceeded the litigation costs the parties thereby avoided." Id.

During McGuire's second testimony, despite the summary judgment order precluding the plaintiffs from introducing evidence of a reverse payment to Ranbaxy, the court allowed McGuire to testify "for context" on the "far greater reverse payment made by AstraZeneca to Ranbaxy to induce it to forego its challenge to AstraZeneca's Nexium patents." Id. The district court also allowed McGuire to testify about Ranbaxy's economic incentives to include a contingent launch provision in its settlement agreement with AstraZeneca. Specifically, McGuire noted that the provision made it "less likely" that subsequent ANDA filers would pursue generic entry. He further stated that the clause "had the effect of reducing the likelihood that Teva would challenge and break the bottleneck, which means for Ranbaxy[,] it became more likely that

[it was] able to use [its] 180-day exclusivity period and make the profits associated with that."

At one point during McGuire's second testimony, the court forbade him from quantifying Ranbaxy's incentive to participate in the overarching conspiracy as "about $700 million in [Ranbaxy's] pocket that [it] otherwise wouldn't have." It ruled as such because the existence of contingent launch provisions, and not that theory, was what kept the plaintiffs' "case against Ranbaxy alive." The court nonetheless allowed McGuire to testify that AstraZeneca netted "hundreds of millions of dollars" by settling with Ranbaxy to "strengthen the 180-day [first-filer] barrier."

Plaintiffs were permitted to introduce expert testimony on the but-for entry dates. For three days, starting on November 18 and after the district court articulated its "misconception," the plaintiffs presented the testimony of Dr. Cheryl Blume, their "lead witness on the issue of the crucial 'but for entry date.'" Id. at 120. Looking back at trial, the district court noted that "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." Id.

2. The District Court's Mid-Trial Shift, Defendants' Mistrial Motion, and the Exclusion of McGuire's Event Study and Other Testimony

On November 18, 2014, the seventeenth day of the trial, the court admitted that it had had a "fairly fundamental misconception" of the plaintiffs' theory of the case. The court then adjusted its thinking about the relevance of the AstraZeneca–Ranbaxy settlement by noting that "[t]he large and unjustified payment to Ranbaxy, which keeps Ranbaxy, given its blocking position [as first filer], off the market until May 27th, 2014, has an effect on all the later ANDA filers, such that if it were to be proved that but for that agreement, . . . Teva could have partnered with Ranbaxy and come to market prior to that date."

In light of this shift, the district court announced that it would alter the jury verdict form and allow the plaintiffs to recall McGuire to testify for a third time. The court also emphasized that its shift in thinking did "not injure[]" the plaintiffs because "they seem to have in the record enough evidence of a large and unjustified payment to Ranbaxy and based upon their expert's testimony it can be argued that it was anticompetitive."

In response to the district court's stated reversal of its position, the defendants filed two motions, to both of which the plaintiffs objected. The first motion was for a mistrial. The second was to exclude McGuire's additional proffered testimony -- an "Event Study" that postulated an earlier entry date had there

not been a reverse payment in the AstraZeneca-Ranbaxy settlement -- under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). The district court first excluded McGuire's Event Study testimony under Daubert. That Study purported 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 [a reverse] payment." While the court acknowledged McGuire's expertise and stated that the Event Study's methodology was "perhaps reliable," the Study did not meet Daubert requirements because there was "no fit" "between the event study and this culmination of the case." The court recognized that the plaintiffs might nonetheless want to call McGuire a third time to testify to "other things" besides the Event Study. It ruled, however, that it still would not allow him to testify to those "additional matters" because to do so would be "simply unfair."

Given that the court had said on November 18 that it would allow the plaintiffs to recall McGuire, the court acknowledged that its "no more McGuire" ruling could "change the plaintiffs' position on mistrial." It directed the plaintiffs to make "tactical decisions" on whether to reassess their initial opposition to the defendants' mistrial motion.

The plaintiffs continued to oppose a mistrial. They pointed out that despite the summary judgment ruling precluding evidence of AstraZeneca's reverse payment to Ranbaxy, such

evidence had nonetheless been presented to the jury under another theory. Indeed, the plaintiffs had introduced evidence on that payment because it was relevant and admissible under the claim of overarching conspiracy.[3] Plaintiffs also argued that the "chopped up" way in which McGuire's earlier testimony was presented to the jury and the court's exclusion of McGuire's Event Study went "a long way to curing whatever prejudice . . . these defendants may have incurred."

Immediately following these statements, the court denied the motion for mistrial.

3. Judgment as a Matter of Law on Conspiracy and Patent Invalidity

At the close of the plaintiffs' case, the defendants moved for judgment as a matter of law on the overarching conspiracy claim, as well as on the question of antitrust causation. The court granted the motion on the conspiracy claim, noting that

[3] The vigor with which the plaintiffs acknowledged the admission of evidence on the Ranbaxy reverse payment is worth noting:

> From the very beginning of this case the payment to Ranbaxy has been in clearly as at least an overt act in furtherance of the conspiracy. . . . But for [the defendants] to come here now and say, Oh, this was never in the case, that simply from our perspective is not true. It was unclear exactly how much and what role that payment was going to make, but it was clear it was in this as an overt act . . . . And we made our tactical choices and [the defendants] made theirs.

"[t]here [wa]s no sufficient evidence here that Ranbaxy and Teva conspired together, [or] that they acted otherwise than in their own individual best interest." Although the court "came within an ace" of granting the motion on causation as well, it decided to deny the motion for "prudential reasons" and let that question go to the jury. The court did grant the defendants' motion on causation with regard to any theory of antitrust causation based on patent invalidity, as it found "no adequate evidence that any of these patents would be adjudicated invalid." Earlier in the trial, the plaintiffs had already told the court that they would not pursue such a theory.

To be sure of the accuracy and consequences of its ruling on patent invalidity, the court invited the parties to present further arguments on that issue following its initial ruling. The court subsequently refined its judgment regarding patent invalidity. Specifically, the court credited the plaintiffs' argument that, as a matter separate from the absolute validity of the Nexium patents, patent holders like AstraZeneca protect their patent monopoly and maximize profit in a world in which patent infringement litigation may loom but has not taken place. Accordingly, the court allowed the plaintiffs, independent of the ruling on patent invalidity, to argue that the defendants could have been incentivized to reduce the risk of patent invalidation -- for instance, by paying to delay the market entry of generics.

On November 24, 2014, Teva settled and dropped out of the suit, leaving only AstraZeneca and Ranbaxy as defendants.

4. Exclusion of Plaintiffs' Proposed Rebuttal Evidence

At the close of the defendants' case on December 2, 2014, the plaintiffs unsuccessfully sought to admit rebuttal evidence, which included the McGuire Event Study that the court had already excluded; a report published by Federal Trade Commission ("FTC") staff and entitled "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions"; and expert testimony from Dr. Keith Leffler. Leffler, an economist, proffered testimony that "virtually all Hatch-Waxman cases can be settled without reverse payments" and that it would have been in both AstraZeneca's and Ranbaxy's economic interest to enter into a payment-free settlement with a February 2012 entry date. The court refused to admit any of this evidence "because it [was] not true rebuttal" and should have been introduced during the plaintiffs' case in chief.

5. Special Verdict Form and Jury Instructions

The district court first provided the parties with the revised verdict form at a December 2, 2014 conference. This form contained the following seven questions:

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

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

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

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?

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

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

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

After the court explained its revisions, it engaged in a colloquy with the parties, which focused, in relevant part, on the plaintiffs' objection that Question 4 applied a legally incorrect "subjective" test for antitrust causation.

The district court instructed the jury the next day. On Question 4, the court explained that answering "yes" to the first three questions was insufficient because "[j]ust making a deal . . . is not enough for liability[;] there has to be a harm." The court further explained that although the question mentioned by name AstraZeneca and Ranbaxy, it was "not necessarily just focusing on the AstraZeneca–Ranbaxy settlement":

> Now, the test here is an objective test. In other words I use the names "AstraZeneca" and "Ranbaxy"

> because those are the folks we're talking about here, but the test is not what they did . . . we know what agreement they entered into, you would have found [in Question 3] that agreement is unreasonably anticompetitive. So then you're asked the question, "Well, suppose they didn't enter into such an agreement, suppose they were settling straight up without any anticompetitive effects, would that settlement license entry date have been earlier than the date they agreed to, May 27th, 2014?"

The court also reviewed Teva's role in the plaintiffs' theory -- namely, that had AstraZeneca not made a reverse payment to Ranbaxy, their settlement agreement would have contained an earlier entry date, which would have allowed Teva to obtain that same earlier date or to partner with Ranbaxy for a joint launch of generic Nexium. Finally, the court informed the jury that a "no" to any question meant that the jury should not consider any subsequent question.

During the sidebar following the charge, each party objected to certain aspects of the court's instructions. The court had earlier warned that the parties had to raise their objections at the end of the charge to preserve them for appeal. The plaintiffs' objections to Question 4 were limited to the district court's colloquial framing of that question. They also objected to other aspects of the instructions unrelated to Question 4.

6. Plaintiffs' Closing Statement

The plaintiffs' closing expressly reminded the jury of the "large and unjustified payment" from AstraZeneca to Ranbaxy.

Plaintiffs' counsel argued that "[i]t's large because it was worth about $690 million to Ranbaxy, or according to [one witness], about $300 million. It was going to cost AstraZeneca, in terms of lost sales, about $500 million of its own revenues that it might be able to get from the sale of [an authorized generic]." The plaintiffs further urged the jury to draw inferences from that payment: "By the fact that there was a payment you can infer that there was a movement of that entry date. Absolutely. And [by] the fact that this payment was so large you can infer that the entry date was moved back and should have been earlier."

Notwithstanding the court's judgment as a matter of law on the issue of patent invalidity, the plaintiffs' closing also questioned the strength of AstraZeneca's Nexium patents and the relevance of those patents to the defendants' settlement agreement. The closing emphasized that the two defendants denied "ever talk[ing] about the strengths and weaknesses of the patent in order to negotiate some kind of date." Further, "[b]ecause . . . there was never a negotiation here where the two companies sat down and said we've got these claims on the patents . . . here's infringement issues, let's see how we can negotiate on the merits of this case a resolution," the plaintiffs urged the jury to find that the AstraZeneca-Ranbaxy deal consisted of "payoffs that weren't related to the merits." Upon the defendants' objections to the plaintiffs' characterization of "the patent

merits a[s] a coin flip" during the closing, the court reminded the jury that "on this record there is no evidence that any of these patents at the end of the day would have been held invalid."

Finally, the plaintiffs' closing discussed at least two mechanisms through which the Ranbaxy reverse payment could have led to an antitrust injury in the form of a delayed generic launch. First, they explained that AstraZeneca faced a "major risk of potential at-risk launch . . . in late 2007 and early 2008" and thus had an incentive to settle with Ranbaxy to avoid that outcome. Next, the plaintiffs reminded the jury about the Lipitor analogy. Articulating the "striking" similarities between Nexium and Lipitor, the plaintiffs emphasized that generic Lipitor launched despite Ranbaxy's regulatory troubles, while generic Nexium did not, because the Lipitor settlement agreement did not contain a no-AG clause and thus provided for an earlier entry date compared to the Nexium settlement agreement.

7. Jury Verdict

After deliberating for two and a half days, the jury returned a verdict for the defendants. The jury answered "yes" to the first three questions, finding that the AstraZeneca-Ranbaxy settlement contained a "large and unjustified payment" and had an "unreasonably anticompetitive" market impact. But the jury answered "no" to Question 4, finding that the plaintiffs had failed to prove that AstraZeneca would have negotiated an entry date

earlier than May 27, 2014. Heeding the court's earlier instructions, the jury stopped after its "no" answer.

C. Post-Trial Proceedings

On December 31, 2014, the plaintiffs moved for a new trial based in part on allegedly contradictory evidence that Ranbaxy had presented in litigation against the FDA in December 2014. One week later, a subset of plaintiffs moved for a permanent injunction under Section 16 of the Clayton Antitrust Act, Pub. L. 63-212, 38 Stat. 730 (codified at 15 U.S.C. §§ 12-27, 29 U.S.C. §§ 52-53). The district court denied both motions. See In re Nexium [Post-Trial Opinion], 309 F.R.D. at 134, 143.

This appeal followed.

IV. ANALYSIS

Plaintiffs have chosen to focus their appeal on the partial grant of summary judgment, the exclusion of certain evidence at trial, alleged errors in the district court's special verdict form and jury instructions, and the grant of judgment as a matter of law on the claim of overarching conspiracy. Plaintiffs argue that any one of these alleged errors entitles them to a new trial.

We disagree and affirm the district court's evidentiary rulings, judgment as a matter of law on overarching conspiracy, and decision to structure the special verdict form and jury instructions in the manner that it did. Further, in light of the

jury verdict and other critical developments at trial on the issue of patent invalidity, we decline to revisit the district court's summary judgment rulings. It would be improper for an appeals court to wade into such pretrial matters when, as here, a confluence of the plaintiffs' trial strategy, the district court's rulings, and the jury verdict rendered harmless any alleged error at the summary judgment stage.

A. Evidentiary Rulings

The plaintiffs challenge numerous evidentiary rulings of the district court. We find no error and affirm.

1. Exclusion of McGuire's Event Study Testimony

The plaintiffs argue that the district court committed reversible error by refusing to allow Dr. Thomas McGuire to testify for a third time after it concluded that the subject of his testimony, the Event Study, was inadmissible under Daubert. We review Daubert determinations for abuse of discretion. Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 81 (1st Cir. 1998) (citing General Elec. Co. v. Joiner, 522 U.S. 136, 141-42 (1997)). Federal Rule of Evidence 702 requires district courts to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand" before admitting it into evidence. Daubert, 509 U.S. at 597. The district court, as gatekeeper, must "ensure that there is an adequate fit between

the expert's methods and his conclusions." Samaan v. St. Joseph Hosp., 670 F.3d 21, 32 (1st Cir. 2012).

We conclude on the merits[4] that the district court did not abuse its discretion in excluding the Event Study and McGuire's corresponding testimony. The court properly found that the Event Study methodology -- which purported to use econometric analysis of stock market data to "estimate an objective entry date without [a reverse] payment" -- did not fit the conclusions for which it was offered. Although such studies had previously been "admitted on valuation, something much more germane to stock price," the study had questionable relevance to hypothesizing the outcome of a settlement agreement, especially one as crucial as the but-for entry date in a reverse-payment case. Furthermore, when asked to offer an example of another study that had used the Event Study methodology to predict settlement terms, the plaintiffs could not produce anything but an unpublished, non-peer-reviewed working paper that McGuire co-authored during the course of this litigation. The exclusion of McGuire's Event Study testimony under these circumstances did not constitute an abuse of discretion.

[4] As a threshold matter, the defendants argue that the plaintiffs are judicially estopped from appealing the exclusion of McGuire's Event Study, as they agreed to give up that evidence to defeat the defendants' mistrial motion. We need not reach this claim.

2. Exclusion of Other Aspects of McGuire's Testimony

The plaintiffs also accuse the district court of improperly forbidding McGuire from testifying about three other issues: (1) specific but-for entry dates, (2) "the purpose and effect of the side deals" between AstraZeneca and Ranbaxy, and (3) the exact size of the reverse payment from AstraZeneca to Ranbaxy. We can quickly dispose of these arguments.

First, as to McGuire's testimony on the but-for entry dates, examining the district court's decision in the context of the overall record makes clear that the exclusion did not prejudice the plaintiffs. During McGuire's second testimony, which took place before the district court's mid-trial epiphany on the Ranbaxy reverse payment's relevance, the court did not allow McGuire to testify that Ranbaxy and Teva "would have been able to enter in 2011" but for the reverse payments. This ruling did not constitute reversible error in light of events at trial that took place both before and after the court's epiphany.

Even before its shift in thinking, the district court gave McGuire leeway to testify about Ranbaxy's economic incentives to enter into the settlement agreement with AstraZeneca. That testimony, in turn, implied how the AstraZeneca-Ranbaxy settlement could have led to delayed generic entry. In particular, McGuire testified, during his second time on the stand, that the contingent launch provision in Ranbaxy's settlement agreement diminished the

likelihood of subsequent ANDA filers seeking to enter the generic Nexium market. "In fact," McGuire testified, "there were no subsequent ANDA filers that pursued this [generic entry] through litigation." The district court also permitted plaintiffs' counsel to ask McGuire whether he had "reach[ed] a conclusion as to whether Ranbaxy had an economic motive to agree to the [contingent launch] clause." McGuire answered in the affirmative and, over an objection, was allowed to elaborate that the contingent launch provision "had the effect of reducing the likelihood that Teva would challenge and break the bottleneck, which mean[t] for Ranbaxy[,] it became more likely that [it was] able to use [its] 180-day exclusivity period and make the profits associated with that." Notwithstanding McGuire's inability to testify to exact but-for entry dates, the district court afforded him great latitude to give testimony on Ranbaxy's economic incentives to block other ANDA filers and thus delay generic entry.

Next, after the court's adjustment in thinking, it informed the parties that it would not allow McGuire to testify a third time out of principles of fairness and that the plaintiffs should consider this ruling's implications on their mistrial-motion calculus. In addition, independent of its rulings regarding McGuire, the court allowed testimony on but-for entry dates from another expert, Dr. Cheryl Blume, whom the court described as the plaintiffs' "lead witness" on this very issue. Blume testified as

part of the plaintiffs' case in chief over three days of trial (November 18 to 20).

In the context of the court's rulings on McGuire and Blume, the plaintiffs continued to oppose a mistrial. The record does not show that they made any objections that they should have been allowed to present cumulative evidence on specific but-for entry dates through McGuire in addition to Blume. In short, the plaintiffs had an opportunity to present evidence on hypothetical earlier entry dates through Blume, and the district court was under no obligation to also permit McGuire to testify on that same issue. The plaintiffs' argument to the contrary seems to be little more than an effort to admit cumulative and weaker evidence. See McDonald v. Fed. Labs., Inc., 724 F.2d 243, 248 (1st Cir. 1984); cf. Fed. R. Evid. 403 ("The [trial] court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."). Plaintiffs have not shown any prejudice resulting from the district court's decision not to permit cumulative evidence, particularly from a witness who had already been allowed to testify twice.

Next, the alleged errors in excluding McGuire's testimony on the side deals and the size of the reverse payment were harmless in light of the jury verdict. The "yes" answer to

Question 2 reflects the jury's finding that AstraZeneca made a large and unjustified payment to Ranbaxy. Furthermore, as to the size of the reverse payment, although McGuire could not assign a specific dollar figure to the value of the reverse payment, the district court did allow him to testify that it was worth "hundreds of millions of dollars."

3. Pretrial Exclusion of Upadhye's Testimony

The plaintiffs also fault the district court for its pretrial decision in limine to exclude testimony from Shashank Upadhye, who sought to provide "a real world business perspective on settlement negotiations for drug patent lawsuits."

Before reaching the merits, we must point out that, despite the district court's clear instructions that its pretrial decisions were "not rulings" and that the parties "must make [their] objections known during the course of the trial," the plaintiffs did not renew at trial their objections to the court's in limine decision regarding Upadhye. In fact, although the plaintiffs listed Upadhye as a witness whom they "m[ight] call" at trial, they never actually attempted to do so. Under these circumstances, the district court's in limine decision may not even serve as proper grounds for a reversal. See, e.g., Littleton v. McNeely, 562 F.3d 880, 891 (8th Cir. 2009).

But even if the plaintiffs had properly objected to the exclusion of Upadhye's testimony, there would be no error.

"Whether a witness is qualified to express an opinion is a matter left to the sound discretion of the trial judge." McDonald, 724 F.2d at 248 (quoting A. Belanger & Sons, Inc. v. U.S. for Use & Benefit of Nat'l U.S. Radiator Corp., 275 F.2d 372, 376 (1st Cir. 1960)). Here, the district court excluded Upadhye's proposed testimony because he was "not [an] economist[]" and "d[id] not have the requisite qualifications to testify." That decision, especially given Upadhye's reliance on his general experience and his failure to cite any methodology undergirding his opinions, was not an abuse of discretion. The district court may also have "regarded [Upadhye's] proffered testimony as cumulative," as McGuire had already testified about the Ranbaxy reverse payment and Upadhye would have offered only a "real world" spin on that testimony. Id.

4. Exclusion of Plaintiffs' Proposed Rebuttal Evidence

The plaintiffs next seek reversal on the ground that the district court's exclusion of their "rebuttal" evidence was error. Not so. "The principal objective of rebuttal is to permit a litigant to counter new, unforeseen facts brought out in the other side's case." Faigin v. Kelly, 184 F.3d 67, 85 (1st Cir. 1999). "[T]he decisions as to what constitutes proper rebuttal evidence . . . lie within the sound discretion of the trial judge and are subject to substantial deference." United States v. LiCausi, 167 F.3d 36, 52 (1st Cir. 1999).

The plaintiffs sought to admit three pieces of evidence, purportedly in an effort to rebut the testimony of two defense witnesses, "that AstraZeneca never 'express[ed] any willingness to agree to any' date other than May 27, 2014." The proposed rebuttal evidence consisted of (1) McGuire's Event Study testimony, which the district court had already rejected as part of the plaintiffs' case in chief; (2) an economic analysis of a no-payment settlement by another expert, Dr. Keith Leffler; and (3) a study published by FTC staff. At oral argument, the plaintiffs insisted that their inability to admit any rebuttal evidence, coupled with other alleged errors of the district court, meant that "all the jury heard was some officers of [the defendants'] company saying they wouldn't do things differently."

Contrary to the plaintiffs' statement, the district court properly refused to admit the plaintiffs' proposed rebuttal evidence, reasoning that it "was hardly true rebuttal testimony because establishing [the date on which the defendants would have agreed to a generic launch but for a reverse payment] was an essential part of the Plaintiffs' prima facie case." Indeed, given the centrality of this date to the entire litigation and especially to the plaintiffs' need to prove an antitrust injury, it was entirely foreseeable that the defendants would assert that the date would not have been earlier than May 27, 2014. It was thus within the district court's discretion to rule that the defendants'

testimony to that effect offered nothing "new" to warrant use of the plaintiffs' proffered evidence as rebuttal. See Faigin, 184 F.3d at 85.

The plaintiffs respond by emphasizing the unique circumstances of this trial. Given that the district court first directed them to focus their case on the Teva reverse payment but radically adjusted its understanding mid-trial to recognize the relevance of the Ranbaxy reverse payment, the plaintiffs argue that the district court was required to give them an opportunity, at rebuttal, "to present evidence relating to the newly revived issue." Alberty-Vélez v. Corporación de Puerto Rico para la Difusión Pública, 242 F.3d 418, 422 (1st Cir. 2001) (quoting Leddy v. Standard Drywall, Inc., 875 F.2d 383, 386 (2d Cir. 1989)). But the record does not support the plaintiffs' contention that the district court did not afford them such an opportunity. Instead, the record portrays the plaintiffs' neglect in seeking to admit relevant testimony after the court course-corrected (with the exception of McGuire's Event Study, which was supportably excluded on Daubert grounds, as discussed above).

The plaintiffs made no effort to seek admission of the FTC study or Leffler's testimony as part of their case in chief, even though they had two days between the district court's epiphany and the end of their case in chief to do so. They offer no explanation on appeal of their failure to seek admission of the

FTC study before resting their case. And while they do explain that they could not call Leffler on short notice because he resided in Seattle, the record does not indicate that the plaintiffs brought this geographical limitation to the district court's attention. In short, the plaintiffs had a window of opportunity to seek admission of the FTC study and Leffler's testimony before resting their case. Given their own failure to do so, we conclude that it was within the district court's discretion to refuse to admit that evidence, which properly belonged in the plaintiffs' case in chief, and not in their rebuttal.

B. Judgment as a Matter of Law on Overarching Conspiracy

The plaintiffs argue that the district court erroneously granted judgment as a matter of law ("JMOL") on the overarching conspiracy claim. They argue that they had proved the existence of contingent launch provisions in the defendants' settlement agreements, that this evidence had sufficed to survive summary judgment, and that thus it necessarily was enough to defeat JMOL. But this reasoning mixes apples and oranges.

We review de novo a district court's decision to grant JMOL. Malone v. Lockheed Martin Corp., 610 F.3d 16, 19 (1st Cir. 2010). An antitrust conspiracy claim under Section 1 of the Sherman Act, 15 U.S.C. § 1, requires evidence of an actual "'agreement[]' -- whether tacit or express." White v. R.M. Packer Co., 635 F.3d 571, 575 (1st Cir. 2011). "[I]ndependent decisions,

even if they lead to the same anticompetitive result as an actual agreement among market actors," are insufficient to sustain a Section 1 conspiracy claim. Id. As a result, mere parallel conduct and "[e]ven 'conscious parallelism,' a common reaction of firms in a concentrated market that recognize their shared economic interests and their interdependence with respect to price and output decisions[,] is not in itself unlawful." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 553–54 (2007) (alterations omitted) (quoting Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 227 (1993)).

The law distinguishes illegal tacit agreements from "mere conscious parallelism" through evidence of "uniform behavior among competitors, preceded by conversations implying that later uniformity might prove desirable or accompanied by other conduct that in context suggests that each competitor failed to make an independent decision." White, 635 F.3d at 576 (emphasis added) (quoting Brown v. Pro Football, Inc., 518 U.S. 231, 241 (1996)); see also Dickson v. Microsoft Corp., 309 F.3d 193, 203 (4th Cir. 2002) (concluding that a "rimless wheel conspiracy" -- in which "various defendants enter into separate agreements with a common defendant, but where the defendants have no connection with one another, other than the common defendant's involvement in each transaction" -- is "not a single, general conspiracy but instead amounts to multiple conspiracies between the common defendant and

each of the other defendants" (citing Kotteakos v. United States, 328 U.S. 750, 755 (1946))).

The plaintiffs point to parallel contingent launch provisions in AstraZeneca's settlements with each generic manufacturer as evidence of the existence of one overarching conspiracy. Under these provisions, the generic manufacturers agreed to delay launching generic Nexium until May 27, 2014, or an earlier date on which AstraZeneca or a court order permitted them to do so. Beyond the provisions, however, the plaintiffs fail to present any evidence that Ranbaxy and Teva agreed to engage in anticompetitive conduct.

Given the dearth of additional evidence, the district court correctly recognized that "[t]here is no sufficient evidence here that Ranbaxy and Teva conspired together, that they acted otherwise than in their own individual best interest." Indeed, some evidence that Ranbaxy and Teva, independent of AstraZeneca, agreed to engage in anticompetitive conduct was critical because self-interest could explain equally well why each might execute a contingent launch provision. After all, as defendant Ranbaxy explains, "[e]ach generic company would have wanted to ensure that no other generic preceded its entry into the market -- and would have sought that assurance by obtaining a contingent launch provision in its settlement agreement." In short, without proving "the existence of a 'rim' to the wheel in the form of an agreement

among" the generic manufacturers, the plaintiffs did not have a viable claim of overarching conspiracy to survive JMOL. United States v. Apple, Inc., 791 F.3d 290, 314 n.15 (2d Cir. 2015).

The three cases that the plaintiffs string cite do not alter our assessment. See United States v. Masonite Corp., 316 U.S. 265 (1942); Interstate Circuit v. United States, 306 U.S. 208 (1939); Toys "R" Us, Inc. v. FTC, 221 F.3d 928 (7th Cir. 2000). The cases do not say, as plaintiffs argue, that interdependent conduct, absent more, suffices to establish overarching conspiracy. Properly read, they in fact reinforce the opposite proposition.

First, contrary to the plaintiffs' argument, Masonite makes no holding on horizontal conspiracy. There, Masonite, a manufacturer of building materials, developed a product called hardboard and obtained patents for both the product and the process for manufacturing it. 316 U.S. at 267–68. When competitors began manufacturing hardboard, Masonite sued each of them for patent infringement, id. at 268–70, but eventually settled each suit on identical terms, including a price-fixing term, id. at 270–73. The Supreme Court upheld the district court's factual findings that each of Masonite's competitors had "acted independently of the others, negotiated only with Masonite, desired the agreement regardless of the action that might be taken by any of the others, did not require as a condition of its acceptance that Masonite

make such an agreement with any of the others, and had no discussions with any of the others." Id. at 275. The Court then held that the individual vertical contracts between Masonite and each competitor violated § 1 of the Sherman Act. Id. That was the extent of Masonite's holding. Indeed, to read Masonite as having found an overarching horizontal conspiracy would be "nonsensical" because "an essential conspiracy element [wa]s missing -- namely, a motive for joint action or interdependence." 6 Areeda & Hovenkamp, Antitrust Law ¶ 1427d (2d ed. 2003).

The second case that the plaintiffs cite, Interstate Circuit, is also of no help to their claim of error. Unlike this case, in which the district court found no evidence to infer any agreement between Ranbaxy and Teva, the Court in Interstate Circuit saw enough circumstantial evidence to find a "tacit agreement" among all defendants. 306 U.S. at 225-27; White, 635 F.3d at 576. There, "a dominant movie theater company sent a letter openly addressed to all eight major national film distributors stating that it would show a distributor's films only if the distributor imposed certain restrictions on later runs of the films in secondary theaters." White, 635 F.3d at 576. "[T]he economic context made it clear that all eight needed to act uniformly or all would lose business, and all eight did in fact impose the conditions." Id. By contrast, here, the district court found

that the plaintiffs had presented insufficient evidence from which to infer even a tacit agreement.

Finally, Toys "R" Us is also inapposite because evidence in that case showed that entering into parallel agreements with Toys "R" Us ("TRU") was against each toy manufacturer's interest unless all of them did so. TRU, "a giant in the toy retailing industry," had executed agreements with various toy manufacturers that TRU would carry the manufacturers' toys only if they promised to curb sales to warehouse club stores like Costco that sold toys at lower prices than did TRU. 221 F.3d at 930. The Seventh Circuit affirmed an FTC finding of a horizontal conspiracy among the toy manufacturers for two reasons. First, "the record . . . included the direct evidence of communications" among the toy manufacturers. Id. at 935. Second, the evidence showed that it was actually against the toy manufacturers' economic interest to curb sales to warehouse clubs unless they all did so:

> The evidence showed that the companies wanted to diversify from TRU, not to become more dependent upon it; it showed that each manufacturer was afraid to curb its sales to the warehouse clubs alone, because it was afraid its rivals would cheat and gain a special advantage in that popular new market niche. . . . [T]he only condition on which each toy manufacturer would agree to TRU's demands was if it could be sure its competitors were doing the same thing.

Id. at 936. The record in this case contains no such evidence.

In Interstate Circuit and Toys "R" Us, there were "plus factors" -- i.e. "additional facts or factors required . . . as a prerequisite to finding that parallel action amounts to a conspiracy." 6 Areeda & Hovenkamp, supra, ¶ 1433e ("Even those courts that say that conscious parallelism is a factor 'to be weighed, and generally to be weighed heavily' in establishing a § 1 violation are usually speaking about fact situations in which there is other evidence of conspiracy." (emphasis added) (footnote omitted)).

The plaintiffs' briefs do not focus on the lack of evidence to prove their claim of overarching conspiracy. Instead, they primarily argue that the district court initially ruled in their favor at summary judgment and that the court should not have reversed itself at the JMOL stage. In so doing, the plaintiffs fail to consider that the summary judgment ruling may have been in error. Nor do they recognize that the JMOL reasoning, not the summary judgment reasoning, has found agreement in at least two other trial courts that have considered the issue. See In re Actos End Payor Antitrust Litig., No. 13-CV-9244(RA), 2015 WL 5610752, at *24 (S.D.N.Y. Sept. 22, 2015); King Drug Co. of Florence, Inc. v. Cephalon, Inc., No. 2:06-CV-1797, 2014 WL 2813312, at *14 (E.D. Pa. June 23, 2014). There was no error.

Finally, the Individual Retailer plaintiffs misrepresent the district court's opinion denying them a new trial. They

contend that after the court recognized its summary judgment ruling as "a bit too sweeping," it nonetheless "reverted to the summary judgment rationale . . . that the evidence was sufficient to support a finding that 'AstraZeneca was the hub of a hub-and-spoke conspiracy.'" Quoted in full, however, the district court actually reaffirmed its JMOL ruling, noting that "[a]t 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." In re Nexium [Post-Trial Opinion], 309 F.R.D. at 115 n.13 (emphasis added). In other words, the court recognized that although the evidence might show one conspiracy between AstraZeneca and Ranbaxy and another disparate conspiracy between AstraZeneca and Teva, the evidence was legally insufficient to tie all three players in an overarching conspiracy. We find no error in the district court's decision to grant JMOL on the overarching conspiracy claim in light of the plaintiffs' inability to cite any supporting evidence other than the parallel contingent launch provisions.

C. Special Verdict Form and Jury Instructions

The final verdict form that went to the jury asked seven questions and was structured so that a "no" answer to any question meant that the jury could stop considering the rest. As relevant here, the first four questions asked:

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

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

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

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?

On appeal, the plaintiffs argue that Question 4 impermissibly "require[d] a specific factual sequence of causation," that it was duplicative of Question 3, that it erroneously posed a "subjective" test about the intent of the defendants, and that its wording was "confusing" and "misled the jury." The defendants respond that all of these objections were either waived or forfeited.

If a party fails to preserve its objections to jury instructions after the jury is charged, those objections are forfeited on appeal and reviewed only for plain error. Booker v. Mass. Dep't of Pub. Health, 612 F.3d 34, 42 (1st Cir. 2010). Plain error, "a hard-to-meet standard," requires the appellant to show "that '(1) an error occurred (2) which was clear or obvious and which not only (3) affected the [appellant's] substantial rights, but also (4) seriously impaired the fairness, integrity, or public reputation of the judicial proceedings.'" Tasker v. DHL Ret.

Savings Plan, 621 F.3d 34, 40–41 (1st Cir. 2010) (alteration in original) (quoting Dávila v. Corp. de P.R. Para La Difusión Pública, 498 F.3d 9, 14–15 (1st Cir. 2007)).

Furthermore, "with respect to special verdicts, 'the law is perfectly clear that parties waive any claim of internal inconsistency by failing to object after the verdict is read and before the jury is discharged.'" Trainor v. HEI Hosp., LLC, 699 F.3d 19, 34 (1st Cir. 2012) (alterations omitted) (quoting Peckham v. Cont'l Cas. Ins. Co., 895 F.2d 830, 836 (1st Cir. 1990)). This has been an "iron-clad rule" in our circuit. Rodriguez-Garcia v. Mun. of Caguas, 495 F.3d 1, 9 (1st Cir. 2007). Although we could altogether decline to hear the plaintiffs' arguments about the verdict form on waiver grounds, the FTC's amicus brief highlights the importance of straightening out the conflation of antitrust violation and antitrust injury that crept into the district court's post-trial opinion and into some of the parties' arguments on appeal. We accept the FTC's invitation to provide greater clarity.

Two of the plaintiffs' four objections seem to arise from this wrongful conflation. The plaintiffs protest that Question 4 was duplicative of Question 3 and that Question 4 held the plaintiffs to an impermissibly stringent causation standard.[5]

[5] In their proposed special jury verdict form, the plaintiffs suggested precisely the same split in questions between antitrust violation and antitrust injury (in the form of a delayed generic entry).

Neither argument holds water, and in fact each shows that the plaintiffs may have obscured the clear law that, as private plaintiffs seeking damages, they must prove not only an antitrust violation but also an antitrust injury that allows recovery of damages.[6]

Private plaintiffs and the FTC as government enforcer stand in different shoes. Under the governing antitrust statutes, the FTC is empowered to directly enforce the substantive antitrust laws. See 15 U.S.C. § 45(a)(2). Meanwhile, private plaintiffs derive their authority to sue from Section 4 or 16 of the Clayton Act and must therefore satisfy the additional evidentiary burdens that those provisions impose. See id. §§ 15, 26. As the FTC's amicus brief aptly explains, "[t]his distinction is rooted in public policy. The interest of private plaintiffs is to remediate an injury they have suffered or may suffer. The interest of the government is to 'prevent and restrain' violations of the antitrust laws along with the attendant social costs such violations can cause."

The Supreme Court has consistently held private plaintiffs to this standard of proving both antitrust violation and antitrust injury. See, e.g., Atl. Richfield Co. v. USA

[6] Because the plaintiffs do not appeal the district court's denial of their post-trial motion for an injunction, they evidently seek a new trial in order to recover damages.

Petroleum Co., 495 U.S. 328, 344 (1990) ("'[P]roof of [an antitrust] violation and of antitrust injury are distinct matters that must be shown independently.' For this reason, . . . the right of action under § 4 of the Clayton Act is available only to those private plaintiffs who have suffered antitrust injury." (quoting Areeda & Hovenkamp, Antitrust Law ¶ 334.2c (1989 Supp.))). A private plaintiff seeking monetary relief must show actual, quantifiable damages "by reason of" the antitrust violation. Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 543 (1983); see also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977) (defining "antitrust injury" as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful").

Assessed under this framework, Questions 3 and 4 are neither duplicative nor both aimed at causation. Rather, the former asks the jury about antitrust violation, while the latter asks about antitrust injury. The jury's "yes" answers to Questions 2 and 3 (large and unjustified payment with anticompetitive effects) confirm its finding that some antitrust violation resulted from the AstraZeneca-Ranbaxy settlement. Question 4, by contrast, inquires whether these private plaintiffs have suffered an "injury of the type the antitrust laws were intended to prevent" by asking whether Ranbaxy (in partnership with Teva) would have

launched a generic earlier than May 27, 2014 but for the antitrust violation found in Question 3. Brunswick, 429 U.S. at 489. The "no" answer to Question 4 thus confirms the jury's finding that notwithstanding the existence of an antitrust violation, the plaintiffs failed to establish an antitrust injury that entitled them to monetary relief.

As Questions 3 and 4 played discrete and independently necessary roles in adjudicating an antitrust suit brought by private plaintiffs, we reject the plaintiffs' protests that the questions led to an "absurd" outcome. There was nothing absurd in the jury verdict. In fact, this circuit has reached similar conclusions in past antitrust cases. See, e.g., Ocean State Physicians Health Plan, Inc. v. Blue Cross & Blue Shield of R.I., 883 F.2d 1101, 1105 (1st Cir. 1989) (observing that district court granted a renewed motion for JMOL in defendant's favor in part because "the jury's award of 'no damages' on the antitrust claim meant that plaintiffs had failed to prove that they had been injured by any illegal conduct by [the defendant]").

The plaintiffs next object that Question 4 erroneously used the defendants' names and framed the relevant inquiry as a subjective, rather than an objective, test. The record refutes this argument. After the plaintiffs initially raised these concerns at the December 2, 2014 conference, the court clarified to the jury that "the test here is an objective test. In other

words[,] I use the names 'AstraZeneca' and 'Ranbaxy' because those are the folks we're talking about here, but the test is not what they did." The plaintiffs failed to renew their objections following these instructions. Examining Question 4 in the context of the verdict form and jury instructions "as a whole," Johnson v. Teamsters Local 559, 102 F.3d 21, 28 (1st Cir. 1996), we conclude that the use of defendants' names did not constitute reversible error.

The plaintiffs lastly argue that Question 4 was confusingly worded and capable of multiple "legally erroneous" interpretations. This objection suffers from the same defect as the others in that it was not preserved during the post-charge sidebar. The forfeited argument is unable to withstand plain error review, especially when examined in the context of the comprehensive instructions that the court provided to facilitate the jury's understanding of the verdict form. First, the plaintiffs' suggestion that the jury could have interpreted Question 4 to be asking "whether AstraZeneca would allow Ranbaxy to get Ranbaxy's product to market" is meritless in light of the court's jury charge:

> The plaintiffs' claim is not that Ranbaxy would have launched, no evidence of that, their claim is that had AstraZeneca not made a large payment to Ranbaxy, they would have settled with a date for generic entry before May 27th, 2014. . . . And that Teva then would have obtained the same or

> earlier date . . . or that . . . Teva would have made a deal with Ranbaxy allowing Teva to launch.

Likewise, the plaintiffs' concern that Question 4 imprecisely used the phrase "anticompetitive settlement," rather than "large and unjustified payment," is alleviated by jury instructions explaining how the presence of a large and unjustified payment in a paragraph IV litigation settlement renders that settlement anticompetitive.

Perhaps the verdict form was inartfully phrased. But in the context of the thorough jury instructions and the plaintiffs' own failure to preserve objections, the plaintiffs cannot argue that any phrasing imperfection "seriously impaired the fairness, integrity, or public reputation of the judicial proceedings." Tasker, 621 F.3d at 41 (quoting Dávila, 498 F.3d at 14–15).

D. Summary Judgment

We finally arrive at the core of the plaintiffs' appeal. The plaintiffs argue that they had but one antitrust causation theory at trial: "In this regulatory climate, generics will get to market in some way, and we can't know exactly how." The district court erred, they say, in prematurely cutting off at summary judgment many causal mechanisms through which they could have proved this theory to a jury. The defendants respond in three ways: (1) the plaintiffs' theory of antitrust causation is actually a hodgepodge of disparate theories, none of which independently

proves causation, (2) later events at trial moot any potential summary judgment error, and (3) the summary judgment ruling was correct on its merits.

Even accepting dubitante the level of generality at which the plaintiffs characterize their causation theory, we agree with the defendants that any error at summary judgment was rendered harmless by the jury verdict and by later trial proceedings on the issue of patent invalidity. We are satisfied that the evidence in support of even those causal mechanisms purportedly excluded at summary judgment was in fact put before the jury, as that evidence was relevant under other concededly admitted theories. The district court recognized the relevance of that evidence and generously admitted much of it notwithstanding the summary judgment ruling (which it later reversed).

Plaintiffs identify four causal theories they say were cut off at summary judgment. First, Ranbaxy could have launched its generic Nexium at risk before February 2009. Second, Teva could have won a final, nonappealable judgment in its paragraph IV suit against AstraZeneca, thereby forcing Ranbaxy to launch its generic within 75 days or forfeit its exclusivity, which would have allowed Teva to launch before May 2014. Third, Ranbaxy could have negotiated an earlier license date with AstraZeneca and launched (either alone or in partnership with Teva) before May 2014. Finally, Ranbaxy could have negotiated an earlier license

date with AstraZeneca and then forfeited its first-filer exclusivity, which would have allowed another manufacturer like Teva to launch before May 2014.

Ordinarily, "[w]e review the merits of the entry of partial summary judgment de novo." Vélez v. Awning Windows, Inc., 375 F.3d 35, 41 (1st Cir. 2004). But we have refused to "reenter th[e] morass" of summary judgment where it was "perfectly clear that, even if [a plaintiff's claim] should not have been dismissed on partial summary judgment, any such mistake was harmless, given the jury's verdict in [the defendant's] favor on [other claims] addressed to the very same [factual circumstances]." Fite v. Dig. Equip. Corp., 232 F.3d 3, 6 (1st Cir. 2000). We have so held in the antitrust context. See Fraser v. Major League Soccer, LLC, 284 F.3d 47, 60-61 (1st Cir. 2002).

An examination of the four supposedly foreclosed causal mechanisms, in light of later events at trial, reveals that the outcome would have been in the defendants' favor even had the mechanisms been explicitly put in questions to the jury. In particular, the first two mechanisms were mooted by the district court's grant of JMOL on any theory involving the invalidity of AstraZeneca's patents. Indeed, the argument that Ranbaxy would have incurred the risk of launching at risk or that Teva would have won its paragraph IV suit against AstraZeneca depends on the theory that AstraZeneca's Nexium patents were invalid or not

infringed by a generic version. The district court's JMOL ruling, however, found "no adequate evidence that any of [the Nexium] patents would be adjudicated invalid." Accordingly, even if the district court had allowed the plaintiffs to present these two causal mechanisms at trial, the court's later judgment would have yielded the same outcome in favor of the defendants.

Plaintiffs respond that they should not have to prove patent invalidity or noninfringement to be able to present their at-risk launch causation theory. They principally rely on two circuit cases to advance this argument, but to no avail. See In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001). Both of these cases were decided before the Supreme Court's Actavis decision, which may call into question aspects of their analyses. Even assuming that the two decisions survive Actavis, they are still inapposite to our inquiry because both cases evaluated allegations of antitrust injury at the Rule 12(b)(6) stage. See In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 765 n.46 (E.D. Pa. 2015), appeal pending, No. 15-3559 (3d Cir.). In In re Cardizem, for instance, the Sixth Circuit held that the defendants' argument -- that their decision to stay out of the generic market was motivated not by a reverse payment, but rather by a fear of damages resulting from patent infringement litigation -- "merely raise[d] a disputed issue of fact that [could

not] be resolved on a motion to dismiss." 332 F.3d at 900. The Cardizem court did not altogether reject the potential relevance of patent invalidity or noninfringement evidence in evaluating the viability of an antitrust-injury theory based on an at-risk launch. So too in Andrx, 256 F.3d at 805, and United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052, 1074 (N.D. Cal. 2014), yet another case that the plaintiffs cite.[7]

In re Wellbutrin XL, a post-Actavis decision at the summary judgment stage, is persuasive. 133 F. Supp. 3d 734. There, the district court granted summary judgment to the defendants, who were producers and distributors of a branded antidepressant drug, on the plaintiffs' at-risk theory of antitrust injury because the plaintiffs proffered no evidence of patent invalidity or noninfringement. Id. at 764–67. The court acknowledged that, if shown, "[t]he existence of a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently precludes competition apart from any agreement and an 'at risk' launch is unlawful absent

[7] In fact, the district court in Teikoku expressly distinguished In re Nexium, describing it as "a case where the generic manufacturer moved for summary judgment, and offered unrebutted evidence 'that an at risk launch was "unlikely" and "extremely risky."'" 74 F. Supp. 3d at 1074. In contrast, Teikoku dealt with "a motion to dismiss and defendants cite[d] to no comparable evidence that [wa]s properly before the [c]ourt at th[at] juncture." Id.

a later finding of patent invalidity or non-infringement." Id. at 764 (citation and alterations omitted).

But there, as here, the plaintiffs did not present such evidence that the brand-name's patents would have been declared invalid or that an at-risk launch would not have infringed the patents. And without such evidence, the "patent served as an independent regulatory bar to [a generic's] launch." Id. at 767. So too here. Upon the conclusion of the plaintiffs' case in chief, the district court saw no evidence that would allow the plaintiffs to overcome the likelihood that AstraZeneca's patents, not its reverse payment to Ranbaxy, were the bar to a generic launch. The district court thus did not err by requiring some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory.

Furthermore, the district court's ruling on patent invalidity did not prejudice the plaintiffs, for two reasons. First, the plaintiffs are simply wrong to insist that the district court decided and ruled out of the case the issue of patent invalidity at summary judgment. In fact, the plaintiffs acknowledged the availability of that line of reasoning -- and their strategic choice not to pursue it -- at a conference on the second day of trial: "We don't plan on proving a patent case inside of an antitrust case. . . . [W]e do not plan to be proving that Teva would have won the [paragraph IV] litigation." The plaintiffs

then reaffirmed their strategic choice on November 20, 2014, at the same conference during which they opposed the defendants' motion for a mistrial. At that conference, they assented to the court's characterization of their position as not having "proved that the patents would have been declared invalid, and [arguing] that that plays no role in this [trial]."

The district court's statements during trial likewise reveal its consistent understanding that the summary judgment ruling did not prevent the plaintiffs from offering patent invalidity evidence if they chose to do so. For instance, in its initial instructions to the jury at the beginning of trial, the district court explained that the plaintiffs would have to "convince [the jury] . . . that Teva entered into its deal with AstraZeneca, staying out of the market, letting AstraZeneca charge its supracompetitive prices for its branded Nexium product, and if it hadn't done that, it could . . . have defeated the patent, AstraZeneca's patents," received FDA approval, and partnered with Ranbaxy to jointly launch a generic. The district court's view of the impact of its summary judgment ruling on patent invalidity did not change by the end of trial. At the December 2, 2014 charge conference, it reminded the plaintiffs: "I think that you will find, when you look at the record, I've never prevented the patent evidence[;] I've said you have to lay an adequate foundation for it." Because the ruling on patent invalidity did not take place

until after the plaintiffs' case in chief, at the JMOL stage, the timing of the ruling could not have foreclosed any evidence that the plaintiffs wished to put forth at trial. Any decision to limit evidence on patent invalidity was a voluntary and strategic choice on the plaintiffs' part.

Second, even after the JMOL ruling, the district court was careful to point out, and correctly so, that its decision did not foreclose the plaintiffs from making any arguments based on AstraZeneca's assessment of risk to its patent monopoly. That is, the court recognized that regardless of the absolute validity or invalidity of patents, business players make reverse payment decisions in an environment in which that validity has not yet been adjudicated. They take into account the risk of litigation and the possibility that patents may be adjudicated invalid or uninfringed. The court explained this distinction between patent invalidity and assessment of risk to the jury: "I went into the case thinking . . . that one of the things the plaintiffs had to prove was that Teva would have won its patent case against AstraZeneca. And I've come to think now that legally that's not key, that's not what the plaintiffs have to prove." In sum, while the JMOL ruling on patent invalidity mooted the causal mechanisms based on at-risk launch and Teva's ability to win a paragraph IV litigation against AstraZeneca, the JMOL ruling did not prejudice the plaintiffs' argument that the defendants had incentives to

violate antitrust laws. Indeed, the jury verdict confirms this lack of prejudice, as it found that AstraZeneca made a large and unjustified payment to Ranbaxy and that their settlement agreement had unreasonably anticompetitive effects.

As for the next two causal mechanisms claimed to have been cut off at summary judgment, the jury's "no" answer to Question 4 renders any error harmless. That answer reflected the jury's finding that AstraZeneca would not have agreed to settlement terms with a license date earlier than May 27, 2014, the date on which two of its medical patents expired. In light of that finding, it made no difference to the outcome of the trial whether the plaintiffs were able to present their theory that Ranbaxy could have negotiated an earlier license date with AstraZeneca and themselves launched or allowed Teva to launch before May 2014.

The plaintiffs respond that the jury had insufficient evidence upon which to answer Question 4 differently. At oral argument, the plaintiffs emphasized that their inability to introduce evidence on the possibility of a Ranbaxy or Teva at-risk launch,[8] or of Ranbaxy's forfeiture of its first-filer status, had meant that the jury had had no information on what "would have

[8] Of course, as we have now repeated numerous times, the plaintiffs voluntarily chose not to pursue the causal mechanism involving Teva's at-risk launch after the district court informed them that such an argument would trigger jury instructions about their need to prove patent invalidity.

motivated AstraZeneca to accept an earlier entry date." In other words, the plaintiffs argue that without evidence on at-risk launch or forfeiture, the jury could not appreciate the threat that Ranbaxy posed to AstraZeneca or the incentive that AstraZeneca had to cut a deal with an earlier entry date.

However, the jury answered "yes" to Questions 2 and 3 in the plaintiffs' favor, despite the supposed exclusion of such evidence. Indeed, this exact evidence -- about Ranbaxy's potential adverse impact on AstraZeneca's bottom line -- must have, and did, come in because the jury in fact found that AstraZeneca felt enough of a threat to offer a large and unjustified payment to Ranbaxy (Question 2) and offer settlement terms in violation of the antitrust laws (Question 3). The plaintiffs fail to explain what other evidence, unique to Question 4, the district court impermissibly excluded to impede the jury's ability to answer that question. To elaborate, while the plaintiffs recycle their grievances about the exclusion of Leffler's and McGuire's testimony on the Event Study, possible but-for entry dates, the purpose and effect of AstraZeneca's side deals with Ranbaxy, and the value of the reverse payment to Ranbaxy, we have already found above that all of this evidence was properly excluded. Ultimately, the jury had sufficient evidence to answer "yes" to Question 4, as well as Questions 2 and 3. Because the plaintiffs cannot point to improperly excluded evidence specific to Question 4, we cannot

accept their argument on the insufficiency of the evidence underlying the jury verdict.

In light of the jury verdict and other events at trial that mooted any summary judgment error, we find no occasion to readjudicate the merits of the district court's pretrial decision. The plaintiffs are not entitled to set aside the jury verdict.

V. CONCLUSION

In any litigation, each party must make "tactical choices" about what pretrial motions to file, what evidence to present, and what objections to renew or forfeit. This case was no different. And despite doubts that the district court harbored about the merits of the plaintiffs' causation theory even before trial commenced, the plaintiffs were able to present their arguments to an attentive jury over six weeks. They were represented by able counsel in every step of the proceeding. Having had that opportunity but having failed to convince the jury that an antitrust injury occurred, the plaintiffs cannot now rehash summary judgment and JMOL rulings, scattered evidentiary decisions, and unpreserved objections to the verdict form in search of a do-over.

We affirm.