IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., *Plaintiff*, v. WATSON LABORATORIES, INC. and ACTAVIS, INC., *Defendants*.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Takeda Pharmaceuticals U.S.A., Inc. files this Complaint for patent infringement against Defendants Watson Laboratories, Inc. and Actavis Inc. and in support thereof alleges as follows:

PARTIES

1. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

2. Upon information and belief, Defendant Watson Laboratories, Inc. ("Watson") is a Nevada Corporation with its principal place of business at 311 Bonnie Circle, Corona, CA 92878.

3. Upon information and belief, Defendant Actavis, Inc. ("Actavis") is a Nevada corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany New Jersey 07054.

4. On information and belief, Watson is a wholly-owned subsidiary of Actavis and is controlled by Actavis.

5. On information and belief, Watson and Actavis submitted, collaborated and/or acted in concert in the preparation of Abbreviated New Drug Application ("ANDA") No. 204461.

JURISDICTION AND VENUE

6. This action for patent infringement arises under 35 U.S.C. § 271.

7. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. This Court has personal jurisdiction over Watson and Actavis at least because both have engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed themselves of this judicial forum by making, shipping, using, offering to sell or selling or causing others to use, offer to sell or sell Watson's pharmaceutical products in this judicial district and deriving substantial revenues from such activities.

9. Watson has been sued for patent infringement in this district and purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court. *See Merck & Co. Inc. v. Watson Laboratories, Inc.*, C.A. No. 05-658.

10. Actavis has been sued for patent infringement in this district and did not contest personal jurisdiction. *See Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. et al.*, C.A. No. 13-1015. Actavis, as Watson Pharmaceuticals, Inc., has purposefully availed itself of the rights and benefits of the Court by asserting counterclaims in this Court. *See, e.g., Sunovion Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc.*, C.A. No. 12-993.

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

STATEMENT OF FACTS RELEVANT TO ALL COUNTS

12. COLCRYS® is used to prevent and treat gout. Gout is a type of severe arthritis typically characterized by extremely painful "flares" (severe and sudden attacks of pain, redness, inflammation, and tenderness in joints) resulting from a build-up of uric acid. COLCRYS® is the only single active ingredient colchicine product approved by the FDA to treat and prevent painful gout flares.

13. The FDA approved COLCRYS® for marketing in the United States under New Drug Application ("NDA") Nos. 22-351, 22-352 and 22-353 pursuant to section 505(b) of the Federal Food Drug and Cosmetics Act ("FFDCA"), 21 U.S.C. § 355(b).

14. Takeda is the lawful owner of all right, title, and interest in and to the following United States patents, including the right to sue and to recover for infringement thereof, which contain one or more claims covering methods of use of COLCRYS®.

A. United Sates Patent Number 7,619,004 ("the '004 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," a copy of which is attached hereto as Exhibit A and incorporated herein by reference as though set forth in full, which was duly and legally issued November 17, 2009, naming Matthew Davis as the inventor.

B. United States Patent Number 7,601,758 ("the '758 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS IN THE TREATMENT OF GOUT FLARES," a copy of which is attached hereto as Exhibit B and incorporated herein by reference as though set forth in full, which was duly and legally issued October 13, 2009, naming Matthew Davis as the inventor.

C. United States Patent Number 7,820,681 ("the '681 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit C and incorporated herein by reference as though set forth in full, which was duly and legally issued October 26, 2010, naming Matthew Davis as the inventor.

D. United States Patent Number 7,915,269 ("the '269 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit D and incorporated herein by reference as though set forth in full, which was duly and legally issued March 29, 2011, naming Matthew Davis as the inventor.

E. United States Patent Number 7,964,647 ("the '647 Patent"), entitled "COLCHICINE COMPOSITIONS AND METHODS," a copy of which is attached hereto as Exhibit E and incorporated herein by reference as though set forth in full, which was duly and legally issued June 21, 2011, naming Matthew Davis as the inventor.

F. United States Patent Number 7,964,648 ("the '648 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit F and incorporated herein by reference as though set forth in full, which was duly and legally issued June 21, 2011, naming Matthew Davis as the inventor.

G. United States Patent Number 7,981,938 ("the '938 Patent"), entitled "COLCHICINE COMPOSITIONS AND METHODS," a copy of which is attached hereto as Exhibit G and incorporated herein by reference as though set forth in full, which was duly and legally issued July 19, 2011, naming Matthew Davis as the inventor.

H. United States Patent Number 8,093,296 ("the '296 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," a copy of which is attached hereto as Exhibit H and incorporated herein by reference as though set forth in full, which was duly and legally issued January 10, 2012, naming Matthew Davis as the inventor.

I. United States Patent Number 8,093,297 ("the '297 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit I and incorporated herein by reference as though set forth in full, which was duly and legally issued January 10, 2012, naming Matthew Davis as the inventor.

J. United States Patent Number 8,097,655 ("the '655 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," a copy of which is attached hereto as Exhibit J and incorporated herein by reference as though set forth in full, which was duly and legally issued January 17, 2012, naming Matthew Davis as the inventor.

K. United States Patent Number 8,415,395 ("the '395 Patent"), entitled "COLCHICINE COMPOSITIONS AND METHODS," a copy of which is attached hereto as Exhibit K and incorporated herein by reference as though set forth in full, which was duly and legally issued April 9, 2013, naming Matthew Davis and Hengsheng Feng as inventors.

L. United States Patent Number 8,415,396 ("the '396 Patent"), entitled "COLCHICINE COMPOSITIONS AND METHODS," a copy of which is attached hereto as Exhibit L and incorporated herein by reference as though set forth in full, which was duly and legally issued April 9, 2013, naming Matthew Davis and Hengsheng Feng as inventors.

M. United States Patent Number 8,440,721 ("the '721 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit M and incorporated herein by reference as though set forth in full, which was duly and legally issued May 14, 2013, naming Matthew Davis as the inventor.

N. United States Patent Number 8,440,722 (the '722 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit N and incorporated herein by reference as though set forth in full, which was duly and legally issued May 14, 2013, naming Matthew Davis as the inventor.

15. The '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721 and '722 Patents are collectively referred to herein as the "Patents."

16. Takeda has submitted patent information to the FDA in connection with its NDA Nos. 22-351, 22-352 and 22-353 for COLCRYS®, and the FDA has published the same in "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

17. Upon information and belief, Watson with assistance and encouragement from Actavis submitted ANDA 204461 to the FDA seeking to market a 0.6 mg oral tablet generic version of COLCRYS® prior to the expiration of Takeda's patent rights.

18. On or about January 31, 2014, Takeda received a letter dated January 30, 2014, and signed by a representative of Watson, purporting to be notice of Watson's filing of ANDA No. 204461 seeking to market a 0.6 mg tablet generic version of COLCRYS® and purportedly containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification")

required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721', and '722 Patents.

19. Under the FFDCA, drug products submitted to the FDA for approval via an ANDA are required to have the same labeling as the reference listed drug, here COLCRYS®, except for changes required because of differences approved under a suitability petition (21 U.S.C. § 355(j)(2)(c); 21 C.F.R. § 314.93) or because the generic drug product and reference listed drug are produced or distributed by different manufacturers (21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. §314.94(a)(8)(iv)).

20. Upon information and belief, the proposed label submitted with ANDA 204461 will be the same as the labeling for COLCRYS® except for changes with respect to production, distribution and manufacture, as permitted by the FFDCA and the FDA.

COUNT I

(Infringement of the '004 Patent Under 35 U.S.C. § 271)

21. Paragraphs 1 to 20 are incorporated herein as set forth above.

22. Watson and Actavis have committed an act of infringement of the '004 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '004 Patent.

23. Watson and Actavis were aware that filing Watson's Paragraph IV Certification with respect to the '004 Patent after the '004 Patent was listed on the Orange Book constituted an act of infringement of the '004 Patent and were aware of the '004 Patent soon after its issuance.

24. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '004 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '004 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

25. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '004 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '004 Patent immediately and imminently upon approval of ANDA No. 204461.

26. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '004 Patent.

27. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '004 Patent.

28. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

29. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT II

(Infringement of the '758 Patent Under 35 U.S.C. § 271)

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

31. Watson and Actavis have committed an act of infringement of the '758 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '758 Patent.

32. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '758 Patent after the '758 Patent was listed on the Orange Book constituted an act of infringement of the '758 Patent and were aware of the '758 Patent soon after its issuance.

33. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '758 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS®

in the methods claimed in Takeda's '758 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

34. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '758 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '758 Patent immediately and imminently upon approval of ANDA No. 204461.

35. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '758 Patent.

36. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '758 Patent.

37. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

38. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT III

(Infringement of the '681 Patent Under 35 U.S.C. § 271)

39. Paragraphs 1 to 38 are incorporated herein as set forth above.

40. Watson and Actavis have committed an act of infringement of the '681 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '681 Patent.

41. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '681 Patent after the '681 Patent was listed on the Orange Book constituted an act of infringement of the '681 Patent and were aware of the '681 Patent soon after its issuance.

42. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '681 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '681 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

43. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '681 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '681 Patent immediately and imminently upon approval of ANDA No. 204461.

44. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '681 Patent.

45. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '681 Patent.

46. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

47. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT IV

(Infringement of the '269 Patent Under 35 U.S.C. § 271)

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

49. Watson and Actavis have committed an act of infringement of the '269 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '269 Patent.

50. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '269 Patent after the '269 Patent was listed on the Orange Book constituted an act of infringement of the '269 Patent and were aware of the '269 Patent soon after its issuance.

51. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '269 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '269 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

52. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '269 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '269 Patent immediately and imminently upon approval of ANDA No. 204461.

53. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '269 Patent.

54. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '269 Patent.

55. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

56. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT V

(Infringement of the '647 Patent Under 35 U.S.C. § 271)

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

58. Watson and Actavis have committed an act of infringement of the '647 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '647 Patent.

59. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '647 Patent after the '647 Patent was listed on the Orange Book constituted an act of infringement of the '647 Patent and were aware of the '647 Patent soon after its issuance.

60. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '647 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS®

in the methods claimed in Takeda's '647 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

61. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '647 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '647 Patent immediately and imminently upon approval of ANDA No. 204461.

62. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '647 Patent.

63. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '647 Patent.

64. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

65. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT VI

(Infringement of the '648 Patent Under 35 U.S.C. § 271)

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

67. Watson and Actavis have committed an act of infringement of the '648 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '648 Patent.

68. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '648 Patent after the '648 Patent was listed on the Orange Book constituted an act of infringement of the '648 Patent and were aware of the '648 Patent soon after its issuance.

69. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '648 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '648 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

70. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '648 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '648 Patent immediately and imminently upon approval of ANDA No. 204461.

71. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '648 Patent.

72. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '648 Patent.

73. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

74. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT VII

(Infringement of the '938 Patent Under 35 U.S.C. § 271 against Watson)

75. Paragraphs 1 to 74 are incorporated herein as set forth above.

76. Watson and Actavis have committed an act of infringement of the '938 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '938 Patent.

77. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '938 Patent after the '938 Patent was listed on the Orange Book constituted an act of infringement of the '938 Patent and were aware of the '938 Patent soon after its issuance.

78. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '938 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '938 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

79. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '938 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '938 Patent immediately and imminently upon approval of ANDA No. 204461.

80. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '938 Patent.

81. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '938 Patent.

82. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

83. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT VIII

(Infringement of the '296 Patent Under 35 U.S.C. § 271 against Watson)

84. Paragraphs 1 to 83 are incorporated herein as set forth above.

85. Watson and Actavis have committed an act of infringement of the '296 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '296 Patent.

86. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '296 Patent after the '296 Patent was listed on the Orange Book constituted an act of infringement of the '296 Patent and were aware of the '296 Patent soon after its issuance.

87. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '296 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS®

in the methods claimed in Takeda's '296 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

88. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '296 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '296 Patent immediately and imminently upon approval of ANDA No. 204461.

89. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '296 Patent.

90. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '296 Patent.

91. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

92. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT IX

(Infringement of the '297 Patent Under 35 U.S.C. § 271)

93. Paragraphs 1 to 92 are incorporated herein as set forth above.

94. Watson and Actavis have committed an act of infringement of the '297 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '297 Patent.

95. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '297 Patent after the '297 Patent was listed on the Orange Book constituted an act of infringement of the '297 Patent and were aware of the '297 Patent soon after its issuance.

96. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '297 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '297 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

97. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '297 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '297 Patent immediately and imminently upon approval of ANDA No. 204461.

98. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '297 Patent.

99. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '297 Patent.

100. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

101. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT X

(Infringement of the '655 Patent Under 35 U.S.C. § 271)

102. Paragraphs 1 to 101 are incorporated herein as set forth above.

103. Watson and Actavis have committed an act of infringement of the '655 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '655 Patent.

104. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '655 Patent after the '655 Patent was listed on the Orange Book constituted an act of infringement of the '655 Patent and were aware of the '655 Patent soon after its issuance.

105. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '655 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '655 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

106. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '655 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '655 Patent immediately and imminently upon approval of ANDA No. 204461.

107. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '655 Patent.

108. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '655 Patent.

109. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

110. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT XI

(Infringement of the '395 Patent Under 35 U.S.C. § 271)

111. Paragraphs 1 to 110 are incorporated herein as set forth above.

112. Watson and Actavis have committed an act of infringement of the '395 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '395 Patent.

113. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '395 Patent after the '395 Patent was listed on the Orange Book constituted an act of infringement of the '395 Patent and were aware of the '395 Patent soon after its issuance.

114. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '395 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS®

in the methods claimed in Takeda's '395 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

115. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '395 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '395 Patent immediately and imminently upon approval of ANDA No. 204461.

116. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '395 Patent.

117. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '395 Patent.

118. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

119. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT XII

(Infringement of the '396 Patent Under 35 U.S.C. § 271)

120. Paragraphs 1 to 119 are incorporated herein as set forth above.

121. Watson and Actavis have committed an act of infringement of the '396 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '396 Patent.

122. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '396 Patent after the '396 Patent was listed on the Orange Book constituted an act of infringement of the '396 Patent and were aware of the '396 Patent soon after its issuance.

123. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '396 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '396 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

124. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '396 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '396 Patent immediately and imminently upon approval of ANDA No. 204461.

125. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '396 Patent.

126. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '396 Patent.

127. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

128. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT XIII

(Infringement of the '721 Patent Under 35 U.S.C. § 271)

129. Paragraphs 1 to 128 are incorporated herein as set forth above.

130. Watson and Actavis have committed an act of infringement of the '721 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '721 Patent.

131. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '721 Patent after the '721 Patent was listed on the Orange Book constituted an act of infringement of the '721 Patent and were aware of the '721 Patent soon after its issuance.

132. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '721 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS® in the methods claimed in Takeda's '721 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

133. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '721 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '721 Patent immediately and imminently upon approval of ANDA No. 204461.

134. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '721 Patent.

135. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '721 Patent.

136. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

137. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

COUNT XIV

(Infringement of the '722 Patent Under 35 U.S.C. § 271)

138. Paragraphs 1 to 137 are incorporated herein as set forth above.

139. Watson and Actavis have committed an act of infringement of the '722 Patent that creates a justiciable case or controversy between Takeda and Watson and between Takeda and Actavis. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson and Actavis committed an act of infringement by submitting an ANDA with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of COLCRYS® prior to expiration of Takeda's '722 Patent.

140. Watson and Actavis were aware that filing Watson's Paragraph IV certification with respect to the '722 Patent after the '722 Patent was listed on the Orange Book constituted an act of infringement of the '722 Patent and were aware of the '722 Patent soon after its issuance.

141. Healthcare providers administering and/or patients using Watson's proposed generic version of COLCRYS® within the United States in the manner and for the indications described in ANDA No. 204661 will be direct infringers of Takeda's '722 Patent under 35 U.S.C. § 271(a). Takeda is informed and believes, and based thereon alleges, that the healthcare providers' and/or patients' infringing use of Watson's proposed generic version of COLCRYS®

in the methods claimed in Takeda's '722 Patent will occur at Watson's behest and with Watson's intent, knowledge, and encouragement.

142. Upon information and belief, Watson knows that its generic COLCRYS® product and the corresponding proposed labeling is especially made or adapted for use in infringing the '722 Patent and that Watson's generic COLCRYS® product and corresponding proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '722 Patent immediately and imminently upon approval of ANDA No. 204461.

143. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204661 be a date which is not earlier than the expiration date of the '722 Patent.

144. Takeda is entitled to a declaration that commercial manufacture, use, offer for sale, sale, and/or importation of Watson's generic version of COLCRYS® before the patent expires will infringe literally or under the doctrine of equivalents and/or indirectly infringe one or more claims of the '722 Patent.

145. Takeda will be irreparably harmed by Watson and Actavis's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

146. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Watson and Actavis.

EXCEPTIONAL CASE

147. Takeda is informed and believes, and based thereon alleges, that Watson and Actavis were aware of the Patents before submitting ANDA 204661 seeking to market a generic copy of COLCRYS®.

148. Watson and Actavis had no basis to submit the ANDA and Paragraph IV Certification. Watson and Actavis's actions render this an exceptional case under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Takeda requests entry of judgment in its favor and against Watson and Actavis as follows:

A. A judgment and decree that Watson and Actavis have infringed Takeda's '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721 and '722 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA No. 204661 with a Paragraph IV Certification seeking to market Watson's generic version of Colcrys® prior to the expiration of the Patents;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204461 seeking approval to manufacture, use, offer for sale, sell in and import into the United States colchicine 0.6 mg oral single-ingredient colchicine tablets which infringes any claim of the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721 and '722 Patents shall be a date that is not earlier than the expiration of the patent containing said claim;

C. Declaring and entering judgment that Watson and Actavis will infringe one of more claims of the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396,

'721 and '722 Patents under one or more of 35 U.S.C. §§ 271 (a), (b) and/or (c) by its manufacture, use, offering to sell, or sale in, or importation into the United States of Watson's generic colchicine product prior to the expiration of the Patents;

D. An Order permanently enjoining Watson and Actavis, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721 or '722 Patents;

E. An Order that if Watson and/or Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of a 0.6 mg oral single-ingredient colchicine tablets before the expiration of the Patents, a judgment be awarded to Takeda for damages resulting from such infringement, together with interest, in an amount to be determined at trial;

F. Declaring this an exceptional case under 35 U.S.C. § 285, and that Takeda be awarded reasonable attorneys' fees and costs; and

G. Such other and further relief as the Court may deem just and proper.

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

/s/ Mary W. Bourke

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