IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ALMIRALL, LLC,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:20-CV-6
Kleeh

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Almirall, LLC ("Almirall"), by its undersigned attorneys, for its Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement brought under the United States Patent Act and the Hatch-Waxman Act, based upon Mylan's submission of Abbreviated New Drug Application No. 213847 (the "Mylan ANDA") to the United States Food and Drug Administration ("FDA").

2. By the Mylan ANDA, Mylan seeks approval to market a generic dapsone gel, 7.5% drug product (the "ANDA Product") prior to the expiration of United States Patent No. 9,517,219 ("the '219 patent"), which covers, *inter alia*, the use of Almirall's ACZONE® Gel, 7.5% drug product, and which is listed accordingly in the FDA's Orange Book.

PARTIES

3. Plaintiff Almirall is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 707 Eagleview Boulevard, Suite 200, Exton, Pennsylvania 19341.

4. Defendant Mylan is a corporation organized and existing under the laws of the State of West Virginia and having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

JURISDICTION AND VENUE

5. This civil action for infringement of the '219 patent arises under 35 U.S.C. § 271 and 21 U.S.C. § 355(j).

6. Original jurisdiction is vested in this Court over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Mylan is registered to do business in the State of West Virginia under Organization Number 20402.

8. Upon information and belief, Mylan, directly or thought its affiliates and agents, is present in, and conducts the business of and derives revenue from, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products, in the State of West Virginia.

9. Mylan has previously consented to and availed itself of the jurisdiction of this Court by, *inter alia*, asserting claims and defenses in other civil actions initiated in this jurisdiction.

10. Mylan's affiliations with the State of West Virginia are such as to render Mylan "at home" in this jurisdiction.

11. Upon information and belief, Mylan, directly or thought its affiliates and agents, participated, in the State of West Virginia, in the preparation and/or filing of the Mylan ANDA, causing injury to Plaintiff Almirall.

12. In its business of developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products, Mylan has purposefully directed

activities at residents of the State of West Virginia.

13. This Court has personal jurisdiction over Mylan.

14. Almirall's assertion of personal jurisdiction is reasonable and fair.

15. By its incorporation, Mylan resides in the State of West Virginia.

16. At 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, and elsewhere in the State, Mylan has a regular and established place of business.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §1400(b).

THE PATENT-IN-SUIT

18. On December 13, 2016, the United States Patent and Trademark Office issued the '219 patent, entitled "Topical Dapsone and Dapsone/Adapalene Compositions and Methods for Use Thereof," a copy of which is attached as **Exhibit A** to this Complaint.

19. Plaintiff Almirall owns all rights, title, and interest in the '219 patent.

ACZONE® GEL, 7.5%

20. Almirall is the holder of approved New Drug Application No. 207154 (the "ACZONE® NDA") for a topical drug product used to treat acne vulgaris, and containing, *inter alia*, 7.5% by weight of the active pharmaceutical ingredient, dapsone. The FDA granted approval of the ACZONE® NDA on February 24, 2016.

21. Almirall markets and sells the subject product of the ACZONE® NDA under the trade name ACZONE® Gel, 7.5%.

22. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '219 patent is listed in the FDA publication, "Approved Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to the ACZONE® NDA and ACZONE® Gel, 7.5%.

THE MYLAN ANDA

23. Mylan is the owner of the Mylan ANDA.

24. On information and belief, Mylan submitted, or caused to be submitted, the Mylan ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), in order to obtain approval to market the ANDA Product as a generic version of ACZONE® Gel, 7.5%.

25. On information and belief, the Mylan ANDA refers to and relies upon the ACZONE® NDA and contains data that, according to Mylan, demonstrate the bioequivalence of the ANDA Product and ACZONE® Gel, 7.5%.

26. On or about November 26, 2019, Almirall received from Mylan, via FedEx Overnight Delivery, a "Notice of Paragraph IV Certification Regarding U.S. Patent Nos. 9,161,926 and 9,517,219 Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 for ANDA No. 213847 (dapsone gel, 7.5%)" (the "Notice Letter").

27. The Notice Letter provides notice that Mylan submitted to the FDA the Mylan ANDA, which included a certification by Mylan, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '219 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product prior to the patent's expiration ("Mylan's Paragraph IV Certification").

28. Mylan attached a memorandum (or "Detailed Statement") to its Notice Letter by which it alleged factual and legal bases for its Paragraph IV Certification. Mylan's Notice Letter provides allegations that the claims of the '219 patent are invalid and/or will not be infringed by acts in relation to the ANDA Product as described in the Mylan ANDA.

29. The Notice Letter provides that Mylan seeks approval to market the ANDA Product before the '219 patent expires.

CLAIM FOR INFRINGEMENT OF THE '219 PATENT

30. Almirall realleges and incorporates by reference Paragraphs 1 through 29 of this Complaint.

31. The Mylan ANDA is an application for FDA approval of Mylan to market the ANDA Product for, *inter alia*, use by physicians treating, and patients having, acne vulgaris.

32. Use of the ANDA Product as described in the Mylan ANDA is a method of treatment claimed in the '219 patent.

33. The submission by Mylan to the FDA of the Mylan ANDA was an act of infringement of the claims of the '219 patent.

34. The claims of the '219 patent are not invalid.

35. The claims of the '219 patent are infringed by acts in relation to the ANDA Product as described in the Mylan ANDA.

36. Approval of the Mylan ANDA prior to the expiration of the '219 patent will injure Plaintiff Almirall as owner of the patent, holder of the ACZONE® NDA, and distributor and seller of ACZONE® Gel, 7.5% in the United States.

37. An actual case or controversy exists between Almirall and Mylan.

38. Almirall will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '219 patent.

39. Almirall has no adequate remedy at law.

40. Almirall is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Almirall prays for judgment in its favor and against Mylan and respectfully requests the following relief:

(a) A judgment that Mylan has infringed one or more claims of the '219 patent under 35 U.S.C. §271(e)(2);

(b) An order, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any approval of the Mylan ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)), shall not be earlier than the expiration of the '219 patent, including any extensions, adjustments, and exclusivities;

(c) A grant, pursuant to 35 U.S.C. § 271(e)(4)(B), of an injunction against Mylan, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, preventing the commercial manufacture, use, offer to sell, or sale of the ANDA Product within the United States, or the importation the ANDA Product into the United States, prior to the expiration of the '219 patent, including any extensions, adjustments, and exclusivities;

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

(e) Costs and expenses in this action; and

(f) Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: January 9, 2020

SCHRADER COMPANION DUFF & LAW, PLLC

By: /s/ *James F. Companion*
James F. Companion (#790)
Sandra K. Law (#6071)
401 Main Street
Wheeling, WV 26003
(304) 233-3390
jfc@schraderlaw.com
skl@schraderlaw.com

Attorneys for Almirall, LLC

Of counsel:

FENWICK & WEST LLP

James S. Trainor
R.J. Shea
902 Broadway, Suite 14
New York, NY 10010
(212) 921-2001
jtrainor@fenwick.com
rshea@fenwick.com

Elizabeth B. Hagan, Ph.D.
1191 Second Avenue, 10th Floor
Seattle, WA 98101
(206) 389-4510
ehagan@fenwick.com

Rebecca A.E. Fewkes
801 California Street
Mountain View, CA 94041
(650) 988-8500
rfewkes@fenwick.com