IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY
This Document Relates To: All Actions	

PLAINTIFFS' SUBMISSION FOLLOWING THE OCTOBER 15, 2014 HEARING REGARDING PROPOSED JURY VERDICT FORM

In accordance with the colloquy with the Court on October 15, 2014, Plaintiffs[1] submit this brief on two issues regarding the Court's proposed verdict sheet.

I. The Plaintiffs' Market Power Verdict Slip Request

First, Plaintiffs respectfully request that the Court delete the following italicized words from Question 2 of the proposed verdict sheet: "Did AstraZeneca exercise market power *within the relevant antitrust market*?" Under controlling First Circuit law that this Court has already held applies to the facts of this case, there is no need to prove a relevant market where, as here, Plaintiffs intend to prove AstraZeneca's market power over Nexium directly.[2]

Second, given the law's unequivocal position that only market power need be shown in this case, and that the final jury instructions will adequately educate the jury on how the concepts of market power relate to the elements required to satisfy the rule of reason in accordance with *Actavis*, no purpose is served by imposing on the jury the need to answer a separate market power question. The Court should therefore simply strike the question in its entirety.

[1] Plaintiffs include the Direct Purchaser Class Plaintiffs, the End-Payor Class Plaintiffs, and Plaintiffs in the *Walgreen* (No. 13-cv-10337-WGY), *Giant Eagle* (No. 13-cv-11305-WGY), *Rite Aid* (No. 13-cv-12074-WGY), and *CVS* (14-cv-11788) actions.

[2] *See In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (denying motions to dismiss) (citing *Costal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996)).

Short Argument

As this Court explained in its opinion denying the motions to dismiss:

> 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." *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996). *This Court need not engage in an extensive analysis of circumstantial evidence of market power because direct evidence of such power is available*—the Direct Purchasers have thoroughly alleged that AstraZeneca, in its position as a monopolist, has been able to charge supracompetitive prices for brand Nexium.[3]

The Court further explained:

> What is more, in this particular case, the Direct Purchasers may not even need to allege a relevant market in order to state their Sherman Act claims. *The relevant market serves merely as a proxy for market power when direct evidence of market power is unavailable.* IIB Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 531a, at 232 (3d ed. 2007) ("Finding the relevant market and its structure is typically not a goal in itself but a mechanism for considering the plausibility of antitrust claims that the defendants' business conduct will create, enlarge, or prolong market power."). *But see id.* ¶ 531a, at 233 ("Even when direct measures of power are feasible, courts would still find market definition useful . . . . Thus, while market definition and computation of market share is often said to be a surrogate for more 'direct' measures of market power, it is often more than a surrogate."). *Where direct evidence of market power is available, however, a plaintiff need not attempt to define the relevant market. Id.* ¶ 531f, at 241. *Such appears to be the case here*, see Direct Purchasers' Compl. ¶¶ 143-145, 147-151 (alleging that "[AstraZeneca] had the power to maintain the price of the drug it sold as Nexium at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Nexium, with the exception of AB-rated generic versions of Nexium," *id.* ¶ 143, and that "AstraZeneca . . . enjoyed high barriers to entry with respect to competition . . . due to patent and other regulatory protections and high costs of entry and expansion," *id.* ¶ 150), *which would tend to eliminate the need formally to define a relevant*

[3] *Nexium*, 968 F. Supp. 2d at 389 (emphasis added).

> *market, see Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97.[4]

In *Coastal Fuels*, the First Circuit held that market power can be shown through either direct evidence of supracompetitive prices *or* evidence of dominance in a well-defined relevant market:

> Market power can be shown through two types of proof. A plaintiff can either show direct evidence of market power (perhaps by showing actual supracompetitive prices and restricted output) or circumstantial evidence of market power … by showing that the defendant has a dominant share in a well-defined relevant market.[5]

Plaintiffs have now stipulated to dismissal of their Section 2 claims, and will be proceeding at trial under Section 1 of the Sherman Act.[6] Because Plaintiffs will provide direct evidence of supracompetitive prices and restricted output, the jury will not need to make any findings about a relevant product market.[7] Plaintiffs alleged and will submit at trial direct evidence of market power, namely that AstraZeneca "had the power to maintain the price of . . . Nexium at supracompetitive levels without losing substantial sales to other products prescribed

[4] *Id.* at 388 n.19 (emphasis added).

[5] 79 F.3d at 196-97 (citations omitted).

[6] *See* ECF Nos. 1047 (Direct Purchaser Class Plaintiffs' Stipulation Regarding Section 2 Claims); 1048 (End-Payor Class Plaintiffs' Stipulation Regarding Certain Claims). Of course, the end-payors are pursuing claims under state law analogues.

[7] *See F.T.C. v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) ("proof 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, 1017-18 (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); *Rebel Oil Co. v. Atlantic Richfield Co*., 51 F.3d 1421, 1434 (9th Cir. 1995); *Flegel v. Christian Hosp*., 4 F.3d 682, 688 (8th Cir. 1993); *Reazin v. Blue Cross & Blue Shield of Kansas, Inc.*, 899 F.2d 951, 966-67 (10th Cir. 1990); *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of Rhode Island*, 239 F. Supp. 2d 180, 192 (D.R.I. 2003). *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 (2004).

In fact, even when a plaintiff elects to demonstrate market power through circumstantial evidence, "'finding the relevant market and its structure is not a goal in itself but a surrogate of market power.'" *Coastal Fuels*, 79 F.3d at 197 (*quoting* IIA Phillip E. Areeda et al., *Antitrust Law* ¶531a (1995)).

and/or used for the same purposes as Nexium, with the exception of AB-rated generic versions of Nexium."[8]

Plaintiffs will present primary – and direct – evidence of AstraZeneca's market power, including: (1) AstraZeneca's own internal analyses showing that only the launch of generic Nexium was expected to cause substantial drops in sales and prices for esomeprazole magnesium (Nexium) and that in the absence of an AB-rated generic, AstraZeneca was able to charge supracompetitive prices for Nexium; (2) that AstraZeneca expected to launch an authorized generic Nexium at lower prices if another generic competitor launched, but dropped those plans and destroyed the authorized generic it had manufactured after executing the series of reverse payment agreements at issue, thereby reducing output; and (3) AstraZeneca enjoyed consistently high profit margins on Nexium despite the presence of other products, demonstrating that such products did not act to constrain Nexium's price to competitive levels.

Plaintiffs will introduce expert testimony by Dr. Meredith Rosenthal, an economist who has concluded that there is abundant evidence demonstrating AstraZeneca's market power directly.

Plaintiffs will prove AstraZeneca's market power directly, without the need to define or prove a relevant market. This Court previously ruled that Plaintiffs may do precisely that under controlling First Circuit law. And, the Supreme Court in *Actavis* stated that the very fact that a brand company is willing to make large reverse payments to its generic competitors "is itself a strong indicator of . . . the power to charge prices higher than the competitive level" because a

[8] *See* Complaint ¶¶143, 144-150, 167, 169. At trial, Plaintiffs may also prove market power by circumstantial evidence.

firm "without that power" is not "likely to pay large sums to induce others to stay out of its market."[9]

If Question 2 is not stricken, it should be revised to read: "Did AstraZeneca exercise market power over Nexium?"

II. The Plaintiffs' Request Regarding Proposed Question No. 3

Plaintiffs also respectfully request that Proposed Question No. 3 be amended. The question should be amended to add the following italicized words: "Was AstraZeneca's *payment to Teva and the contingent launch provision in the* Nexium settlement with Teva unreasonably anticompetitive, i.e., do any anticompetitive effects of *those provisions* outweigh any pro-competitive justifications?"

Actavis requires the Defendants to justify *payments* in settlements, not *settlements* in and of themselves.[10]

Actavis repeatedly held that payments to eliminate *the risk* that the patents at issue would be found invalid or not infringed —the *risk* that competition would break out—was *anti*competitive.[11] Defendants cannot defend the *settlements* by arguing that they eliminated risk, as all settlements do. Instead, the defendants must show procompetitive justifications to defend why the *payments* are in the settlement. Defendants have previously offered this "risk" justification for their settlements,[12] and this Court properly rejected it as a matter of law, ruling

[9] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) (internal citations and quotations omitted).

[10] The only justifications Defendants should be permitted to advance at trial are that AstraZeneca's payments to the Generic Defendants: (1) reflected fair value for the services they provided to AstraZeneca; or (2) were no greater than AstraZeneca's saved litigation expenses. All of the other justifications that Defendants proffer are not cognizable as a matter of law.

[11] *Actavis*, 133 S.Ct. at 2233, 2236, 2237.

[12] *See* Defendant Ranbaxy's Memorandum of Law in Support of its Motion to Dismiss Direct Purchasers' Consolidated Amended Complaint, Docket No. 139, at 1, 2, 3 (arguing that Plaintiffs' Complaints should be dismissed because the settlement ended the "risks and uncertainties" of the patent litigation); AstraZeneca

that the payments had not "produced any [cognizable] countervailing procompetitive benefits whatsoever."[13]

Under the rule-of-reason, Defendants must offer a justification for the *aspect* of the agreement challenged as anticompetitive (here, the payments and contingent launch provisions).[14] "An antitrust defendant may show . . . that legitimate justifications are present, thereby explaining the presence of the *challenged term* and showing the lawfulness *of that term* under the rule of reason."[15] Here, Plaintiffs do not allege it was anticompetitive for the defendants to *settle*; rather, Plaintiffs allege that AstraZeneca's *payments* to the would-be generics[16] and contingent launch provisions are anticompetitive.

Drug manufacturers "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration,

---

Defendants' Memorandum in Support of Their Motion to Dismiss the Direct Purchasers' Consolidated Amended Complaint (Dkt. No. 131) Pursuant to Federal Rule of Civil Procedure 12(b)(6), Docket No. 135 at 1, 2, 3, 8, 9-10 (arguing that Plaintiffs' Complaints should be dismissed because the settlements provided for generic entry prior to expiration of the patents).

[13] *Nexium*, 968 F. Supp. 2d at 392-93.

[14] Nor can Defendants try to show that the agreement as a whole is procompetitive and that the anticompetitive aspect was necessary to achieve the agreement, *i.e.*, that the anticompetitive aspect is "ancillary" to an otherwise procompetitive agreement. *See, e.g.*, Hovenkamp ¶1908b (in assessing whether a restraint is ancillary, "some determination must be made whether the challenged agreement is an essential part of [the procompetitive] arrangement, or whether it is completely unnecessary," i.e. whether it is an "inherent feature" of the procompetitive arrangement or "simply an unnecessary, output-limiting appendage"). That path is not open to Defendants here, however, because *Actavis* held as a matter of law that exclusion payments are not necessary to achieve settlements. 133 S. Ct. at 2237.

[15] *Actavis*, 133 S. Ct. at 2236 (emphasis added); *see also Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 117 (1984) (defendants must justify the "specific restraints on football telecasts that are challenged in this case"); *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1112 (1st Cir. 1994) (courts must "exclude[e] justifications that are so unrelated to the challenged practice that they amount to a collateral attempt to salvage a practice that is decidedly in restraint of trade").

[16] *See, e.g.*, End-Payor Plaintiffs' Corrected Consolidated Amended Class Action Complaint, Dkt. No. 114, at ¶109 ("AstraZeneca's *payments* to the Generic Defendants under the Exclusion Payment Agreements demonstrate Defendants' anticompetitive purpose and intent.") (emphasis added); *id.* at ¶185 ("The purpose and effect of the *payments* flowing from AstraZeneca to Generic Defendants under the Agreements was to delay generic competition to Nexium and there is no legitimate, nonpretextual, procompetitive business justification for the *Exclusion Payments* that outweighs their harmful effects.") (emphasis added).

without the patentee paying the challenger to stay out prior to that point."[17] The "potential for genuine adverse effects on competition" flows from *payments* to delay generic entry, *not* settlements in general"[18]

Two examples in *Actavis* establish the Supreme Court's focus on potential pro-competitive justifications for the *payments*, not the settlements:

> The reverse *payment*, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That *payment* may reflect compensation for other services that the generic has promised to perform . . . Where 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.[19]

The Court unambiguously concluded that, "one who makes such a *payment*" must be able to "explain and to justify *it*."[20]

Thus, the justification that defendants have urged throughout this litigation—that *the settlements* eliminated the risk that the patents would be found to be invalid or not infringed—is not recognizable, and Question 3 should be amended.

Actavis holds that eliminating patent risk is *anti*competitive, not pro-competitive. *Actavis* states at least six times that the *anticompetitive* aspect of the payments is that they eliminate the risk that the patents at issue will be found invalid and/or not infringed. A payment is

---

[17] *Actavis*, 133 S. Ct. at 2237.

[18] *Id.* at 2234 (internal citation omitted); *see also, id.* at 2235 ("The *payment* may. . . provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in a competitive market.") (emphasis added); *id.* at 2235 ("The rationale behind a *payment* of this size cannot in every case be supported by traditional settlement considerations.") (emphasis added); *id.* at 2237 (by "examining the size of the payment," a court "may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent…"); *id.* (the "likelihood of a reverse payment bringing about anticompetitive effects" is based on "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification").

[19] *Id*. at 2236 (emphasis added).

[20] *Id*. at 2237 (emphasis added).

anticompetitive because it "prevent[s] *the risk* of competition," and preventing such a risk is "the relevant anticompetitive harm."[21] "[M]aintain[ing] supracompetitive prices to be shared among the patentee and the challenger rather than face *what might have been* a competitive market . . . [is] the very anticompetitive consequence that underlies the claim of antitrust unlawfulness."[22]

Here, Defendants concede – indeed, they insist – that it was uncertain who would have won the underlying patent cases. Eliminating the risk that the generics would have won – the risk that competition would have broken out – is *anti*competitive.

III. Question Regarding Authorized Generic Nexium

Finally, as discussed at the October 15 hearing, Plaintiffs propose to substitute "large" for "substantial" in Question 1, and add the following language at the end of Question 4: "and would an authorized generic version of Nexium have launched in or about that time?"

IV. Conclusion

For the foregoing reasons, Plaintiffs request that the Court amend the verdict slip as set forth herein. A copy of Plaintiffs' proposed amended jury verdict form, which incorporates these changes, is attached hereto as Exhibit 1.

[21] *Id*. at 2236; *see also id.* at 2233 (the antitrust violation occurs when "A, the plaintiff, pays money to defendant B purely so B will give up the patent fight"); *id.* at 2236 (the antitrust concern is "that a patentee is using its monopoly profits to *avoid the risk* of patent invalidation or a finding of noninfringement"); *id.* ("[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"); *id*. at 2233 (rejecting dissent approach that would permit "a patent holder [] to simply 'pa[y] a competitor to respect its patent' and quit its invalidity or noninfringement claim. . . .") (internal citation omitted).

[22] *Id*. at 2236 (emphasis added); *see also Engine Specialties, Inc.*, 605 F.2d at 15. Moreover, the three dissenting justices in *Actavis* agree. *See Actavis*, 133 S. Ct. at 2240 (Roberts, C.J., dissenting) (*Actavis* subjects payments to antirust liability where there is "'uncertainty' about whether the patent is actually valid"); *id*. at 2242 (*Actavis* "subject[s] [reverse payments] to antitrust scrutiny merely because the validity of the patent was uncertain"); *id*. at 2244 ("The majority seems to think that even if the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court."); *id*. ("[T]he majority would impose antitrust liability based on the parties' subjective uncertainty about that legal conclusion."); *id*. at 2245 (the majority's logic is "that taking away any chance that a patent will be invalidated is itself an antitrust problem").

Dated: October 16, 2014

/s/ Thomas M. Sobol
Thomas M. Sobol, BBO No. 471770
David S. Nalven, BBO No. 547220
Donna M. Evans, BBO No. 554613
Kristen A. Johnson, BBO No. 667261
HAGENS BERMAN SOBOL SHAPIRO
LLP55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Tel: (617) 482-3700
Fax: (617) 482-3003
tom@hbsslaw.com
davidn@hbsslaw.com
donnae@hbsslaw.com
kristenp@hbsslaw.com

Liaison Counsel and Co-lead Counsel for the Direct Purchaser Class

David F. Sorensen
Daniel Simons
Caitlin G. Coslett
Nicholas Urban
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel: (215) 875-3000
Fax: (215) 875-4604
dsorensen@bm.net
dsimons@bm.net
ccoslett@bm.net

Bruce E. Gerstein
Joseph Opper
Elena Chan
Ephraim R. Gerstein
GARWIN GERSTEIN & FISHER LLP
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055
Fax: (212) 764-6620
bgerstein@garwingerstein.com
jopper@garwingerstein.com
echan@garwingerstein.com
egerstein@garwingerstein.com

Co-lead Counsel for the Direct Purchaser Class

Glen DeValerio (BBO #122010)
BERMAN DeVALERIO
One Liberty Square
Boston, MA 02109
Tel: (617) 542-8300
Fax: (617) 542-1194
gdevalerio@bermandevalerio.com

Todd A. Seaver (BBO #645874)
BERMAN DeVALERIO
One California Street, Suite 900 San Francisco, CA 94111
Tel: (415) 433-3200
Fax: (415) 433-6382
tseaver@bermandevalerio.com

Liaison Counsel for the End-Payor Class

Steve D. Shadowen
HILLIARD & SHADOWEN LLC
39 West Main Street
Mechanicsburg, PA 17055
Tel: (855) 344-3298
steve@hilliardshadowenlaw.com

Anne Fornecker
Daniel Gonzales
HILLIARD & SHADOWEN LLC
919 Congress Ave., Suite 1325
Austin, TX 78701
Tel: (512) 851-8990
anne@hilliardshadowenlaw.com
daniel@hilliardshadowenlaw.com

Kenneth A. Wexler
Bethany R. Turke
Justin N. Boley
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Tel: (312) 346-2222
Fax: (312) 346-0022
kaw@wexlerwallace.com
brt@wexlerwallace.com

jnb@wexlerwallace.com

J. Douglas Richards
George Farah
Sharon K. Robertson
Hiba Hafiz
COHEN MILSTEIN SELLERS & TOLL, PLLC
88 Pine Street, 14th Floor
New York, New York 10005
Tel: (212) 838-7797
Fax: (212) 838-7745
drichards@cohenmilstein.com
srobertson@cohenmilstein.com

Jayne A. Goldstein
POMERANTZ LLP
1792 Bell Tower Lane
Suite 203
Weston, FL 33326
Tel: 954-315-3454
Fax: 954-315-3455
jagoldstein@pomlaw.com

Co-Lead Counsel for the End-Payor Class

Scott E. Perwin
Lauren C. Ravkind
Anna T. Neill
KENNY NACHWALTER P.A.
1100 Miami Center
201 South Biscayne Boulevard
Miami, FL 33131
Tel: 305-373-1000
Fax: 305-372-1861

Counsel for Walgreen Plaintiffs

Barry L. Refsin
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER
One Logan Square, 27th Floor
Philadelphia, PA. 19103
Tel: 215-568-6200

Monica L. Rebuck
HANGLEY ARONCHICK SEGAL

PUDLIN & SCHILLER
4400 Deer Path Road, Suite 200
Harrisburg, PA 17110
Tel.: 717-364-1007

Counsel for Rite Aid and CVS

Bernard D. Marcus
Moira Cain-Mannix
Brian C. Hill
Erin Gibson Allen
MARCUS & SHAPIRA LLP
One Oxford Centre, 35th Floor
Pittsburgh, PA 15219
Tel.: 412-338-3344

Counsel for Giant Eagle, Inc.

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: October 16, 2014

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