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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA AG and JAGOTEC AG *Plaintiffs,* v. WATSON LABORATORIES, INC. – FLORIDA, ACTAVIS PHARMA, INC., ANDRX CORPORATION., and ACTAVIS, INC. *Defendants.*	CIVIL ACTION No. Document Filed Electronically **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Horizon Pharma AG and Jagotec AG (collectively "Plaintiffs") by their attorneys, for their complaint against Watson Laboratories, Inc. – Florida, Actavis

Pharma, Inc., Andrx Corporation, and Actavis, Inc. (collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Watson's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Horizon's pharmaceutical product RAYOS® prior to the expiration of United States Patent Nos. 6,488,960 ("the '960 patent"), 6,677,326 ("the '326 patent"), 8,309,124 ("the '124 patent"), 8,168,218 ("the '218 patent"), and 8,394,407 ("the '407 patent") which cover RAYOS® and its use.

THE PARTIES

2. Plaintiff Horizon Pharma AG is a company organized and existing under the laws of Switzerland, with a principal place of business at Kagenstrasse 17, CH-4153 Reinach, Switzerland.

3. Plaintiff Jagotec AG is a company organized and existing under the laws of Switzerland, with a principal place of business at Eptingerstrasse 61, CH-4132 Muttenz, Switzerland.

4. On information and belief, Defendant Watson Laboratories, Inc. – Florida ("WLF") was formerly known as Andrx Pharmaceuticals, Inc. On information and belief, WLF is a corporation organized and existing under the laws of the State of Florida, with a principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, WLF is in the business of, *inter alia*, developing,

manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

5. On information and belief, Defendant Actavis Pharma, Inc. ("Actavis Pharma") was formerly known as Watson Pharma, Inc. On information and belief, Actavis Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. On information and belief, Actavis Pharma is in the business of, *inter alia*, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by WLF and/or for which WLF is the named applicant of the approved ANDAs.

6. On information and belief, Defendant Actavis, Inc. ("Actavis") was formerly known as Watson Pharmaceuticals, Inc. ("WPI") until on or around January 24, 2013. On information and belief, Actavis is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. On information and belief, Actavis is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this district, through its own actions and through the actions of its agents and subsidiaries, including at least WLF, Actavis Pharma and Andrx Corporation.

7. On information and belief, Defendant Andrx Corporation ("Andrx") is a corporation organized and existing under the laws of the State of Delaware, having a

principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Andrx is in the business of, *inter alia,* marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this district, through its own actions and through the actions of its agents and subsidiaries, including at least WLF.

8. On information and belief, WPI acquired Andrx Pharmaceuticals on or around November 3, 2006. On information and belief, WPI renamed Andrx Pharmaceutials as WLF.

9. On information and belief, WLF is a wholly-owned subsidiary of Andrx, which is a wholly owned subsidiary of Actavis.

10. On information and belief, Actavis Pharma is another wholly-owned subsidiary of Actavis.

11. On information and belief, Actavis organizes its operations by divisions—including at least Generics, Brands, and Distribution—and, before the name change, WPI reported its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. On information and belief, WPI consolidated its financial results with subsidiaries in its SEC filings at least since 2007 and did not file separate reports to the SEC for each subsidiary.

12. On information and belief, Actavis' Generics division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, each Defendant acts as an agent of the other and/or works in concert with each other as integrated parts of the Generics Division. On information and belief, the Generics Division develops and submits Abbreviated New Drug Applications

("ANDAs") to the FDA, relying on contributions from at least WLF, Actavis Pharma and Andrx.

13. On information and belief, the head of the Generics Division is an employee of Actavis, the Generic Division's products are developed and manufactured by at least WLF, and the Generic Division's products are marketed, sold, and distributed throughout the United States, including in New Jersey, by at least Actavis Pharma. On information and belief, WLF, Actavis Pharma, and Andrx are parties to one or more contractual agreements regarding the distribution of generic pharmaceutical products.

14. On information and belief, each Defendant shares with the others at least some common employees, officers, and directors.

15. On information and belief, WLF, Andrx, and Actavis Pharma are within the control of Actavis for purposes of responding to discovery in this action.

16. On information and belief, Defendants collaborated in the research and development of WLF's ANDA No. 204867 ("Watson's ANDA") for prednisone delayed-release tablets ("the Watson Products"), continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the Watson Products throughout the United States, including in the State of New Jersey, in the event the FDA approves Watson's ANDA.

17. On information and belief, WLF has submitted to the jurisdiction of this Court in at least six prior New Jersey actions (*Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida*, Civil Action No. 13-1669; *Depomed, Inc. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358; *Warner Chilcott Co., et al. v. Watson Labs., Inc. – Florida*,

Civil Action No. 11-5989; *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241; *Mallinckrodt Inc. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-6424). On information and belief, WLF has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-1669).

18. On information and belief, Actavis has submitted to the jurisdiction of this Court in at least nine prior New Jersey actions (*Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084;[1] *Depomed, Inc. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358; *Noven Pharms. v. Watson Labs., Inc., et al.*, Civil Action No. 11-5997;[2] *Shire LLC, et al. v. Amneal Pharms. LLC*, et al., Civil Action No. 11-3781; *King Pharms. Inc., et al. v. Actavis, Inc., et al.*, Civil Action No. 09-6585; *Shire LLC v. Actavis South Atlantic, LLC, et al.*, Civil Action No. 09-479; *King Pharms. Inc., et al. v. Actavis, Inc., et al.*, Civil Action No. 07-5041; *Sanofi-Aventis U.S. LLC, et al. v. Actavis Totowa LLC, et al.*, Civil Action No. 07-3142). On information and belief, Actavis has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084).

19. On information and belief, Actavis Pharma has submitted to the jurisdiction of this Court in at least six prior New Jersey actions (*Astrazeneca AB, et al. v.*

[1] Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on July 6, 2012. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis Inc.
[2] Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on November 4, 2011. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis Inc.

Watson Labs., Inc. – Florida, et al., Civil Action No. 13-3038; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084;[3] *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241;[4] *Teva Neuroscience, Inc., et al. v. Watson Pharma, Inc., et al.*, Civil Action No. 10-5078;[5] *Duramed Pharms. v. Watson Pharma, Inc.*, Civil Action No. 07-5941;[6] *Hoffman La-Roche Inc., et al. v. Cobalt Pharms. Inc.*, et al., Civil Action No. 07-4539).[7] On information and belief, Actavis Pharma has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084). On information and belief, Actavis Pharma is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003854.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

21. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their presence in New Jersey, having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law such that they should reasonably anticipate being haled into court in this judicial district, previously consenting

[3] Watson Pharma, Inc. submitted to the jurisdiction of this Court on July 6, 2012. Watson Pharma, Inc. thereafter changed its name to Actavis Pharma, Inc.
[4] Watson Pharma, Inc. submitted to the jurisdiction of this Court on May 3, 2010. Watson Pharma, Inc. thereafter changed its name to Actavis Pharma, Inc.
[5] Watson Pharma, Inc. submitted to the jurisdiction of this Court on December 23, 2010. Watson Pharma, Inc. thereafter changed its name to Actavis Pharma, Inc.
[6] Watson Pharma, Inc. submitted to the jurisdiction of this Court on March 3, 2008. Watson Pharma, Inc. thereafter changed its name to Actavis Pharma, Inc.
[7] Watson Pharma, Inc. submitted to the jurisdiction of this Court on September 1, 2011. Watson Pharma, Inc. thereafter changed its name to Actavis Pharma, Inc.

to personal jurisdiction in this Court, availing themselves of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including WLF products, within this judicial district, and through their intent to market and sell the Watson Products, if approved, to residents of this judicial district.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

PATENTS-IN-SUIT

23. On December 3, 2002, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '960 patent titled "Corticosteroid Formulation." At the time of its issue, the '960 patent was assigned to Arakis, Ltd., Babraham Hall, Babraham, Cambridge, United Kingdom (now known as Sosei R&D Ltd., Chesterford Research Park, Little Chesterford, Saffron Walden, Essex, United Kingdom), which later assigned the '960 patent to Nitec Pharma AG (now known as Horizon Pharma AG), Kagen-Strasse 17, Reinach Switzerland CH-4153. Horizon Pharma AG is the sole current assignee of the '960 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '960 patent is attached hereto as Exhibit A.

24. On January 13, 2004, the PTO duly and legally issued the '326 patent titled "Corticosteroid Formulation Comprising Less Than 2.5 mg Prednisolone for Once Daily Administration." At the time of its issue, the '326 patent was assigned to Arakis,

Ltd., Chesterford Research Park, Little Chesterford, Saffron Walden, Essex, United Kingdom (now known as Sosei R&D Ltd., Chesterford Research Park, Little Chesterford, Saffron Walden, Essex, United Kingdom), which later assigned the '960 patent to Nitec Pharma AG (now known as Horizon Pharma AG), Kagen-Strasse 17, Reinach Switzerland CH-4153. Horizon Pharma AG is the sole current assignee of the '326 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '326 patent is attached hereto as Exhibit B.

25. On November 13, 2012, the PTO duly and legally issued the '124 patent titled "Delayed Release Tablet with Defined Core Geometry." Jagotec AG is the sole current assignee of the '124 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '124 patent is attached hereto as Exhibit C.

26. On May 1, 2012, the PTO duly and legally issued the '218 patent titled "Delayed Release Tablet with Defined Core Geometry." Jagotec AG is the sole current assignee of the '218 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '218 patent is attached hereto as Exhibit D.

27. On March 12, 2013, the PTO duly and legally issued the '407 patent titled "Delayed Release Tablet with Defined Core Geometry." Jagotec AG is the owner of the '407 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '407 patent is attached hereto as Exhibit E.

RAYOS®

28. Horizon Pharma, Inc. is the owner of the approved New Drug Application No. 202020 ("the RAYOS® NDA") for prednisone delayed-release tablets in 1 mg, 2 mg, and 5 mg dosage strengths, which are sold by Horizon Pharma USA, Inc. under the trade name RAYOS®. The RAYOS® tablets are currently approved for use as an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation; for the treatment of certain endocrine conditions; and for palliation of certain neoplastic conditions.

29. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '960, '326, '124, '218 and '407 patents are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the RAYOS® NDA.

30. The '960 and '326 patents are listed in the Orange Book for the 1 mg and 2 mg strength RAYOS® tablets. The '124 and '407 patents are listed in the Orange Book for the 1 mg, 2 mg, and 5 mg strength RAYOS® tablets. The '218 patent is listed in the Orange Book for the 5 mg strength RAYOS® tablets.

31. The '960, '326, '124, '218 and '407 patents cover the RAYOS® product.

WATSON'S ANDA

32. On information and belief, WLF submitted ANDA No. 204867 ("the Watson ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market prednisone delayed-release tablets in 1 mg, 2 mg, and 5 mg dosage strengths. On

information and belief, the Watson ANDA is seeking approval to market the Watson Products as an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation; for the treatment of certain endocrine conditions; and for palliation of certain neoplastic conditions.

33. The Watson ANDA refers to and relies upon the RAYOS® NDA and contains data that, according to Watson, demonstrate the bioequivalence of the Watson Products and RAYOS®.

34. Plaintiffs have received from WLF a letter, dated July 15, 2013 (the "Watson Notification"), stating that WLF had included a certification in the Watson ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '960, '326, '124, '218 and '407 patents are invalid or will not be infringed by the commercial manufacture, use or sale of the Watson Products (the "Paragraph IV Certification").

COUNT I FOR INFRINGEMENT OF U.S. PATENT 6,488,960

35. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

36. Defendants have infringed the '960 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products in 1 mg and 2 mg strengths prior to the expiration of the '960 patent.

37. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products in 1 mg and 2 mg strengths into the United States during the term of the '960 patent would further infringe the '960 patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated July 15, 2013, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification with respect to the '960 patent.

39. Upon information and belief, Defendants had actual and constructive notice of the '960 patent prior to filing Watson's ANDA, and Defendants' infringement of the '960 patent has been, and continues to be, willful.

40. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '960 patent, or any later expiration of exclusivity for the '960 patent to which they become entitled.

41. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '960 patent.

42. Plaintiffs have no adequate remedy at law.

43. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT 6,677,326

44. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

45. Defendants have infringed the '326 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products in 1 mg and 2 mg strengths prior to the expiration of the '326 patent.

46. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products in 1 mg and 2 mg strengths into the United States during the term of the '326 patent would further infringe the '326 patent under 35 U.S.C. § 271(a), (b) and/or (c).

47. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated July 15, 2013, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification with respect to the '326 patent.

48. Upon information and belief, Defendants had actual and constructive notice of the '326 patent prior to filing Watson's ANDA, and Defendants' infringement of the '326 patent has been, and continues to be, willful.

49. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '326 patent, or any later expiration of exclusivity for the '326 patent to which they become entitled.

50. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '326 patent.

51. Plaintiffs have no adequate remedy at law.

52. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT 8,309,124

53. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

54. Defendants have infringed the '124 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products in 1 mg, 2 mg and 5 mg strengths prior to the expiration of the '124 patent.

55. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products in 1 mg, 2 mg and 5 mg into the United States during the term of the '124 patent would further infringe the '124 patent under 35 U.S.C. § 271(a), (b) and/or (c).

56. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated July 15, 2013, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification with respect to the '124 patent.

57. Upon information and belief, Defendants had actual and constructive notice of the '124 patent prior to filing Watson's ANDA, and Defendants' infringement of the '124 patent has been, and continues to be, willful.

58. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's

ANDA be a date that is not earlier than the expiration of the '124 patent, or any later expiration of exclusivity for the '124 patent to which they become entitled.

59. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '124 patent.

60. Plaintiffs have no adequate remedy at law.

61. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT 8,168,218

62. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

63. Defendants have infringed the '218 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products in 5 mg dosage strength prior to the expiration of the '218 patent.

64. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products in 5 mg dosage strength into the United States during the term of the '218 patent would further infringe the '218 patent under 35 U.S.C. § 271(a), (b) and/or (c).

65. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated July 15, 2013, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification with respect to the '218 patent.

66. Upon information and belief, Defendants had actual and constructive notice of the '218 patent prior to filing Watson's ANDA, and Defendants' infringement of the '218 patent has been, and continues to be, willful.

67. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '218 patent, or any later expiration of exclusivity for the '218 patent to which they become entitled.

68. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '218 patent.

69. Plaintiffs have no adequate remedy at law.

70. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V FOR INFRINGEMENT OF U.S. PATENT 8,394,407

71. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

72. Defendants have infringed the '407 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products in 1 mg, 2 mg and 5 mg prior to the expiration of the '407 patent.

73. Watson's commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products in 1 mg, 2 mg

and 5 mg into the United States during the term of the '407 patent would further infringe the '407 patent under 35 U.S.C. § 271(a), (b) and/or (c).

74. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated July 15, 2013, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification with respect to the '407 patent.

75. Upon information and belief, Defendants had actual and constructive notice of the '407 patent prior to filing Watson's ANDA, and Watson's infringement of the '407 patent has been, and continues to be, willful.

76. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '407 patent, or any later expiration of exclusivity for the '407 patent to which they become entitled.

77. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '407 patent.

78. Plaintiffs have no adequate remedy at law.

79. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Horizon Pharma AG and Jagotec AG pray for a judgment in their favor against Defendants Watson Laboratories, Inc. – Florida, Actavis Pharma, Inc., Andrx Corporation, and Actavis, Inc., and respectfully request the following relief:

A. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 6,488,960;

B. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 6,677,326;

C. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 8,309,124;

D. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 8,168,218;

E. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 8,394,407;

F. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Products in 1 mg and 2 mg dosage strengths within the United States, or importing the Watson Products into the United States, prior to the expiration date of the ’960 patent;

G. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Products in 1 mg and 2 mg dosage strengths within the United States, or importing the Watson Products into the United States, prior to the expiration date of the ’326 patent;

H. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Products in 1 mg, 2 mg and 5 mg dosage strengths within the United States, or importing the Watson Products into the United States, prior to the expiration date of the '124 patent;

I. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Products in 5 mg dosage strength within the United States, or importing the Watson Products into the United States, prior to the expiration date of the '218 patent;

J. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Products in 1 mg, 2 mg and 5 mg dosage strengths within the United States, or importing the Watson Products into the United States, prior to the expiration date of the '407 patent;

K. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Products within the United States, or import the Watson Products in 1 mg and 2 mg dosage strengths into the United States, prior to the expiration of the '960 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

L. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Products within the United States, or import the Watson Products in 1 mg and 2 mg dosage strengths into the United States, prior to the expiration of the '326 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

M. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Products within the United States, or import the Watson Products in 1 mg, 2 mg and 5 mg dosage strengths into the United States, prior to the expiration of the '124 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

N. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Products within the United States, or import the Watson Products in 5 mg dosage strength into the United States, prior to the expiration of the '218 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

O. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Products within the United States, or import the Watson Products in 1 mg, 2 mg and 5 mg dosage strengths into the United States, prior to the expiration of the '407 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

P. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

Q. Costs and expenses in this action; and

R. Such other and further relief as the Court deems just and proper.

Date: August 26, 2013

/s/ Karen A. Confoy

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