

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re: Prograf Antitrust Litigation	MDL No. 2242
This Document Relates To: All Direct Purchaser Class Actions	Civil Action No. 1:11-md-02422-RWZ

**DIRECT PURCHASER PLAINTIFFS’
MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION FOR PRELIMINARY APPROVAL OF PROPOSED CLASS ACTION
SETTLEMENT WITH ASTELLAS PHARMA, US, INC. (“ASTELLAS”)**

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4 <i>Newberg on Class Actions</i> §11:25, at 38-39 (4th ed. 2002)	4, 7
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I. INTRODUCTION

Direct Purchaser Plaintiffs¹ and the certified class of direct purchasers (the “Class,” collectively, the “Plaintiffs”) respectfully submit this Memorandum of Law in support of their Motion for Preliminary Approval of the Proposed Class Action Settlement with Astellas Pharma, US, Inc. (“Astellas”), the defendant in *In re Prograf Antitrust Litigation*, Civil Action No. 1:11-md-10344-RWZ (the “Class Action”).

In exchange for Astellas’s agreement to pay Plaintiffs \$98,000,000.00, plus interest earned while in escrow, in consideration, the proposed settlement releases Astellas from all claims by Plaintiffs in the Class Action (the “Settlement”). Plaintiffs respectfully request that the Court enter a preliminary approval order, substantially in the form annexed to Plaintiffs’ Motion for Preliminary Approval as Ex. 1, by which the Court will preliminarily approve the Settlement between Plaintiffs and Astellas as embodied in the Settlement Agreement, attached to the Declaration of Bruce E. Gerstein (“Gerstein Decl.”) as Ex. 1. This motion for preliminary approval, which is supported by Astellas, is unopposed.²

II. PROCEDURAL AND FACTUAL BACKGROUND

Plaintiffs in the Direct Purchaser Class Action alleged that Astellas violated the federal antitrust laws (15 U.S.C. § 2) by filing an objectively baseless citizen petition with the United States Food and Drug Administration to illegally delay FDA approval of a generic version of the prescription drug Prograf (tacrolimus). Plaintiffs allege that, as a result of Astellas’ antitrust violations, they were forced to pay artificially inflated prices for tacrolimus. Astellas denies

¹ Burlington Drug Company, Inc., King Drug Company of Florence, Inc., Louisiana Wholesale Drug Co., Inc., Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors and Stephen L. LaFrance Holdings, Inc., and Uniondale Chemists, Inc.

² As detailed below, preliminary approvals of proposed class action settlements are procedural in nature and do not involve determinations on the merits of the proposed settlement, as long as the settlement falls within the range of possible approval. See *In re Prudential Securities Inc. Ltd. P’ships. Litig.*, 163 F.R.D. 200, 209 (S.D.N.Y.1995).

Plaintiffs' allegations of unlawful or wrongful conduct, and denies that any conduct challenged by Plaintiffs caused any damage whatsoever, and have asserted a number of defenses to Plaintiffs' claims. The Court is familiar with the parties' factual and legal positions, having ruled on significant motion practice including Astellas's motion to dismiss, Astellas's motion for summary judgment, various discovery disputes, and extensive pretrial briefing. These motions touched upon virtually every aspect of this Class Action, which the parties have aggressively litigated for close to four years.

On April 23, 2013, this Court certified a class consisting of:

All persons or entities in the United States and its territories that purchased Prograf directly from Astellas from April 8, 2008 to December 31, 2011 (the "class period"). Excluded from the class are Astellas and its officers, directors, management, employees, parents, subsidiaries, and affiliates, and federal government entities.³

This Court also designated Burlington Drug Company, Inc., King Drug Company of Florence, Inc., Louisiana Wholesale Drug Company, Inc., Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors and Stephen L. LaFrance Holding, Inc., and Uniondale Chemists, Inc. class representatives and Hagens Berman Sobol Shapiro LLP and Garwin Gerstein & Fisher LLP as Class Counsel.⁴

After intensive arm's-length negotiations, fact and expert discovery including, among other things, the production and inspection of hundreds of thousands of pages of documents, depositions of Astellas's employees, Astellas's experts, and third-party witnesses, substantial briefing on the legal issues (including motions to dismiss, summary judgment, *Daubert*, and motions *in limine*), consultation with economic, scientific and regulatory experts regarding

³ Order, *In re Prograf Antitrust Litig.*, 11-md-2242, (D.Mass. April 23, 2013) (Doc. 216 at 1.)

⁴ *Id.* at 3-4.

numerous relevant legal, evidentiary, and economic issues, successfully defeating a motion for summary judgment filed by Astellas, and preparing the case for trial, Plaintiffs, on behalf of the Direct Purchaser Class, agreed, subject to the Court's approval, to settle their claims against Astellas.

The proposed Settlement Agreement, which is attached to the Gerstein Decl. as Ex. 1, provides for Astellas to pay \$98,000,000.00 (ninety-eight million dollars) to be distributed among the Class as outlined in the Settlement Agreement in exchange for a full and complete settlement and release of all claims that Plaintiffs have asserted or could have asserted in the Direct Purchaser Class Action.⁵

The first step in the settlement approval process is the submission of the proposed Settlement to the Court for preliminary approval, followed by communication of the terms of the proposed Settlement to the Class for its consideration. If the Court grants Plaintiffs' motion, the terms of the proposed Settlement will be communicated directly to the Class members by U.S. mail, at the addresses at which each Class member previously successfully received notice of pendency of this Action. Notice will also be published in *The Pink Sheet*. Defendant has reviewed and agreed to the proposed forms of notice. Accordingly, this motion seeks entry of the proposed Preliminary Approval Order attached to the Gerstein Decl. as Exhibit 2, which provides for: (i) preliminary approval of the proposed Settlement; (ii) approval of the proposed form and manner of notice; and (iii) establishment of the proposed schedule leading up to and including the Fairness Hearing.

III. PRELIMINARY APPROVAL SHOULD BE GRANTED

"Settlement agreements enjoy great favor with the courts as a preferred alternative to

⁵ The release, as set forth in Paragraph 11 of the Settlement Agreement, specifically excludes all claims arising in the ordinary course of business between Direct Purchaser Class members and the "Released Parties" concerning product liability, breach of contract, breach of warranty or personal injury.

costly, time-consuming litigation.”⁶ Approval of a class action settlement under Fed. R. Civ. P. 23(e) involves a two-step process. First, counsel submits the proposed terms of settlement and the court makes a preliminary fairness evaluation.⁷ In this preliminary evaluation of a proposed settlement, the court determines only whether the settlement has “obvious deficiencies” or whether “it is in the range of fair, reasonable, and adequate.”⁸ In this Circuit and elsewhere, settlements are favored, particularly of class actions.⁹

“At the preliminary approval stage, the Court need not make a final determination regarding the fairness, reasonableness and adequateness of a proposed settlement; rather the Court need only determine whether it falls within the range of possible approval.”¹⁰ “Ultimately, the more fully informed examination required for final approval will occur in connection with the Final Fairness Hearing, where arguments for and against the proposed settlement will be presented after notice and an opportunity to consider any response provided by the potential Class Members.”¹¹

If the Court finds that the parties reached the settlement as a result of good-faith negotiations and after sufficient discovery, then a presumption of fairness attaches to the settlement.¹² Courts in this Circuit have looked to four factors to determine whether a settlement is entitled to such a presumption: “(1) the negotiations occurred at arm’s length; (2) there was

⁶ *Fid. & Guar. Ins. Co. v. Star Equip. Corp.*, 541 F.3d 1, 5 (1st Cir. 2008).

⁷ See *Federal Judicial Center, Manual for Complex Litigation* §21.632 (4th ed. 2004) (hereafter “*Manual*”); see also 4 *Newberg on Class Actions* §11:25, at 38-39 (4th ed. 2002) (endorsing two-step process).

⁸ *In re M3Power Razor Sys. Mktg. & Sales Prac. Litig.*, 270 F.R.D. 45, 52 (D. Mass. 2010) (Woodlock, J.) (citing *Manual* §21.632).

⁹ *In re Lupron Mktg. & Sales Practices Litig.*, 228 F.R.D. 75, 88 (D. Mass. 2005) (citing *City P’ship Co. v. Atl. Acquisition Ltd. P’ship*, 100 F.3d 1041, 1043 (1st Cir. 1996)).

¹⁰ *In re Puerto Rican Cabotage Antitrust Litig.*, 269 F.R.D. 125, 140 (D. Mass. 2010) (Dominguez, J.) (citations omitted).

¹¹ *In re M3 Power Razor Sys.*, 270 F.R.D. at 62.

¹² See *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 588 F.3d 24, 32-33 (1st Cir. 2009).

sufficient discovery; (3) the proponents of the settlement are experienced in similar litigation; and (4) only a small fraction of the class objected.”¹³ As explained below, this settlement more than satisfies the relevant criteria for preliminary approval.

A. The Proposed Settlement Is the Product of Good Faith, Extensive, Arm’s-Length Negotiations

The proposed Settlement resulted from extensive arm’s-length negotiations undertaken in good faith between Plaintiffs, Class Counsel, and Astellas, respectively. Notably, the parties engaged in negotiations before an independent mediator who facilitated the settlement, which other courts in this Circuit have found to satisfy the first prong.¹⁴ The negotiations included a full-day mediation session and subsequent shuttle-diplomacy with the highly respected and experienced mediator Professor Eric Green, over the course of three months. The mediation actively involved not only Class Counsel and counsel for Defendant, but also representatives of the parties, in person and by telephone.

The parties’ settlement negotiations did not begin until after over three years of litigation, after significant discovery and motion practice on Astellas’s motion to dismiss, Astellas’s summary judgment motion, *Daubert* motions, and extensive pretrial briefing. The negotiations ended on the eve of trial. As a result, the parties have had the opportunity to scrutinize the strengths and weaknesses of the pending claims and defenses, and to consider, among other issues, liability, causation and damages. Ultimately, the narrowing of issues that naturally occurred during pretrial motion practice and discovery enabled the parties to reach the proposed Settlement. Because of the extensive, arm’s-length bargaining involved, there is no

¹³ *In re Lupron Mktg. & Sales Pracs. Litig.*, 345 F. Supp. 2d 135, 137 (D. Mass. 2004) (Stearns, J.). The fourth factor is more often relevant for purposes of final approval, after notice has issued and class members have been given an opportunity to object to a settlement.

¹⁴ *Rolland v. Cellucci*, 191 F.R.D. 3, 6 (D. Mass. 2000) (Finding the fact that parties engaged the services of a mediator significant to establishment of arms-length negotiating.); *Scovil v. FedEx Ground Package Sys.*, 2014 U.S. Dist. LEXIS 33361 at *15-*16 (D. Me. Mar. 14, 2014) (Same.).

issue (or even a suggestion) of any collusive aspect to the proposed Settlement.

B. There Was More Than Sufficient Discovery and Investigation for Class Counsel for the Class to Make an Informed Decision

Prior to filing suit, Class Counsel undertook a comprehensive investigation of the facts and law giving rise to the claims alleged. This investigation included, among other things, meeting with the named Class representatives, reviewing transactional data related to the purchase of Prograf, and conducting extensive industry, legal, regulatory, scientific, and economic research.

Subsequent discovery in this case spanned over two years. In all, Plaintiffs reviewed and analyzed more than 317,700 documents and almost three million pages produced by Astellas and various non-parties. Armed with this written and electronic discovery, counsel for the Direct Purchaser Class deposed Astellas's current and former executives and employees, experts, and various non-parties, nineteen depositions in all. Counsel for the Direct Purchaser Class also retained and worked with expert witnesses in evaluating scientific, regulatory and economic issues relating to liability and damages. As a result, issues relating to liability, causation and damages have been developed sufficiently for counsel for the Direct Purchaser Class to make an informed decision regarding the proposed Settlement. Plaintiffs' counsel have prepared this case for trial and only settled with Astellas a few weeks before trial was set to commence.

C. The Proponents of the Settlement Are Highly Experienced in Antitrust Litigation

Class Counsel believes that this is a fair settlement and is in the best interests of the Class. The Class is represented by lawyers who have extensive antitrust class action experience, and who this Court appointed based on that experience.¹⁵ Co-Lead Counsel and the other firms

¹⁵ See, Motion for Appointment of Class Counsel for Direct Purchaser Plaintiffs, *In re Prograf Antitrust Litig.*, 11-md-2242, (D.Mass. April 2, 2012) (Doc. 60, 60-2, 60-3).

representing the Direct Purchaser Class are on the forefront of antitrust litigation and complex litigation generally, as well as having specialized in Hatch-Waxman Direct Purchaser antitrust actions. Significantly, the proposed Class is composed primarily of many of the same wholesalers and retail entities that composed the classes in many prior cases, and no member of the proposed Class has objected to the adequacy of class counsel in obtaining prior settlements. Other courts have also recognized class counsel's expertise in this field and have been repeatedly adjudged class counsel adequate under Rule 23(a)(4) and 23(g).¹⁶ Thus, Class counsel are well-versed in both prosecution and settlement of this type of litigation.

Accordingly, Class counsel's recommendations are entitled to great weight. Indeed, courts have repeatedly and explicitly deferred to the judgment of experienced counsel who have conducted arm's-length negotiations in approving proposed class settlements.¹⁷ The presumption in favor of such settlements reflects courts' understanding that vigorous, skilled negotiation protects against collusion and advances the fairness interests of Rule 23(e).

D. Initial Reaction of Class Members Is Fully Supportive of the Settlement Making a Second-Opt Out Period Unnecessary

Class members were given the opportunity to opt-out of the class when the Court first certified it.¹⁸ The proposed Settlement Agreement does not provide for a second opt-out period and Fed. R. Civ. P. 23(e) does not require one.¹⁹ In cases like here where the class members are,

¹⁶ *Id.*

¹⁷ See, e.g., *Rolland* 191 F.R.D. at 10 ("When the parties' attorneys are experienced and knowledgeable about the facts and claims, their representations to the court that the settlement provides class relief which is fair, reasonable and adequate should be given significant weight."); *Bussie v. Allmerica Fin. Corp.*, 50 F. Supp. 2d 59, 77 (D. Mass. 1999) ("The Court's fairness determination also reflects the weight it has placed on the judgment of the parties' respective counsel, who are experienced attorneys and have represented to the Court that they believe the settlement provides to the Class relief that is fair, reasonable and adequate.") *Manual* § 30.42; 4 *Newberg on Class Actions*, § 11.41.

¹⁸ Pursuant to the Court's Order dated August 6, 2013 (Doc. 288), a "Notice of Pendency of Class Action" in a form approved by the Court, was sent to putative class members. Opt-out elections were required to be postmarked by October 31, 2013. No parties/entities have elected to opt-out of the class.

¹⁹ See *In re Carbon Black Antitrust Litig.*, No. 03-10191 (D. Mass. Nov. 29, 2006) (preliminarily approving

and have been, well-protected in the litigation and settlement negotiations, “it is not necessary to provide the class members with an opportunity to opt-out of the settlement.”²⁰

Given the circumstances of this case, and of the history of this type of pharmaceutical antitrust litigation in general, a second opt-out period is not needed. The class was given a lengthy period to opt-out when it was initially certified. And, the class is composed of sophisticated businesses who have participated in a number of prior, similar class actions relating to allegations of delayed generic competition. Their experience and sophistication, combined with the prior opt-out opportunity and the other protections afforded the class, make a second opt-out period unnecessary. Class members retain their right to object to the settlement, including to the absence of a second opt-out opportunity. If any such objections are lodged, the Court can determine at that time whether a second opt out period is needed. Although formal notice of settlement has not yet been sent, counsel for Plaintiffs have spoken with the named Plaintiffs and a number of members of the Class to describe the proposed Settlement. None has indicated that they oppose the Settlement. As such, a formal hearing on preliminary approval is unnecessary.²¹

settlement and explaining that “[i]n light of the previous notice to class members of the pendency of this action and the certification of the class, which complied fully with the requirements of Rule 23 and due process, there is no need for an additional opt-out opportunity pursuant to Rule 23(e)[(4)]”); *In re Tricor Direct Purchaser Antitrust Litig.*, No. 05-340, Order Preliminarily Approving Direct Purchaser Class’s Proposed Settlement ¶ 4 (D. Del. Jan. 8, 2009) (“there is no need for an additional opt-out period under Fed. R. Civ. P. 23(e)(4)”); *In re Ovcon Antitrust Litig.*, No. 05-2195 (D.D.C. Nov. 9, 2005) (preliminarily approving settlement and ordering that no second opt-out opportunity was needed).

²⁰ *In re MetLife Demutualization Litig.*, 689 F. Supp. 2d 297, 345-46 (E.D.N.Y. 2010).

²¹ A hearing is neither necessary nor required under Fed. R. Civ. P. 23(e) at the preliminary approval stage. As explained in the MANUAL FOR COMPLEX LITIGATION, § 21.632 at 382 (4th ed. 2005) (the “Manual”), “[i]n some cases, this initial evaluation can be made on the basis of information already known, supplemented as necessary by briefs, motions, or informal presentations by parties.” See *Curiale v. Lenox Group, Inc.*, 2008 WL 4899474 (E.D. Pa. Nov. 14, 2008) (court granting preliminary approval without hearing).

E. The Proposed Settlement is in the Best Interest of the Class

Having evaluated the strength of Plaintiffs' claims and the merits of Astellas's anticipated defenses, Counsel for Plaintiffs feel strongly that the consideration offered by Astellas in the settlement is fair and that the settlement is in the best interests of the Class, since even if Plaintiffs established a violation, damages at trial would be highly dependent on the jury's findings on Sandoz's "but-for" generic entry date, a hotly disputed issue. Under Plaintiffs' model, Sandoz would have entered in September 2008, for damages of \$185,000,000, while Astellas submitted expert opinion modeling generic entry just before it actually occurred. If the jury accepted Astellas's model, damages would have been negligible.

Accordingly, based on the above factors, this Court should grant preliminary approval of the proposed Settlement.

IV. PLAINTIFFS WILL MOVE THE COURT TO APPROVE NOTICE TO THE CLASS AND TO SCHEDULE A FAIRNESS HEARING AND SET CORRESPONDING DEADLINES.

Federal Rule of Civil Procedure 23(e)(1) provides that "[t]he court must direct notice in a reasonable manner to all class members who would be bound by the propos[ed settlement]." Proposed Notice, in a form already proven successful in this case in notifying the Class of the pendency of this action, is attached to the Gerstein Decl. as Ex. 3. Specifically, the Class is a finite group of sophisticated business, consisting of 25 members. The identity of Class members has already been determined and notice of pendency of class action effectuated by direct mail.²² Thus the direct mail method is sufficient to provide notice of this settlement. In addition, Class Counsel will post the Settlement Agreement on their websites, on the website of the Claims Administrator, and in *The Pink Sheet*, in a form attached as Ex. 4 to the Gerstein Decl.

²² Direct Purchaser Plaintiffs' Notice of Filing of Declaration of Notice Administrator Concerning Delivery of Notice, *In re Prograf Antitrust Litig.*, 11-md-2242 (D.Mass. Sept. 13, 2013) (Doc. 294). *See also*, Docs. 347, 288.

The proposed notice fairly describes the proposed Settlement and its legal significance, thereby satisfying the requirements of Rule 23(e). Specifically, the proposed Notice provides a description of the Class, and the procedural status of the litigation. Additionally, it sets forth the significant terms of the proposed Settlement, including the total amount of money Defendant has agreed to pay to the Class and the releases that Defendant will receive if the Settlement is finally approved. The Notice also outlines the proposed Plan of Allocation which describes how the amount that each Class Member will be entitled to receive from the Settlement Fund will be calculated. The Notice outlines the court approval process for the proposed Settlement, Class counsel's request for attorneys' fees and reimbursement of expenses, and Class counsel's request for incentive awards for the Class Representatives.²³ The proposed Notice also advises Class members of their rights under Rule 23, including the right to object to, and to be heard as to the reasonableness and fairness of, the proposed Settlement and Plan of Allocation. The form and manner of notice that Plaintiffs propose will therefore satisfy the notice requirements of Rule 23(e), as well as the due process requirements which must be met in order to bind each member of the Class.²⁴

V. THE COURT SHOULD APPROVE THE PROPOSED FINAL SETTLEMENT SCHEDULE, INCLUDING SETTING A DATE FOR THE FAIRNESS HEARING.

Plaintiffs propose the following schedule for completing the approval process:

Dissemination of Notices to the Class in the	Within 20 days of entry of the Order
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²³ Class counsel recommend incentive awards for the Class Representatives as follows: \$100,000 to each of Louisiana Wholesale Drug Co., Inc. and King Drug Company of Florence, Inc.; \$75,000 to each of Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors and Stephen L. LaFrance Holdings, Inc., and Burlington Drug Company, Inc.; and \$50,000 to Uniondale Chemists, Inc. The different amounts reflect the different roles each played in the case, including but not limited to potential trial roles, mediation roles, and initiation of suit. All Named Plaintiffs also participated substantially in discovery.

²⁴ See *Grimes v. Vitalink Communications Corp.*, 17 F.3d 1553, 1560-61 (3d Cir. 1994) (direct mail notice found sufficient under Rule 23).

form and manner proposed	preliminarily approving the Settlement
Filing of Plaintiffs' motion for final approval of the Settlement and the Plan of Allocation	30 days before the date set for the Fairness Hearing
Submission of Class Counsel's application for Attorneys' Fees and Expenses, and Application for Incentive Awards to the Class Representatives	30 days before the date set for the Fairness Hearing
Deadline for Class Members to object to the Settlement and Fee Application	14 days before the date set for the Fairness Hearing
Fairness Hearing	To Be Determined By the Court ²⁵

Any Class member who objects to the settlement may be heard at the fairness hearing.

Relatedly, Plaintiffs request that the Court approve the retention of Rust Consulting as the Claims Administrator to oversee the dissemination of the Notices to the Class, and ultimately, the administration of the Settlement. As stated on its website, www.rustconsulting.com/About_Rust, Rust Consulting has extensive experience in class action claims administration, including with respect to antitrust litigation in the pharmaceutical industry.

VI. CONCLUSION

For the foregoing reasons, Class Plaintiffs respectfully request that the Court grant preliminary approval of the Settlement. A proposed order granting these requests accompanies the motion for preliminary approval as Ex. 1.

Dated: January 22, 2015

/s/ Bruce Gerstein

²⁵ Due to the need to give notice to the Class of the terms of the Settlement, and their rights with respect to the Settlement, Class Counsel respectfully suggest that the Fairness Hearing be scheduled at least 100 days after preliminary approval.

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CERTIFICATE OF SERVICE

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

Dated: January 22, 2015

/s/ Bruce E. Gerstein
Bruce E. Gerstein