IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., *Plaintiff*, v. WATSON LABORATORIES, INC., *Defendant*.	Civil Action No. 14-268-SLR

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Takeda Pharmaceuticals U.S.A., Inc. files this Amended Complaint for patent infringement against Defendant Watson Laboratories, Inc. 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.

JURISDICTION AND VENUE

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

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

5. This Court has personal jurisdiction over Watson at least because it has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself 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.

6. 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.

7. 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

8. COLCRYS® is primarily used to prevent and treat gout flares. 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.

9. COLCRYS® is also used to treat Familial Mediterranean Fever ("FMF"). FMF is a rare, autosomal recessive, auto-inflammatory disease characterized by recurrent and/or chronic inflammation. COLCRYS® is the only single-active-ingredient oral colchicine product approved by the FDA to treat FMF.

10. 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).

11. As part of the FDA approval for COLCRYS®, Takeda received Orphan Drug exclusivity, which expires July 29, 2016.

12. In 2009, as a result of extensive research by Mutual Pharmaceutical Company, Inc. ("Mutual"), a former affiliate of Takeda, the FDA for the first time approved an oral single-active-ingredient colchicine product: COLCRYS®. Through its groundbreaking research, Mutual discovered important new information about colchicine, including previously unknown information concerning safety and efficacy, tolerability, dangerous side effects, and interactions with other medicines and substances.

13. 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 7,906,519 ("the '519 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," 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 March 15, 2011, naming Matthew Davis as the inventor.

B. United States Patent Number 7,935,731 ("the '731 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," 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 May 3, 2011, naming Matthew Davis as the inventor.

C. United States Patent Number 8,093,298 ("the '298 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND

MACROLIDE ANTIBIOTICS," 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 January 10, 2012, naming Matthew Davis as the inventor.

D. 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 D 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.

E. 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 E 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

F. 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 F 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.

G. 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 G 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.

H. 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 H 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.

I. 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 I 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.

J. United States Patent Number 7,964,647 ("the '647 Patent"), entitled "COLCHICINE COMPOSITIONS AND METHODS," 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 June 21, 2011, naming Matthew Davis as the inventor.

K. United States Patent Number 7,981,938 ("the '938 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 July 19, 2011, naming Matthew Davis as the inventor.

L. 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 L 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.

M. 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 M 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.

N. United States Patent Number 8,415,395 ("the '395 Patent"), entitled "COLCHICINE COMPOSITIONS AND METHODS," 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 April 9, 2013, naming Matthew Davis and Hengsheng Feng as inventors.

O. United States Patent Number 8,415,396 ("the '396 Patent"), entitled "COLCHICINE COMPOSITIONS AND METHODS," a copy of which is attached hereto as Exhibit O 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.

P. 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 P 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.

Q. 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 Q 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.

14. The ‘519, ‘731, ‘298, ‘648 and ‘297 Patents are collectively referred to herein as the “FMF Patents.”

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 “Gout Patents.”

16. All of the above-listed patents are collectively referred to herein as the “COLCRYS® Patents.”

17. The COLCRYS® Patents are listed in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as the “Orange Book”), maintained by the FDA as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1).

THE GOUT AND FMF MARKETS IN THE UNITED STATES

18. Pursuant to the guidelines established by the Rare Disease Act of 2002, the National Institute of Health Office of Rare Diseases classifies FMF as a “rare disease” with fewer than 200,000 affected individuals in the United States. In contrast, according to the American College of Rheumatology National Health and Nutrition Examination Survey, as of 2008, 8.3 million people in the United States suffered from gout.

19. According to national prescription data from Encuity Research, for the ten-year period between June 2004 and June 2013, approximately only 15,000 colchicine prescriptions were written for FMF patients in the United States over the past ten years. According to this national prescription data, less than one percent (0.16%) (or 1 in 625) of patients prescribed

colchicine were being treated for FMF. And among prescriptions written for FDA-approved uses for colchicine—gout and FMF—approximately 0.18% (or 1 in 555) of the prescriptions were for FMF, while approximately 99.82% of the prescriptions were for gout.

20. On information and belief, Watson intends to manufacture its generic version of COLCRYS® in quantities that far exceed the available market for the treatment of FMF in the United States. On further information and belief, Watson intends to manufacture and sell its generic version of COLCRYS® to the gout market for the treatment and prevention of gout.

PHYSICIAN AND PHARMACY PRESCRIBING PRACTICES

21. Physicians make prescribing decisions for medication based on their knowledge, experience, training, review of the medical literature, and review of the PDR or package insert for the brand drug. Physicians generally obtain information about the indications for which a drug may be prescribed from the label for the brand drug. Physicians generally do not receive generic drug labels, nor do doctors generally read indications printed on generic drug labels. Indeed, by the time a generic version of a branded drug becomes available, physicians typically have had years of experience prescribing the brand drug, and will follow the same prescribing practices for the generic version. Thus, physicians generally prescribe the generic drug for all of the approved indications associated with the brand name drug whether or not that indication appears on the generic label. Physicians are permitted to, and frequently do, prescribe drugs (including generic drugs) for such "off-label" uses. On information and belief, if Watson markets a generic version of COLCRYS® with a label containing only an FMF indication, physicians will nonetheless prescribe colchicine for gout consistent with their previous prescriptions practices for COLCRYS®. *See* Declaration of Dr. Chad S. Boomershine M.D., Ph.D. ("Boomershine Decl.") ¶¶ 9, 11, 12, a copy of which is attached hereto as Exhibit R.

22. Physicians do not control whether a pharmacist fills a prescription with a brand drug or with any particular generic version. The majority of states allow pharmacists to decide whether to substitute generic drugs for brand name drugs if the patient approves. In fourteen states, substitution of the generic version of a drug is mandatory. *See* 2014 National Association of Boards of Pharmacy (NABP) *Survey of Pharmacy Law* at 67 (reporting that fourteen states require "mandatory" generic substitution and that thirty-eight states permit pharmacists to substitute a generic drug with patient approval), a copy of which is attached hereto as Exhibit S. Lower cost for the patient and larger profits margins for the pharmacists make substitution a regular occurrence. *See, e.g.*, Jim Edwards, Moneywatch—CBS News, *How Pharmacists Keep Cash That Could Be Yours on Each Generic Prescription* (May 27, 2011), http://www.cbsnews.com/news/how-pharmacists-keep-cash-that-could-be-yours-on-each-generic-prescription/, a copy of which is attached hereto as Exhibit T. Thus, where a generic version of a brand drug exists, pharmacists regularly will substitute the generic drug for the brand, irrespective of whether the generic drug is FDA-approved for the indication for which the brand drug was prescribed.

23. On information and belief, physicians regularly use the phrase "colchicine" instead of Colcrys® when writing prescriptions for patients suffering from gout flares. *See* Boomershine Decl. ¶ 10. Prior to 2009, non-FDA approved colchicine was prescribed in the United States, and the way to prescribe the drug prior to 2009 was to use the term "colchicine." Historical prescription data indicates that many treating physicians have maintained the practice of using the term "colchicine" when writing prescriptions despite the approval of Colcrys® in 2009. As a result of this practice, generic colchicine will be sold even in states without mandatory substitution laws.

WATSON'S ACTIONS GIVING RISE TO THIS SUIT

24. Upon information and belief, Watson submitted ANDA No. 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.

25. 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 ("Watson's First PIV Notice Letter").

26. After reviewing Watson's First PIV Notice Letter, and within 45 days of receipt of Watson's letter, Takeda filed a lawsuit against Watson in this District alleging, *inter alia*, that pursuant to 35 U.S.C. § 271, Watson had committed an act of infringement by submitting an ANDA with a Paragraph IV Certification seeking approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product for the treatment and prevention of gout flares prior to expiration of Takeda's Gout Patents (*See* C. A. No. 14-268 (SLR) (D. Del.).)

27. Shortly after being sued for infringement in this District for submitting ANDA No. 204461, Watson voluntarily elected to abandon its request for FDA approval with respect to the treatment and prevention of gout flares.

28. Takeda received a letter dated May 9, 2014, and signed by a representative of Watson, purporting to be notice of the filing of ANDA No. 204461 seeking to engage in the

commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to the FMF Patents. ("Watson's Second PIV Notice Letter"). The stated purpose of the letter was to notify Takeda that Watson had filed a certification under 21 C.F.R. § 314.95 in conjunction with its ANDA to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product for the treatment of FMF. Watson's Second PIV Notice Letter alleges that Takeda's FMF Patents listed in the Orange Book covering the use of COLCRYS® to treat FMF are invalid and/or will not be infringed by commercial use or sale of Watson's Proposed Product.

29. Watson's Second PIV Notice Letter further informed Takeda that its proposed labeling does not include dosing instructions or safety information for the treatment or prevention of gout flares.

30. Upon information and belief, Watson submitted a label amendment to the FDA such that the proposed label originally submitted with ANDA No. 204461 was being amended for the purpose of limiting FDA approval of its Proposed Product to the treatment of FMF and that, pursuant to §355(j)(2)(A)(viii), Watson seeks to carve out from the FDA-approval COLCRYS® label, *inter alia*, information regarding the treatment and prevention of gout flares, including all dosing instructions for the treatment and prevention of gout flares.

31. Takeda's FDA approved product label for COLCRYS® contains, *inter alia*, methods of using COLCRYS® as disclosed and claimed in the Gout Patents, including the use of colchicine to treat and prevent gout flares with or without concomitant administration of another substance.

32. Takeda's FDA approved product label for COLCRYS® contains, *inter alia*, methods of using COLCRYS® as disclosed and claimed in the FMF Patents, including the use of colchicine to treat FMF when a patient is or is not taking another substance.

33. 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)).

34. If Watson's generic colchicine product is approved by the FDA, Watson will infringe and/or induce others to infringe one or more claims of the FMF Patents.

35. If Watson's generic colchicine product is approved by the FDA, Watson will contribute to the infringement of one or more claims of the Gout Patents.

36. Upon information and belief, Watson has made, and continues to make, substantial preparation in the United States for the commercial manufacture, use, offer to sell, sale, and/or importation of its Proposed Product prior to Takeda's COLCRYS® Patents expiry.

37. Watson's actions, including, but not limited to, the development of its Proposed Product and the filing of ANDA No. 204461 with a Paragraph IV Certification, indicate a refusal to change the course of its actions despite its knowledge of Takeda's unexpired COLCRYS® Patents.

38. Upon information and belief, Watson continues to seek approval of ANDA No. 204461 from the FDA to engage in the commercial use, manufacture, sale, offer to sell or

importation of its Proposed Product for the treatment of FMF prior to the expiry of Takeda's COLCRYS® Patents.

39. Upon information and belief, Watson intends to manufacture, offer for sale and sell generic COLCRYS® in quantities that far exceed the market for treatment of FMF. Upon information and belief, Watson knows of Takeda's gout patents, and knows that its generic version of COLCRYS® will be sold to the gout market for the treatment and prevention of gout flares in a manner that infringes Takeda's Gout Patents.

40. Upon information and belief, Watson's generic version of COLCRYS® will be substantially used for the treatment and prevention of gout flares. Upon information and belief, any use of Watson's generic version of COLCRYS® product that will not infringe claims of one or more of the Gout Patents will be insubstantial.

41. Takeda commenced this action within 45 days of receiving Watson's Second PIV Notice Letter.

COUNT I

(Infringement of the '519 Patent)

42. Paragraphs 1 to 41 are incorporated herein as set forth above.

43. Watson has committed an act of infringement of the '519 Patent that creates a justiciable case or controversy between Takeda and Watson.

44. Watson's submission of its ANDA No. 204461 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product to treat FMF prior to expiration of the '519 Patent constitutes infringement of one or more claims of the '519 Patent under 35 U.S.C. § 271(e)(2)(A).

45. Unless enjoined by the Court, upon FDA approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will induce infringement of the '519 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Watson's Proposed Product in the United States. On information and belief, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Watson's Proposed Product with knowledge of the '519 Patent and knowledge that its acts are encouraging infringement.

46. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

47. Takeda does not have an adequate remedy at law.

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

COUNT II

(Infringement of the '731 Patent)

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

50. Watson has committed an act of infringement of the '731 Patent that creates a justiciable case or controversy between Takeda and Watson.

51. Watson's submission of its ANDA No. 204461 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product to treat FMF prior to expiration of the '731 Patent constitutes infringement of one or more claims of the '731 Patent under 35 U.S.C. § 271(e)(2)(A).

52. Unless enjoined by the Court, upon FDA approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will induce infringement of the '731 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Watson's Proposed Product in the United States. On information and belief, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Watson's Proposed Product with knowledge of the '731 Patent and knowledge that its acts are encouraging infringement.

53. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

54. Takeda does not have an adequate remedy at law.

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

COUNT III

(Infringement of the '298 Patent)

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

57. Watson has committed an act of infringement of the '298 Patent that creates a justiciable case or controversy between Takeda and Watson.

58. Watson's submission of its ANDA No. 204461 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product to treat FMF prior to expiration of the '298 Patent constitutes infringement of one or more claims of the '298 Patent under 35 U.S.C. § 271(e)(2)(A).

59. Unless enjoined by the Court, upon FDA approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will induce infringement of the '298 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Watson's Proposed Product in the United States. On information and belief, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Watson's Proposed Product with knowledge of the '298 Patent and knowledge that its acts are encouraging infringement.

60. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

61. Takeda does not have an adequate remedy at law.

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

COUNT IV

(Infringement of the '648 Patent)

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

64. Watson has committed an act of infringement of the '648 Patent that creates a justiciable case or controversy between Takeda and Watson.

65. Watson's submission of its ANDA No. 204461 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product to treat FMF prior to expiration of the '648 Patent constitutes infringement of one or more claims of the '648 Patent under 35 U.S.C. § 271(e)(2)(A).

66. Unless enjoined by the Court, upon FDA approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will induce infringement of the '648 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Watson's Proposed Product in the United States. On information and belief, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Watson's Proposed Product for the treatment of FMF with knowledge of the '648 Patent and knowledge that its acts are encouraging infringement.

67. Watson has knowledge of the '648 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '648 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the treatment and prevention of gout flares, knowing the same to be especially made for use in infringement of the '648 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

68. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '648 Patent with respect to the use of generic Colcrys® to prevent and treat gout flares. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '648 Patent and that the claims of the '648 Patent are valid.

69. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

70. Takeda does not have an adequate remedy at law.

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

COUNT V

(Infringement of the '297 Patent)

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

73. Watson has committed an act of infringement of the '297 Patent that creates a justiciable case or controversy between Takeda and Watson.

74. Watson's submission of its ANDA No. 204461 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product to treat FMF prior to expiration of the '297 Patent constitutes infringement of one or more claims of the '297 Patent under 35 U.S.C. § 271(e)(2)(A).

75. Unless enjoined by the Court, upon FDA approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will induce infringement of the '297 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Watson's Proposed Product in the United States. On information and belief, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Watson's Proposed Product for the treatment of FMF with knowledge of the '297 Patent and knowledge that its acts are encouraging infringement.

76. Watson has knowledge of the '297 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '297 Patent by others, by

offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '297 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

77. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '297 Patent with respect to the use of generic Colcrys® to prevent and treat gout flares. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '297 Patent and that the claims of the '297 Patent are valid.

78. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

79. Takeda does not have an adequate remedy at law.

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

COUNT VI

(Infringement of the '004 Patent)

81. Paragraphs 1 to 80 are incorporated herein as set forth above.

82. Watson has knowledge of the '004 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '004 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the treatment and prevention of gout flares, knowing the same to

be especially made for use in infringement of the '004 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

83. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '004 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '004 Patent and that the claims of the '004 Patent are valid.

84. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

85. Takeda does not have an adequate remedy at law.

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

COUNT VII

(Infringement of the '758 Patent)

87. Paragraphs 1 to 86 are incorporated herein as set forth above.

88. Watson has knowledge of the '758 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '758 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the treatment and prevention of gout flares, knowing the same to be especially made for use in infringement of the '758 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

89. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '758 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '758 Patent and that the claims of the '758 Patent are valid.

90. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

91. 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.

COUNT VIII

(Infringement of the '681 Patent)

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

94. Watson has knowledge of the '681 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '681 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the treatment and prevention of gout flares, knowing the same to be especially made for use in infringement of the '681 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

95. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '681 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys®

product will contribute to the infringement of one or more claims of the '681 Patent and that the claims of the '681 Patent are valid.

96. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

97. Takeda does not have an adequate remedy at law.

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

COUNT IX

(Infringement of the '269 Patent)

99. Paragraphs 1 to 98 are incorporated herein as set forth above.

100. Watson has knowledge of the '269 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '269 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the treatment and prevention of gout flares, knowing the same to be especially made for use in infringement of the '269 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

101. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '269 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '269 Patent and that the claims of the '269 Patent are valid.

102. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

103. Takeda does not have an adequate remedy at law.

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

COUNT X

(Infringement of the '647 Patent)

105. Paragraphs 1 to 104 are incorporated herein as set forth above.

106. Watson has knowledge of the '647 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '647 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '647 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

107. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '647 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '647 Patent and that the claims of the '647 Patent are valid.

108. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

109. 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.

COUNT XI

(Infringement of the '938 Patent)

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

112. Watson has knowledge of the '938 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '938 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '938 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

113. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '938 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '938 Patent and that the claims of the '938 Patent are valid.

114. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

115. Takeda does not have an adequate remedy at law.

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

COUNT XII

(Infringement of the '296 Patent)

117. Paragraphs 1 to 116 are incorporated herein as set forth above.

118. Watson has knowledge of the '296 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '296 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '296 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

119. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '269 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '269 Patent and that the claims of the '269 Patent are valid.

120. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

121. Takeda does not have an adequate remedy at law.

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

COUNT XIII

(Infringement of the '655 Patent)

123. Paragraphs 1 to 122 are incorporated herein as set forth above.

124. Watson has knowledge of the '655 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '655 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '655 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

125. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '655 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '655 Patent and that the claims of the '655 Patent are valid.

126. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

127. 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.

COUNT XIV

(Infringement of the '395 Patent)

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

130. Watson has knowledge of the '395 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '395 Patent by others, by

offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '395 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

131. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '395 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '395 Patent and that the claims of the '395 Patent are valid.

132. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

133. Takeda does not have an adequate remedy at law.

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

COUNT XV

(Infringement of the '396 Patent)

135. Paragraphs 1 to 134 are incorporated herein as set forth above.

136. Watson has knowledge of the '396 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '396 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to

be especially made for use in infringement of the '396 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

137. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '396 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '396 Patent and that the claims of the '396 Patent are valid.

138. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

139. Takeda does not have an adequate remedy at law.

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

COUNT XVI

(Infringement of the '721 Patent)

141. Paragraphs 1 to 140 are incorporated herein as set forth above.

142. Watson has knowledge of the '721 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '721 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '721 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

143. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '721 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys® product will contribute to the infringement of one or more claims of the '721 Patent and that the claims of the '721 Patent are valid.

144. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

145. 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.

COUNT XVII

(Infringement of the '722 Patent)

147. Paragraphs 1 to 146 are incorporated herein as set forth above.

148. Watson has knowledge of the '722 Patent. Unless enjoined by the court, upon approval of ANDA No. 204461 and expiration of Takeda's Orphan Drug exclusivity, Watson, in violation of 35 U.S.C. § 271(c), will contribute to infringement of the '722 Patent by others, by offering to sell, selling, or distributing within the United States or importing into the United States generic COLCRYS® for the prevention and treatment of gout flares, knowing the same to be especially made for use in infringement of the '722 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use.

149. There is an actual and justiciable controversy between Takeda and Watson concerning the infringement and validity of the '722 Patent. Takeda is entitled to a declaration that Watson's manufacture, use, sale, offer for sale and/or importation of its generic Colcrys®

product will contribute to the infringement of one or more claims of the '722 Patent and that the claims of the '722 Patent are valid.

150. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court.

151. Takeda does not have an adequate remedy at law.

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

EXCEPTIONAL CASE

153. Takeda is informed and believes, and based thereon alleges, that Watson was aware of the COLCRYS® Patents before submitting ANDA No. 204461 and its label amendment to the FDA.

154. Watson had no basis to submit ANDA No. 204461 and or a Paragraph IV Certification. Watson'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 has infringed one or more claims of the FMF Patents (the '519, '731, '298, '648, and '297 Patents) under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA No. 204461 with a Paragraph IV Certification seeking approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Watson's Proposed Product to treat FMF prior to the expiration of the Patents;

B. Declaring and entering judgment that Watson will infringe one or more claims of the FMF Patents (the '519, '731, '298, '648, and '297 Patents) under 35 U.S.C. § 271

(b) by its manufacture, use, offering to sell, sale, and importation into the United States of its Proposed Product to treat FMF prior to the expiration of the FMF Patents;

C. Declaring and entering a judgment that Watson will infringe one of more of the claims of the Gout Patents (the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721, and '722 Patents) under 35 U.S.C. § 271(c) by its manufacture, use, offering to sell, sale, and importation into the United States of its Proposed Product prior to the expiration of the Gout Patents;

D. 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 FMF Patents shall be a date that is not earlier than the expiration of the patent containing said claim;

E. A judgment enjoining Watson, 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, including Watson's Proposed Product, that infringes the COLCRYS® Patents, including any extensions;

F. An Order that if Watson 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;

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

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

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

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