IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	**CORRECTED PUBLIC VERSION** C.A. No. 19-2216-RGA **JURY TRIAL DEMANDED** [redacted] [redacted]

COMPLAINT

Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda" or "Plaintiff"), by their undersigned attorneys, for their Complaint against defendant Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant"), herein allege as follows:

NATURE OF THE ACTION

1. Takeda brings this civil action against Mylan for breach of the 2017 License Agreement[1], attached hereto as Exhibit A, under Delaware law, and for patent infringement under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 7,906,519 ("the '519 patent"); 7,935,731 ("the '731 patent"); 8,093,298 ("the '298 patent"); 7,964,648 ("the '648 patent"); 8,093,297 ("the '297 patent"); 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296

[redacted]

patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent") (collectively, the "Patents-in-Suit").

THE PARTIES

2. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at One Takeda Parkway, Deerfield, Illinois 60015.

3. Upon information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, and its principal place of business is located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

JURISDICTION AND VENUE

4. This Court has original jurisdiction over the contract claims in this matter pursuant to 28 U.S.C. §§ 1332, in that the matter in controversy is between parties that are diverse, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

5. This Court has subject-matter jurisdiction over this action with respect to the patent claims, pursuant to 28 U.S.C. §§ 1331 and 1338(a) because the action arises under the patent laws of the United States.

6. This Court also has subject-matter jurisdiction over this action pursuant to this Court's December 28, 2017 Order in *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 16-987-RGA (D. Del. Dec. 28, 2017) (D.I. 71) ("Order," which is attached as Exhibit B and is incorporated herein by reference as though set forth in full, in which this Court retained jurisdiction to enforce the parties' settlement agreement) (Ex. B, Order at ¶ 2).

7. [redacted]

8. Venue is proper under 28 U.S.C. § 1391(b) and (c) [redacted]

9. Further, on information and belief, Mylan has extensive contacts with the State of Delaware. Mylan is registered to do business in Delaware (File Number 4809319), has appointed an agent in Delaware to receive service of process, and is licensed to distribute drugs in Delaware. For example, on information and belief, Mylan has designated its registered agent for the State of Delaware as Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. Also, Mylan is actively registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License No. A4-0001719) and "Distributor/Manufacturer CSR" (License No. DM-00007571).

10. On information and belief, Mylan regularly does business in Delaware by selling and distributing generic pharmaceutical products. On information and belief, Mylan directly or through its affiliates and agents, formularies, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States and in Delaware. On information and belief, Mylan derives substantial revenue from products sold or consumed in Delaware.

11. On information and belief, Mylan has previously availed itself of this forum by litigating, as a defendant, over 50 other civil actions initiated in this jurisdiction, including, for example, in *Takeda Pharmaceutical U.S.A., Inc., v. Mylan Pharmaceuticals Inc.*, C.A. 13-cv-987-SLR (D. Del. Dec. 15, 2016) (D.I. 9) (where Takeda asserted claims involving patent infringement of the same Patents-in-Suit now at issue in the present matter) and affirmatively

invoked this Court's jurisdiction by asserting counterclaims in many of those cases, including, for example *UCB, Inc. v. Mylan Pharmaceuticals Inc.*, C.A. 16-cv-1214-LPS (D. Del. Sept. 16, 2013) (D.I. 11), and in *Teijin Ltd. v. Mylan Pharmaceuticals Inc.*, C.A. 13-cv-01781-SLR (D. Del. Nov. 27, 2013) (D.I. 10).

12. On information and belief, the Mylan ANDA Product will, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing in Delaware and dispensed by pharmacies located within Delaware, all of which will have a substantial effect on Delaware. On information and belief, Mylan knows and intends that the Mylan ANDA Product will be distributed and sold in the United States, including in Delaware. If Mylan is permitted to market the Mylan ANDA Product, Takeda will be specifically harmed by Mylan's sales of the Mylan ANDA Product, including its sales in Delaware.

13. [redacted]

14. [redacted]

BACKGROUND FACTS

A. Takeda's Colcrys® Product

15. Colcrys® (colchicine, USP) tablets, 0.6 mg is approved by the FDA for the prophylaxis and treatment of gout flares in adults and familial Mediterranean fever ("FMF") in adults and children 4 years or older.

16. Gout is an extremely painful rheumatologic condition characterized by chronic manifestations and acute flares, which are often caused by the accumulation of uric acid.

17. Colcrys® is also used to treat Familial Mediterranean Fever ("FMF"). FMF is a rare inherited, disease characterized by abdominal pain and significant morbidity.

18. Colcrys® was the first pharmaceutical product approved by the Food and Drug Administration ("FDA") that contained colchicine as the sole active ingredient. While colchicine had been used in the United States for many years before the approval of Colcrys®, use of single-ingredient colchicine was not approved by FDA.

19. In 2006, the FDA encouraged the pharmaceutical industry to submit a New Drug Applications ("NDA") for previously unapproved drugs in order for FDA to substantively evaluate older drug products by modern standards.

20. Mutual Pharmaceutical Company, Inc. ("Mutual") sponsored a clinical study that revealed important new information about colchicine administration. The study revealed that a substantially lower total dose of colchicine was effective to treat gout flares compared to the previous standard of care dose, resulting in significantly fewer adverse events. The study also identified potentially lethal interactions between certain classes of drugs and colchicine.

21. Mutual submitted NDAs for single-ingredient colchicine tablets under Section 505(b)(2) of the Federal Food, Drug and Consumer Act. Mutual submitted: (1) NDA No. 22-351 for the treatment of acute gout, (2) NDA No. 22-352 for the treatment of FMF, and (3) NDA No. 22-353 for the prevention of gout flares in the chronic treatment of gout.

22. FDA approved NDA No. 22-352 on July 29, 2009. FDA approved NDA No. 22-351 on July 30, 2009. FDA approved NDA No. 22-353 on October 16, 2009.

23. Takeda is currently the holder of NDA Nos. 22-351, 22-352, and 22-353.

B. Takeda's Colcrys® Patents

24. Takeda is the lawful owner of all right, title, and interest in and to the following United States patents set forth in paragraphs 25-40 below, including the right to sue and to

recover for infringement thereof, which contain one or more claims covering methods of using Colcrys®.

25. The ’519 patent, titled “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, was duly and legally issued March 15, 2011, naming Matthew W. Davis as the inventor. The ’519 patent claims, *inter alia*, a method of treating a patient in need of treatment for Familial Mediterranean Fever with colchicine by orally administering an adjusted daily dosage amount of colchicine wherein the patient is receiving concomitant administration of ritonavir.

26. The ’731 patent, titled “Methods For Concomitant Administration of Colchicine and Macrolide Antibiotics,” a copy of which is attached hereto as Exhibit D and incorporated herein by reference as though set forth in full, was duly and legally issued May 3, 2011, naming Matthew W. Davis as the inventor. The ’731 patent claims, *inter alia*, a method of using colchicine for the treatment of Familial Mediterranean Fever comprising orally administering a reduced colchicine dosage amount to a patient who is concomitantly receiving clarithromycin.

27. The ’298 patent, titled “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” a copy of which is attached hereto as Exhibit E and incorporated herein by reference as though set forth in full, was duly and legally issued January 10, 2012, naming Matthew W. Davis as the inventor. The ’298 patent claims, *inter alia*, a method of using colchicine for the treatment of Familial Mediterranean Fever by orally administering a reduced dosage amount of colchicine to a adult or child who is concomitantly receiving clarithromycin.

28. The ’648 patent, titled “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, was duly and legally issued June 21, 2011, naming Matthew W. Davis as the inventor. The ’648 patent claims, *inter alia*, a method of treating a patient with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of ketoconazole.

29. The ’297 patent, titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” a copy of which is attached hereto as Exhibit G and incorporated herein by reference as though set forth in full, was duly and legally issued January 10, 2012, naming Matthew W. Davis as the inventor. The ’297 patent claims, *inter alia*, a method of treating a patient in need of treatment for gout or familial Mediterranean fever with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of a recommended daily dosage amount of ritonavir.

30. The ’004 patent, titled “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, was duly and legally issued November 17, 2009, naming Matthew W. Davis as the inventor. The ’004 patent claims, *inter alia*, a method of using colchicine for prophylactic treatment of gout flares in a human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin.

31. The ’758 patent, titled “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares,” a copy of which is attached hereto as Exhibit I and incorporated herein by reference as though set forth in full, was duly and legally issued October 13, 2009, naming Matthew W. Davis as the inventor. The ’758 patent claims, *inter alia*, a method of using colchicine to treat a gout flare in a human patient who is receiving concomitant administration of clarithromycin or erythromycin.

32. The ’681 patent, titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” a copy of which is attached hereto as Exhibit J and incorporated herein by reference as though set forth in full, was duly and legally issued October 26, 2010, naming Matthew W. Davis as the inventor. The ’681 patent claims, *inter alia*, a method of treating a patient in need of treatment for the prophylaxis of gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to a patient who is receiving concomitant administration of ritonavir.

33. The ’269 patent, titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” a copy of which is attached hereto as Exhibit K and incorporated herein by reference as though set forth in full, was duly and legally issued March 29, 2011, naming Matthew W. Davis as the inventor. The ’269 patent claims, *inter alia*, a method of treating a patient in need of treatment for gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine wherein the patient is receiving concomitant administration of ritonavir.

34. The ’647 patent, titled “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, was duly and legally issued June 21, 2011, naming Matthew W. Davis as the inventor. The

'647 patent claims, *inter alia*, a method of treating a patient having an acute gouty arthritis attack with colchicine.

35. The '938 patent, titled "Colchicine Compositions and Methods," a copy of which is attached hereto as Exhibit M and incorporated herein by reference as though set forth in full, was duly and legally issued July 19, 2011, naming Matthew W. Davis as the inventor. The '938 patent claims, *inter alia*, a method of treating a gout flare with colchicine in a patient undergoing colchicine prophylactic treatment of gout flares.

36. The '296 patent, titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," a copy of which is attached hereto as Exhibit N and incorporated herein by reference as though set forth in full, was duly and legally issued January 10, 2012, naming Matthew W. Davis as the inventor. The '296 patent claims, *inter alia*, a method of using colchicine to treat gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when the patient is receiving concomitant administration of clarithromycin.

37. The '655 patent, titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," a copy of which is attached hereto as Exhibit O and incorporated herein by reference as though set forth in full, was duly and legally issued January 17, 2012, naming Matthew W. Davis as the inventor. The '655 patent claims, *inter alia*, a method of using colchicine for prophylactic treatment of gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin.

38. The '395 patent, titled "Colchicine Compositions and Methods," a copy of which is attached hereto as Exhibit P and incorporated herein by reference as though set forth in full,

was duly and legally issued April 9, 2013, naming Matthew W. Davis and Hengsheng Feng as inventors. The ’395 patent claims, *inter alia*, a method of treating a patient having a gout flare.

39. The ’396 patent, titled “Colchicine Compositions and Methods,” a copy of which is attached hereto as Exhibit Q and incorporated herein by reference as though set forth in full, was duly and legally issued April 9, 2013, naming Matthew W. Davis and Hengsheng Feng as inventors. The ’396 patent claims, *inter alia*, a method of treating a patient having a gout flare.

40. The ’721 patent, titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” a copy of which is attached hereto as Exhibit R and incorporated herein by reference as though set forth in full, was duly and legally issued May 14, 2013, naming Matthew W. Davis as the inventor. The ’721 patent claims, *inter alia*, a method of treating a patient in need of treatment for acute gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of verapamil.

41. The ’722 patent, titled “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” a copy of which is attached hereto as Exhibit S and incorporated herein by reference as though set forth in full, was duly and legally issued May 14, 2013, naming Matthew W. Davis as the inventor. The ’722 patent claims, *inter alia*, a method of treating a patient in need of treatment for prophylaxis of gout flares with colchicine, comprising orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of verapamil.

42. The ’647, ’938, ’395, and ’396 patents are collectively referred to herein as the “Acute Gout Flare Patents.”

43. The ’519, ’731, ’298, ’297, ’004, ’758, ’681, ’269, ’648, ’296, ’655, ’721, and ’722 patents are collectively referred to herein as the “Drug-Drug Interaction” or “DDI Patents.”

44. The FDA’s official publication of approved drugs (the “Orange Book”) lists the Patents-in-Suit in connection with pharmaceutical product, Colcrys®. Pursuant to 21 U.S.C. § 355(b)(1), the Patents-in-Suit are listed in the FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “Orange Book”) as covering Colcrys®.

C. Previous Colcrys® Litigation with Mylan, C.A. No. 16- 987-RGA (D. Del.)

45. In 2016, Mylan submitted Abbreviated New Drug Application (“ANDA”) No. 209470 to the FDA (“the Mylan ANDA”), seeking approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of generic 0.6 mg oral colchicine tablets—a generic version of Colcrys® (“the Mylan ANDA Product”).

46. [redacted], Mylan notified Takeda of the submission of the Mylan ANDA to FDA. As filed, the Mylan ANDA sought approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of the Mylan ANDA Product to treat Familial Mediterranean Fever. (*See also* D.I. 9, C.A. No. 16-987-RGA, Answer to ¶ 65) (admitting Mylan sought “FDA approval for its generic colchicine tablets for the treatment of familial Mediterranean fever (FMF) in adults and children 4 years or older”).

47. The Mylan ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to, the ’519, ’731, ’298, ’648, and ’297 patents (hereinafter, the “Paragraph IV Notice Letter”). Mylan asserted in its Paragraph IV Notice Letter that it is entitled to bring its product to market prior to the expiration of Takeda’s ’519, ’731, ’298, ’648, and ’297 patents because those patents are invalid, unenforceable, and/or would not be infringed.

48. Mylan's Paragraph IV Notice Letter did not state that Mylan sought approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of the Mylan ANDA Product for the treatment or prevention of gout flares.

49. On October 24, 2016, Takeda sued Mylan in this District asserting that the Mylan ANDA Product, if sold and marketed, would infringe all of the Patents-in-Suit (i.e. all seventeen patents listed in the Orange Book for Colcrys®).

50. During litigation, Mylan admitted that it had submitted to FDA a statement under 35 U.S.C. § 355(j)(2)(A)(viii) to the FDA with respect to Takeda's Gout Patents (*see* D.I. 9, C.A. No. 16-987-RGA, Answer to ¶ 42), whereby Mylan, further admitted that it "has 'carved out' the indication for the treatment of 'gout flares' from its label." (*See* D.I. 9, C.A. No. 16-987-RGA, Answer to ¶ 71).

1. Takeda Settled Its Infringement Claims Against Mylan

51. [redacted]

52. [redacted]

[redacted]

53. [redacted]

[redacted]

54. [redacted]

[redacted]

55. [redacted]

[redacted]

[redacted]

56. [redacted]

57. [redacted]

58. [redacted]

59. Following execution of the Settlement Agreement and License Agreement, Takeda and Mylan signed and jointly filed a stipulation voluntarily dismissing the pending litigation, attached hereto as Exhibit T. On December 28, 2017, this Court so-ordered that stipulation, and retained jurisdiction to enforce the parties' agreements. (Ex. B).

2. Takeda's Settlements with Mylan's Competitors

60. In addition to Mylan, several other generic-drug manufacturers have submitted ANDAs to the FDA seeking approval to make and sell generic versions of Colcrys®. Over several years, Takeda filed and settled litigations against each of these ANDA applicants.

61. [redacted]

62. [redacted]

MYLAN'S ACTIONS GIVING RISE TO THIS SUIT

A. Mylan's Breach of the License Agreement with Takeda

63. On or about September 16, 2019, Mylan received approval from the FDA of the Mylan ANDA (i.e. ANDA No. 209470).

64. Upon information and belief, on or about November 25, 2019, Mylan launched the Mylan ANDA Product and entered the United States market. Specifically, Mylan began to manufacture, have manufactured, use, import, distribute, market, offer to sell, have sold, and/or sell the Mylan ANDA Product in the United States. For example, the National Drug Code

registry lists November 25, 2019, as the "Start Marketing Date" for the Mylan ANDA Product. A screenshot from the National Drug Code registry list is attached as Exhibit U.

65. A generic-drug manufacturer generally must undertake substantial preparations before introducing a drug to the United States market. For example, the manufacturer must manufacture, or arrange to have manufactured, a sufficient quantity of the drug to satisfy anticipated demand upon market entry. It must store that inventory pending market entry. It must solicit orders from wholesalers, retailers, and other customers. And it must arrange for product importation, distribution, and other logistics. Because each of these tasks is time- and resource-consuming and requires the negotiation of often complex and interlocking contracts, they typically require weeks or months to complete.

66. Upon information and belief, Mylan has made substantial preparations for the commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Product in the United States. Specifically, upon information and belief, Mylan has begun manufacturing Mylan ANDA Product and/or arranging for its manufacture; storing the Mylan ANDA Product; importing the Mylan ANDA Product into the United States; taking other steps to develop an inventory of the Mylan ANDA Product; discussing the Mylan ANDA Product's upcoming availability with potential customers; and booking sales orders for the Mylan ANDA Product. [redacted]

67. [redacted]

[redacted]

68. [redacted]

69. Upon information and belief, Mylan has already begun the process of notifying customers of the availability of the Mylan ANDA Product. [redacted]. Upon information and belief, the Mylan ANDA Product has been sold and commercialized with its label containing instructions for use by doctors, pharmacists, other healthcare professionals, and patients..

70. Mylan's preparation to launch, and the actual launch of, the Mylan ANDA Product are breaches of the License Agreement. In addition, Mylan's unauthorized and unlicensed pre-marketing activities and launch of its product constitute infringement of the Patents-in-Suit.

71. As a result, upon information and belief, the unauthorized and unlicensed launch of the Mylan ANDA Product will, at least, incentivize licensed competitors of Mylan to launch

their own generic colchicine products irreparably harming Takeda by dramatically reducing Takeda's and the Takeda/Par authorized generic product's share of the market and causing the price of colchicine products (including Colcrys® brand) to immediately, substantially, and irrevocably decline.

MYLAN'S INFRINGEMENT OF THE PATENTS-IN-SUIT

72. Takeda's FDA approved product label for Colcrys® teaches and encourages, *inter alia*, methods of using Colcrys® claimed in the Patents-in-Suit, including the use of colchicine for prophylaxis and to treat gout or FMF when a patient is or is not taking another substance. (*See, e.g.*, Ex. Y, Colcyrs® Label at Table 1).

73. The approved labeling for Colcrys® directs doctors, pharmacists, other healthcare professionals, and patients to practice the claimed methods of Takeda's Patents-in-Suit.

74. Under the Federal Food, Drug, and Cosmetic Act, 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), 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)), or because the ANDA applicant has made a section viii carve-out for one of the indications on the label of the reference listed drug.

75. On information and belief, the approved label for Mylan's generic Colcrys® (colchicine) product (revised: 7/2019) is available online at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=85acf34c-06c6-40ea-95f4-060d5de99277, a copy of which is attached hereto as Exhibit Z. Upon information and belief, Mylan's approved product is indicated for the prophylaxis and treatment of gout flares in adults and treatment of familial Mediterranean fever ("FMF") in adults and children 4 years or older.

76. On information and belief, the approved label for Mylan's generic Colcrys® product directs doctors, pharmacists, other healthcare professionals, and patients to practice the following dosing information for prophylaxis of gout flares:

> The recommended dosage of colchicine tablets for prophylaxis of gout flares for adults and adolescents older than 16 years of age is 0.6 mg once or twice daily. The maximum recommended dose for prophylaxis of gout flares is 1.2 mg/day. An increase in gout flares may occur after initiation of uric acid-lowering therapy, including pegloticase, febuxostat and allopurinol, due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Colchicine tablets are recommended upon initiation of gout flare prophylaxis with uric acid-lowering therapy. Prophylactic therapy may be beneficial for at least the first six months of uric acid-lowering therapy.

(Ex. Z, Mylan's Label at § 2.1). On information and belief, the approved label for Mylan's generic Colcrys® product directs doctors, pharmacists, other healthcare professionals, and patients to practice the following dosing information for the treatment of gout flares:

> The recommended dose of colchicine tablets for treatment of a gout flare is 1.2 mg (two tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later. Higher doses have not been found to be more effective. The maximum recommended dose for treatment of gout flares is 1.8 mg over a one-hour period. Colchicine tablets may be administered for treatment of a gout flare during prophylaxis at doses not to exceed 1.2 mg (two tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later. Wait 12 hours and then resume the prophylactic dose.

(Ex. Z, Mylan's Label at § 2.1). On information and belief, the approved label for Mylan's generic Colcrys® product directs doctors, pharmacists, other healthcare professionals, and patients to practice the claimed methods of Takeda's Acute Gout Flare Patents. For example, claim 1 of the '647 patent recites:

> A method of treating a patient having an acute gouty arthritis attack with colchicine consisting of administering 1.2 mg oral colchicine to a human patient having an acute gouty arthritis attack at the onset of the acute gouty arthritis attack, followed by 0.6 mg oral colchicine one hour later.

(Ex. L at claim 1).

77. On information and belief, the approved label for Mylan's generic Colcrys® product directs doctors, pharmacists, other healthcare professionals, and patients to practice the following dosing information for FMF:

> The recommended dosage of colchicine tablets for FMF in adults is 1.2 mg to 2.4 mg daily. Colchicine tablets should be increased as needed to control disease and as tolerated in increments of 0.3 mg/day to a maximum recommended daily dose. If intolerable side effects develop, the dose should be decreased in increments of 0.3 mg/day. The total daily colchicine tablets dose may be administered in one to two divided doses.

(Ex. Z, Mylan's Label at § 2.2). Additionally, on information and belief, the approved label for Mylan's generic Colcrys® product directs doctors, pharmacists, other healthcare professionals, and patients to practice to practice the following dosing information for pediatric patients:

> The recommended dosage of colchicine tablets for FMF in pediatric patients 4 years of age and older is based on age. The following daily doses may be given as a single or divided dose twice daily:
>
> Children 4 to 6 years: 0.3 mg to 1.8 mg daily
>
> Children 6 to 12 years: 0.9 mg to 1.8 mg daily
>
> Adolescents older than 12 years: 1.2 mg to 2.4 mg daily

(Ex. Z, Mylan's Label at § 2.3).

78. On information and belief, the approved label for Mylan's generic Colcrys® product directs doctors, pharmacists, other healthcare professionals, and patients to practice the claimed methods of Takeda's DDI Patents. Mylan's generic Colcrys® product labeling states that "[c]o-administration of colchicine tablets with drugs known to inhibit CYP3A4 and/or P-glycoprotein (P-gp) increases the risk of colchicine-induced toxic effects (*Table 1*). If patients are taking or have recently completed treatment with drugs listed in Table 1 within the prior 14 days, the dose adjustments are as shown on the table below *[see DRUG INTERACTIONS (7)]*."

(Ex. Z, Mylan's Label at § 2.4; *see also id.* § 7 ("Table 1 provides recommendations for strong and moderate CYP3A4 inhibitors and P-gp inhibitors.")). Table 1 is reproduced *in part* below:

Table 1. Colchicine Tablets Dose Adjustment for Coadministration with Interacting Drugs if no Alternative Available*

Strong CYP3A4 Inhibitors†							
		Gout Flares				**FMF**	
		Prophylaxis of Gout Flares		**Treatment of Gout Flares**			
Drug	**Noted or Anticipated Outcome**	**Original Intended Dosage**	**Adjusted Dose**	**Original Intended Dosage**	**Adjusted Dose**	**Original Intended Dosage**	**Adjusted Dose**
Atazanavir Clarithromycin Darunavir/ Ritonavir‡ Indinavir Itraconazole Ketoconazole Lopinavir/ Ritonavir‡ Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Tipranavir/ Ritonavir‡	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 mg to 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)
Moderate CYP3A4 Inhibitors							
		Gout Flares				**FMF**	
		Prophylaxis of Gout Flares		**Treatment of Gout Flares**			
Drug	**Note or Anticipated Outcome**	**Original Intended Dosage**	**Adjusted Dosage**	**Original Intended Dosage**	**Adjusted Dosage**	**Original Intended Dosage**	**Adjusted Dosage**
Amprenavir‡ Aprepitant Diltiazem Erythromycin Fluconazole Fosamprenavir‡(pro-drug of Amprenavir) Grapefruit juice Verapamil	Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.	0.6 mg twice a day 0.6 mg once a day	0.3 mg twice a day or 0.6 mg once a day 0.3 mg once a day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 mg to 2.4 mg	Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

(Ex. Z, Mylan's Label at Table 1).

79. On information and belief, the approved label for Mylan's generic Colcrys® product directs doctors, pharmacists, other healthcare professionals, and patients to practice dose adjustments for colchicine when co-administered with ketoconazole, verapamil, ritonavir, clarithromycin, and other drugs. These dose adjustments are disclosed and claimed in Takeda's DDI Patents. For example, claim 1 of the '298 patent recites the following:

> 1. A method of using colchicine for the treatment of Familial Mediterranean Fever in a human adult or child > 12 years of age in need of treatment thereof, said method comprising:
>
> orally administering a reduced colchicine dosage amount to the human adult or child > 12 years of age in need of treatment for Familial Mediterranean Fever who is concomitantly receiving administration of clarithromycin within 1 to 2 days of oral administration of colchicine,
>
> wherein the reduced colchicine dosage amount is reduced compared to a daily dosage amount to be administered in the absence of concomitant clarithromycin,
>
> wherein the daily dosage amount to be administered in the absence of concomitant clarithromycin is a maximum of 2.4 mg per day, and wherein the reduced colchicine dosage amount is a maximum of 0.6 mg per day.

(Ex. E, claim 1). The dose adjustment table in the colchicine tablets provides that the usual intended dose of colchicine for FMF is a maximum of 2.4 mg. When colchicine is used with a strong CYP3A4 inhibitor such as clarithromycin, the colchicine tablets teaches that it should be adjusted from 2.4 mg per day to a reduced colchicine dosage of 0.6 mg per day (which may be given as 0.3 mg twice per day).

80. On information and belief, the approved label for Mylan's generic Colcrys® product contains a Table 6, which describes doses of co-administered, such as ketoconazole, verapamil, ritonavir, clarithromycin, and others.

81. Accordingly, on information and belief, the approved label for Mylan's generic Colcrys® product, like the labeling for Colcrys®, directs doctors, pharmacists, other healthcare

professionals, and patients to practice the claimed methods of Takeda's Patents-in-Suit. (*See, e.g.*, Ex. Z, Mylan's Label).

82. Upon information and belief, Mylan has and/or will induce others to infringe one or more claims of the Patents-in-Suit. Specifically, Mylan's label explicitly instructs doctors, pharmacists, other healthcare professionals, and patients to administer the Mylan ANDA Product according to methods claimed in one or more claims of the Patents-in-Suit. Such inducement is undertaken by Mylan with full awareness of all of the Patents-in-Suit, each of which was asserted by Takeda in *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 16-987-RGA (D. Del.), and identified in the Settlement Agreement and accompanying License Agreement attached hereto as Exhibit A. Such inducement is undertaken by Mylan, on information and belief, with full awareness and intent that Mylan's actions and the actions of the induced persons would infringe the Patents-in-Suit.

83. On information and belief, the Mylan ANDA Product has been or will be administered for the prophylaxis and treatment of acute gout flares and for the treatment of FMF.

84. On information and belief, Mylan's label demonstrates Mylan's specific intent that a doctor, pharmacist, other healthcare professional, or patient administer the Mylan ANDA Product according to the instructions on Mylan's labeling regarding treatment of acute gout flares and thus has and/or will directly infringe one or more claims of the Acute Gout Flare Patents.

85. On information and belief, Doctors, pharmacists, other healthcare professionals, and patients will administer the Mylan ANDA Product according to the instructions on Mylan's

labeling regarding the treatment of acute gout flares and thus has and/or will thus infringe one or more claims of the Acute Gout Flare Patents.

86. On information and belief, Mylan's label demonstrates Mylan's specific intent that, when concomitant administration is necessary or desirable, a doctor, pharmacist, other healthcare professional, or patient administer the Mylan ANDA Product according to the instructions on Mylan's labeling regarding dose reduction during concomitant administration and thus directly infringe one or more of claims of the DDI Patents.

87. On information and belief, Mylan will contribute or has contributed to the infringement of the Patents-in-Suit by offering to sell, selling, or distributing within the United States or importing into the United States the Mylan ANDA Product, knowing the same to be especially made for use in infringement of the Patents-in-Suit and not a staple article or commodity of commerce suitable for substantial noninfringing use. Mylan's infringement, including its contributory infringement, is described in further detail in Takeda's Complaint filed as D.I. 1 in C.A. No. 16-987-RGA, which is incorporated by reference herein.

88. On information and belief, some gout and FMF patients will undergo concomitant treatment with colchicine for gout and FMF and ketoconazole for a fungal infection.

89. On information and belief, some gout and FMF patients will undergo concomitant treatment with colchicine for gout and FMF and ritonavir for HIV or other viral infections.

90. On information and belief, some gout and FMF patients will undergo concomitant treatment with colchicine for gout and FMF and clarithromycin for bacterial infections, including *H. pylori*.

91. On information and belief, some gout patients will undergo concomitant treatment with colchicine for the treatment and/or prevention of acute gout flares and verapamil for hypertension, angina pectoris, cardia arrhythmia, and/or other disorders.

92. On information and belief, patients concomitantly taking ketoconazole, ritonavir, and/or clarithromycin with colchicine will be prescribed the Mylan ANDA Product according to the instructions on Mylan's labeling regarding dose reductions in accordance with Takeda's DDI Patents by doctors or other healthcare professionals. Such doctors, healthcare professionals, and patients thus has and/or will directly infringe one or more of claims of the DDI Patents.

COUNT I

(Breach of the License Agreement)

93. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

94. Takeda and Mylan are parties to the 2017 Settlement Agreement and License Agreement, which are valid, enforceable, and supported by adequate consideration.

95. [redacted]

96. Mylan's contractual obligations were clear and unequivocal, and any conditions required for Mylan's performance under the 2017 Settlement Agreement and License Agreement occurred and were satisfied. Takeda stands ready, willing, and able to perform the License Agreement and has fulfilled all of its duties thereunder to date.

97. Each unauthorized sale of the Mylan ANDA Product has proximately caused, and continues to cause, harm to Takeda by reducing the number of units and the price per unit of Colcrys® that Takeda is able to sell. In addition, Mylan's sustained launch likely will cause Takeda to incur irreversible price erosion and long-term loss of market share, both of which are irreparable injuries. Unless enjoined, Mylan undoubtedly will place a flood of products into the distribution channels. [redacted] The impact to Takeda of this market competition is likely to be immediate and devastating.

98. Each unauthorized sale of the Mylan ANDA Product has proximately caused, and continues to cause, harm to Takeda by reducing the number of units and the price per unit of the authorized generic colchicine product that Par is able to sell. In addition, Mylan's sustained launch likely will cause Takeda to incur irreversible price erosion and long-term loss of market share, both of which are irreparable injuries. Unless enjoined, Mylan undoubtedly will place a flood of products into the distribution channels. [redacted]

99. Absent prompt injunctive relief, Mylan's unauthorized sale of the Mylan ANDA Product inevitably will lead to irreparable harm including, but not limited to, price erosion, loss of goodwill, reputational harm, and loss of business opportunities. [redacted]

100. [redacted]

[redacted]

COUNT II

(Infringement of the ’519 Patent)

101. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

102. [redacted]

103. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’519 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’519 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

104. As a result of Mylan’s infringement of the ’519 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

105. Mylan’s past and continuing infringement of the ’519 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT III

(Infringement of the ’731 Patent)

106. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

107. [redacted]

108. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’731 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’731 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

109. As a result of Mylan’s infringement of the ’731 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

110. Mylan’s past and continuing infringement of the ’731 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT IV

(Infringement of the ’298 Patent)

111. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

112. [redacted]

113. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’298 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’298 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

114. As a result of Mylan’s infringement of the ’298 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

115. Mylan’s past and continuing infringement of the ’298 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT V

(Infringement of the ’648 Patent)

116. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

117. [redacted]

118. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’648 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’648 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

119. As a result of Mylan's infringement of the '648 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

120. Mylan's past and continuing infringement of the '648 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT VI

(Infringement of the '297 Patent)

121. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

122. [redacted]

123. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the '297 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '297 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

124. As a result of Mylan's infringement of the '297 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

125. Mylan's past and continuing infringement of the '297 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate

remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT VII

(Infringement of the '004 Patent)

126. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

127. [redacted]

128. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the '004 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '004 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

129. As a result of Mylan's infringement of the '004 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

130. Mylan's past and continuing infringement of the '004 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT VIII

(Infringement of the '758 Patent)

131. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

132. [redacted]

133. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’758 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’758 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

134. As a result of Mylan’s infringement of the ’758 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

135. Mylan’s past and continuing infringement of the ’758 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT IX

(Infringement of the ’681 Patent)

136. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

137. [redacted]

138. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’681 patent and without license or authorization from

Takeda, Mylan has infringed one or more claims of the ’681 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

139. As a result of Mylan’s infringement of the ’681 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

140. Mylan’s past and continuing infringement of the ’681 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT X

(Infringement of the ’269 Patent)

141. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

142. [redacted]

143. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’269 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’269 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

144. As a result of Mylan’s infringement of the ’269 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

145. Mylan's past and continuing infringement of the '269 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XI

(Infringement of the '647 Patent)

146. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

147. [redacted]

148. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the '647 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '647 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

149. As a result of Mylan's infringement of the '647 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

150. Mylan's past and continuing infringement of the '647 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XII

(Infringement of the ’938 Patent)

151. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

152. [redacted]

153. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’938 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’938 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

154. As a result of Mylan’s infringement of the ’938 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

155. Mylan’s past and continuing infringement of the ’938 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT XIII

(Infringement of the ’296 Patent)

156. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

157. [redacted]

158. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’296 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’296 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

159. As a result of Mylan’s infringement of the ’296 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

160. Mylan’s past and continuing infringement of the ’296 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan’s infringement is enjoined by this Court.

COUNT XIV

(Infringement of the ’655 Patent)

161. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

162. [redacted]

163. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’655 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’655 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

164. As a result of Mylan's infringement of the '655 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

165. Mylan's past and continuing infringement of the '655 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XV

(Infringement of the '395 Patent)

166. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

167. [redacted]

168. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the '395 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '395 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

169. As a result of Mylan's infringement of the '395 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

170. Mylan's past and continuing infringement of the '395 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate

remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XVI

(Infringement of the '396 Patent)

171. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

172. [redacted]

173. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the '396 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the '396 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

174. As a result of Mylan's infringement of the '396 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

175. Mylan's past and continuing infringement of the '396 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

COUNT XVII

(Infringement of the '721 Patent)

176. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

177. [redacted]

178. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’721 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’721 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

179. As a result of Mylan’s infringement of the ’721 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

COUNT XVIII

(Infringement of the ’722 Patent)

180. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

181. [redacted]

182. By manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States prior to the expiration of the ’722 patent and without license or authorization from Takeda, Mylan has infringed one or more claims of the ’722 patent, and/or induced and/or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c).

183. As a result of Mylan’s infringement of the ’722 patent, Takeda has been damaged and will be further damaged, and is entitled to recover damages as set forth in 35 U.S.C. § 284 in such amount as may be established at trial of this action, including enhanced damages.

184. Mylan's past and continuing infringement of the '722 patent have caused, are causing, and/or will cause Takeda to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Mylan's infringement is enjoined by this Court.

EXCEPTIONAL CASE

185. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

186. Mylan is aware of all of the Patents-in-Suit, each of which was asserted by Takeda in *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 16-987-RGA (D. Del.), [redacted]

187. [redacted]

188. Mylan's actions—including, but not limited to, manufacturing, having manufactured, using, importing, distributing, marketing, offering to sell, having sold, and/or selling the Mylan ANDA Product in the United States, [redacted]—indicate a refusal to change the course of its actions despite its knowledge of Takeda's unexpired Patents-in-Suit.

189. Based on the foregoing conduct, Mylan's infringing acts are willful and deliberate, rendering this an exceptional case and entitled Takeda to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

ATTORNEYS' FEES

190. Takeda restates and incorporates by reference its previous allegations above, as if fully set forth herein.

191. Takeda has retained the undersigned counsel to represent it in this action and has agreed to pay the reasonable and necessary fees of these attorneys. [redacted] Takeda is also entitled to an award of attorneys' fees in connection with its claim for patent infringement under 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

192. Takeda demands a jury trial on all claims, damages, and all other issues that are triable to a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment and declaration that Mylan has breached the express terms of the License Agreement;

B. An order directing Mylan to specifically perform its obligations under the License Agreement;

C. A judgment and declaration that Mylan has infringed one or more claims of the Patents-in-Suit, or induced or contributed to such infringement, under 35 U.S.C. § 271(a), (b), and (c);

D. An entry of a temporary restraining order and preliminary and permanent injunctive relief enjoining and restraining Mylan and its affiliates, subsidiaries, directors, employees, agents, representatives, licensees, successors, assigns, and all other persons acting or

attempting to act in active concert or participation with it or acting on its behalf, from further infringement of the Patents-in-Suit, or from further breaching any contractual obligation owed by Mylan to Takeda;

E. A judgment awarding Takeda all damages resulting from Mylan's breaches of the License Agreement in an amount to be determined at trial;

F. An award of damages sufficient to compensate Takeda for Mylan's infringement of the Patents-in-Suit, including lost profits suffered by Takeda as a result of Mylan's infringement;

G. A judgment and declaration that Mylan's infringement of the Patents-in-Suit has been willful and deliberate, and for an award to Takeda of treble damages pursuant to 35 U.S.C. § 284;

H. An order requiring Mylan to recall, remove, or destroy all the Mylan ANDA Product that has been introduced to the market;

I. An order declaring this an exceptional case under 35 U.S.C. § 285 and awarding to Takeda its reasonable attorneys' fees, costs, and expenses;

J. An award of pre- and post-judgment interest, and the taxation of all allowable costs against Mylan; and

K. For such other and further relief as this Court deems just and proper.

Dated: December 02, 2019

/s/ Francis DiGiovanni

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