IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. 12-

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Cephalon, Inc. ("Cephalon" or "Plaintiff") for its complaint against Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Defendants" or "Mylan Defendants"), to the best of its knowledge, information and belief, hereby alleges as follows:

THE PARTIES

1. Plaintiff Cephalon, Inc. ("Cephalon") is a Delaware corporation having a principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

2. On information and belief, Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

3. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.

4. On information and belief, Defendant Mylan Inc. is the parent company of Mylan Pharmaceuticals; Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

5. On information and belief, Defendant Mylan Pharmaceuticals is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States. On information and belief, Defendant Mylan Inc. conducts its North American operations, in part, through Mylan Pharmaceuticals. Together, the Mylan Defendants collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) within the United States generally and the State of Delaware specifically.

JURISDICTION AND VENUE

6. This is an action for infringement of United States Patent No. 8,119,158 ("the '158 patent" or "patent-in-suit") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*., including §§ 271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the '158 patent under 28 U.S.C. §§ 2201 and 2202. A copy of the '158 patent is attached as Exhibit A.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

8. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Mylan Defendants.

9. This Court has personal jurisdiction over the Mylan Defendants by virtue of the fact that, *inter alia*, they have committed—or aided, abetted, contributed to, or participated in the commission of—the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff, a Delaware corporation.

10. In addition, this court has personal jurisdiction over the Mylan Defendants by virtue of their systematic and continuous contacts with the State of Delaware.

11. On information and belief, the Mylan Defendants plan to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, its aforementioned business of preparing generic pharmaceuticals to distribute in the State of Delaware.

12. In addition, the Mylan Defendants have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

14. On February 21, 2012, the ’158 patent, titled “Effervescent Oral Fentanyl Dosage Form and Methods of Administering Fentanyl,” was duly and legally issued by the PTO. Cephalon is the lawful owner, by assignment, of all right, title and interest in and to the ’158 patent, including all right to sue and recover for infringement thereof.

15. Cephalon is the holder of an approved New Drug Application (“NDA”) No. 21-947 for FENTORA® brand fentanyl buccal tablets. In conjunction with NDA No. 21-947, Cephalon listed with the U.S. Food and Drug Administration (“FDA”) U.S. Patent Nos. 6,200,604 (“the ’604 patent”), 6,974,590 (“the ’590 patent”), 7,862,832 B2 (“the ’62,832 patent”), 7,862,833 B2 (“the ’833 patent”), and 8,092,832 (“the ’92,832 patent”) which cover oral dosage forms and methods of using the approved FENTORA® brand fentanyl buccal tablets. On or about February 28, 2012, Cephalon listed the ’158 patent with the FDA. On or about

February 29, 2012, Cephalon notified Defendants of the existence of the ’158 patent. The ’604, ’590, ’62,832, ’833, ’92,832, and ’158 patents appear in the Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for FENTORA®.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENT-IN-SUIT

16. On information and belief, the Mylan Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

17. On information and belief, Defendant Mylan Pharmaceuticals, jointly with, and/or as the agent or alter ego of its parent Mylan Inc., submitted ANDA No. 202577 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(j). That ANDA seeks FDA approval for the commercial manufacture, use and sale throughout the United States including Delaware of generic fentanyl buccal tablets containing 0.3 mg of fentanyl citrate (“the Mylan Generic Product”). ANDA No. 202577 specifically seeks FDA approval to market the Mylan Generic Product prior to the expiration of the ’604 patent and prior to expiration of the ’590 patent.

18. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Mylan Pharmaceuticals alleged in ANDA No. 202577 that the claims of the ’604 patent and the claims of the ’590 patent are not infringed by the commercial manufacture, use or sale throughout the United States of the Mylan Generic Product, and/or that the claims of the ’604 patent and ’590 patent are invalid and/or unenforceable. Cephalon received written notification of ANDA No. 202577 and Mylan Pharmaceuticals’ §505(j)(2)(A)(vii)(IV) allegations from Mylan Pharmaceuticals on or about January 11, 2011 (“First Paragraph IV Notice Letter”).

19. The stated purpose of the First Paragraph IV Notice Letter was to notify Plaintiff that Mylan Pharmaceuticals had filed a certification with the FDA under 21 C.F.R. §

314.50(i)(1)(i)(A)(4) in conjunction with ANDA No. 202577 for approval, *inter alia*, to commercially manufacture and sell a generic version of Plaintiff's FENTORA® brand fentanyl buccal tablets. The First Paragraph IV Notice Letter alleges that the claims of the '604 patent and '590 patent are invalid.

20. ANDA No. 202577 has since been amended by the Mylan Defendants to include a reference to fentanyl citrate buccal tablets containing additional strengths of fentanyl citrate (0.1 mg, 0.2 mg, 0.4 mg, 0.6 mg, and 0.8 mg) ("the Amended ANDA").

21. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Mylan Pharmaceuticals alleged in the Amended ANDA that the claims of the '604 patent, the '590 patent, the '62,832 patent, and the '833 patent are not infringed by the commercial manufacture, use or sale throughout the United States of Mylan's generic 0.1 mg, 0.2 mg, 0.4 mg, 0.6 mg, and 0.8 mg fentanyl citrate buccal tablets ("the Mylan Generic Product"), and/or that the claims of the '604 patent, the '590 patent, the '62,832 patent, and the '833 patent are invalid and/or unenforceable. Cephalon and CIMA received written notification of the Amended ANDA and Mylan Pharmaceuticals' §505(j)(2)(A)(vii)(IV) allegations from Mylan Pharmaceuticals on or about September 29, 2011 ("Second Paragraph IV Notice Letter").

22. The '158 patent had not issued at the time Mylan Pharmaceuticals submitted its certification under § 505(j)(2)(A)(vii)(IV) of the FFDCA.

23. In a separate action, *Cephalon, Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 11-164-SLR, Cephalon and CIMA Labs, Inc. ("CIMA") asserted the '604 and '590 patents against Defendants. The parties subsequently stipulated to amend the complaint to assert allegations of infringement of the '62,832 and '833 patents. In another separate action, *Cephalon, Inc. v.*

Mylan Pharmaceuticals Inc., C.A. No. 12-73-SLR, Cephalon asserted the '92,832 patent against Defendants.

24. Defendants have made, and continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import the Mylan Generic Product prior to patent expiry.

25. Defendants' actions, including, but not limited to, the development of the Mylan Generic Product and the filing of an ANDA with a Paragraph IV certification, indicate a refusal to change the course of their action in the face of acts by Plaintiff.

26. On information and belief, Defendants continue to seek approval of ANDA No. 202577 from the FDA and intend to commercially manufacture, market and sell fentanyl buccal tablets. Accordingly, Cephalon makes the following allegations on information and belief and subject to Fed. R. Civ. P. 11(b)(3):

COUNT I
(Infringement of the '158 Patent Under 35 U.S.C. § 271(e)(2))

27. Paragraphs 1 to 26 are incorporated herein as set forth above.

28. Defendants, acting jointly, submitted ANDA No. 202577 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Mylan Generic Product. By submitting ANDA No. 202577, Defendants, individually and collectively, committed an act of infringement with respect to the '158 patent under 35 U.S.C. § 271(e)(2)(A).

29. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 202577 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Mylan Generic Product. By submitting ANDA No. 202577,

Mylan Pharmaceuticals has committed an act of infringement with respect to the '158 patent under 35 U.S.C. § 271(e)(2)(A).

30. When Mylan Pharmaceuticals submitted ANDA No. 202577 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Mylan Generic Product, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit ANDA No. 202577 and/or causing its agent or alter ego to submit ANDA No. 202577, Mylan Inc. committed an act of infringement with respect to the '158 patent under 35 U.S.C. § 271(e)(2)(A).

31. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product prior to patent expiry will constitute direct and/or contributory infringement of the '158 patent, and/or active inducement of infringement of the '158 patent.

COUNT II
(Declaratory Judgment of Infringement of the '158 Patent Under 35 U.S.C. § 271(a), (b) or (c))

32. Paragraphs 1 to 31 are incorporated herein as set forth above.

33. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

34. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

35. Defendants have made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Mylan Generic Product.

36. Defendants' actions indicate a refusal to change the course of their action in the face of acts by Plaintiff.

37. Any commercial manufacture, use, offer for sale, and/or importation of the Mylan Generic Product prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '158 patent.

38. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product by either or both of Defendants prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the '158 patent.

INJUNCTIVE RELIEF

39. Plaintiff will be irreparably harmed by the Mylan Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

a. That judgment be entered that Defendants, individually and/or collectively, have infringed the '158 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202577 under the FFDCA, and that the commercial manufacture, use, offer for sale, and/or importation of the Mylan Generic Product prior to patent expiry will constitute an act of infringement of the '158 patent;

b. That judgment be entered that Mylan Pharmaceuticals has infringed the '158 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202577 under the FFDCA, and

that the commercial manufacture, use, offer for sale, sale and/or importation of the Mylan Generic Product prior to patent expiry will constitute an act of infringement of the ’158 patent;

c. That judgment be entered that Mylan Inc. has infringed the ’158 patent under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Mylan Pharmaceuticals or allowing Mylan Pharmaceuticals to act as its agent or alter ego in submitting ANDA No. 202577 under the FFDCA, and that the commercial manufacture, use, offer for sale, and/or importation of the Mylan Generic Product prior to patent expiry will constitute an act of infringement of the ’158 patent;

d. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 202577 shall be a date that is not earlier than the expiration date of the ’158 patent including any extensions;

e. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan Inc., Mylan Pharmaceuticals, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’158 patent;

f. That a declaration be issued under 28 U.S.C. § 2201 that if Mylan Inc., Mylan Pharmaceuticals, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the ’158 patent;

g. That damages or other monetary relief be awarded to Plaintiff under 35 U.S.C. § 271(e)(4)(C) as appropriate;

h. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiff be awarded reasonable attorneys' fees and costs; and

i. That this Court award such other and further relief as it may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues appropriately tried by a jury.

DATED: February 29, 2012

FISH & RICHARDSON P.C.

By: /s/ *Gregory R. Booker*

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