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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

CEPHALON, INC. and CIMA LABS, INC., Plaintiffs, vs. WATSON PHARMACEUTICALS, INC. and WATSON LABORATORIES, INC., Defendants.	CASE NO. 3:08-cv-308 **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Cephalon, Inc. and CIMA Labs, Inc. (collectively, "Plaintiffs") for their complaint against Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively "Defendants" or "Watson"), to the best of their knowledge, information and belief, 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 10000 Valley View Road, Eden Prairie, Minnesota 55344.

3. Defendant Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a

corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

4. Defendant Watson Laboratories, Inc. ("Watson Laboratories") is a Nevada corporation having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

5. Defendant Watson Laboratories is a wholly-owned subsidiary of Defendant Watson Pharmaceuticals, and the two have common officers and directors.

6. Defendant Watson Pharmaceuticals develops, manufactures, and/or markets pharmaceutical products throughout the United States, including in this judicial district, through its own actions and through the actions of its agents and operating subsidiaries, including Watson Laboratories, Inc.

JURISDICTION AND VENUE

7. 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) and 271(b) 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.

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

9. This Court has personal jurisdiction over the Defendants by virtue of their incorporation in Nevada.

10. In addition, Plaintiffs allege, in the following paragraphs on information and belief, that this Court has personal jurisdiction over Defendants Watson Pharmaceuticals and Watson Laboratories for the additional reasons set forth below and for other reasons to be determined.

11. This Court has personal jurisdiction over Defendant Watson Pharmaceuticals by virtue of, inter alia, its systematic and continuous contacts with

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Nevada through its distribution of pharmaceutical products throughout the United States, including Nevada.

12. Watson Pharmaceuticals and Watson Laboratories are agents of each other, and of other Watson subsidiaries that distribute pharmaceutical products into Nevada with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the fentanyl citrate buccal tablets described in ANDA 79-075 (defined below).

13. If ANDA 79-075 is approved, the Watson Generic Products (defined below), which are charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in Nevada, and/or prescribed by physicians practicing and dispensed by pharmacies located within Nevada, all of which would have a substantial effect on Nevada.

14. Watson Pharmaceuticals and Watson Laboratories are alter egos of each other, and of other Watson subsidiaries that distribute pharmaceutical products into Nevada with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the fentanyl citrate buccal tablets described in ANDA 79-075.

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

BACKGROUND

Genesis of The Delaware and Nevada Actions

16. As discussed in further detail below, Watson filed ANDA 79-075 seeking to market a generic version of Cephalon's FENTORA® brand fentanyl buccal tablets.

17. Cephalon markets and distributes FENTORA® nationwide, including in the District of Nevada. The filing of ANDA 79-075 evidences an intent by Watson to compete with Cephalon and place its product into every market where FENTORA® is currently found, including the District of Nevada.

18. In April 2008, as required by applicable federal law, Defendants sent

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Plaintiffs a Paragraph IV letter (defined below) that they had filed ANDA 79-075 with the FDA seeking approval to engage in the commercial manufacture, use or sale throughout the United States, including Nevada, of a generic version of Plaintiffs' patented drug product, FENTORA®. 21 U.S.C. § 355(j)(2)(B)(i)(iii).

19. Under the Hatch-Waxman Act of 1984, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter ("45-day window") in order to receive certain benefits under the Act, including a 30-month stay of approval of the generic drug. 21 U.S.C. § 355 (c)(3)(c).

20. On June 2, 2008, within the 45-day window, Plaintiffs filed and served an action against Watson Pharmaceuticals and Watson Laboratories for infringement of the patents-in-suit in the United States District Court for the District of Delaware, Civil Action No. 08-330 (the "Delaware Action"). A copy of the Complaint in the Delaware Action is attached hereto as Exhibit C.

21. Defendants Watson Pharmaceuticals and Watson Laboratories are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by addressing all of Plaintiffs' claims for infringement of the patents-in-suit in the Delaware Action.

22. Upon information and belief, Plaintiffs understand that Watson may nevertheless contest personal jurisdiction in Delaware. The Hatch-Waxman Act does not address squarely the consequences of the grant of a motion to dismiss for lack of personal jurisdiction in a plaintiff's chosen forum. It is possible that such a dismissal could result in a plaintiff losing the benefit of the 30-month stay of ANDA approval even if the plaintiff refiled the action in another jurisdiction, since the refiling would occur after the 45-day window. Therefore, district courts have countenanced the filing of additional "protective suits" within the 45-day window to ensure a plaintiff will not lose the benefits of the 30-month stay should the court in the chosen forum dismiss the action for lack of personal jurisdiction. See e.g., Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 2007 WL 4284877 (W.D. Mich. Dec. 3, 2007); PDL Biopharma, Inc. v. Sun

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Pharmaceutical Industries, Ltd., 2007 WL 2261386 (E.D. Mich. Aug. 6, 2007); Celgene Corp. v. Abrika Pharmaceuticals, Inc., 2007 WL 1456156 (D.N.J. May 17, 2007).

23. Accordingly, although Plaintiffs believe the District of Delaware has personal jurisdiction over both Defendants, and Delaware -- the state both Plaintiffs are incorporated in -- is their preferred choice of forum to litigate the claims for relief set forth in this Complaint, Plaintiffs beg the Court's indulgence and file this Complaint as a "protective suit" to protect Plaintiffs' rights under the Hatch-Waxman Act in the event the District of Delaware determines there is no personal jurisdiction over the Defendants in Delaware.

Conduct of the Defendants in Dealings With Cephalon

24. As discussed above, Watson Pharmaceuticals and Watson Laboratories share common officers and directors and hold themselves out to the public generally, and in the Paragraph IV letter to Cephalon specifically, as a unified operation.

25. For example, the Paragraph IV letter received by Cephalon in this case was transmitted on Watson Pharmaceuticals stationery and directed Cephalon to send any correspondence or requests for confidential access to any information related to the ANDA to Kenton M. Walker, who was identified as "Counsel-Intellectual Property, Watson Pharmaceuticals, Inc."

26. Such Paragraph IV letter on the aforementioned Watson Pharmaceuticals letterhead was signed, however, by a person identifying himself as Ernest Lengle, Ph.D., "Executive Director, Regulatory Affairs, Watson Laboratories, Inc." By such actions, Watson Laboratories held out to the public generally and to Cephalon specifically, that Dr. Engle had actual or at least apparent authority to bind Watson Pharmaceuticals.

27. In an ANDA communication unrelated to this case dated June 19, 2006, from Watson to Warner Chilcott, Inc., Ernest Lengle, Ph.D was identified as "Executive Director, Regulatory Affairs, Watson Pharmaceuticals, Inc."

28. In response to the Paragraph IV letter to Cephalon, Cephalon wrote, as it had been instructed by Dr. Engle in his capacity as Executive Director, Regulatory

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Affairs, Watson Laboratories, to "Kenton M. Walker, Counsel-Intellectual Property, Watson Pharmaceuticals, Inc." In its response, Cephalon asked for further information as to the identity of the Watson entities that participated in the filing of ANDA 79-075 because of the confusing nature of the Paragraph IV letter – specifically, the references to both Watson Pharmaceuticals and Watson Laboratories.

29. In response, Kenton M. Walker wrote back, declining to provide the various Watson entities' roles in the ANDA filing. In this letter -- now on Watson Laboratories stationery -- Walker described himself for the first time to Cephalon as "Counsel-Intellectual Property, Watson Laboratories, Inc."

30. In prior dealings with Cephalon, Watson has also acted as a unified entity.

31. Watson Pharma, Inc. ("Watson Pharma") is a Delaware corporation having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

32. Watson Pharma is a wholly-owned subsidiary of Defendant Watson Pharmaceuticals, and the two share at least certain common officers and directors.

33. On August 2, 2006, Watson Pharma entered into an agreement with Cephalon captioned "Oral Transmucosal Fentanyl Citrate Sales Agent Agreement" (the "Fentanyl Citrate Agreement").

34. The Fentanyl Citrate Agreement appoints Watson Pharma as non-exclusive sales agent for another fentanyl-citrate product that contains the same controlled substance for a similar indication as the formulations used in the methods described in the patents-in-suit.

35. In the Fentanyl Citrate Agreement, Watson Pharma agreed that Delaware law governed the Fentanyl Citrate Agreement and its interpretation.

36. In addition, Watson Pharma agreed to bind not only itself, but other Watson entities, including its parent, defendant Watson Pharmaceuticals, and its sister company, defendant Watson Laboratories, in certain undertakings. Also, the Fentanyl Citrate Agreement specified that any notice issued pursuant to the agreement was to be

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delivered to the general counsel of Watson Pharmaceuticals (and not Watson Pharma), further demonstrating the close relationship among the Watson companies.

37. The Fentanyl Citrate Agreement also incorporated a Quality Technical Agreement. The Quality Technical Agreement was signed on September 21, 2006, by a person identified in the Quality Technical Agreement as Senior Vice President Quality Assurance for defendant Watson Pharmaceuticals, notwithstanding the fact that the contracting parties were Cephalon and Watson Pharma.

THE PATENTS IN SUIT

38. 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 right, title and interest in and to the '604 patent, including all right to sue and recover for infringement thereof.

39. 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 right, title and interest in and to the '590 patent, including all right to sue and recover for infringement thereof.

40. 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") 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

41. Upon information and belief, Defendant Watson Laboratories, jointly with, and/or as the agent or alter ego of its parent Watson Pharmaceuticals, submitted

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Abbreviated New Drug Application ("ANDA") No. 79-075 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale throughout the United States including Nevada 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 Watson Generic Products"). ANDA No. 79-075 specifically seeks FDA approval to market the Watson Generic Products prior to the expiration of the '604 patent and prior to expiration of the '590 patent.

42. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Watson alleged in ANDA No. 79-075 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 including Nevada of the Watson Generic Products, and that the claims of the '604 patent are invalid and unenforceable. CIMA Labs received written notification of ANDA No. 79-075 and Watson's §505(j)(2)(A)(vii)(IV) allegations from Watson on or about April 21, 2008 ("Paragraph IV letter"). Such Paragraph IV letter was sent on the letterhead of Watson Pharmaceuticals with instructions to send any request for confidential access to Kenton M. Walker, Counsel – Intellectual Property, Watson Pharmaceuticals. Cephalon received a similar Paragraph IV letter on or about April 22, 2008.

43. The stated purpose of the Paragraph IV letters was to notify Plaintiffs that Defendants had filed a certification with the FDA under 21 C.F.R. § 314.95(c)(1) in conjunction with ANDA 79-075 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 Watson Generic Products would not infringe the Listed Patents and that the claims of the '604 patent are invalid.

44. The Paragraph IV letters failed to comply with the requirements of 21 U.S.C. § 355 (j)(2)(B)(iv)(II), inter alia, because they contain very limited information about the generic formulation for which Defendants filed ANDA No. 79-075.

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45. Since receiving the Paragraph IV letters, Plaintiffs have attempted several times to obtain information on the Watson Generic Products and to procure a copy of ANDA No. 79-075 from Watson. Initially, Watson was unwilling to provide ANDA No. 79-075 to Plaintiffs except under conditions that would not allow Plaintiffs to meaningfully process the information contained in the ANDA. Through an extended negotiation process Watson has withdrawn some of its objections to disclosure of its ANDA to Plaintiffs but has not yet provided the ANDA for Plaintiffs' review.

46. Plaintiffs have also repeatedly requested that Watson disclose any role that Watson Pharmaceuticals, Watson Laboratories or any other Watson entity had in the preparation of the data contained in the ANDA, the preparation of the ANDA and the anticipated manufacture, use, distribution, importation, and sale throughout the United States including Nevada of the Watson Generic Products. However, Watson was unwilling to disclose this information to Plaintiffs.

47. Plaintiffs sought from Defendants detailed information on the formulation of the Watson Generic Products and a copy of ANDA No. 79-075 for the purpose of evaluating Defendants' claim that they do not infringe the patents-in-suit but were unable to obtain such information before filing suit. Accordingly, Plaintiffs make the following allegations on information and belief and subject to Fed. R. Civ. P. 11(b)(3):

COUNT I

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

48. Paragraphs 1 to 47 are incorporated herein as set forth above.

49. Defendants, acting jointly, submitted ANDA No. 79-075 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 Nevada of the Watson Generic Products. By submitting the application, Defendants, individually and collectively, committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

50. Watson Laboratories, acting jointly with Watson Pharmaceuticals, and/or as

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its agent or alter ego, submitted ANDA No. 79-075 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 Nevada of the Watson Generic Products. By submitting the application, Watson Laboratories has committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

51. When Watson Laboratories submitted ANDA No. 79-075 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 Nevada of the Watson Generic Products, it was acting jointly with Watson Pharmaceuticals and/or acting as Watson Pharmaceutical's agent or alter ego. By acting jointly with Watson Laboratories to submit the application and/or causing its agent or alter ego to submit the application, Watson Pharmaceuticals committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

52. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '604 patent.

COUNT II

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

53. Paragraphs 1 to 52 are incorporated herein as set forth above.

54. Watson Pharmaceuticals actively induced Watson Laboratories to submit ANDA No. 79-075 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 Nevada of the Watson Generic Products. By actively inducing submission of the ANDA, Watson Pharmaceuticals has committed an act of indirect infringement with respect to the '604 patent under 35 U.S.C. § 271(b).

55. Any commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '604 patent.

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COUNT III

(Declaratory Judgment of Infringement of the '604 Patent Under 35 U.S.C. § 271(a))

56. Paragraphs 1 to 55 are incorporated herein as set forth above.

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

58. 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 that actual case or controversy requires a declaration of rights by this Court.

59. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Watson Generic Products.

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

61. Any commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '604 patent.

62. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products by either or both of Defendants prior to patent expiry will infringe the '604 patent.

COUNT IV

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

63. Paragraphs 1 to 62 are incorporated herein as set forth above.

64. Defendants, acting jointly, submitted ANDA No. 79-075 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 Nevada of the Watson Generic Products prior to patent expiry. By submitting the application, Defendants, individually and collectively, committed an act of infringement with respect to the '590

patent under 35 U.S.C. § 271(e)(2)(A).

65. Watson Laboratories, acting jointly with Watson Pharmaceuticals, and/or as its agent or alter ego, submitted ANDA No. 79-075 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 Nevada of the Watson Generic Products prior to patent expiry. By submitting the application, Watson Laboratories has committed an act of infringement with respect to the '590 patent under 35 U.S.C. § 271(e)(2)(A).

66. When Watson Laboratories submitted ANDA No. 79-075 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 Nevada of the Watson Generic Products prior to patent expiry, it was acting jointly with Watson Pharmaceuticals and/or acting as Watson Pharmaceuticals' agent or alter ego. By acting jointly with Watson Laboratories to submit the application and/or causing its agent or alter ego to submit the application, Watson Pharmaceuticals committed an act of infringement with respect to the '590 patent under 35 U.S.C. § 271(e)(2)(A).

67. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '590 patent.

COUNT V

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

68. Paragraphs 1 to 67 are incorporated herein as set forth above.

69. Watson Pharmaceuticals actively induced Watson Laboratories to submit ANDA No. 79-075 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 Nevada of the Watson Generic Products prior to patent expiry. By actively inducing submission of the ANDA, Watson Pharmaceuticals has committed an act of indirect infringement with respect to the '590 patent under 35 U.S.C. § 271(b).

70. The commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '604 patent.

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COUNT VI

(Declaratory Judgment of Infringement of the '590 Patent Under 35 U.S.C. § 271(a))

71. Paragraphs 1 to 70 are incorporated herein as set forth above.

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

73. 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 that actual case or controversy requires a declaration of rights by this Court.

74. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Watson Generic Products prior to patent expiry.

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

76. The commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '590 patent.

77. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products prior to patent expiry by either or both of Defendants will infringe the '590 patent.

EXCEPTIONAL CASE

78. Watson Laboratories was aware of the '604 patent and '590 patent prior to filing ANDA No. 79-075.

79. Watson Pharmaceuticals was aware of the '604 patent and '590 patent prior to filing ANDA No. 79-075.

80. The actions of Watson Pharmaceuticals and Watson Laboratories, individually and collectively, render this an exceptional case under 35 U.S.C. § 285.

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INJUNCTIVE RELIEF

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

82. Plaintiffs will be irreparably harmed by Watson Pharmaceuticals' 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 Defendants, individually and/or collectively, have infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 79-075 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent;

b. That judgment be entered that Watson Laboratories has infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 79-075 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent;

c. That judgment be entered that Watson Pharmaceuticals has infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Watson Laboratories or allowing Watson Laboratories to act as its agent or alter ego in submitting ANDA No. 79-075 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent;

d. That judgment be entered that Watson Pharmaceuticals has infringed the '604 patent under 35 U.S.C. § 271(b) by inducing Watson Laboratories to submit ANDA No. 79-075 under the Federal Food Drug, and Cosmetic Act, and that the

commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent;

e. 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. 79-075 shall be a date which is not earlier than the expiration date of the '604 patent including any extensions;

f. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Watson Pharmaceuticals, Watson Laboratories, 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 '604 patent;

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

h. That a declaration be issued under 28 U.S.C. § 2201 that if Watson Pharmaceuticals, Watson Laboratories, 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 Watson Generic Products prior to patent expiry, it will constitute an act of infringement of the '604 patent;

i. That judgment be entered that Defendants, individually and/or collectively, have infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 79-075 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent;

j. That judgment be entered that Watson Laboratories has infringed the

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'590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 79-075 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent;

k. That judgment be entered that Watson Pharmaceuticals has infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Watson Laboratories or allowing Watson Laboratories to act as its agent or alter ego in submitting ANDA No. 79-075 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent;

l. That judgment be entered that Watson Pharmaceuticals has infringed the '590 patent under 35 U.S.C. § 271(b) by inducing Watson Laboratories to submit ANDA No. 79-075 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent;

m. 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. 79-075 shall be a date which is not earlier than the expiration date of the '590 patent including extensions;

n. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Watson Pharmaceuticals, Watson Laboratories, 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 '590 patent;

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

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p. That a declaration be issued under 28 U.S.C. § 2201 that if Watson Pharmaceuticals, Watson Laboratories, 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 Watson Generic Products prior to patent expiry, it will constitute an act of infringement of the '590 patent;

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

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

DATED this 3 day of June, 2008.

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