

MODEL JURY INSTRUCTIONS: TRIAL BY *ACTAVIS*

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The Supreme Court in *FTC v. Actavis, Inc.*,¹ reiterated the well-established doctrine that “overly restrictive patent licensing agreements” are subject to antitrust scrutiny “both within the settlement context and without.” The Court held that nothing in the Patent Act shields “reverse payments” in the pharmaceutical industry from such scrutiny.² And rule-of-reason analysis of reverse payments is precluded by neither the “general legal policy favoring settlement” nor the “fear that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent.”³

The *Actavis* Court “leave[s] to the lower courts the structuring of the . . . rule-of-reason antitrust litigation.”⁴ In order to help courts provide that structure, this paper offers Model Jury Instructions and a Model Verdict Slip for a typical reverse payment case.

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1. 133 S. Ct. 2223, 2232 (2013).
2. *Id.* at 2233.
3. *Id.* at 2234.
4. *Id.* at 2238.

These Model documents grew out of the authors' experiences in representing plaintiffs in the first post-*Actavis* reverse payment case tried to a jury. In that case, *In re Nexium (Esomeprazole) Antitrust Litigation*,⁵ the jury answered a series of special interrogatories, finding that Defendants' reverse-payment agreement violated the Sherman Act, but that, absent the violation, Defendants would not have entered into an alternative agreement with an earlier generic-entry date.⁶ The Model Jury Instructions and Model Jury Verdict Slip that we offer here are *not* those that the Court in *Nexium* actually used, but are crafted with the benefit of the experience that we gained in that trial.⁷

The reader will readily see that the Model Jury Instructions cover many of the issues addressed by other participants in this symposium, including what counts as a "payment;" compared to what is a payment "large;" which justifications for the payment are cognizable and which are not; who has the burden of proof to show that the payment is large and unjustified; must plaintiffs define a relevant market if they are relying on direct evidence of market power; how should the jury weigh likely anticompetitive effects against any procompetitive effects; what is the role of the patent merits; and what is the proper standard for causation? The Model Instructions also include an overview of the Hatch-Waxman Act to orient jurors to the framework of these cases.

The Model Verdict Slip assumes that the court has separated the trial into phases and that the first phase includes the elements of violation and impact through a determination of whether a generic version of the brand drug would have entered the market but for the antitrust violation and if so, when. Determining the quantum of damages, and the right to equitable relief, is left for the second phase of the trial. Bifurcation along these lines permits all plaintiffs, whether direct or indirect purchasers and whether class plaintiffs or opt-outs, to participate in the first trial.

Specifically, the verdict form requires the jury to determine whether there was a large payment that was unreasonably restrictive of competition and whether, absent the payment, generic entry would likely have occurred sooner than it did. If jurors answer those questions in favor of plaintiffs, the form then requires jurors to determine the but-for

5. No. 12-md-02409 (D. Mass.).

6. As of the date of this writing, Plaintiffs' motions for a new trial in the *Nexium* case and for an injunction (based on the jury's affirmative answers to the first three questions) are pending in the district court.

7. We are aware of only one other set of Model Jury Instructions for reverse payment cases in the wake of *Actavis*. See Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 *Antitrust* 16, 20–21 (2013).

entry dates for other generics and/or an authorized generic as applicable. If the jury in the first phase of the trial answers all of these questions, all that is left for the second phase is equitable relief and the calculation of damages using the first jury's findings regarding when but-for entry would have occurred and by how many other generics. In order to avoid pass-on and other thorny issues, the court can provide separate phase-two proceedings for each of the different varieties of plaintiffs.

Depending on whom you ask, the *Nexium* trial taught any number of lessons. But one thing it undoubtedly taught is that jurors need help understanding the interplay between the antitrust and patent laws, and Hatch-Waxman. These Model documents can help other courts structure the cases for trial, and can help academics and others identify and grapple with the legal and practical issues that the cases raise.

**UNITED STATES DISTRICT COURT
DISTRICT OF _____**

In re: PRESCRIPTION DRUG ANTITRUST LITIGATION
This Document Relates To:

MDL No. ____

Civil Action No. ____

MODEL JURY INSTRUCTIONS

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PROPOSED JURY INSTRUCTION 1***Introduction***

Basically, plaintiffs allege that [Brand Company] made a large payment to [Generic Company] in return for [Generic Company] agreeing to delay launching its generic until [Date]. Plaintiffs allege that absent the large payment, a generic would have become available earlier and purchasers would have been able to buy the less expensive generic instead of the more expensive brand. That is generally plaintiffs' theory. It is for you to judge it, but in doing so, you should apply these instructions.

PROPOSED JURY INSTRUCTION 2

The Hatch-Waxman Act

This case involves brand and generic drugs, and you have learned about how the United States Food and Drug Administration, or the “FDA,” approves drugs. I am going to give you a brief explanation of the drug approval process to help you understand better the evidence that has been presented at trial.

Federal law requires that drug companies apply for and obtain approval from the

FDA before they can sell a drug in this country.⁸ The first company to develop a drug files an application called a New Drug Application or “NDA.”⁹ The NDA contains technical information on the chemicals in the drug, the method of manufacturing it, and its effect on the human body.¹⁰ The purpose of the New Drug Application is to demonstrate to the FDA that the drug is safe and effective for its proposed uses.¹¹

If the FDA concludes after reviewing the application that the drug is both safe and effective, it approves the New Drug Application and allows the drug to be sold in the United States.¹² Drugs approved under the New Drug Application process are often called “brand-name drugs” because manufacturers market them under a brand name rather than under the drug’s chemical name. [Name of brand name drug], the prescription drug at issue in this case, is an example of a brand-name drug. The active ingredient in [Brand name drug] is a chemical called [chemical or generic name].

The FDA also approves generic drugs.¹³ Generic drugs have the same active ingredient as the brand drug, but are usually sold under their chemical name. If you buy Tylenol, for example, you are buying the brand name version. The active ingredient in Tylenol is acetaminophen. If you buy a bottle just labeled acetaminophen, it’s the generic. The same goes for prescription drugs. [Brand name] is the brand name; the generic is called [generic name].

8. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–392 (2014).

9. Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”), 21 U.S.C. § 355 (2014).

10. *Id.* § 355(b)(1).

11. *Id.*

12. *Id.* § 355(c)(1)(A).

13. *Id.* § 355(b)(1).

You have heard evidence about a federal law that governs how generic drugs are approved. Its full name is the “Drug Price Competition and Patent Term Restoration Act of 1984,” but it is more commonly called the “Hatch-Waxman Act” or simply “Hatch-Waxman.”¹⁴ The Hatch-Waxman Act covers the requirements and procedures for determining that a generic is as safe and effective as the brand drug. As suggested by its full name, Hatch-Waxman was intended in part to encourage price competition between brand and generic manufacturers.

The Hatch-Waxman Act requires that the generic drug be essentially the same as the brand-name drug: the generic drug must contain the same active chemical ingredient as the brand-name drug, must be in the same dosage form (*i.e.*, tablet or capsule) and the same dosage strength as the brand-name drug, and must be bioequivalent to the brand-name drug.¹⁵

A manufacturer gets FDA approval to market a generic drug by filing an Abbreviated New Drug Application,¹⁶ also known as an “A-N-D-A,” or an “ANDA.” The generic company need not demonstrate all over again that the drug is safe and effective, because the FDA has already concluded that the brand drug is safe and effective. The generic company just needs to demonstrate that the generic drug is “bioequivalent” to the approved brand-name drug. “Bioequivalent” means that the generic drug has the same effect in the patient’s body as the brand-name drug.¹⁷ The generic company must also prove that it can manufacture the drug to the required specifications.¹⁸ So that is some basic background on the requirements and procedures for establishing that a generic drug is safe and effective.

The Hatch-Waxman Act also addresses how and when brand and generic drug companies can compete with each other. Brand-drug manufacturers often assert that the brand drug, or the process for making it, is covered by one or more patents. A patent is a legal document issued by the United States Patent and Trademark Office, or “PTO,” that describes an invention and allows the patent owner to file a lawsuit seeking to exclude other manufacturers from making, using, offering to sell, or selling the claimed invention within the United States.¹⁹ If a person or entity sells something without permission and it is covered by a patent, the patent owner can sue the seller for what is called

14. *Id.* § 355.

15. *Id.* § 355(j)(2)(A).

16. *Id.* § 355(j)(1–2).

17. *Id.* § 355(j)(8)(B).

18. *Id.* § 355(j)(2)(A)(vi).

19. 35 U.S.C. § 271 (2014).

“patent infringement.” The person sued has a number of potential defenses, including that the patent is invalid, that it can’t be enforced for certain reasons, or that there is no infringement even if the patent is valid.

Brand drug manufacturers often claim that sale of a competing generic drug would infringe one or more of the brand manufacturer’s patents, while generic manufacturers often claim, in response, that their generic versions of brand drugs do not infringe or that the patents are not valid or not enforceable, or all of the above.

To promote these kinds of patent challenges, the Hatch-Waxman Act requires that a brand manufacturer filing a New Drug Application list all of its patents that it contends would be infringed by the sale of a competing generic.²⁰ The list is kept in an FDA publication called the “Orange Book”²¹ because the paper version literally had an orange cover. By listing the patents in the Orange Book, the FDA is not making any judgments about whether the patents are valid or could be infringed. The FDA simply lists the patents that the brand drug manufacturers ask it to list.²²

When a generic manufacturer submits an ANDA seeking FDA approval to market a generic version of the brand drug, the Hatch-Waxman Act requires the generic manufacturer to make one of four certifications regarding the patents that the brand manufacturer has listed in the Orange Book concerning the drug.²³ The particular type of patent certification involved in this case is known as a “Paragraph IV Certification.”²⁴ In a Paragraph IV Certification, the generic manufacturer certifies that, although the brand manufacturer has listed certain patents in the Orange Book with respect to the brand drug, selling the generic drug before those patents expire will not infringe the patents because the patents are not valid or not enforceable or simply do

20. 21 U.S.C. § 355(b)(1).

21. The term “Orange Book” refers to the FDA’s publication formally titled “Approved Drug Products with Therapeutic Equivalence Evaluations” and specifically its Patent and Exclusivity Information Addendum, which the FDA is required to update every thirty days. *Id.* § 355(j)(7)(A).

22. *In re Bupirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) (“the FDA is required by law to publish the information in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1) & (e)(2) (‘Upon submission of patent information under [these] subsection[s], the Secretary shall publish it.’). Hence, the FDA’s actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing.”).

23. 21 U.S.C. § 355(b)(2)(A).

24. *Id.* § 355(j)(2)(A)(vii)(IV).

not cover the generic drug, meaning the generic does not infringe the brand's patent.²⁵

Under the Hatch-Waxman Act, within 45 days after receiving notice of the Paragraph IV Certification, the brand manufacturer can bring a patent infringement lawsuit against the generic manufacturer in federal court.²⁶ That federal court will then decide who is right: are the patents valid and infringed, or not?

If the brand manufacturer brings a patent infringement lawsuit within 45 days, the Hatch-Waxman Act provides that the FDA cannot approve the generic drug for 30 months or until there is a court ruling in the patent case declaring the patent invalid or not infringed, whichever happens first.²⁷ You may have heard the lawyers or witnesses referring to this as the “30-month stay”—because final FDA approval of the generic drug is “stayed”—or held up—for up to 30 months. A brand company is not required to sue within 45 days; the brand can choose to wait and sue later but by suing within 45 days the brand is able to get the advantage of the 30-month stay, which is not available if the brand files suit after the 45 day period.

At the end of the 30-month stay, the FDA may approve an ANDA even if the patent lawsuit has not ended or settled. If this happens, the generic manufacturer may choose to launch its generic product into the market “at risk”—that is, at risk of later losing the infringement case. Losing an infringement case after marketing at risk can result in the generic manufacturer having to pay damages to the brand patent holder.²⁸

In passing the Hatch-Waxman Act, part of what Congress wanted to encourage is for generic manufacturers to challenge the validity and applicability of patents on brand drugs. Congress understood both that some brand patents are invalid and that generic companies can develop generics that do not infringe the patents even if they are valid. Congress wanted to give generic drug companies a financial incentive to do the work needed to challenge brand drug patents and demonstrate that they are invalid, or invent around them, which means developing a generic

25. *Id.*

26. *Id.* § 355(c)(3)(C).

27. *Id.* § 355(c)(3)(C)(i).

28. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231 (D. Mass. 2014); *see also* 35 U.S.C. § 271(e)(4)(C) (2014) (providing that damages may be awarded “only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug”); 35 U.S.C. § 284 (2014) (providing for “damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer”).

that does not infringe.²⁹ So Congress created a kind of reward to encourage generic manufacturers to challenge brand patents.³⁰

You have heard the lawyers and witnesses refer to this reward as the “180-day exclusivity.” Here is how it works: the first generic manufacturer that files a Paragraph IV Certification with respect to a particular brand drug—often called a “first filer”—can get a period of 180 days (six months) as the only ANDA-approved version of that drug on the market.³¹ The Hatch-Waxman Act prohibits the FDA from granting approval of any other manufacturer’s ANDA for that drug until 180 days after the first generic manufacturer that filed a Paragraph IV Certification enters the market.³²

This 180-day period of exclusivity can be very valuable. In some cases, it can even be worth hundreds of millions of dollars, depending on the sales of the corresponding brand drug.³³ The reason that the generic company often can earn so much during a six-month period of exclusivity is that a generic company with 180 days of exclusivity will be the only generic company whose ANDA will be approved until that 180 day period expires. As a result, the first filer will generally be able to charge a higher price for its generic product during the period of exclusivity than if it had to compete against other generic manufacturers and will not have to share generic sales with other generic companies.³⁴

Unless it forfeits its exclusivity,³⁵ the first Paragraph IV filer can get this 180-day exclusivity regardless of when it enters the market: the first-filer gets the 180-day exclusivity if the 30-month stay expires and it launches; it gets the exclusivity if it does not launch until after the court decides the patent case; and in many circumstances it gets the 180-day exclusivity even if it settles the patent case rather than winning it at trial.³⁶

29. H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

30. *See id.*

31. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

32. *Id.*

33. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (“[T]his 180-day period of exclusivity can prove valuable, [potentially] ‘worth several hundred million dollars.’”).

34. *See* FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 41–48 (2011), *available at* <http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf>.

35. 21 U.S.C. § 355(j)(5)(D) (discussing ways first-filer can forfeit exclusivity).

36. 21 U.S.C. § 355(j)(5)(B)(iv)(I); *see also Nexium*, 42 F. Supp. 3d at 246 (D. Mass. 2014) (“Because no other manufacturer may launch a product until 180 days after the first filer has done so, a first filer’s delay effectively delays all of its competitors’ entries, creating a bottleneck in the market that postpones the date on which any generic product will become available.”).

[If case involves an authorized generic] When I just described the 180-day exclusivity, I was very careful to say that it prevents the FDA from granting approval only to any other manufacturer's ANDA during that period. The 180-day exclusivity does *not* apply to the brand company itself. The brand company can keep selling its own brand drug during the 180 day period and afterwards. A brand company can also decide to sell what is called an "authorized generic."³⁷ An authorized generic is the brand drug, sold by the brand company or by another company that the brand company authorizes, but with a generic label and usually at generic prices. The brand can sell an authorized generic whenever it wishes to, but it usually does not start selling one until a competing generic company is ready to launch its generic. The reason is that if the brand company launched the authorized generic before it faced generic competition, the brand company would just be taking branded sales from itself.

[If applicable] You heard testimony regarding other aspects of this 180-day exclusivity—for example, under certain circumstances the Paragraph IV first-filer might in effect transfer that exclusivity right to another generic manufacturer.³⁸ The Paragraph IV first-filer may also give up or "relinquish" its exclusivity; once the 180-day exclusivity is relinquished, it is no longer a barrier preventing other generic applicants from obtaining final approval.³⁹

37. *Teva Pharm. Indus. v. FDA*, 410 F.3d 51, 54 (D.C. Cir. 2005); 21 U.S.C. § 355(t)(3).

38. Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Bert W. Rein, Wiley Rein & Fielding LLP (Jul. 2, 2004) (responding to Citizen Petition at Docket No. 2004P-0227), *available at* <http://www.regulations.gov/#/documentDetail;D=FDA-2004-P-0014-0002> (follow "View Attachment" hyperlink).

39. *Id.* at 4–5.

PROPOSED JURY INSTRUCTION 3

1. Overview of Verdict Slip

Turning to the verdict sheet. It has ____ questions.

Question 1 asks: “Did [Brand Company] exercise market power over prescription [generic name of drug]?” As a jury you will have to decide whether to check yes or no. A “yes” is a finding for the plaintiffs; a “no” is a finding for the defendants. Note that when I use the term [generic name of drug] throughout these instructions, I am referring to the chemical name for [brand name drug].

Question 2 asks: “Did the settlement of the [Brand-Generic] patent litigation involve a large payment by [Brand Company] to [Generic Company]?” This is also a yes or no question. A “yes” is a finding for the plaintiffs; a “no” is a finding for the defendants.

Question 3 asks: “Was [Brand Company’s] settlement with [Generic Company] unreasonably anticompetitive, i.e., do the likely anticompetitive effects of the agreement(s) outweigh any procompetitive justifications shown by the defendants for the payment(s)?” This is another yes or no question. A “yes” is a finding for the plaintiffs; a “no” is a finding for the defendants.

Question 4 asks: “Had it not been for the [Brand-Generic] agreement(s), would a generic version of [drug] have come to market before [date allowed under the challenged settlement]?” Again, yes or no. A “yes” is a finding for the plaintiffs; a “no” is a finding for the defendants.

If you answer Question 4 “yes,” then you must answer Question 5. Question 5 asks, “If so, what is a reasonable estimate as to when?” This question asks you to reasonably estimate the month and year that a generic version of [drug] would have come to market, before [Date], if reasonable pharmaceutical companies in [Brand and Generic Company’s] positions had not entered into a settlement with a large payment.

[If applicable] The next question, Question 6, asks “Would an authorized generic have entered at or about the same time?” This is a yes or no question—you should check yes if you conclude that [Brand Company] would have launched an authorized generic at or about the same time that another generic entered. A “yes” is a finding for the plaintiffs; a “no” is a finding for the defendants.

[If applicable] The next question, Question 7, asks “Would additional generics have entered thereafter?” This is also a “yes” or “no” question. If you answer “yes,” you then must answer Question 8, which asks “If so, what is a reasonable estimate as to how many and when?”

PROPOSED JURY INSTRUCTION 4

2. Purpose of the Antitrust Laws

The direct purchaser plaintiffs have brought suit under a United States law known as the Sherman Antitrust Act.⁴⁰ The purpose of the Sherman Act is to preserve free and unfettered competition in the marketplace. The Sherman Act rests on the central premise that competition produces the best allocation of our economic resources—the lowest prices, the highest quality, and the greatest material progress.⁴¹

[If applicable] The end-payor plaintiffs have brought suit under the laws of 25 states and the District of Columbia that serve similar purposes.⁴²

40. 15 U.S.C. § 1 (2014).

41. ABA SECTION OF ANTITRUST LAW, MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES A-2 (2005) [hereinafter ABA MODEL JURY INSTRUCTIONS].

42. **Arizona:** *Bunker's Glass v. Pilkington PLC*, 47 P. 3d 1119, 1124 (Ariz. Ct. App. 2002) (“The underlying purpose of the Arizona antitrust act is to establish a ‘public policy of first magnitude’ in furthering a competitive economy.”); **California:** *Turnbull & Turnbull v. ARA Transp., Inc.*, 268 Cal.Rptr. 856, 865 (Ct. App. 1990) (“Unfair Practices Act’s legitimate purpose of safeguarding the public against the creation or perpetuation of monopolies and of fostering and encouraging competition. This purpose is basically the same as that of the Sherman Act.”); **Florida:** FLA. STAT. § 501.202 (2014), Purposes; rules of construction (purposes include “protect[ing] the consuming public and legitimate business enterprises from those who engage in unfair methods of competition”); **Hawaii:** *Island Tobacco Co., Ltd. v. R.J. Reynolds Indus., Inc.*, 513 F. Supp. 726, 738 (D. Haw. 1981) (“[l]egislative history of Hawaii’s antitrust law clearly indicates that the state laws are to be interpreted and construed in harmony with analogous federal antitrust laws”); *see also* *Beerman v. Toro Mfg. Corp.*, 615 P.2d 749, 754 (Haw. 1980) (“the Hawaii legislature intended HRS § 480-2 . . . to provide consumers with individual causes of action where they have been injured by a deceptive trade practice.”); **Iowa:** IOWA CODE § 553.2 (2013) (“This chapter shall be construed to complement and be harmonized with the applied laws of the United States which have the same or similar purpose as this chapter. This construction shall not be made in such a way as to constitute a delegation of state authority to the federal government, but shall be made to achieve uniform application of the state and federal laws prohibiting restraints of economic activity and monopolistic practices.”); **Kansas:** *State v. Consumers Warehouse Mkt., Inc.*, 329 P.2d 638, 643 (Kan. 1958) (“There can be no doubt the purpose of the Act, stated in a general way, is to safeguard the public against the creation of monopolies and to foster and encourage competition by the prohibition of unfair practices.”); **Maine:** *Tri-State Rubbish, Inc. v. Waste Mgmt., Inc.*, 875 F. Supp. 8, 14 (D. Me. 1994) (“[t]he Maine antitrust statute parallels the Sherman Act”); **Massachusetts:** MASS. GEN. LAWS ANN. ch. 93, § 1 (West 2014) (“It is the purpose of this chapter to encourage free and open competition in the interests of the general welfare and economy by prohibiting unreasonable restraints of trade and monopolistic practices in the commonwealth.”); **Michigan:** MICH. COMP. LAWS ANN. § 445.773 (West 2014) (“The establishment, maintenance, or use of a monopoly, or any attempt to establish a monopoly, of trade or

commerce in a relevant market by any person, for the purpose of excluding or limiting competition or controlling, fixing, or maintaining prices, is unlawful.”); **Minnesota**: Howard v. Minn. Timberwolves Basketball Ltd. P’ship, 636 N.W.2d 551, 556 (Minn. Ct. App., 2001) (“Minnesota antitrust law should be interpreted consistently with federal court interpretations of federal antitrust law.”); **Mississippi**: MISS. CODE ANN. § 75-21-39 (West 2014) (“This chapter shall be liberally construed in all courts to the end that trusts and combines may be suppressed, and the benefits arising from competition in business preserved to the people of this state.”); **Nebraska**: Ploog v. Roberts Dairy Co., 240 N.W. 764, 765 (Neb. 1932) (“The aim of our antitrust laws is to preserve inviolate the principle of free, fair and open competition.”); **Nevada**: NEV. REV. STAT. ANN. § 598A.050 (West 2014) (“The provisions of this chapter shall be construed in harmony with prevailing judicial interpretations of the federal antitrust statutes.”); **New Mexico**: N.M. STAT. ANN. § 57-1-15; *see also* United Nuclear Corp. v. Gen. Atomic Co., 597 P.2d 290, 310 (N.M. 1979) (“The underlying purposes behind both the federal and state Laws are the same, to establish a ‘public policy of first magnitude’; that is, promoting the national interest in a competitive economy.”); **New York**: Columbia Gas of N.Y. v. N.Y. State Elec. & Gas Corp., 28 N.Y.2d 117, 127 (1971) (“We have previously declared that section 340 encourages a ‘strong public policy in favor of free competition for New York’ and represents ‘a public policy of the first magnitude.’” (citations omitted)); **North Carolina**: DKH Corp. v. Rankin-Patterson Oil, 506 S.E.2d 256, 258 (N.C. Ct. App. 1998) (Chapter 75 of the North Carolina General Statutes “was modeled after the Sherman Act and many of Chapter 75’s provisions closely resemble it.”); **North Dakota**: 81 Op. N.D. Atty Gen. 35 (N.D. 1981) (recognizing that North Dakota’s statute is “similar to the Sherman Antitrust Act” and noting that “the federal system provides instruction as to what courses of action are permissible, and what courses of action are prohibited”); **Oregon**: Jones v. City of McMinnville, 244 F. App’x 755, 758 (9th Cir. 2007) (finding that Oregon and federal antitrust statutes are “almost identical” and that Oregon courts look to federal decisions as “persuasive”) (quoting OR. REV. STAT. §§ 646.725, 646.730, 646.715(2); Or. Laborers-Emp’rs Health & Welfare Trust Fund v. Philip Morris, Inc., 185 F.3d 957, 963 n.4 (9th Cir. 1999)); **Rhode Island**: ERI Max Entm’t, Inc. v. Streisand, 690 A.2d 1351, 1353 (R.I. 1997) (“The purpose of antitrust laws is to protect competition, not [individual] competitors.” (citing UXB Sand & Gravel, Inc. v. Rosenfield Concrete Corp., 599 A.2d 1033, 1035 (R.I. 1991)); **South Dakota**: House of Seagram, Inc., Seagram Distillers Co. Div. v. Assam Drug Co., 83 S.D. 320, 327 (1968) (“[T]he antitrust laws are for the protection of the public.”); *see also* S.D. CODIFIED LAWS § 37-1-22 (2014) (“Judicial interpretations of similar statutes as guide. It is the intent of the Legislature that in construing this chapter, the courts may use as a guide interpretations given by the federal or state courts to comparable antitrust statutes.”); **Tennessee**: Leggett v. Duke Energy Corp., 308 S.W.3d 843, 852 (Tenn. 2010) (The Tennessee Trade Practices Act “is a general antitrust statute establishing that various anticompetitive practices are ‘against public policy, unlawful, and void’”); **Utah**: UTAH CODE ANN. § 76-10-3102 (West 2014) (“The purpose of this [Utah Antitrust Act] is, therefore, to encourage free and open competition in the interest of the general welfare and economy of this state by prohibiting monopolistic and unfair trade practices, combinations and conspiracies in restraint of trade or commerce and by providing adequate penalties for the enforcement of its provisions.”); **Vermont**: Otis-Wisher v. Fletcher Allen Health Care, Inc., 951 F. Supp. 2d 592, 603 (D. Vt. 2013) (The purpose of the Vermont Consumer Fraud Act is “to protect the public from unfair and deceptive business practices and to encourage fair and honest competition.”); **West Virginia**: Princeton Ins. Agency, Inc. v. Erie Ins. Co., 690 S.E.2d 587, 598 (W. Va. 2009) (“the overarching objective of antitrust laws is to protect competition rather than competitors.”); **Wisconsin**: Huntley v. Malone & Hyde, Inc., 541 N.W.2d 838, n.5 (Wis. Ct. App. 1995) (“As we have already noted, the antitrust laws protect *competition*, not

PROPOSED JURY INSTRUCTION 5

3. [If applicable] State Law Claims

The state laws under which the end-payors have brought suit also attempt to protect competition. The end-payor plaintiffs' claims under these state laws track claims under the federal antitrust statute, the Sherman Act, and similarly declare illegal the same anticompetitive conduct alleged by the direct purchaser plaintiffs.

Because the end-payor plaintiffs' claims under the laws of the 25 states and the District of Columbia are to be interpreted and construed in harmony with the Sherman Act, if you find that the defendants are liable under the Sherman Act under the instructions I am about to give you, you should also find that they are liable under the laws of the District of Columbia and 25 states, namely: Arizona, California, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin.⁴³

competitors."); D.C. CODE § 28-4501(b) (2015) ("The purpose of this chapter is to promote the unhampered freedom of commerce and industry throughout the District of Columbia[.]").

43. See *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 275, 278 (D. Mass. 2004) (finding that "[w]ith respect to substantive matters," the statutes of twelve "Exemplar States"—Arizona, California, Florida, Kansas, Maine, Massachusetts, Michigan, Minnesota, New York, North Carolina, Tennessee, and Vermont—are "uniformly parallel to their federal counterparts, the Sherman Act and the Federal Trade Commission Act."); see also *Wedgewood Inv. Corp. v. Int'l Harvester Co.*, 613 P.2d 620, 623 (Ariz. Ct. App. 1979) ("The Arizona legislature clearly intended to strive for uniformity between federal and state antitrust laws."); D.C. CODE § 28-4515 (2012) (harmonization provision); *Island Tobacco Co., Ltd. v. R.J. Reynolds Indus., Inc.*, 513 F. Supp. 726, 738–39 (D. Haw. 1981) ("[L]egislative history of Hawaii's antitrust law clearly indicates that the state laws are to be interpreted and construed in harmony with analogous federal antitrust laws."); IOWA CODE § 553.2 (2013) (harmonization provision; purpose is "to achieve uniform application of the state and federal laws prohibiting restraints of economic activity and monopolistic practices."); *Tri-State Rubbish, Inc. v. Waste Mgmt., Inc.*, 875 F. Supp. 8, 14 (D. Me. 1994) ("Maine antitrust statute parallels the Sherman Act."); MICH. COMP. LAWS ANN. § 445.784(2) (West 2014) (harmonization provision) ("It is the intent of the legislature that in construing all sections of this act, the courts shall give due deference to interpretations given by the federal courts to comparable antitrust statutes, including, without limitation, the doctrine of per se violations and the rule of reason."); *State by Humphrey v. Alpine Air Prods., Inc.*, 490 N.W.2d 888, 894 (Minn. Ct. App. 1992), *aff'd*, 500 N.W.2d 788 (Minn. 1993) ("Minnesota antitrust law should be interpreted consistently with federal court interpretations of the Sherman Act unless state law is clearly in conflict with federal law."); NEV. REV. STAT. § 598A.050 (2014) (harmonization provision); N.M. STAT. ANN. § 57-1-15 (West 2014) (harmonization provision; purpose is "to achieve uniform application of the state and federal

PROPOSED JURY INSTRUCTION 6

A. Market Power Over [generic name of drug] [Question 1]

Turning to Question 1, it asks: “Did [Brand Company] exercise market power over prescription [generic name of drug]?” As part of assessing whether defendants unreasonably restrained trade, you must consider whether [Brand Company] had market power with respect to the sale of prescription [generic or chemical name of drug], which is the generic or chemical name of [brand name of drug].⁴⁴

laws prohibiting restraints of trade and monopolistic practices.”); *Anheuser-Busch, Inc. v. Abrams*, 520 N.E.2d 535, 539 (N.Y. 1988) (“the Donnelly Act—often called a ‘Little Sherman Act’—should generally be construed in light of Federal precedent and given a different interpretation only where State policy, differences in the statutory language or the legislative history justify such a result”); *DKH Corp. v. Rankin-Patterson Oil*, 506 S.E.2d 256, 258 (N.C. Ct. App. 1998) (Chapter 75 of the North Carolina General Statutes “was modeled after the Sherman Act and many of Chapter 75’s provisions closely resemble it.”); 35 Op. N.D. Atty Gen. 76, 108 (N.D. 1981) (“Drawing from the body of knowledge developed in the federal system provides instruction as to what courses of action are permissible, and what courses of action are prohibited.”); S.D. CODIFIED LAWS § 37-1-22 (West 2014) (harmonization provision) (“It is the intent of the Legislature that in construing this chapter, the courts may use as a guide interpretations given by the federal or state courts to comparable antitrust statutes.”); UTAH CODE ANN. § 76-10-926 (West 2013) (harmonization provision); W.VA. CODE § 47-18-16 (2015) (harmonization provision) (“This article shall be construed liberally and in harmony with ruling judicial interpretations of comparable federal antitrust statutes.”); *Conley Publ’g Grp. Ltd. v. Journal Commc’ns., Inc.*, 665 N.W.2d 879, 885–86 (Wis. 2003), *overruled on other grounds by Olstad v. Microsoft Corp.*, 700 N.W.2d 139 (Wis. 2005) (“Wisconsin courts have followed federal court interpretations of Sections 1 and 2 of the Sherman Act and have construed Wisconsin antitrust statutes in conformity with these federal court interpretations. This is longstanding policy.”); *accord* CAL. BUS. & PROF. CODE § 16750(a) (West 2014); D.C. CODE § 28-4509 (West 2012); HAW. REV. STAT. § 480-3 (2014); *Comes v. Microsoft Corp.*, 646 N.W. 2d 440, 446 (Iowa 2002); KAN. STAT. ANN. § 50-161(b) (2014); *Bellinder v. Microsoft Corp.*, No. 00-C-0855, 2001 WL 1397995, at *8 (D. Kan. Sept. 7, 2001); ME. REV. STAT. tit. 10, § 1104(1) (2014); MICH. COMP. LAWS ANN. § 445.778(2) (West 2014); MINN. STAT. § 325D.57 (2014); NEV. REV. STAT. § 598A.210(2) (2014); *Pooler v. R.J. Reynolds Tobacco Co.*, No. CV00-02674, 2001 WL 403167, *1–2 (D. Nev. Apr. 4, 2001); N.M. STAT. ANN. § 57-1-3(A) (West 2014); N.Y. GEN. BUS. LAW § 340(6) (McKinney 2010); *Hyde v. Abbott Labs.*, 473 S.E.2d 680, 682, 685 (N.C. Ct. App. 1996); N.D. CENT. CODE ANN. § 51-08.1-08(3) (West 2014); P.R. LAWS ANN. tit. 10, § 268(a) (2014); S.D. CODIFIED LAWS § 37-1-33 (2014); *Freeman Indus. LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 519–20 (Tenn. 2005); UTAH CODE ANN. § 76-10-919(1)(a) (LexisNexis 2014); W. VA. CODE R. § 142-9-1 (2014); WIS. STAT. ANN. § 133.18(1)(a) (West 2014).

44. If “anti-competitive effects of conduct can be ascertained through means short of extensive market analysis, and where no countervailing competitive virtues are evident, a lengthy analysis of market power is not necessary.” *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 110 n.42 (1984). Thus, there is no separate requirement to prove market power. However, where proof of detrimental effects is unclear, proof of market power may serve as a surrogate. *See Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1367 (3d Cir.

PROPOSED JURY INSTRUCTION 7

1. Market Power Defined

A company with market power can charge a higher price than it might otherwise charge in a competitive market. Market power is the ability (a) to control prices or (b) to exclude competition. Market power is the power to charge a price higher than the competitive price without losing so many sales to competing firms as to make the artificially high price unsustainable and unprofitable.⁴⁵ The “competitive level” is the price that would be charged in a market with fair competition.

A large payment from a brand manufacturer to a prospective generic competitor is itself a strong indicator of market power—namely, the power to charge prices higher than the competitive level.⁴⁶ This is because it would be illogical for a brand company to make a large

1996) (“Due to the difficulty of isolating the market effects of the challenged conduct, however, such proof is often impossible to make. Accordingly, the courts allow proof of the defendant’s ‘market power’ instead. Market power—the ability to raise prices above those that would prevail in a competitive market—is essentially a ‘surrogate for detrimental effects.’”) (quoting *United States v. Brown Univ.*, 5 F.3d 658, 668–69 (3d Cir. 1993)).

45. *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 445 n.2 (3d Cir. 1997) (“The basic definition of market power is ‘the power to raise prices above competitive levels without losing so many sales that the price increase is unprofitable.’”) (quoting HERBERT HOVENKAMP, *FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE* § 3.1, at 79 (1994)); *DSM Desotech Inc. v. 3D Sys. Corp.*, 749 F.3d 1332, 1340 (Fed. Cir. 2014) (“The key inquiry in a market power analysis is whether the defendant has the ability to raise prices without losing its business”) (internal quotations omitted) (quoting *42nd Parallel N. v. E St. Denim Co.*, 286 F.3d 401, 405–06 (7th Cir. 2002)); ABA MODEL JURY INSTRUCTIONS, *supra* note 41, at A-6 (“[M]arket power[] has been defined as an ability profitably to raise prices above those that would be charged in a competitive market for a sustained period of time. A firm that possesses market power generally can charge higher prices for the same goods or services than a firm in the same market that does not possess market power.”); *Id.* at C-4 (“[A] firm is a monopolist if it can profitably raise prices substantially above the competitive level for a significant period of time”). *See also* *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966) ([M]onopoly power is “the power to control prices or exclude competition.”); *United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) (“[M]onopoly power . . . has been defined as the ability ‘to control prices or exclude competition’”) (quotations and citations omitted); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (“[A] firm is a monopolist if it can profitably raise prices substantially above the competitive level.” (quoting 2A PHILLIP E. AREEDA ET AL., *ANTITRUST LAW* ¶ 501, at 85 (1995))).

46. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) (“[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. *See* [7 Areeda 3d ed. 2010]), ¶ 1503, at 392–393. At least, the ‘size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power’—namely, the power to charge prices higher than the competitive level. *12 id.*, ¶ 2046, at 351.”).

payment to delay competition if the brand did not have market power—there would be no point in making a payment to delay competition if existing competition had already pushed prices down to the competitive level.

There are two ways that plaintiffs can prove that [Brand Company] has market power: through either direct evidence or indirect evidence.⁴⁷ Either way is sufficient to show that [Brand Company] had market power. The plaintiffs do not need to prove market power using both direct evidence *and* indirect evidence.

To check “Yes” on Question 1, and find in plaintiffs’ favor, you need only conclude that plaintiffs have proved [Brand Company]’s market power by one of these two methods.

47. *In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (“Market power can be proven in one of two ways: either by (1) ‘direct evidence of market power (perhaps by showing actual supracompetitive prices and restricted output)’ or by (2) ‘circumstantial evidence of market power . . . [which] show[s] that the defendant has a dominant share in a well-defined relevant market and that there are significant barriers to entry in that market and that existing competitors lack the capacity to increase their output in the short run.’”) (quoting *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196–97 (1st Cir. 1996)); *see also Rebel Oil Co., Inc. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995); *Harrison Aire, Inc. v. Aerostar Int’l, Inc.*, 423 F.3d 374, 380–81 (3d Cir. 2005).

If a plaintiff establishes market power via direct proof, the plaintiff need not also define the relevant market. *See Nexium*, 968 F. Supp. 2d at 388 n.19 (“[T]he Direct Purchasers may not even need to allege a relevant market in order to state their Sherman Act claims.”); *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 460–61 (1986) (“[P]roof of actual detrimental effects, such as a reduction of output, can obviate the need for an inquiry into market power”) (quotations omitted); *Re/Max Int’l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1018 (6th Cir. 1999) (citations omitted) (same); *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 307 n.3 (3d Cir. 2007) (same); *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 107–08 (2d Cir. 2002) (same); *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (same); *Flegel v. Christian Hosp.*, 4 F.3d 682, 688 (8th Cir. 1993) (same); *Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, 899 F.2d 951, 966–67 (10th Cir. 1990) (same); *see also Eric L. Cramer & Daniel Berger, The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F.L. REV. 81, 85–86 (2004).

PROPOSED JURY INSTRUCTION 8

2. Direct Proof of Market Power

I will now instruct you on the first method of proving market power, direct proof of market power. Under the direct method, plaintiffs can meet their burden by showing that [Brand Company] had the ability to maintain prices above competitive levels⁴⁸ or to exclude competition for a significant period of time.⁴⁹ The “competitive level” is the price that would be charged in a market with full and fair competition.

In considering whether there is direct proof of [Brand Company]’s power to control prices and exclude competition, you may consider what [Brand Company] and its generic competitors expected would occur if a generic version of [brand name drug] became available. In other words, if [Brand Company] expected that a generic version of [brand name drug] would be priced significantly below the brand and would take sales from the brand, then you may conclude that [Brand Company] had market power over [drug]. You may also consider whether [Brand Company] was earning higher than competitive profit margins—if [Brand Company] did not have market power such profit margins would have been competed away.⁵⁰ Finally, remember that patents themselves help to assure market power, and that a brand company without market power is unlikely to pay large sums to induce others to stay out of its market.⁵¹

If you find by direct proof that [Brand Company] had market power over [generic name of drug], then you must answer Question 1 “Yes,” for the plaintiffs, and move on to Question 2. If you do not find by direct proof that [Brand Company] had market power over [generic name of drug], you must continue your deliberations as to Question 1 and must

48. *Nexium*, 968 F. Supp. 2d at 389 (“Market power can be proven in one of two ways,” including “direct evidence of market power (perhaps by showing actual supracompetitive prices and restricted output)”) (quoting *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196–97 (1st Cir. 1996)).

49. See ABA MODEL JURY INSTRUCTIONS, *supra* note 41, at C-23 (“[M]onopoly power is the power to control prices and exclude competition in a relevant antitrust market. More precisely, a firm is a monopolist if it can profitably raise or maintain prices substantially above the competitive level for a significant period of time.”)

50. *Actavis*, 133 S. Ct. at 2236 (“[T]he Commission has referred to studies showing that reverse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power.”).

51. *Id.*

decide whether there is indirect proof of [Brand Company]'s market power.

PROPOSED JURY INSTRUCTION 9

3. Indirect Proof of Market Power in a Relevant Market

I will now instruct you on the second method of proving market power, through indirect proof. Again, plaintiffs are not required to prove market power using both methods, so you only need to reach this second method if you find that plaintiffs did not prove market power through direct evidence.

This second approach requires plaintiffs to show that it is more likely than not that [Brand Company] had market power in a relevant market.

The term “market” has a special meaning in antitrust law, and is not used the same way that you or I use the term “market” in our everyday or business conversations. Whether products are in the same market for antitrust purposes depends on whether a seller of one product faces enough price competition from the seller of another product so that the first seller cannot profitably raise or maintain its price above competitive levels.⁵² If there is such price competition, then the two products are in

52. *Nexium*, 968 F. Supp. 2d at 387–88 (“The reasonable interchangeability of a set of products is not dependent on the similarity of their forms or functions; instead, [s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.”) (quoting *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc.*, 508 F.2d 547, 552 (1st Cir. 1974)); *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 437–38 (3d Cir. 1997) (“products in a relevant market are characterized by a cross-elasticity of demand, in other words, the rise in price of a good within a relevant product market would tend to create a greater demand for other like goods in the market”) (internal quotes and citations omitted); *Spirit Airlines, Inc. v. N.W. Airlines, Inc.*, 431 F.3d 917, 933 (6th Cir. 2005) (“[R]easonable interchangeability may be gauged by . . . consumer response (cross-elasticity); that is, consumer sensitivity to price levels at which they elect substitutes for the defendant’s product or service”); *FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1240–42 (8th Cir. 2011) (two drugs deemed to be in separate markets due to lack of price competition although they treat the same ailment); *Lucas Auto. Eng’g, Inc. v. Bridgestone/Firestone, Inc.*, 275 F.3d 762, 767 (9th Cir. 2001); *Syufy Enterps. v. Am. Multicinema, Inc.*, 793 F.2d 990, 994 (9th Cir. 1986) (market analysis must consider not only whether products are “interchangeable in use” but also “whether there is ‘cross-elasticity of demand’ between excluded and included products”); *SmithKline Corp. v. Eli Lilly & Co., Inc.*, 575 F.2d 1056, 1064–65 (3d Cir. 1978) (despite Lilly’s evidence that “for virtually every purpose for which hospital physicians use cephalosporins, they also use other antibiotics . . . the cephalosporins and non-cephalosporin anti-infectives do not demonstrate significant positive cross-elasticity of demand insofar as price is concerned,” and should therefore not be placed in the relevant product market); *Allen-Myland, Inc. v. Int’l Bus. Machines Corp.*, 33 F.3d 194, 206 (3d Cir. 1994) (“The key test for determining whether one product is a substitute for another is whether there is a cross-elasticity of demand between them: in other words, whether the demand for the second good would

the same relevant market; if there is not such price competition, they are not.

Here, plaintiffs' position is that the relevant product market is branded and generic versions of [drug] only. Defendants' position is that the relevant market includes other drugs that treat the same disease or disorder as [drug].

A relevant antitrust market can be limited to a single prescription drug such as a brand name drug and its generic prescription equivalents.⁵³

For antitrust purposes, "a relevant market is made up of commodities reasonably interchangeable by consumers for the same purposes."⁵⁴ The reasonable interchangeability of a set of products does not depend on the similarity of their forms or functions; instead, "[s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes."⁵⁵ There is cross elasticity of demand between two products if an increase in the price of one causes unit sales of the other to increase.

The mere fact that other drugs may be used to treat the same conditions as [drug at issue] does not tell you anything about [Brand Company]'s market power.⁵⁶ The relevant question is whether those other products constrained or restricted [Brand Company]'s ability to charge above-competitive prices for [brand name drug]—that is, did [Brand Company] drop the price of [brand name drug] or lose significant sales when those other products entered the market? If other products did not constrain [Brand Company] from selling prescription [drug] at

respond to changes in the price of the first"); *Auburn News Co. v. Providence Journal Co.*, 504 F. Supp. 292, 302 (D.R.I. 1980), *rev'd on other grounds by* 659 F.2d 273 (1st Cir. 1981) (citing *Brown Shoe, Co., Inc. v. United States*, 370 U.S. 294 (1962)) ("When one gets down to brass tacks, or any other specific product, almost all products have substitutes: even buses, skywriters and road signs compete with newspapers for advertising. Antitrust law, however, is only concerned with products reasonably interchangeable with one another, in other words, products for which there is some cross elasticity of demand").

53. *Nexium*, 968 F. Supp. 2d at 388 (citing *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005)); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680–81 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003); *see also* *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2008 WL 169362, at *7 (S.D.N.Y. Jan. 18, 2008).

54. *Nexium*, 968 F. Supp. 2d at 387 (citing *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956) (internal quotations omitted)).

55. *Id.* at 388 (citing *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc.*, 508 F.2d 547, 552 (1st Cir. 1974)); *accord Brown Shoe Co.*, 370 U.S. at 325.

56. *Id.* (citing *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 n.1 (8th Cir. 1988)).

prices higher than the competitive level, those products are not in the same relevant market as [drug at issue].

To determine whether another drug is in the relevant market with prescription [drug], you should consider whether a small but significant increase in the price of prescription [drug] for a sustained period of time would result or did result in a substantial number of consumers switching from prescription [drug] to another drug. During the trial, you have heard this referred to as the “SSNIP” test for “small but significant non-transitory increase in price.” A significant increase in price is 5% or more; non-transitory means the price increase was in effect for a lasting period of time, for example a year.⁵⁷

The parties agree that the relevant geographic market is the United States.

Once you define the relevant market, you must determine whether [Brand Company] has market power within that market.

If you find that the relevant market is limited to brand and generic versions of [drug at issue], then you are finding that [Brand Company] has market power because [Brand Company] had 100% of such a market since it sold all of that drug during the relevant time, and you are finding for the plaintiffs.

On the other hand, if you find that the relevant market includes, for example, all other drugs that treat the same condition as [drug], then you must determine whether [Brand Company] nevertheless has market power within that market. In making that determination, you may consider such facts as [Brand Company]’s market share within that

57. See ABA MODEL JURY INSTRUCTIONS, *supra* note 41, at C-7–C-8 (“To determine whether products are reasonable substitutes for each other, you should consider whether a small but significant permanent increase in the price of one product would result in a substantial number of consumers switching from that product to another. Generally speaking, a small but significant increase in price is approximately a five percent increase in price not due to external cost factors If you find that such switching would occur, then you may conclude that the products are in the same product market.”); U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, HORIZONTAL MERGER GUIDELINES § 4.1 (2010) (reciting the “hypothetical monopolist test” and defining relevant product market to include only those products that if a “small but significant non-transitory increase in price” were taken, purchasers would switch to alternative products); *In re Se. Milk Antitrust Litig.*, 739 F.3d 262, 277–78 (6th Cir. 2014) (applying hypothetical monopolist test in context of geographic market; “[u]sing the hypothetical monopolist as an entity that controls all the suppliers in a proposed market, a question is posed: could a monopolist profit if it imposed a ‘small but significant non-transitory increase in price’ (‘SSNIP’)? Typically, the increase that is posited is five percent. If buyers in a defined area would respond to a small, lasting increase in price—a SSNIP—by purchasing from another supplier, rendering the SSNIP unprofitable, the market has been too narrowly defined.”) (footnotes and citation omitted).

market, as well as indications of market power such as those I detailed above.

If you find that plaintiffs have proven that [Brand Company] has market power over prescription [drug] through indirect proof, you have found for plaintiffs on this question and you must answer “yes” to Question 1 and proceed to Question 2. If you find that plaintiffs have not proven market power over prescription [generic name of drug] either through direct **or** indirect proof, you must answer “no” to Question 2 and you have found for the defendants.

PROPOSED JURY INSTRUCTION 10

B. Patent Settlements Can Violate the Antitrust Laws

Before I move to Question 2 on the Verdict Sheet, I want to provide some general instructions about the settlement of pharmaceutical patent litigation and plaintiffs' claims.

You have heard evidence that [Brand Company] has various patents that allegedly cover [Brand name drug]. This is not a patent case, however, and in deciding whether defendants' agreement violated the antitrust laws, you do not have to and are not being asked to decide whether any of [Brand Company]'s patents was or was not valid, or was or was not infringed by [Generic Company]. As of the time that [Brand Company] and [Generic Company] reached the agreements that plaintiffs challenge, [Generic Company] asserted that [Brand Company]'s patents covering [Brand name drug] were [invalid or not infringed or both]. The patent issues were being litigated. [Generic Company] was challenging the patents and [if applicable] no court decision in the patent cases had been reached. A patent:

[M]ay or may not be valid, and may or may not be infringed. '[A] valid patent excludes all except its owner from the use of the protected process or product[.]' And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an invalidated patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe.⁵⁸

In this case, it is not your role to determine whether [Brand Company]'s patents are valid, or would have been infringed.⁵⁹ Rather, you are to consider whether the antitrust laws were violated by an alleged payment from [Brand Company] to [Generic Company] to delay the entry date for generic version of [drug]. Plaintiffs here are purchasers of [drug] and are, broadly speaking, alleging that the [Brand Company-Generic Company] agreement reached on [Date] delayed the availability of generic [drug] in the United States and violated the antitrust laws. Antitrust law protects competition, and so alleging that defendants

58. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013).

59. The court may need to decide whether the patent merits are relevant to the question, for example, of causation depending on the plaintiff's theory of causation.

violated the antitrust laws means that the defendants are alleged to have harmed competition.

If [Brand Company] paid [Generic Company] to avoid the risk that its patents would be held invalid or not infringed, or to maintain its profits from [brand name drug], or to delay the date when generic versions of [brand name drug] would be available, that payment can violate the antitrust laws.⁶⁰

Patent settlements can sometimes violate the antitrust laws,⁶¹ and plaintiffs do not need to prove that [Brand Company]'s patents covering [Brand name drug] were either invalid or not infringed in order to prove that the [Brand Company-Generic Company] settlement violated the antitrust laws.

60. *Actavis*, 133 S. Ct. at 2236–37.

61. *Id.* at 2232.

PROPOSED JURY INSTRUCTION 11**C. Sherman Act Section 1 and State Laws****1. Plaintiffs Allege Payments to Delay Generic Entry**

The plaintiffs challenge the agreement(s) between [Brand Company] and [Generic Company], in evidence as Exhibit(s) [___], that provided that [Generic Company] would not launch its generic until [Date], [or unless another generic launched earlier][if applicable], and [if applicable] that [Brand Company] would not launch an “authorized generic” version of [Brand name drug] during the first 180 days after [Generic Company] was on the market. [Or other time period as applicable] [If applicable] [Brand Company] and [Generic Company] also entered into additional agreements that plaintiffs allege included large payments that are in evidence as [Exhibits ____].

Plaintiffs allege that [Brand Company] made a large payment to [Generic Company] through the “no authorized generic” or “No AG” promise in Exhibit ____, [and/or] through the other agreements, Exhibits _____, and in return, [Generic Company] agreed not to launch its generic [drug] until [date]. [Add more detail of agreements at issue as applicable].

PROPOSED JURY INSTRUCTION 12

2. Section 1 Prohibits Contracts, Combinations and Conspiracies That Unreasonably Restrain Trade.

To establish that an agreement is a violation of Section 1 of the Sherman Act and the state laws, the plaintiffs must prove the following by a preponderance of the evidence:

First, the existence of a contract or combination or conspiracy between [Brand Company] and [Generic Company]. You may find that the agreements signed by [Brand Company] and [Generic Company] constitute such a contract or combination or conspiracy between them.⁶² Plaintiffs are not required to prove some other agreement.

Second, that the contract or combination or conspiracy unreasonably restrained trade;⁶³ and

62. 15 U.S.C. § 1 (2012) (emphasis added) (“Every *contract* . . . in restraint of trade . . . is declared to be illegal.”); *United States v. Am. Linen Supply Co.*, 141 F. Supp. 105, 115 (N.D. Ill. 1956) (“Section 1 of the Sherman Act condemns restraints of trade whether effected by means of contracts or by means of a conspiracy.”) (citing *Int’l Salt Co. v. United States*, 332 U.S. 392 (1947)); *United States v. Nat’l Football League*, 116 F. Supp. 319, 321 (E.D. Pa. 1953) (football league by-laws constituted contract in violation of Section 1 of Sherman Act), *superseded by statute*, Sports Broadcasting Act of 1961, 15 U.S.C. § 1291, *as recognized in Shaw v. Dallas Cowboys Football Club, Ltd.*, 172 F.3d 299, 302 (3d Cir. 1999). If direct evidence of an agreement is present, there is no need to present the jury with an elaborate instruction concerning how to assess whether there is an agreement using circumstantial evidence. *Cf. In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 n.7 (3d Cir. 2004) (noting “strictures of *Matsushita* do not apply when a plaintiff provides direct evidence of a conspiracy” because “no inferences are required from direct evidence to establish a fact and thus a court need not be concerned about the reasonableness of the inferences to be drawn from such evidence.”) (discussing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986)).

63. Plaintiffs do not need to define the relevant market if market power can be shown directly, *e.g.*, through proof of high profit margins or anticompetitive effects. *See Nexium*, 968 F. Supp. 2d at 388 n.19 (“[T]he Direct Purchasers may not even need to allege a relevant market in order to state their Sherman Act claims”); *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447, 460–61 (1986) (quotations omitted) (“[P]roof of actual detrimental effects, such as a reduction of output, can obviate the need for an inquiry into market power”); *Re/Max Int’l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1018 (6th Cir. 1999) (citations omitted) (same); *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 307 n.3 (3d Cir. 2007) (same); *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 107–08 (2d Cir. 2002) (same); *Rebel Oil Co. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (same); *Flegel v. Christian Hosp., Ne.-Nw.*, 4 F.3d 682, 688 (8th Cir. 1993) (same); *Reazin v. Blue Cross & Blue Shield of Kansas, Inc.*, 899 F.2d 951, 966–67 (10th Cir. 1990) (same); *see also Cramer & Berger*, *supra* note 47.

However, to the extent that plaintiffs must prove market power, that showing is subsumed under the second element of restraint of trade.

Third, that the restraint caused delay of the entry of one or more generic versions of [drug] into the market.⁶⁴

Source: ABA MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES (2005) A-3, Instruction 2 (modified).

64. [If applicable] The parties have stipulated that defendants' conduct affects interstate commerce, so that element is not listed separately. The parties have also stipulated that defendants' conduct affects intrastate commerce, so that element is not listed separately.

PROPOSED JURY INSTRUCTION 13

3. The Rule of Reason

Under Section 1 of the Sherman Act and analogous state laws, a restraint of trade is illegal only if it is found to be unreasonable. You must determine, therefore, whether the restraints challenged here—the alleged payments and the delay of the entry of generic [drug] into the market—are unreasonable. In making this determination, you must determine whether the plaintiffs have proven that the challenged restraint has harmed competition. The questions on the verdict sheet and my instructions will guide your deliberations on this issue.

Source: ABA MODEL JURY INSTRUCTIONS IN CIV. ANTITRUST CASES (2005) A-4, Instruction 3A (modified).

PROPOSED JURY INSTRUCTION 14

D. Large Payment [Question 2]

Question 2 on the verdict sheet asks you “Did the settlement of the [Brand-Generic] patent litigation involve a large payment by [Brand Company] to [Generic Company]?”

A “large” payment includes one that is more than [Brand Company]’s reasonably estimated saved patent litigation costs in settling with [Generic Company].⁶⁵ If you find that any payment made or promised by [Brand Company] to [Generic Company] was more than the amount that [Brand Company] reasonably would have had to pay its patent lawyers to continue its patent case against [Generic Company] to completion, or to settle it without making a large payment, whichever is less, then [Brand Company]’s payment to [Generic Company] was “large.” Recall that you heard evidence from both plaintiffs and defendants regarding estimates of [Brand Company]’s saved litigation costs.

[As applicable] You also heard evidence concerning the size or dollar value of the “no authorized generic” or “No AG” promise made by [Brand Company] to [Generic Company]. And you heard evidence of the payments made or promised by [Brand Company] to [Generic Company] through the other agreements they reached.

Defendants may try to show that the size of the payment was no more than the money that [Brand Company] would have paid its own lawyers to pursue its patent suit had it not settled its patent case against [Generic Company]; that is, the payment was not “large.”⁶⁶ Or, defendants may try to show that the payment constituted fair value for services to be provided within the same market as [Brand name drug]⁶⁷

65. *Actavis*, 133 S. Ct. at 2236.

66. *Id.* at 2236 (noting that “offsetting or redeeming virtues are sometimes present” if the payment was “no more than a rough approximation of the litigation expenses saved through the settlement”); *id.* (payment may reflect “traditional settlement considerations . . . , such as avoided litigation costs”).

67. *Law v. NCAA*, 902 F. Supp. 1394, 1406 (D. Kan. 1995), *aff’d*, 134 F.3d 1010 (10th Cir. 1998); *see also* *Paladin Assocs., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1157 n.11 (9th Cir. 2003) (based on *Topco*, procompetitive effects in one market cannot justify anticompetitive effects in a separate market); *Los Angeles Mem. Coliseum Comm’n v. Nat’l Football League*, 726 F.2d 1381, 1392 (9th Cir. 1984) (“[T]he relevant market provides the basis on which to balance competitive harms and benefits of the restraint at issue.”); *In re NCAA Student-Athlete Name & Likeness Licensing Litig.*, 37 F. Supp. 3d 1126, 1151 (N.D. Cal. 2014) (“[T]he NCAA cannot restrain competition in the ‘college education’ market for Division I football and basketball recruits or in the ‘group licensing’ market for Division I football and basketball teams’ publicity rights in order to promote competition in those

by [Generic Company]; that is, the payment was not at all for the purpose of causing delay.⁶⁸ For example, a brand manufacturer might prove that it simply paid a generic manufacturer an amount that it would otherwise pay its lawyers, and a payment of that size cannot necessarily be said to be obtaining more protection from competition than the manufacturer could reasonably expect to result from the patent lawsuit.

If you find that payments made by [Brand Company] to [Generic Company] as provided for in the agreements were for “fair value,” that is not necessarily a defense, however, if you find the agreements compensated [Generic Company] for agreeing to delay the generic entry date until [date].⁶⁹ In other words, even if the payment made by the brand to the generic company could be considered “fair value” for service the generic agreed to provide, if you find the reason the brand provided this business opportunity to the generic was that the generic agreed to delay launching its generic version of [drug], you may find that the payment was “large.”

markets for women’s sports or less prominent men’s sports.”). *Accord Actavis*, 133 S. Ct. at 2236 (payments might be justified when they “reflect compensation for other services that the generic has promised to perform—such as distributing *the patented item* or helping to *develop a market for that item*”) (emphasis added); *Sullivan v. Nat’l Football League*, 34 F.3d 1091, 1112 (1st Cir. 1994) (suggesting (though not holding) that “it seems improper to validate a practice that is decidedly in restraint of trade simply because the practice produces some unrelated benefits to competition in another market”).

68. *Actavis*, 133 S. Ct. at 2236 (noting that “offsetting or redeeming virtues are sometimes present . . . if the “payment . . . reflect[s] compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item.”); *id.* (payment may reflect “traditional settlement considerations . . . , such as . . . fair value for services”).

69. See *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, Nos. 2:06-CV-1797, 2:06-CV-1833, 2:06-CV-2768, 2:08-CV-2141, 2015 WL 356913, at *15 (E.D. Pa. Jan. 28, 2015).

PROPOSED JURY INSTRUCTION 15

1. Brands and Generics Do Not Need to Make or Receive Payments in order to Settle Patent Cases.

Remember that in the patent lawsuit between [Brand Company] and [Generic Company], there were no money damages for [Brand Company] to recover from [Generic Company]. That is because [Generic Company] had not entered the market with its generic and so could not be liable to [Brand Company] for infringement damages. Although there is no damage claim to compromise in Hatch-Waxman patent cases like this, brand and generic pharmaceutical companies can still settle their patent cases while also obeying the law by simply compromising on the date when the generic may enter the market.⁷⁰ No large payment by the brand to the generic company is needed or necessary to reach this type of lawful settlement. The idea behind such a lawful settlement is that the brand and generic will bargain with each other over the strengths and weaknesses of the patent suit brought by the brand against the generic. The brand will naturally say it has a strong case and so the date when the generic enters the market should be later, while the generic will argue the opposite, that the brand's patent is invalid or not infringed or both, and so the entry date should be earlier. When the brand and generic negotiate a settlement in this way, the entry date that they agree upon is generally considered fair and reasonable and therefore the settlement is generally considered lawful.⁷¹

If the brand makes a large payment to the generic, however, the payment likely delays the entry date. The logic is that if the brand company makes a large payment to the generic, the brand must be getting something from the generic in return. As the Supreme Court has held, unless the defendants provide some other explanation, what the brand is getting in return is likely an anticompetitive agreement by the generic to delay the introduction of its generic drug.⁷² The delay does not have to be a delay of [Generic Company]'s own generic, but can include delaying other generics because [Generic Company] has 180 days of

70. *Actavis*, 133 S. Ct. at 2237.

71. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751–52 (E.D. Pa. 2014).

72. *Actavis*, 133 S. Ct. at 2236 (holding that an “unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival” which “in turn suggests that the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market”).

exclusivity, and so a payment to delay [Generic Company] can have the foreseeable effect of delaying other generic companies.

PROPOSED JURY INSTRUCTION 16

2. Unlawful Payments Can Be in a Form Other than Cash

[If applicable] A payment by a brand company to a generic does not have to be in cash to be illegal. A payment can take other forms, including the form of a promise by [Brand Company] not to launch an authorized generic during [Generic Company]’s 180-day exclusivity period.⁷³ Remember that [Brand Company] was free to launch an authorized generic version of [drug] at any time; nothing in Hatch-Waxman or any other law or regulation could have prevented [Brand Company] from launching an authorized generic version of its own brand drug whenever it wished to, including during [Generic Company]’s 180 days of exclusivity. That exclusivity period would only stop other generic companies from obtaining approval from the FDA, but has no application to authorized generics. Therefore, if [Brand Company] promised [Generic Company] that it would not launch an authorized generic in return for [Generic Company]’s promise to not launch a generic until [date], [Brand Company]’s promise can constitute a large payment. [If applicable] If you find that [Brand Company] made such a promise in exchange for [Generic Company]’s promise to not to launch its generic, I instruct you that the payment was large, because there is no dispute its dollar value was much larger than any possible saved litigation costs.

73. *In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516 (SRU), __ F. Supp. 3d __, 2015 WL 1311352, at *11 (D. Conn. March 23, 2015) (“A majority of courts to have examined the issue” have concluded “that ‘payment’ is not limited to cash transfers.”) (collecting cases). *Id.* at *13–14 (brand’s agreement not to introduce an authorized generic can constitute unlawful payment to generic); *Niaspan*, 42 F. Supp. 3d at 751–52 (same); *Nexium*, 42 F. Supp. 3d at 262 (finding that unlawful reverse payments are not limited to monetary payments); *Nexium*, 968 F. Supp. 2d at 392 (“Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment . . . This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone. Adopting a broader interpretation of the word ‘payment,’ on the other hand, serves the purpose of aligning the law with modern-day realities.”); *see also* *Time Ins. Co. v. AstraZeneca AB*, No. 14-4149, 2014 WL 4933025, at *3, *9 (E.D. Pa. Oct. 1, 2014) (order granting plaintiff’s motion to remand) (reverse payments may “take forms other than cash”).

PROPOSED JURY INSTRUCTION 17

E. Weighing Likely Anticompetitive Effects and Procompetitive Justifications [Question 3]

The third question asks you “Was [Brand Company’s] settlement with [Generic Company] unreasonably anticompetitive, i.e., do the likely anticompetitive effects of the agreement(s) outweigh any procompetitive justifications shown by the defendants for the payment(s)?”

Plaintiffs allege that [Brand Company] made a large payment to [Generic Company] to get [Generic Company] to agree to accept [date] as the date for generic entry. According to plaintiffs, this payment violated the antitrust laws because it induced [Generic Company] to quit its challenge to [Brand Company’s] patents, agree to the [date] entry date, and thereby delay the entry of—and prevent consumers from having access to—competing, less expensive, generic versions of prescription [drug].

Plaintiffs may demonstrate a likely harmful effect on competition if they can show that [Brand Company] made a large payment to [Generic Company] to eliminate the risk [Brand Company] faced of losing the patent lawsuit, or to delay generic competition, or to maintain and to share patent-generated monopoly profits.⁷⁴

There is no dispute that [Brand Company] and [Generic Company] entered into a settlement agreement relating to [drug]. The agreement was introduced into evidence. [If applicable] There is no dispute that [Brand Company] and [Generic Company] entered into an agreement that provided that [Brand Company] would not introduce an “authorized generic” version of [Brand name drug] during [Generic Company]’s 180-day exclusivity period. [If applicable] There is no dispute that [Brand Company] and [Generic Company] entered into other agreements at the same time.

[As applicable] The parties do dispute, however, whether [Brand Company]’s promise concerning an authorized generic constituted a payment to [Generic Company] in exchange for [Generic Company]’s agreement to delay launching its generic until [Date]. And the parties dispute whether the other agreements that [Brand Company] entered

74. *Actavis*, 133 S. Ct. at 2234–35; *see also id.* at 2236 (“The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.”).

into with [Generic Company] were ways for [Brand Company] to pay [Generic Company] for delay, or were instead solely for “fair value,” meaning [Brand Company] was paying [Generic Company] fair value for actual goods or services that [Generic Company] provided rather than in any way paying for the purpose of or in exchange for delay.

Those disputes are for you to decide.

To find for plaintiffs, you do not need to find that all the agreements that [Brand Company] and [Generic Company] entered into included large payments from [Brand Company] to [Generic Company]. To find for the plaintiffs, it is enough if you find that any of those agreements, either alone or in combination, contained a large payment.

Defendants are entitled to defend this case by showing that any payment that [Brand Company] made to [Generic Company] was justified by some pro-competitive effect or benefit.

Defendants have the burden of producing evidence to show any such procompetitive justification.⁷⁵

Any proposed procompetitive justification must explain why *the payment* was procompetitive. Put differently, it is not enough for the defendants to show that settling their patent case generally, on any terms, was procompetitive; the defendants must show that consumers benefited from *the payment itself* because the payment is what is being

75. *Actavis*, 133 S. Ct. at 2236 (holding the “antitrust *defendant may show* in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term”) (emphasis added); *id.* at 2237 (“one who makes such a payment may be unable to explain and to justify it”); *Nexium*, 42 F. Supp. 3d at 262 (holding that upon proof of anticompetitive intent through means such as the size and scale of the reverse payment, “*the burden then shifts to the Defendants to show that a challenged payment was justified by some pro[competitive] objective. For example, ‘[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.’*”) (quoting *Actavis*, 133 S. Ct. at 2236 (emphasis added)). This is consistent with the general rule that defendants have the burden of proving procompetitive justifications in rule of reason cases. See *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003) (“Once that initial burden is met, the burden of production shifts to the defendants, who must provide a procompetitive justification for the challenged restraint.”) (citing *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir. 1993)); *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993) (“If a plaintiff meets his initial burden of adducing adequate evidence of market power or actual anti-competitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently procompetitive objective.”); *Se. Milk Antitrust Litig.*, 739 F.3d at 272 (if plaintiff meets initial burden “the burden then shifts to the defendant to produce evidence that the restraint in question has ‘procompetitive effects’ that are sufficient ‘to justify’ the otherwise anticompetitive injuries.”) (alteration in original) (citations omitted); 7 PHILIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1504(b) (2003) (“[T]he burden shifts to the defendant to show that the restraint in fact serves a legitimate objective.”).

challenged, and brand and generic companies can settle legally without payments.

A payment is “unjustified” if it was made for (1) the purpose of delaying generic competition or (2) eliminating the risk of generic competition or (3) to permit the brand company to share patent-generated monopoly profits with its generic competitor.⁷⁶ Although [Brand Company] and [Generic Company] may have reasons that they preferred to settle with large payments going from [Brand Company] to [Generic Company], the relevant question for you in this trial is: “What are those reasons?” If the basic reason that [Brand Company] and [Generic Company] preferred to settle with large payments was a “desire to maintain and to share patent-generated monopoly profits . . . the antitrust laws are likely to forbid the arrangement.”⁷⁷ If you find that maintaining or sharing monopoly profits was the basic reason for the [Brand Company]-[Generic Company] payment, you may find the payment from [Brand Company] to [Generic Company] was unjustified.

If you find the reason for the payment was to eliminate the risk of competition, then it is unjustified. In other words, [Brand Company] and [Generic Company] settled their patent litigation, but if you find that [Brand Company] made a large payment to [Generic Company] to eliminate the risk that [Brand Company] would lose the patent litigation between them, then the payment was unjustified.⁷⁸

Further, if you find the payment was made to delay generic competition, you must find the payment was unjustified.⁷⁹

76. *Actavis*, 133 S. Ct. at 2236–37.

77. *Id.* at 2237.

78. *Actavis*, 133 S. Ct. at 2236 (paying to “prevent the risk of competition” is “the relevant anticompetitive harm”).

79. *Id.* at 2237.

PROPOSED JURY INSTRUCTION 18

F. Impermissible Defenses

1. Patents Are Not A Defense.

As I have mentioned, there are certain defenses or justifications for a large payment that you may *not* consider, meaning they are simply not proper legal defenses and you may not consider them.

Under the law, [Brand Company] and [Generic Company] are not immune from antitrust liability just because [Brand Company] had patents relating to [drug]. The mere fact that [Brand Company] has patents relating to [drug] that expired after [date of entry provided under agreement being challenged]—is not a defense.⁸⁰ Under the law, a brand company holding a patent must still obey the antitrust laws, and a patent does not immunize or shield the defendants' conduct from liability under the antitrust laws.⁸¹ The patent laws do not allow a brand pharmaceutical company with a patent to pay a generic competitor to quit its patent challenge and stay away from the brand's market.⁸²

80. *Id.* at 2230–31 (“[T]o refer, as the Circuit referred, simply to what the holder of valid patent could do does not by itself answer the antitrust question.”); *id.* at 2231 (“The paragraph IV litigation in this case put the patent’s validity at issue, as well as its actual preclusive scope.”); *id.* at 2236 (“[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.”).

81. *Id.* at 2231.

Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well. And indeed, contrary to the Circuit’s view that the only pertinent question is whether ‘the settlement agreement . . . fall[s] within’ the legitimate ‘scope’ of the patent’s ‘exclusionary potential,’ this Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent . . . [R]ather than measure the length or amount of a restriction solely against the length of the patent’s term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.

Id. (internal citations omitted).

82. *Id.* at 2233 (rejecting the notion that “a patent holder may simply ‘pa[y] a competitor to respect its patent’ and quit its patent invalidity or noninfringement claim”) (alteration in original).

Plaintiffs do not have to prove that any of [Brand Company]’s [Brand name drug] patents are invalid or would not have been infringed in order to prove that defendants violated the antitrust laws.⁸³ The antitrust laws restrict the ways that brand and generic companies may legally settle their patent lawsuits. Brand and generic companies, as I told you, are allowed to settle without large payments going from the brand to the generic, by simply compromising on the date of generic entry.

Put simply, the defendants are not immune from antitrust laws merely because [Brand Company] had patents. Instead, you must follow my instructions to decide whether or not there is liability in this case under the antitrust laws.⁸⁴

83. See *Aggrenox*, 2015 WL 1311352, at *9–11 (plaintiff need not plead or prove that the brand’s patent is invalid or not infringed, but rather plead and ultimately prove that brand made a large payment to the generic).

84. *Actavis*, 133 S. Ct. at 2230 (rejecting the argument that one party’s ownership of a patent which, “if valid and infringed, might have permitted it to charge” high drug prices because the patent does not “immunize the [alleged reverse payment] agreement from antitrust attack”); *id.* at 2231 (A “*valid* patent excludes all except its owner from the use of the protected process or product But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe.”) (citation and internal quotation marks omitted).

PROPOSED JURY INSTRUCTION 19**2. Permitting Entry Before the Last Patent Expires Is Not a Defense.**

You may *not* consider as a defense the fact that the [Brand Company] and [Generic Company] agreement permitted a generic to launch before the last patent related to [drug] expired.

Under the law, [Brand Company] and [Generic Company] are not immune from antitrust liability just because their agreement permitted generic entry before [Brand Company]'s last patent relating to [drug] expired.

The issue for you to decide is instead whether by making a large payment to [Generic Company], [Brand Company] was able to delay the date on which generic [drug] would have otherwise been available in the United States.⁸⁵

85. *Id.* at 2230 (even if “the agreement’s anticompetitive effects fall within the scope of the exclusionary potential of the patent . . . we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack”) (citation and internal quotation marks omitted); *see also* Edlin et al., *supra* note 7, at 16, 20–21.

PROPOSED JURY INSTRUCTION 20

3. Settling Based On “Business Reasons” Is Not A Defense.

You may *not* consider the fact that [Brand Company] and/or [Generic Company] decided to settle for “business reasons” as a defense.

Under the law, [Brand Company] and [Generic Company] are not immune from antitrust liability just because they decided to settle with a payment for “business reasons” or that a settlement with a payment made “business sense.”

Defendants cannot avoid antitrust liability by claiming that their agreements made business sense because the agreements helped or protected their profits.⁸⁶ Breaking the antitrust laws may let a lawbreaker make more money; but that is no defense.

86. See, e.g., *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 221 (1940) (“Ruinous competition, financial disaster, evils of price cutting and the like appear throughout our history as ostensible justifications for price-fixing. If the so-called competitive abuses were to be appraised here, the reasonableness of prices would necessarily become an issue in every price-fixing case. In that event the Sherman Act would soon be emasculated.”); *id.* at 221 (“Congress . . . has not permitted the age-old cry of ruinous competition and competitive evils to be a defense to price-fixing conspiracies.”); *Freeman v. San Diego Ass’n of Realtors*, 322 F.3d 1133, 1152 n.24 (9th Cir. 2003) (“It does not matter that Fallbrook and Valley Center would have operated at a loss in a competitive environment. Their precarious financial situation may have explained their intransigence, but it does not transform it into a viable defense. If there is any argument the Sherman Act indisputably forecloses, it is that price fixing is necessary to save companies from losses they would suffer in a competitive market.”); see *Socony-Vacuum Oil Co.*, 310 U.S. at 221. (“While a competitor who fixes prices to stem his losses may be a more sympathetic character than one who does so to fatten his purse, he enjoys no favored legal position.”); *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 695–96 (1978) (rejecting defense that agreed ban on competitive bidding benefitted consumers); *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 116–17 (1984) (rejecting defense that agreed rule restricting televised games boosted attendance at live games); *LePage’s, Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) (defense that defendant was merely “act[ing] in furtherance of its economic interests does not constitute the type of business justification that is an acceptable defense to § 2 monopolization”); *Meijer Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 63 n.24 (D.D.C. 2008) (“[a]lthough the Court does not reach the merits of Barr’s proffered procompetitive benefits, the Court notes that ‘benefits’ are only procompetitive when they promote and protect competition, not competitors . . . and when they do not rely on the assumption that competition itself is unreasonable”) (citations omitted).

As the Supreme Court explained in *Actavis*, “[i]f the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.” *Actavis*, 133 S. Ct. at 2237.

PROPOSED JURY INSTRUCTION 21

4. Avoidance Of Risk In The Patent Litigation Is Not A Defense.

You may *not* consider as a defense the fact that [Brand Company] and [Generic Company] avoided risk in their patent litigation by settling.

Under the law, [Brand Company] and [Generic Company] are not immune from antitrust liability just because they settled to avoid risk.

[Brand Company] cannot justify any large payment to [Generic Company] as a way to avoid the risk that [Brand Company] might lose its patent infringement lawsuit and consequently any exclusivity it had with respect to [Brand name drug].⁸⁷ “The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And ... that consequence constitutes the relevant anticompetitive harm.”⁸⁸

Nor can [Generic Company] try to justify agreeing to a large payment as a way to avoid the risk it would lose the patent case. It may be that [Brand Company] made the payment, and [Generic Company] took it, to avoid the risks of what would happen in their patent suit. But that is not a defense. To the contrary, if you conclude that the payment was made by [Brand Company] and accepted by [Generic Company] to avoid the risks of patent litigation, you should conclude that the payment was unjustified.⁸⁹

87. The Supreme Court has explained that a brand name drug company’s mere desire to settle and forestall the danger of losing its infringement action or to protect its monopoly profits are examples of anticompetitive harm, not valid justifications. *Actavis*, 133 S. Ct. at 2236–37 (“The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”) (citing 12 AREEDA ¶ 2046, at 350–52 (3d. ed. 2012)).

88. *Id.*

89. *Id.* at 2236–37.

PROPOSED JURY INSTRUCTION 22

5. Legality of Agreement Not Dependent on Who Would Have Won or Lost Patent Case

You have heard that [Brand Company] and [Generic Company] were involved in litigation over [Brand Company]’s patents on [drug], but as I have explained, you do not need to decide who would have won the patent cases. The question is whether defendants’ agreement contained a large payment that delayed generic entry.

If you conclude, for example, that a fair and reasonable settlement between [Brand Company] and [Generic Company], one without a large payment, would have included a date for generic entry before [date], you can conclude that the payment delayed generic entry. For the purposes of determining harm to competition, you should follow my instructions on that and you should not try to decide who you think may actually have won, or lost, the patent cases.⁹⁰

90. Reverse payment agreements raise anticompetitive concerns because they foreclose brand company patent risks. *Actavis* explicitly states “the payment (if otherwise unexplained) likely seeks to prevent the *risk* of competition. And, as we have said, *that consequence constitutes the relevant anticompetitive harm.*” *Actavis*, 133 S. Ct. at 2236 (emphasis added). When an agreement arises out of an infringement lawsuit, by definition the actual preclusive power of the patent is in doubt. A patent “may or may not be valid, and may or may not be infringed.” *Id.* at 2231. And while a “valid patent excludes all except its owner from the use of the protected process or product . . . an invalidated patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe.” *Id.* A “paragraph IV litigation . . . put[s] the patent’s validity at issue, as well as its actual preclusive scope. The parties’ settlement end[s] that litigation.” *Id.* Ultimately, questions concerning the putative strength of the patent are subsumed by the jury’s consideration of the large payment. *Actavis*, 133 S. Ct. at 2236 (“An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival. And that fact, in turn, suggests that the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.”); *Id.* at 2236–37 (“In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”) (citing 12 P. AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶ 2046, pp. 350–52 (3d ed. 2012)); *Actavis*, 133 S. Ct. at 2237 (“Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.”).

PROPOSED JURY INSTRUCTION 23

G. Plaintiffs May Rebut By Showing Likely Anticompetitive Effects Outweigh Any Legitimate Procompetitive Benefits

If defendants can demonstrate a procompetitive justification for any large payment, the burden then shifts back to the plaintiffs, who must show that the restraints are, on balance, likely anticompetitive.⁹¹ You must balance the likely competitive benefits of the payments against their competitive harms. If the likely competitive harms outweigh the likely competitive benefits, then the challenged restraint is unreasonable.

Plaintiffs also may satisfy their burden by showing that defendants' asserted procompetitive goals could have been adequately addressed by means less restrictive of competition.⁹² In other words, plaintiffs can prevail if they can show, for example, that defendants could have settled on terms that accomplished the procompetitive benefits proven by

91. See *King Drug Co.*, 2015 WL 356913, at *7–8; *Nexium*, 42 F. Supp. 3d. at 262–63 (“If the Defendants can demonstrate a pr[o]competitive justification, the burden shifts back to the Plaintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance.”) (citing *Sullivan v. Nat’l Football League*, 34 F.3d 1091, 1111 (1st Cir. 1994) (“[T]he rule of reason analysis requires a weighing of the injury and the benefits to competition attributable to a practice that allegedly violates the antitrust laws.”)).

92. See *Silver v. New York Stock Exch.*, 373 U.S. 341, 361 (1963) (“[S]elf-regulation is to be regarded as justified in response to antitrust charges only to the extent necessary to protect the achievement of the aims of the Securities Exchange Act”); *Nat’l Society of Prof’l Engr’s v. United States*, 435 U.S. 679, 699–700 (1978) (Blackmun, J., concurring) (“For even accepting petitioner’s assertion that product quality is one such benefit, and that maintenance of the quality of engineering services requires that an engineer not bid before he has made full acquaintance with the scope of a client’s desired project [. . .] petitioner Society’s rule is still grossly overbroad.”); *Sullivan*, 34 F. 3d at 1103 (“One basic tenet of the rule of reason is that a given restriction is not reasonable, that is, its benefits cannot outweigh its harm to competition, if a reasonable, less restrictive alternative to the policy exists that would provide the same benefits as the current restraint.”); *Kreuzer v. Am. Acad. of Periodontology*, 735 F.2d 1479, 1494–95 (D.C. Cir. 1984) (“[E]ven if evidence existed in the record to support the asserted justification that the limited practice requirement improved the quality of patient care, it must be shown that the means chosen to achieve that end are the least restrictive available.”); *Addamax Corp. v. Open Software Found., Inc.*, 888 F. Supp. 274, 283 (D. Mass. 1995) (“If the defendant then comes forward with a legitimate justification for the conduct, the plaintiff must show that the same legitimate purpose could have been obtained through less restrictive means.”); see also *Wilk v. Am. Med. Ass’n*, 719 F.2d 207, 227 (7th Cir. 1983) (reversing district court and advising that on remand “[t]he jury should be instructed in appropriate language to the following effect: [. . .] that [defendants’ asserted procompetitive goal] could not have been adequately satisfied in a manner less restrictive of competition.”), *aff’d*, 735 F.2d 217 (1983).

defendants but did not include a large payment to [Generic Company] that delayed generic entry until [date]. If the competitive harm does not outweigh the likely competitive benefits, then the challenged restraint is not unreasonable. In conducting this analysis, you must consider the likely benefits and harm to competition and consumers, not just to a single competitor or group of competitors.⁹³

93. *Cf.* ABA MODEL JURY INSTRUCTIONS, *supra* note 41, at A-12, Instruction 3-D (“If you find that the challenged restraint was reasonably necessary to achieve competitive benefits, then you must balance those competitive benefits against the competitive harm resulting from the same restraint. If the competitive harm substantially outweighs the competitive benefits, then the challenged restraint is unreasonable. If the competitive harm does not substantially outweigh the competitive benefits, then the challenged restraint is not unreasonable. In conducting this analysis, you must consider the benefits and harm to competition and consumers, not just to a single competitor or group of competitors.”).

PROPOSED JURY INSTRUCTION 24**H. Causation**

If you answer Questions 1–3 “yes,” then you must answer Questions 4, 5, and 6.

The basic injury that all plaintiffs allege is that they paid more for [drug] than they would have paid for generic versions of [drug] had such generics become available before [date], and the difference in price between what plaintiffs paid and what they would have paid is called an “overcharge.” [If applicable] You are not, in this trial, determining the dollar amount of any overcharges plaintiffs may have suffered; you are answering questions which—if you find for the plaintiffs—can be used later to determine that amount.

PROPOSED JURY INSTRUCTION 25**1. Market Entry Before [Date] [Question 4]**

Question 4 asks: “Had it not been for the [Brand-Generic] agreement(s), would a generic version of [drug] have come to market before [date allowed under the challenged settlement]?”

PROPOSED JURY INSTRUCTION 26

a. Material Cause of Delay

The plaintiffs must show that [Brand Company] and [Generic Company]’s conduct in entering into settlement agreement(s) that include large and unjustified payments caused a delay in the availability of generic [drug]. Plaintiffs allege that absent [Brand Company]’s payments to [Generic Company], one or more generic versions of [drug] would have reached the market before [date]. To the extent that the plaintiffs’ injuries were caused by [Brand Company] and [Generic Company]’s agreement(s), then those injuries are the result of an unlawful reduction in competition and they constitute antitrust injury.⁹⁴

For the purposes of this trial, you need only determine if defendants’ agreement(s) were a material cause of the delay of generic [drug].⁹⁵ Plaintiffs meet their burden if they show that the defendants’ agreement substantially contributed to the delay, even though other factors may have also contributed to the delay and plaintiffs’ injuries.⁹⁶

You should keep in mind that, in seeking to prove this, plaintiffs are given a considerable amount of leeway or latitude in proving what would have happened but for defendants’ agreement.⁹⁷ Proving *what would*

94. The First Circuit is “fully aware of the difficulty of proving [antitrust] injury and the concomitant need to apply ‘lenient’ standards of proof.” *Allen Pen Co. v. Springfield Photo Mount Co.*, 653 F.2d 17, 21–22 (1st Cir. 1981).

95. See *Nexium*, 42 F. Supp. 3d at 267 (“Plaintiffs need not prove that the antitrust violation was the sole cause of their injury, but only that it was a material cause.”) (quoting *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 14 (1st Cir. 1979)); see also *Coastal Fuels Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 194 (1st Cir. 1996) (“[I]n order to collect damages as a private plaintiff, Coastal must show that CAPECO’s offense was a ‘material cause’ of injury.”); *Addamax Corp. v. Open Software Found., Inc.*, 964 F. Supp. 549, 554 (D. Mass. 1997) (to prevail on an antitrust claim, a plaintiff “must show that [defendant’s antitrust] violation was a ‘material cause’ of its injury”); *In re Prograf Antitrust Litig.*, No. 11-MD-02242, 2014 WL 4745954, at *6 (D. Mass. Jun. 10, 2014) (“To prevail on an antitrust claim, a plaintiff ‘must show that [defendant’s antitrust] violation was a ‘material cause’ of its injury.”) (quoting *Addamax*, 964 F. Supp. at 554).

96. See *Nexium*, 42 F. Supp. 3d at 267 (“An antitrust violation can be the proximate cause of a plaintiff’s injury even if there are additional independent causes of the injury.”) (quoting *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627–28 (E.D. Pa. 2011)); see also *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 n.9 (1969) (“It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury . . .”).

97. *Standard Oil Co. of Ca. v. United States*, 337 U.S. 293, 309–10 (1949) (“[T]o demand that bare inference be supported by evidence as to what would have happened but

have happened had the defendants not broken the antitrust laws is “rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts.”⁹⁸ “When a firm has engaged in anticompetitive conduct, courts should be reluctant to demand too much certainty in proving that such conduct caused anticompetitive harm because ‘[t]o some degree, the defendant is made to suffer the uncertain consequences of its own undesirable conduct.’”⁹⁹

for the adoption of the practice that was in fact adopted or to require firm prediction of an increase of competition as a probable result of ordering the abandonment of the practice, would be a standard of proof, if not virtually impossible to meet, at least most ill-suited for ascertainment by courts.”; involving claim for injunctive relief); *Zenith Radio Corp.*, 395 U.S. at 123 (recognizing “practical limits” on the burden of proving antitrust injury; proving *what would have happened* is “rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts”) (emphasis added); *Sullivan v. Nat’l Football League*, 34 F.3d 1091, 1103–05 (1st Cir. 1994) (affirming jury verdict even though “the evidence of causation is not overwhelming” because plaintiff presented a feasible hypothetical scenario of what would have happened, absent the defendant’s anticompetitive conduct, through expert testimony which “provided enough of a basis for [the expert’s] opinions and had sufficient facts to back [the] opinions up”); *In re Microsoft Corp. Antitrust Litig.*, 699 F. Supp. 2d 730, 748 (D. Md. 2010) (“When a firm has engaged in anticompetitive conduct, courts should be reluctant to demand too much certainty in proving that such conduct caused anticompetitive harm because ‘[t]o some degree, the defendant is made to suffer the uncertain consequences of its own undesirable conduct.’”), *rev’d on other grounds*, 429 F. App’x 254 (4th Cir. 2011) (quoting 3 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 651c, at 78); *Spear Pharm., Inc. v. William Blair & Co.*, 610 F. Supp. 2d 278, 285 (D. Del. 2009) (FDA’s delay in approving a generic manufacturer’s ANDA did not break the chain of causation originating from the defendant’s citizen petition, because “to qualify as a superseding cause, the cause must be unforeseeable. According to Plaintiffs, the delay of their ANDA was not only foreseeable, but intended.”) (citations omitted).

98. *Zenith Radio Corp.*, 395 U.S. at 123.

99. *In re Microsoft Corp.*, 699 F. Supp. 2d at 748.

PROPOSED JURY INSTRUCTION 27

b. Plaintiffs Need Not Prove Defendants Were The Sole Cause Of Delay

Plaintiffs do not have to prove that defendants' agreement was the sole, or only, cause of the delay in the availability of generic [drug] before [date]. Nor do plaintiffs need to identify or eliminate all other factors that could potentially contribute to the delayed availability of generic versions of [drug] before [date].

Plaintiffs are not required to show that the defendants' acts were a greater cause of delay than other factors. Plaintiffs need only show that the delay to some degree resulted from the defendants' agreement.¹⁰⁰

Plaintiffs may recover even if there is an additional cause of plaintiffs' injury, if that additional cause was itself caused by defendants' antitrust violation, or if that other cause was a foreseeable consequence of the defendants' original antitrust violation.¹⁰¹

100. U.S. Football League v. Nat'l Football League, 644 F. Supp. 1040, 1052 (S.D.N.Y. 1986), *aff'd*, 842 F.2d 1335 (2d Cir. 1988) (affirming use of similar instruction); *see also* KEVIN F. O'MALLEY, JAY E. GRENIG & HON. WILLIAM C. LEE, 3A FED. JURY PRAC. & INSTR. §§ 150:70–150:71 (6th ed.); 3A FED. JURY PRAC. & INSTR. §§ 150:70–150:71 (6th ed.); Drumgold v. Callahan, No. 11-CV-01304, 2013 U.S. App. LEXIS 2301, at *49–50 (1st Cir. Jan. 31, 2013) (citing RESTATEMENT (THIRD) OF TORTS § 27 (reviewing the “concurrent causation principle”)); United States v. Kearney, 672 F.3d 81, 98 (1st Cir. 2012) (citing W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 41, at 268 (5th ed. 1984); RESTATEMENT (THIRD) OF TORTS § 27 (2010) (“If multiple acts occur, each of which under § 26 alone would have been a factual cause of the physical harm at the same time in the absence of the other act(s), each act is regarded as a factual cause of the harm.”)); Haverhill Gazette Co. v. Union Leader Corp., 333 F.2d 798, 806 (1st Cir. 1964) (adopting in antitrust context the “usual rule” of tort law that “a plaintiff may recover for loss to which defendant's wrongful conduct substantially contributed, notwithstanding other factors contributed also” and plaintiff need not prove challenged conduct is a “more substantial [cause] than any other”) (citing RESTATEMENT OF TORTS § 431 (1934) (internal quotes omitted)). “[A]ntitrust violations are essentially ‘tortious acts.’” Associated Gen. Contractors of Cal., Inc. v. Carpenters, 459 U.S. 519, 547 (1983). Consequently, “venerable principles of tort causation” apply in antitrust cases. Jack Walters & Sons Corp. v. Morton Bldg., Inc., 737 F.2d 698, 708–09 (7th Cir. 1984); *see also* Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp., 959 F.2d 468, 486 (3d Cir. 1992) (same); DAN B. DOBBS ET AL., THE LAW OF TORTS § 189 (2d ed. 2011) (“It would be a windfall [if the actor] were to escape liability for the harm merely because another [force] was also sufficient to cause the same harm.”); W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 41 (5th ed. 1984).

101. *Nexium*, 42 F. Supp. 3d at 269 (“Thus, to distill these cases, summary judgment on questions of causality is not appropriate where the plaintiff was injured by intervening conduct proximately caused by the defendant's antitrust action, or where such intervening conduct was a foreseeable consequence of the defendant's antitrust action. Summary

PROPOSED JURY INSTRUCTION 28

If you find that the defendants' conduct was not a material cause of the delay of entry of generic [drug]—that is, did not contribute to the delay of generic [drug] in any way—then you should find for the defendants on Question 4.

judgment is appropriate, however, where there is insufficient proof of causation, or where the intervening conduct was independently caused by a government actor.”); *see also id.* at 268 (“drawing from the common law principles of proximate cause, courts have held that intervening conduct ‘does not sever the chain of causation where that [third-party] conduct was a foreseeable consequence of the original antitrust violation’”) (quoting *Flonase*, 798 F. Supp. 2d at 627–28); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, 2010 U.S. Dist. LEXIS 36303, at *21–28 (D. Del. Apr. 13, 2010) (noting challenged sham litigation may have caused excluded generic company to divert resources from its ANDA pursuit; lack of FDA approval does not require dismissal for lack of standing/causation); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756–57 (E.D. Pa. 2003) (FDA approval not required; noting allegedly frivolous lawsuit may have caused generic company to divert resources from pursuing its ANDA and “generated circumstances which are responsible for the lack of FDA approval itself”); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 2013 U.S. Dist. LEXIS 70968, at *57 (E.D. Tenn. May 20, 2013) (FDA approval not necessary); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 545–46 (D.N.J. 2000) (same); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901–02 (7th Cir. 2004) (generic competitor could state claim even though it had yet to file an ANDA). *Accord In re Pharm. Indust. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 207–08 (D. Mass. 2004) (holding that an “intervening act” breaking chain of causation must “be unforeseeable and completely independent of any act undertaken by the original actor”).

PROPOSED JURY INSTRUCTION 29

2. Reasonable Estimate As To When A Generic [Brand name drug] Would Have Come To Market [Question 5]

Question 5 asks you “If so, what is a reasonable estimate as to when?”, and asks you to estimate a month and year.

If you answer “Yes” to Question 4, you *must* provide a reasonable estimate of the date on which a generic version of [drug] would have come to market.

Plaintiffs’ theory is that had there not been an antitrust violation, [explain theory].

In estimating the date for Question 5, you may conclude or decide that there is some uncertainty. If defendants’ agreement has made it difficult to decide exactly when a generic would have entered without their unreasonably anticompetitive agreement in place, then the defendants are not allowed to benefit from that uncertainty.¹⁰² The law prohibits a defendant whose own unlawful conduct has created uncertainty about the damage a plaintiff has suffered, or as applicable here, the date a generic would have entered, from benefitting from that same uncertainty.¹⁰³ So you should estimate the date as best you can based on the evidence,¹⁰⁴ but you must not speculate.

102. *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264 (1946) (“where the defendant by his own wrong has prevented a more precise computation, the jury may [. . .] make a just and reasonable estimate of the damage based on relevant data and render its verdict accordingly [. . .] juries are allowed to act on probable and inferential as well as (upon) direct and positive proof. Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim. It would be an inducement to make wrongdoing so effective and complete in every case as to preclude any recovery, by rendering the measure of damages uncertain.”) (citations omitted); *see also id.* at 265–66 (“Difficulty of ascertainment is [not to be] confused with right of recovery.”) (quoting *Story Parchment*, 282 U.S. at 565); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 272 (D. Mass. 2004) (Young, J.).

103. *Bigelow*, 327 U.S. at 265 (“The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created.”); *see also Eastman Kodak Co. v. S. Photo Materials Co.*, 273 U.S. 359, 379 (1927) (“a defendant whose wrongful conduct has rendered difficult the ascertainment of the precise damages suffered by the plaintiff, is not entitled to complain that they cannot be measured with the same exactness and precision as would otherwise be possible”); *J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 566–67 (1981) (“[o]ur willingness to accept a degree of uncertainty in these cases rests in part on the difficulty of ascertaining business damages as compared, for example, to damages resulting from a personal injury or from condemnation of a parcel of land. The vagaries of the marketplace usually deny us sure knowledge of what plaintiff’s situation would have been in the absence of the defendant’s antitrust violation. But our willingness also rests on the principle

PROPOSED JURY INSTRUCTION 30

3. Authorized Generic Entry [and other entry] [Questions 6-8]

[If applicable] Question 6 asks “Would an authorized generic have entered at or about the same time?”

Once you have estimated the date in answering Question 5, you should decide whether, had such a generic entered, [Brand Company] would have launched its own authorized generic at or about the same time. This is just a yes or no question. The same rules about uncertainty that I just gave you apply to this question too.

[If applicable] Question 7 asks “Would additional generics have entered thereafter?” Once you have estimated the date in answering Question 5, you should decide whether, had such a generic entered, other generic companies [identify] would have entered also. This is just a yes or

articulated in cases such as *Bigelow*, that it does not come with very good grace for the wrongdoer to insist upon specific and certain proof of the injury which it has itself inflicted”).

104. See *MCI Commc'ns Corp. v. AT&T*, 708 F.2d 1081, 1161 (7th Cir. 1983) (“Once causation of damages has been established, the amount of damages may be determined by a just and reasonable estimate . . .”); *Comeau v. Rupp*, 810 F. Supp. 1127, 1144 n.8 (D. Kan. 1992) (“By urging the court to refuse consideration of this deposition testimony, the Accountants fail to recognize that plaintiff’s proof of causation in this case is rendered more difficult by the very nature of the claims: negligent omissions on the part of defendants that in turn caused inaction on the part of the RCSA Board. Because this necessarily poses the causation question of what “would have” happened if the Accountants had adequately fulfilled their duties, it is difficult to understand how the FDIC could prove its case without at least some of the testimony that the Accountants deride as “self-serving” and “speculative.” To accept the Accountants’ argument would allow them to profit from an uncertainty of their own creation, notwithstanding that [t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created.”) (internal quotation and citations omitted); *DeLoach v. Philip Morris Cos., Inc.*, 206 F.R.D. 551, 564 (M.D.N.C. 2002) (“A plaintiff in an antitrust case need only introduce evidence sufficient for a jury to estimate the amount of damages.”) (citing *Bigelow*, 327 U.S. at 264–65); *Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 484 (3d Cir. 1998) (“Once causation is established, the jury is permitted to calculate the actual damages suffered using a reasonable estimate, as long as the jury verdict is not the product of speculation or guess work.”) (internal quotation and citation omitted); *Momand v. Universal Film Exchs., Inc.*, 172 F.2d 37, 43–44 (1st Cir. 1948), *cert. denied*, 336 U.S. 967 (1949) (“It is well appreciated that a plaintiff has a difficult task in an anti-trust suit and that adherence to strict requirements of proof as to exact quantity of damage may deprive him of the substance of his rights. The law has gone far to ease that burden by permitting proof of losses which border on the speculative, in order to implement the policy of the anti-trust laws.”).

no question. If you answer “yes,” then you must answer Question 8, which asks “If so, what is a reasonable estimate as to how many and when?” In answering this question, the same rules about uncertainty I gave you before apply to this question too.

UNITED STATES DISTRICT COURT
DISTRICT OF _____

IN RE: PRESCRIPTION DRUG) MDL No. _____
ANTITRUST LITIGATION) CIVIL ACTION No.:
) _____

JURY VERDICT

1. Did [Brand Company] exercise market power over prescription [generic name of drug]?

_____ no _____ yes

2. Did the settlement of the [Brand-Generic] patent litigation involve a large payment by [Brand Company] to [Generic Company]?

_____ no _____ yes

3. Was [Brand Company's] settlement with [Generic Company] unreasonably anticompetitive, i.e., do the likely anticompetitive effects of the agreement(s) outweigh any procompetitive justifications shown by the defendants for the payment(s)?

_____ no _____ yes

4. Had it not been for the [Brand-Generic] agreement(s), would a generic version of [drug] have come to market before [date allowed under the challenged settlement]?

_____ no _____ yes

5. If so, what is a reasonable estimate as to when?

_____, 20____.
Month Year

6. [If applicable] Would an authorized generic have entered at or about the same time?

_____ no _____ yes

7. [If applicable] Would additional generics have entered thereafter?

_____ no _____ yes

8. If so, what is a reasonable estimate as to how many and when?

Number _____, Entry Date _____

Number _____, Entry Date _____

Date:

Foreperson