IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| CEPHALON, INC., and CIMA LABS, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.<br><br>Defendants. | Civil Action. No. 08-330 SLR<br><br>**PUBLIC VERSION**<br>**Filed: February 4, 2009** |

**AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Cephalon, Inc. and CIMA LABS, INC. (collectively, "Plaintiffs") for their Amended Complaint, pursuant to Fed. R. Civ. P. 15(a)(1)(A), against Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, 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 7325 Aspen Lane, Brooklyn Park, Minnesota 55428.

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 share at least some common officers and directors.

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

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

8. 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 and Watson Pharma.

## JURISDICTION AND VENUE

9. 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.

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

11. This Court has personal jurisdiction over Defendant Watson Pharma because Watson Pharma is a Delaware corporation.

12. This Court has personal jurisdiction over Defendant Watson Pharmaceuticals, pursuant to Fed. R. Civ. P. 12(h), because Watson Pharmaceuticals has not challenged personal jurisdiction in this action.

13. In addition, this Court also has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma because they, either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and derive substantial revenue from services, or things used or consumed in Delaware in that, among other things:

a. [redacted]

b. [redacted]

14. Watson Pharmaceuticals, Watson Laboratories and Watson Pharma are agents of each other with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic fentanyl citrate buccal tablets described in ANDA [redacted] (as defined below). More specifically, each of Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, as part of Watson Pharmaceuticals' "Generic Division", will manufacture, market, and/or sell the Watson Generic Products, should FDA approval be granted.

15. If ANDA [redacted] is approved, the Watson Generic Products, which are charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

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

## BACKGROUND

17. As discussed in further detail below, Watson Pharmaceuticals and Watson Laboratories filed ANDA [redacted] seeking approval to market a generic version of Cephalon's FENTORA® brand fentanyl citrate buccal tablets.

18. FENTORA® is used to treat breakthrough pain in adult patients with cancer who are regularly using other opioid pain medicines around-the-clock for their constant cancer pain.

19. Cephalon markets and distributes FENTORA® nationwide, including in the District of Delaware. The filing of ANDA [redacted] evidences an intent by

Defendants to compete with Cephalon and place their product into every market where FENTORA® is currently found, including the District of Delaware.

20. Watson Pharmaceuticals is engaged in the development, marketing, sale, and distribution of brand and generic pharmaceutical products, and would be similarly engaged in the development, marketing, sale, and distribution of the Watson Generic Products (as defined below).

21. Watson Pharmaceuticals organizes its operations into three segments or divisions. The three divisions are Generic, Brand, and Distribution.

22. Watson Pharmaceuticals reports its financial results to its investors by reference to the performance of its operating divisions, and not the performance of its individual subsidiaries.

23. The Board of Directors of Watson Pharmaceuticals (the "Board") oversees the operations of Watson Pharmaceuticals, which includes the Generic Division of Watson Pharmaceuticals.

24. The Board created a Regulatory Compliance Committee comprised of outside directors of Watson Pharmaceuticals that assists the Board with its oversight responsibilities with respect to any and all regulations related to the import, export, development, manufacturing, marketing, distribution, and sale of Watson Pharmaceuticals' products, including the federal Food, Drug and Cosmetic Act, and the regulations promulgated thereunder.

25. The oversight responsibilities of the Regulatory Compliance Committee, and the Board, include the development, preparation, and submission of the ANDA, and the manufacture, marketing and sale of the Watson Generic Products.

26. [redacted]

27. [redacted]

28. [redacted]

29. [redacted]

30. [redacted]

31. [redacted]

32. [redacted]

33. [redacted]

34. [redacted]

35. [redacted]

36. [redacted]

37. [redacted]

38. [redacted]

39. [redacted]

40. [redacted]

41. Following the filing of the ANDA, consistent with Watson Pharmaceuticals' divisional structure described above, Watson Pharmaceuticals and Watson Laboratories notified Cephalon of the ANDA through the transmission of the Paragraph IV letter (as defined below).

42. 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."

43. The 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.

44. 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."

45. 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 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 [redacted] because of the confusing nature of the Paragraph IV letter – specifically, the references to both Watson Pharmaceuticals and Watson Laboratories.

46. In response, Kenton M. Walker wrote back, declining to provide the various Watson entities' role 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."

## THE PATENTS IN SUIT

47. 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.

48. 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.

49. Cephalon is the holder of an approved New Drug Application ("NDA") No. 21-947 for FENTORA® brand fentanyl citrate 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 citrate 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 citrate buccal tablets.

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

50. Defendant Watson Laboratories, jointly with, and/or as the agent of its parent Watson Pharmaceuticals submitted Abbreviated New Drug Application

("ANDA") [redacted] 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 Delaware 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 [redacted] 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.

51. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Watson alleged in ANDA [redacted] 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 Delaware of the Watson Generic Products, and that the claims of the '604 patent are invalid, unenforceable and/or not infringed. CIMA received written notification of ANDA [redacted] 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.

52. 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. § 314.50(i)(1)(i)(A)(4) in conjunction with ANDA [redacted] for approval, *inter alia*, to commercially manufacture and sell generic versions of Cephalon's FENTORA® brand fentanyl citrate

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.

53. 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[redacted].

54. After receiving the Paragraph IV letters, Plaintiffs attempted several times to obtain information on the Watson Generic Products and to procure a copy of ANDA [redacted] from Watson. Plaintiffs did not receive a copy of ANDA[redacted] prior to filing the original Complaint.

55. During discovery in this action, Defendants produced ANDA[redacted] or portions of ANDA[redacted], on an outside attorneys-eyes only basis pursuant to Delaware Local Rule 26.2, because a protective order is not yet in place in this action. Neither employees of Cephalon, nor any of Cephalon's technical experts have been able to review these materials.

56. Accordingly, Plaintiffs continue to allege that subject to appropriate discovery the commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products as described in ANDA[redacted] prior to patent expiry will infringe one or more claims of the patents-in-suit either literally or under the doctrine of equivalents.

**COUNT I**
**(Infringement of the '604 Patent Under 35 U.S.C. § 271(e)(2))**
**(Watson Pharmaceuticals, Watson Laboratories and Watson Pharma)**

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

58. Defendants, acting jointly, submitted ANDA[redacted] 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 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).

59. Watson Laboratories, acting jointly with its co-Defendants, and/or as agent of its co-Defendants, submitted ANDA [redacted] 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 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).

60. When Watson Laboratories submitted ANDA [redacted] 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 Watson Generic Products, it was acting jointly with its co-Defendants and/or acting as the agent of its co-Defendants. By acting jointly with Watson Laboratories to submit the application, and/or causing their agent to submit the application, Watson Pharmaceuticals and Watson Pharma committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

61. 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))**
**(Watson Pharmaceuticals and Watson Pharma)**

62. Paragraphs 1 to 61 are incorporated herein as set forth above.

63. Watson Pharmaceuticals and Watson Pharma, individually and collectively, actively induced Watson Laboratories to submit ANDA [redacted] 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 Watson Generic Products.

64. Watson Pharmaceuticals and Watson Pharma will be actively involved in the manufacture, marketing, and sale of the Watson Generic Products, should FDA approval be granted.

65. Any such commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '604 patent. By engaging in a cooperative venture with its co-Defendants, and each of them, to submit the ANDA 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 Watson Generic Products, Watson Pharmaceuticals and Watson Pharma committed an act of indirect infringement with respect to the '604 patent under 35 U.S.C. § 271(b).

## COUNT III
**(Declaratory Judgment of Infringement of the '604 Patent Under 35 U.S.C. § 271(b) or (c))**
**(Watson Pharmaceuticals, Watson Laboratories and Watson Pharma)**

66. Paragraphs 1 to 65 are incorporated herein as set forth above.

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

68. 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.

69. 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.

70. Defendants' actions, including, but not limited to, the filing of ANDA [redacted] with a Paragraph IV certification, indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

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

72. 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 any or all 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))**
**(Watson Pharmaceuticals, Watson Laboratories and Watson Pharma)**

73. Paragraphs 1 to 72 are incorporated herein as set forth above.

74. Defendants, acting jointly, submitted ANDA [redacted] 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 Watson Generic Products. 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).

75. Watson Laboratories, acting jointly with its co-Defendants, and/or as agent of its co-Defendants, submitted ANDA [redacted] 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 Watson Generic Products. 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).

76. When Watson Laboratories submitted ANDA [redacted] 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 Watson Generic Products, it was acting jointly with its co-Defendants and/or acting as the agent of its co-Defendants. By acting jointly with Watson Laboratories to submit the application, and/or causing their agent to submit the application, Watson Pharmaceuticals and Watson Pharma committed an act of infringement with respect to the '590 patent under 35 U.S.C. § 271(e)(2)(A).

77. 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))**
**(Watson Pharmaceuticals and Watson Pharma)**

78. Paragraphs 1 to 77 are incorporated herein as set forth above.

79. Watson Pharmaceuticals and Watson Pharma, individually and collectively, actively induced Watson Laboratories to submit ANDA [redacted] 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 Watson Generic Products.

80. Watson Pharmaceuticals and Watson Pharma will be actively involved in the manufacture, marketing, and sale of the Watson Generic Products, should FDA approval be granted.

81. Any such commercial manufacture, use, offer for sale, and/or importation of the Watson Generic Products prior to patent expiry will infringe the '590 patent. By engaging in a cooperative venture with its co-Defendants, and each of them, to submit the ANDA 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 Watson Generic Products, Watson Pharmaceuticals and Watson Pharma committed an act of indirect infringement with respect to the '590 patent under 35 U.S.C. § 271(b).

**COUNT VI**
**(Declaratory Judgment of Infringement of the '590 Patent Under 35 U.S.C. § 271(b) or (c))**
**(Watson Pharmaceuticals, Watson Laboratories and Watson Pharma)**

82. Paragraphs 1 to 81 are incorporated herein as set forth above.

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

84. 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.

85. 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.

86. Defendants' actions, including, but not limited to, the filing of ANDA [redacted] with a Paragraph IV certification, indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

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

88. 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 any or all Defendants will infringe the '590 patent.

**EXCEPTIONAL CASE**

89. On information and belief, Defendants' 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**

90. 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.

91. 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.

92. Plaintiffs will be irreparably harmed by Watson Pharma'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 Defendants, individually and collectively, have infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA [redacted] 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 [redacted] 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 and Watson Pharma or allowing Watson Laboratories to act as its agent in submitting ANDA [redacted] 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 Pharma has infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Watson Pharmaceuticals and Watson Laboratories or allowing Watson Laboratories to act as its agent in submitting ANDA [redacted] 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;

e. That judgment be entered that Watson Pharmaceuticals and Watson Pharma have infringed the '604 patent under 35 U.S.C. § 271(b) or (c) by inducing Watson Laboratories to submit ANDA [redacted] under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Watson Pharmaceuticals and Watson Pharma will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products prior to patent expiry, which will constitute an act of infringement of the '604 patent;

f. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA [redacted] shall be a date which is not earlier than the expiration date of the '604 patent including any extensions;

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

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

i. That a declaration be issued under 28 U.S.C. § 2201 that if Watson Pharmaceuticals, Watson Pharma, 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;

j. That judgment be entered that Defendants, individually and collectively, have infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA [redacted] 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;

k. That judgment be entered that Watson Laboratories has infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA [redacted] 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;

l. 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 and Watson Pharma or allowing Watson Laboratories to act as its agent in submitting ANDA [redacted] 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;

m. That judgment be entered that Watson Pharma has infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Watson Pharmaceuticals and

Watson Laboratories or allowing Watson Laboratories to act as its agent in submitting ANDA [redacted] 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;

n. That judgment be entered that Watson Pharmaceuticals and Watson Pharma have infringed the '590 patent under 35 U.S.C. § 271(b) or (c) by inducing Watson Laboratories to submit ANDA [redacted] under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Watson Pharmaceuticals and Watson Pharma will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Watson Generic Products prior to patent expiry, which will constitute an act of infringement of the '590 patent;

o. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA [redacted] shall be a date which is not earlier than the expiration date of the '590 patent including any extensions;

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

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

r. That a declaration be issued under 28 U.S.C. § 2201 that if Watson Pharmaceuticals, Watson Pharma, 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;

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

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

Dated: January 16, 2009

FISH & RICHARDSON P.C.

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