IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

HORIZON MEDICINES LLC, HORIZON THERAPEUTICS IRELAND DAC, HZNP MEDICINES LLC, and HZNP FINANCE LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
	)	**ANDA CASE**
ALEOR DERMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Horizon Medicines LLC, Horizon Therapeutics Ireland DAC, HZNP Medicines LLC, and HZNP Finance Ltd. (collectively "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Defendant Aleor Dermaceuticals Ltd. ("Defendant" or "Aleor") of an Abbreviated New Drug Application ("ANDA") No. 212506 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a diclofenac sodium topical solution 2% ("Aleor ANDA Product"), a generic version of Plaintiffs' PENNSAID® 2%, prior to the expiration of U.S. Patent No. 9,066,913 (the "'913 patent"). Aleor notified HZNP Medicines, LLP, Horizon Therapeutics Ireland DAC, and Horizon Pharma Inc. that it had submitted this ANDA by a letter dated June 6, 2022 (the "Notice Letter"). Upon information and belief, Aleor's ANDA Product will be marketed as a generic competing product to

PENNSAID® 2%, a product Plaintiffs market for the treatment of the pain of osteoarthritis of the knee(s).

PARTIES

2. Plaintiff Horizon Medicines LLC is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1 Horizon Way, Deerfield, Illinois 60015.

3. Plaintiff Horizon Therapeutics Ireland DAC is a corporation organized and existing under the laws of Ireland, with a principal place of business at 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland.

4. Plaintiff HZNP Finance Ltd., f/k/a HZNP Medicines LLC is a corporation organized and existing under the laws of Bermuda, with a principal place of business at 21 Laffan Street, Hamilton HM 09, Bermuda HM.

5. Upon information and belief, Aleor is a company organized and existing under the laws of India, with a principal place of business at 5th Floor, Administrative Building Alembic Limited, Alembic Road, Vadodara, Gujarat, 390003, India. Upon information and belief, Aleor is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Aleor under Federal Rule of Civil Procedure 4(k) because, upon information and belief, Aleor is organized under the laws of India.

8. This Court has personal jurisdiction over Aleor because, among other things, Aleor has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hauled into court here. Upon information and belief, Aleor develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

9. Aleor has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

10. Upon information and belief, if Aleor's ANDA is approved, Aleor will directly or indirectly manufacture, market, sell, and/or distribute Aleor's ANDA Product within the United States, including in Delaware, consistently with Aleor's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Aleor regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including Delaware. Upon information and belief, Aleor's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Aleor's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would

constitute infringement of Plaintiffs' '913 patent in the event that Aleor's ANDA Product is approved before the '913 patent expires.

11. Upon information and belief, Aleor derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Aleor and/or for which Aleor is named applicant on approved ANDAs. Upon information and belief, various products for which Aleor is the named applicant on approved ANDAs. Upon information and belief, various products for which Aleor is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

12. For the reasons described above, among others, the filing of ANDA No. 212506 was suit-related conduct with a substantial connection to Delaware and this District, the exercise of personal jurisdiction over Aleor does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Aleor.

13. Upon information and belief and based on the foregoing, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Aleor is a foreign entity incorporated in India and may be sued in any judicial district in the United States.

THE '913 PATENT

14. The '913 patent, entitled, "Diclofenac Topical Formulation," was duly and legally issued by the United States Patent and Trademark Office ("the USPTO") on June 30, 2015. A copy of the '913 patent is attached as Exhibit A.

15. The '913 patent was issued to HZNP Limited, which later assigned the '913 patent to HZNP Medicines LLC. HZNP Medicines LLC currently is the sole assignee and owner of all right, title and interest in and to the '913 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium and method for treating pain due to

osteoarthritis of a knee of a patient comprising applying a topical diclofenac formulation to a knee of a patient with pain.

16. Claim 1 of the ’913 patent covers a “topical formulation comprising: diclofenac sodium present at 2% w/w; DMSO present at about 40 to about 50% w/w; ethanol present at 23-29% w/w; propylene glycol present at 10-12% w/w; hydroxypropyl cellulose; and water to make 100% w/w, wherein the formulation has a viscosity of 500-5000 centipoise.”

17. Claim 8 of the ’913 patent covers a “topical formulation of claim 1, wherein the DMSO is present at 45.5% w/w.”

18. Claim 9 of the ’913 patent covers a “topical formulation of claim 8, wherein the hydroxypropyl cellulose is present at 2.5% w/w.”

19. Claim 12 of the ’913 patent covers a “method for treating pain due to osteoarthritis of a knee of a patient in need thereof, said method comprising: administering to the knee a topical formulation of claim 9, wherein the administration of the formulation is twice daily.”

PENNSAID® 2%

20. PENNSAID® 2% is a nonsteroidal anti-inflammatory drug indicated for the topical treatment of the pain of osteoarthritis of the knee(s).

21. PENNSAID® 2% is a topical formulation comprising diclofenac sodium present at 2% w/w; DMSO present at about 40 to about 50% w/w; ethanol present at 23-29% w/w; propylene glycol present at 10-12% w/w; hydroxypropyl cellulose; and water to make 100% w/w, wherein the formulation has a viscosity of 500-5000 centipoise.

22. Horizon Therapeutics Ireland DAC is the holder of approved New Drug Application No. 204623 (“PENNSAID® 2% NDA”) for PENNSAID® 2%.

23. Horizon Medicines LLC sells PENNSAID 2% in the United States pursuant to NDA No. 204623.

24. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '913 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for PENNSAID® 2%.

25. The '913 patent covers PENNSAID® 2%.

ALEOR'S INDUCED INFRINGEMENT OF THE '913 PATENT

26. Horizon Medicines LLC's FDA-approved product label for PENNSAID® 2% teaches and encourages, *inter alia*, methods of using PENNSAID® 2% claimed in the '913 patent, including the use of diclofenac sodium topical solution 2% w/w for the treatment of osteoarthritis of the knee. (*See* Ex. B, PENNSAID® 2% Label.)

27. 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, 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.

28. Upon information and belief, the Aleor ANDA refers to and relies upon the PENNSAID® 2% NDA and contains data that, according to Aleor, demonstrate the bioequivalence of the Aleor ANDA Product and PENNSAID® 2%.

29. Upon information and belief, the proposed label of the Aleor ANDA Product will advise doctors and patients, like the PENNSAID® 2% Label, that Aleor's Product "is a

nonsteroidal anti-inflammatory drug indicated for the treatment of the pain of osteoarthritis of the knee(s)." (Ex. B, PENNSAID® 2% Label, at Indications and Usage.)

30. Upon information and belief, the proposed label of the Aleor ANDA Product will advise doctors and patients that its product is: "For relief of the pain of osteoarthritis (OA) of the knee(s), the recommended dose is 40 mg of diclofenac sodium (2 pump actuations) on each painful knee, 2 times a day. Apply diclofenac sodium topical solution to clean, dry skin." (*Id*. at § 2.1 General Dosing Instructions.)

31. Upon information and belief, the Aleor ANDA Product is a topical formulation comprising diclofenac sodium present at 2% w/w; DMSO present at 45.5% w/w; ethanol present at 23-29% w/w; propylene glycol present at 10-12% w/w; hydroxypropyl cellulose present at 2.5% w/w; and water to make 100% w/w. (*Id*. at 11 Description.)

32. Accordingly, upon information and belief, the proposed label for the Aleor ANDA Product, like the labeling for PENNSAID® 2%, recites the method of using a topical formulation of diclofenac sodium 2% w/w according to claim 12 of the '913 patent.

33. Upon information and belief, the proposed label for the Aleor ANDA Product, like the labeling for PENNSAID® 2%, directs doctors, pharmacists, other healthcare professionals, and patients to practice the method recited in claim 12 of the '913 patent.

34. Upon information and belief, the proposed label of the Aleor ANDA Product demonstrates Aleor's specific intent that a doctor, pharmacist, other healthcare professional, or patient administer the Aleor ANDA Product according to the instructions on Aleor's labeling and thus directly infringes claim 12 of the '913 patent.

COUNT I

(Infringement of the '913 Patent Under 35 U.S.C. § 271(e)(2))

35. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

36. Upon information and belief, Aleor's ANDA product is covered by claim 12 of the '913 patent.

37. Upon information and belief, Aleor's ANDA Product and its use in accordance with and as directed by Aleor's proposed labeling for that product will infringe claim 12 of the '913 patent, either literally or under the doctrine of equivalents.

38. In its Notice Letter, Aleor did not dispute that the use of Aleor's ANDA Product in accordance with and as directed by the Aleor's proposed labeling for that product would meet the claim limitations of at least claim 12 of the '913 patent. Moreover, administration of PENNSAID® 2% according to the approved labeling meets the limitations of claim 12 of the '913 patent, and Aleor's ANDA Product is a generic copy of PENNSAID® 2%. Therefore, upon information and belief, Aleor's ANDA Product also meets the limitations of at least claim 12 of the '913 patent.

39. Upon information and belief, Aleor filed as part of ANDA No. 212506 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '913 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Aleor's ANDA Product.

40. The purpose of filing ANDA No. 212506 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aleor's ANDA Product prior to the expiration of the '913 patent.

41. Aleor's submission of ANDA No. 212506 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aleor's ANDA Product prior to the expiration of the '913 patent is an act of infringement of the '913 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, the Aleor intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aleor's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 212506 and any amendments thereto, i.e., prior to the expiration of the '913 patent.

43. Upon information and belief, the Aleor has knowledge of the claims of the '913 patent at least because the '913 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Plaintiffs' PENNSAID® 2% drug product. Notwithstanding this knowledge, Aleor continues to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aleor's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 212506 and any amendments thereto.

44. Upon information and belief, Aleor plans and intends to, and will, actively induce infringement of claim 12 of the '913 patent when ANDA No. 212506 and any amendments thereto are approved and will do so with specific intent to induce infringement of the '913 patent under 35 U.S.C. § 271(b). Further upon information and belief, Aleor plans and intends to, and will, do so immediately and imminently upon approval.

45. Upon information and belief, Aleor knows that Aleor's ANDA Product is especially made or adapted for use in infringing the '913 patent, and that Aleor's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Aleor plans and

intends to, and will, contribute to infringement of claim 12 of the '913 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 212506 and any amendments thereto.

46. The foregoing actions by Aleor constitute and/or will constitute infringement of the '913 patent, active inducement of infringement of the '160 patent, and contribution to the infringement by others of the '913 patent either literally or under the doctrine of equivalents.

47. Unless Aleor is enjoined from infringing the '913 patent, actively inducing infringement of the '913 patent, and contributing to the infringement by others of the '913 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II

(Declaratory Judgment of Patent Infringement of '913 Patent Under 35 U.S.C. § 271(b) and/or (c))

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

49. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.,* including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

50. Upon information and belief, Aleor has knowledge of the '913 patent and Aleor has filed ANDA No. 212506 seeking authorization to commercially manufacture, use, offer for sale, and sell Aleor's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 212506, physicians, health care providers, and/or patients will use Aleor's ANDA Product in accordance with the instructions and/or label provided by Aleor and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '913 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

51. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Aleor's ANDA Product so labeled, if approved by the FDA, will induce and contribute to the infringement of claim 12 of the '913 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

52. Upon information and belief, Aleor knows and intends that physicians, health care providers, and/or patients will use Aleor's ANDA Product in accordance with the instructions and/or label provided by the '913 patent, including at least claim 12, with the requisite intent under 35 U.S.C. § 271(b).

53. Upon information and belief, if the FDA approves ANDA No. 212506, Aleor will sell or offer to sell Aleor's ANDA Product specifically labeled for use in practicing claim 12 of the '913 patent, wherein Aleor's ANDA Product is a material part of the invention claimed in the '913 patent, wherein Aleor knows that physicians will prescribe and patients will use Aleor's ANDA Product for practicing claim 12 of the '913 patent, and wherein Aleor's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Aleor will thus contribute to the infringement of the '913 patent under 35 U.S.C. § 271(c).

54. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aleor as to liability for the infringement of the '913 patent. Aleor's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Aleor's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

a) declare that claim 12 of the '913 patent is valid and enforceable;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Aleor infringed the '913 patent by submitting ANDA No. 212506 to the FDA to obtain approval to commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States Aleor's ANDA product prior to the expiration of the '913 patent;

c) declare that Aleor's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Aleor's ANDA Product prior to the expiration of the '913 patent constitutes infringement of claim 12 of the '913 patent under 35 U.S.C. § 271(b) and/or (c);

d) order that the effective date of any FDA approval of Aleor's ANDA Product shall be no earlier than the expiration date of the '913 patent, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Aleor, and all persons acting in concert with Aleor, from seeking, obtaining, or maintaining final approval of ANDA No. 212506 until the expiration of the '913 patent, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin Aleor, and all persons acting in concert with Aleor, from commercially manufacturing, using, offering for sale, or selling Aleor's ANDA Product within the United States, or importing Aleor's ANDA Product into the United States, until the expiration of the '913 patent, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) enjoin Aleor, and all persons acting in concert with Aleor, from commercially manufacturing, using, offering for sale, or selling Aleor's ANDA Product within the United States, or importing Aleor's ANDA Product into the United States, until the expiration of the '913 patent,

including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 283;

h) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

i) grant Plaintiffs such further and additional relief that this Court deems just and proper.

/s/ Nathan R. Hoeschen

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