

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF MICHIGAN

IN RE PRANDIN DIRECT
PURCHASER ANTITRUST
LITIGATION

C.A. No. 2:10-cv-12141-AC-DAS

Judge Avern Cohn

THIS DOCUMENT RELATES TO:
ALL ACTIONS

Magistrate Judge Donald A. Scheer

**DECLARATION OF CO-LEAD COUNSEL IN SUPPORT OF CLASS
COUNSEL'S UNOPPOSED MOTION FOR AN AWARD OF ATTORNEYS'
FEES, REIMBURSEMENT OF EXPENSES, AND PAYMENT OF
INCENTIVE AWARDS TO THE CLASS REPRESENTATIVES**

1. I am a partner in the law firm of Cafferty Clobes Meriwether & Sprengel LLP located in Ann Arbor, Michigan. I am licensed to practice in the states of Michigan and Illinois. I was previously appointed by the Court as Co-Lead Counsel for the Plaintiff Class in this action, along with Hagens Berman Sobol Shapiro LLP, located in Cambridge, Massachusetts and Berger & Montague, P.C., located in Philadelphia, Pennsylvania. I was also appointed Liaison Counsel.¹ I provide this declaration in support of Class Counsel's Unopposed

¹ Order, October 2, 2014, Doc. 64 at 6. In that same Order, the Court also certified for settlement purposes the following class:

All persons and entities in the United States and its territories who purchased Prandin directly from Defendants from May 6, 2009 until the June 30, 2014. Excluded from the Class are Defendants and their parents, employees, subsidiaries, and affiliates, and all federal governmental entities.

Motion for an Award of Attorneys’ Fees, Reimbursement of Expenses, and Payment of Incentive Awards to the Class Representatives.² I have personal knowledge of the facts set forth herein and, if called as a witness, I could competently testify to the matters set forth herein.

A. The procedural history and background.

2. This Court presided over patent infringement litigation filed by Novo Nordisk A/S and Novo Nordisk, Inc. (collectively “Novo”) against a generic manufacturer (Caraco Pharmaceutical Labs., Ltd.) and its parent (Sun Pharmaceutical Industries, Ltd.) concerning Novo’s U.S. Pat. No. 6,677,358 (“the ’358 patent”), which claimed the combination of repaglinide (which Novo markets under the brand-name Prandin) with metformin. *Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Inc.*, No. 2:05-cv-40188 (E.D. Mich.) (“the Caraco action”). On May 6, 2009, faced with the potential FDA approval of Caraco’s inexpensive generic repaglinide, Novo switched the “use code” narrative for the ’358 patent reference in the FDA’s “Orange Book.” Specifically, Novo filed a new use code narrative (U-968) that, Plaintiffs allege, expanded the description of the claim under the ’358 patent beyond the repaglinide-metformin

Id. at 2.

² Class Counsel refers to Co-Lead Counsel and the other firms experienced in pharmaceutical antitrust litigation that made substantial contributions to the prosecution of this case: Faruqi & Faruqi, LLP, Taus, Cebulash & Landau, LLP, Cohen Millstein Sellers & Toll PLLC, and Heim, Payne & Chorush, LLP.

combination. Plaintiffs allege that Novo's new use code narrative was so broad that it included all approved uses of repaglinide, including two uses that were the subject of expired patents.

3. On September 24, 2009, this Court held that Caraco was entitled to a mandatory injunction requiring Novo to delist the new use code narrative, and reinstate a former use code narrative. *Novo Nordisk A/S v. Caraco Pharm. Labs.*, 656 F. Supp. 2d 729 (E.D. Mich. 2009). Novo appealed, however, and on April 14, 2010, the Federal Circuit vacated the injunction on the ground that the provision of the Hatch-Waxman Act relied upon by Caraco (*i.e.*, 21 U.S.C. § 355(j)(5)(C)(ii)(I)) could not be applied to use code narratives. *Novo Nordisk A/S v. Caraco Pharmaceutical Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010). As a result of the appeal and the Federal Circuit's decision, Novo continued to maintain a use code narrative that prevented the FDA from approving abbreviated new drug applications ("ANDAs") that "carved out" the repaglinide-metformin combination. It was in this environment that Plaintiffs here brought these antitrust actions.

4. On May 28, 2010, Plaintiff American Sales Company, LLC filed a class action complaint against Novo Nordisk A/S and Novo Nordisk, Inc. (collectively "Novo" or "Defendants"). E.D. Mich. No. 2:10-cv-12141. Plaintiff alleged that Defendants unlawfully blocked FDA approval and market entry of bioequivalent, but less expensive, generic repaglinide that would have competed

with Defendants' more expensive, branded Prandin. Plaintiff Rochester Drug Co-Operative, Inc. filed a complaint on June 7, 2010 (E.D. Mich. No. 2:10-cv-12235) asserting similar facts and claims.

5. On August, 27, 2010, the Court entered Case Management Order No. 1 (Doc. No. 16) that, among other things, consolidated the two actions under the caption *In re Prandin Direct Purchaser Antitrust Litigation*.

6. On August 30, 2010, Plaintiffs filed a Consolidated Complaint. Doc. No. 18. In Count I, Plaintiffs asserted a claim for monopolization in violation of Section 2 of the Sherman Act (15 U.S.C. § 2) premised on the submission of a baseless use code narrative to the FDA. In addition, in Count II, Plaintiffs asserted a monopolization claim for violation Section 2 premised on fraudulent procurement of the '358 patent.³

7. On October 29, 2010, Novo filed two separate motions to dismiss, attacking the Consolidated Complaint for lack of standing and failure to allege antitrust injury (Doc. No. 23) and for failure to plead exclusionary conduct for lack of standing (Doc. No. 24). Defendants' relied heavily on regulatory issues that Caraco was facing, which, they maintained, broke the chain of causation between the alleged antitrust violations and Plaintiffs' alleged injury. Plaintiffs filed

³ This type of claim is called a "Walker Process claim" after *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

memoranda in oppositions to both motions on December 13, 2010. Doc. Nos. 29-31. Defendants filed their replies on January 10, 2011. Docs. 34-36.

8. Meanwhile, while the parties here were briefing the motions to dismiss, the bench trial in the *Caraco* action concluded. In addition, on December 23, 2010, Caraco filed a petition for a writ of certiorari with the Supreme Court of the United States (2010 WL 5399206), challenging the Federal Circuit decision vacating this Court's injunction.

9. On January 19, 2011, the Court held that the '358 patent was invalid as obvious and that it was unenforceable due to inequitable conduct. *Novo Nordisk A/S v. Caraco Pharm. Labs.*, 775 F. Supp. 2d 985, 1025 (E.D. Mich. 2011). This was a positive development vis-à-vis Plaintiffs' *Walker Process* claim, which Novo had moved to dismiss for lack of standing. *See, e.g., In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 691-92 (2d Cir. 2009) ("We therefore hold only that purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct.").

10. On January 26, 2011, Novo appealed the judgment in the *Caraco* action to the United States Court of Appeals for the Federal Circuit. Doc. No. 525, Civ. No. 05-40188. In addition, on June 27, 2011, the Supreme Court granted Caraco's petition for a writ of certiorari. *Caraco Pharmaceutical Labs., Ltd. v. Novo Nordisk A/S*, 131 S. Ct. 3057 (2011).

11. As events played out in the appellate courts, use code U-968 remained listed with the FDA, precluding FDA approval of ANDAs that could not possibly infringe the '358 patent.

12. On April 17, 2012, in a unanimous decision, the Supreme Court reversed the Federal Circuit's decision vacating the use code injunction. *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 182 L.Ed. 678 (2012). On July 30, 2012, the Federal Circuit ordered Novo to file a corrected use code within twenty days. *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, 688 F.3d 766 (Fed. Cir. 2012).

13. With Defendants' motions to dismiss the Consolidated Complaint still pending, the Court corresponded with counsel on October 22, 2012 and questioned "whether any action on its part is appropriate at this time." Plaintiffs responded that the motions to dismiss should be scheduled for oral argument at the Court's convenience. Defendants responded that the action should be stayed pending the outcome of the appeal in the *Caraco* action.

14. On October 29, 2012, the Court corresponded with counsel again and stated that: "Given the changing nature of the underlying facts it is best to defer further consideration of these cases until the *Caraco v. Novo* case is returned to the Court."

15. On June 18, 2013, the Federal Circuit affirmed the district court's determination that the '358 patent was invalid as obvious, but reversed the determination that it was unenforceable due to inequitable conduct. *Novo Nordisk A/S v. Caraco Pharmaceutical Labs., Ltd.*, 719 F.3d 1346 (Fed. Cir. 2013).

16. On November 7, 2013, following the *Caraco* action's return to the Court from the Federal Circuit, the Court conducted a joint status conference for both the *Caraco* action and this action. At that status conference, counsel for Plaintiffs indicated that, given the Federal Circuit's ruling on inequitable conduct, the *Walker Process* claim would not be pursued. In effect, the Court's determination to let underlying events play out before addressing dismissal motions helped narrow the issues in dispute. The Court requested that Plaintiffs file an amended complaint.

17. Pursuant to the Court's request, Plaintiffs filed their First Amended Consolidated Class Action Complaint on December 9, 2013 ("FAC"). Doc. 48. The FAC included a single claim for monopolization based on the alleged submission of a baseless use code. Defendants filed a Motion to Dismiss the FAC on January 15, 2014. Doc. Nos. 50-51. Plaintiffs filed a Response to Defendants' Motion to Dismiss the FAC on February 24, 2014. Doc. No. 52. Defendants filed a Reply on their Motion to Dismiss FAC on March 14, 2014. Doc. No. 55. A hearing on Defendants' Motion to Dismiss the FAC was scheduled for June 17,

2014. As addressed below, the parties reached an agreement in principle on the eve of the argument.

B. The litigation of this action was intensive and complex.

18. As the above discussion demonstrates, this litigation involved a great deal of factual complexity, including the interaction of the antitrust laws with the patent laws and the Hatch-Waxman Act. Plaintiffs' claims required Class Counsel to analyze (a) the medical, pharmaceutical, and regulatory bases of Novo's claims that its Orange Book use code narrative change was valid; (b) the scientific and legal bases of Novo's claims that the '358 patent" was valid and enforceable and not procured by fraud; (c) the readiness, willingness, and ability of generic manufacturer Caraco to manufacture generic repaglinide, either at Caraco's Detroit facility or at a plant in Cranbury, New Jersey operated by its parent Sun Pharmaceutical Industries, Ltd.; (d) the antitrust market for drugs to treat Type 2 diabetes; and (e) the pricing and distribution of Prandin.

19. The litigation was also hard fought. Plaintiffs' initial complaints, consolidated pursuant to the Court's order, asserted a claim for monopolization premised on the submission of a baseless use code narrative to the FDA, and a second claim for monopolization premised on the alleged *Walker Process*-type fraudulent procurement of the '358 patent. Novo moved to dismiss this complaint, and that motion was fully briefed. Later, however, the Federal Circuit decision

reversing this Court's determination that the '358 patent was procured through inequitable conduct, raised a potentially insurmountable obstacle to Plaintiffs' *Walker Process* claim. As a result, Class Counsel were required to prepare an amended consolidated complaint asserting a single claim for monopolization based on the alleged submission of a baseless use code. Defendants again moved to dismiss. That motion was also fully briefed by Class Counsel.

20. During the course of the litigation and investigation, Class Counsel became aware of evidence that raised questions about Caraco's ability to manufacture generic repaglinide in a "but for" world without Novo's alleged use code manipulation. From the outset of this litigation, Class Counsel had been in close contact with counsel for Caraco, which voluntarily provided a plethora of materials related to the patent litigation between Caraco and Novo that were not subject to a protective order. Class Counsel also investigated this information through public sources, including public court dockets, SEC filings, FDA files (through Freedom of Information Act requests and otherwise), press reports, and other sources.

21. Class Counsel subsequently served a subpoena on Caraco for confidential materials, resulting in the production of over 300,000 pages of documents. Class Counsel thoroughly reviewed these documents.

22. In reviewing of information obtained independent of Caraco, as well as Caraco's production, Class Counsel identified evidence that raised concerns about Caraco's wherewithal to obtain FDA approval to market generic Prandin sooner than it did, notwithstanding Novo's alleged anticompetitive conduct. Indeed, the allegedly unlawful use code narrative was removed in August 2012, yet FDA approval did not occur until July 2013.

23. Class Counsel's concerns were reinforced by the declaration of Caraco President GP Singh Sachdeva. Doc. No. 55-1. The declaration described challenges that Caraco faced regarding launching generic Prandin, attaching a dozen exhibits in support. Thus, while Class Counsel remain confident that Defendants' alleged use code manipulation violated the antitrust laws, Mr. Sachdeva's testimony, and the documents relating to it, if credited, raised serious concerns about the strength of Plaintiffs' case as related to the essential antitrust element of causation. Mr. Sachdeva's testimony, if credited, demonstrated that, notwithstanding the alleged use code manipulation, Caraco would not have been able to obtain approval from FDA to market generic Prandin any earlier than it did, in July 2013.

C. Settlement negotiations were intense but professional and always at arm's length.

24. In Case Management Order No. 1, entered on August 27, 2010, the Court designated Co-Lead Counsel and specified responsibilities, including

“determining the timing and substance of any settlement negotiations with defendants, and agreeing to any such settlement”. Doc. No. 16 ¶ 4(g). Thus, following Class Counsel’s review and analysis of Caraco’s production and other non-discovery investigatory materials, Class Counsel approached Novo’s counsel in May 2014 about the potential for settlement. Because of the open dialogue among counsel, and Class Counsel’s thorough investigation of the facts, the parties were in a good position at that point to discuss settlement in earnest. The final negotiations were intense, but in June 2014, the parties reached an agreement in principle that they were able to report to the Court. Following further negotiations throughout July and August 2014, during which the specific terms of the agreement were negotiated and reduced to writing, the parties submitted a proposed settlement agreement to the Court dated September 5, 2014. All settlement discussions were at arm’s-length.

D. Class Counsel devoted many hours to prosecute the case despite the risk of non-payment.

25. In Case Management Order No. 1, entered on August 27, 2010, the Court designated Co-Lead Counsel and specified responsibilities, including “assigning work of other counsel” (Doc. No. 16 ¶ 4(d)) and “designating attorneys to appear at hearings and conferences with the Court” (Doc. No. 16 ¶ 4(f)). This action involved complex antitrust, regulatory, medical, and pharmaceutical issues that were investigated intensely. As set forth above, from the inception of this

case, Class Counsel vigorously pursued this action, committing their services and resources to prosecute the case. Class Counsel proceeded with efficiency, as well as skill, and attorney resources were deployed only when necessary given the underlying litigation events and factual developments.

26. Class Counsel provided legal services to the Class and advanced litigation expenses with no assurance of repayment. To date, Class Counsel have neither been paid for their efforts nor reimbursed for their out-of-pocket expenses. Instead, their compensation and expense reimbursement was contingent upon obtaining a recovery on behalf of the Class.

E. Class Counsel's experience and specialized expertise conferred substantial value and enabled a positive result.

27. The attorneys who prosecuted this case have particular expertise in direct purchaser impeded generic competition cases. Because of Class Counsel's experience and expertise in pharmaceutical matters, they were able to negotiate from a position of strength, making clear their preparedness to litigate the case. Through bringing this experience to bear, as well as their detailed knowledge of the case, Class Counsel were able to negotiate a settlement amount that provides an excellent resolution and immediate cash payment to the Class.

28. For many years, Class Counsel have been active in an area of pharmaceutical industry antitrust litigation. The area is somewhat of a specialty, with a significant amount of unique law, regulatory background, and industry facts

that require experience, knowledge, and training to practice responsibly and effectively. Class Counsel's experience in these matters was critical to the negotiation of the settlement.

29. Over the last 10 or more years, one or more of Class Counsel have been court-appointed lead counsel, co-lead counsel, or a member of the steering committee in virtually all pharmaceutical antitrust cases in the country. A small representative sample of these cases includes:

- *In re Cardizem CD Antitrust Litig.*, MDL Docket No. 1278 (E.D. Mich.)
- *In re K-Dur Antitrust Litig.*, No. 01-cv-1652 (D.N.J.)
- *In re Tricor Antitrust Litig.*, C.A. No. 05-cv-340 (D. Del.)
- *In re Flonase Antitrust Litig.*, No. 08-cv-3149 (E.D. Pa.)
- *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431 (E.D. Pa.)
- *In re Skelaxin Antitrust Litig.*, No. 12-MD-2343 (E.D. Tenn.)
- *In re Nexium Antitrust Litig.*, No.12-md-2409-WGY (D. Mass.)

30. Recoveries for our clients in pharmaceutical matters alone (including the classes they represent and other purchaser classes) are estimated in the billions of dollars. A complete list of Class Counsel's cases is included in the declarations of individual Class Counsel annexed hereto.

31. Because of this experience and expertise, Class Counsel were positioned not only to litigate the case efficiently, but also to settle the case appropriately on terms favorable to the Class.

F. Class Counsel's lodestar and expenses in detail.

32. All Plaintiffs' counsel kept contemporaneous time records, which were regularly reported to Co-Lead Counsel Hagens Berman Sobol Shapiro LLP, as required by Case Management No. 1 (Doc. No. 16 ¶ 7). Annexed hereto as Exhibits A-H are the sworn declarations of each Class Counsel specifying (by professional) the number of hours and total lodestar based on current rates that each firm recorded in its prosecution of this case; the amounts advanced for litigation expenses by category of expense, by each firm, and the professional qualifications and experience of each firm.

33. Based on these sworn declarations, the table below sets forth, in summary, each Class Counsel's hours and lodestar through October 31, 2014, based on the contemporaneous, daily time records regularly prepared and maintained by each firm. The table also sets forth each Class Counsel's total expenses, through October 31, 2014⁴ as reflected on each firm's books and records, which are prepared from expense vouchers, receipts, and other source materials and represent an accurate recording of the expenses incurred. Each Class Counsel's detailed time and expense records are available for review should the Court wish to examine them.

⁴ Each firm's expenses are included from inception through October 31, 2014. Class Counsel will separately apply for reimbursement of any further reimbursable expenses if and as they arise.

CLASS COUNSEL'S FEES AND EXPENSES BY FIRM			
Firm	Total Hours	Total Lodestar	Total Expenses
Berger & Montague, P.C.	380.00	\$178,593.00	\$8,966.74
Cafferty Clobes Meriwether & Sprengel, LLP	927.70	\$633,560.50	\$3,945.93
Cohen Millstein Sellers & Toll PLLC	174.75	\$121,135.00	\$916.01
Faruqi & Faruqi, LLP	1,052.10	\$603,936.00	\$6,939.79
Hagens Berman Sobol Shapiro, LLP	481.20	\$288,043.50	\$2,019.08
Heim, Payne & Chorus, LLP	13.85	\$10,012.50	\$245.30
Radice Law Firm, PC	42.00	\$21,895.00	\$0.00
Taus, Cebulash & Landau, LLP	448.50	\$243,640.00	\$1684.40
TOTAL	3,520.10	\$2,100,815.50	\$24,717.25

34. In addition to the expense listed above, Class Counsel collectively incurred additional expenses for expert economist services (Greylock McKinnon Associates), purchase of pharmaceutical sales data (IMS Health), and notice/settlement administration costs incurred by court-appointed claims administrator (Rust Consulting Inc.). These expenses, set forth below, have been appropriately incurred, but have not yet paid. Detailed invoices from these professional service providers are available for review should the Court wish to examine them.

EXPENSES INCURRED FOR PROFESSIONAL SERVICES		
Organization	Services	Total Expenses
Greylock McKinnon Associates	Expert Analysis and Preparation of Report	\$73,087.50
IMS Health	Sales Data for Prandin and Generic Repaglinide	\$4,500.00
Rust Consulting	Claims Administration	\$5,171.07
TOTAL		\$123,258.57

35. In sum, Class Counsel invested a total of 3,520.10 hours prosecuting this complex, contingent litigation, resulting in a lodestar of \$2,100,815.50 and advanced a total of \$147,975.82 in out-of pocket expenses.

G. Class Representatives' direct participation and efforts conferred a substantial benefit on the class.

36. Class Representatives American Sales Company, LLC and Rochester Drug Co-Operative, Inc. expended significant effort in prosecuting this action for the benefit of the Class. Each reviewed the case before filing and filed a case despite the risk of retaliation inherent in suing prescription drug suppliers. Without their participation the Class would have recovered nothing. Moreover, the Class Representatives monitored the litigation and related patent actions over four-and-a-half years, and advised and consulted on settlement negotiations, turning their attention away from their business as distributors of pharmaceutical products.

37. In recognition of the Class Representatives' service to the class, and the risk they took, Class Counsel request incentive awards of \$50,000 to be paid to

each Class Representative. In Co-Lead Counsel's experience, and as the precedents in the accompanying memorandum show, the amounts requested are well within the acceptable range of payments awarded by courts in the other recent direct purchaser antitrust cases and in this Circuit, and is well-deserved.

H. Class Counsel will perform all further work necessary to finalize the settlement and distribute the settlement proceeds.

38. After having prepared the preliminary approval papers and the Court's approval on October 2, 2014, Co-Lead Counsel have been continuing to oversee the notice and settlement administration process. Co-Lead Counsel caused individual notice to be mailed by the Settlement Administrator to all known class members – 30 entities – on October 17, 2014. The settlement website, www.Prandindirectsettlement.com, went live one day later. To date, more than 45 after notice was sent, the Settlement Administrator has received no objections or exclusion requests. The postmark deadline for submission of objections and opt-out notices is December 1, 2014.

39. Class Counsel will continue to devote time to settlement approval, including the preparing for and appearing at the Fairness Hearing and responding to class member inquiries involving settlement. Final approval papers will be submitted by December 16, 2014, and the Court has scheduled the Fairness Hearing for January 14, 2015.

I declare under penalties of perjury that the foregoing is true and correct to the best of my knowledge, information, opinion, and belief.

Date: November 18, 2014

/s/ Patrick E. Cafferty

Patrick E. Cafferty

Co-Lead and Liaison Counsel for the Class

CERTIFICATE OF SERVICE

I hereby certify that on November 18, 2014, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system which will send notification of such filing to all counsel of record.

/s/ Patrick E. Cafferty
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