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14 TAKEDA PHARMACEUTICAL CO., LTD.,

15 TAKEDA PHARMACEUTICALS U.S.A., INC.,

16 AND TAKEDA PHARMACEUTICALS

AMERICA, INC.

17 **UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

18 TAKEDA PHARMACEUTICAL CO., LTD.,  
19 TAKEDA PHARMACEUTICALS U.S.A., INC.,  
20 AND TAKEDA PHARMACEUTICALS  
AMERICA, INC.,

**COMPLAINT FOR PATENT  
INFRINGEMENT**

21 Plaintiffs,

22 v.

23 MYLAN INC. AND MYLAN  
24 PHARMACEUTICALS INC.,

25 Defendants.

1 Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc.,  
2 and Takeda Pharmaceuticals America, Inc. (collectively, “Plaintiffs”), state the following as their  
3 Complaint against Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively,  
4 “Defendants”):

5 **I.**

6 **THE PARTIES**

7 1. Plaintiff Takeda Pharmaceutical Company Limited (“TPC”) is a Japanese  
8 corporation with a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka,  
9 Japan. TPC’s business includes the research, development, and marketing of pharmaceutical  
10 products. TPC manufactures dexlansoprazole delayed release capsules.

11 2. TPC is the owner of record and assignee of U.S. Patent No. 7,339,064 (the “’064  
12 Patent”).

13 3. Plaintiff Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda  
14 Pharmaceuticals North America, Inc. (“TPNA”), is a Delaware corporation with a principal place  
15 of business at One Takeda Parkway, Deerfield, IL 60015. TPUSA’s business includes the research,  
16 development, and marketing of pharmaceutical products. TPUSA is the registered holder of  
17 approved New Drug Application No. 22-287. In addition, TPUSA has the exclusive right to import  
18 dexlansoprazole delayed release capsules into the United States. TPUSA purchases  
19 dexlansoprazole delayed release capsules manufactured by TPC from TPC and imports them into  
20 the United States.

21 4. Plaintiff Takeda Pharmaceuticals America, Inc. (“TPA”), is a Delaware corporation,  
22 having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPA’s business  
23 includes the purchase, sale, and marketing of pharmaceutical products. TPA has the exclusive right  
24 to purchase dexlansoprazole delayed release capsules from TPUSA and sell those capsules to the  
25 public in the United States. TPA sells dexlansoprazole delayed release capsules manufactured by  
26 TPC that it purchases from TPUSA to the public in the United States.

1           5.       Plaintiffs are informed and believe, and thereupon allege, that Defendant Mylan Inc.  
2 is a Pennsylvania corporation with a principal place of business at 1500 Corporate Drive,  
3 Canonsburg, Pennsylvania 15317. Plaintiffs are further informed and believe, and thereupon allege,  
4 that Defendant Mylan Inc. was formerly known as Mylan Laboratories Inc.

5           6.       Plaintiffs are informed and believe, and thereupon allege, that Defendant Mylan  
6 Pharmaceuticals Inc. is a West Virginia corporation with a principal place of business at 781  
7 Chestnut Ridge Rd. Morgantown, West Virginia 26505 and is a wholly owned subsidiary of  
8 Defendant Mylan Inc. On the basis of Defendant Mylan Inc.'s Form 10-K filed with the United  
9 States Securities and Exchange Commission for the fiscal Year ended December 31, 2012,  
10 Plaintiffs are informed and believe, and thereupon allege that "[Defendant Mylan Inc.'s] sales in  
11 the U.S. are derived principally through [its] wholly owned subsidiary [Defendant] Mylan  
12 Pharmaceuticals Inc." Plaintiffs are informed and believe, and thereupon allege, that the acts of  
13 Defendant Mylan Pharmaceuticals, Inc. complained of herein were and are aided and abetted by,  
14 and done with the cooperation, participation, and assistance of Defendant Mylan Inc. Plaintiffs are  
15 further informed and believe, and thereupon allege, that Defendant Mylan Pharmaceuticals Inc. and  
16 Defendant Mylan Inc. have officers and/or directors in common.

17           7.       Upon information and belief, Defendants Mylan Pharmaceuticals Inc. and Mylan  
18 Inc. are both in the business of, among other things, manufacturing, marketing, and selling generic  
19 copies of branded pharmaceuticals throughout the United States.

20           8.       Unless specifically stated otherwise, the acts complained of herein were committed  
21 by, on behalf of, and/or for the benefit of Defendants.

22                                 **II.**

23                                         **NATURE OF THE ACTION**

24           9.       This is an action for patent infringement. This action relates to an Abbreviated New  
25 Drug Application ("ANDA"), ANDA No. 205-205, filed by Defendants with the United States  
26 Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs'  
27 DEXILANT products.



1 Defendant Mylan Inc.'s website states: "The bulk of Mylan's product portfolio, which consists of  
2 more than 1000 individual products, includes high quality, more affordable generic medications  
3 sold throughout the world." Defendant Mylan Pharmaceuticals Inc.'s website states: "Mylan  
4 Pharmaceuticals has one of the largest product portfolios in the U.S., consisting of more than 200  
5 products. According to IMS Health, one of every 12 prescriptions dispensed in the U.S. is a Mylan  
6 product." Plaintiffs are informed and believe, and thereupon allege, that Defendant Mylan Inc. has  
7 a wholly owned subsidiary, Mylan Specialty L.P., with a manufacturing facility in Napa,  
8 California.

9 14. Defendant Mylan Pharmaceuticals Inc. is a subsidiary of Mylan, Inc., and its website  
10 contains a link to Defendant Mylan Inc.'s certification pursuant to California Health and Safety  
11 Code § 119402 at the following address: <http://investor.mylan.com/declaration.cfm>.

12 15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1391(d),  
13 and/or 1400(b).

#### 14 IV.

#### 15 **INTRADISTRICT ASSIGNMENT**

16 16. For purposes of intradistrict assignment pursuant to Civil Local Rules 3-2(c) and 3-  
17 5(b), this Intellectual Property Action is to be assigned on a district-wide basis.

#### 18 V.

#### 19 **FACTUAL BACKGROUND**

##### 20 **A. Asserted Patent**

21 17. On March 4, 2008, U.S. Patent No. 7,339,064, titled "Benzimidazole Compound  
22 Crystal," was duly and legally issued to TPC, as assignee of named inventors Akira Fujishima, Isao  
23 Aoki, and Keiji Kamiyama. A true and correct copy of the '064 Patent is attached as Exhibit A to  
24 this Complaint.

25 18. The expiration date of the '064 Patent is June 15, 2020.  
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**B. DEXILANT**

19. Plaintiff TPUSA is the registered holder of approved New Drug Application No. 22-287 for the manufacture and sale of the drug dexlansoprazole, a proton pump inhibitor, for the treatment of all grades of erosive esophagitis, maintaining healing of esophagitis, and treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (“GERD”). Plaintiff TPA sells dexlansoprazole in the United States under the trade name DEXILANT, in 30 mg and 60 mg dosage forms. The 30 mg and 60 mg dosage forms of DEXILANT were approved by the FDA on January 30, 2009.<sup>1</sup>

20. Plaintiffs are informed and believe, and thereupon allege, that DEXILANT is the first and only acid reflux disease treatment specifically designed for the release of medicine in two stages over time. The key to this two-stage release is DEXILANT’s Dual Delayed Release™ formulation (“DDR”). DDR combines two different types of granules in one pill. DEXILANT releases one dose of medicine within an hour of taking a pill. Then, around four to five hours after ingestion, DEXILANT releases a second dose of medicine.

**C. Infringement by Defendants**

21. Plaintiffs are informed and believe, and thereupon allege, that Defendants submitted ANDA No. 205-205 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market dexlansoprazole delayed release capsules in the 30 mg and 60 mg dosage forms (the “ANDA Products”) as a generic version of DEXILANT, prior to the expiration date of the ’064 Patent.

22. Plaintiffs are informed and believe, and thereupon allege, that Abbreviated New Drug Application (“ANDA”) No. 205-205 was filed under the name of Defendant Mylan Pharmaceuticals Inc. Plaintiffs are further informed and believe, and thereupon allege, that

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<sup>1</sup> Plaintiffs originally marketed the drug dexlansoprazole under the proprietary name KAPIDEX. On March 4, 2010, the FDA announced that TPNA would start marketing KAPIDEX under the new name DEXILANT to avoid potential confusion with two other medications, CASODEX and KADIAN.

1 Defendant Mylan Inc. has and had at all times relevant to this action control over the activities of  
2 Defendant Mylan Pharmaceuticals Inc., including Defendant Mylan Pharmaceuticals Inc.’s filing of  
3 ANDA No. 205-205 and that Defendant Mylan Inc. was actively involved in the submission of  
4 ANDA No. 205-205.

5 23. On July 19, 2013, TPUSA received a letter dated July 17, 2013 and, on July 22,  
6 2013, TPUSA received a materially identical letter dated July 18, 2013 (the “Notice Letters”) via  
7 overnight delivery from Defendants addressed to TPC, TPUSA, and TPNA. These were the first  
8 Notice Letters that any of the Plaintiffs received related to ANDA No. 205-205.

9 24. On July 22, 2013, TPC received copies of both Notice Letters from Defendants.

10 25. The Notice Letters state that the ANDA included a Paragraph IV Certification that,  
11 in Defendant Mylan Pharmaceuticals Inc.’s opinion, that certain patents owned by Takeda are  
12 invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of  
13 the ANDA Products.

14 26. Plaintiffs are informed and believe, and thereupon allege, that the ANDA does not  
15 provide any valid basis for concluding that the ’064 Patent is invalid, unenforceable, or will not be  
16 infringed by the commercial manufacture, use, or sale of the ANDA Products.

17 27. Plaintiffs are informed and believe, and thereupon allege, that the submission of the  
18 ANDA to the FDA constitutes infringement of the ’064 Patent under 35 U.S.C. § 271(e)(2).  
19 Moreover, any commercial manufacture, use, offer to sell, sale, or import of the ANDA Products  
20 would infringe the ’064 Patent under 35 U.S.C. § 271(a)–(c).

21 28. Plaintiffs have filed two actions against Defendants for infringement of additional  
22 patents, *Takeda Pharmaceutical Co., Ltd. v. Mylan Inc. and Mylan Pharmaceuticals, Inc.*, No.  
23 5:13-cv-4002 LHK (PSG) (N.D. Cal.), relating to infringement of U.S. Patent Nos. 6,462,058,  
24 6,664,276, 6,939,971, 7,285,668, and 7,790,755, and *Takeda Pharmaceutical Co., Ltd. v. Mylan*  
25 *Inc. and Mylan Pharmaceuticals, Inc.*, No. 5:13-cv-4002 LHK (PSG) (N.D. Cal.), relating to U.S.  
26 Patent Nos. 8,173,158 and 8,173,187, in this District, which are currently pending before Judge  
27 Lucy H. Koh.

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**VI.**

**CLAIMS FOR RELIEF**

**COUNT I**

**(Patent Infringement of U.S. Patent No. 7,339,064)**

29. Plaintiffs incorporate by reference and reallege paragraphs 1 through 28 above as though fully restated herein.

30. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205-205 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products was an act of infringement of the '064 Patent.

31. Unless Defendants are enjoined by the Court from the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '064 Patent. Plaintiffs do not have an adequate remedy at law.

**COUNT II**

**(Declaratory Judgment as to U.S. Patent No. 7,339,064)**

32. Plaintiffs incorporate by reference and reallege paragraphs 1 through 31 above as though fully restated herein.

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

34. Plaintiffs are informed and believe, and thereupon allege, that Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the ANDA Products prior to patent expiry.

35. Plaintiffs are informed and believe, and thereupon allege, that Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the ANDA Products upon receipt of final FDA approval of ANDA No. 205-205.



1 36. Pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Defendants' commercial  
2 manufacture, use, sale, or offer for sale within the United States or importation into the United  
3 States of the ANDA Products would constitute infringement of the '064 Patent.

4 37. Plaintiffs are informed and believe, and thereupon allege, that Defendants'  
5 infringing commercial manufacture, use, sale, or offer for sale within the United States or  
6 importation into the United States of the ANDA Products complained of herein will begin  
7 following FDA approval of ANDA No. 205-205.

8 38. Defendants maintain, on information and belief, and Plaintiffs deny, that the '064  
9 Patent is invalid or unenforceable. Accordingly, there is a real, substantial, and continuing  
10 justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants'  
11 commercial manufacture, use, sale, offer for sale, or importation into the United States of the  
12 ANDA Products according to ANDA No. 205-205 will infringe one or more claims of the '064  
13 Patent. Plaintiffs thus are entitled to a declaration that the making, using, sale, offer for sale, and  
14 importation into the United States of the ANDA Products according to ANDA No. 205-205  
15 infringe one or more claims of the '064 Patent.

16 **VII.**

17 **PRAYER FOR RELIEF**

18 WHEREFORE, Plaintiffs pray for judgment as follows:

- 19 A. For a declaration that Defendants have infringed the '064 Patent;
- 20 B. For a declaration that the commercial use, sale, offer for sale, manufacture, and/or  
21 importation by Defendants of the ANDA Products would infringe the '064 Patent;
- 22 C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date  
23 for approval of the ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.  
24 § 355(j)), be no earlier than the expiration date of the '064 Patent, including any extensions or  
25 adjustments;
- 26 D. For an order preliminarily and permanently enjoining Defendants and their  
27 affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors,  
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1 assigns, and all those acting for them and on their behalf, or acting in concert with them directly or  
2 indirectly, from infringing the '064 Patent; and

3 E. For such other and further relief as this Court deems just and proper.  
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5 Respectfully Submitted,

6 DATED: January 21, 2014

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ERIC K. CHIU  
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10 By:           /s/ Heather E. Takahashi            
11 HEATHER E. TAKAHASHI

12 Attorneys for Plaintiffs  
13 TAKEDA PHARMACEUTICAL CO., LTD.,  
14 TAKEDA PHARMACEUTICALS U.S.A., INC.,  
15 AND TAKEDA PHARMACEUTICALS  
16 AMERICA, INC.  
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