UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA INDIRECT PURCHASER ANTITRUST LITIGATION

No. 1:15-cv-6549 (CM) (RWL)

DECISION AND ORDER DENYING THE MOTION TO DECERTIFY THE CLASS

McMahon, J:

In ruling on the motions *in limine*, the court noted Plaintiff Class's position that exemplary (punitive) damages in this case (which is brought under numerous different state laws) would have to be calculated on a state-by-state basis – some by the court, some by the jury – unlike in the related direct purchaser plaintiff ("DPP") case, where punitive damages would be calculated by a single trier of fact under a single standard. I wondered whether the pursuit of exemplary damages in this action would render it impossible to try the issue of damages on a class-wide basis. (*See* Docket No. 890). On August 25, the court held a virtual conference to discuss the issue. Defendants made what was, in effect, a letter motion to decertify the class as to all issues, but at least as to damages. At the end of the August 25 conference, the court set a briefing schedule on that motion.

As a result, pending before the court is Defendants' motion to decertify the class. (*See* Docket No. 897). Defendants argue that the damages portion of this case (as opposed to the liability portion) cannot be tried on a class-wide basis. Specifically, Defendants argue that the Plaintiff Class's expert's class-wide damages model violates due process, because his aggregate damages

estimate does not consider government subsidies, premium "pass-ons," or Pharmacy Benefit Manager ("PBM") rebates and discounts. They also argue that the Plaintiff Class does not account for the interstate and intra-class conflicts presented by the fact that different class members have varying antitrust, consumer protection, and unjust enrichment claims under 27 different jurisdictions.

The Plaintiff Class opposes the motion to decertify on the grounds that aggregate damages are perfectly appropriate in this case, and that individualized issues raised in the damages portion of the trial do not warrant decertification as long as class-wide issues predominate as to the liability portion of the case. (*See* Docket No. 904).

For the reasons set forth below, Defendants' motion to decertify the class is DENIED.

BACKGROUND

This case's factual background and relevant regulatory scheme have been recounted at length in other opinions. (*See* the court's (i) February 11, 2021, Order on the Motion to Certify the Class, *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527 (S.D.N.Y. 2021) (Docket No. 656); and (ii) June 11, 2021, Order on the *Daubert* Motions and the Motions for Partial Summary Judgment, *In re Namenda Indirect Purchaser Antitrust Litig.*, 2021 WL 2403727 (S.D.N.Y. 2021) (Docket No. 689). [1]

[1] *See also New York v. Actavis, PLC* ("*Namenda I*"), No. 14-cv-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. Schneiderman ex rel. New York v. Actavis, PLC* ("*Namenda II*"), 787 F.3d 638 (2d Cir. 2015); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC* ("*Namenda III*"), No. 15-cv-7488, 2016 WL 4992690 (S.D.N.Y. Sept. 13, 2016) (denying motion to dismiss federal claims brought by direct purchasers); *In re Namenda Direct Purchaser Antitrust Litig.* ("*Namenda IV*"), No. 15-cv-7488 (CM), 2017 WL 4358244, at *1 (S.D.N.Y. May 23, 2017) (granting in part and denying in part direct purchasers' motion for collateral estoppel and partial summary judgment); *In re Namenda Direct Purchaser Antitrust Litig.* ("*Namenda V*"), 331 F. Supp.3d 152 (S.D.N.Y. 2018) (certifying class of direct purchasers); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc (Namenda VI)*, No. 15-cv-6549, 2018 WL 7197233 (S.D.N.Y. Dec. 26, 2018) (denying Defendants' motion to dismiss in this indirect-purchaser action); *In re Namenda Indirect Purchaser Antitrust Litig. ("Namenda VII")*, No. 15-cv-6549, 2021 WL 1000489 (S.D.N.Y. Jan. 12, 2021).

Only the facts relevant to the motion to decertify the class are summarized below. Unless otherwise mentioned, the facts detailed are not in dispute.

A. The Parties

Lead plaintiff Sergeants Benevolent Association Health & Welfare Fund ("SBA") is a fund that administers the prescription drug benefit plan for active and retired New York City Police Department sergeants and their dependents. It represents a class of "end payors" or indirect purchasers of Namenda, which includes – subject to some exceptions – "All Third-Party Payors who indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the price for Namenda IR 5 or 10 mg tablets, their AB-rated generic equivalents, and/or Namenda XR capsules" (the "Plaintiff Class" or "Plaintiffs"). (*See* Docket No. 489).

Third-party payors ("TPPs") are entities (besides the patient or the health care provider) that provide reimbursement for health care expenses. They include insurance companies, government payors like Medicare, and self-insured health and welfare plans run by employers. TPPs are indirect purchasers because they do not purchase drugs directly from the manufacturer (in contrast to direct purchasers like wholesalers). Instead, they pay reimbursement for the purchases made by the individual consumers that they insure.

The court certified the following Plaintiff Class:

> All Third-Party Payors who indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the purchase price for branded Namenda IR 5 or 10 mg tablets, their AB-rated generic equivalents, and/or Namenda XR capsules, other than for resale in Alabama, Arizona, California, D.C., Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island (for purchases after July 15, 2013), South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, for consumption by themselves, or their members, employees, insureds, participants, or beneficiaries, from June 1, 2012 through December 31, 2017.
>
> Excluded from the proposed Class are: (a) Defendants and Defendants' parents, subsidiaries and affiliates; (b) fully-insured health care plans (i.e., health plans that

> purchased insurance from another third-party payor covering 100% of the insureds' prescription drug benefits on behalf of the Plan's members and beneficiaries); (c) all federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans; (d) Pharmacy Benefit Managers ("PBMs"); and (e) all judges presiding in this case, their chambers staff, and any members of their immediate families, and all counsel of record.

Docket No. 656 at 80-81.

Defendant Forest Laboratories is a limited-liability company incorporated in Delaware that manufactures and sells branded pharmaceutical products. Forest is a wholly owned subsidiary of Defendant Actavis PLC (now known as Allergan PLC). Defendants Merz GmbH & Co. KGaA.; Merz Pharma GmbH & Co. KGaA; and Merz Pharmaceuticals GmbH (collectively "Merz") are headquartered in Germany and are also engaged in the development, production, and distribution of pharmaceutical products (Forest, Actavis, and Merz, "Defendants").

B. Namenda

Namenda IR (immediate release) and Namenda XR (extended release) (collectively "Namenda") are brand-name prescription drugs that contain the active ingredient memantine. Namenda is used to treat Alzheimer's disease and has been commercially successful ever since Forest introduced Namenda IR to the U.S. market in 2003. Total annual sales of Namenda IR grew to approximately $1.5 billion by 2013, the same year that Forest launched Namenda XR. *Namenda II*, 787 F.3d at 647.

Although both versions of Namenda were patent protected, the patents had different expiration dates. Therein lies the dispute driving this lawsuit. The Plaintiff Class alleges that Defendants acted anticompetitively in attempting to protect Namenda's market advantage afforded by the patents, ultimately resulting in indirect purchasers paying higher prices for memantine than would otherwise have been the case but-for Defendants' conduct.

C. The Hatch-Waxman Act and Generic Competition

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, a pharmaceutical company must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") any time it wishes to market a new brand-name drug. The NDA must provide the agency with scientific data showing that the drug is safe and effective. This generally requires conducting preclinical and clinical trials and can take many years. *Namenda II*, 787 F.3d at 643; 21 U.S.C. § 355. Although the process is costly and time consuming, once a patented drug is approved, it enjoys a period of exclusivity on the market (generally twenty years) – effectively, a government-sanctioned monopoly. A brand-name drug's developer can recoup its investment into the drug during this exclusivity period because the drug faces no competition from generics. However, once the exclusivity period ends and generic versions of the drug enter the market, it generally results in the brand-name drug losing more than 80% to 90% of its market share within six months – a process known in the industry as going off the "patent cliff." *Namenda II*, 787 F.3d at 647.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98–417, 98 Stat. 1585. Hatch-Waxman attempted to serve a dual purpose: to lower drug prices for consumers by encouraging greater generic competition with brand-name drugs; and to incentivize innovation from branded drug manufacturers by providing for patent extensions beyond the standard 20-year patent term. *Namenda II*, 787 F.3d at 644.

To increase generic competition, Hatch-Waxman permits generic manufacturers to file an Abbreviated New Drug Application ("ANDA"), which allows them to "piggy-back" on an already-approved branded drug's NDA information to show that the generic is safe and effective. *Id.* at 644. The generic manufacturer can forgo any independent preclinical and clinic trials but must

certify that the generic has the same active ingredients as, and is "bioequivalent" to, the already-approved brand-name drug. *Ibid*; *see also* 21 U.S.C. § 355(j). Two drugs are "bioequivalent" if their "rate and extent of absorption" are not significantly different. 21 U.S.C. § 355(j)(8)(B)(i). This means that for a generic to be "bioequivalent" to a branded drug, it must deliver the same amount of the active ingredient in the same period of time. By allowing generic manufacturers to "piggy-back" their ANDAs on the studies of already-approved drugs, Hatch-Waxman reduced the development costs of lower-priced generics, speeding their introduction to the market. *Namenda II*, 787 F.3d at 644.

Apart from the federal regulatory landscape, states also heavily incentivize generic competition through drug-substitution laws – laws which either permit or require pharmacists to replace a prescribed brand-name drug with a lower-priced, "therapeutically equivalent" generic if there is no express direction from the prescribing doctor that the prescription must be filled with the brand-name drug *(i.e.,* "dispense as written."). *Id.* at 645. Whether a generic is "therapeutically equivalent" to the branded drug is state-dependent, but most states follow the FDA's guidance and will only substitute a generic if the FDA designates it as "AB-rated" in a publication known as the "Orange Book." *Ibid.* An AB-rated generic is one that is both "bioequivalent" to the brand-name drug and pharmaceutically equivalent in that it has the "same active ingredient, dosage form, strength, and route of administration." *Id.*

D. Generic Exclusivity and the Generic Settlements

To succeed on an ANDA application, a generic manufacturer must also submit a certification to the FDA describing the implications of the generic on patents held by the branded manufacturer. The relevant certification here is the "Paragraph IV" route, so named after 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

In a Paragraph IV certification, the generic manufacturer states that any relevant patent held by the brand-name manufacturer "is invalid or will not be infringed by the manufacture, use, or sale" of the generic. *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). Submitting an ANDA under Paragraph IV exposes the applicant to patent litigation. A branded manufacturer has 45 days after the submission to initiate a patent-infringement action against the ANDA applicant. If the branded manufacturer files a lawsuit, the FDA "must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court." *Ibid.*; *see also* 21 U.S.C. § 355(j)(5)(B)(iii).

Hatch-Waxman provides incentives for generic manufacturers who incur the risk of patent litigation. The generic manufacturers that first file a Paragraph IV certification (as many "first" certifications are submitted on the same day) receive a 180-day exclusive marketing period for that generic. No other generic manufacturer can market their drug during this period. "If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Actavis*, 570 at 144 (citation omitted).

Like any lawsuit, the parties can decide to settle the patent-infringement litigation arising out of the ANDA. However, in such a scenario, it is usually the plaintiff (the brand-name manufacturer and patent holder) that pays to settle the case against the defendant (the generic manufacturer and alleged infringer). Thus, these settlements are called "reverse payments" or "reverse settlements."

Because these payments tend to preclude, rather than encourage, market entry of generic competitors, "there is reason for concern that settlements taking this form tend to have significant

adverse effects on competition." *Id.* at 148. For this reason, the Supreme Court has held that reverse payments are not immune from antitrust scrutiny. *Id.* at 141.

Defendants' reverse settlements to several generic manufacturers form SBA's theory of liability in this case.[2]

E. Factual History and Anticompetitive Allegations

In June 2000, Merz provided Forest with an exclusive license to U.S. Patent No. 5,061,703 (the "'703 Patent"), which gave Forest the right to market a memantine hydrochloride-based drug used to treat moderate to severe Alzheimer's disease. Forest developed Namenda IR and began marketing it in the U.S. following FDA approval in late 2003. *Namenda II*, 787 F.3d at 647. Namenda IR's exclusivity period based on the '703 Patent was originally set to expire on April 11, 2010, but in March of 2009, Forest succeeded in obtaining a five-year extension to the expiration date to April 11, 2015. Forest succeeded in later applying for another six-month extension, such that the final expiration date of the patent was October 11, 2015. *Namenda IV*, 2017 WL 4358244, at *6.

Starting in October 2007, at least fourteen generic manufacturers – some of whom were defendants in this litigation and have since settled – submitted ANDAs with the FDA in preparation to enter the market. These ANDAs provided Paragraph IV certifications, notifying Forest of their view that the '703 Patent was either invalid or was not infringed by the generic manufacturers' versions of their memantine product. (Second Amended Complaint at ¶ 72). Forest commenced litigation against these manufacturers in January 2008, thus triggering the automatic

[2] The court declined to certify the class as to Plaintiffs' other theory of liability – the hard switch theory – on the grounds that individualized issues predominate over class-wide issues as to that theory. The "pay for delay" scheme (which involves the reverse settlements to generic manufacturers delaying the market entry of generic memantine such that it purportedly resulted in TPPs reimbursing more for branded Namenda products that would have otherwise been generics) is the only theory of liability remaining in the class action and it's the only theory of liability which will be tried in this case.

30-month stay under Hatch-Waxman, during which the validity of the '703 Patent was to be litigated. (*Id.* at ¶ 74).

Beginning in early 2010, several of the generic manufacturers began receiving word that their ANDAs were ready for approval following the expiration of the 30-month stay. (*Id.* at ¶¶ 85-86). Thus, generic versions of Namenda IR could have theoretically entered the market as early as mid-2010. This did not occur, however, because Forest entered into several reverse payment settlements with the generic manufacturers such that the manufacturers agreed not launch their generic versions of Namenda IR until after July 11, 2015. (*Id.* at ¶ 79). The Plaintiff Class alleges that these reverse payments were anticompetitive – effectively, a "pay-for-delay" scheme designed to limit.

On February 11, 2021, this court granted in part and denied in part SBA's motion for class certification. *Namenda VIII*, 2021 WL 509988. The court certified only the "pay for delay" theory of antitrust liability and denied certification as to the hard-switch theory. This means that only the only basis for liability to be found on a class-wide basis (as well as for class-wide damages) pertains to the reverse settlement of the Paragraph IV lawsuits.

LEGAL STANDARDS

An order granting a motion for class certification is ordinarily reviewable by application to the regional circuit court pursuant to Rule 23(f) of the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 23(f) ("A court of appeals may permit an appeal from an order granting or denying class-action certification under this rule if a petition for permission to appeal is filed with the circuit clerk within ten days after the order is entered"). Defendants did not make such an application.

A motion for decertification of an already-certified class must show that decertification is appropriate due to a change of circumstances that arises from subsequent events in the litigation.

It is true that, after the class is certified, the district court "remains free to modify it in the light of subsequent developments in the litigation." *General Tel. Co. of the Southwest v. Falcon*, 457 U.S. 147, 160 (1982). A district court that has certified a class under Rule 23 "can always alter, or indeed revoke, class certification at any time before final judgment is entered should a change in circumstances" render a class action no longer appropriate. *Cordes & Co. Fin. Serv., Inc. v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 104 n. 9 (2d Cir. 2007). But the court should not disturb its prior findings in favor of certification "absent 'some significant intervening event,' or 'a showing of compelling reasons to reexamine the question.'" *Doe v. Karadzic*, 192 F.R.D. 133, 136–137 (S.D.N.Y.2000) (internal citations omitted). Moreover, faced with a motion to decertify the court must also take account of the progression of the litigation. *Langley v. Coughlin*, 715 F. Supp. 522, 552 (S.D.N.Y.1989) ("the Court must take into consideration that an eve-of-trial decertification could adversely and unfairly prejudice class members, who may be unable to protect their own interests."); *see also Woe v. Cuomo*, 729 F.2d 96, 107 (2d Cir.1984) (finding abuse of discretion where district court decertified the class after granting summary judgment in part).

An application to "decertify" a class that does not rely on a change in circumstances, but rather seeks to reargue points made in opposition the original certification, should ordinarily be denied as stealth attempt to enlarge the Rule 23(f) deadline.

DISCUSSION

I. THE MOTION TO DECERTIFY THE CLASS IS DENIED.

Defendants argue that class certification is tentative and subject to revision at any time. They submit that the fact that the court granted (in part) the motion for class certification and certified the Plaintiff Class on the reverse payment theory does not mean that this case should actually be tried as a class action. (*See* Docket No. 898 at 4) (citing Fed. R. Civ. P. 23(c)(1)(C)

which provides, "An order that grants or denies class certification may be altered or amended before final judgment"). According to Defendants, the class-wide damages model proposed by the Plaintiff Class violates due process and does not account for the purported interstate and intra-class conflicts regarding enhanced damages.

The court disagrees that the motion is appropriately made. I also disagree on the merits.

It is true that in the Second Circuit a "district court may decertify a class if it appears that the requirements of Rule 23 are not in fact met." *Sirota v. Solitron Devices, Inc.*, 673 F.2d 566, 572 (2d Cir.1982). But that is only true if there has been "some significant intervening event," *Langley v. Coughlin*, 715 F. Supp. 522, 553 (S.D.N.Y.1989), *appeal dismissed*, 888 F.2d 252 (2d Cir.1989), or "a showing of compelling reasons to reexamine the question," *Wilder v. Bernstein*, 645 F. Supp. 1292, 1311–12 (S.D.N.Y.), *aff'd*, 848 F.2d 1338 (2d Cir.1988).

Defendants identify no significant intervening event that has occurred since class certification in this case, so the standard is whether defendants have shown a "compelling reason" to reexamine the question that was already decided after full briefing. And indeed, when the court raised the question, my interest was limited to the issue of punitive/exemplary damages – my original question did not suggest, and was not intended to suggest, that I thought it necessary or appropriate to reopen the issue of ALL damages, though that is in fact what has transpired.

The movant bears a heavy burden to prove the necessity of taking such a drastic step as decertifying a class a month before trial is set to begin. *Gordon v. Hunt*, 117 F.R.D. 58, 61 (S.D.N.Y. 1987). When faced with a motion to decertify a previously-certified class, courts "should also consider the stage of the litigation and whether an eve-of-trial decertification could adversely and unfairly prejudice class members who may be unable to protect their own interests." *Gortat v. Capala Bros.*, 2012 WL 1116495, at *2 (E.D.N.Y. Apr. 3, 2012), *aff'd*, 568 F. App'x 78

(2d Cir. 2014) (internal quotation marks omitted). Of course, the court is only considering decertification of the Plaintiff Class as to damages, so the interests of class members would continue to be protected through a liability finding – where there is absolutely no question that common issues predominate (indeed, where there are nothing but common issues). However, the fact that we are on the eve of a trial at which both liability and damages are set to be tried as a class action is certainly something I am not free to ignore.

I note here that many courts (including, I have no doubt, this one) have from time to time said that common issues predominated "*at the class certification stage*" or "*at class certification*" – language suggesting that if we made it as to the point of "*at trial*," some higher standard need be met. But, of course, that is not the case.

It is "*at class certification*" that a court is supposed to figure out whether common issues predominate such that the case can be tried as a class action. So the court is, in effect, faced with a (very) belated motion for reargument. Defendants' suggestion that, because no indirect purchaser plaintiff ("IPP") class action has ever been tried to verdict, no court has actually dealt with the question of damages commonality at the trial of an IPP case is nonsense. In the court's class certification decision, I cited to numerous cases certifying IPP classes – all of which involved multiple state laws – all of which dealt with this very issue. (Docket No. 656 at 70; *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. at 571) (citing *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1, 33-39 (E.D.N.Y. 2020) (certifying a class of end-payor plaintiffs whose claims arose from the antitrust laws of more than 30 states); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352 (D. R.I. 2019) (29 states); *In re Lidoderm Antitrust Litig.*, 2017 WL 679367, at * 27 (S.D.N.Y. 2017) (17 states)).

The fact that those cases settled, rather than going to trial (or to verdict if a trial began), is (or should be) of no moment to the class certification analysis – including whether a class whose members may be entitled to varying damage enhancements that would be available pursuant to the different state antitrust and consumer protection statutes should remain certified through trial.

Even if individualized inquiries are necessary to try the damages case, that fact alone "is not sufficient to defeat class certification." *Roach v. T.L. Cannon Corp.*, 778 F.3d 401, 405 (2d Cir. 2015) (quoting *Seijas v. Republic of Argentina,* 606 F.3d 53, 58 (2d Cir.2010)). It logically follows that it is also not sufficient to decertify a class so close to trial.

Nonetheless, in their brief Defendants rehash the arguments they made in opposition to class certification over two years go. They argue that (i) damages cannot be awarded on a class-wide basis because of the varying rebate, discount, and other price adjustments available to and utilized by at least some of the class members; and (ii) because different jurisdictions provide for different damages enhancements and mechanisms for awarding such damages, Defendants will not be able to assert affirmative defenses on a class-wide basis.

The court disagreed "at class certification," and I disagree now.

A. Predominance is satisfied.

To satisfy Rule 23(b)(3), questions of law or fact common to class members must *predominate* over any questions affecting only individual members. Predominance requires a showing that: "(1) resolution of any material legal or factual questions can be achieved through generalized proof, and (2) these common issues are more substantial than the issues subject only to individualized proof." *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108, 118 (2d Cir. 2013). A common question is one where "the same evidence will suffice for each member to make a *prima facie* showing [or] the issue is susceptible to generalized, class-wide proof," while an individualized question is one where class members "will need to present evidence that varies from

member to member." *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 136 S. Ct. 1036, 1045 (2016) (quoting 2 W. Rubenstein, Newberg on Class Actions § 4:50, pp. 196–197 (5th ed. 2012)). Which is to say that evidence is common if any class member can use it to prove its claim against the defendants; evidence is individual if it is only applicable to one class member and is otherwise irrelevant to the claims of the other class members.

The requirement that common questions be "more substantial" than individual ones means that "predominance is a comparative standard." *In re Petrobras Secs.*, 862 F.3d 250, 268 (2d Cir. 2017). "The mere existence of individual issues will not suffice to defeat certification. Rather, the balance must tip such that these individual issues predominate." *Sykes v. Mel S. Harris and Assocs. LLC*, 780 F.3d 70, 87 (2d Cir. 2015). This ensures that only "fatal" differences among class members, which may "make use of the class-action device inefficient or unfair," will derail certification. *Amgen, Inc. v. Connecticut Retirement Plans and Trust Funds*, 568 U.S. 455, 133 S. Ct. 1184, 1197 (2013). Indeed, "common issues predominate when liability is determinable on a class-wide basis, *even where class members have individualized damages.*" *B & R Supermarket, Inc. v. Mastercard Int'l, Inc.*, No. 17-cv-2738 (MKB), 2021 WL 234550, at *21 (E.D.N.Y. Jan. 19, 2021) (emphasis added). A class can be properly certified (and maintained through trial) as long as the substantive questions and common proof of *liability* predominate over the individualized issues that will affect only damages. In this case, the questions of law and fact relevant to determining damages are common to the class, and the damages estimate "roughly reflect[s] the aggregate amount owed to class members." *Seijas v. Republic of Argentina*, 606 F.3d 53, 58-59 (2d Cir. 2010).

That all issues relating to liability are subject to common proof is indisputable, and I don't intend to regurgitate that discussion again (again, for a full analysis, *see* Order on the Motion to

Certify the Class, Docket No. 656). Instead, I turn to the two arguments made by Defendants in favor of decertification as to the issue of damages.

B. Aggregate damages are perfectly permissible in this case.

The crux of Defendants' argument is that class-wide damages cannot be awarded in this case because any "aggregate" overcharge would need to account for "staggering variation: thousands of insurers reducing their out-of-pocket costs by transacting in different ways (*e.g.*, subsidies, premiums), at different times (prospectively or retroactively), and to varying degrees with different stakeholders (government payors, PBMs, consumers) in 27 different jurisdictions—indeed, for many class members, in multiple states at once." (Docket No. 898 at 1).

Defendants cite *Jacob v. Duane Reade, Inc.*, 293 F.R.D. 578, 592 (S.D.N.Y. 2013), *aff'd*, 602 F. App'x 3 (2d Cir. 2015) for the proposition that "whenever damages calculations require significant degrees of individualized proof, defendants are entitled to respond to and address such variances—in fact, due process requires it." According to Defendants, the Supreme Court "implied" in *Comcast v. Behrend*, 569 U.S. 27 (2013) that due process rights are violated if a court simply assumes that aggregate proof reflects class-wide damages. (Docket No. 898 at 4). Thus, Defendants submit once again that *Comcast* and due process mandate decertification, because the Plaintiff Class's damages expert Dr. Vogt does not take into account individualized issues regarding government subsidies, premium "pass-ons," or PBM rebates and discounts.

I rejected this argument when I certified the IPP class on the reverse payment theory of liability. Defendants are reminded that, to the extent they are arguing that *Comcast* overturned the well-established rule in this Circuit that "the fact that damages may have to be ascertained on an individual basis is not sufficient to defeat class certification under Rule 23(b)(3)," they are wrong. *Roach*, 778 F.3d at 405 (quoting *Seijas*, 606 F.3d at 58).

Comcast involved an antitrust class action in which the plaintiffs presented a model for calculating damages that failed to measure damages resulting from the particular antitrust injury on which the defendant's liability in that action was premised, as opposed to other theories of antitrust impact that were rejected by the district court. 569 U.S. at 35 ("at the class-certification stage (*as at trial*), any model supporting a 'plaintiff's damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation'") (emphasis added) (quoting ABA Section of Antitrust Law, Proving Antitrust Damages: Legal and Economic Issues 57, 62 (2d ed. 2010)).

That is simply not the case here. Indeed, Defendants' suggestion – that, in calculating an aggregate amount of damages suffered by the Plaintiff Class, Dr. Vogt does not take into account the various offsets that were available to individual class members – is just plain wrong.

The Supreme Court in *Comcast* indeed held that aggregate damages are not appropriate when the estimate represents the aggregate of multiple theories of liability. But they are appropriate in cases like this, where common proof can be used to estimate class-wide damages tied to a single theory of liability. Indeed, the use of an aggregate model to estimate damages is well established in this Circuit; it is implied by the very existence of the class action mechanism. *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 546 (S.D.N.Y. 2021) (citing *Hickory Secs. Ltd. v. Republic of Argentina*, 493 F. App'x 156, 159 (2nd Cir. 2012)). All that is required is that the damages estimate offered by the class roughly reflects the *aggregate* amount owed to the class members on each theory of liability. *Id.* at 552.

In this case, the Plaintiff Class will try only one theory of liability: the reverse payments theory. So right off the bat, *Comcast* is inapposite – there are no multiple theories of recovery in this case to complicate the estimate of aggregate damages. Dr. Vogt's opinion properly relies only

on proof common to the entire class – overall spending of the class members on memantine – and calculates his damages estimate accordingly. Defendants incorrectly focus on the individual transactions of each class member and erroneously argue that they are entitled to defend the case literally on a prescription-by-prescription analysis. In this Circuit, that is simply not so.

Dr. Vogt and Plaintiff Class will present to the jury an estimate of the *total damages* suffered by the entire IPP class attributable to the pay-for-delay scheme. In this case, "aggregate class-wide damages equal the difference between the costs paid by class members" for brand Namenda IR and XR "in the actual world versus the costs class members would have paid for" generic Namenda IR "in the 'but-for' world" had there been no pay-for-delay." *In re Restasis*, 335 F.R.D. at 30 (quoting *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 232 (E.D. Pa. 2012)).

In making that calculation, Dr. Vogt has made allowances for the various offsets that a class member would have to prove in order to collect their individual damages. Dr. Vogt analyzed rebate and discount data and adjusted the prices used in his overcharge calculations to account for those offsets. As a result, the amount of aggregate damages that Plaintiffs will ask the jury to find does not exceed the aggregate amount of damages that the entire class suffered – which is what is not allowed. *Hickory Sec. Ltd. v. Republic of Argentina*, 493 F. App'x 156, 159 (2d Cir. 2012) (the district court must ensure that aggregate calculations do not result in inflated damage figures). And if Defendants believe that there is some type of rebate or offset that Dr. Vogt ignored, they can (and will) cross examine him about that – and the court will instruct the jury that they cannot award aggregate damages in excess of the amount suffered by the class, which means net of all offsets.

As I ruled on the motions *in limine* (as I believe I said in the *Daubert* decision), Defendants' criticisms of Dr. Vogt's work do not present legal issues for the court to resolve. The court only rules on what the measure of damages is. And the measure of damages is the actual damage – the

out-of-pocket cost – that is suffered by a third-party payor as a result of being overcharged for memantine. Whether Dr. Vogt has calculated that measure correctly in light of the various government reimbursement programs presents a question of fact for the trier of fact – not a ruling of law for the court to make. Whether aspects of what Plaintiffs characterize as premiums operate to reduce the out-of-pocket cost of memantine to a third-party payor is also a question of fact for the trier of fact – not a ruling of law for the court to make. All of this is fair game for cross examination. (*See* Docket No. 890 at 23).

Class members do not need to present proof of individual overcharges at trial; that does not occur in any class action of which I am aware. Rather, they must present proof of their injury during a post-verdict claims process in order to collect from the class-wide award. That process can be structured so that, if they choose to do so, Defendants can cross examine every person who presents a claim and challenge the right of any class member to obtain a specific sum – or any sum, for that matter – out of the pot that is the jury's class-wide damages verdict. Nothing about asking a jury to award aggregate damages precludes such individualized cross examination; the jury simply fixes the size of the pot. The situation in this case is no different (albeit slightly more complicated) than the situation in a shareholder class action. In such a case, a jury fixes the total aggregate amount of damages, and then every shareholder class member who wants to participate in the recovery must come forward with proof of purchase of whatever number of shares they claim to have purchased, on whatever date during the class period, at whatever price, in order to recover damages in a shareholder class action. Each shareholder paid her own price (or prices) for her own shares; some shareholders may have paid a non-market price because (to take one example) they held options.

But the fact that each individual class member will at some point have to present personalized proof in order to receive any money does not defeat predominance or mean that a jury cannot come up with a number for aggregate damages out of which individual awards will be made. As long as the Plaintiff Class proffers evidence of the total overcharge and takes care to make adjustments for any offsets – so that Dr. Vogt's estimate of class-wide damages does not exceed the total amount by which the class was in fact damaged – there is no due process violation and no predominance problem.

In this case, class members will have to come forward with evidence of the amount by which they were overcharged, which will be the amount they actually paid for memantine on particular dates. Those amounts will necessarily be less any rebates or government reimbursements that they received. Plaintiffs insist that, when calculating class-wide aggregate damages, Dr. Vogt took estimates of those rebates and reimbursements into account, using what struck the court (during *Daubert*) as appropriate methodologies. If Defendants, through cross examination, establish that he actually did not do what the Plaintiff Class has represented that he did, we might have a problem. But right now, we have a properly certified class. And the fact that the calculation of class-wide damages is not as straightforward as the calculation of damages in a securities fraud class action does not mean that the class should be decertified – especially in light of the Second Circuit's recognition that the burden of proving antitrust damages is not as rigorous as in other types of cases, because of the inherent limitations involved in establishing what the market price of the commodity or service would have been in an unmanipulated market. *New York v. Julius Nasso Concrete Corp.*, 202 F.3d 82, 88 (2d Cir. 2000).

C. Variation among the state laws as to enhanced damages is manageable.

Defendants' second argument – that the Plaintiff Class's claims under the various state antitrust and consumer protection statutes are unmanageable because the different states provide

for different enhanced damages – is unpersuasive. Variation among the state laws on punitive damages does not warrant decertification of the class as to damages.

Courts routinely certify multistate class actions brought under state antitrust and consumer protection statutes to recover damages incurred from a defendant's anticompetitive conduct.[3] State law requirements regarding enhanced damages are precisely the kind of variation that special verdict forms are designed to address. *Restasis*, 335 F.R.D. at 39 (specifically identifying special jury questions as a mechanism for managing state law variations on enhanced damages); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2017 WL 4621777, at *20 (D. Mass. Oct. 16, 2017) (same); *In re Lidoderm*, 2017 WL 679367, at *27 (same).

Essentially, Defendants argue that the individual and state-by-state damages inquiries required to try the damages portion of the case demonstrate that predominance is not (or is no longer) satisfied. The court raised the question, but after careful thought I conclude that this does not present a Rule 12(b)(3) problem. Whether punitive damages are warranted will be decided on the basis of the evidence that is common to everyone – the evidence related to liability. Whether that evidence satisfies the standard for punitive damages in this state or that state is a simple matter of jury instructions and properly constructed verdict sheets.

All members of the class allege that Defendants' actions forced all of them to pay supracompetitive prices for memantine. That each class member will have to prove how much it

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[3] *See, e.g., In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 307-308 (D. Mass. 2021) (certifying a class of end-payors under 21 state antitrust laws and 11 consumer protection laws); *In re Opana ER Antitrust Litig.*, No 14 C 10150, 2021 WL 3627733 (N.D. Ill. June 4, 2021) (certifying a class of end-payors under the laws of 27 jurisdictions); *Restasis* 335 F.R.D. at 41 (certifying a class of consumers and third-party payors under the antitrust and consumer protection law of 32 jurisdictions); *In re Loestrin 24 FE Antitrust Litig.*, 410 F.Supp.3d 352 (D.R.I. 2019) (certifying end-payor class under the laws of 29 jurisdictions); *In re Solodyn (Minocycline Hydrocholoride) Antitrust Litig.*, Civil Action No. 14-md-02503, 2017 WL 4621777, at *19 (D. Mass. Oct. 16, 2017) (certifying class of end-payors under the laws of 40 different jurisdictions).

paid for Namenda in order to *collect* damages does not mean that the damages phase of the trial should not proceed as a class action.

In short, "individual damages determinations do not defeat class certification." *Dial Corp v. News Corp.,* 314 F.R.D. 108, 120 (S.D.N.Y. 2015). No heightened standard of predominance applies in this case just because we are approaching trial. Moreover, Defendants are not entitled to defend the case on a transaction-by-transaction or class member-by-class member basis. The jury will award aggregate damages.

CONCLUSION

The motion to decertify the class as to damages is denied.

This constitutes the decision and order of the court. It is a written opinion. The clerk of the court is directed to close the open motion at Docket Number 897.

Dated: September 19, 2022

U.S.D.J.

BY ECF TO ALL COUNSEL