IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.

CEPHALON, INC. and
CIMA LABS, INC.,

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

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**COMPLAINT FOR PATENT INFRINGEMENT**

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Plaintiffs Cephalon, Inc. and CIMA LABS, INC. (collectively, "Plaintiffs") for their complaint against Sandoz, Inc. ("Sandoz" or "Defendant"), to the best of their knowledge, information and believe, hereby allege 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. Plaintiff CIMA LABS, INC. ("CIMA") is a Delaware corporation having a principal place of business at 7325 Aspen Lane, Brooklyn Park, Minnesota 55428.

3. On information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, with a place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540 and at 2555 West Midway Boulevard, Broomfield, CO 80020.

4. On information and belief, Sandoz is in the business of manufacturing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district.

## JURISDICTION AND VENUE

5. This is an action for infringement of United States Patent Nos. 6,200,604 B1 ("the '604 patent") and 6,974,590 B2 ("the '590 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(e)(2) , 271(b), and 271(c), and for a declaratory judgment of infringement of the '604 and '590 patents under 28 U.S.C. §§ 2201 and 2202. A copy of the '604 patent is attached as Exhibit A. A copy of the '590 patent is attached as Exhibit B.

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

7. This Court has personal jurisdiction over Defendant by virtue of its incorporation under the laws of Colorado.

8. This Court also has personal jurisdiction over Defendant by virtue of Defendant's continuous and systematic contacts with Colorado, including the operation of Defendant's manufacturing facility located in Broomfield, Colorado.

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

## THE PATENTS IN SUIT

10. On March 13, 2001, the '604 patent, titled "Sublingual Buccal Effervescent," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff

CIMA is the lawful owner by assignment of all rights, title and interest in and to the '604 patent, including all rights to sue and recover for infringement thereof.

11. On December 13, 2005, the '590 patent, titled "Sublingual Buccal Effervescent," was duly and legally issued by the PTO. Plaintiff CIMA is the lawful owner by assignment of all rights, title and interest in and to the '590 patent, including all rights to sue and recover for infringement thereof.

12. 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") the '604 and '590 patents (the "Listed Patents" or the "patents-in-suit") which cover methods of using the approved FENTORA® brand fentanyl buccal tablets. The '604 and '590 patents appear in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for FENTORA®. Cephalon is also the sole licensee of the patents-in-suit in the United States with the authority to sell fentanyl buccal tablets.

## ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE '604 AND '590 PATENTS

13. On information and belief, Defendant actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

14. On information and belief, Defendant reviewed the patents-in-suit and certain commercial and economic information relating to FENTORA®, including estimates of the revenues generated by the sale of FENTORA®, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market fentanyl citrate buccal tablets.

15. On information and belief, Defendant Sandoz submitted ANDA No. 200676 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). ANDA No. 200676 seeks FDA approval for the commercial manufacture, use, offer for sale, and/or sale of generic fentanyl citrate buccal tablets containing 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.6 mg and 0.8 mg of fentanyl citrate (the "Sandoz Generic Products"), throughout the United States, including Colorado. ANDA No. 200676 specifically seeks FDA approval to market the Sandoz Generic Products prior to expiration of the '604 and '590 patents.

16. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, in ANDA No. 200676, Sandoz alleged that the claims of the '604 patent and the claims of the '590 patent are not infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products throughout the United States, including Colorado. Cephalon received written notification of ANDA No. 200676 and of Sandoz's § 505(j)(2)(A)(vii)(IV) allegations from Sandoz on or about January 6, 2010 ("Paragraph IV letter"). Sandoz's Paragraph IV letter states that Sandoz has submitted data to the FDA regarding the alleged "bioavailability and/or bioequivalence" of the Sandoz Generic Products and FENTORA®.

17. The stated purpose of the Paragraph IV letter was to notify Plaintiffs that Defendant had filed a certification with the FDA under 21 C.F.R. § 314.95(c)(1) in conjunction with ANDA No. 200676 for approval, *inter alia*, to commercially manufacture and sell generic versions of Cephalon's FENTORA® brand fentanyl buccal tablets. The Paragraph IV letter stated that the Sandoz Generic Products would not infringe the Listed Patents.

18. The Paragraph IV letter thereto failed to comply with the requirements of 21 U.S.C. § 355 (j)(2)(B)(iv)(II) because, *inter alia*, they contained very limited information about the generic formulation for which Defendant filed ANDA No. 200676.

19. Defendant continues to seek approval of ANDA No. 200676 from the FDA and intends to continue in the commercial manufacture, marketing and sale of fentanyl citrate buccal tablets.

## COUNT I

### Infringement of the '604 Patent Under 35 U.S.C. § 271(e)(2)

20. Paragraphs 1 through 19 are incorporated herein as set forth above.

21. Defendant submitted ANDA No. 200676 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products throughout the United States, including Colorado, prior to patent expiry. By submitting this application, Defendant committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

22. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '604 patent.

## COUNT II

### Declaratory Judgment of Infringement of the '604 Patent Under 35 U.S.C. § 271(b) or (c)

23. Paragraphs 1 through 22 are incorporated herein as set forth above.

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

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

26. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import the Sandoz Generic Products.

27. Defendant's actions, including, but not limited to, the filing of ANDA No. 200676 with a Paragraph IV certification and provision of a wholly inadequate 'Detailed Statement' under 21 U.S.C. § 355(c)(3)(D)(i)(III), indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

28. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '604 patent.

29. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '604 patent.

## COUNT III

### Infringement of the '590 Patent Under 35 U.S.C. § 271(e)(2)

30. Paragraphs 1 through 29 are incorporated herein as set forth above.

31. Defendant submitted ANDA No. 200676 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products throughout the United States, including

Colorado, prior to patent expiry. By submitting the application, Defendant committed an act of infringement with respect to the '590 patent, under 35 U.S.C. § 271(e)(2)(A).

32. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '590 patent.

## COUNT IV

### Declaratory Judgment of Infringement of the '590 Patent Under 35 U.S.C. § 271(b) or (c)

33. Paragraphs 1 through 32 are incorporated herein as set forth above.

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

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

36. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Sandoz Generic Products prior to patent expiry.

37. Defendant's actions, including, but not limited to, the filing of ANDA No. 200676 with a Paragraph IV certification and provision of a wholly inadequate 'Detailed Statement' under 21 U.S.C. § 355(c)(3)(D)(i)(III), indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

38. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '590 patent.

39. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry by Defendant will constitute contributory infringement and/or active inducement of infringement of the '590 patent.

## EXCEPTIONAL CASE

On information and belief, Defendant's Paragraph IV certification was baseless, and the arguments presented therein without merit, thereby rendering this an exceptional case under 35 U.S.C. § 285.

## INJUNCTIVE RELIEF

Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

## PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

A. That judgment be entered that Defendant has infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 200676 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent;

B. 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. 200676 shall be a date that is not earlier than the expiration date of the '604 patent, inclusive of any extensions;

C. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of any drug product covered by the '604 patent, within (or into) the United States;

D. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. § 271(e)(4)(C) as appropriate with respect to the '604 patent;

E. That a declaration be issued under 28 U.S.C. § 2201 that if Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry, it will constitute an act of infringement of the '604 patent;

F. That judgment be entered that Defendant has infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 200676 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent;

G. That judgment be entered that Sandoz has infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 200676 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Sandoz Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent under § 271;

H. 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. 200676 shall be a date that is not earlier than the expiration date of the '590 patent inclusive of any extensions;

I. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its 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 '590 patent;

J. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. § 271(e)(4)(C) as appropriate with respect to the '590 patent;

K. That a declaration be issued under 28 U.S.C. § 2201 that if Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz Generic Products prior to patent expiry, it will constitute an act of infringement of the '590 patent;

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

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

Dated: February 18, 2010

By: *s/ Hugh Q. Gottschalk*

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