

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

THE HOSPITAL AUTHORITY OF)	
METROPOLITAN GOVERNMENT OF)	
NASHVILLE AND DAVIDSON)	
COUNTY, TENNESSEE, d/b/a/)	
NASHVILLE GENERAL HOSPITAL,)	NO. 3:15-cv-01100
)	JUDGE CRENSHAW
Plaintiff,)	
)	
v.)	
)	
MOMENTA PHARAMCEUTICALS,)	
INC., and SANDOZ, INC.)	
)	
Defendants.)	

MEMORANDUM OPINION

Before the Court is a Report and Recommendation of the Magistrate Judge (“R&R”) (Doc. No. 114) recommending that the Court deny Defendants’ joint Motion to Transfer (Doc. No. 58), Defendant Momenta Pharmaceuticals, Inc.’s (“Momenta”) Motion to Dismiss or Transfer for Improper Venue (Doc. No. 62), and Defendants’ joint Motion to Dismiss (Doc. No. 65). Defendants have filed timely objections to the R&R (Doc. Nos. 117 & 119), and Plaintiff has responded (Doc. Nos. 123–24). Defendants have filed two Motions for Leave to File a Reply (Doc. Nos. 125–26), which Plaintiff has opposed (Doc. No. 127). Those motions for leave to reply are hereby **GRANTED**. The Court has reviewed the R&R, the parties’ briefs, and conducted a de novo review of the record. For the following reasons, the Court **ADOPTS in part** and **DECLINES TO ADOPT in part** the R&R. Momenta’s Motion to Dismiss or Transfer and the joint Motion to Transfer are **DENIED**. Defendants’ joint Motion to Dismiss is **GRANTED in part** and **DENIED in part**, and Plaintiff’s claims for damages are **DISMISSED**.

I. BACKGROUND¹

Plaintiff is a metropolitan hospital authority that purchases the drugs it administers, including the anticoagulant enoxaparin, from the wholesaler McKesson Corporation (“McKesson”). (Doc. No. 1 at ¶¶ 10–11.) Pursuant to its contract with McKesson, Plaintiff pays the cost of enoxaparin plus a percentage adjustment. (Id.) Enoxaparin itself was formerly subject to a patent held by non-party Sanofi-Aventis (“Aventis”), but that patent was held to be unenforceable in 2007. (Id. at ¶ 23.) Defendant Momenta, however, is the assignee of a patent for a chemical process used to test the quality of enoxaparin (“Method <207>”). In 2003, Momenta entered into a collaboration agreement with Sandoz, whereby Sandoz eventually began manufacturing and selling generic enoxaparin. (Id. at ¶¶ 39, 50) In addition to profit-sharing, the agreement calls for Momenta to receive several million dollars in “milestone payments” if Sandoz remains the sole supplier of generic enoxaparin. (Id. at ¶ 27.) Put simply, the agreement gives Momenta a powerful incentive to use whatever rights it has to prevent other parties from entering the generic enoxaparin market.

The United States Pharmacopeial Convention (“USP”) is a scientific nonprofit organization that sets standards related to the strength, quality, and purity of medications. (Id. at ¶ 32.) USP standards are enforceable as binding by the United States Food and Drug Administration (“FDA”). 21 U.S.C. § 351(b). As a “biologic” pharmaceutical—that is to say, a pharmaceutical produced through an organic process using animal tissue—with diverse-sized molecules, enoxaparin presents significant challenges in assuring consistency between batches produced. (Doc. No. 1 at ¶¶ 37–38.) In light of those challenges, by 2007, USP was considering

¹ Because this case is before the Court on motions to dismiss, the facts are set forth as alleged in the Complaint. (Doc. No. 1.)

the adoption of mandatory, standardized testing to assure that enoxaparin produced met the chemical criteria approved by the FDA. (Id. at ¶ 39.) Aventis—which, at the time, had its own patent application pending that would reach Method <207>—proposed that that method be adopted as the USP-approved test. (Id. at ¶¶ 39–42.) Defendants, who participated in the relevant USP review panel, objected to adopting a method to which Aventis would have a patent. (Id. at ¶ 42.) After discussions with USP, Aventis agreed to abandon its patent application. (Id. at ¶ 44.) Unbeknownst to the rest of the panel, however, Momenta had its own patent application pending that, when granted, would give Momenta patent rights that could arguably be asserted against third parties that used Method <207>. In December of 2009, the USP adopted Method <207>. (Id. at ¶ 47.) Momenta’s patent was issued not long thereafter. (Id. at ¶ 48.) Plaintiff posits that, if Momenta had properly disclosed its patent application, USP would either have required Momenta to abandon the application as it did with Aventis, or USP would have selected an alternative test that would not have been subject to patent protection. (Id. at ¶ 46.)

Defendants became the first entities authorized by the FDA to produce generic enoxaparin. (Id. at ¶ 50.) Amphastar Pharmaceuticals, Inc. (“Amphastar”), which is not a party to this case, received FDA approval to sell generic enoxaparin later, but Defendants promptly sued Amphastar in the District of Massachusetts to prevent it from using Method <207>. (Id. at ¶¶ 50–52.) Although Defendants initially obtained a temporary restraining order (“TRO”) and preliminary injunction, the injunction was eventually stayed and Amphastar became able to manufacture and sell generic enoxaparin—albeit belatedly. (Id. at ¶¶ 61–63.) Plaintiff alleges that, between the time the TRO was issued and when the preliminary injunction was stayed, Defendant enjoyed monopoly power in the market for generic enoxaparin. (Id. at ¶ 64.) Plaintiff claims to have been

harmful by the resultant inflated prices paid for enoxaparin. (Id. at ¶¶ 66–74.) The underlying litigation in the District of Massachusetts remains ongoing.

Plaintiff brought this case pleading four counts under the Sherman Act arising out of Defendants’ conspiracy to take advantage of the USP process to secure Sandoz’s position as the sole supplier of generic enoxaparin. (Id. at ¶¶ 81–104.) Plaintiff seeks damages, declaratory relief, and injunctive relief. (Id. at ¶¶ A-I.) Defendants seek either dismissal or transfer to the District of Massachusetts based on inappropriate venue or dismissal on the merits. The R&R recommends that those requests be denied.

II. OBJECTIONS

Although not so numbered by the Defendants, the Court identifies the following objections to the R&R from Defendants’ briefing:

1. Venue in this Court is statutorily barred under 28 U.S.C. § 1391 and the Clayton Act, 15 U.S.C. § 22 (Doc. No. 118 at 5–18);
2. If the Court determines that venue is not statutorily barred, it should nevertheless transfer the case to the district of Massachusetts as the more convenient forum (Doc. No. 120 at 15–25);
3. Plaintiff’s claims should also be dismissed because Plaintiff is an indirect purchaser who is not entitled to the so-called “cost-plus” exception (Id. at 9–13); and
4. Plaintiff’s claims should be dismissed as barred by the Noerr-Pennington doctrine² (Id. at 5–9);
5. Plaintiff’s claims should be dismissed because they are premised on a non-mandatory industry standard (Id. at 13–15).

The Court will not unnecessarily recapitulate the reasoning in the R&R on issues where the R&R is adopted.

² “Noerr-Pennington” refers to two cases: E. R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); and United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

III. PROCEDURAL ISSUES

A. Venue

The Court adopts the Magistrate Judge’s well-reasoned analysis, which follows the lead of other federal circuits that have concluded that the Clayton Act’s grant of nationwide jurisdiction in antitrust cases, 15 U.S.C. § 22 (“Section 12”), may be read in concert with the general civil venue statute’s provision establishing that a corporate defendant is considered to “reside” in any district in which it is subject to personal jurisdiction, 28 U.S.C. § 1391(c)(2). See In re Auto. Refinishing Paint Antitrust Litig., 358 F.3d 288, 296–97 (3d Cir. 2004) (“We, therefore, hold that the service of process provision on foreign corporations is independent of, and does not require satisfaction of, the specific venue provision under Section 12 of the Clayton Act.”); Go-Video, Inc. v. Akai Elec. Co., 885 F.2d 1406, 1413 (9th Cir. 1989) (“[W]e conclude that process may be served on an antitrust defendant pursuant to 15 U.S.C. § 22 in cases where venue is not established under that section but lies properly under 28 U.S.C. § 1391(d).”); Delong Equip. Co. v. Washington Mills Abrasive Co., 840 F.2d 843, 855 n.16 (11th Cir. 1988) (writing, after applying the Section 12 service of process provision, that “[b]ecause we conclude that venue is established under the general federal venue statute, we do not reach the appropriateness of venue under § 12 of the Clayton Act.”). But see KM Enters., Inc. v. Global Traffic Techs., Inc., 725 F.3d 718, 730 (7th Cir. 2013) (“Section 12 provides an additional option, but one that requires use of the service and venue rules as a package.”); Daniel v. Am. Bd. of Emergency Med., 428 F.3d 408, 427 (2d Cir. 2005) (“[Section 12’s] service of process provision can properly confer personal jurisdiction over a defendant only when the action is brought in the district . . . where Section 12 venue lies.”); GTE New Media Servs. Inc. v. BellSouth Corp., 199 F.3d 1343, 1351 (D.C. Cir. 2000) (“A party seeking to take advantage of Section 12’s liberalized service provisions must follow the dictates of both of its clauses.”). Although the language of Section 12 is ambiguous, the reading adopted

by the Magistrate Judge, as well as the Third, Ninth, and Eleventh Circuits,³ better reflects the underlying history and purposes of both the Clayton Act and the general venue statute.

Accordingly, venue is permissible in this Court. Objection 1 is overruled.

B. Convenience of Forum

The Court agrees with and adopts the Magistrate Judge’s balancing of both the “private interest” and “public interest” factors governing requests to transfer a case to a more convenient forum pursuant to 28 U.S.C. 1404(a). See Hefferan v. Ethicon Endo–Surgery Inc., 828 F.3d 488, 498 (6th Cir. 2016). While the Court recognizes that the core facts underlying the ongoing litigation in the District of Massachusetts are plainly relevant to this matter, and litigation in Massachusetts would likely be more convenient for Momenta and some witnesses, that alone is insufficient to overcome the deference afforded to Plaintiff’s choice of forum and the likely inconvenience Plaintiff would face by its action being transferred. Objection 2 is overruled.

IV. SUBSTANTIVE ISSUES

A. Standard of Review

For purposes of a motion to dismiss under Rule 12(b)(6), the Court must take all the factual allegations in the Amended Complaint as true. Ashcroft v. Iqbal, 556 U.S. 662, 677 (2009). To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face. Id. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the

³ Momenta disputes whether the Eleventh Circuit’s opinion in DeLong Equipment Co., 840 F.2d 843 at 855 n.16, can truly be read as endorsing the rule later adopted more explicitly by the Third and Ninth Circuits. The Court’s review of the Eleventh Circuit’s opinion confirms that, at the very least, that court assumed that the rule allowing an integrated reading of the general venue statute and Section 12 was applicable. In any event, a detailed parsing of this single out-of-circuit case is of little importance to the Court’s decision here.

defendant is liable for the misconduct alleged. Id. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. Id. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief. Id. at 679. A legal conclusion couched as a factual allegation need not be accepted as true on a motion to dismiss, nor are recitations of the elements of a cause of action sufficient. Fritz v. Charter Twp. of Comstock, 592 F.3d 718, 722 (6th Cir. 2010).

B. Indirect Purchaser Rule

In the prototypical antitrust case brought by a purchaser, a seller engages in some anticompetitive conduct that allows him to charge an inflated price to a buyer, and the buyer suffers the injury. That picture is complicated, however, when that innocent buyer becomes a seller himself. The initial buyer—now a middleman between the initial seller and the end consumer—may pass some or even all of the overcharge to a second buyer, or “indirect purchaser.” Generally speaking, though, federal antitrust law does not permit an indirect purchaser to “sue to recover the overcharges passed on to [it] by a middleman.” Cty. of Oakland v. City of Detroit, 866 F.2d 839, 848 (6th Cir. 1989) (citing Illinois Brick Co. v. Illinois, 431 U.S. 720, 729 (1977)). That prohibition has come to be known as the “indirect purchaser rule.” See, e.g., id. at 849.

As the Supreme Court has conceded, an unfortunate consequence of the indirect purchaser rule is that it “denies recovery to those indirect purchasers who may have been actually injured by antitrust violations.” Illinois Brick, 431 U.S. at 746. The Court nevertheless adopted the bar, not because direct purchasers are necessarily worthier plaintiffs, but to avoid injecting factual and legal complexity that could undermine the effectiveness of the antitrust enforcement regime. Id. at 745–46 (“[W]e conclude that the legislative purpose in creating a group of private attorneys general to

enforce the antitrust laws . . . is better served by holding direct purchasers to be injured to the full extent of the overcharge paid by them than by attempting to apportion the overcharge among all that may have absorbed a part of it.”). The Court expressed particular concern about requiring courts to determine, on a case-by-case basis, how much of the original seller’s overcharge was borne by the middleman, or “passer,” and how much was borne by the indirect purchaser, or “passee.” Illinois Brick, 431 U.S. at 741–42. Limiting recovery to direct purchasers, on the other hand, allows courts to avoid the “uncertainties and difficulties in analyzing price and out-put decisions ‘in the real economic world rather than an economist’s hypothetical model.’” Id. at 731–32 (quoting Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 493 (1968)).

The Supreme Court has acknowledged the possibility of an exception to the indirect purchaser rule, however, where the indirect purchaser bought the good in question pursuant to a “pre-existing cost-plus contract” whereby the “customer is committed to buying a fixed quantity regardless of price.” Id. at 736. Such contracts avoid the typical uncertainties associated with calculating indirect purchaser damages, because “[t]he effect of the overcharge is essentially determined in advance, without reference to the interaction of supply and demand that complicates the determination in the general case.” Id.

Defendants argue that the cost-plus exception does not apply here for two reasons: (1) Plaintiff failed to allege, in its Complaint, that its cost-plus contract with McKesson predates the conduct underlying this case; and (2) although Plaintiff’s contract with McKesson did include cost-plus pricing, it did not commit Plaintiff to purchasing a particular quantity of enoxaparin. As to the first of these objections, the Court adopts the well-reasoned analysis of the R&R concluding that the Court, in the interests of judicial economy, is permitted to consider not only the Complaint but Plaintiff’s supplemental declaration stating that its cost-plus contract dates to August 14, 2010.

(Doc. No. 114 at 23 (citing Doc. No. 77).) The Court is therefore permitted to acknowledge Plaintiff's adequate allegation that the purchase contract possesses "the essential characteristic of pre-existence" that would permit Plaintiff to avail itself of the cost-plus exception. Jewish Hosp. Ass'n of Louisville, Ky., Inc. v. Stewart Mech. Enters., Inc., 628 F.2d 971, 976 (6th Cir. 1980).

Defendants' second argument, however, is more persuasive. Plaintiff has been unable to produce any Supreme Court or Sixth Circuit Court of Appeals case law clearly establishing that a plaintiff is entitled to avail itself of the cost-plus exception based on a contract that does not contain a fixed purchase quantity. The R&R nevertheless concludes that the cost-plus exception applies here because the hospital must buy enoxaparin in whatever quantity is dictated by the needs of its patient population, rendering Plaintiff the "functional equivalent" of a purchaser with a fixed quantity contract. (Doc. No. 115 at 25–26 (quoting SDI Reading Concrete, Inc. v. Hilltop Basic Res., Inc., 576 F. Supp. 525, 530 (S.D. Ohio 1983))).

Plaintiff's position is perhaps best understood in the context of why the Supreme Court mentioned fixed-quantity provisions when discussing the possibility of an exception, rather than merely cost-plus pricing alone. As the Supreme Court observed in Illinois Brick, classical economic assumptions tell us that one key factor in determining how an increase in price will be apportioned between passer and passee is the relative elasticity of supply and demand in the underlying relationship.⁴ 431 U.S. at 741–42. Elasticity, the Supreme Court observed, can be difficult to measure in ordinary circumstances. Id.; see also Jewish Hosp. Ass'n, 628 F.2d at 974 ("Even under the simplifying assumptions of economic theory, calculating the amount of the pass-

⁴ "Elasticity" refers to "the responsiveness of a dependent economic variable to changes in influencing factors." *Elasticity*, Merriam-Webster Dictionary (online ed.). A product with highly elastic demand, then, would be one for which demand would dramatically decrease in response to an increase in price. Also relevant to the apportionment of the overcharge is the degree of competition in the market for the relevant product. Illinois Brick, 431 U.S. at 742.

through at any level would involve resolving conflicting expert opinions as to the elasticity of demand for the particular product.”). Demand under a preexisting fixed-quantity contract, however, is perfectly inelastic by definition, because the buyer is locked into buying a particular amount, even in the face of an increase in price. See In re Wyo. Tight Sands Antitrust Cases, 695 F. Supp. 1109, 1114 fn. (D. Kan. 1988), aff’d, 866 F.2d 1286 (10th Cir. 1989), aff’d sub nom. Kansas v. UtiliCorp United, Inc., 497 U.S. 199 (1990). A buyer who faces an increase in price under a contract with cost-plus pricing but no fixed-quantity provision, on the other hand, can choose to buy less, causing some of the overcharge to fall on the seller.⁵ Id.

Here, there is no contract term pursuant to which the Court can assume perfect inelasticity of demand. Nor can one infer inelasticity merely from the nature of the product. The sometimes grim truth is that demand for medical treatments—even unique, potentially life-saving ones—is not necessarily perfectly inelastic. The decision to choose one treatment over another may be—and in some instances is even *legally required to be*—driven by cost. A patient in this state’s Medicaid system, for example, is entitled only to coverage for care that presents “the least costly alternative course of diagnosis and treatment adequate to treat the [patient’s] condition.” John B. v. Emkes, 852 F. Supp. 2d 957, 970 (M.D. Tenn. 2012) (quoting Tenn. Comp. R. & Regs. 1200-13-16-.05(1)), aff’d, 710 F.3d 394 (6th Cir. 2013). “Where there are less costly alternative courses of diagnosis or treatment . . . that are adequate for the medical condition of the enrollee, more costly alternative courses of diagnosis or treatment are not [considered] medically necessary” and therefore are not reimbursable. Tenn. Code Ann. § 71-5-144(b)(3). Medicaid is just one

⁵ Similarly, if a contract has a fixed-quantity provision but calls for a fixed price rather than cost-plus pricing, any increase in cost will be borne by the middleman—rendering indirect purchaser liability particularly inappropriate.

example—it stands to reason that other payers may have similar or other cost control mechanisms that constrain or direct the care administered.

Plaintiff has alleged that enoxaparin has “distinct physical, chemical, and biological properties,” and that there are no other anticoagulant drugs that would be “considered as clinically equivalent to enoxaparin” or a “close substitute for enoxaparin.” (Doc. No. 1 at ¶ 19.) Mere uniqueness of a product, though, does not necessarily establish perfect inelasticity. A drug, for example, could be unique but offer only a minor advantage over otherwise adequate alternatives, such as a small reduction in the incidence of an inconvenient but not life-threatening side effect. Rational payers may be willing to pay a bit more for that benefit, but would presumably, at some price point, switch to the slightly less desirable competitor. None of this is to suggest that Plaintiff’s demand for enoxaparin in reality either is or is not elastic. Rather, the point is that trying to answer that question would require a highly situation-specific look at both the medical considerations and the economics of the underlying treatment and coverage decisions.⁶ Embarking upon that kind of tricky, situational analysis, however, “would entail the very problems that the [indirect purchaser] rule was meant to avoid.” Illinois Brick, 431 U.S. at 745.

For that reason, the Supreme Court in Illinois Brick specifically considered whether to recognize an exception for certain low-elasticity factual situations—“for example, where a price-fixed good is a small but vital input into a much larger product, making the demand for the price-fixed good highly inelastic”—and declined. Id. at 743–44. The Court similarly declined to

⁶ Another potential source for elasticity is the fact that a hospital’s patient population may not necessarily be static. One can imagine, for example, a hospital that specializes in a particular type of care, but then faces an increase in the costs of that type of care due to an increase in the related pharmaceutical prices. That hospital might choose to focus its resources on other areas of treatment, and by extension other patients. Again, this is not to say that anything of the sort has happened or would happen here—merely that the factual assumptions underlying the functional equivalent analysis are more complex than they may seem at first blush.

recognize an exception based on the peculiarities of the utilities market in Kansas v. Utilicorp, 497 U.S. at 208. There, the Court made clear that, “even assuming that any economic assumptions underlying the Illinois Brick rule might be disproved in a specific case, we think it an unwarranted and counterproductive exercise to litigate a series of exceptions.” Id. at 217. As Plaintiff points out, at least one circuit has taken a contrary approach, basing an exception to the indirect purchaser bar on situational market conditions. See In re Beef Indus. Antitrust Litig., 600 F.2d 1148, 1166 (5th Cir. 1979). Insofar as that precedent remains viable following Kansas v. Utilicorp, however, this Court still finds it incompatible with the principle that the very purpose of Illinois Brick is to avoid a market-specific inquiry.

Cost-plus contracts with fixed-quantity provisions present a unique situation, because in those transactions the inelasticity of demand exists by virtue of a legal mandate, not the factual particulars of the goods or transactions at issue. Opening the cost-plus exception to transactions that merely involve the functional equivalent of a fixed-quantity provision, however, would unavoidably lead the Court back into the factual and analytical thicket that Illinois Brick was intended to avoid. “[T]he need to inquire into the precise operation of market forces would negate the simplicity and certainty that could justify a cost-plus contract exception.” Kansas v. Utilicorp, 497 U.S. at 218. This Court will not embark down that road when the Supreme Court has so strongly cautioned against it. Objection 3 is therefore sustained: Plaintiff’s claims are subject to the indirect purchaser rule. Defendants are entitled to dismissal of Plaintiff’s claims for damages.

A number of circuits, however, have held that the indirect purchaser bar is not an obstacle to injunctive or declaratory relief. Lakeland Reg’l Med. Ctr., Inc. v. Astellas US, LLC, 763 F.3d 1280, 1290 (11th Cir. 2014); Campos v. Ticketmaster Corp., 140 F.3d 1166, 1172 (8th Cir. 1998); Lucas Auto. Eng’g, Inc. v. Bridgestone/Firestone, Inc., 140 F.3d 1228, 1235 (9th Cir. 1998);

McCarthy v. Recordex Serv., Inc., 80 F.3d 842, 856 (3d Cir.), cert. denied, 519 U.S. 825 (1996); In re Beef Indus. Antitrust Litig., 600 F.2d at 1167. This distinction arises from the courts' correctly observing that "[t]he concerns of the direct purchaser rule have mainly to do with . . . complexities . . . that do not arise when the courts must consider the propriety of injunctive relief." Campos, 140 F.3d at 1172. The thorny questions of precise apportionment of damages that underlie the rule will not be an issue insofar as a plaintiff is not permitted to seek monetary damages. The Court accordingly will join those other courts and hold that the indirect purchaser bar does not defeat Plaintiff's claims insofar as they seek purely declaratory or injunctive relief.

C. The Noerr-Pennington Doctrine

Under the Noerr-Pennington doctrine, "defendants are immune from antitrust liability for engaging in conduct (including litigation) aimed at influencing decisionmaking by the government." Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S. Ct. 1749, 1757 (2014) (citing Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56 (1993)). The Noerr-Pennington doctrine embodies "the principle that the antitrust laws regulate business, not politics." VIBO Corp. v. Conway, 669 F.3d 675, 684 (6th Cir. 2012) (quoting City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 383 (1991)). As such, "[w]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint." Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988) (quoting Noerr, 365 U.S. at 136). Noerr-Pennington immunity reaches not only cases where the anticompetitive restraint arises purely out of government action, but also those where the "anticompetitive restraint results directly from private action . . . [that] is 'incidental' to a valid effort to influence governmental action." Id. (quoting Noerr, 365 U.S. at 143).

Defendants argue that the Noerr-Pennington doctrine requires dismissal of this case because the only injury that Plaintiff has alleged is its payment of higher prices as a direct result of Momenta's patent action against Amphastar, and that patent action is a petitioning of the government (specifically, the judicial branch) for action. As the Magistrate Judge correctly observed, however, the crux of the anticompetitive scheme that Plaintiff alleges is not the patent case against Amphastar but rather Momenta's actions surrounding the purported adoption of Method <207> by the USP. That scheme happened to lead to a lawsuit between Amphastar and Momenta, Amphastar Pharm. Inc. v. Momenta Pharm., Inc., No. 16-2113, 2017 WL 876260, at *4 (1st Cir. Mar. 6, 2017) (reversing dismissal based on Noerr-Pennington doctrine), but the anticompetitive effect would have been the same if Amphastar had instead simply acquiesced to Momenta's interpretation of its rights, allowing Momenta to enjoy its monopoly without the need to resort to litigation. The ultimate competitive harm arises from the combination of the Method <207> patent rights with the method's adoption by the USP, not the fact that Momenta happened to need to go to court to enforce those rights. Objection 4 is overruled.

D. Non-Mandatory Standard


Defendants argue finally that Plaintiff's claims should be dismissed on the ground that USP's adoption of Method <207> expressly left open the possibility of using an unspecified adequate alternative test to assure that its quality standards were met. Even if that is technically true, however, the effect of the testing requirement on the market for enoxaparin depends on the relative feasibility of those other potential tests, as well as the likelihood that they would be considered adequate alternatives to Method <207> under the USP standards. If the only alternative tests are prohibitively expensive, for example, USP's testing requirement is the effective

equivalent of specifically mandating the use of Method <207> alone. The fact-intensive questions underlying this issue are inappropriate for decision on a motion to dismiss. Objection 5 is overruled.

V. CONCLUSION

For the foregoing reasons, the Court **ADOPTS in part** and **DECLINES TO ADOPT in part** the R&R. Momenta's Motion to Dismiss or Transfer and the Defendants' joint Motion to Transfer are **DENIED**. Defendants' joint Motion to Dismiss is **GRANTED in part** and **DENIED in part**, and Plaintiff's claims for damages are **DISMISSED**.

An appropriate order will issue.



WAVERLY D. CRENSHAW, JR.
UNITED STATES DISTRICT JUDGE