**Nos. 15-2005 & 15-2006**

# United States Court of Appeals
## For the First Circuit

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

IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

*On Appeal from the United States District Court*
*for the District of Massachusetts*

Case No. 12-md-02409-WGY

## CONSOLIDATED REPLY BRIEF OF DIRECT PURCHASER AND END-PAYOR CLASS PLAINTIFFS-APPELLANTS

Thomas M. Sobol
Kristen A. Johnson
James J. Nicklaus
Kristie A. LaSalle
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Tel: (617) 482-3700

Bruce E. Gerstein
Joseph Opper
Elena K. Chan
GARWIN GERSTEIN & FISHER, LLP
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055

David F. Sorensen
Ellen Noteware
Daniel C. Simons
Caitlin G. Coslett
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel: (215) 875-3000

*Counsel for Direct Purchaser Class Plaintiffs-Appellants*

Steve D. Shadowen
HILLIARD SHADOWEN LLP
919 Congress Avenue, Suite #1325
Austin, TX 78701
Tel: (512) 993-3078

Kenneth A. Wexler
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Tel: (312) 346-2222

Matthew Wessler
GUPTA WESSLER PLLC
1735 20th Street, NW
Washington, DC 20009
Tel: (202) 888-1741

*Counsel for End-Payor Class Plaintiffs-Appellants*

** Parties and additional counsel listed within*

No. 15-2005

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.

Plaintiffs-Appellants

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 PHARMACY, INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARITEN INSURANCE COMPANY; EMPHESYS INSURANCE COMPANY; HUMANA BENEFIT PLAN OF ILLINOIS, INC.; HUMANA INSURANCE COMPANY; HUMANA HEALTH INSURANCE COMPANY OF FLORIDA, INC.; HUMANA INSURANCE OF PUERTO RICO, INC.; HUMANA INSURANCE OF KENTUCKY; ARCADIAN HEALTH PLAN, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.; ARCADIAN HEALTH PLAN OF LOUISIANA, INC.; ARCADIAN HEALTH PLAN OF NORTH CAROLINA, INC.; CAREPLUS HEALTH PLANS, INC.; CARITEN HEALTH PLAN INC.; CHA HMO, INC.; HUMANA EMPLOYERS HEALTH PLAN OF GEORGIA, INC.; HUMANA ADVANTAGECARE PLAN; HUMANA HEALTH BENEFIT PLAN OF LOUISIANA, INC.; HUMANA HEALTH COMPANY OF NEW YORK, INC.; HUMANA HEALTH PLAN, INC.; HUMANA HEALTH PLAN OF CALIFORNIA, INC.; HUMANA HEALTH PLAN OF OHIO, INC.; HUMANA HEALTH PLAN OF TEXAS, INC.; HUMANA HEALTH PLANS OF PUERTO RICO, INC.; HUMANA MEDICAL PLAN, INC.; HUMANA MEDICAL PLAN OF MICHIGAN, INC.; HUMANA MEDICAL PLAN OF UTAH, INC.; HUMANA REGIONAL HEALTH PLAN, INC.; HUMANA WISCONSIN HEALTH ORGANIZATION INSURANCE CORPORATION; M.D. CARE INC.; LABORERS INTERNATIONAL UNION OF NORTH

AMERICA LOCAL 345 HEALTH CARE FUND, on behalf of itself and all others similarly situated

Plaintiffs

v.

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

Defendants-Appellees

DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Defendants

---

No. 15-2006

IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

---

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

Plaintiffs - Appellants

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.; 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 PHARMACY, INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARITEN HEALTH PLAN INC.; CARITEN INSURANCE COMPANY; ARCADIAN HEALTH PLAN, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.;

ARCADIAN HEALTH PLAN OF LOUISIANA, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.; CAREPLUS HEALTH PLANS, INC.; EMPHESYS INSURANCE COMPANY; HUMANA BENEFIT PLAN OF ILLINOIS, INC.; CHA HMO, INC.; HUMANA INSURANCE COMPANY; HUMANA HEALTH INSURANCE COMPANY OF FLORIDA, INC.; HUMANA INSURANCE OF PUERTO RICO, INC.; HUMANA INSURANCE COMPANY OF KENTUCKY; HUMANA EMPLOYERS HEALTH PLAN OF GEORGIA, INC.; HUMANA ADVANTAGECARE PLAN; HUMANA HEALTH BENEFIT PLAN OF LOUISIANA, INC.; HUMANA HEALTH COMPANY OF NEW YORK, INC.; HUMANA HEALTH PLAN, INC.; HUMANA HEALTH PLAN OF CALIFORNIA, INC.; HUMANA HEALTH PLAN OF OHIO, INC.; HUMANA HEALTH PLAN OF TEXAS, INC.; HUMANA HEALTH PLANS OF PUERTO RICO, INC.; HUMANA MEDICAL PLAN, INC.; HUMANA MEDICAL PLAN OF MICHIGAN, INC.; HUMANA MEDICAL PLAN OF UTAH, INC.; HUMANA REGIONAL HEALTH PLAN, INC.; HUMANA WISCONSIN HEALTH ORGANIZATION INSURANCE CORPORATION; M.D. CARE INC.; HUMANA INSURANCE COMPANY OF NEW YORK; ARCADIAN HEALTH PLAN OF NORTH CAROLINA, INC; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 345 HEALTH CARE FUND, on behalf of itself and all others similarly situated

Plaintiffs

v.

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

Defendants-Appellees

TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES, LTD.

Defendants

---

No. 15-2007

IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

---

WALGREEN CO.; 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

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; FRATERNAL ORDER OF POLICE MIAMI LODGE 20 INSURANCE TRUST FUND; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOCIATION 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; A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN; AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; BURLINGTON DRUG COMPANY INC.; MEIJER DISTRIBUTION, INC.; MEIJER, INC.; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and others similarly situated; VALUE DRUG COMPANY; AMERISOURCEBERGEN DRUG CORPORATION; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 345 HEALTH CARE FUND; CARITEN INSURANCE COMPANY; EMPHESYS INSURANCE COMPANY; HUMANA BENEFIT PLAN OF ILLINOIS, INC.; HUMANA INSURANCE COMPANY; HUMANA HEALTH INSURANCE COMPANY OF FLORIDA, INC.; HUMANA INSURANCE OF PUERTO RICO, INC.; HUMANA INSURANCE COMPANY OF KENTUCKY; ARCADIAN HEALTH PLAN, INC.; ARCADIAN HEALTH PLAN OF GEORGIA, INC.; ARCADIAN HEALTH PLAN OF LOUISIANA, INC.; ARCADIAN HEALTH PLAN OF NORTH CAROLINA, INC.; CAREPLUS HEALTH PLANS, INC.; CARITEN HEALTH PLAN INC.; CHA HMO, INC.; HUMANA EMPLOYERS HEALTH PLAN OF GEORGIA, INC.; HUMANA ADVANTAGECARE PLAN; HUMANA HEALTH BENEFIT PLAN OF LOUISIANA, INC.; HUMANA HEALTH COMPANY OF NEW YORK, INC.; HUMANA HEALTH PLAN, INC.; HUMANA HEALTH PLAN OF CALIFORNIA, INC.; HUMANA HEALTH PLAN OF OHIO, INC.; HUMANA HEALTH PLAN OF TEXAS, INC.; HUMANA HEALTH PLANS OF PUERTO RICO, INC.; HUMANA MEDICAL PLAN, INC.; HUMANA MEDICAL PLAN OF MICHIGAN, INC.; HUMANA MEDICAL PLAN OF UTAH, INC.; HUMANA REGIONAL HEALTH PLAN, INC.; HUMANA WISCONSIN HEALTH ORGANIZATION INSURANCE CORPORATION; M.D. CARE INC.

Plaintiffs

v.

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

Defendants-Appellees

TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES, LTD.

Defendants

## TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Page(s)**

## Cases

**Statutes**



**Other Authorities**

# I. INTRODUCTION

This is the first reverse payment antitrust case to be tried to a jury after the Supreme Court's landmark decision in *FTC v. Actavis, Inc.*[1] More will follow. Our opening brief demonstrated that the district court – despite an earnest, roll-up-the-sleeves effort to preside over a complex trial in a cutting edge area – committed serious errors of law that infected the case's DNA from inception.

The appeal pivots on cause-in-fact. Despite the uncontroversial rule that antitrust causation should be left to the jury, at summary judgment the district court threw out broad areas of proof of delayed generic entry. At trial, laboring under what it later conceded was a "fundamental misconception," the court excluded the kind of evidence that is the hallmark of antitrust cause-in-fact – objective economic evidence of how a competitive market would have yielded earlier generic entry. And the instructions on law should have taught the jury to build on its finding that the defendants committed anticompetitive acts to estimate when generic Nexium would have been available earlier under objective, competitive conditions. Instead, the verdict form reduced antitrust cause-in-fact to a one-sided swearing contest – if the wrongdoers' executives *say* they would not have done things differently, the case is over.

The defendants offer no persuasive response. Errors occurred, they say, but "no trial is perfect," especially one as "lengthy and complex as this one." In

[1] 133 S. Ct. 2223 (2013).

their view, this Court should overlook the problems because they are merely "quotidian and fact-bound" mistakes that always occur in the hustle of trial.

That view is wrong. At each stage, the court misapprehended fundamental principles of antitrust cause-in-fact. And the court's application of causation law to the facts – where the rubber really hits the road – makes bad law and worse policy.

Accepting the defendants' invitation to overlook these infirmities and affirm the judgment not only sanctions a proceeding that went off the rails, but also invites other courts to repeat the same errors. This Court should not endorse the district court's view of how antitrust trials adjudicate the impact of anticompetitive actions on real world results. The judgment should be vacated and a new trial ordered.

## II. ARGUMENT

### A. Errors at summary judgment precluding evidence of cause-in-fact require reversal.

The purchasers came to summary judgment loaded for bear. We could prove that AstraZeneca's 2008 reverse payment to Ranbaxy was worth *over $600 million* and delayed generic competition for *six years*, until May 2014. Precisely *how* earlier entry would have occurred absent the huge payment could not be known with certainty because the defendants' anticompetitive agreement intervened. That is a conundrum in every antitrust case. Recognizing that certainty is impossible in proving but-for entry scenarios, courts generally allow evidence that is plausible. Here, voluminous evidence, economic analysis, and industry realities showed there were a number of plausible avenues by which, had AstraZeneca not made its enormous payment, generic entry would have occurred before May 2014. But at summary judgment, the district court confused uncertainty with speculation and gutted all but one narrow approach to causation, forcing the purchasers into a Rube Goldberg presentation that fundamentally misshaped the entire case.

The defendants relegate to the back of their briefs their responses to the district court's summary judgment errors. But those rulings unleashed a cascade

of causation-related errors that doomed the entire case – it was, the court later admitted, when it "lost its way."[2]

### 1. The district court applied an erroneous standard of proof to antitrust cause-in-fact.

#### a. Cause-in-fact is highly fact dependent.

Causation "is normally grist for the jury's mill."[3] While in rare cases a court can find evidence of cause-in-fact wanting, to "warrant withdrawal of the issue from the jury, the evidence and the inferences reasonably extractable therefrom . . . must be such as to permit thoughtful fact-finders to reach but one reasoned conclusion."[4]

The defendants do not dispute this, though they try to avoid the principle, citing an assortment of unhelpful, non-antitrust cases.[5] But three of this Court's antitrust decisions show how the standard for proof of cause-in-fact applies to determine whether, absent anticompetitive conduct, market conditions would have made a plaintiff better off.

The first two grew out of the Sullivan family's dispute with the NFL. In *Sullivan v. NFL* (*Sullivan II*),[6] William ("Billy") Sullivan, then-owner of the

---

[2] ADD-190 (Aug. 7, 2013 Am. Mem. & Order New Trial ("New Trial Mem.")).

[3] *Peckham v. Cont'l Cas. Ins. Co.*, 895 F.2d 830, 837 (1st Cir. 1990).

[4] *Id.*

[5] AstraZeneca Br. 58-59; Ranbaxy Br. 71-73.

[6] 34 F.3d 1091 (1st Cir. 1994).

Patriots (*before* its Super Bowl glory days), claimed the league's policy disallowing public sale of ownership stock prevented him from selling a minority interest in the Patriots to pay his debts.[7] This Court canvassed the evidence – including Sullivan's expert's opinion, economic evidence, and an analogy to an earlier stock sale by the fabled Boston Celtics (a different sport, league, time, and owner, and winner of 16 championships)[8] – to examine a hypothetical: could someone in Sullivan's position have sold Patriots stock had the NFL's policy not been in place? This Court held as "a matter of law" that Sullivan's expert "provided enough of a basis . . . to support, in combination with the evidence from other sources, a jury finding" that Sullivan could have sold his Patriots stock if permitted to do so.[9] This Court set aside its "skepticism that Sullivan would have succeeded in his public offering" because it "cannot say that, as a matter of law, the evidence was so overwhelming that no reasonable jury could find that the NFL's policy harmed Sullivan by preventing him from doing something he would otherwise have been able to do."[10]

William's son Charles, who owned rights to the Patriots' stadium, brought a separate suit, claiming the NFL's stock-sale restriction inhibited refinancing the

---

[7] *Id.* at 1103.

[8] *Id.* at 1102, 1105-06.

[9] *Id.* at 1105.

[10] *Id.* at 1106.

stadium.[11] Despite the tenuous link, on the issue of cause-in-fact this Court found that "Sullivan alleged, and presented evidence, of a causal connection between the application of the NFL Rule and [his] inability to refinance the stadium because the sale of Patriots' stock to the public was prohibited."[12]

The last of this trio is *RSA Media, Inc., v. Media Group, Inc.*,[13] a case of paltry causation evidence. To prove its antitrust claim against Media Group (a Boston-area billboard company with a large market share), RSA had to prove that, were it not for the complained-of conduct, it could construct and operate new outdoor advertising billboards despite enormous local resistance.[14] The only specific evidence RSA cited was a single prior variance, and its president "admitted that it was impossible to assess the likelihood of receiving a variance . . . ."[15]

---

[11] *Sullivan v. Tagliabue* (*Sullivan I*), 25 F.3d 43, 47-48 (1st Cir. 1994).

[12] *Id.* at 47. Charles ultimately lost his case on grounds not relevant here. *Id.* at 51-52 (discussing standing and remote damages issues).

[13] 260 F.3d 10 (1st Cir. 2001).

[14] *Id.* at 14.

[15] *Id.* Ranbaxy cites two unavailing sufficiency-of-the-evidence cases. *See Advo, Inc. v. Phila. Newspapers*, 51 F.3d 1191, 1198 (3d Cir. 1995) ("theoretical speculation" insufficient); *Virgin Atl. Airways Ltd. v. British Airways PLC*, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999) (subjective testimony by two executives insufficient).

These cases teach that cause-in-fact is not demanding: it requires only some evidence of "a causal connection between the illegal practice and the injury."[16] Even if a court has some misgivings, so long as some evidence is presented to show the anticompetitive conduct caused some injury, causation is for a jury.

The defendants do not apply this standard, but instead defend the district court's rulings by arguing the facts. But that just demonstrates the court employed a standard far stricter than that applied in *Sullivan I* and *II*.

**b. Antitrust cause-in-fact may be established by cumulative proof.**

An antitrust plaintiff "need not exhaust all possible alternative sources of injury" in establishing causation.[17] A plaintiff need only show that some set of events "– *or a cumulation of them* – makes it more likely than not" that the violation caused injury.[18] No "specific sequence of events" is required.[19] So long as there is a causal link between the defendant's violation and the injury, it is "beside the point" that "no one can assign exact probabilities" to each event.[20]

---

[16] *Sullivan II*, 34 F.3d at 1103.

[17] *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969).

[18] *Davis v. United States*, 670 F.3d 48, 53 (1st Cir. 2012) (emphasis added).

[19] *Id.* at 53.

[20] *Id.* at 54.

AstraZeneca concedes this principle.[21] Ranbaxy apparently does too,[22] though it then challenges it by citing irrelevant cases about standards for federal antitrust standing and intervening acts.[23] Neither defendant challenges the fact, so fundamental to understanding causation here, that in the pharmaceutical industry the inexorable economic push for earlier generic availability may occur through multiple paths. And while they address these multiple paths as discrete possibilities, the defendants do not dispute that generic pathways are interdependent alternatives, where the absence of one may increase the likelihood of another.

The district court's insistence of proof of "only one theory" simply disregarded regulatory realities the parties themselves did not dispute.[24]

---

[21] AstraZeneca Br. 61 (conceding a plaintiff "may prove that a series of events, as opposed to one isolated act, caused it harm").

[22] Ranbaxy Br. 72 (describing the "uncontroversial proposition that multiple events, or a series of events, can cause injury in the same way a single event can").

[23] *Id.* at 71-72 (citing *Blue Shield of Va. v. McCready*, 457 U.S. 465 (1982) (antitrust standing) and *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391 (7th Cir. 1993) (intervening acts)).

[24] *Verizon Comm'cns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-12 (2004) (antitrust analysis must reflect "the distinctive economic and legal setting of the regulatory industry to which it applies," especially "a regulatory structure designed to deter and remedy anticompetitive harm").

### 2. The district court erroneously precluded proof that the patent barriers would be overcome earlier.

The evidence showed multiple ways generic companies could overcome patent risks and obtain earlier FDA approval. The court rejected most, leaving only one meandering scenario for trial.

#### a. The court incorrectly precluded evidence of a payment-free AstraZeneca-Ranbaxy settlement.

A fundamental observation of *Actavis* is that payment-laden settlements yield later agreed entry dates, while payment-free settlements are practical and likely yield earlier entry dates.[25]

The district court got this wrong. At summary judgment, it mistakenly thought the AstraZeneca-Ranbaxy agreement could "not be the source of antitrust damages" and dismissed any theory of cause-in-fact that flowed from AstraZeneca's $600 million payment to Ranbaxy.

Everyone agrees – that was error. AstraZeneca, though, downplays this as a "shift" unrelated to causation that "only affected which payment plaintiffs had to prove was large and unjustified."[26] But there is no "only" about this. Rather than have front and center AstraZeneca's $600 million payment to Ranbaxy, which caused a markedly later agreed entry date, the court focused the trial and the jury on the secondary payment to Teva, which occurred later in time *and* was

[25] 133 S. Ct. at 2234-35, 2237.

[26] AstraZeneca Br. 68.

magnitudes smaller in size. At trial, Ranbaxy saw the court's late-trial turnabout as so prejudicial it moved for a mistrial; now it argues that decision does not warrant a new trial.

On the sixteenth day of trial, the court conceded its "fairly fundamental misconception."[27] But despite the (apparent) realization, it continued to exclude evidence of the impact of the $600 million payment to Ranbaxy.[28] The defendants point to no corrective action by the court. The "fundamental misconception" led to fundamental prejudice.

**b. The court incorrectly precluded evidence of Ranbaxy at-risk entry.**

The summary judgment order also precluded evidence at trial of the prospect that, absent the AstraZeneca-Ranbaxy reverse payment settlement, a reasonable generic in Ranbaxy's shoes would have launched generic Nexium at risk well before 2014.[29] The district court impermissibly weighed – and discounted – evidence showing that Ranbaxy, AstraZeneca, and Teva all contemplated Ranbaxy's likely at-risk launch.[30]

---

[27] JA-5491 (Nov. 18 Trial Tr.).

[28] JA-5890-91 (Nov. 20 Trial Tr.); ADD-212 (New Trial Mem.).

[29] ADD-100-02 (Sept. 4, 2014 Mem. & Order Summ. J. ("Sept. 4. Mem.")).

[30] ADD-72 (Sept. 4. Mem.); JA-2348 (Class Pls.' Opp'n Ranbaxy SoF, Resp. No. 7 n.12); JA-2044-49 (Class Pls.' L.R. 56.1 Resp. Defs.' SoF re Ranbaxy Settlement ¶¶ 67-78); JA-2068 (Class Pls.' Opp'n Teva SoF Causation ¶ 2 & nn.4-5); JA-2304-07 (Teva Forecast). Two experts backed the likelihood of a

(*Continued*)

The defendants present no excuse for this classic summary judgment error; instead, they adopt the district court's spin on subjective evidence of Ranbaxy's at-risk entry. They treat Ranbaxy's self-serving arguments as undisputed and unimpeachable fact and declare the issue settled, ignoring substantial contrary evidence the purchasers presented at summary judgment.[31]

**c. The court incorrectly precluded evidence of a Teva at-risk entry.**

Overwhelming summary judgment evidence showed a rational company in Teva's shoes would have launched at risk as well.[32] Teva frequently launched generics at risk,[33] often collaborating with other companies (including Ranbaxy).[34] Teva's summary judgment motion never contested – and therefore

---

Ranbaxy at-risk launch. SA-2464, 2475 (Blume Report ¶¶ 67, 101); JA-2412, 2418-21 (Upadhye Report ¶¶ 49, 81-92).

[31] AstraZeneca Br. 72; Ranbaxy Br. 77-79.

[32] JA-2081-82 (Class Pls.' Opp'n Teva SoF Causation ¶ 18 & nn.36-39); JA-2068 (*id.* ¶ 2 & nn.4-5); JA-2150-51 (Blume Report ¶¶ 99-100 & nn.179-84) (launch partnerships); JA-2158 (*id.* ¶ 122) (launch incentives); JA-2160-61 (*id.* ¶¶ 131-34) (Teva at-risk launch); JA-2212-13 (Blume Rebuttal ¶ 34 & nn.95-99) (launch partnerships); JA-2420-21 (Upadhye Report ¶¶ 89-92) (launch partnership).

[33] JA-2081-82 (Class Pls.' Opp'n Teva SoF Causation ¶ 18 & n.38); *see* JA-2068 (*id.* ¶ 2 & nn.4-5) ("Teva's preconspiracy planning documents all stated, or necessarily implied, that Teva would launch, 'at risk.'"); *see also* JA-5576 (Nov. 18 Trial Tr.); JA-5883 (Nov. 20 Trial Tr.).

[34] JA-2081 (Class Pls.' Opp'n Teva SoF Causation ¶ 18 & nn.35-36) (describing evidence of Teva at-risk launch alone or in partnership with Ranbaxy); *see also, e.g.*, JA-5571 (Nov. 18 Trial Tr.) (discussing Teva and Ranbaxy's joint at-risk launch of generic Accupril).

the purchasers never addressed – this causation path.[35] The summary judgment order and later memorandum made no mention of it. Yet the court later declared the purchasers had "only one theory" – which did not include a potential at-risk entry by Teva (on its own or with Ranbaxy).[36]

Despite the pretrial limitations, some evidence of at-risk entry by a rational generic company in Teva's position sporadically dribbled into the trial. But after the evidence went in, the court later decided it would "charge [at-risk launch] out of the case."[37] This was error.

The defendants do not challenge the adequacy of the purchasers' evidence. Nor did the court. The defendants instead argue that an at-risk launch would have been "illegal" because AstraZeneca's patents had not yet been declared invalid or non-infringed.[38] But antitrust injury may flow from aborted at-risk launches;[39] there is nothing "illegal" about such launches.[40]

---

[35] JA-645 (Teva Defs.' Mem. Supp. Mot. Summ. J. Causation).

[36] JA-2994 (Sept. 30, 2014 Final Pretrial Conf. Tr.); *see also* JA-2997 (*id.*) ("Stuff that is not relevant to that theory, I'm excluding, because I've decided it on summary judgment.").

[37] JA-6902 (Dec. 2 Trial Tr.).

[38] Ranbaxy Br. 74-75; AstraZeneca Br. 40-41.

[39] *See, e.g.*, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 911 (6th Cir. 2003) (noting "a trier of fact may well find" the brand's "payment renders incredible the defendants' claim that [the generic] would have refrained from marketing [during the litigation] simply because of its fear of infringement damages"); *Andrx Pharms. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (reversing because a reasonable juror could conclude that, but for a reverse

(*Continued*)

The Hatch-Waxman Act does not foreclose at-risk entry – it only forestalls it for 30 months, after which the brand company must obtain an injunction to stop generic entry.[41] Here, AstraZeneca never attempted to show it would have obtained such an injunction.[42] The mere existence of patents under litigation does not prevent a launch – as *Actavis* recognizes, such a patent "may or may not

---

payment, the generic would have launched at risk); *see also King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 309 F.R.D. 195, 201 (E.D. Pa. 2015) (certifying a class where "but-for [reverse] payments, the Generic Defendants would have launched generic Provigil at risk"); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma U.S.A., Inc.*, 74 F. Supp. 3d 1052, 1074 (N.D. Cal. 2014) (antitrust injury from an aborted at-risk launch is cognizable); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 756 (E.D. Pa. 2014) (a showing that generics planned to launch at risk can show antitrust injury); *In re Lipitor Antitrust Litig.*, No. 12-cv-2389, 2013 WL 4780496, at *24 (D.N.J. Sept. 5, 2013) (same); *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 534-35 (D.N.J. 2004) (same); *Biovail Corp. Int'l. v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 767-68 (D.N.J. 1999) (same).

[40] Purchasers' Br. 123-24; *see, e.g., Anesta AG v. Mylan Pharms., Inc.*, No. 08-cv-889, 2014 WL 3976456, at *2 (D. Del. Aug. 14, 2014) ("[A]lthough their launch was at risk, it was not illegal when it took place.").

[41] *See, e.g., Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666, 672, 684 (D.N.J. 2007) (denying brand's motion for an injunction).

[42] *See Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 526 (Fed. Cir. 2012) (to prove likelihood of success, patentee must prove validity and infringement are "more likely than not"); *Young v. Memorial Hermann Hosp. Sys.*, 573 F.3d 223, 236 (5th Cir. 2009) ("[M]ore likely than not" means "it is more probable, i.e., more than 50% likely"). AstraZeneca could not enjoin an August 2015 at-risk launch of generic Nexium by Mylan, *see* Mem. Op., *AstraZeneca AB v. Mylan Labs. Ltd.*, No. 12-cv-01387 (D.N.J. July 31, 2015), ECF No. 214 (denying motion for preliminary injunction), or even obtain an injunction pending appeal, *see* Order, *AstraZeneca AB v. Mylan Labs. Ltd.*, No. 15-1889 (Fed. Cir. Aug. 3, 2015), ECF No. 16.

be valid, and may or may not be infringed."[43] The defendants' "illegality" argument seeks to resurrect the old "scope-of-the-patent" test jettisoned by *Actavis*.

None of the defendants' citations salvage their argument. *In re Canadian Import Antitrust Litigation*[44] involved conduct (importation of Canadian drugs) indisputably prohibited by federal law,[45] and in *RSA*, this Court did not find erecting billboards illegal as a matter of law, but rather unproven as a matter of fact.[46]

---

[43] *Actavis*, 133 S. Ct. at 2231; *see also King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.* (*Lamictal*), 791 F.3d 388, 401 (3d Cir. 2015) (*Actavis* contemplated antitrust liability "notwithstanding the possible validity or infringement of the patent in question" (citing *Actavis*, 133 S. Ct. at 2233)); *id.* at 403 (explaining actual invalidity is immaterial (citing *Actavis*, 133 S. Ct. at 2236-27)); Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046c2 (4th ed. 2013 & Supp. 2015) ("Under *Actavis*, purchasers seeking antitrust overcharge damages from an anticompetitive pay-for-delay settlement should be able to proceed without proving patent invalidity.").

[44] 470 F.3d 785 (8th Cir. 2006).

[45] *Id.* at 791. The same is true of *Access Telecom, Inc. v. MCI Telecommunications Corp.*, 197 F.3d 694, 712-13 (5th Cir. 1999).

[46] 260 F.3d at 15. The same is true for *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998), where a difficult regulatory regime, along with the plaintiff's anemic evidence, foreclosed proof of injury, and *CBC Cos. v. Equifax, Inc.*, 561 F.3d 569, 573 (6th Cir. 2009), where "the federal regulations [were] the more likely basis for any putative injury." None of the defendants' citations comes close to the broad proposition they urge – a proposition that would directly conflict with *Actavis*.

### d. The court incorrectly precluded evidence of a generic victory in the patent litigation.

During discovery, the purchasers amassed considerable evidence to show the generics, more likely than not, would have won the patent litigation, and done so well before May 2014. AstraZeneca had previously discovered and marketed the active enantiomer under the brand name Prilosec, so the Nexium enantiomer patent was nothing new.[47] At a minimum, the validity of the patents was hotly contested in the infringement litigation by more than a dozen expert witnesses.[48] AstraZeneca's multiple challenges in proving infringement of the patents demonstrated its likely inability to ever do so.[49]

---

[47] EX-1600, 1602 (Trial Ex. 138, July 19, 2007 Ranbaxy Letter). This exhibit was part of the summary judgment record. JA-2392 (Gerstein Decl. Opp'n Summ. J. ¶ 66).

[48] *Compare* JA-2938-44 (Pls.' Summ. Evid.) *with* JA-2962-64 (AstraZeneca's Summ. Evid.).

[49] AstraZeneca could not have proved infringement of the crystalline esomeprazole salt patents because the generic products did not contain the specific trihydrate claimed by these patents, JA-2939-40 (Pls.' Summ. Evid.); *see also* SA-323-24, 338-39 (Sunstein Report), or of the enteric coating formulation patent because the generics' products did not contain hydroxypropyl cellulose, *see, e.g.*, EX-1603 (Trial Ex. 138, July 19, 2007 Ranbaxy Letter); *see also* SA-325-28 (Sunstein Report). The process patent was likely invalid for anticipation or obviousness. JA-2940 (Pls.' Summ. Evid.); JA-7396, 7418-20 (Burgess Report ¶¶ 17, 92-101); *see also* SA-331-34 (Sunstein Report). And in any event, generic companies could have designed around the patent. JA-7396, 7421-24 (Burgess Report ¶¶ 18, 102-11); JA-7519-21 (Burgess Rebuttal ¶¶ 131-37); *see also* SA-334 (Sunstein Report). AstraZeneca's own expert conceded that generic companies sell generic Nexium worldwide despite this formulation patent. JA-6288-92 (Nov. 21 Trial Tr.).

The patent facts were so well developed during discovery in this case that, at summary judgment, no defendant challenged the sufficiency of the purchasers' evidence that the generics would have won the underlying infringement actions; the parties had a factual dispute on the issue.[50]

But in its summary judgment order, the district court – breaking from its prior Rule 12(b)(6) ruling that the "probability of successful patent invalidity or unenforceability claims" could raise triable factual issues[51] – declared that proof the generics would have won the underlying patent cases would be "sheer speculation, and the Court pays it no mind."[52] The court ruled it "is too speculative *as matter of law* to assume that [a generic] would have prevailed in all its actions and seen those rulings affirmed by the Federal Circuit."[53] But in making these rulings, the court did not have before it the mountain of evidence showing the clear factual disputes on the issue.

---

[50] Purchasers' Br. 80 n.331.

[51] JA-364-65 (Sept. 11, 2013 Mem. & Order Mot. Dismiss).

[52] ADD-144 (Sept. 4, 2014 Mem. & Order Summ. J. ("Sept. 4 Mem.")). The Supreme Court has recognized legal malpractice claims may require a showing of what would have happened in litigation but for the complained-of conduct. *See Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013) ("In cases like this one, in which the attorney's alleged error came in failing to make a particular argument, the causation element requires a "case within a case" analysis of whether, had the argument been made, the outcome of the earlier litigation would have been different.").

[53] ADD-144 (Sept. 4 Mem.) (emphasis added).

The defendants' arguments on appeal are somewhat odd. AstraZeneca argues the only evidence *at trial* predicting a result in the patent litigation was Teva's "confidence" in its position.[54] But that makes no sense. The court precluded the evidence *at summary judgment*; so, at trial, the purchasers could not try to prove that which the court had already precluded as a matter of law. AstraZeneca also claims the jury would have been left adrift in finding *when* AstraZeneca's ultimate loss would have occurred.[55] Not so. A lawyer and former generic-company executive experienced in many Hatch-Waxman cases opined on the time frame,[56] providing factual support for this opinion.[57] That evidence did not come in at trial because the judge excluded it before trial.[58]

Ranbaxy cites the same Federal Circuit reversal rates *of claims construction rulings* that the district court incorrectly relied upon,[59] and an Eleventh Circuit ruling *reversed* in *Actavis*.[60]

---

[54] AstraZeneca Br. 73.

[55] *Id.* at 72-73.

[56] JA-2440-43 (Upadhye Report ¶¶ 155-59).

[57] *Id.*

[58] *See infra* Section B.6.

[59] *See* Ranbaxy Br. 85 (citing ADD-144 (Sept. 4 Mem.)). If general studies elucidate anything, it is that generics prevail in Hatch-Waxman litigation nearly 75% of the time. FTC, *Generic Drug Entry Prior to Patent Expiration* vi (July 2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (reporting 73% success rate from 1992 to 2002); John R. Allison, Mark A. Lemley & David

(*Continued*)

### e. The rulings precluding evidence of how generics address patent issues were prejudicial.

By rejecting evidence that Ranbaxy or Teva could have won their respective patent litigations or launched at risk, the district court foreclosed the jury from considering the logical means by which rational generic makers address patent hurdles. The prejudice is manifest.[61]

Equally prejudicial, however, is that these rulings deprived the jury of compelling evidence as to why a rational brand company in AstraZeneca's shoes would have settled the patent litigation without a large reverse payment, even if it meant accepting an entry date earlier than May 2014. Rather than risk a *complete* loss of its monopoly in litigation, a brand will settle without a payment by using the relative strength of its patent suit to reach a compromise entry date.[62] The court's rulings, however, erroneously deprived the jury of crucial evidence of why a rational company in AstraZeneca's shoes would have accepted

---

L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) (reporting 74% success rate for patent challengers).

[60] Ranbaxy Br. 85 (citing *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012), *rev'd on other grounds sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013)).

[61] *See* Purchasers' Br. 89-97.

[62] *Actavis*, 133 S. Ct. at 2236 ("[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition."). The Court explained drug companies can settle "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 2237.

an earlier entry date had it not paid $600 million to delay its generic competitors' entry.[63]

### 3. The district court erroneously precluded proof that generics would have earlier received FDA approval.

The purchasers sought to prove that generic Nexium could have reached the market because a rational company in Ranbaxy's shoes would have (i) acquired earlier ANDA approval or (ii) relinquished its 180-day exclusivity to allow another company to enter the market (for a fee, of course); or (iii) if not, the FDA would have stripped Ranbaxy of its 180-day exclusivity. At summary judgment, the district court rejected the first and third possibilities and curtailed the second. This caused irreparable prejudice.[64]

#### a. The court incorrectly precluded evidence showing Ranbaxy could get earlier FDA approval.

Substantial evidence showed a company in Ranbaxy's position could have gotten FDA approval earlier if it had tried.[65] And it showed the FDA was not

---

[63] *Cf. Lamictal*, 791 F.3d at 405 ("[W]hen the parties' settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted."); *Niaspan*, 42 F. Supp. 3d at 752 (Supreme Court's conclusion that drug companies can settlement without payments "is premised on the theory that, when bargaining for an early entry date alone, the parties are likely to agree on a date that reasonably approximates each party's relative strength in the infringement litigation.").

[64] Purchasers' Br. 44-54.

[65] Purchasers' Br. 38-40, 91-97; SA-2690-2702 (Class Pls.' Opp'n Ranbaxy Mot. for Summ. J.); SA-2714-16, 2718-22, 2724-31, 2733-34, 2736-39 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 13, 18, 20, 21, 22, 27, 28, 30, 36, 37, and 43).

only willing but motivated to expedite applications to avoid bottlenecking generic entry.[66] But at summary judgment, the district court precluded evidence that a rational actor in Ranbaxy's position could obtain ANDA approval earlier than May 2014.[67] This was error.

The court wrongly rejected *as a matter of law* the analogy to Ranbaxy's Lipitor ANDA.[68] It was undisputed that Ranbaxy had an agreed-upon 2011 entry date for generic Lipitor; and overcame its regulatory difficulties, moved production to the U.S., and got early FDA approval for *that* generic. The purchasers' experts, presenting in painstaking detail the parallels, concluded a company in Ranbaxy's position could have accomplished the same with generic Nexium if it was trying to do so.

In *Sullivan II*, this Court accepted the analogy to the Celtics stock sale to show a Patriots stock sale was realistic.[69] The Lipitor analogy here was far better

---

[66] SA-2571-73, 2575-85, 2587-90 (Bennett Rebuttal ¶¶ 13-15, 20-43, 47-50) (addressing the handling of Ranbaxy's Nexium ANDA under the AIP); SA-3175-80 (Morrison Suppl. Report ¶¶ 13-20) (same).

[67] Purchasers' Br. 49-52.

[68] ADD-104 (Sept. 4 Mem.).

[69] 34 F.3d at 1101; *see also Napier v. F/V Deesie, Inc.*, 454 F.3d 61, 69 (1st Cir. 2006) (reversing summary judgment despite various flaws in the evidence); *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627-33 (E.D. Pa. 2011) (denying summary judgment despite multiple intervening ANDA deficiencies); *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-cv-7343, 2008 WL 4580016, at *5 (S.D.N.Y. Oct. 14, 2008) (denying summary judgment despite evidence of hurdles to FDA approval).

developed, and the purchasers' experts' use of it should not have been rejected as a matter of law.

An antitrust expert has considerable leeway in selecting a benchmark to opine on the consequences of anticompetitive acts.[70] As Judge Rya Zobel recently wrote, evaluating an expert's selected analog "generally involves weighing facts," so "deciding '[w]hether the plaintiff has met this burden of showing comparability ordinarily is a question for the trier of fact,'" and thus "[c]ourts have been reluctant to determine comparability before trial."[71] Once an expert proffers an admissible benchmark, "[i]t is then for the jury to evaluate the reliability of the underlying data, assumptions, and conclusions."[72]

---

[70] *In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 434 (E.D. Pa. 2015) (The "benchmark data need not be perfect but only reasonably similar."); *Cason-Merenda v. Detroit Med. Ctr.*, No. 06-cv-15601, 2013 WL 1721651, at *10 (E.D. Mich. Apr. 22, 2013) (cross-examination at trial is available to identify any benchmark deficiencies); *In re Nw. Airlines Corp. Antitrust Litig.*, 197 F. Supp. 2d 908, 928-29 (E.D. Mich. 2002) (noting benchmarks need only be "somewhat comparable," not "wholly identical," because "certainty generally is unattainable").

[71] *In re Prograf Antitrust Litig.*, No. 11-md-2242, 2014 WL 7641156, at *3 (D. Mass. Dec. 23, 2014) (quoting 1 Am. Bar Ass'n, *Antitrust Law Developments* 786 (7th ed. 2012)).

[72] *In re Urethane Antitrust Litig.*, 768 F.3d 1245, 1263 (10th Cir. 2014); *see also ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, No. 10-cv-248, 2011 WL 11762001, at *3 (E.D. Va. Aug. 3, 2011) (noting it is for the jury to decide if plaintiff's expert used proper benchmarks); *Fleischman v. Albany Med. Ctr.*, 728 F. Supp. 2d 130, 150 (N.D.N.Y. 2010) (accepting expert's benchmarks at summary judgment; "the opportunity to cross-examine [the expert] at *trial*" will "assign the appropriate weight to the expert's opinions" (emphasis added)).

The appellees' defend the court's ruling with a buckshot of sweeping misstatements claiming "no" evidence supports the Lipitor analogy.[73] But these summary statements ignore the record[74] and the evidence described in the purchasers' opening brief.[75]

- The FDA has a policy of granting exceptions to regulatory holds when generic entry dates are imminent.[76] Thus an earlier agreed entry date for Nexium would have accelerated FDA action.[77] Experts are permitted to so testify.[78]

---

[73] AstraZeneca Br. 69; Ranbaxy Br. 79-81.

[74] SA-2491 (Blume Report ¶ 156); SA-2527-29 (Blume Rebuttal ¶¶ 23-25), SA-2579, 2585 (Bennett Rebuttal ¶¶ 29, 42); SA-3154 (Blume Suppl. Report ¶ 19); SA-3175, 3177-78 (Morrison Suppl. Report ¶¶ 13, 19, n.21); SA-2720-22, 2724-31, 2736-39 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 22, 27, 28, 30 & 43); SA-2698-2702 (Class Pls.' Opp'n Ranbaxy Mot. for Summ. J.); SA-2639-40 (Class Pls.' Opp'n AstraZeneca Mot. for Summ. J).

[75] *See* Purchasers' Br. 95-96 & nn.387-88 (collecting evidence explaining and supporting the Lipitor benchmark).

[76] Purchasers' Br. 26 n.86, 39 n.162, & 91-92 nn.371-72; *see* SA-3170-71, 3185-86 (Morrison Suppl. Report ¶¶ 3, 32) (citing CDER Manual, titled *Review Order of Original ANDAs, Amendments and Supplements, and Prioritization of Review of Original ANDAs*); *see also* SA-3177-80 (Morrison Suppl. Report ¶¶ 19-20 & nn.21-22); ADD-222 (New Trial Mem.) (FDA revoked Ranbaxy's exclusivity and approved Teva's generic in January 2015, about when Ranbaxy's exclusivity would have expired had it launched in May 2014).

[77] *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (refusing to dismiss although first filer lacked approval because it was "possible" the defendants' alleged sham litigation was "responsible for the lack of FDA approval"); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000) (non-approval does not defeat causation, if earlier approval "would be meaningless" due to the defendants' conduct).

[78] For example, in *In re Terazosin Hydrochloride Antitrust Litigation*, MDL No. 317, 2005 WL 5955705 (S.D. Fla. Feb. 1, 2005), the court allowed an expert's testimony that the "FDA *would* have" acted "earlier than it actually did" where the

(*Continued*)

- The FDA would have made an exception to Ranbaxy's regulatory hold for generic Nexium, just as it had for generic Lipitor.[79]

- "[I]f Ranbaxy had negotiated an early entry date with AstraZeneca, the consent decree's relinquishment date also would have been correspondingly earlier."[80]

- The FDA's decision to expedite review of the generic Lipitor ANDAs showed why the FDA would have done so for generic Nexium too.[81]

---

expert "simply expect[ed] to opine that [an ANDA filer] would have obtained the exact same outcome in the 'but for' world that it eventually obtained in the real world." *Id.* at *4. Here, the court precluded such testimony by improperly narrowing the purchasers' case.

[79] *See, e.g.*, *supra* notes 74-76; SA-2724-27, 2731 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 27, 30) (detailing lockstep AIP negotiation for all Ranbaxy's "Priority ANDAs" from 2009-2011); SA-3175-80, 3184-86 (Morrison Suppl. Report ¶¶ 13-20, 31-33); JA-2623 (May 11, 2011 FDA Mem.) ("[T]he application subject to the AIP has the potential to significantly delay the approval of *any* ANDA for the drug," which is "inconsistent with both the specific goals of the exclusivity and the broader goals of Hatch-Waxman."). Causation theories have survived summary judgment with far less. *See, e.g.*, *Flonase*, 798 F. Supp. 2d at 631-32 (denying summary judgment even though the plaintiffs' regulatory expert cited no real-world comparators).

[80] ADD-105 (Sept. 4 Mem.); SA-2698-2702 (Class Pls.' Opp'n Ranbaxy Mot. for Summ. J.); SA-2724-31 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 27, 28, 30); SA-2894-97 (Pls.' Mem. Supp. Mot. Recons. Payment-Free Settlement); SA-2462-63 (Blume Report ¶ 64); SA-2591 (Bennett Rebuttal ¶ 54); SA-3184-86 (Morrison Suppl. Report ¶¶ 31-33).

[81] ADD-113 (Sept. 4 Mem.) ("A reasonable jury could infer that the FDA would have been as concerned about the possibility of a regulatory bottleneck for generic Nexium as it was for generic Lipitor."); *see also* SA-2848-51, 2853-62 (Pls.' Mem. Supp. Mot. Recons. New Evid.); SA-2936-38 (Pls.' Reply AstraZeneca Opp'n Mot. Recons. New Evid.); SA-2917-21 (Pls.' Reply Ranbaxy Opp'n Mot. Recons. New Evid.); SA-2894-97 (Pls.' Mem. Supp. Mot. Recons. Payment-Free Settlement); *see also supra* notes 74-76, 79-80.

- The barriers to bringing generic Lipitor to market were no less – and likely greater – than those for generic Nexium, yet Ranbaxy overcame those problems.[82]

- Given "the demonstrated ability of Ranbaxy to manufacture a nearly identical product . . . to generic Nexium as early as 2008," the purchasers met "the summary judgment threshold on the prerequisite question of whether Ranbaxy physically could have manufactured the product at the Ohm plant before 2014."[83]

- The generic Lipitor ANDA encountered the same hurdles the Nexium one did regardless of the different dates the ANDAs were filed,[84] making the analogy all the more compelling.

In the end, the court's preclusion of evidence of Ranbaxy's ability to get earlier FDA approval contradicted other rulings regarding Ranbaxy's manufacturing capability. The court found sufficient evidence that Ranbaxy had the ability to make generic Nexium earlier,[85] but that Ranbaxy "*curtailed its activities* in light of the entry date it had negotiated with AstraZeneca" and

---

[82] SA-2860-62 (Pls.' Mem. Supp. Mot. Recons. New Evid.); SA-2916-17 (Pls.' Reply Ranbaxy Opp'n Mot. Recons. New Evid.).

[83] ADD-96 (Sept. 4. Mem.); *see also* Purchasers' Br. 93-94, 94-95 nn.387 & 388; SA-2724-27, 2731 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 27, 30); SA-2698-2702 (Class Pls.' Opp'n Ranbaxy Mot. for Summ. J.); SA-2859-61 (Pls.' Mem. Supp. Mot. Recons. New Evid.); 2916-2917 (Pls.' Reply Ranbaxy Opp'n Mot. Recons. New Evid.).

[84] Purchasers' Br. 93-95 nn.387-88; SA-2724-27, 2731 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 27, 30); SA-2698-2702 (Class Pls.' Opp'n Ranbaxy Mot. for Summ. J.); SA-2859-61 (Pls.' Mem. Supp. Mot. Recons. New Evid.); 2916-2917 (Pls.' Reply Ranbaxy Opp'n Mot. Recons. New Evid.).

[85] ADD-96 (Sept. 4 Mem.).

otherwise "would have had the will to enter the market sooner" than May 2014.[86] Ranbaxy had "capacity at its Ohm, New Jersey plant to manufacture generic Nexium" and could have "site transfer[red] its production facilities well before 2014."[87] The defendants' insistence the record lacked any evidence supporting the Lipitor analogy conflicts with these findings – which cannot be reconciled with the court's ruling that earlier FDA approval was impossible.

**b. The court incorrectly precluded evidence showing Ranbaxy would earlier monetize its exclusivity.**

When assessing the Ranbaxy agreement, the court rejected evidence that a rational actor in Ranbaxy's position (facing challenges with its own ANDA) might sell (that is, relinquish) its exclusivity to another generic.[88] But when assessing Teva's situation, it concluded the evidence of such a deal was adequate.[89] Before the district court, the defendants recognized the inconsistency as irreconcilable.[90]

Now the defendants call the inconsistency harmless because some proof was admitted at trial of a potential deal between Ranbaxy and Teva.[91] But like other evidence admitted before the court's late-trial shift, the purchasers could

[86] ADD-94-95 (emphasis added).

[87] ADD-95.

[88] Purchasers' Br. 88-89.

[89] *Id.* at 87-88.

[90] *Id.* at 89.

[91] AstraZeneca Br. 68.

only argue that, in the absence of payments to *Teva*, a company in Teva's position would have *purchased* Ranbaxy's exclusivity; they were barred from showing that if *Ranbaxy* had not been paid $600 million, a company in Ranbaxy's position would have *sold* its exclusivity. The result would have been different had the evidence been permitted to answer the degree to which *Ranbaxy* would turn for alternative monetization had it not received a $600 million payoff from AstraZeneca.[92]

**c. The court incorrectly precluded evidence showing Ranbaxy would earlier forfeit its exclusivity.**

If Ranbaxy overcame patent barriers to generic entry, yet failed to get to market, it faced forfeiture of its 180-day exclusivity.[93] At summary judgment, evidence showed different ways such forfeiture might occur, paving the way for other generics to enter.[94]

---

[92] AstraZeneca concedes that the late-trial "shift" "affected which payments plaintiffs had to prove . . . ." AstraZeneca Br. 68.

[93] *See, e.g.*, SA-2727, 2731 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 27, 30); SA-2354-55 (Class Pls.' Opp'n Teva Mot. Summ. J. Causation); SA-2630, 2639 (Class Pls.' Opp'n AstraZeneca Mot. Summ. J. Causation); SA-2698-702 (Class Pls.' Opp'n Ranbaxy Mot. Summ. J.); SA-2853-62 (Pls.' Mem. Supp. Mot. Recons. New Evid.); SA-2917-21 (Pls.' Reply Ranbaxy Opp'n Mot. Recons. New Evid).

[94] *See, e.g.*, SA-2698-702 (Class Pls.' Opp'n Ranbaxy Mot. for Summ. J.); SA-2894-97 (Pls.' Mem. Supp. Mot. Recons. Payment-Free Settlement); SA-2727, 2731 (Class Pls.' Opp'n Ranbaxy SoF, Resp. Nos. 27, 30); SA-2378-79 (Class Pls.' Opp'n Teva SoF Causation, Resp. No. 10).

The district court found the evidence of a potential earlier Ranbaxy forfeiture quite sound.[95] However, the court barred all forfeiture evidence on the ground that, even if forfeiture occurred, it saw no evidence that "*another* generic manufacturer would have timely gathered the technical competency and FDA approval necessary for such a launch."[96] But it needed to look no further than its own finding – *in its own summary judgment decision* – that "a reasonable juror [could] conclude that Teva was well on its way to obtaining tentative approval as early as 2008."[97]

AstraZeneca attempts to smooth over this glaring inconsistency, suggesting the purchasers "failed to show when other generic manufacturers, like Teva, would recognize that Ranbaxy was not going to meet . . . deadline[s]" and speed up their own efforts.[98] But that is not true. The district court found "a reasonable juror [could] conclude that Teva was well on its way to obtaining

---

[95] ADD-105 (Sept. 4 Mem.) ("The Plaintiffs present a sufficient argument" that the consent decree relinquishment date "was chosen with the Ranbaxy Settlement's May 27, 2014, entry date in mind, and that if Ranbaxy had negotiated an early entry date with AstraZeneca," the relinquishment date "would have been correspondingly earlier."); ADD-113 (*id.*) ("A reasonable jury could infer that the FDA would have been as concerned about the possibility of a regulatory bottleneck for generic Nexium as it was for generic Lipitor.").

[96] ADD-106 (Sept. 4 Mem.) (emphasis added).

[97] ADD-141-42 (Sept. 4 Mem.).

[98] AstraZeneca Br. 66-67.

tentative approval as early as 2008,"[99] and Teva itself described its ANDA as "in an approvable state" in mid-2009.[100] Teva closely monitored the status of Ranbaxy's first-to-file products,[101] and its 2008 declaratory judgment action was intended to cause potential forfeiture of Ranbaxy's 180-day exclusivity.[102] Teva monitored Ranbaxy's progress with generic Nexium in light of the AIP, stating "*we can't let this slip by. We need to be there day one . . . .*"[103] And the purchasers' statement of facts collected the evidence that the forfeiture deadline, and Teva's timed entry, would move earlier in time if the agreed entry date did.[104]

In the end, AstraZeneca concedes that whether Teva could have sped up its efforts "was a disputed issue of fact"[105] – so resolving that issue on summary judgment was error.

---

[99] ADD-141-42 (Sept. 4 Mem.).

[100] JA-2110 (Teva Presentation to Ranbaxy/Daiichi).

[101] JA-2170 (Blume Report ¶¶ 163-64).

[102] JA-2071-72 (Class Pls.' Opp'n Teva SoF Causation ¶ 8); *see also* JA-4009 (Oct. 30 Trial Tr.).

[103] JA-2170 (Blume Report ¶ 164) (quoting a Teva executive's email, sent the day after the Consent Decree was published, that Teva had "compiled . . . information regarding . . . potential opportunities if Ranbaxy relinquishes their exclusivity," including Nexium, and Teva's CEO's response).

[104] SA-2378-79 (Class Pls.' Opp'n Teva SoF Causation, Resp. No. 10 n.17) (collecting evidence the forfeiture deadline would move earlier with agreed entry); SA-2381 (*id.* at n.23) (detailing evidence that "Teva prioritizes ANDA projects and launch preparations based on expected entry date").

[105] AstraZeneca Br. 67; ADD-141 (Sept. 4 Mem.).

AstraZeneca also suggests forfeiture was relevant only under a scenario where rational companies in AstraZeneca's and Ranbaxy's positions would have agreed to earlier entry.[106] But earlier forfeiture of Ranbaxy's 180-day exclusivity would have occurred under a scenario where Ranbaxy could not launch within 75 days after prevailing in the patent suit.[107] Earlier forfeiture also followed if Ranbaxy could not launch after Teva prevailed in the patent suit;[108] indeed, before the AstraZeneca-Ranbaxy agreement, Teva intended to litigate its patent challenges to victory, forcing Ranbaxy to launch or forfeit.[109]

The defendants contend any error in dismissing the forfeiture theory was harmless because the jury found Ranbaxy would not have agreed to an earlier date.[110] But the order rejecting the forfeiture theory also prejudiced the purchasers' case in showing how a rational Ranbaxy would have relinquished its 180-day exclusivity (via a partnership) rather than suffering a total forfeiture of that highly valuable asset. This error, like the others the court committed, curtailed the purchasers' causation case and kept critical evidence from the jury.

---

[106] AstraZeneca Br. 67.

[107] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

[108] *Id.*

[109] JA-2071-72 (Class Pls.' Opp'n Teva SoF Causation ¶ 8); *see also* JA-4009 (Oct. 30 Trial Tr.).

[110] AstraZeneca Br. 68.

So the verdict – rendered after so many errors – could not cure the original error.[111]

**B. Errors at trial precluding evidence of cause-in-fact require reversal.**

Through the first 16 days of trial, the district court gave one reason for barring the purchasers from introducing objective economic evidence related to how the payment to Ranbaxy caused injury: "in light of" the court's summary judgment ruling, it was "immaterial" whether, had there not been a payment, Ranbaxy's "date would have been moved up."[112] After realizing its mistake, the court gave another reason for excluding it: that it would be "unfair" to the defendants to allow Dr. McGuire to testify on "the issue of would they have cut a deal," or of the "enormous value of the AstraZeneca-Ranbaxy settlement to AstraZeneca."[113]

Neither AstraZeneca nor Ranbaxy defends the court's reasons for these rulings. That is understandable. The first was based on the court's "fairly

---

[111] *Cf. Shinseki v. Sanders*, 556 U.S. 396, 411-12 (2009) (The factors informing a "'harmless-error' determination" include "an estimation of the likelihood that the result would have been different" and "a consideration of the error's likely effects on the perceived fairness, integrity, or public reputation of judicial proceedings . . . .").

[112] JA-5189 (Nov. 12 Trial Tr.). The defendants focus primarily on Dr. McGuire's event study; but the event study went to damages, which is only indirectly related to cause-in-fact.

[113] JA-5890 (Nov. 20 Trial Tr.).

fundamental misconception" about Ranbaxy causation.[114] The second acknowledged the court had dug itself a hole, and so "in the management of the case [it would be] unfair" to the defendants to admit the obviously "relevant" evidence.[115]

Instead, the defendants argue it was harmless to keep the jury from learning the objective economic circumstances that would have driven rational manufacturers in AstraZeneca's and Ranbaxy's shoes to an earlier entry date. And they do so in a case where the defendants' executives repeatedly testified to their *subjective conjectures* they would not have agreed to earlier entry under any circumstances.[116] Implicit in the defendants' argument is the contention that objective economic evidence is unimportant to cause-in-fact, so we start there.

### 1. Cause-in-fact is a matter of objective economic fact, not self-reported subjective intentions.

Ranbaxy argues that, for antitrust cause-in-fact, this Court prefers "assessments of subjective considerations by the trier of fact" and, therefore, the jury should "consider the hypothetical decisions *of the actual parties* to the case."[117] In Ranbaxy's view, an antitrust trial reduces to a Perry Mason moment when a

---

[114] JA-5491 (Nov. 18 Trial Tr.).

[115] JA-5890 (Nov. 20 Trial Tr.).

[116] *See, e.g.*, JA-3796, 3812-13 (Oct. 28 Trial Tr.); JA-4442-43 (Nov. 4 Trial Tr.); JA-6776-77 (Dec. 1 Trial Tr.); JA-7180-81 (Dec. 3 Trial Tr.).

[117] Ranbaxy Br. 48-49.

defendant's executives either break down and concede, or refuse to concede, that something would have been different but for their unlawful conduct. If the executives stick to their story, there is no liability.

That is not the law.

*United States v. Falstaff Brewing Corp.*[118] shows how objective economic evidence prevails in antitrust law. In determining whether Falstaff would likely enter a market, the question was "not what Falstaff's internal company decisions were but whether, given its financial capabilities and conditions in the New England market, it would be reasonable to consider it a potential entrant into that market."[119] The proper question was whether "*rational* beer merchants in New England [could conclude] that Falstaff might well build a new brewery to supply the northeastern market," so the district court should have "appraised *the economic facts* about Falstaff and the New England market . . . ."[120] Indeed, *Falstaff* emphasized that economic evidence "is the lifeblood of antitrust law," and therefore the most important evidence is the "objective economic facts."[121] The Supreme Court found reversible error in a district court's over-reliance upon executives' self-reported intentions rather than expert and other testimony

---

[118] 410 U.S. 526 (1973).

[119] *Id.* at 533

[120] *Id.* (emphasis added).

[121] *Id.* at 534 n.13

establishing the objective economic circumstances that drive rational manufacturers' actions.[122]

This Court faithfully applies *Falstaff*. In *Sullivan II*, this Court found the evidence of cause-in-fact sufficient not because Sullivan thought he could sell some Patriots stock, but because he introduced objective evidence of market conditions that would have enabled someone in his position to do so.[123] An expert economist testified that a market for Patriots stock existed, and an investment bank had offered an $80 million loan contingent on NFL approval of the stock sale.[124]

*Addamax Corp. v. Open Software Foundation, Inc.*[125] affirmed a district court's finding that the defendants' conduct did not materially cause Addamax's failure in the market. Dispositive were the objective economic facts – Addamax's late market entry; its entry "with a high-priced, overbuilt and uncertified product"; the existence of substantial competitors; and unfavorable "changes in market conditions."[126]

---

[122] *Id.* at 537; *see also id.* at 534 (subjective testimony from company insiders is "not necessarily the last word" on antitrust causation).

[123] 34 F.3d at 1104-05.

[124] *Id.*

[125] 152 F.3d 48, 49 (1st Cir. 1998).

[126] *Id.* at 54.

And in *RSA* this Court found insufficient the plaintiff's subjective testimony that "it was possible for it to obtain a [billboard] permit"; instead, the objective market evidence showed the difficulty of procuring permits and, given those difficulties, the improbability that RSA could break into the billboard market.[127] Ranbaxy's other citations are inapposite.[128]

AstraZeneca takes a less radical position than Ranbaxy; but the question is not whether causation is "purely objective."[129] The question is whether causation is *so purely subjective* that exclusion of all objective economic evidence was harmless. The answer is no.

**2. The court wrongly excluded Dr. McGuire' four central opinions on the effect of AstraZeneca's payment to Ranbaxy on the agreed entry date.**

The district court's exclusion of Dr. McGuire's economic testimony plainly requires reversal. For the first 16 days of trial, the court forbade the purchasers from offering *any* evidence that AstraZeneca paid Ranbaxy $600 million to push back entry and that, without such a payment, rational law-abiding parties in the defendants' position would have reached an earlier agreed entry date. When the

---

[127] 260 F.3d at 14-15.

[128] In *Coastal Fuels, Inc. v. Caribbean Petroleum Corp.*, 175 F.3d 18, 31-32 (1st Cir. 1999), the defendant did not offer any evidence whatsoever to counter the plaintiff's subjective testimony: "Given this failure," this Court affirmed the plaintiff's verdict.

[129] AstraZeneca Br. 34 (citing *Barkan v. Dunkin' Donuts, Inc.*, 627 F.3d 34, 39-40 (1st Cir. 2010) (discussing principles of contract law)).

district court had its late-trial realization about the effect of the payment, the purchasers tried again to counter the defendants' self-serving, subjective claims with Dr. McGuire's expert economic evidence. The court again precluded it.

Dr. McGuire's excluded testimony was built around the Supreme Court's economic insight that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size . . . ."[130] Dr. McGuire would have answered the key cause-in-fact questions: was the payment "just" the relatively-modest side deals, or also the no-AG clause? What did the no-AG clause cost AstraZeneca? If the no-AG clause was very costly to AstraZeneca (as it was), what does that tell us, economically, about a rational brand manufacturer's willingness to have made substantial *lawful* concessions (earlier agreed entry) if the unlawful alternative (the no-AG clause) were unavailable? Dr. McGuire would have answered these key questions as follows:

1. The no-AG clause was a payment from AstraZeneca to Ranbaxy;[131]

2. The cost to AstraZeneca of forgoing an AG was *$600 million*;[132]

3. Absent the payment, rational economic actors would have agreed to entry sometime earlier than May 2014;[133] and

---

[130] *Actavis*, 133 S. Ct. at 2227.

[131] Purchasers' Br. 109-10.

[132] *Id.* at 107.

[133] *Id.* at 106-07.

4. The side deals' purpose was to provide income to Ranbaxy during the delay.[134]

The district court prohibited all of this objective economic evidence because Dr. McGuire would have testified three times,[135] and it would have been "unfair" to the defendants given his prior summary judgment ruling.[136] But the district court itself had chopped up Dr. McGuire's testimony.[137] And its admission would be "unfair" due to the testimony's relevance and power, which are grounds to admit, not exclude, it.

At trial, the purchasers made a written proffer of these four central economic opinions.[138] We explained them in our opening brief.[139]

The defendants only try to justify the exclusion of the fourth of these propositions. The defendants argue that Dr. McGuire was not competent to testify whether the deals reflected fair value for services.[140] But they misunderstand the proffered opinion. (Other evidence showed the side deals were

---

[134] *Id.* at 108.

[135] JA-5890 (Nov. 20 Trial Tr.).

[136] *Id.*

[137] JA-3011-13 (Sept. 30, 2014 Pretrial Conf.); JA-4826-27 (Nov. 7 Trial Tr.).

[138] *See* JA-6044-52 (Pls.' Evid. Proffer).

[139] Purchasers' Br. 105-10.

[140] AstraZeneca Br. 49-50. The defendants are wrong on that issue, too. As an economist, Dr. McGuire was plainly qualified to testify to the services' value, Class Pls.' Opp'n Mot. Exclude McGuire, ECF No. 731, as the district court found – "I find McGuire to be perfectly qualified," JA-2585 (Jan. 21, 2014 Pretrial Conf. Tr.). The defendants do not argue this finding was an abuse of discretion.

at above-market rates).[141] Dr. McGuire's fourth opinion is not that the side deals were valued above market, but that they provided replacement income to Ranbaxy during a waiting period.[142] That opinion, which the defendants do not deny Dr. McGuire was qualified to render, went directly to proving there was a period of delay, compared to what rational parties would have agreed to absent the unlawful payments.

Having not seriously attacked the first four opinions, the defendants present *Daubert* challenges to two of Dr. McGuire's *other* opinions. The court's final verdict form, Questions 3 and 4,[143] both asked (in part) cause-in-fact questions – whether generics would have been available sometime earlier than May 2014. Dr. McGuire's four central opinions were directly relevant to those questions. Question 5 – which the jury never reached – asked for estimation of a specific earlier entry date. The defendants offer justifications only for the exclusion of evidence directed to that point. As to *that* point, Dr. McGuire would have testified:

> 5. A standard "event study" shows that a mutually advantageous entry date would have been January 2011;[144] and

---

[141] *See, e.g.*, JA-6702-08 (Dec. 1 Trial Tr.); EX-1134 (Trial Ex. 103, Authorized Generic Partnership Presentation).

[142] Purchasers' Br. 108.

[143] We later address the legal incorrectness of Question 4. *See infra* Section C.2.

[144] Purchasers' Br. 107-08.

6. Other economic modeling shows a mutually advantageous entry date from December 2008 to September 2010.[145]

The fact remains that the defendants do not address our challenge to the district court's exclusion of Dr. McGuire's central economic opinions that the no-AG clause was a payment costing AstraZeneca $600 million, absent which rational manufacturers would have agreed to generic entry well before May 2014.[146]

### *3.* Judicial estoppel does not preclude review of the erroneous exclusion of Dr. McGuire's testimony.

The defendants do not, as they cannot, argue the purchasers failed to preserve their rights to the court's exclusion of Dr. McGuire's testimony. We sought its introduction repeatedly, made a written proffer, and sought reconsideration, and the court expressly reserved our rights.[147] So instead, the defendants argue the purchasers are judicially estopped from objecting to the improperly excluded testimony and that its improper exclusion was harmless. Those arguments fail.

---

[145] Purchasers' Br. 107.

[146] Because the harm from a reverse payment is generic delay, a no-AG payment may be valued based on its benefit to the generic (because the benefit induces delay). The benefit to a generic is higher than its cost to the brand because an AG lowers all generic prices. But even just focusing on its cost to AstraZeneca, the no-AG payment here was enormous.

[147] JA-5957 (Nov. 20 Trial Tr.); JA-6042-251 (Pls.' Evid. Proffer).

Judicial estoppel does not prevent the purchasers from appealing the erroneous exclusion of this key testimony.[148] The purchasers did not "prevail[] in one phase of a case on an argument and then rely[] on a contradictory argument to prevail in another phase."[149] In opposing Ranbaxy's mistrial motion, we argued that excluding Dr. McGuire prejudiced us and helped the defendants.[150] And in our motion for a new trial, and here on appeal, we consistently argue that excluding Dr. McGuire prejudiced us (and therefore helped the defendants).[151] Our "earlier and later positions" were not "clearly inconsistent."[152]

The defendants suggest the purchasers bargained away the right to complain of the rulings excluding Dr. McGuire's testimony in exchange for the

---

[148] *Contra* AstraZeneca Br. 45.

[149] AstraZeneca Br. 45 (quoting *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001)). The defendants try to shoe-horn their argument into the "judicial estoppel" rubric because the law is clear that a party does not waive arguments for a new trial by having opposed an adverse party's motion for mistrial. *See, e.g.*, *In re Air Crash Disaster*, 86 F.3d 498, 517 (6th Cir. 1996); *Cal. v. Altus Fin. S.A.*, 540 F.3d 992, 1004 n.10 (9th Cir. 2008).

[150] JA-5986-90 (Nov. 20 Afternoon Hr'g Tr.).

[151] Mem. Supp. Class Pls.' Mot. New Trial 23-32, 35-59, ECF No. 1451; Purchasers' Br. 102-10.

[152] *Perry v. Blum*, 629 F.3d 1, 9 (1st Cir. 2010); *see also Healey v. Spencer*, 765 F.3d 65, 76 (1st Cir. 2014) (earlier and later positions must be "mutually exclusive").

court denying Ranbaxy's mistrial motion.[153] We did not. When the mistrial motion was argued, the court had already excluded Dr. McGuire's testimony and our case-in-chief was closed.[154] Our point at the mistrial argument was simply that the court's late-trial realization that Ranbaxy was in the case "in a more direct way," coupled with its ruling excluding Dr. McGuire's Ranbaxy-specific testimony, prejudiced the purchasers, not Ranbaxy.

**4. The erroneous exclusion of Dr. McGuire's testimony was not harmless.**

The defendants cannot establish "with a fair degree of assurance that the erroneous ruling did not substantially sway the jury."[155] The erroneous exclusion of Dr. McGuire's testimony "materially curtailed the [purchasers'] opportunity to present their theory of the case to the jury."[156]

---

[153] The purchasers did *not* argue that excluding Dr. McGuire was a "cure" for any prejudice to the defendants "while" the district court was deciding whether to exclude him, *contra* AstraZeneca Br. 44, and they did *not* "sacrifice further testimony from Dr. McGuire in order to defeat the defendants' mistrial motion," *contra id.* at 45.

[154] The district court excluded Dr. McGuire's testimony at the morning session on November 20, 2014. JA-5889-91 (Nov. 20 Trial Tr.). Purchasers rested two hours later. JA-5958 (*id.*). Purchasers made their "cure" argument during the oral argument on the mistrial motion later that afternoon. JA-5989-90 (Nov. 20 Afternoon Hr'g Tr.).

[155] *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 87 (1st Cir. 1998); *see also Blake v. Pellegrino*, 329 F.3d 43, 49 (1st Cir. 2003).

[156] *Ruiz-Troche*, 161 F.3d at 88.

The district court forbade the purchasers from introducing Dr. McGuire's proffered testimony that the AstraZeneca no-AG promise was a huge payment and that, absent that payment, rational actors in AstraZeneca's and Ranbaxy's shoes would have agreed to earlier entry:

- "I'm not interested, as a matter of law, in whether there was any payment from AstraZeneca to Ranbaxy. I'm not interested in had there not been a payment, Ranbaxy would have done this, that or the other thing . . . ."[157]
- "Now, the business about whether [Ranbaxy's] date would have been moved up to me is immaterial in light of my rulings . . . ."[158]

Expert testimony is essential to establishing antitrust cause-in-fact; appellate courts routinely reverse the improper exclusion of such testimony.[159] And objective economic evidence here would have countered defense executives' subjective statements they would not have agreed to earlier entry absent the no-AG clause.

Nor does the verdict render the error harmless.[160] First, the jury's conclusion (in its answer to Question 2) that AstraZeneca made some large payment to Ranbaxy does not nullify the prejudice from excluding Dr. McGuire's

---

[157] JA-5186 (Nov. 12 Trial Tr.).

[158] JA-5189 (*id.*); *see also* JA-5160 (*id.*) ("I'm not letting McGuire get into payments from Ranbaxy."); JA-5363 (Nov. 13 Trial Tr.).

[159] Purchasers' Br. 103-04.

[160] AstraZeneca Br. 49; Ranbaxy Br. 54 n.4.

testimony that the *no-AG clause* was a payment.[161] It is impossible to know whether the jury found the payment was the no-AG clause – costing AstraZeneca hundreds of millions of dollars – or the side deals – worth only some tens of millions to Ranbaxy. And the size of the payment is a key determinant of how much delay it caused.[162] Nor does the jury's affirmative answer to Question 3 (deciding the Ranbaxy agreement caused some delay) render harmless the exclusion of Dr. McGuire's testimony; the court also posed Question 4 (to which the jury answered "no"), and that question asked specifically whether a payment-free settlement would result in an earlier agreed entry date. Dr. McGuire's excluded testimony directly addressed Question 4.

Second, theoretical opinions that delay in general was valuable to AstraZeneca is no substitute for Dr. McGuire's more specific (but excluded) testimony that the no-AG clause was a payment of sufficient size (worth over $600 million) to cause a delay.[163] That AstraZeneca wanted delay did not negate the need for expert testimony that AstraZeneca used the no-AG clause to accomplish the delay it wanted.

---

[161] *Contra* AstraZeneca Br. 49; Ranbaxy Br. 54-55 n.4.

[162] Purchasers' Br. 74 (citing *Actavis*, 133 S. Ct. at 2237).

[163] *Contra* AstraZeneca Br. 42-43. The district court permitted Dr. McGuire to testify that AstraZeneca had an economic motive to lead the overall conspiracy among all of the generic manufacturer defendants – a claim that is not at issue on this appeal. JA-5378-80, 5405 (Nov. 13 Trial Tr.).

Third, the court's error was not rendered harmless by the purchasers' closing arguments: arguments are not evidence.[164] We argued – without the aid of any expert testimony – that the no-AG clause was a payment, without which rational parties would reach a settlement with an earlier agreed entry date.[165] We relied on a document from Ranbaxy's files about the economic benefit of the no-AG clause to Ranbaxy[166] and a single AstraZeneca document.[167] We had no expert testimony from Dr. McGuire about the *cost* of the no-AG clause to AstraZeneca or how rational parties would have reached an earlier entry date without it.[168] Without that testimony, the jury may not have understood that a no-AG clause is a payment to the generic manufacturer; may have decided AstraZeneca gave up little or nothing by agreeing to the no-AG clause; and may have concluded therefore AstraZeneca and Ranbaxy would not have agreed to an earlier entry date absent the no-AG clause.

On the broader question of whether reverse payments generally cause delay, the purchasers were relegated to extrapolating from Dr. McGuire's earlier

---

[164] *Contra* AstraZeneca Br. 47.

[165] JA-7215-19, 7229-30 (Dec. 3 Trial Tr.).

[166] JA-7215 (Dec. 1 Trial Tr.); EX-2008-174 (Trial Ex. 176, Ranbaxy Spreadsheet).

[167] JA-7211-12 (Dec. 1 Trial Tr.); EX-1609-20 (Trial Ex. 142, Apr. 7, 2008 Scenario Review Presentation).

[168] It is an abuse of discretion to prohibit an expert witness from putting facts in context. *See, e.g.*, *Pagés-Ramírez v. Ramírez-González*, 605 F.3d 109, 115-16 (1st Cir. 2010).

testimony, *i.e.*, that AstraZeneca's payment *to Teva* likely delayed *Teva*'s entry into the market.[169] The district court prohibited Dr. McGuire from applying this general principle to the key AstraZeneca-Ranbaxy agreement. And even the purchasers' closing arguments were neutered by the lack of expert testimony that the no-AG clause was a payment.

In short, the purchasers' "star witness"[170] was prohibited from giving objective economic evidence that: (i) the no-AG pledge was a payment; (ii) the payment was worth $600 million; (iii) absent the payment, rational actors would have agreed to an earlier entry date; and (iv) the side deals provided income to Ranbaxy during the period of delay.[171] Instead, we were left with evidentiary scraps on what turned out to be a specific question on the verdict slip. This prejudice requires reversal.

Finally, Ranbaxy calls the court's evidentiary errors harmless because the purchasers offered "no" evidence of other elements, so no jury could find for the purchasers regardless.[172] Not so. The trial evidence showed Teva's ANDA had

---

[169] JA-4871-72, 4916-17 (Nov. 7 Trial Tr.).

[170] ADD-209 (Sept. 4 Mem.) (court's characterization).

[171] Purchasers' Br. 55-56, 102-03, 109.

[172] Ranbaxy Br. 63-68.

only "minor" deficiencies, and would have been approved by 2009;[173] but Teva changed its "Target Launch Date" to 2014 and put its ANDA "on hold" due to the AstraZeneca-Ranbaxy deal.[174] But if Ranbaxy's entry date had been earlier, Teva's would have been, too.[175] And Ranbaxy faced pressure from all sides to partner with Teva: the FDA was demanding relinquishment,[176] and Teva was pressing litigation to "force Ranbaxy to start marketing" or else "forfeit" exclusivity[177] while pursuing Ranbaxy for a partnership.[178] From this, a jury

---

[173] JA-5528-29 (Nov. 18 Trial Tr.) ("[E]very request" by the FDA was "'minor,'" "easily answered," and "did not require significant effort to address."); JA-5529-31 (*id.*).

[174] *Compare* EX-2181 (Trial Ex. 180, Mar. 26, 2008 Major Milestone Report) (pre-settlement, Teva projects "Early As Launch" as "Apr-09") *with* EX-2192 (Trial Ex. 181, Mar. 27, 2008 Major Milestone Report) (post-settlement, changed to "Nov-14."); *see also* EX-1638 (Trial Ex. 147, May 9, 2008 Email); EX-850 (Trial Ex. 58, Teva Spreadsheet); EX-2203 (Trial Ex. 183, Critical Date List) (post-settlement priority list shows "critical date" of "Nov. 1 2014").

[175] JA-4532-33 (Nov. 5 Trial Tr.) (Teva would not want to be "embarrassed" on the sidelines); JA-4453 (Nov. 4 Trial Tr.) ("Teva needed to be in the market on the first day that it could possibly be" or else in-house counsel "would be fired."); JA-4018-19 (Oct. 30 Trial Tr.) (in-house counsel testifying that getting earliest possible entry date is "why we litigate").

[176] JA-5560 (Nov. 18 Trial Tr.) (Ranbaxy faced "danger of potentially losing their exclusivities if they didn't meet certain hurdles.").

[177] EX-991 (Trial Ex. 67, IVAX Pharms., Inc.'s Opp'n Defs.' Mot. Dismiss, *IVAX Pharms., Inc. v. AstraZeneca AB*, No. 08-cv-2165 (D.N.J.)).

[178] JA-4095-97 (Oct. 30 Trial Tr.) (Teva had "something to offer" Ranbaxy in June 2009: "if Teva's file was in an approvable state earlier than Ranbaxy," they "could potentially do a deal . . . ."); JA-5573-75 (Nov. 18 Trial Tr.) (Ranbaxy and Teva would have partnered because Teva's ANDA "was at approvable status" by 2009).

could conclude that, if Ranbaxy had agreed to an earlier entry date, it would have partnered with Teva (as it had twice before),[179] and, if Ranbaxy rejected a partnership and failed to obtain timely approval, Teva could capitalize on Ranbaxy's forfeiture.[180] The only question left unanswered by this evidence was *when* rational actors in Ranbaxy's and AstraZeneca's shoes would have agreed generic Nexium could enter the market – an answer that could have been provided by Dr. McGuire's excluded testimony.

**5. The court erroneously excluded Dr. McGuire's testimony on a specific agreed entry date.**

The district court also excluded Dr. McGuire's testimony estimating a specific entry date agreeable to rational parties in AstraZeneca's and Ranbaxy's shoes absent the $600 million payoff. Although the jury never reached this issue, the excluded testimony also bore indirectly on cause-in-fact (if the jury could estimate when earlier entry would have been, perforce they would conclude there was some delay). The district court erred in excluding it.

---

[179] JA-4253-54 (Oct. 31 Trial Tr.) (discussing quinapril and generic Lipitor agreements). Ranbaxy's agreement to relinquish to Teva if its Lipitor ANDA lacked approval by November 2011 is strong circumstantial evidence that, with Nexium, Ranbaxy would pursue a similar "hedge strategy." JA-4097-98 (Oct. 30 Trial Tr.) (confirming Lipitor/Nexium parallels); EX-1419 (Trial Ex. 133, Road Map to 2015 Presentation) (Aug. 2009 Ranbaxy plan for "key products" under AIP shows, given Nexium's "2014 launch timing," a "hedge strategy" was "not critical").

[180] EX-2205 (Trial Ex. 184, Jan. 26, 2012 Email) (noting for esomeprazole Teva and others "can launch May 27, 2014 if Ranbaxy does not retain exclusivity").

*The Event Study.* The district court excluded Dr. McGuire's event study because it purportedly lacked "fit": it "would have no bearing on whether Ranbaxy and Teva would have partnered to produce a generic form of Nexium in the absence of the AstraZeneca-Ranbaxy Settlement Agreement."[181] This was error. Under the terms set by the district court's summary judgment and late-trial rulings, the purchasers' evidence of earlier generic entry proceeded in two steps: (i) absent AstraZeneca's payments to Ranbaxy, its entry date would have been earlier than May 2014; and (ii) Teva and Ranbaxy would have partnered to produce generic Nexium at that time. Dr. McGuire's event study related to the *first* step. The district court abused its discretion in precluding the testimony on the ground that it did not *also* relate to the second step.[182]

The defendants do not try to justify the exclusion of the study on the ground the court invoked. Instead, they suggest the court "misspoke" – that when the court excluded the study because there was no "fit between the event study" and when "Ranbaxy and *Teva* would have cut a deal,"[183] the court meant to

[181] ADD-212 (New Trial Mem.); *see also* JA-5889-91 (Nov. 20 Trial Tr.).

[182] *See, e.g.*, *Jaasma v. Shell Oil Co.*, 412 F.3d 501, 514 (3d Cir. 2005) (excluding expert "based on a misunderstanding of the purpose of the expert testimony" is abuse of discretion).

[183] AstraZeneca Br. 47 n.7; JA-5889 (Nov. 20 Trial Tr.).

say the study lacked fit as to when "Ranbaxy and [*AstraZeneca*] would have cut a deal."[184]

Not so. The court later wrote that it precluded the study because it did not relate to "whether Ranbaxy *and Teva* would have partnered to produce a generic form of Nexium in the absence of the AstraZeneca-Ranbaxy Settlement Agreement."[185] The district court did not "misspeak."

Nor could the court have excluded this testimony on the ground the defendants now advance. Dr. McGuire applied basic economic principles to conclude that the one-day, $3 billion increase in AstraZeneca's stock value quantified the value of the delay AstraZeneca purchased from Ranbaxy.[186] Such studies are routinely used in litigation to assess the impact of a noteworthy event on a specific market.[187] The court could not have excluded (and did not exclude)

---

[184] AstraZeneca Br. 47 n.7.

[185] ADD-212 (New Trial Mem.) (emphasis added). The defendants' suggestion that the district court could have precluded the study as untimely is negated by the court's refusal to do so and, more broadly, on the court's well-known practice of allowing, and even encouraging, supplemental expert reports. *See, e.g.*, JA-5396-401 (Nov. 13 Trial Tr.).

[186] JA-6246 (McGuire Suppl. Report ¶ 14); *see* Pls.' Suppl. Trial Br. Supp. McGuire Event Study 2-3, ECF No. 1254.

[187] Pls.' Suppl. Trial Br. Supp. McGuire Event Study 4-5, ECF No. 1254.

the study merely because Dr. McGuire applied basic economic tools to the particular task of calculating the delay in a pay-for-delay deal.[188]

*The Alternative Specific Entry Date.* The purchasers preserved for appeal the exclusion of Dr. McGuire's alternative specific entry dates of December 2008 to September 2010.[189] Our written proffer advised that Dr. McGuire would testify to "expected dates of generic entry," attaching and citing his report "at ¶ 3,"[190] which opines that "[a] range of launch dates that would have been reached in a competitive negotiation free of a reverse payment is December, 2008 to September, 2010."[191]

The defendants assert that Dr. McGuire's opinion on these entry dates was "inadmissible under *Daubert*" because it relied on factual predicates that purportedly lack record support – namely, that the patents that expired post-May 2014 had no "practical ability" to prevent Ranbaxy's entry, and that the

---

[188] *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 151 (1999) ("It might not be surprising is a particular case . . . that a claim made by a scientific witness has never been the subject of peer review, for the particular application at issue may never previously have interested any scientist."); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 246 (5th Cir. 2002) (abuse of discretion to exclude testimony merely because expert was studying a novel issue).

[189] *Contra* AstraZeneca Br. 48; Ranbaxy Br. 54.

[190] JA-6044 (Pls.' Evid. Proffer).

[191] JA-6060 (Frank & McGuire Report ¶ 3). Dr. McGuire's event study did not "replace[]" his original opinion regarding specific dates (*contra* AstraZeneca Br. 48); they presented alternative, and entirely consistent, methods of estimating the payment-free entry date.

negotiators knew that the other patents were "highly likely" to be found invalid.[192] But the defendants never moved to exclude this opinion on that basis before or during trial.[193] And evidence showed AstraZeneca never even tried to keep generic manufacturers out of the market after May 2014.[194] Dr. McGuire's own testimony would have shown that AstraZeneca paid Ranbaxy double the profits Ranbaxy would have made had it won the patent case[195] – a payment of a size that patentees make "[o]nly when the patent is very weak."[196]

**6. Exclusion of Mr. Upadhye's testimony was improper, not waived, and not harmless.**

At the January 21, 2014 pretrial conference, the district court definitively excluded Mr. Upadhye from testifying at trial: "these two lawyers, Shashank Upadhye and John Thomas, *they won't testify.* They're lawyers, not economists," so "they do not have the requisite qualifications to testify. So, we're not going to hear from either one of them. *That is the Court's finding.*"[197]

---

[192] AstraZeneca Br. 48.

[193] *See* Defs.' Objs. Further Expert Testimony McGuire, ECF No. 1225; Defs.' Obj. Pls.' Recall Dr. McGuire, ECF No. 1236.

[194] *See, e.g.*, JA-3586-87 (Oct. 27 Trial Tr.); JA-4301-02 (Oct. 31 Trial Tr.); JA-4343 (Nov. 4 Trial Tr.).

[195] JA-6126 (Frank & McGuire Report ¶ 166).

[196] JA-6130 (*id.* ¶ 180); *see also* JA-6106-08 (*id.* ¶¶ 114, 118).

[197] ADD-4 (Jan. 21, 2014 Pretrial Conf. Tr.) (emphasis added); *see also* ADD-1 (Feb. 7, 2014 Elec. Clerk's Notes) ("The Court announces" that "the lawyer[] Updahye [sic] . . . will not testify.").

AstraZeneca asserts that the district court excluded Upadhye "without prejudice,"[198] citing a ruling nine months after the January conference later involving motions *in limine* on evidentiary issues unrelated to Mr. Upadhye.[199] The district court's order excluding Mr. Upadhye was "unconditional"; the purchasers were not required to renew their objection at trial.[200]

The defendants do not attempt to defend the district court's ruling on its own terms – nor could they. The purchasers did not offer Mr. Upadhye as an economic expert, so his lack of economics qualifications was immaterial.

The defendants instead fault Mr. Upadhye for relying on his experience rather than a structured methodology.[201] But Mr. Upadhye was not offering a scientific or technical opinion susceptible to a step-wise methodology. Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[202] announce a "flexible" test for the admissibility of expert testimony. *Daubert*'s factors (including whether the expert used a reliable methodology) are not a "definitive

---

[198] AstraZeneca Br. 53.

[199] *Id.* (citing JA-3057-58 (Oct. 20, 2014 Charge Conf. Tr.)). The district court marched through the various motions *in limine* to which it was referring; none related to Mr. Upadhye's exclusion. JA-3057-73 (Oct. 20, 2014 Charge Conf. Tr.).

[200] *Fusco v. Gen. Motors Corp.*, 11 F.3d 259, 262-63 (1st Cir. 1993); Fed. R. Evid. 103; Fed. R. Evid. 103 advisory committee's note to 2000 amendment.

[201] AstraZeneca Br. 53.

[202] 509 U.S. 579 (1993).

checklist";[203] a court assessing non-scientific expert testimony should "consider the specific factors in *Daubert*" only if they are "reasonable measures of the reliability" of a particular expert's testimony.[204] With non-scientific and non-technical expertise, "the relevant reliability concerns may focus upon *personal knowledge* or *experience*,"[205] because the other "*Daubert* factors (peer review, publication, potential error rate, etc.) are not applicable to this kind of testimony, whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it."[206] Where an expert opines on negotiation or settlement of disputes, courts assess reliability based on the expert's experience, not adherence to a structured methodology.[207]

The error was prejudicial. Without Mr. Upadhye's testimony, the jury was left with only the defendants' executives' subjective testimony. The jury was entitled to hear about the practice of settling Hatch-Waxman cases and how the

[203] *Id.* at 593.

[204] *See Kumho Tire*, 526 U.S. at 152.

[205] *Id.* at 150 (emphasis added).

[206] *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000).

[207] *See, e.g., Binghamton-Johnson City Joint Sewage Bd. v. Am. Alternative Ins. Corp.*, No. 12-cv-553, 2015 WL 5023650, at *5 (N.D.N.Y. Aug. 25, 2015) (permitting expert to "assist[] the jury" in understanding, *inter alia*, "the general standard practices and customs of the insurance business" and "how this particular policy is structured and how its provisions relate to each other" "*based on his training and experience*" (emphasis added)); *Sullivan v. Am. Int'l Grp., Inc.*, No. 07-cv-254 , 2008 WL 2876534, at *4 (E.D. Ky. July 22, 2008) (permitting expert testimony based on "experience conducting settlement and mediation conferences").

highly complicated terms in the AstraZeneca-Ranbaxy agreement functioned to protect Ranbaxy during the six years of negotiated delay.

### C. Errors in the instructions of law and verdict form regarding cause-in-fact require reversal.

The district court's last-minute change to the special verdict form, coupled with flawed instructions on cause-in-fact, converted a victory for the purchasers into a verdict for the defendants. By answering "yes" to Question 3, the jury found that the agreement between AstraZeneca and Ranbaxy delayed entry for generic Nexium. But the court then asked the jury to answer another, subjectively-worded causation question – for which the district court itself supplied the answer. The district court's confusing and legally flawed instructions and verdict form were the last chapter in its cause-in-fact mistakes. They provide independent grounds for reversal.

#### 1. The answer to Question 3 satisfied cause-in-fact because the jury concluded the reverse payment caused some delay of generic Nexium.

Our opening brief explained that the jury's answering "yes" to Question 3 can mean only one thing – it found that AstraZeneca's reverse payment to Ranbaxy "caused some 'unreasonable' delay of the entry of generic Nexium."[208]

That finding satisfies cause-in-fact under the Clayton Act. This Court explained in *Sullivan II* that, to establish causation, an antitrust plaintiff must

[208] Purchasers' Br. 120.

prove that "there is a causal connection between the illegal practice and the injury."[209] A finding that the AstraZeneca-Ranbaxy reverse payment (the illegal practice) caused at least some delay (the purchasers' injury) meets that standard. Question 3 asked the jury the relevant question – was there some delay in generic entry from the reverse payment? The jury concluded there was.

In response, the defendants first contend the jury's answer to Question 3 says "nothing" about causation.[210] They argue the issue of whether "proof [shows] an agreement is anticompetitive" is analytically separate from injury; to them, showing a reverse payment agreement is anticompetitive does not necessarily establish that any "delay of generic entry" occurred.[211]

But the district court's actual instructions (which control for this case) disprove this interpretation of the "yes" answer to Question 3. When charging on the question, the court explained the jury "*must determine*" that "the restraints challenged here, the alleged payment *and the delay of entry* of generic [Nexium] . . . into the market are unreasonable."[212] The court continued, telling

---

[209] 34 F.3d at 1103.

[210] AstraZeneca Br. 30.

[211] *Id.* (quoting FTC *Amicus* Br. 8-9).

[212] JA-7126 (Dec. 3 Trial Tr.) (emphases added).

the jury that to answer "yes" it "must determine" the purchasers "*ha[d] proven* the challenged restraint has harmed competition."[213]

So that charge required more than a conclusion the reverse payment prevented a "*risk* of competition."[214] The court instructed the jury that it must find the purchasers had "proven" that both the reverse payment settlement *and* "the delay of entry of generic Nexium" were "unreasonable" in order to conclude the agreement "harmed competition." Because the "the nature and extent of the unlawful conspiracy must be ascertained in the light of the instructions given to the jury,"[215] the jury could only answer "yes" to Question 3 if it concluded that the purchasers had, in fact, proven that the settlement caused an unreasonable delay of entry.

Any doubt that Question 3's reference to "anticompetitive effects" meant delay – and only delay – is erased by the court's clarification during deliberations. The jury asked the court to "further define, explain, 'unreasonably anticompetitive,' 'anticompetitive effects,' and 'procompetitive justifications.'"[216] Once again, the court told the jury that, to answer "yes" to Question 3, it must find that the defendants' reverse payment agreement delayed entry of generic

---

[213] *Id.* (emphasis added).

[214] AstraZeneca Br. 30.

[215] *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 254-55 (1946).

[216] JA-7539 (Dec. 4 Trial Tr.).

Nexium. The district court offered only one definition of "anticompetitive effect" ("conduct that moves the license date of the AstraZeneca-Ranbaxy license further into the future is an anticompetitive effect"), and gave the jury only one reason why that conduct could be anticompetitive ("it prevents . . . Ranbaxy, and perhaps people backing up Ranbaxy . . . from entering the market").[217] The district court offered only one example of an anticompetitive effect – delay. And a jury is not only "presumed to follow its instructions" but also presumed to "understand a judge's answer to its question."[218]

Beyond the court's actual charge here – which, remarkably, neither defendant opts to explain at all – the FTC's brief confirms that Question 3 required a finding of "causation of injury-in-fact."[219] The defendants selectively quote the FTC's brief,[220] but ignore the FTC's core point: the only rational interpretation of Question 3 is that it combines the "existence of an antitrust violation, which requires a general showing of harm to the competitive process," with the requirement that a plaintiff prove "it suffered an injury-in-fact caused by

---

[217] JA-7541 (*id.*). The court further tied the instruction to delay, explaining that "[a]nything" making the "licensed entry date earlier in time has a procompetitive effect because if a generic could enter the market, the evidence is pretty clear that the price structure of the market would change and people could buy a lower cost generic." *Id.*

[218] *Weeks v. Angelone*, 528 U.S. 225, 234 (2000).

[219] FTC *Amicus* Br. 2 n.1.

[220] *See, e.g.*, AstraZeneca Br. 30.

the violation."[221] The jury thus found a "causal connection" between the defendants' substantial and unjustified payment and the purchasers' injury.[222]

The defendants' late-breaking efforts to find an alternative explanation fail. They argue delay was just an "example" of several "factor[s]" the jury might have "considere[d] in determining whether the settlement was unreasonably anticompetitive."[223] AstraZeneca suggests the jury "credited plaintiffs' argument that the settlement was not 'on the merits.'"[224] Ranbaxy says maybe the jury considered the "business competitive situation."[225] Both suggest that maybe the jury concluded "the settlement was unreasonably anticompetitive" because it "eliminate[d] the risk AstraZeneca faced of losing the patent lawsuit."[226]

But none of these alternatives work. First, they do not square with the court's instructions. The court defined "the restraints challenged here" as the

---

[221] FTC *Amicus* Br. 2. The FTC suggests that it was "error" for the district court to do so. *Id.* at 4. But this is a private action, not an FTC case, and so the court and the parties were free to craft the jury instructions to merge into one jury question multiple elements of a private claim. The bit of turf preservation behind the FTC's brief is understandable; some FTC actions do not require proof of injury.

[222] *Sullivan II*, 34 F.3d at 1103.

[223] AstraZeneca Br. 31.

[224] *Id.*

[225] Ranbaxy Br. 46.

[226] AstraZeneca Br. 31.

"alleged payment and delay of entry of generic [Nexium]."[227] And the district court *nowhere* instructed the jury to consider *any* other factors (not even a settlement not "on the merits") as a possible anticompetitive effect of the agreement – a point the defendants are forced to concede.[228] That leaves the defendants with only one option: to hunt for isolated references in closing arguments or draft proposed instructions.[229] But unused instructions and closing arguments cannot override the district court's articulation of the law.[230]

What's more, some of the suggested alternatives are not even examples of "anticompetitive effects" – they are, in fact, "pro-competitive justifications."[231] A defendant, for example, that proves its reverse payment is less than its expected litigation costs (and was made to avoid those costs), or that proves its side deal was for "fair value" and not at all for delay is proving a potential *defense*.[232] No one – not the purchasers, not the defendants, and not the court – had in mind any possible anticompetitive effect other than delay.

---

[227] JA-7891 (Dec. 3 Trial Tr.).

[228] *See* AstraZeneca Br. 31.

[229] *See id.* (citing reference in closing to the possibility of an "improper business deal" and a non-merits-based settlement (JA-7222 (Dec. 3 Trial Tr.))).

[230] *Cf. Taylor v. Kentucky*, 436 U.S. 478, 488-89 (1978) ("[A]rguments of counsel cannot substitute for instructions by the court.").

[231] ADD-181 (Dec. 3 Final Jury Verdict Form).

[232] *Actavis*, 133 S. Ct. at 2236.

### 2. The district court's incorrect approach to antitrust cause-in-fact led it to add a legally incorrect and misleading Question 4.

Although the jury's affirmative answer to Question 3 resolved cause-in-fact in the purchasers' favor, the district court mistakenly believed the jury should *also* answer a question about whether that generic entry would have occurred in a specific manner selected by the court. This approach was flawed in concept and in execution.

Question 4 (and 6) demanded the jury accept or reject a precise path between the violation (the unlawful payment) and the harm (maintenance of supracompetitive prices through delayed competition). But antitrust causation does not require such particularity, nor is such particularity practical in this industry. While the defendants defend the *wording* of Question 4[233] and the jury's *answer*,[234] they never once explain why it was necessary or correct to ask the question in the first place.

Jury verdicts must be overturned where a flawed jury instruction "prejudices a party's substantial rights because it misleads the jury or misstates or unduly complicates the correct legal standard."[235] Here, the district court's instructions on and the wording of Question 4 were both misleading and wrong –

---

[233] *See* AstraZeneca Br. 31-32, 37.

[234] *See id.* at 31.

[235] *John G. Danielson, Inc. v. Winchester-Conant Props., Inc.*, 322 F.3d 26, 49 (1st Cir. 2003).

not even the defendants can agree on what the question meant – and justify reversal.

**a. Question 4 couched cause-in-fact as a subjective issue, not as a matter of objective economic fact.**

AstraZeneca argues that the district court's wording of Question 4 and its instructions should be affirmed because the court's instructions correctly labeled Question 4 as "an objective test," so the jury was "fairly" apprised of the correct standard when answering the question.[236] But the "use of labels" in a jury instruction that "offer[s] little differentiation" between competing standards does not cure the confusion that a lay person would reasonably experience even if, "[f]or a lawyer," the meaning would be "obvious."[237] Here, the district court's labeling of Question 4 as requiring an "objective test" came nowhere close to "fairly presenting" the correct legal standard.[238]

Consider first that Question 4 – by its terms – asked a subjectively-worded question without any qualification: "Would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?"[239] No one – neither AstraZeneca nor Ranbaxy – disputes that this

---

[236] AstraZeneca Br. 34.

[237] *Action House, Inc. v. Koolik*, 54 F.3d 1009, 1014 (2d Cir. 1995).

[238] AstraZeneca Br. 34 (citing *Johnson v. Teamsters Local 559*, 102 F.3d 21, 28 (1st Cir. 1996)); Ranbaxy Br. 49 (citing *RSA*, 260 F.3d at 4-15); *Coastal Fuels*, 175 F.3d at 31-32.

[239] ADD-174 (Jury Verdict).

question is subjective. That should end the matter. This Court "presume[s] that each of the jury's answers is a 'good faith response[]' to the question[] presented.'"[240] Had the district court genuinely believed the test was objective (as it appeared to concede) it should have styled the question objectively – it is black-letter law that an "objective analysis" requires that the jury be asked to decide what a "reasonable" actor "in [the] defendant's position" would have done.[241] By asking the jury what "th[ese] defendant[s] would have done," by contrast, the district court imposed a "subjective" inquiry.[242]

The district court's reference to an objective test during its charge "did nothing to dispel" the confusion.[243] To the contrary, the court's toggling between subjective and objective instructions leaves more than just "some doubt" that the jury could have "properly understood" either its task or the distinction between a subjective and objective inquiry.[244] Immediately after instructing the jury "the test here is an objective test," the court told the jury that that it was "using the names 'AstraZeneca' and 'Ranbaxy' because those are the folks we're talking

---

[240] *Drumgold v. Callahan*, 707 F.3d 28, 65 (1st Cir. 2013) (quoting *Crane v. Consol. Rail Corp.*, 731 F.2d 1042, 1050 (2d Cir. 1984)) (alterations in original); *see also United States v. Segal*, 339 F. Supp. 2d 1039, 1044 (N.D. Ill. 2004) (A court "must assume" the jury "answered the actual question on the verdict form.").

[241] *Cartier v. Lussier*, 955 F.2d 841, 843 (2d Cir. 1992).

[242] *United States v. Kennell*, 15 F.3d 134, 136-37 (9th Cir. 1994).

[243] *Action House*, 54 F.3d at 1014.

[244] *Id.*

about here."[245] And, even though it observed that "the test is not what [the defendants] did, we know what they did," the district court further clouded this message by reframing the operative question to focus specifically on the defendants themselves: "So then you're asked [in Question 4], '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?"[246] And it followed that instruction with this statement: "Now, look, if it wouldn't have been, that question is answered 'no' and the case is over."[247]

A lay jury could not discern what the proper inquiry was here. The court did not define what an "objective test" meant, and offered no meaningful differentiation between an inquiry focused on the defendants' subjective reasons for their conduct and an inquiry focused on the conduct of rational actors in the defendants' shoes.[248] Question 4, and its related instructions, therefore "conveyed

---

[245] JA-7129 (Dec. 3 Trial Tr.).

[246] *Id.*

[247] *Id.*

[248] *See, e.g.*, *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (noting an "objective definition" asks for the perspective of a "reasonable consumer acting reasonably under the circumstances"); *United States v. Wright*, 582 F.3d 199, 205 (1st Cir. 2009) (defining "objective" standard for reasonable suspicion for a *Terry* stop by focusing "not on what the officer himself believed but, rather, on what a reasonable officer in his position would have thought"); *United States v. Moya*, 74

(*Continued*)

a contradictory and confusing statement of the law" on one of the key causation questions adopted by the court.[249] That was error. As this Court has explained, a district court must "elaborate the meaning of controlling legal standards in terms of the particular facts of the case" where the risk of confusion is high given the "unusually complex" nature of the case.[250]

It need not have been this way. Less than 24 hours before it charged the jury, the district court appeared to understand that an objective framing of Question 4 required explaining the meaning of Question 4's "objective test" to the jury. It told the parties that it would frame Question 4's inquiry this way: "objectively would companies similarly situated have agreed that . . . Ranbaxy might launch a generic version of Nexium before May 27, 2014."[251] But, without explanation (or notice), the district court simply did not give this instruction when it ultimately charged the jury; instead, it opted to focus on whether the two named defendants here would have agreed that Ranbaxy might enter sooner. That error requires reversal.[252]

---

F.3d 1117, 1119 (11th Cir. 1996) (defining an "objective standard" by reference to the "perspective" of a "reasonable person").

[249] *Kennedy v. Town of Billerica*, 617 F.3d 520, 530 (1st Cir. 2010).

[250] *Aubin v. Fudala*, 782 F.2d 280, 283 (1st Cir. 1983).

[251] JA-7840 (Dec. 2 Trial Tr.).

[252] *See Kingsley v. Hendrickson*, 135 S. Ct. 2466, 2477 (2015) (instructions that, taken "[t]ogether," included "features suggest[ing] the jury should weigh

(*Continued*)

### b. The defendants cannot defend the court's subjective standard of cause-in-fact.

As we have explained,[253] in the antitrust context, causation – the question of what would have happened in the absence of the wrongdoer's anticompetitive conduct – is an objective one. On appeal, the defendants pay lip service to the core principle that a factfinder must "appraise[] the economic facts" about the objective market and rational actors in it to determine antitrust causation.[254] But the district court never explained this to the jury. Instead, the court's instructions left no room for the jury to consider objective evidence about what rational actors would have done – a clear violation of blackletter antitrust law. The upshot: the district court's fundamentally flawed conception of antitrust causation – which infected the case from summary judgment to trial – preordained a defense verdict.

Even if the jury understood it should consider objective evidence, the court left it with none to consider.[255] And then the court repeatedly suggested to the jury the answer it should reach. The plain interpretation of Question 4's "Ranbaxy might launch a generic version of Nexium" is that the court was asking

---

respondents' subjective reasons" for their conduct was reversible error where test was an objective one).

[253] *See supra* Section B.1.

[254] *Falstaff*, 410 U.S. at 534.

[255] *See supra* Section B.

whether Ranbaxy would launch its ANDA product. But even before the testimony started, the court told the jury "Ranbaxy never had the capacity to bring its generic to market."[256] During trial, the court periodically reminded the jury "[t]here's no evidence that Ranbaxy ever would have entered," and admonished them: "[d]on't get thinking of Ranbaxy making some early entry. No evidence of that. We're not going to hear any evidence of that."[257] It later elaborated that it had "determined as a matter of law that there is no sufficient evidence that Ranbaxy could ever bring a generic Nexium product to market prior to May 27, 2014," explaining that "once [it made] that determination as a matter of law, these parties are all stuck with it," and its ruling "takes that factual issue out of the case."[258] In its jury instructions, it repeatedly reminded the jury, "there's no sufficient evidence that Ranbaxy, at any time prior to May 27, 2014, could have brought its generic version of Nexium to the market . . . that's settled."[259]

---

[256] JA-3211 (Oct. 21 Trial Tr.); *see also* JA-3217 (Oct. 21 Trial Tr.) ("Ranbaxy could never bring its stuff to market."); JA-3218(Oct. 21 Trial Tr.) (Ranbaxy "couldn't bring its product to market.").

[257] JA-5377 (Nov. 13 Trial Tr.).

[258] JA-5606-08 (Nov. 18 Trial Tr.).

[259] JA-7094 (Dec. 3 Trial Tr.); *see also* JA-7107-08 (*id.*) (stating "it was and is clear that Ranbaxy could never get to market prior to May 27th, 2014"); JA-7118 (*id.*) ("Remember, there's no sufficient evidence in this case that Ranbaxy could itself have launched a generic before May 27th, 2014.").

We made this point in our opening brief and asked how a jury could ever have answered Question 4 other than "no" given the district court's own "admonitions" to the jury that it was "settled" that Ranbaxy could never have brought "a generic Nexium product to market prior to May 27, 2014."[260] In response, the defendants offer no response – none.

### 3. This Court should decline the defendants' invitation to overlook these serious errors.

Instead of defending the merits of the district court's jury instructions and verdict form, the defendants largely invite this Court to overlook the errors. This Court should not do so.

The claims of instructional and verdict-form error were properly preserved. This Court has explained that, under Rule 51, "[t]he judge must apprise the parties of the proposed instructions, consider requested instructions, and note objections before charging the jury."[261] "An objection lodged at that time preserves the underlying issue for appeal."[262]

Here, the purchasers raised all of their core objections at this crucial stage of the case. The day before charging the jury, the district court held a final charge conference with the parties and "apprise[d]" them of all the "proposed

---

[260] Purchasers' Br. 128-29.

[261] *Drumgold*, 707 F.3d at 52.

[262] *Id.*

instructions" and verdict-form questions.[263] In particular, it was at this final charge conference when the district court first told the parties that it planned to propose several "different" and "new" jury questions:[264]

**Draft verdict slip at charge conference (Dec. 2)**

3. Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, i.e. were outweighed by pro-competitive justifications outweighed by any anticompetitive effects of that agreement?

_____ no _____ yes

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

_____ no _____ yes

5. If so, when?

_____, 20_____

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

_____ no _____ yes

7. If so, when?

_____, 20_____

The purchasers objected. Counsel stressed that, "[i]n an antitrust case, when we reach the question as to what would have happened, it is an objective test, not a subjective test, meaning what would reasonable companies in each of their shoes have done differently if they had not engaged in the unlawful activity?"[265] "[T]his is a distinction," counsel explained, "which is not just minor

[263] *Id.*; *see* JA-6898-99 (Dec. 2 Trial Tr.); JA-6814-22 (Pls.' Mot. Amend Verdict Sheet); JA-7065-71 (Pls.' Submission re Objective Standard Jury Verdict Form); JA-7072-80 (Pls.' Submission re Jury Instructions).

[264] JA-6895 (Dec. 2 Trial Tr.).

[265] JA-6899 (*id.*).

in this case, but is major."[266] Counsel urged the district court to return to the original formulation, which "was simply a more general question" and framed objectively: "if there had not been the anticompetitive agreements, when would [a] generic product ha[ve] launched?"[267] The court refused and proceeded to impose its sequential framework.

That prompted another round of objections. "[I]f we're going to go that way," counsel told the court, "that's completely against *Actavis* and wrong as a matter of law."[268] Again, counsel suggested the proper approach was the "more general question . . . 'If it hadn't been for these agreements, would there have been earlier generic launch?'"[269] This would have permitted the jury to answer "a question that encompassed two possibilities . . . an earlier entry date, but also, under this evidence permitted, that there would have been an at-risk launch."[270] The district court "consider[ed]" the purchasers' alternative requested instructions, and "note[d]" their objections but dismissed them, delivering the verdict form to the jury as follows:

---

[266] *Id.*

[267] JA-6901 (*id.*).

[268] JA-6904 (*id.*).

[269] JA-6915 (*id.*).

[270] *Id.*

**Final verdict slip to jury (Dec. 3)**

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

_____ no _____ yes

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

_____ no _____ yes

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

_____, 20_____

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

_____ no _____ yes

This verdict form, and the charge delivered to the jury, did not change from the previous day's conference when the purchasers raised their core objections.

Under this Court's case law, that means "the underlying issue[s]" are "preserve[d] for appeal."[271] It also means that the defendants are wrong that the absence of a contemporaneous objection to the instructions or a verdict form at the time they are delivered to the jury automatically triggers waiver. Where a plaintiff earlier "made it clear to the court that he objected" to the court's charge

[271] *Drumgold*, 707 F.3d at 52.

and "the court made it clear to counsel that further objection would be futile,"[272] the issue is preserved – especially in cases where there has been no showing that any delay in objecting prejudiced the defendant.[273]

A party cannot be said to have invited instructional error where it (i) proposed jury instructions that would have avoided the error, (ii) objected to its opponents' instructions, (iii) expressed concern over the district court's proposed instructions, and (iv) reiterated the concern in a post-verdict motion.[274] All of these boxes are checked here.[275] Under First Circuit law, that is more than enough to preserve the challenge. The charge conference colloquies not only put everyone on notice that the purchasers objected to the final instructions and verdict form, but they gave the district court ample opportunity to correct its course.

---

[272] *Elzubier v. Sony Music Holdings, Inc.*, 564 F. App'x 545, 547 (11th Cir. 2014); *see also Obsidian Fin. Grp., LLC v. Cox*, 740 F.3d 1284, 1289 (9th Cir. 2014) (jury instructions issue sufficiently preserved where the district court was informed of objections and rejected them definitively before the close of evidence); *Hazle v. Crofoot*, 727 F.3d 983, 994 n.9 (9th Cir. 2013) (instructional challenges preserved where plaintiff "adequately informed the court of his position numerous times" and the court stated it "was aware of [plaintiffs'] request that the jury be [so] instructed").

[273] *King v. Kramer*, 763 F.3d 635, 639 (7th Cir. 2014) (reversing and remanding for a new trial).

[274] *Armstrong v. Shirvell*, 596 F. App'x 433, 451 n.6 (6th Cir. 2015)

[275] JA-7528-33 (Pls.' Notice Preservation Appellate Rights re Jury Instructions).

And the purchasers' challenge concerning the jury verdict form on appeal is to the form itself, *not* (as the defendants contend) that the jury's answers to Questions 3 and 4 were simply inconsistent.[276] Question 4 set forth an erroneous heightened causation standard; its wording incorrectly restricted cause-in-fact to one scenario *and* failed to reflect the required objective component under antitrust causation. So regardless of how the jury answered the question, Question 4 itself was legally objectionable. (We cited the different answers to Questions 3 and 4 to show that the only logical resolution of the apparent inconsistency is that the jury, understandably, interpreted Question 4 as asking a purely subjective question about AstraZeneca's desires).

In any event, even absent a timely objection, this Court will overturn a verdict based on plainly erroneous instructions if the error seriously impaired the "fairness" or "integrity" of the proceedings,'"[277] or if the error affects a party's substantial rights.[278] Likewise, failure to object to an inconsistent verdict is not so "iron-clad" a barrier to appellate review as the defendants contend: this Court

---

[276] *See* AstraZeneca Br. 28.

[277] *Diaz-Fonseca v. Puerto Rico*, 451 F.3d 13, 36 (1st Cir. 2006).

[278] *Chestnut v. City of Lowell*, 305 F.3d 18, 20 (1st Cir. 2002) (vacating verdict and remanding for a new trial where court's unobjected-to jury instructions were contrary to Supreme Court precedent).

will still review – and reverse – an inconsistent or ambiguous verdict that presents "a fundamental flaw that infects the judgment below."[279]

Because the instructional errors here "determined the jury's standard of judgment on the basic issue in the case," they require a new trial under even the "plain error" doctrine.[280] There can be "no confidence" that the jury's verdict was "unaffected by the instruction error."[281] The instructional errors here constituted substantial, incurable prejudice. "Parties are entitled to jury instructions that reflect the correct legal standards."[282] "The instructions here did not fulfill these goals, and the jury's verdict was distorted as a result."[283] Where an erroneous instruction involves an "issue essential to [the jury's] deliberations" that "prevent[s] the jury" from "fairly evaluating" the evidence and "finding for [the purchasers]," a new trial is warranted.[284]

---

[279] *Dopp v. HTP Corp.*, 947 F.2d 506, 516 (1st Cir. 1991).

[280] *United States v. Aitken*, 755 F.2d 188, 193-94 (1st Cir. 1985) (reversing verdict after district court improperly reversed objective and subjective standards).

[281] *Drumgold*, 707 F.3d at 53.

[282] *John G. Danielson*, 322 F.3d at 49.

[283] *Id.*

[284] *Kennedy*, 617 F.3d at 529; *Drumgold*, 707 F.3d at 53.

## III. CONCLUSION

The judgments should be vacated and the cases remanded to the district court for a trial conducted in a manner consistent with longstanding, important principles of antitrust causation.

Dated: May 18, 2016

Respectfully submitted,

**/s/ Thomas M. Sobol**

Thomas M. Sobol
David S. Nalven
Kristie A. LaSalle
James J. Nicklaus
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Tel.: (617) 482-3700

Bruce E. Gerstein
Joseph Opper
Elena K. Chan
Ephraim R. Gerstein
GARWIN, GERSTEIN & FISHER LLP
88 Pine Street, 10th Floor
New York, NY 10005
Tel.: (212) 398-0055

David F. Sorensen
Ellen Noteware
Daniel C. Simons
Caitlin G. Coslett
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel.: (215) 875-3000

Linda P. Nussbaum
NUSSBAUM LAW GROUP, P.C.
570 Lexington Avenue, 19th Floor
New York, NY 10022
Tel.: (212) 702-7054

*Counsel for Direct Purchaser Class Plaintiffs-Appellants*

**/s/ Steve D. Shadowen**
Steve D. Shadowen
HILLIARD & SHADOWEN LLC
919 Congress, Suite 1325
Austin, TX 78701
Tel.: (512) 993-3073

Kenneth A. Wexler
Bethany R. Turke
Justin N. Boley
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Tel.: (312) 346-2222

J. Douglas Richards
Sharon K. Robertson
Donna M. Evans
COHEN MILSTEIN SELLERS & TOLL, PLLC
88 Pine Street, 14th Floor
New York, NY 10005
(212) 838-7797

Jayne A. Goldstein
POMERANTZ LLP
1792 Bell Tower Lane
Weston, FL 33326
(954) 315-3454

Matthew Wessler
GUPTA WESSLER PLLC
1735 20th Street, NW
Washington, DC 20009
Tel: (202) 888-1741

*Counsel for End-Payor Class Plaintiffs-Appellants*

## CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the foregoing brief is in 14-point Bell MT proportional font and contains 16,958 words (exclusive of the caption, table of contents, table of authorities, signature block, and certifications) and thus is in compliance with the type-volume limitations set forth in Fed. R. App. P. 32(a)(7)(B), as modified by this Court's Order of May 9, 2015.

Dated: May 18, 2016

**/s/ Thomas M. Sobol**
Thomas M. Sobol

## CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was served by filing it on the court's CM/ECF system and additionally via electronic mail to all counsel of record.

Dated: May 18, 2016

**/s/ Thomas M. Sobol**
Thomas M. Sobol