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Attorneys for Plaintiffs Melinta Therapeutics, LLC, Melinta Subsidiary Corp., and Rempex Pharmaceuticals, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MELINTA THERAPEUTICS, LLC, MELINTA SUBSIDIARY CORP., and REMPEX PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. _____
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. Melinta seeks a declaratory judgment (1) that Defendant's attempted delivery of the Notice Letter on December 8, 2020, purporting to notify Melinta that Defendant's ANDA contained a paragraph IV certification pursuant to 21 U.S.C. § 355(j) and 21 C.F.R. § 314.95, did not commence the 45-day window for Melinta to file suit to obtain a 30-month stay

of FDA approval of Defendant's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (2) that Defendant must resend its Notice Letter and obtain proper confirmation of receipt by Melinta; and (3) that the 45-day window will run only from the actual date of receipt by Melinta following Defendant resending its Notice Letter; or, in the alternative (4) that the 45-day window began no earlier than March 31, 2021, when Melinta first discovered the Notice Letter.

2. In addition, if this Court finds that Defendant is not required to resend the Notice Letter, this is a civil action for patent infringement involving U.S. Patent Nos. 9,278,105 (the "'105 patent"), attached as Exhibit A, and 9,084,802 (the "'802 patent"), attached as Exhibit B. This action arises out of Defendant's submission of ANDA No. 214934 seeking FDA approval to manufacture, use, and/or sell a generic version of Melinta's Minocin® (minocycline) for injection ("Minocin®") product before the expiration of the '105 patent and '802 patent.

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 44 Whippany Rd, Suite 280, Morristown, NJ 07960. 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 44 Whippany Rd, Suite 280, Morristown, NJ 07960.

5. Plaintiff Rempex Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 44 Whippany Rd, Suite 280, Morristown, NJ 07960. 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 Parkway, 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 New Jersey.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Defendant at least because, upon information and belief, on December 7, 2020 Defendant purposefully attempted to deliver notice of the filing of Defendant's ANDA ("Notice Letter") to Melinta in New Jersey, and Defendant's failure to ensure that Melinta properly received the Notice Letter has a substantial connection to New Jersey.

10. 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 New Jersey, before the expiration of the '105 patent and the '802 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 New Jersey; Defendant's activities with respect to its ANDA product will be purposefully directed at New Jersey (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 New Jersey

and/or administered to patients in New Jersey; and Defendant does or will do business in, and has or will have customers in, New Jersey.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because, *inter alia*, Defendant's attempted delivery and failure to ensure that Melinta properly received the Notice Letter occurred in New Jersey.

BACKGROUND

Melinta's NDA and Asserted Patents

12. Melinta (via Rempex Pharmaceuticals, Inc.) is 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.

13. The '105 patent, titled "Tetracycline Compositions," issued on March 8, 2016. The '105 patent was assigned to Rempex Pharmaceuticals, Inc., which subsequently assigned the '105 patent to Melinta. The '105 patent describes and claims methods of treating bacterial infection comprising, *inter alia*, intravenous administration of compositions comprising 7-dimethylamino-tetracyline antibiotic and a magnesium cation, with a certain molar ratio, pH, and osmolality.

14. The '802 patent, titled "Tetracycline Compositions," issued on July 21, 2015. The '802 patent was assigned to Rempex Pharmaceuticals, Inc., which subsequently assigned the '802 patent to Melinta. The '802 patent describes and claims methods of treating bacterial infection consisting of intravenous administration of compositions consisting of minocycline, a magnesium cation, and a base, with a certain molar ratio, pH, and other properties.

15. Melinta owns the '105 patent and '802 patent.

16. The ’105 patent and ’802 patent are listed in the FDA’s “Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations” in connection with NDA No. 050444 for Minocin®.

Defendant’s ANDA and Notice Letter

17. Upon information and belief, Defendant prepared and submitted ANDA No. 214934 to the FDA with a paragraph IV certification seeking approval to manufacture, use or sell Defendant’s ANDA Product before the expiration of the ’105 patent and ’802 patent.

18. Defendant’s December 7, 2020 Notice Letter purported to notify Melinta that its ANDA contained a paragraph IV certification pursuant to 21 U.S.C. § 355(j) alleging that the ’105 patent and ’802 patent are invalid, unenforceable, and/or will not be infringed by the ANDA Product, and purported to attach a “detailed statement of the legal and factual bases” for the paragraph IV certification.

19. On information and belief, Defendant attempted to transmit the Notice Letter to Melinta via Federal Express “Priority Overnight” service, which was sent on December 7, 2020, in an attempt to serve Melinta the Notice Letter on December 8, 2020.

20. There is no reasonable basis to conclude that Melinta received the Notice Letter on or around December 8, 2020. Like many other businesses in the United States and around the world, Melinta’s corporate offices have been effectively closed to the public, and employees have been directed to work from home, since March, 2020. Melinta’s offices have been locked and accessible only by access card. To accommodate the shut-down, Melinta arranged to receive mail and other deliveries through a formal procedure that ensured designated employees would timely open, review, and appropriately route electronic and hard copies of inbound correspondence. Upon information and belief, Melinta’s internal process for handling mail has

correctly taken in and routed hundreds of letters and packages over the last twelve months without fail, including a significant number of time-sensitive legal notices.

21. The Notice Letter did not go through this established process and was not sorted or organized with the remainder of received business and legal correspondence. Rather, the Notice Letter was first discovered by Melinta's General Counsel on March 31, 2021.

22. Melinta downloaded the Federal Express tracking information (attached as Exhibit C) which states that the package was "signed for" on December 8, 2020 by "A. MELNTA." Melinta has reviewed its records and has no employee with that name.

23. Federal Express had formally suspended its signature process prior to and including December 8, 2020. The Federal Express December 2, 2020 signature suspension notification is attached as Exhibit D. Moreover, upon information and belief, Defendant did not specify that a signature was required when sending the package via Federal Express.

24. Upon information and belief, Defendant therefore could not have had a reasonable expectation when it chose not to require a signature that Defendant would obtain a "signature proof of delivery" from a Melinta representative.

25. According to Federal Express policy, if a shipper requested a recipient signature but that was refused or infeasible, drivers were to enter the recipient's first initial and last name and enter "C-19" in the place of a signature image. But no "C-19" representation exists on the confirmation documentation, consistent with the fact that the driver made no contact with an individual from Melinta on December 8, 2020.

26. This action was filed within 45 days of March 31, 2021. Melinta is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5).

COUNT I – DECLARATORY JUDGMENT

27. Melinta repeats and realleges each of the foregoing paragraphs 1-26, as if fully set forth herein.

28. Congress and the FDA are aware that the receipt of notice of a paragraph IV patent certification affects patent enforcement and procedural rights.[1]

29. Statutory provision 21 U.S.C. § 355(j)(5)(B)(iii) requires that after "receipt" by the NDA holder and patent owner of notice of a paragraph IV patent certification the NDA holder/patent owner have 45 days to file a patent infringement action, which will in turn commence a 30-month stay of approval of the ANDA from the date of receipt of the notice letter:

> if the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification . . . If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order . . . . (emphasis added).

30. The critical 45-day window therefore is calculated after "receipt" of a paragraph IV notice, which is one of the core elements that make the Hatch-Waxman Act system function as intended. Mere delivery (*e.g.*, leaving a package on a doorstep) does not suffice because of the importance of the legal rights implicated and the effects of the notice.

31. 21 C.F.R. § 314.95(e) states that "signature proof of delivery" may be acceptable to demonstrate receipt. That term contemplates signature evidencing receipt by the addressee.

[1] *See, e.g.*, "FDA is interested in ensuring that patent owners and NDA holders receive notification of actions that may affect their patents." 63 Fed. Reg. 11,174, 11,175 (March 6, 1998; proposed rule withdrawn on other grounds).

32. The purported transmission of Defendant's Notice Letter did not occur according to usual procedures, and there is no signature proof of delivery.

33. Defendant's purported delivery of the Notice Letter on December 8, 2020 was defective and did not result in Melinta receiving the Notice Letter, as required by 21 U.S.C. § 355(j)(5)(B)(iii) to trigger the 45-day period for Melinta to bring an action for patent infringement to obtain a 30-month stay of FDA approval of Defendant's ANDA.

34. An actual, substantial, definite, concrete, and justiciable controversy of sufficient immediacy and reality exists between Melinta and Defendant to warrant issuance of a declaratory judgment to resolve whether delivery of the Notice Letter was defective and failed to trigger the 45-day window to file suit to obtain the 30-month stay of FDA approval. A judicial declaration is necessary and appropriate because a loss of the 30-month stay as a result of Defendant's failure to ensure that Melinta properly received the Notice Letter would cause substantial and irreparable harm to Melinta.

35. Accordingly, Melinta requests judgment that Defendant's purported delivery on December 8, 2020 did not trigger the 45-day window to file suit; that Defendant must resend its Notice Letter and obtain credible proof of actual delivery to Melinta; and that Defendant must amend its ANDA to provide accurate and updated documentation of the date of receipt of notice of its paragraph IV certification. Any amendment that claims December 8, 2020, or any other date before notice was received is not accurate, and must be amended to reflect the actual receipt date.

36. Further, Melinta requests judgment that the 45-day window under 21 U.S.C. § 355(j)(5)(B)(iii) will run only from the actual date of receipt by Melinta following Defendant resending its Notice Letter. Until that occurs, the FDA cannot presume the notice to be complete

and sufficient pursuant to 21 C.F.R. § 314.107(f) and cannot approve Defendant's ANDA prior to expiration of the '105 patent and '802 patent.

37. In the alternative, at a minimum, Melinta requests judgment that the 45-day window began no earlier than March 31, 2021 when Melinta first discovered the Notice Letter, and that this Complaint was filed within 45 days of that date, such that the 30-month stay of FDA approval of Defendant's ANDA shall commence as of March 31, 2021.

COUNT II – INFRINGEMENT OF THE '105 PATENT

38. Melinta repeats and realleges each of the foregoing paragraphs 1-37, as if fully set forth herein.

39. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 214934 with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Defendant's ANDA Product before the expiration of the '105 patent was an act of infringement of the '105 patent.

40. Upon information and belief, Defendant had actual knowledge of the '105 patent prior to its ANDA submission and was aware that the filing of its ANDA would constitute an act of infringement of the '105 patent.

41. If Defendant's ANDA is approved, upon information and belief, Defendant's manufacture, use, offer to sell, sale, and/or importation of Defendant's ANDA Product before the expiration of the '105 patent would infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '105 patent; would induce infringement of one or more claims of the '105 patent pursuant to 35 U.S.C. § 271(b); and/or would constitute contributory infringement of one or more claims of the '105 patent pursuant to 35 U.S.C. § 271(c). If Defendant's ANDA is approved, upon information and belief, Defendant specifically intends to

and will infringe, actively induce infringement of, and/or contribute to infringement of the '105 patent, and intends to and will do so immediately upon approval.

42. Upon information and belief, Defendant's ANDA Product will contain the active ingredient minocycline, which is a 7-dimethylamino-tetracycline antibiotic. Upon information and belief, Defendant's ANDA Product will have the same formulation and properties as Minocin®. 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 . . . ."

43. Upon information and belief, Defendant's ANDA product will be accompanied by a product label, prescribing information, and/or instructions for use that will substantially copy the Minocin® label. Upon information and belief, physicians will follow such instructions for use when administering Defendant's ANDA Product. Upon information and belief, the label for Defendant's ANDA product will induce physicians to treat bacterial infections in a manner within the scope of one or more claims of the '105 patent. Upon information and belief, Defendant knows that physicians who act according to the label for Defendant's ANDA Product will infringe one or more claims of the '105 patent, and Defendant has specific intent to actively encourage physicians to infringe one or more claims of the '105 patent. If Defendant's ANDA is approved, upon information and belief, physicians will in fact directly infringe one or more claims of the '105 patent.

44. Defendant's Notice Letter does not include any allegation that a physician using Defendant's ANDA Product following the accompanying label will not directly infringe the '105 patent.

45. Upon information and belief, there are no substantial non-infringing uses of Defendant's ANDA Product, and therefore the marketing of Defendant's ANDA Product will contribute to infringement of one or more claims of the '105 patent. Upon information and belief, Defendant knows that its ANDA Product is especially made or adapted for use in infringing the '105 patent and is not suitable for substantial non-infringing use.

46. Upon information and belief, Defendant's contentions regarding invalidity, unenforceability, and non-infringement of the '105 patent in its "detailed statement of the legal and factual bases" attached to its Notice Letter are without merit and lack a good-faith basis. Upon information and belief, Defendant does not have a reasonable basis for believing that its ANDA Product would not infringe the '105 patent.

47. Melinta is 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 '105 patent or the expiration date of any exclusivity to which Melinta is or becomes entitled.

48. Melinta will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '105 patent. Melinta does not have an adequate remedy at law. Considering the balance of hardships between Melinta and Defendant, injunctive relief is warranted. The public interest favors entry of an injunction.

49. Melinta reserves the right to assert that this case is exceptional and that Melinta is entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III – INFRINGEMENT OF THE '802 PATENT

50. Melinta repeats and realleges each of the foregoing paragraphs 1-49, as if fully set forth herein.

51. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 214934 with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Defendant's ANDA Product before the expiration of the '802 patent was an act of infringement of the '802 patent.

52. Upon information and belief, Defendant had actual knowledge of the '802 patent prior to its ANDA submission and was aware that the filing of its ANDA would constitute an act of infringement of the '802 patent.

53. If Defendant's ANDA is approved, upon information and belief, Defendant's manufacture, use, offer to sell, sale, and/or importation of Defendant's ANDA Product before the expiration of the '802 patent would infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '802 patent; would induce infringement of one or more claims of the '802 patent pursuant to 35 U.S.C. § 271(b); and/or would constitute contributory infringement of one or more claims of the '802 patent pursuant to 35 U.S.C. § 271(c). If Defendant's ANDA is approved, upon information and belief, Defendant specifically intends to and will infringe, actively induce infringement of, and/or contribute to infringement of the '802 patent, and intends to and will do so immediately upon approval.

54. Upon information and belief, Defendant's ANDA Product will contain the active ingredient minocycline, which is a 7-dimethylamino-tetracycline antibiotic. Upon information and belief, Defendant's ANDA Product will have the same formulation and properties as Minocin®. 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 . . . ."

55. Upon information and belief, Defendant's ANDA product will be accompanied by a product label, prescribing information, and/or instructions for use that will substantially copy the Minocin® label. Upon information and belief, physicians will follow such instructions for use when administering Defendant's ANDA Product. Upon information and belief, the label for Defendant's ANDA product will induce physicians to treat bacterial infections in a manner within the scope of one or more claims of the '802 patent. Upon information and belief, Defendant knows that physicians who act according to the label for Defendant's ANDA Product will infringe one or more claims of the '802 patent, and Defendant has specific intent to actively encourage physicians to infringe one or more claims of the '802 patent. If Defendant's ANDA is approved, upon information and belief, physicians will in fact directly infringe one or more claims of the '802 patent.

56. Defendant's Notice Letter does not include any allegation that a physician using Defendant's ANDA product following the accompanying label will not directly infringe the '802 patent.

57. Upon information and belief, there are no substantial non-infringing uses of Defendant's ANDA Product, and therefore the marketing of Defendant's ANDA Product will contribute to infringement of one or more claims of the '802 patent. Upon information and belief, Defendant knows that its ANDA Product is especially made or adapted for use in infringing the '802 patent and is not suitable for substantial non-infringing use.

58. Upon information and belief, Defendant's contentions regarding invalidity, unenforceability, and non-infringement of the '802 patent in its "detailed statement of the legal and factual bases" attached to its Notice Letter are without merit and lack a good-faith basis. Upon

information and belief, Defendant does not have a reasonable basis for believing that its ANDA Product would not infringe the '802 patent.

59. Melinta is 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 '802 patent or the expiration date of any exclusivity to which Melinta is or becomes entitled.

60. Melinta will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '802 patent. Melinta does not have an adequate remedy at law. Considering the balance of hardships between Melinta and Defendant, injunctive relief is warranted. The public interest favors entry of an injunction.

61. Melinta reserves the right to assert that this case is exceptional and that Melinta is entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Melinta respectfully requests:

A. Judgment that (1) Defendant's purported delivery of the Notice Letter on December 8, 2020 did not commence the 45-day window for Melinta to file suit to obtain a 30-month stay of FDA approval of Defendant's ANDA; (2) Defendant must resend its Notice Letter and obtain proper confirmation of receipt by Melinta; and (3) the 45-day window will run only from the actual date of receipt by Melinta following Defendant resending its Notice Letter; or, in the alternative (4) the 45-day window began no earlier than March 31, 2021;

B. Judgment that Defendant's submission of ANDA No. 214934 infringed the '105 patent and '802 patent pursuant to 35 U.S.C. § 271(e)(2)(A);

C. 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, will infringe the '105 patent and '802 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

D. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4) 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 '105 patent and '802 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. An order pursuant to 35 U.S.C. § 271(e)(4) 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 '105 patent and '802 patent, including any extensions and/or additional periods of exclusivity to which Melinta is or becomes entitled;

F. An award of money damages and any other appropriate relief if 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 '105 patent and '802 patent, including any extensions and/or additional periods of exclusivity to which Melinta is or becomes entitled;

G. Judgment that the claims of the '105 patent and '802 patent are valid and enforceable;

H. Judgment that Melinta is entitled to costs and expenses in this action; and

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

Dated: May 13, 2021

/s/Liza M. Walsh
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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiff that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: May 13, 2021

Respectfully submitted,

s/ Liza M. Walsh

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, inter alia, injunctive relief.

Dated: May 13, 2021

Respectfully submitted,

s/ Liza M. Walsh

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