UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Novartis and Par Antitrust Litigation	**1:18-cv-04361-AKH**
This Document Relates to: **All Direct Purchaser Actions**	

DIRECT PURCHASER CLASS PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF UNOPPOSED MOTION FOR CERTIFICATION OF A SETTLEMENT CLASS, APPOINTMENT OF CLASS COUNSEL, PRELIMINARY APPROVAL OF PROPOSED SETTLEMENT, APPROVAL OF THE FORM AND MANNER OF NOTICE TO THE CLASS AND PROPOSED SCHEDULE FOR A FAIRNESS HEARING

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Direct Purchaser Class Plaintiffs Drogueria Betances, LLC ("Betances"), Rochester Drug Co-Operative, Inc. ("RDC"), FWK Holdings, LLC ("FWK") and KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("KPH") ("Named Plaintiffs," "Direct Purchaser Class Plaintiffs," or "Plaintiffs"), respectfully submit this Memorandum of Law in Support of their Unopposed Motion for Certification of a Settlement Class, Appointment of Class Counsel, Preliminary Approval of Proposed Settlement, Approval of the Form and Manner of Notice to the Class and Proposed Schedule for a Fairness Hearing.

I. INTRODUCTION

Plaintiffs and Novartis Pharmaceuticals Corporation and Novartis AG ("Novartis") have reached a settlement by which Novartis will pay $126,850,000.00 (one hundred twenty-six million, eight hundred fifty thousand dollars) in cash into an escrow fund for the benefit of all members of the Class (the "Class") as defined *infra* at 5, in exchange for dismissal of the litigation between Plaintiffs and Novartis with prejudice and certain releases (the "Settlement"). All the terms of the Settlement are set forth in the Settlement Agreement dated December 23, 2022 ("Settlement Agreement") (annexed as Exhibit 1 to the Declaration of Bruce E. Gerstein (the "Gerstein Decl.")).

Preliminary approval of the proposed Settlement is appropriate. Plaintiffs and Novartis entered into the Settlement after close to five years of intense, well-developed litigation and extensive mediation. Counsel for both sides are experienced in class actions and pharmaceutical antitrust litigation and are well-positioned to assess the risks and merits of this case. The Settlement assures that all Class members will receive a cash settlement payment now. The Settlement also assures that the litigation against Novartis will end, while avoiding continued litigation and potential appeals.

Accordingly, Plaintiffs respectfully request that the Court enter the proposed order preliminarily approving the Settlement (Exhibit A to the Settlement Agreement) which provides for the following:

1. Preliminary approval of the proposed Settlement Agreement and the documents necessary to effectuate the Settlement, including a proposed notice plan and form of notice to the Class (Exhibit B to the Settlement Agreement) and a proposed plan of allocation (attached as Exhibit 2 to the Gerstein Decl.) for settlement funds as described in the proposed form of notice;
2. Certification of the Class for purposes of settlement (Novartis does not oppose certification of a direct purchaser class under Federal Rule of Civil Procedure 23 for purposes of the Settlement);
3. Pursuant to Federal Rule of Civil Procedure 23(c)(1)(B) and 23(g), appointment of Garwin Gerstein & Fisher LLP as Lead Counsel for purposes of the Settlement;
4. Appointment of RG/2 Claims Administration LLC ("RG/2") as settlement administrator;
5. Appointment of First State Trust Company as escrow agent for the settlement funds (the Escrow Agreement is annexed as Exhibit D to the Settlement Agreement); and
6. A proposed settlement schedule, including the scheduling of a Fairness Hearing to consider: (a) Plaintiffs' request for final approval of the Settlement and entry of a proposed order and final judgment (Exhibit C to the Settlement Agreement); (b) Class Counsel's[1] application for an award of attorneys' fees and reimbursement of expenses, payment of administrative costs, and service awards to the Named Plaintiffs; and (c) Plaintiffs' request for dismissal of this action against Novartis with prejudice.

II. BACKGROUND

A. Plaintiffs' Claims and Procedural Background

On May 16, 2018, Named Plaintiff Drogueria Betances, LLC filed the first antitrust lawsuit on behalf of all direct purchasers challenging Novartis's conduct regarding the prescription pharmaceutical Exforge. *See* ECF No. 1. Plaintiffs alleged that Novartis and generic drug maker Par Pharmaceutical, Inc. ("Par") had unlawfully delayed the availability of less expensive, generic

[1] Class Counsel are Garwin Gerstein & Fisher LLP; Smith Segura Raphael & Leger, LLP; Faruqi & Faruqi, LLP; Odom & Des Roches, LLC; Berger Montague PC; Heim Payne & Chorush LLP; Kaplan Fox & Kilsheimer, LLP; Roberts Law Firm, P.A.; and Sperling & Slater, P.C.

versions of Exforge through an unlawful "reverse payment" agreement. *See FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). After the resolution of Novartis's and Par's 12(b)(6) motions, the case proceeded through intensive discovery, including production and review of millions of pages of documents, and numerous fact depositions.

In prosecuting this action, Plaintiffs prevailed on several discovery-related disputes (*e.g.*, ECF Nos. 167, 253), reviewed Novartis's, Par's, and third-parties' document productions comprising millions of pages of documents, took nineteen fact and five expert depositions, and defended four fact and ten expert depositions (38 depositions overall). Between January 11 and February 1, 2022, Plaintiffs submitted *Daubert* motions on four narrowly-tailored subjects and opposed six of Novartis's *Daubert* motions. Plaintiffs filed their motion for class certification and class certification reply brief on March 15, 2022 and April 29, 2022 respectively. ECF Nos. 493 and 510. Plaintiffs next opposed Novartis's two extensive motions for summary judgment on causation and the statute of limitations on June 23, 2022. ECF Nos. 550 and 551. At the Court's suggestion (Aug. 4, 2021 Hearing Tr. at 63:25-64:2), Plaintiffs submitted a privilege waiver/preclusion motion, arguing that Novartis placed legal advice "at issue" by asserting defenses that relied on subjective beliefs implicating legal advice. ECF No. 357. This motion, which was fully briefed at the time of settlement, had the potential, if granted, to substantially narrow Novartis's available defenses.

Following summary judgment briefing, Plaintiffs began preparing for trial that was scheduled for January 9, 2023. ECF No. 379. To that end, Plaintiffs served on Novartis proposed jury instructions, a proposed verdict sheet, proposed fact stipulations, a proposed *voir dire*, and a draft joint final pretrial order. Plaintiffs also began drafting and compiling trial exhibit lists, deposition designations, and motions *in limine*.

B. Settlement Negotiations and the Proposed Settlement

After summary judgment briefing and the start of significant trial preparations, Plaintiffs and Novartis agreed to mediation with Eric D. Green of Resolutions, LLC. The mediation lasted a full day, and the settlement negotiations between Class Counsel and attorneys for Novartis were hard fought and at arm's-length. In conducting negotiations, Class Counsel assessed this action in light of their extensive experience litigating similar delayed generic entry cases, the Supreme Court's decision in *Actavis* and its progeny, and the opinions issued by this Court over the course of the litigation.

Under the proposed Settlement, Novartis will pay $126,850,000.00 (one hundred twenty-six million, eight hundred fifty thousand dollars) in cash for the benefit of all Class members in exchange for dismissal of the litigation between Plaintiffs and Novartis and certain releases.

Plaintiffs have proposed the form and manner of notice of the proposed Settlement Agreement to the Class, and the procedures by which Class members may: (a) receive their share of settlement funds; (b) seek exclusion from the Class or object to the proposed Settlement Agreement; and (c) object to Class Counsel's application for attorney's fees of up to one-third of the settlement amount, reimbursement of reasonable expenses incurred in prosecuting this action and service awards for the Named Plaintiffs. Final approval of the proposed Settlement Agreement will result in the dismissal with prejudice of Plaintiffs' claims against Novartis.

III. ARGUMENT

A. THE REQUIREMENTS FOR CERTIFICATION OF A SETTLEMENT CLASS HAVE BEEN MET

Plaintiffs and Novartis have agreed, subject to the Court's approval, to the certification of a class for purposes of settlement. The requirements of Rule 23 do not change when certification is requested pursuant to settlement, except that "a district court need not inquire whether the case,

if tried, would present intractable management problems . . . for the proposal is that there be no trial." *In re Am. Int'l Grp. Secs. Litig*., 689 F.3d 229, 239 (2d Cir. 2012) (quoting *Amchem Prods., v. Windsor*, 521 U.S. 591, 620 (1997)).

Thus, the Court must still assess "whether the proposed class satisfies Rule 23(a)'s four threshold requirements" of: (1) whether "the class is so numerous that joinder of all members is impracticable," (2) whether "there are questions of law or fact common to the class," (3) whether "the claims or defenses of the representative parties are typical of the claims or defenses of the class," and (4) whether "the representative parties will fairly and adequately protect the interests of the class." *In re Am. Int'l Grp. Secs. Litig*., 689 F.3d at 239. The district court must also determine whether the action can be maintained under Rule 23(b)(1), (2), or (3). *Id*.

Here, the proposed settlement Class is defined as follows:

> All persons or entities in the United States, including its territories, possessions, and the Commonwealth of Puerto Rico, who purchased Exforge directly from Novartis, or who purchased a generic version of Exforge directly from Par, at any time during the Class Period from September 21, 2012, until March 30, 2015 ("Exforge Direct Purchasers"). Excluded from the Class are Novartis and Par and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.
>
> Also excluded from the Class for purposes of this Settlement Agreement are: the following entities: CVS Pharmacy, Inc. (which includes Omnicare), Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Walgreen Co., The Kroger Co. (which includes Peytons), and H-E-B L.P. ("Retailer Plaintiffs").

Settlement Agreement at ¶ 1.

Courts have certified similar classes in dozens of other generic delay cases,[2] including for purposes of settlement.[3]

[2] *See In re Opana ER Antitrust Litig.*, 2021 WL 3627733 (N.D. Ill. June 4, 2021); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294 (D. Mass. 2021); *In re Glumetza Antitrust Litig.*, 336 F.R.D. 468 (N.D. Cal. 2020); *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, 421 F. Supp. 3d 12 (E.D. Pa. 2019), *aff'd* 967 F.3d 264 (3d Cir. 2020); *In re Niaspan Antitrust Litig.*, 397 F. Supp. 3d 668 (E.D. Pa. Aug. 13, 2019); *In re Loestrin 24 Fe Antitrust Litig.*, 2019 WL 3214257 (D.R.I. July 2, 2019); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152 (S.D.N.Y. 2018); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2017 WL 4621777 (D. Mass. Oct. 16, 2017); *Am. Sales Co., LLC v. Pfizer, Inc.*, 2017 WL 3669604 (E.D. Va. July 28, 2017), *adopted*, 2017 WL 3669097 (E.D. Va. Aug. 24, 2017); *In re Lidoderm Antitrust Litig.*, 2017 WL 679367 (N.D. Cal. Feb. 21, 2017); *In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47 (D. Mass. 2013); *In re Prograf Antitrust Litig.*, 2013 WL 2395083 (D. Mass. Apr. 23, 2013); *In re Wellbutrin XL Antitrust Litig.*, 2011 WL 3563385 (E.D. Pa. Aug. 11, 2011); *In re Neurontin Antitrust Litig.*, 2011 WL 286118 (D.N.J. Jan. 25, 2011); *Am. Sales Co. Inc. v. SmithKline Beecham Corp.*, 274 F.R.D. 127 (E.D. Pa. 2010) ("*Flonase*"); *In re Wellbutrin SR Direct Purch. Antitrust Litig.*, 2008 WL 1946848 (E.D. Pa. May 2, 2008*); In re K-Dur Antitrust Litig.*, 2008 WL 2699390 (D.N.J. Apr. 14, 2008), *aff'd*, 686 F.3d 197 (3d Cir. 2012); *Teva Pharms. USA, Inc. v. Abbott Lab'ys*, 252 F.R.D. 213 (D. Del. 2008); *La. Wholesale Drug Co. v. Sanofi-Aventis*, 2008 WL 11399716 (S.D.N.Y. Apr. 10, 2008) ("*Arava*"); *In re Nifedipine Antitrust Litig.*, 246 F.R.D. 365 (D.D.C. 2007); *Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293 (D.D.C. 2007) ("*Ovcon*"); *In re Relafen Antitrust Litig.*, 218 F.R.D. 337 (D. Mass. 2003); *In re Buspirone Patent Litig.*, 210 F.R.D. 43 (S.D.N.Y. 2002); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297 (E.D. Mich. 2001).

[3] *See In re DDAVP Direct Purchaser Antitrust Litig.*, 2011 WL 13318188 (S.D.N.Y. Aug. 16, 2011); *In re OxyContin Antitrust Litig.*, 2010 WL 11493630 (S.D.N.Y. Sept. 27, 2010) (certifying settlement class); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 2020 WL 6193857 (E.D.N.Y. Oct. 6, 2020) (same); *In re Aggrenox Antitrust Litig.*, 2017 WL 4278788 (D. Conn. Sept. 19, 2017) (same); *In re Asacol Antitrust Litig.*, 2017 WL 4118967 (D. Mass. Sept. 14, 2017) (same); *In re Prandin Direct Purchaser Antitrust Litig.*, 2014 WL 8335997 (E.D. Mich. Oct. 2, 2014) (same); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 2014 WL 11669877 (E.D. Tenn. Apr. 30, 2014) (same); *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co., Inc.*, 2014 WL 631031 (E.D. Pa. Feb. 18, 2014) (same); *Rochester Drug Co-Op., Inc. v. Braintree Lab'ys Inc.*, 2012 WL 12910047 (D. Del. Feb. 6, 2012) (same); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, 2011 WL 13097266 (D. Del. Nov. 16, 2011) (same); *Meijer, Inc. v. Abbott Lab'ys*, 2008 WL 4065839 (N.D. Cal. Aug. 27, 2008) ("*Norvir*") (same); *In re Children's Ibuprofen Oral Suspension Antitrust Litig.*, No. 04-mc-00535 (D.D.C. Jan. 9, 2006), ECF No. 24 (same); *In re Remeron Direct Purchaser Antitrust Litig.*, No. 03-cv-0085 (FSH) (D.N.J. Aug. 30, 2005), ECF No. 181 (same); *N. Shore Hematology and Oncology Assoc.*, No. 04-cv-00248 (D.D.C. Sept. 10, 2004), ECF No. 21 (same); *J.B.D.L. Corp. v. Wyeth-Ayerst Lab'ys, Inc.*, 225 F.R.D. 208 (S.D. Ohio 2003) (same).

1. Rule 23 Requirements[4]

(a) Numerosity and Impracticability of Joinder

Under Fed. R. Civ. P. 23(a)(1), "[c]ertification is appropriate when 'the number of class members is sufficiently large so that joinder of all members would make litigation needlessly complicated and inefficient.' In this Circuit, 'numerosity is presumed at a level of 40 members.'" *Feliciano v. Corelogic Rental Prop. Sols.*, LLC, 332 F.R.D. 98, 106 (S.D.N.Y. 2019) (Hellerstein, J.) (quoting *Banyai v. Mazur*, 205 F.R.D. 160, 163 (S.D.N.Y. 2002) and *Consol. Rail Corp. v. Hyde Park*, 47 F.3d 473, 483 (2d Cir. 1995)). As an initial matter, the Class includes at least 50 members and so numerosity may be presumed.

Moreover, to meet this requirement, joinder need not be impossible. *See Robidoux v. Celani,* 987 F.2d 931, 935 (2d Cir. 1993) ("Impracticable does not mean impossible."). Rather, the Court must look at the Class as a whole and assess if "the difficulty or inconvenience of joining all members of the class make use of the class action appropriate." *Vida Longevity Fund, LP v. Lincoln Life & Annuity Co. of N.Y.*, 2022 WL 986071, at *3 (S.D.N.Y. Mar. 31, 2022) (citing *Cent. States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.*, 504 F.3d 229, 244-45 (2d Cir. 2007)). "Determination of practicability depends on all the circumstances surrounding a case, not on mere numbers." *Buffalo Laborer Sec. Fund v. J.P. Jeanneret Assocs. (In re Beacon Assocs. Litig.)*, 2012 WL 1569827, at *3 (S.D.N.Y. May 3, 2012) (quoting *Robidoux*, 987 F.2d at 936)). "Relevant considerations include judicial economy arising from the avoidance of a multiplicity of actions, geographic dispersion of class members, financial resources of class members, [and] the ability of claimants to institute individual suits." *Orellana v. One If By Land*

[4] Plaintiffs incorporate by reference the arguments made in support of their motion for certification of a litigation class. ECF No. 497.

Rest. LLC, 2020 WL 5768433, at *6 (S.D.N.Y. Sep. 22, 2020) (quoting *Robidoux*, 987 F.2d at 935)).

Geographic dispersion of the Class and judicial economy strongly support certification here, as the proposed Class is spread across 23 states and Puerto Rico. ECF No. 494-3, Leitzinger Rpt., Exs. 5-6. *See Restasis*, 2020 WL 6193857, at *2 (Rule 23(a)(1) met where "[a]ccording to data produced in this litigation, the Direct Purchaser Settlement Class has at least 37 members geographically dispersed throughout the United States"); *Namenda*, 331 F. Supp. 3d at 214 (class members' "disparate locations constitutes both a significant and practical difficulty to joinder.") (citation omitted). Litigating the claims of a geographically dispersed class on a one-by-one basis is impracticable, given the complexity of this case and the associated volume of discovery and motion practice. It is far more practicable to resolve the claims here via settlement on a classwide basis.

(b) Commonality

The commonality requirement of Rule 23(a)(2) "is met if plaintiffs' grievances share a common question of law or of fact." *Beach v. JPMorgan Chase Bank, Nat'l Ass'n*, 2019 WL 2428631, at *6 (S.D.N.Y. June 11, 2019). *See also Marisol A. v. Giuliani*, 126 F.3d 372, 376 (2d Cir. 1997). It "does not require that all issues be identical as to all class members." *Beach*, 2019 WL 2428631, at *6; *Marisol A.*, 126 F.3d at 376. Rather, it requires only that common questions exist "at the core of the cause of action alleged." *In re Dynex Capital Sec. Litig.*, 2011 WL 781215, at *2 (S.D.N.Y. Mar. 7, 2011).

Here, as in all delayed generic antitrust cases, all class members allege injury due to the same misconduct. *See, e.g.*, *Arava*, 2008 WL 11399716 at *2 ("classwide claims, issues, and defenses are questions of law or fact common to the Direct Purchaser Class that satisfy Rule 23(a)(2)."); *DDAVP*, 2011 WL 13318188, at *1 (similar); *Oxycontin*, 2010 WL 11493630, at *1-

2 (similar); *Buspirone*, 210 F.R.D. at 57 (similar). The common issues here include: whether Novartis possessed monopoly or market power during the relevant period; whether Novartis made a reverse payment to Par to delay Par's market entry with a less expensive generic version of Exforge; whether Par could and would have entered the market earlier absent the alleged payment; whether the challenged conduct violated the antitrust laws; and the amount of overcharge Plaintiffs incurred.

(c) Typicality

"Rule 23(a)(3) requires 'the claims of the class representatives be typical of those of the class, and is satisfied when each class member's claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant's liability.'" *Buffington v. Progressive Advanced Ins. Co.*, 342 F.R.D. 66, 71 (S.D.N.Y. 2022) (quoting *Robinson v. Metro-N. Commuter R.R.*, 267 F.3d 147, 155 (2d Cir. 2001)). Class members' claims need not be "identical," and "differences in the amount of damages, date, size or manner of purchase, the type of purchaser . . . and other such concerns will not defeat class certification when plaintiffs allege that the same unlawful course of conduct affected all members of the proposed class." *In re Air Cargo Shipping Servs. Antitrust Litig.*, 2014 WL 7882100, at *31 (E.D.N.Y. Oct. 15, 2014) (citations omitted), *rpt. and rec. adopted*, 2015 WL 5093503 (E.D.N.Y. July 10, 2015). *See also Ovcon*, 246 F.R.D. at 301-02 (typicality requirement is satisfied even if some class members have larger damage claims than others or are proceeding under assignment because "typicality refers to the nature of the claims of the representative, not the individual characteristics of the plaintiff."). In dozens of similar cases, the typicality requirement was satisfied where the named plaintiffs asserted that a defendant's conduct delayed generic entry and sought overcharges for themselves and the class. *E.g.*, *Namenda*, 331 F. Supp. 3d at 214 (typicality satisfied where "claims arise from the same course of conduct alleged by all class members"); *Arava*, 2008 WL 11399716, at *2

(typicality satisfied where named plaintiff "alleges on behalf of the proposed Direct Purchaser Class the very same manner of injury from the very same course of conduct that it complains of for itself, and [] asserts on its own behalf the same legal theory that it asserts for the Class."); *DDAVP*, 2011 WL 13318188, at *2 (similar); *Oxycontin*, 2010 WL 11493630, at *2 (similar); *Buspirone*, 210 F.R.D. at 57 (similar); n.4, *supra.* For the same reasons, the typicality requirement is met here.

(d) Adequacy of Representation

Rule 23(a)(4) requires that the class representatives "fairly and adequately protect the interests of the class." *Cordes & Co. Fin. Servs. v. A.G. Edwards & Sons,* 502 F.3d 91, 99 (2d Cir. 2007). The Court must consider "whether (1) the plaintiff's interests are antagonistic to the interest of other members of the class and (2) plaintiff's attorneys are qualified, experienced, and able to conduct the litigation." *Id*. at 94 (citation omitted). Plaintiffs meet both criteria.

A proposed class representative is adequate under Rule 23(a)(4) unless it has non-speculative conflicts with absent class members that are "so palpable as to outweigh the substantial interest of every class member in proceeding with the litigation." *In re NASDAQ Mkt.-Makers Antitrust Litig.*, 169 F.R.D. 493, 514-15 (S.D.N.Y. 1996).

To preclude certification, a "conflict must be more than merely speculative or hypothetical." *In re Visa Check/MasterMoney Antitrust Litig*, 280 F.3d 124, 145 (2d Cir. 2001) (citation omitted). Where a defendant's actions form the basis of the antitrust claim, "named plaintiffs and their counsel have the same core objectives as would absent class members." *In re Carbon Black Antitrust Litig.*, 2005 WL 102966, at *14 (D. Mass. Jan. 18, 2005) (citation omitted). Here, as in similar prior cases, "all of the class members have the same financial incentive for purposes of the litigation – *i.e.*, proving that they were overcharged and recovering damages based on that overcharge." *K-Dur*, 686 F.3d at 223. The interests of the Named Plaintiffs are perfectly

aligned with those of absent Class members. In addition, the Named Plaintiffs have repeatedly been found adequate in several similar actions, by District Courts and Courts of Appeals. *E.g.*, *In re Zetia (Ezetimibe) Antitrust Litig.*, 7 F.4th 227, 236 (4th Cir. 2021) (FWK and RDC adequate); *Namenda*, 331 F. Supp. 3d at 213-14 (RDC adequate); *Lidoderm*, 2017 WL 679367, at *2 n.5, 15 (RDC and Betances adequate); *Glumetza*, 336 F.R.D. at 482-83 (KPH adequate); *Restasis*, 2020 WL 6193857, at *2 (FWK, RDC, and KPH adequate).

As for the adequacy of Class Counsel, the Court previously appointed Garwin, Gerstein & Fisher LLP ("GGF") as Interim Lead Counsel for the DPPs. *See* ECF No. 59 ¶ 8. Since then, Interim Lead Counsel have worked diligently, harmoniously, and efficiently with other counsel for the Class (collectively, "Class Counsel"). GGF has extensive experience in similar antitrust class actions and has served as Class Counsel in many pharmaceutical antitrust cases. GGF is experienced and qualified and readily satisfies Rules 23(a)(4) as well as Rule 23(g).[5]

2. All Requirements of Rule 23(b)(3) Are Satisfied

(a) Common Issues Predominate as to Antitrust Impact

Rule 23(b)(3) requires that the Court find that: (1) common questions of law or fact predominate over individual questions; and (2) a class action is superior to other available methods of adjudication. *Cordes*, 502 F.3d at 94. Both requirements are met here.

[5] *See* GGF Firm Resume (filed at ECF No. 46-1). *See also In re Bystolic Antitrust Litig.*, No. 20-cv-05735 (S.D.N.Y. Nov. 12, 2020) (ECF No. 86) (same); *J M Smith Corp. v. AstraZeneca Pharms. L.P.*, 2020 WL 7867552, at *2 (D. Del. Nov. 13, 2020) (same); *Suboxone*, No. 13-md-02445 (E.D. Pa. Sept. 27, 2019) (ECF No. 588) (same); *Namenda*, No. 15-cv-07488-CM (S.D.N.Y. Dec. 16, 2016) (ECF No. 125) (appointing GGF interim co-lead class counsel); *Niaspan*, 397 F. Supp. 3d at 681 (GGF "qualified, experienced, and able to conduct the proposed litigation"); *In re Aggrenox Antitrust Litig.*, No. 3:14-md-02516 (D. Conn. June 6, 2014) (ECF No. 94) (appointing GGF interim lead class counsel).

Under Second Circuit law, antitrust injury "poses two distinct questions," one legal and one factual. *Id.* at 106. The legal question is "whether any such injury is 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *Id.* (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)). Here, "[t]here is only one type of injury alleged in the Complaint – overcharges paid" by purchasers as the result of Novartis's antitrust violation. *Id*. at 107. This Court has emphasized that "the proper measure of damages is the full amount of the overcharge[.]" *In re Namenda Direct Purchaser Antitrust Litig*., 2017 WL 2693713, at *6 (S.D.N.Y. June 21, 2017) (citing *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 489 (1968)). Thus, "the legal question raised by the antitrust injury element is common to the class." *Cordes*, 502 F.3d at 108.

The second question concerning antitrust injury is "the familiar factual question" of "whether injury-in-fact is susceptible to common proof in this case." *Id*. at 106. Plaintiffs need not demonstrate that they were actually injured, only "that class-wide injury or 'impact' is capable of proof at trial through evidence that is common to the class rather than individual to its members." *Dial Corp. v. News Corp.*, 314 F.R.D. 108, 114-15 (S.D.N.Y. 2015). Class certification is therefore proper even if this Court were to find that "the issue of injury-in-fact presents individual questions, [because] it does not necessarily follow that they predominate over common ones." *Cordes*, 502 F.3d at 108.

Here, Plaintiffs allege injury in the form of overcharges resulting from Novartis's alleged reverse payment to Par to delay the market entry of generic Exforge. Plaintiffs' economist, Dr. Jeffrey Leitzinger opines that absent this delay (*i.e.*, with unimpaired generic competition beginning earlier than September 2014), all or nearly all members of the proposed Class would have (a) purchased lower-priced generic Exforge instead of the higher-priced brand Exforge

(commonly called "brand-generic overcharges"); and/or (b) paid lower prices for generic Exforge (commonly called "generic-generic overcharges"). ECF No. 494-3, Leitzinger Rpt. ¶¶ 48-60.

First, Dr. Leitzinger reviews extensive empirical economic research concluding that generics quickly replace brands at substantially lower prices, with generic prices falling even further as the number of generic competitors increases. *Id*. ¶¶ 15-25, 43-44. This research demonstrates the robust procompetitive impact of unimpaired generic entry (and by implication how those effects are lost with impaired generic entry) and is strong common evidence of Class-wide impact here. *Id*. ¶¶ 48-49.

Second, Dr. Leitzinger cites forecasts and other documents prepared by Novartis, Par, and other generic Exforge manufacturers concluding that generic Exforge would follow this same pattern, quickly capturing most brand Exforge sales at lower prices, with generic Exforge prices falling even lower as the number of generic Exforge competitors increases. *Id*. ¶¶ 35-36, 40-41. These forecasts are common, Class-wide evidence showing that delaying generic competition causes overcharges.

Third, Dr. Leitzinger considers what happened after Par finally launched in September 2014, and concludes, based on his analysis of the brand and generic Exforge sales data produced by Novartis, Par, and the other generic Exforge manufacturers, that the Class paid less for generic Exforge than for brand Exforge upon generic launch, and that the price of generic Exforge fell substantially lower once additional generic competitors, including the unlawfully delayed AG Exforge, launched. *Id*. ¶¶ 26-29, 37. In addition, the data show that the Class rapidly replaced its brand Exforge purchases with lower-priced generic Exforge following Par's generic Exforge launch in September 2014. *Id.* ¶¶ 28, 50-52. During the first six months following Par's September 30, 2014 launch, generic Exforge captured approximately 70% of the total brand and generic

Exforge sales, and after a few years generic Exforge was capturing *nearly 100%* of total brand and generic Exforge sales. *Id.* ¶ 51. Generic Exforge also was priced significantly lower than brand Exforge — prior to Par's September 2014 generic launch, the Class paid an average of $5.91 per tablet for brand Exforge; during Par's exclusivity period as the only generic on the market, the Class paid an average of $3.85 per tablet (a 35% discount below the pre-generic entry brand price); and after five additional generics entered the market on March 31 or April 1, 2015, the price the Class paid for generic Exforge plummeted to $0.41 per tablet. *Id.* ¶¶ 28-29 & Ex. 3. Further, the sales data show that every Class member who bought brand and generic Exforge paid less for the generic than it paid for the brand, and that every single Class member who bought generic Exforge from Par paid less for the generic after additional generic competitors launched, including the AG from Novartis. *Id.* ¶¶ 52, 57 & Figs. 3-4. This is overwhelming evidence that the predictable and substantial price drops associated with unimpaired generic entry lowers prices market-wide and would have caused all or nearly all Class members to pay lower prices had it started earlier.

Finally, Dr. Leitzinger concludes that because Class members are intermediaries in the chain of pharmaceutical distribution, there is no reason to think that any Class member exclusively served a small enough fraction of the prescription base such that the Class member would not benefit from generic competition by paying less. *Id*. ¶ 51.

Numerous courts have held the foregoing kinds of evidence sufficient to establish antitrust injury on a class-wide basis. *E.g.*, *Namenda*, 331 F. Supp. 3d at 215-16 (studies, defendant's analyses, and sales data sufficient forms of common proof of antitrust injury); *Buspirone,* 210 F.R.D. at 58 (same).[6]

[6] *See also, e.g.*, *Niaspan,* 397 F. Supp. 3d at 685 ("academic and government research," "internal projection forecasts," and data "common evidence . . . sufficient to establish antitrust injury on a *(cont'd next page)*

(b) Common Issues Predominate as to Damages

The predominance requirement is further satisfied where, as here, aggregate damages to the Class can be reliably measured using class-wide evidence. *See*, *e.g.*, *Namenda*, 331 F. Supp. 3d at 177-81 (approving aggregate damages). *See also Suboxone*, 967 F.3d at 271-72 (same); *Niaspan*, 397 F. Supp. 3d at 689 (same); *Loestrin*, 2019 WL 3214257, at *16 (same). "The standard method of measuring damages in price enhancement cases is overcharge." *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 2693713, at *7 (S.D.N.Y. June 21, 2017) (quoting *Howard Hess Dental Laboratories Inc. v. Dentsply International, Inc.*, 424 F.3d 363, 374 (3d Cir. 2005)).

Here, Dr. Leitzinger used the same basic methodology to measure aggregate Class overcharge damages as has been approved in similar cases. *See* ECF No. 494-3, Leitzinger Rpt. ¶¶ 61-75.[7] Dr. Leitzinger's model satisfies the requirement that evidence of damages "measure[s] only those damages attributable to [the] theory" of liability and harm advanced by the direct purchasers — *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013) — namely, the unlawful delay and impairment of generic competition.

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classwide basis"); *Solodyn*, 2017 WL 4621777, at *7-8 ("economic research," "forecasting documents," and data "sufficiently reliable to show common impact"); *Celebrex*, 2017 WL 3669604, at *14-15 (same); *Lidoderm*, 2017 WL 679367, at *9-10 (forecasts and literature are sufficient common proof); *Wellbutrin XL*, 2011 WL 3563385, at *12 (literature, defendants' forecasts); *Neurontin,* 2011 WL 286118, at *6-8 (literature, defendants' analyses, and sales data); *Flonase*, 274 F.R.D. at 136 (literature, defendants' analyses, and sales data); *Norvir*, 2008 WL 4065839, at *8-9 (same); *Tricor*, 252 F.R.D. at 229-30 (studies and empirical evidence); *Wellbutrin SR*, 2008 WL 1946848, at *8 (literature and data); *K-Dur*, 2008 WL 2699390, at *14-19 (studies, defendants' analyses, and sales data); *Nifedipine*, 246 F.R.D. at 370-71 & n.10 (same); *Ovcon,* 246 F.R.D. at 308-10 (same); *Relafen*, 218 F.R.D. at 343-46 (same); *Premarin*, 225 F.R.D. at 217-218 (same); *Buspirone*, 210 F.R.D. at 58 (same); *Cardizem*, 200 F.R.D. at 308 (same).

[7] *See*, *e.g.*, *Niaspan*, 397 F. Supp. 3d at 689 ("Dr. Leitzinger's aggregate damages model properly captures damages only attributable to DPPs' single theory of unlawful conduct"); *Loestrin,* 2019 WL 3214257, at *16 (approving Dr. Leitzinger's methodology and finding it applicable to the class as a whole) (internal quotation omitted); *Solodyn*, 2017 WL 4621777, at *9-10 (same); *Lidoderm*, 2017 WL 679367, at *10 (same); *Wellbutrin XL*, 2011 WL 3563385, at *14-15 (same); *K-Dur*, 2008 WL 2699390, at *19 (same) (citation omitted).

Actual prices and purchase volumes. Dr. Leitzinger uses common evidence — market-wide transaction-level sales data produced by Novartis, Par and other generic Exforge manufacturers — to determine the prices the Class paid for brand and generic Exforge and the volumes they purchased. ECF No. 494-3, Leitzinger Rpt., ¶ 75.

But-for volumes. To model but-for volumes, Dr. Leitzinger simply takes the generic substitution rates following Par's generic entry in September 2014, and moves them earlier in time (often referred to as a "before and after" or "backcasting" method), *id.*, ¶ 66, "a 'judicially recognized and commonly accepted' method of modeling classwide antitrust damages, [that] has previously served as the basis for a finding of predominance on the question of damages." *Flonase*, 274 F.R.D. at 136 (quoting *K-Dur*, 2008 WL 2699390, at *20).

But-for prices. To model but-for generic prices, Dr. Leitzinger relied on a combination of (a) the actual pricing experience following Par's delayed entry and (b) Novartis's, Par's and other generic manufacturers' forecasts regarding generic pricing. ECF No. 494-3, Leitzinger Rpt., ¶¶ 67-71. As the Court explained in *Namenda*: "The use of Defendants' own forecasts to model a but-for world has been held to be a sound economic methodology. Indeed, it is commonly used in courts considering generic delay damages." 331 F. Supp. 3d at 182 (citing *King Drug Co. of Florence v. Cephalon, Inc.*, 309 F.R.D. 195, 212 (E.D. Pa. 2015)). To model but-for brand prices, Dr. Leitzinger backcast Novartis's actual brand discounts following generic entry to the earlier date on which generic entry would have occurred absent the unlawful conduct. ECF No. 494-3, Leitzinger Rpt., ¶ 72.

Dr. Leitzinger then calculated overcharges by taking the difference between actual prices paid (based upon the transaction data produced in this case) and but-for prices, and then multiplying it by the actual unit sales volume. *Id.* ¶¶ 61-62. In formulaically calculating aggregate

Class damages, Dr. Leitzinger relies only on evidence common to the Class, *id.* ¶¶ 9.c, 75, thus this is not a case where "[q]uestions of individual damage calculations will inevitably overwhelm questions common to the class." *Comcast*, 569 U.S. at 34.

(c) A Class Action Is Superior to Other Methods of Adjudication

Under Rule 23(b)(3) a court may assess the superiority of the class action mechanism by weighing class members' interest in pursuing separate actions, the extent of any independent litigation already commenced by class members, the desirability of concentrating the litigation in a single forum, and the difficulties likely to be encountered in the management of the class action. Fed. R. Civ. 23(b)(3). As multiple other courts have recognized in generic delay cases, class treatment is superior to resolving class members' claims on an individual basis. *See*, *e.g.*, *Arava*, 2008 WL 11399716 at *10; *Buspirone*, 210 F.R.D. at 58; *OxyContin*, 2010 WL 11493630, at *2. Moreover, since the request for class certification is only for purposes of settlement "the Court need not inquire as to whether the case, if tried, would present management problems." *Nichols v. Noom, Inc.*, 2022 WL 2705354, at *6 (S.D.N.Y. July 12, 2022).

Given that this case has already progressed for almost five years and is ready for trial, class treatment is far superior to individualized treatment of Class members' claims. Specifically, class treatment will "achieve economies of time, effort, and expense, and promote . . . uniformity of decisions as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." *Amchem Prods.*, 521 U.S. at 615 (citations omitted).

(d) Class Counsel Meet the Requirements of Rule 23(g)

Under Rule 23(g), a court that certifies a class must appoint class counsel. Class counsel is charged with fairly and adequately representing the interests of the class. Fed. R. Civ. P. 23(g)(1)(B). In appointing class counsel, the Court must consider: (1) the work counsel has done in identifying or investigating potential claims; (2) counsel's experience in handling class actions,

other complex litigation, and similar claims; (3) counsel's knowledge of the applicable law; and (4) the resources counsel will commit to representing the class. *See* Fed. R. Civ. P. 23(g)(1)(A)(i-iv); *Noble v. 93 Univ. Place Corp.,* 224 F.R.D. 330, 339-40 (S.D.N.Y. 2004).

The Court appointed GGF as interim lead counsel for the Class on August 3, 2018. ECF No. 59 ¶ 8. Plaintiffs respectfully request that the Court now appoint GGF as lead counsel. Harnessing decades of experience in litigating pharmaceutical antitrust cases, GGF and counsel for the class vigorously and efficiently pursued this litigation on behalf of the proposed Class for close to five years, including by identifying, investigating and filing this action ahead of any other plaintiff, engaging in extensive fact and expert discovery, pursuing class certification, filing and opposing discovery and *Daubert* motions, opposing two summary judgment motions, and diligently readying this case for trial.

B. THE PROPOSED SETTLEMENT MEETS THE STANDARD FOR PRELIMINARY APPROVAL

Settlement approval under Fed. R. Civ. P. 23(e) "is within the Court's discretion, which should be exercised in light of the general judicial policy favoring settlement." *In re Sumitomo Copper Litig.*, 189 F.R.D. 274, 280 (S.D.N.Y. 1999) (cleaned up); *Wal-Mart Stores, Inc. v. Visa U.S.A. Inc.*, 396 F.3d 96, 116-17 (2d Cir. 2005) (cleaned up) (the Second Circuit is "mindful of the strong judicial policy in favor of settlements, particularly in the class action context. The compromise of complex litigation is encouraged by the courts and favored by public policy.") Absent "fraud or collusion," courts "should be hesitant to substitute [their] judgment for that of the parties who negotiated the settlement." *Christine Asia Co. v. Yun Ma*, 2019 WL 5257534, at *8 (S.D.N.Y. Oct. 16, 2019) (quoting *In re EVCI Career Colls. Holding Corp. Sec. Litig.*, 2007 WL 2230177, at *4 (S.D.N.Y. July 27, 2007)).

There are two steps to approval: preliminary and final approval. *See* Fed. R. Civ. P. 23(e). At preliminary approval, the Court must assess whether it "will likely be able to approve the proposal" under the four factors enumerated by Rule 23(e)(2):

(A) "the class representatives and class counsel have adequately represented the class";

(B) "the proposal was negotiated at arm's length";

(C) "the relief provided for the class is adequate," after accounting for

(i) "the costs, risks, and delay of trial and appeal,"

(ii) "the effectiveness of any proposed method of distributing relief to the class, including the method of processing class-member claims,"

(iii) "the terms of any proposed award of attorney's fees, including timing of payment," and

(iv) "any agreement required to be identified under Rule 23(e)(3)"; and

(D) "the proposal treats class members equitably relative to each other."

Fed. R. Civ. P. 23(e)(2). The first two factors focus on "procedural fairness," while the latter two factors (and associated subfactors) focus on "substantive fairness." *Christine Asia*, 2019 WL 5257534, at *9–10.

Before Rule 23(e)(2)(C)'s four-factor framework was codified in December 2018, courts in this Circuit employed the nine-factor framework of *City of Detroit v. Grinnell Corporation*, 495 F.2d 448, 463 (2d Cir. 1974).[8] The 2018 amendments to Rule 23 were intended to "add to, rather than displace, the *Grinnell* factors," and there is "significant overlap" under the two frameworks.

[8] The nine *Grinnell* factors are: (i) "the complexity, expense and likely duration of the litigation," (ii) "the reaction of the class to the settlement," (iii) "the stage of the proceedings and the amount of discovery completed," (iv) "the risks of establishing liability," (v) "the risks of establishing damages," (vi) "the risks of maintaining the class action through the trial," (vii) "the ability of the defendants to withstand a greater judgment," (viii) "the range of reasonableness of the settlement fund in light of the best possible recovery," and (ix) "the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation." *Grinnell*, 495 F.2d at 463.

In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig., 330 F.R.D. 11, 29 (E.D.N.Y. 2019) (citing 2018 Advisory Notes to Fed. R. Civ. P. 23, Subdiv. (e)(2)). *See also Leonard v. John Hancock Life Ins. Co. of N.Y.*, 2022 WL 501204, at * 1 (S.D.N.Y. Jan. 10, 2022) (Hellerstein, J.) (considering Rule 23(e)(2) and *Grinnell* together for purposes of preliminary approval); *Geiss v. Weinstein Co. Holdings LLC*, 474 F. Supp. 3d 628, 636 (S.D.N.Y. 2020) (Hellerstein, J.) ("I must consider whether I am likely to find that the settlement is 'fair, reasonable, and adequate in light of the factors enumerated in Rule 23(e)(2) and" *Grinnell*.). Thus, this brief addresses both sets of factors, noting where they overlap.[9]

1. The Settlement Is Procedurally Fair

The Court must first consider whether "the class representatives and class counsel have adequately represented the class" and whether "the proposal was negotiated at arm's length." Fed. R. Civ. P. 23(e)(2)(A)–(B). In assessing adequacy of representation, the Court focuses on whether "1) plaintiff's interests are antagonistic to the interest of other members of the class and 2) plaintiff's attorneys are qualified, experienced and able to conduct the litigation." *Cordes*, 502 F.3d at 99. Where experienced class counsel has negotiated an arm's length agreement after "meaningful discovery," a "presumption of fairness, reasonableness, and adequacy" attaches. *McReynolds v. Richards–Cantave,* 588 F.3d 790, 803 (2d Cir. 2009) (citation omitted); *Christine Asia*, 2019 WL 5257534, at *9. That presumption also applies "when a settlement is reached with the assistance of a mediator." *Puddu v. 6D Glob. Techs.*, 2021 WL 1910656, at *4 (S.D.N.Y. May 12, 2021). Here, the presumption of fairness, reasonableness, and adequacy applies.

[9] The Court need not consider the second *Grinnell* factor – the "reaction of the class" – at this time. *See, e.g., In re Warner Chilcott Ltd. Sec. Litig.*, No. 06-cv-11515 (WHP), 2008 WL 5110904, at *2 (S.D.N.Y. Nov. 20, 2008) ("Since no notice has been sent, consideration of this factor is premature.").

Plaintiffs' interests are aligned with the remainder of the settlement Class: each suffered the same injury (overcharges on purchases of brand and generic Exforge) and have the same interest in maximizing recovery from Novartis. *See In re Global Crossing Secs. & ERISA Litig.*, 225 F.R.D. 436, 453 (S.D.N.Y. 2004) ("There is no conflict between the class representatives and the other class members. All share the common goal of maximizing recovery."); *see also* 1 Newberg on Class Actions § 3:58 (5th ed. 2021) ("Adequacy does not require complete identity of claims or interests between the proposed representative and the class. All that is required . . . is sufficient similarity of interest such that there is no affirmative antagonism between the representative and the class." (citations omitted)).

Class Counsel is highly qualified. They have represented classes in numerous other generic delay cases dating back to the late 1990s and are highly experienced in the prosecution of pharmaceutical antitrust litigation. Class Counsel's view as to the fairness of the settlement is well informed: discovery has long since closed, dispositive motions have been filed and trial preparations were well underway as of the settlement.

The agreement was also reached at arm's length, including participating in an all-day in-person mediation session in Boston supervised by a highly experienced, respected, and neutral mediator, Eric D. Green of Resolutions, LLC. *See D'Amato v. Deutsche Bank*, 236 F.3d 78, 85 (2d Cir. 2001) (recognizing that a mediator's involvement in "settlement negotiations helps to ensure that the proceedings were free of collusion and undue pressure"). This Court should find that Rule 23(e)(2)(A) and (B) are met and that the Settlement is therefore procedurally fair.

2. The Settlement is Substantively Fair

Next, the Court must assess substantive fairness. Rule 23(e)(2)(C) enumerates four factors to be considered: (i) "the costs, risks, and delay of trial and appeal," (ii) "the effectiveness of any proposed method of distributing relief to the class, including the method of processing class-

member claims," (iii) "the terms of any proposed award of attorney's fees, including timing of payment," and (iv) "any agreement required to be identified under Rule 23(e)(3)."

(a) Costs, Risks, and Delay of Trial and Appeal

Rule 23(e)(2)(C)(i) requires courts to consider "the costs, risks, and delay of trial and appeal." This inquiry overlaps with *Grinnell* factors one (the "complexity, expense, and likely duration of the litigation") and factors four, five, and six (the risks of establishing liability and damages and maintaining the class). *See In re Payment Card*, 330 F.R.D. at 36. In assessing these risks, the Court need not "decide the merits of the case," "resolve unsettled legal questions," or "foresee with absolute certainty the outcome of the case." *Fleisher v. Phx. Life Ins. Co.*, 2015 WL 10847814, at *8 (S.D.N.Y. Sep. 9, 2015) (cleaned up). "[R]ather, the Court need only assess the risks of litigation against the certainty of recovery under the proposed settlement." *Id.* (quoting *Global Crossing*, 225 F.R.D. at 459). Courts recognize that "the complexity of Plaintiff's claims *ipso facto* creates uncertainty." *In re Currency Conversion Fee Antitrust Litig.*, 263 F.R.D. 110, 123 (S.D.N.Y. 2009) (citation omitted).

"Antitrust actions are inherently complex." *In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508, 533 (E.D. Mich. 2003). Here, layered on top of the complex economic issues associated with a typical antitrust case are additional regulatory and patent issues about which the jury would need to be educated. Just as in *Cardizem*, these issues include "regulatory issues arising out of the Hatch-Waxman Act; patent law issues relevant to the Defendants' patent litigation underlying the[ir] Agreement; the intricacies of the pharmaceutical industry from a sales and marketing perspective; the scientific and production processes involved with investing and commercializing branded and generic pharmaceutical products; and the FDA regulations applicable to reviewing and approving pharmaceutical products and new manufacturing facilities and processes." *Id*. at 533-34. Resolving

those claims would require "conflicting testimony by experts" and credibility assessments. *Fleisher*, 2015 WL 10847814, at *20.

Novartis, represented by one of the largest and most capable law firms in the world, has vigorously disputed liability, causation and damages, and has filed multiple motions for summary judgment. While Plaintiffs believe that their positions are strong, they would have to prevail as to every contested issue, whereas Novartis would have to prevail on just a single defense to defeat Plaintiffs' claims or severely devalue them. How a jury would resolve the contested issues is opaque at best. *See State of W. Va. v. Chas. Pfizer & Co.*, 314 F. Supp. 710, 743-44 (S.D.N.Y. 1970), *aff'd*, 440 F.2d 1079 (2d Cir. 1971) ("[N]o matter how confident one may be of the outcome of litigation, such confidence is often misplaced."). To wit:

Existence of a Reverse Payment. Novartis has contested that the agreement it entered with Par contained a reverse payment, arguing that the plain text of the agreement and its negotiation history do not support Plaintiffs' view. Even if Plaintiffs were able to convince the jury that the agreement did contain a reverse payment, Plaintiffs would also have to prove that the payment was "large." *Actavis*, 570 U.S. at 157. To prove that the payment was large, Plaintiffs submitted expert testimony that the reverse payment exceeded the value of Novartis's avoided litigation costs. *Id.* at 159; ECF No. 409-55, Elhauge Rpt. Table 4. But Novartis's economic expert opined that the payment was smaller than Novartis's avoided litigation costs, and made other arguments disputing whether the payment was large. ECF No. 409-76, Baker Rpt. § VI.C.

Market Power. Plaintiffs and their experts have argued that the relevant antitrust market is limited to Exforge and its generic versions. Novartis and its experts have argued that the relevant market is much broader than that, encompassing multiple other hypertension drugs and that Novartis did not have market power in the broader hypertension market. Absent proof of market

power in a relevant market, Plaintiffs may be unable to establish an antitrust violation. *Caruso Mgmt. Co. v. Int'l Council of Shopping Ctrs.*, 403 F. Supp. 3d 191, 210 (S.D.N.Y. 2019).

Causation. Even if Plaintiffs prove that there was a reverse payment, they would still have to prove that the reverse payment actually resulted in delayed competition that harmed them. *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 65-66 (2d Cir. 2012) (discussing causation requirement). To that end, Plaintiffs intended to prove that Par was planning to launch when Novartis's '578 patent expired on September 21, 2012, or alternatively, that it would have been economically rational for Novartis and Par to have entered into an alternative license agreement with an earlier generic entry date of July 13, 2013 unpolluted by the reverse payment. In both scenarios, Plaintiffs intended to prove that Novartis would have launched authorized generic Exforge at the same time as Par's generic launch. Plaintiffs also would attempt to prove that other generic companies were ready, willing and able to launch generic Exforge earlier. Novartis has marshalled primary and expert evidence to contest all of Plaintiffs' causation theories, filing *Daubert* and summary judgment motions. *E.g.,* ECF No. 538. If successful, these motions would hamper Plaintiffs' case. *E.g., In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 39 (1st Cir. 2016) ("although the plaintiffs had proved an antitrust violation in the form of a large and unjustified reverse payment from AstraZeneca to Ranbaxy, the plaintiffs had not shown that they had suffered an antitrust injury that entitled them to damages."); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734 (E.D. Pa. 2015) (granting summary judgment for defendants on grounds, *inter alia*, that the purchaser plaintiffs could not prove that they had suffered antitrust injury), *aff'd*, 868 F.3d 132 (3d Cir. 2017).

Statute of Limitations. Novartis has mounted an aggressive attack on Plaintiffs' claims on statute of limitations grounds. Specifically, Novartis has sought summary judgment on the issues

of fraudulent concealment and continuing violations. ECF No. 539. While Plaintiffs are confident as to the timeliness of their claims, if the Court or a jury determined that Novartis and Par did not fraudulently conceal the reverse payment from Class members, the value of Plaintiffs' claim could drop dramatically, eliminating potentially hundreds of millions of dollars in damages from the period September 21, 2012 through May 16, 2014 (four years before Drogueria Betances's complaint).

Even if Plaintiffs were to prevail at trial, this case would likely be tied up in years of post-trial briefing and appellate practice. *See Fleisher*, 2015 WL 10847814, at *6 ("The Settlement also ends future litigation and uncertainty. Even if the Class could recover a judgment at trial and survive any decertification challenges, post-verdict and appellate litigation would likely have lasted for years."); *Strougo ex rel. Brazilian Equity Fund, Inc. v. Bassini*, 258 F. Supp. 2d 254, 258 (S.D.N.Y. 2003) ("The potential for this litigation to result in great expense and to continue for a long time suggest that settlement is in the best interests of the Class.").

These many risks and delays weigh in favor of approval.

(b) Range of Reasonableness of the Settlement Fund

This Court must consider "the range of reasonableness of the settlement fund," both in light of the risks discussed in the previous subsection and "in light of the best possible recovery." *Grinnell*, 495 F.2d at 463.

The recovery of **$126,850,000**, when compared to the damages at issue in the litigation, is exceptional. Plaintiffs' overcharge damages are calculated as the difference between the price they paid for brand and generic Exforge under the anticompetitive conditions that prevailed and competitive conditions in a but-for world absent Novartis's unlawful conduct. Assuming Plaintiffs could collect damages dating back to May 16, 2014 (4 years prior to the filing of the first complaint filed on behalf of the Class), and but-for generic entry on July 13, 2013 (the no-reverse payment

agreed-upon entry date – *supra* 24), damages would be $176.2 million in aggregate overcharges. ECF No. 494-5, Second Supp. Leitzinger Rpt. at Ex. 19A. The proposed settlement represents 72% of the $176,200,000 in overcharges.[10] This monetary relief is far greater than needed to justify the settlement as reasonable. *See Grinnell Corp.*, 495 F.2d at 455 & n.2 (recognizing that "a satisfactory settlement" could amount to a small fraction – such as "a hundredth or even a thousandth part of a single percent of the potential recovery"). For example, in *Fleisher*, Judge McMahon held that a settlement with a cash award amount equal to 68.5% of COI overcharges was *"*one of the most remunerative settlements this court has ever been asked to approve." *See Fleisher*, 2015 WL 10847814, at *11. Courts routinely approve settlements with substantially lower-percentage awards. *See, e.g.*, *In re Air Cargo Shipping Servs. Antitrust Litig.*, 2009 WL 3077396, at *9 (E.D.N.Y. Sept. 25, 2009) (approving settlement value that was 10.5% of total damages); *In re Currency Conversion Fee Antitrust Litig.*, 2006 WL 3247396, at *6 (S.D.N.Y. Nov. 8, 2006) (approving settlement cash award that was 10–15% of total damages). Furthermore, "settlement assures immediate payment of substantial amounts to Class Members, 'even if it means sacrificing speculative payment of a hypothetically larger amount years down the road.'" *Charron v. Pinnacle Grp. N.Y. LLC*, 874 F. Supp. 2d 179, 201 (S.D.N.Y. 2012) (citation omitted).

These results are excellent for the Class, especially in light of the many risks, uncertainties, and delays that Plaintiffs faced. And Class Counsel's view of the reasonableness of the settlement

[10] Plaintiffs also offer another causation theory – that Par would have launched upon the expiry of Novartis's '578 patent – and the Settlement recovery amounts to 68% of the $186.6 million overcharge that Plaintiffs would seek under that causation benchmark, assuming they could recover damages incurred during the four years preceding the Drogueria Betances complaint. *Id*. If Plaintiffs had prevailed on fraudulent concealment, an issue on which Defendants sought Summary Judgment, the Settlement recovery amounts to 44% of the overcharge under an no-payment settlement scenario and 29% of the overcharge under a launch after expiry of the '578 patent scenario. *Id*. at Ex. 18A.

is given considerable weight because they are closest to the facts and risks associated with the litigation. *See In re Hi- Crush Partners L.P. Sec. Litig.*, 2014 WL 7323417, at *5 (S.D.N.Y. Dec. 19, 2014) ("[Lead Counsel's] opinion is entitled to great weight." (quotation marks and citation omitted)).

(c) The Proposed Plan of Allocation is Effective, Fair and Reasonable

Next, Rule 23(e)(2)(C)(ii) requires that the "proposed method of distributing relief" be "effective." A distribution plan satisfies the Rule if it is "reasonable" and has a "rational basis," especially if "recommended by experienced and competent class counsel." *In re Payment Card*, 330 F.R.D. at 40 (quoting *In re WorldCom, Inc. Sec. Litig.*, 388 F. Supp. 2d 319, 344 (S.D.N.Y. 2005)).

The proposed plan of distribution meets this standard. As described in the proposed notice to Class members, and as set forth in the appended Direct Purchaser Class Plaintiffs' [Proposed] Plan of Allocation for the Direct Purchaser Class and accompanying Declaration Related to Proposed Settlement Allocation Plan by Dr. Leitzinger (*see* Gerstein Decl. at Exs. 2-3), the proceeds of the proposed Settlement in this case, net of Court-approved attorneys' fees, service awards for Named Plaintiffs, and costs of litigation ("Net Settlement Fund"), will be paid to Class members who submit timely and valid claims based on each Class member's *pro rata* share of the Class's total purchases of brand and/or generic Exforge during the relevant damages time periods during which Direct Purchaser Plaintiffs' expert calculated damages. This plan is "similar to plans that have previously been approved by courts in analogous cases and implemented with a high degree of success and efficiency" and should be approved here as well. *See e.g. In re Namenda*

Direct Purchaser Antitrust Litig., 462 F. Supp. 3d 307, 316-17 (S.D.N.Y. 2020) (collecting cases).[11]

(d) The Terms of Any Proposed Award of Attorney's Fees

The Court also considers the terms of any proposed award of attorney's fees, including timing of payment. Fed. R. Civ. P. 23(e)(2)(C)(iii). Under the Settlement, Class Counsel will apply for an award of attorneys' fees not to exceed 33 1/3% of the of the value of the Settlement, plus reimbursement of litigation expenses. Class Counsel will not receive any funds until the Court has granted its fee request. Awards of this magnitude have been deemed reasonable in comparable generic delay antitrust actions.[12] Class Counsel's fee request therefore does not weigh against preliminary approval and will be briefed more fulsomely at the final approval stage.

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[11] *See also* 4 Alba Conte & Herbert Newberg, Newberg on Class Actions, § 12.35, at 350 (4th ed. 2002) (noting that pro-rata allocation of a settlement fund "is the most common type of apportionment of lump sum settlement proceeds for a class of purchasers" and "has been accepted and used in allocating and distributing settlement proceeds in many antitrust class actions"); *Beneli v. BCA Fin. Servs., Inc*., 324 F.R.D. 89, 105-06 (D.N.J. 2018) ("In particular, pro rata distributions are consistently upheld, and there is no requirement that a plan of allocation differentiat[e] within a class based on the strength or weakness of the theories of recovery.") (citation and internal quotation marks omitted); *In re Packaged Ice Antitrust Litig*., 2011 WL 6209188, at *15 (E.D. Mich. Dec. 13, 2011) ("Typically, a class recovery in antitrust or securities suits will divide the common fund on a pro rata basis among all who timely file eligible claims, thus leaving no unclaimed funds.") (quoting 3 Newberg on Class Actions, § 8:45 (4th ed. 2011)); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*., 1:14-md-02503-DJC, ECF Nos. 1163, 1179 (D. Mass.) (pro rata shares of settlement fund computed on basis of claimants' brand and generic purchases); and *In re Lidoderm Antitrust Litig*., 3:14-md-02521-WHO, ECF Nos. 1004-5, 1004-6, 1054 (N.D. Cal.) (pro rata shares of settlement fund computed on basis of claimants' brand and generic purchases).

[12] *See, e.g.*, Order, *In re: Opana ER Antitrust Litig.*, 1:14-cv-10150 (N.D. Ill. Nov. 3, 2022) at ECF No. 1085 (awarding 36% of $145M settlement); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521 (N.D. Cal. Sept. 20, 2018) (awarding 27 ½% of $166M settlement); *Am. Sales Co., LLC v. Pfizer, Inc.*, 14-cv-361 (E.D. Va. Apr. 18, 2018) (awarding 33 ⅓% of $94M settlement); *In re Modafinil Antitrust Litig.*, No. 07-1979 (E.D. Pa. Oct. 16, 2015) (awarding 27 ½% of $512M settlement); *In re Prograf Antitrust Litig.*, No. 11-md-2242 (D. Mass. May 20, 2015) (awarding 33 ⅓% of $98M settlement); *In re Neurontin Antitrust Litig.*, No. 02-1830 (D.N.J. Aug. 6, 2014) (awarding 33 ⅓% of $191M settlement); *In re Flonase Antitrust Litig.*, No. 08-cv-3149 (E.D. Pa. June 14, 2013) *(cont'd next page)*

(e) Any Agreement Required to Be Identified Under Rule 23(e)(3)

Rules 23(e)(2)(C)(iv) and 23(e)(3) require that any agreement "made in connection with the proposal" be identified. Plaintiffs and Novartis have entered into an agreement under which Novartis may terminate this Agreement after the Opt-Out Period expires, if the percentage of the Settlement Class (as measured against the settlement amount) that submits requests for exclusion from the Settlement Class exceeds the percentage set forth in a confidential settlement addendum (which will be provided to the Court upon request). Settlement Agreement § 14.

3. The Plan of Allocation Treats Class Members Equitably

The final Rule 23(e)(2) factor requires the Court to assess whether "the proposal treats class members equitably relative to each other." Fed. R. Civ. P. 23(e)(2)(D). As set forth above at § III.B.2.c, the proposed plan of allocation (filed herewith), which is similar to plans of allocation that have been accepted repeatedly by other courts, treats Class members equitably by distributing damages on a *pro rata* basis.

4. The Proposed Settlement Satisfies Other Relevant Factors

(a) Stage of Proceedings.

The Court must also consider the third *Grinnell* factor, "[t]he stage of the proceedings and the amount of discovery completed." *Grinnell*, 495 F.2d at 463. The Court assesses whether Plaintiffs "have obtained a sufficient understanding of the case to gauge the strengths and

(awarding 33 ⅓% of $150M settlement); *In re Tricor Antitrust Litig.*, No. 05-cv-340 (D. Del. April 23, 2009) (awarding 33 ⅓% of $250M settlement); *In re Relafen Antitrust Litig.*, 2004 U.S. Dist. LEXIS 28801 (D. Mass. April 9, 2004) (awarding 33 ⅓% of $175M settlement); *In re Buspirone Antitrust Litig.*, 2003 U.S. Dist. LEXIS 26538 (S.D.N.Y. April 11, 2003) (awarding 33 ⅓% of $220M settlement). *See also Mohney v. Shelly's Prime Steak, Stone Crab & Oyster Bar*, 2009 WL 5851465, at *5 (S.D.N.Y. Mar. 31, 2009) ("Class Counsel's request for 33% of the Settlement Fund is typical in class action settlements in the Second Circuit").

weaknesses of their claims and the adequacy of the settlement." *In re AOL Time Warner, Inc.*, 2006 WL 903236, at *10 (S.D.N.Y. Apr. 6, 2006).

Here, Plaintiffs engaged in extensive discovery, briefing on class certification, *Daubert* and summary judgment motions, as well as trial preparation before engaging in a day-long mediation with an experienced mediator before reaching agreement with Novartis. Plaintiffs took and defended 38 complex depositions. All of the class representatives and some putative class members were deposed. Class Counsel had a robust record against which to measure the adequacy of the proposed Settlement. This factor also supports approval.

(b) Defendants' Ability to Withstand a Greater Judgment

The Court also considers "the ability of the defendants to withstand a greater judgment." *Grinnell Corp.*, 495 F.2d at 463. Here, even if Novartis could withstand a greater judgment, this does not undermine the fairness of the Settlement. *See, e.g.*, *Fleisher*, 2015 WL 10847814, at *9 (noting that defendant's ability to pay more "does not, standing alone, indicate the settlement is unreasonable or inadequate" (citation omitted)).

(c) Scope of the Release

Courts may also look to the scope of the release. *See Payment Card*, 330 F.R.D. at 42 n.41. Here, the Settlement Class would release "all claims related to the Direct Purchaser Class Action that accrued prior to the date of this Settlement Agreement." Ex. 1, Settlement Agreement § 11(a). The release is appropriate. *See Wal-Mart Stores*, 396 F.3d at 107 ("The law is well established in this Circuit and others that class action releases may include claims not presented and even those which could not have been presented as long as the released conduct arises out of the 'identical factual predicate' as the settled conduct.").

C. THE PROPOSED FORM AND MANNER OF NOTICE ARE APPROPRIATE

1. Form of Notice

Under Rule 23(e), class members are entitled to reasonable notice of a proposed settlement before it is finally approved by the Court, and to notice of the final Fairness Hearing. *See* MANUAL FOR COMPLEX LITIGATION, § §§ 21.312, 21.633 (4th ed. 2005) ("MANUAL"). For 23(b)(3) classes, the court must "direct to class members the best notice that is practical under the circumstances, including individual notice to all members who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B). There are two components of notice: (1) the form of the notice; and (2) the manner in which notice is sent to Class members.

The proposed form of notice is based on notices approved by courts in similar cases. *See, e.g.*, *In re Namenda Direct Purchaser Antitrust Litig.*, 1:15-cv-07488, ECF No. 919-1, at Ex. B (S.D.N.Y.) (notice); *id*. at ECF No. 920, ¶ 7 (approving the form and manner of notice); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 1:14-md-02503-DJC, ECF No. 1094-1, at Ex. B (D. Mass.) (notice); *id.* at ECF No. 1095, ¶¶ 6-9 (approving the form and manner of notice); *In re Lidoderm Antitrust Litig.*, 3:14-md-02521-WHO, ECF No. 1004-7 (N.D. Cal.) (notice); *id.* at ECF No. 1018, ¶¶ 6-9 (approving the form and manner of notice); *In re K-Dur Antitrust Litig.*, No. 01-cv-1652 (SRC)(CLW), ECF No. 1044-5, at Ex. B (D.N.J.) (notice); *id.* at ECF No. 1045, ¶ 5 (approving form and manner of notice).

The proposed notice is designed to alert Class members to the proposed Settlement by using a bold headline, and the plain language text provides important information regarding the terms of the proposed Settlement, including the nature of the action; the definition of the Class; the identity of the counter party, here Novartis; the significant terms of the proposed Settlement including the total amount Novartis has agreed to pay to the Class; that a Class member may opt

out of the settlement Class or object to all or any part of the proposed Settlement and the process and deadline for doing so, including entering an appearance through an attorney if the Class member desires; the process for obtaining a portion of the Settlement proceeds; the final approval process for the proposed Settlement and Class Counsel's request for attorneys' fees of up to 33 1/3% of the settlement amount (net of Court-approved reimbursed costs and expenses and service awards), reimbursement of all litigation expenses, and incentive awards to the Named Plaintiffs; the schedule for completing the settlement approval process, including the submission of the motion for final approval of the Settlement, and the submission of the motion for attorneys' fees, expenses, and incentive awards to the Named Plaintiffs; and the binding effect of a final judgment on members of the Class. *See generally* Exhibit B to the Settlement Agreement.

In addition, the proposed notice prominently features proposed Lead Counsel's contact information and information about proposed Lead Counsel's website where the Settlement documents, the proposed plan of allocation, and supplemental information will be provided, as well as contact information for the settlement administrator. *Tiro v. Public House Invs., LLC*, 2013 WL 2254551, at *5 (S.D.N.Y. May 22, 2013) (approving notice that "describes the terms of the settlement, informs the class about the allocation of attorneys' fees and costs, and provides specific information regarding the date, time, and place of the final approval hearing").

Finally, the proposed notice informs the class that in light Par's August 16, 2022 bankruptcy filing (S.D.N.Y. Case No. 22-22546), the Named Plaintiffs have stipulated to dismissal with prejudice of their claims against Par (ECF No. 585), and that class members do not need to opt out of the class to pursue claims against Par. *See* Ex. B to the Settlement Agreement at 1, 10.

2. Manner of Notice

Plaintiffs propose to send notice by first-class United States mail to each Class member, all of which are business entities. The list of Class members was drawn from Novartis and Par's

electronic transactional sales data and/or are otherwise known to Class Counsel. In circumstances in which all class members can be identified, the best method of notice is individual notice. *See* MANUAL, § 21.311 at 488 ("Rule 23(c)(2)(B) requires that individual notice in 23(b)(3) actions be given to class members who can be identified through reasonable effort."). Individual notice by first class mail has been recognized as appropriate. *See, e.g. In re Namenda Direct Purchaser Antitrust Litig.*, 2020 U.S. Dist. LEXIS 93189, at *7 (S.D.N.Y. May 27, 2020) (notice by first class mail "constituted the best notice practicable"); *In re Take Two Interactive Sec. Litig.*, 2010 WL 11613684, at *12 (S.D.N.Y. June 29, 2010) (citing *In re Global Crossing Securities and ERISA Litigation*, 225 F.R.D. at 448). As discussed above, courts have approved similar notice plans in similar generic suppression cases brought by direct purchasers.

D. RG/2 IS AN APPROPRIATE SETTLEMENT ADMINISTRATOR

Plaintiffs request that RG/2 be appointed as the settlement administrator. RG/2 will oversee the administration of the Settlement, including disseminating notice to the Class, calculating each Class member's *pro rata* share of the Net Settlement Fund in conjunction with Dr. Leitzinger, and distributing settlement proceeds. RG/2 has been appointed claims administrator in this district in the past. *See, e.g.*, *Bryant v. Potbelly Sandwich Works, LLC*, 2020 WL 563804 (S.D.N.Y. Feb. 4, 2020).

E. FIRST STATE TRUST COMPANY IS AN APPROPRIATE ESCROW AGENT

Plaintiffs request that First State Trust Company serve as escrow agent, as it has done in prior class actions. Novartis has approved this selection. *See* Ex. D to the Settlement Agreement (Escrow Agreement).

F. THE PROPOSED SCHEDULE IS FAIR AND SHOULD BE APPROVED

As set forth in the proposed order appended hereto as Exhibit A, Plaintiffs propose the following schedule for completing the Settlement approval process:

- Within 10 days of filing of the Settlement Agreement and motion for preliminary approval, Novartis shall serve notices pursuant to the Class Action Fairness Act of 2005 ("CAFA notices");

- Within 15 days from the date of preliminary approval, notice shall be mailed to each member of the Class;

- No later than 14 days before the expiration of the deadline for Class members to object to the settlement and/or attorneys' fees, expenses and service awards, Class Counsel will file all briefs and materials in support of the application for attorneys' fees, expenses and service awards;

- Within 30 days from the date that notice is mailed to each member of the Class, Class members may opt out of the Class or object to the Settlement and/or attorneys' fees, expenses and incentive awards;

- No later than 21 days after the expiration of deadline for Class members to object to the Settlement and/or attorneys' fees, expenses and service awards, Class Counsel will file all briefs and materials in support of final approval of the settlement; and

- On a date to be set by the Court no earlier than 90 days following Novartis's service of the CAFA notices, and after the expiration of the deadline for Class members to file any objections, the Court will hold a final Fairness Hearing.

This schedule is fair to Class members since it provides ample time for consideration of the Settlement and Class Counsel's request for fees, expenses and incentive awards before the deadline for submitting objections. Specifically, Class members will have the notice for 30 days before the deadline to opt out of the Class or object to the Settlement, and will have Class Counsel's request for fees, expenses and incentive awards for two weeks before the deadline to object to Class Counsel's request for fees, expenses and incentive awards. In addition, the schedule allows the full statutory period for Novartis to serve their Class Action Fairness Act notices pursuant to

28 U.S.C. § 1715, and for regulators to review the proposed settlement and, if they choose, advise the Court of their view.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court enter an order, substantially in the form of Ex. A to the Settlement Agreement, granting Plaintiffs' unopposed motion for class certification, preliminarily approving the settlement, appointing Garwin Gerstein & Fisher LLP as Lead Counsel for purposes of settlement, appointing RG/2 as settlement administrator, appointing First State Trust Company as escrow agent, and setting a proposed schedule.

Dated: December 28, 2022

Respectfully submitted,

/s/ Bruce E. Gerstein

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing memorandum was served on all parties of record through the Court's Electronic Case Filing and Case Management system on December 28, 2022.

/s/ Bruce E. Gerstein
Bruce E. Gerstein