IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MELINTA THERAPEUTICS, LLC, MELINTA SUBSIDIARY CORP., and REMPEX PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. 24-cv-4180
v.	)	
NEXUS PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Melinta Therapeutics, LLC, Melinta Subsidiary Corp., and Rempex Pharmaceuticals, Inc. (collectively, "Melinta" or "Plaintiffs"), for their Complaint against Defendant Nexus Pharmaceuticals, Inc. ("Nexus" or "Defendant"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement involving newly-issued U.S. Patent No. 11,944,634 (the "'634 patent"), attached as Exhibit A. The '634 patent covers Plaintiffs' Minocin® (minocycline) for injection ("Minocin®") product. This action arises out of Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 214934 seeking FDA approval to manufacture, use, and/or sell a generic version of Minocin® prior to expiration of the '634 patent.

2. This action is related to Case No. 1:21-cv-02636 in this District before the Honorable John F. Kness, in which Plaintiffs asserted that other patents covering Minocin® (which are related to the '634 patent) are infringed by Defendant's ANDA No. 214934. In June 2023, the

Court held a trial in that case. (Case No. 1:21-cv-02636, D.I. 241-244.) The parties are awaiting the Court's merits decision.

THE PARTIES

3. Plaintiff Melinta Therapeutics, LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 389 Interpace Pkwy., Suite 450, Parsippany, NJ 07054. Melinta Therapeutics, LLC was formed in November 2020 from a conversion of Melinta Therapeutics, Inc., a Delaware corporation.

4. Plaintiff Melinta Subsidiary Corp. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 389 Interpace Pkwy., Suite 450, Parsippany, NJ 07054.

5. Plaintiff Rempex Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 389 Interpace Pkwy., Suite 450, Parsippany, NJ 07054. Rempex Pharmaceuticals, Inc. is a wholly owned subsidiary of Melinta Therapeutics, LLC.

6. Upon information and belief, Defendant is a corporation organized and existing under the laws of Illinois, having its principal place of business at 400 Knightsbridge Pkwy., Lincolnshire, IL 60069.

7. Upon information and belief, Defendant is in the business of, among other things, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in Illinois.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

9. Defendant consented to personal jurisdiction in this Court in the related Case No. 1:21-cv-02636 concerning Defendant's same ANDA No. 214934 and Plaintiffs' related patents covering Minocin®. Defendant's paragraph IV notice letter concerning the '634 patent states that "Nexus will not object to the personal jurisdiction in the Illinois courts."

10. This Court also has personal jurisdiction over Defendant at least because, upon information and belief, Defendant is incorporated in Illinois and has its principal place of business in Lincolnshire, Illinois, thereby demonstrating that Defendant has continuous and systematic contacts with Illinois.

11. This Court also has personal jurisdiction over Defendant at least because, upon information and belief, Defendant is the owner of ANDA No. 214934 and is seeking FDA approval to engage in the commercial use, sale, and/or distribution of 100 mg/vial generic minocycline hydrochloride (Defendant's "ANDA Product") throughout the United States, including in Illinois, before the expiration of the '634 patent; if Defendant's ANDA receives final approval, Defendant's ANDA Product will be marketed, sold, offered for sale, distributed, and/or used by Defendant in Illinois; Defendant's activities with respect to its ANDA product will be purposefully directed at Illinois (either directly or indirectly, *e.g.*, through wholesalers, distributors, etc.), and Defendant will derive revenue therefrom; Defendant's ANDA Product will be prescribed by physicians practicing in Illinois and/or administered to patients in Illinois; and Defendant submitted its ANDA from Illinois.

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Defendant is incorporated in Illinois.

BACKGROUND

Plaintiffs' NDA and Asserted Patent

13. Plaintiffs (via Rempex Pharmaceuticals, Inc.) are the owner of NDA No. 050444 concerning 100 mg/vial minocycline hydrochloride for injection, marketed under the trade name Minocin® (minocycline) for injection. Minocin® is indicated in the treatment of certain bacterial infections.

14. The '634 patent, titled "Tetracycline Compositions," issued on April 2, 2024. The '634 patent describes and claims, *inter alia*, intravenous formulations comprising minocycline antibiotic and magnesium cations, with a certain molar ratio, pH, and other properties.

15. Plaintiffs are the assignee and owner of the '634 patent.

16. On April 2, 2024, the '634 patent was listed in the FDA's "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations" in connection with Plaintiffs' NDA No. 050444 for Minocin®.

Defendant's ANDA Product

17. Upon information and belief, Defendant's ANDA No. 214934 has not yet been approved by the FDA.

18. Upon information and belief, because the '634 patent is listed in the Orange Book, Defendant was required to submit a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii). Defendant certified pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that in its opinion the '634 patent is invalid, unenforceable, and/or will not be infringed by Defendant's ANDA Product. On May 9, 2024, Defendant provided Plaintiffs with the required paragraph IV notice letter including what purports to be a detailed statement of the factual and legal basis of its opinion that the '634 patent is invalid, unenforceable, and/or will not be infringed. 21 U.S.C. §§ 355(j)(2)(B)(ii)(II) and 355(j)(2)(B)(iv)(II).

COUNT I – PATENT INFRINGEMENT

19. Plaintiffs repeat and reallege each of the foregoing paragraphs 1-18, as if fully set forth herein.

20. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 214934 seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Defendant's ANDA Product is an act of infringement of the Orange Book-listed '634 patent.

21. Defendant's manufacture, use, offer to sell, sale, and/or importation of Defendant's ANDA Product before the expiration of the '634 patent infringes, either literally and/or under the doctrine of equivalents, one or more claims of the '634 patent and/or constitutes contributory infringement of one or more claims of the '634 patent pursuant to 35 U.S.C. § 271(c).

22. As the undisputed trial evidence in Case No. 1:21-cv-02636 established, Defendant's ANDA Product is an exact copy of Minocin®, including having the same formulation and properties. Pursuant to 21 C.F.R. § 314.94(a)(9)(iii), an ANDA drug product intended for parenteral use "must contain the same inactive ingredients and in the same concentration as the reference listed drug . . . ."

23. Defendant's ANDA Product is an intravenous formulation comprising an aqueous solution of minocycline and a magnesium cation wherein, *inter alia*: the molar ratio of the magnesium cation to the minocycline is greater than 4:1; the formulation has a pH greater than 4 and less than 7; administration of the formulation results in reduced injection site hemolysis relative to intravenous administration of a control formulation that does not include magnesium; the formulation has an osmolality less than about 500 mOsm/kg; the formulation comprises a base, such as NaOH; and the concentration of minocycline is at least 10 mg/mL.

24. Defendant expressly informed the Court that it has already manufactured commercial stock of its generic minocycline product, and that it intends to sell that product immediately upon receiving final FDA approval. (Case No. 1:21-cv-02636, D.I. 261.)

25. Upon information and belief, Defendant's stock of generic minocycline product was manufactured within, or imported into, the United States. Upon information and belief, Defendant is manufacturing and/or continuing to manufacture its ANDA product during the term of the '634 patent. Upon information and belief, Defendant has already made commercial offers for sale of its generic minocycline product within the United States. Upon information and belief, Defendant has contracts in place under which it has offered to sell its ANDA product during the term of the '634 patent. Upon information and belief, Defendant is continuing and/or will continue to offer to sell its ANDA product during the term of the '634 patent.

26. Defendant's ANDA product is a material component of the claimed invention of the '634 patent, and there are no substantial non-infringing uses of Defendant's ANDA Product. Defendant knows that its ANDA Product is especially made or adapted for use in infringing the '634 patent and is not suitable for any substantial non-infringing use. If Defendant's ANDA is approved, physicians and/or healthcare providers will in fact directly infringe one or more claims of the '634 patent.

27. The '634 patent was duly issued by the U.S.P.T.O. and is presumed valid and enforceable.

28. Plaintiffs are entitled to relief pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Defendant's ANDA must be a date which is not earlier than the later of the expiration date of the '634 patent or the expiration date of any exclusivity to which Plaintiffs are or become entitled.

29. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '634 patent. Absent injunctive relief, Plaintiffs do not have an adequate remedy at law. Considering the balance of hardships between Plaintiffs and Defendant, injunctive relief is warranted. The public interest favors entry of an injunction.

30. Plaintiffs reserve the right to assert that this case is exceptional and that Plaintiffs are entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that the commercial manufacture, use, offer for sale, and/or sale of Defendant's ANDA Product within the United States, and/or the importation of Defendant's ANDA Product into the United States, would infringe or infringes the '634 patent pursuant to 35 U.S.C. §§ 271(a) and/or (c);

B. A permanent injunction restraining and enjoining Defendant and its affiliates, subsidiaries, officers, agents, attorneys, employees, and those acting in privity or concert with them, from the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendant's ANDA Product until after the expiration of the '634 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

C. An order that the effective date of any final FDA approval of Defendant's ANDA must be a date that is not earlier than the expiration of the '634 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. An award of money damages and any other appropriate relief to the extent Defendant makes, uses, sells, or offers to sell Defendant's ANDA Product within the United States, or imports Defendant's ANDA Product into the United States, prior to the expiration of the '634

patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. Judgment that the claims of the '634 patent are valid and enforceable;

F. Judgment that Plaintiffs are entitled to costs and expenses in this action; and

G. An award of such other and further relief as this Court deems just and proper.

May 21, 2024

POLSINELLI PC

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