IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UCB, INC., UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG	)	
Plaintiffs,	)	
v.	)	Case No. 2:22-cv-216
MYLAN TECHNOLOGIES INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc., UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Mylan Technologies Inc. ("MTI"), and hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon MTI's acts of infringement arising from the submission of Abbreviated New Drug Application ("ANDA") No. 209982 ("MTI's ANDA" or "the MTI ANDA") and amendments thereto to the United States Food and Drug Administration ("FDA") to seek approval to market generic versions of Plaintiffs' Neupro® transdermal system ("MTI's ANDA Products" or "the MTI ANDA Products"), prior to the expiration of United States Patent Nos. 8,246,979 ("the '979 Patent"), 8,246,980 ("the '980 Patent"), 10,130,589 ("the '589 Patent"), and 10,350,174 ("the '174 Patent"). Plaintiffs seek declaratory and injunctive relief precluding such infringement, damages (if any), attorneys' fees, costs, and any other relief the Court deems just and proper.

THE PARTIES

2. Plaintiff UCB, Inc. ("UCB, Inc.") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

3. Plaintiff UCB Pharma GmbH ("UCB Pharma," and collectively with UCB, Inc., "UCB") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Alfred Nobel Strasse 10, 40789 Monheim, Germany.

4. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Lohmannstrasse 2, 56626 Andernach, Germany.

5. On information and belief, Defendant MTI is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 110 Lake Street, St. Albans, Vermont 05478.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and alleges infringement of the '979, '980, '589, and '174 Patents. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202. Venue is proper in this district pursuant to 28 U.S.C. § 1391 and § 1400(b).

7. This Court has personal jurisdiction over MTI. MTI, the MTI ANDA holder, has its principal place of business within this judicial district at 110 Lake Street, St. Albans, Vermont, which MTI admitted in prior litigation. *See UCB, Inc., et al. v. Mylan Techs., Inc.*, No. 19-cv-128-CR, ECF No. 21 at ¶ 5 (D. Vt. Sept. 3, 2019); *UCB, Inc., et al. v. Mylan Techs., Inc., et al.*, No.

17-cv-322-LPS, ECF No. 17 at 2 (D. Del. July 19, 2017); *UCB, Inc., et al. v. Mylan Techs., Inc., et al.*, No. 17-cv-322-LPS, ECF No. 18 at ¶ 3 (D. Del. July 19, 2017). Additionally, MTI developed the accused MTI ANDA Products and submitted the MTI ANDA to FDA from this judicial district, which MTI admitted in prior litigation. *See UCB, Inc., et al. v. Mylan Techs., Inc., et al.*, No. 17-cv-322-LPS, ECF No. 17 at 3 (D. Del. July 19, 2017); *UCB, Inc., et al. v. Mylan Techs., Inc., et al.*, No. 17-cv-322-LPS, ECF No. 18 at ¶ 7 (D. Del. July 19, 2017).

8. On information and belief, MTI, directly or through its affiliates and agents, develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. On information and belief, upon receiving FDA approval, MTI, directly or through its affiliates and agents, intends to market and sell the proposed generic products at issue in this litigation, Rotigotine Transdermal System (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours) as described in amendments to the MTI ANDA (i.e., MTI's ANDA Product) throughout the United States, including in Vermont, to list purported generic versions of Neupro® on Vermont's prescription drug formulary, and to seek Medicaid reimbursements for sales of purported generic versions of Neupro® in Vermont. On information and belief, MTI, directly or through its affiliates and agents, has engaged in systematic and continuous contacts with the State of Vermont. MTI is accordingly "at home" in this judicial district.

9. MTI has previously consented to personal jurisdiction in this judicial district in prior litigation concerning the MTI ANDA and earlier versions of the MTI ANDA Products. *See, e.g., UCB, Inc., et al. v. Mylan Techs. Inc.*, No. 19-cv-128-CR, ECF No. 21 at ¶ 7 (D. Vt. Sept. 3, 2019); *see also UCB, Inc., et al. v. Mylan Techs., Inc., et al.*, No. 17-cv-322-LPS, ECF No. 91 at 2–3 (D. Del. Aug. 21, 2019).

10. MTI regularly invokes the jurisdiction of the courts of this judicial district by filing counterclaims in other actions before this judicial district. *See, e.g.*, *Bristol-Myers Squibb Co. v. Mylan Techs. Inc.*, No. 01-cv-18-WKS, ECF No. 21 (D. Vt. Apr. 4, 2001); *Alza Corp. et al. v. Mylan Labs. Inc. et al.*, No. 02-cv-20-WKS, ECF No. 3 (D. Vt. Feb. 15, 2002); *Alza Corp. v. Mylan Labs., Inc. et al.*, No. 02-cv-213-WKS, ECF No. 6 (D. Vt. Mar. 20, 2002); *UCB, Inc. et al. v. Mylan Techs., Inc.*, No. 19-cv-128-CR, ECF No. 21 (D. Vt. Sept. 3, 2019); *UCB, Inc. et al. v. Mylan Techs., Inc., et al.*, No. 19-cv-148-WKS, ECF No. 8 (D. Vt. Apr. 19, 2017) (transferred from the District of Delaware with MTI's consent).

11. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and § 1400(b) at least because, as set forth above, Defendant MTI has its principal place of business within this judicial district, developed the accused MTI ANDA Products within this judicial district, and submitted the MTI ANDA to FDA from this judicial district.

12. MTI has previously consented to venue in this judicial district as a defendant and counterclaim plaintiff in an earlier patent infringement action brought by Plaintiffs concerning the MTI ANDA and earlier versions of MTI's ANDA Products. *See UCB, Inc., et al. v. Mylan Techs., Inc.*, No. 19-cv-128-CR, ECF No. 21 at ¶ 6 (D. Vt. Sept. 3, 2019).

NEUPRO®

13. Plaintiffs make and sell the Neupro® transdermal system (Rotigotine Transdermal System), a treatment for the signs and symptoms of idiopathic Parkinson's disease ("PD") and moderate-to-severe Restless Legs Syndrome ("RLS"). PD affects movement, producing motor symptoms such as tremor, slowed movement, rigidity, and postural instability. PD can also cause neuropsychiatric disturbances, including disorders of speech, cognition, mood, behavior, and thought. RLS is characterized by uncomfortable or odd sensations in a person's limbs, which cause an irresistible urge to move the body for temporary relief.

14. Neupro® is the first FDA-approved product containing rotigotine, a synthetic dopamine agonist. In PD, neurodegeneration results in the loss of dopamine-producing neurons and reduced activity within certain dopaminergic pathways, and restoring activity to these systems with a dopamine agonist such as rotigotine may improve the clinical signs of PD. Rotigotine is also called (6S)-6-{propyl[2-(2-thienyl)ethyl]amino}-5,6,7,8-tetrahydro-1-naphthalenol; or (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol.

15. Neupro® is also the first FDA-approved transdermal treatment for PD. Neupro® is a transdermal system that provides continuous delivery of rotigotine for 24 hours following application to intact skin. The product is a thin, matrix-type transdermal system composed of three layers: a backing film, drug matrix, and protective liner. The liner protects the drug matrix during storage and is removed just prior to application. Neupro® is approved and marketed in six different strengths: 1 mg/ 24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours.

16. Neupro®'s transdermal delivery of rotigotine has been shown to provide stable plasma levels of rotigotine over 24 hours, which may prevent or reduce long-term motor complications and motor fluctuations that are associated with unstable or fluctuating dopaminergic stimulation. Neupro® also offers other advantages. For example, by delivering drug via transdermal application, Neupro® bypasses gastrointestinal complications that may be associated with PD. In addition, Neupro®'s once-daily formulation for 24 hours of treatment may improve early morning and nighttime symptoms of PD, as well as patient compliance.

17. Plaintiff UCB, Inc. is the holder of New Drug Application ("NDA") No. 021829 for Neupro® (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours). FDA initially approved NDA No. 021829 in May 2007, for the treatment of signs

and symptoms of early stage idiopathic PD. Following manufacturing and process changes to address product stability, and following additional clinical trials, in April 2012, FDA approved a new formulation of Neupro® for additional indications—i.e., for the treatment of the signs and symptoms of advanced stage idiopathic PD, and for the treatment of moderate-to-severe RLS. In its April 2012 approval of Neupro®, FDA granted Neupro® three years of regulatory exclusivity pursuant to 21 C.F.R. § 314.108.

THE ASSERTED PATENTS

18. The '979 Patent, titled "Transdermal Delivery System for the Administration of Rotigotine," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on August 21, 2012. The '979 Patent is owned by Plaintiff UCB Pharma. A true and correct copy of the '979 Patent is attached as Exhibit A.

19. The '980 Patent, titled "Transdermal Delivery System," was duly and lawfully issued by the USPTO on August 21, 2012. The '980 Patent is owned by Plaintiff UCB Pharma. A true and correct copy of the '980 Patent is attached as Exhibit B.

20. The '589 Patent, titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine," was duly and lawfully issued by the USPTO on November 20, 2018. The '589 Patent is co-owned by Plaintiffs UCB Pharma and LTS. A true and correct copy of the '589 Patent is attached as Exhibit C.

21. The '174 Patent, titled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine," was duly and lawfully issued by the USPTO on July 16, 2019. The '174 Patent is co-owned by Plaintiffs UCB Pharma and LTS. A true and correct copy of the '174 Patent is attached as Exhibit D.

22. The '979, '980, '589, and '174 Patents, among other patents (collectively, the "Neupro® Listed Patents"), are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for Neupro®.

THE MTI ANDA AND AMENDMENTS

23. On information and belief, MTI is the owner of the MTI ANDA.

24. On information and belief, MTI has submitted, or caused to be submitted, the MTI ANDA and amendments to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of MTI's ANDA Products, as purported generic versions of Neupro® prior to the expiration of the Neupro® Listed Patents.

25. Beginning in 2017, MTI has sent or caused to be sent multiple letters purporting to provide notice of certification in connection with patents listed in the Orange Book in connection with Neupro® pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 314.94 and 314.95.

26. On information and belief, MTI sent a letter dated February 27, 2017, to Plaintiffs and UCB Manufacturing Ireland Limited ("UCB Manufacturing") purporting to provide notice of certification concerning five patents that have been listed in the Orange Book for Neupro®, including, *inter alia*, the '979 and '980 Patents ("February 27, 2017 Notice Letter"). In the February 27, 2017 Notice Letter, MTI did not contest infringement as to claims 1–5 and 7–18 of the '979 Patent or claim 17 of the '980 Patent with respect to the versions of the MTI ANDA Products then proposed for approval.

27. On March 24, 2017, Plaintiffs and UCB Manufacturing brought an action for patent infringement against MTI, Mylan Pharmaceuticals, Inc., and Mylan, Inc. in the United States District Court for the District of Delaware in *UCB, Inc., et al. v. Mylan Techs., Inc., et al.*, No. 17-cv-322-LPS (D. Del.) ("Delaware -322 Action"). Plaintiffs and UCB Manufacturing asserted, *inter*

alia, infringement of claims of the '979 and '980 Patents based on the versions of the MTI ANDA Products then proposed for approval. *See* No. 17-cv-322-LPS, ECF No. 1 (D. Del. Mar. 24, 2017).

28. On July 16, 2019, following the issuance of the '589 and '174 Patents by the USPTO, Plaintiffs brought an action for patent infringement against MTI in this district in *UCB, Inc., et al. v. Mylan Techs., Inc.*, No. 19-cv-128-CR (D. Vt.) ("Vermont -128 Action"). Specifically, Plaintiffs asserted infringement of the '589 and '174 Patents based on the MTI ANDA Products that were proposed for approval in the MTI ANDA at that time. *See* No. 19-cv-128-CR, ECF No. 1 (D. Vt. July 16, 2019).

29. On information and belief, MTI sent a letter dated July 29, 2019 to Plaintiffs and UCB Manufacturing purporting to provide notice of certification concerning the '589 and '174 Patents, which have been listed in the Orange Book for Neupro® ("July 29, 2019 Notice Letter"). In the July 29, 2019 Notice Letter, MTI did not contest infringement of any claims of the '589 Patent based on its originally proposed ANDA Products. With respect to the '174 Patent, in its July 29, 2019 Notice Letter, MTI contested infringement of claims 7 and 16 based on its originally proposed ANDA Products.

30. On August 12, 2019, Plaintiffs filed an Amended Complaint in the Vermont -128 Action. *See* No. 19-cv-128-CR, ECF No. 16 at ¶¶ 20–25 (D. Vt. Aug. 12, 2019).

31. On August 21, 2019, the parties in the Delaware -322 Action, including Defendant MTI, agreed to the transfer of that action to this district and further agreed to the dismissal of Mylan Pharmaceuticals Inc. and Mylan Inc. from the action. *See* No. 17-cv-322-LPS, ECF No. 91 (D. Del. Aug. 21, 2019).

32. On August 26, 2019, the U.S. District Court for the District of Delaware adopted the parties' stipulation in the Delaware -322 Action and ordered the transfer of that action to this

district. *See* No. 17-cv-322-LPS, ECF No. 92 (D. Del. Aug. 26, 2019). The action was assigned civil action number 19-cv-148-WKS (D. Vt.) ("Vermont -148 Action").

33. On May 13, 2020, the parties in the Vermont -128 Action filed a proposed Stipulation and Order in which MTI stipulated that it "will not contest allegations of infringement for Claims 1-3, 4, 7, and 10-12 of the '589 patent and Claims 1-2, 5-6 and 14-15 of the '174 patent," *see* No. 19-cv-128-CR, ECF No. 97 at 2 (D. Vt. May 13, 2020), which this Court so ordered, *see* No. 19-cv-128-CR, ECF No. 98 (D. Vt. May 13, 2020).

34. On June 16, 2020, UCB, Inc., UCB Pharma, UCB Manufacturing, and LTS covenanted not to sue MTI "for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA . . . infringes any claim of the '979, '980, '591, or '150 patents," as more specifically set forth in the covenant ("June 16, 2020 Covenant"). Among other things, the June 16, 2020 Covenant provides that "[t]he Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020 . . . ." *Id.* at ¶ 3. Under the June 16, 2020 Covenant, if MTI "modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to alter the infringement analysis with respect to any claim of the '979, '980, '591, or '150 Patents – th[e] Covenant will not constitute a promise by Plaintiffs not to sue Mylan based on any such revised (or Supplemental) ANDA, or any accordingly modified product or its manufacture." *Id.*

35. On July 17, 2020, the parties in the Vermont -148 Action stipulated that the claims against MTI based on the then-proposed ANDA Products identified in the MTI ANDA with respect to the asserted patents in that action, including the '979, '980, and '591 Patents, were to be "dismissed with prejudice in accordance with" the June 16, 2020 Covenant. *See* No. 19-cv-148-

WKS, ECF No. 96 at ¶ 1 (D. Vt. July 17, 2020). The stipulation provides that the "dismissal is made without prejudice to Plaintiffs' ability to assert the Covenant Patents for any other ANDA or as provided in the Covenant." *Id.* The stipulation was subsequently so ordered by this Court. *See* No. 19-cv-148-WKS, ECF No. 97 (D. Vt. July 20, 2020).

36. In parallel with the above-referenced actions against MTI, Plaintiffs also asserted claims of the '589 Patent in a separate infringement action in the United States District Court for the District of Delaware against Actavis Laboratories UT, Inc. ("Actavis") following receipt of a purported Paragraph IV notice letter in connection with Actavis's ANDA seeking approval to market purported generic versions of Neupro®. *See UCB, Inc. et al. v. Actavis Laboratories UT, Inc.*, No. 19-cv-474 (D. Del. filed Mar. 6, 2019) ("Actavis Action").

37. On March 26, 2021, the U.S. District Court for the District of Delaware entered Post-Trial Findings of Fact and Conclusions of Law in the Actavis Action finding claims 1–3, 7, and 10–12 of the '589 Patent invalid. *See* No. 19-cv-474, ECF No. 191 (D. Del. Mar. 26, 2021). Final Judgment was entered in the Actavis Action on April 7, 2021. *See* No. 19-cv-474, ECF No. 196 (D. Del. Apr. 7, 2021).

38. On May 13, 2020, the parties in the Vermont -128 Action filed a proposed Stipulation and Order, which was subsequently so ordered by this Court. *See* No. 19-cv-128-CR, ECF No. 98 (D. Vt. May 13, 2020). The Stipulation and Order provided that "Plaintiffs have alleged in the action that Mylan has infringed Claims 1, 2, 3, 4, 6, 7, 10, 11, 12, 13, 14, 19, and 20 of [the '589 Patent] and Claims 1, 2, 4, 5, 6, 8, 9, 14, and 15 of [the '174 Patent] . . . ." *Id.* at 2. The Stipulation and Order further provided that MTI "will not contest allegations of infringement for Claims 1-3, 4, 7, and 10-12 of the '589 patent and Claims 1-2, 5-6 and 14-15 of the '174 patent." *Id.*

39. On May 3, 2021, Plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the decision in the Actavis Action, *see* No. 19-cv-474, ECF No. 200 (D. Del. May 3, 2021), with the Actavis appeal subsequently being docketed at No. 21-1924 (Fed. Cir. May 6, 2021).

40. On June 8, 2021, the parties in the Vermont -128 Action filed a Proposed Judgment and Stipulated Dismissal. *See* No. 19-cv-128-CR, ECF No. 137 (D. Vt. June 8, 2021). Among other things, the Proposed Judgment and Stipulated Dismissal provided that "Mylan has stipulated to infringement of Claims 1, 2, 3, 4, 6, 7, 10, 11, 12, 13, 14, 19, and 20 of the '589 Patent and Claims 1, 2, 4, 5, 6, 8, 9, 14, and 15 of the '174 Patent . . . ." *Id.* The parties' submission requested, *inter alia*, that the trial record, Final Judgment, and Findings of Fact and Conclusions of Law from the Actavis Action concerning the '589 Patent be adopted, "preserving the parties' right to appeal such decision as if issued by this Court." *Id.* at 2. As to the '174 Patent claims, the parties proposed that "[a]ll claims, defenses, and requests for relief pled by Plaintiffs and Mylan with respect to the '174 Patent are dismissed, with prejudice . . . ." *Id.* This Court so ordered the proposed judgment and stipulated dismissal. *See* No. 19-cv-128-CR, ECF No. 138 (D. Vt. June 8, 2021).

41. On July 9, 2021, Plaintiffs filed a Notice of Appeal to the Federal Circuit from the decision in the Vermont -128 Action, *see* No. 19-cv-128-CR, ECF No. 143 (D. Vt. July 9, 2021), with the MTI appeal subsequently being docketed at No. 21-2336 (Fed. Cir. Sept. 22, 2021).

42. On November 19, 2021, the Federal Circuit consolidated the Actavis and MTI appeals. *See* No. 21-2336, ECF No. 19 (Fed. Cir. Nov. 19, 2021).

43. The Federal Circuit heard oral argument for the consolidated appeals on October 4, 2022. *See* No. 21-1924, ECF No. 64 (Fed. Cir. Oct. 4, 2022).

44. As of the date this Complaint was filed, the Federal Circuit has not issued a decision in the consolidated appeals.

45. On information and belief, MTI sent Plaintiffs a letter dated October 27, 2022, purportedly regarding "Notice of Paragraph IV Certification Regarding U.S. Patent Nos. 8,246,979, 8,246,980, 8,617,591, 9,925,150, 10,130,589, and 10,350,174 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. 209982 (NEUPRO® (rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours))" ("October 27, 2022 Notice Letter").

46. MTI's October 27, 2022 Notice Letter represented that MTI had submitted and amended ANDA No. 209982, with a purported Paragraph IV certification for patents including the '979, '980, '589, and '174 Patents. The October 27, 2022 Notice Letter purports to provide notice of certification concerning at least the '979, '980, '589, and '174 Patents pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 314.94 and 314.95.

47. MTI's October 27, 2022 Notice Letter represented that MTI was providing the letter to Plaintiffs "based on an ANDA amendment submitted to FDA addressing previous FDA inquiries sent to [MTI]." Specifically, the letter represented that MTI's ANDA amendment "includes changes to the components of [MTI's] ANDA Products." Applicable regulations require that "[a]n amendment to an ANDA is required to contain an appropriate patent certification . . . if approval is sought . . . [t]o make *other than minor changes in a product formulation* . . . ." 21 C.F.R. § 314.96(d)(1)(iii) (emphasis added).

48. On information and belief, the changes made in MTI's ANDA amendment to at least the components of the MTI ANDA Product are substantial. On information and belief, MTI has revised and/or supplemented the ANDA and modified its proposed production and the

manufacture thereof. The MTI ANDA Product now proposed in MTI's ANDA following the amendment is not essentially the same as the MTI ANDA Product proposed before the amendment.

49. According to applicable regulations, notice letters such as the October 27, 2022 Notice Letter must contain a detailed statement of the factual and legal basis for the ANDA applicant's opinion that any patents are invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7).

50. For at least one claim of each of the '979, '980, '589, and '174 Patents, the October 27, 2022 Notice Letter failed to allege that MTI's ANDA Products would not meet the limitations of that claim, particularly in light of the MTI ANDA amendment that changed at least the components of MTI's ANDA Products. The February 27, 2017 Notice Letter addressing the '979 and '980 Patents, and the July 29, 2019 Notice Letter addressing the '589 and '174 Patents, similarly failed to allege that MTI's ANDA Products would not meet the limitations of at least one claim of each patent.

51. Plaintiffs diligently sought to investigate MTI's amendment to its ANDA and its changes to the MTI ANDA Products within the forty-five day window for bringing suit after receipt of a Paragraph IV notice letter, as set forth under 21 U.S.C. § 355(j)(5)(B)(iii). In the October 27, 2022 Notice Letter, MTI purported to offer confidential access to portions of MTI's ANDA on terms and conditions set forth in the October 27, 2022 Notice Letter. MTI's terms and conditions attempted to impose numerous unreasonable restrictions on Plaintiffs relating to, for example, who could view MTI's ANDA, well beyond those that would apply under a protective

order. For example, MTI's offer did not permit any scientific experts to access MTI's ANDA and amendments. Such restrictions were improper. *See, e.g.*, 21 U.S.C. § 355(j)(5)(C)(i)(III). Beginning with correspondence on November 12, 2022, outside counsel for Plaintiffs sought to negotiate in good faith with counsel for MTI in an attempt to reach agreement on reasonable terms of confidential access to MTI's ANDA. Plaintiffs explained the above issues to MTI's counsel and proposed reasonable, alternative terms of access that are consistent with protective orders that MTI has agreed to previously. Plaintiffs sent further correspondence to counsel for MTI seeking to negotiate regarding the terms of MTI's offer on November 14, 2022, and again on November 15, 2022. After one week of delay, on November 22, 2022, counsel for MTI agreed to Plaintiffs' proposal and produced "ANDA amendment documents" to Plaintiffs one day later, in the afternoon on November 23—the Wednesday before the Thanksgiving holiday. Due to the unexpected timing of the production and the significant amount of material produced (including tens of thousands of pages of technical information) Plaintiffs experienced delays in accessing and reviewing the MTI ANDA amendments. Plaintiffs first were able to access MTI's ANDA on November 27—two weeks prior to the end of the forty-five day window set forth under the Hatch-Waxman Act. MTI's production further hindered Plaintiffs' ability to analyze MTI's ANDA amendment. Although MTI produced "ANDA amendment documents," MTI did not produce, *inter alia*, product samples of the MTI ANDA Product, which has newly changed components, to allow Plaintiffs to engage in scientific testing of the product for investigative purposes.

52. On information and belief, FDA has not approved the MTI ANDA and amendments.

53. On information and belief, if FDA approves the MTI ANDA and amendments, MTI will manufacture, offer for sale, or sell the MTI ANDA Products within the United States.

54. On information and belief, if FDA approves the MTI ANDA and amendments, MTI will actively induce or contribute to the manufacture, use, offer for sale, or sale of the MTI ANDA Products.

55. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the October 27, 2022 Notice Letter. Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I: INFRINGEMENT OF THE '979 PATENT

56. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–55 as if fully set forth herein.

57. Plaintiffs own all rights, title, and interest in and to the '979 Patent.

58. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

59. MTI has infringed at least claims 1–18 of the '979 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting and continuing to pursue the MTI ANDA and amendments and by submitting a Paragraph IV certification seeking FDA approval prior to the expiration of the '979 Patent.

60. MTI's commercial manufacture, use, sale, or offer for sale, in the United States of the MTI ANDA Products would directly infringe and would actively induce and contribute to infringement of the '979 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the MTI ANDA and amendments, MTI will make, use, offer to sell, or sell the MTI ANDA Products within the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '979 Patent.

61. On information and belief, MTI has actual and constructive notice of the '979 Patent. MTI is aware that maintaining the MTI ANDA with the request for FDA approval prior to the expiration of the '979 Patent constitutes an act of infringement of the '979 Patent.

62. MTI did not contest infringement of any claims of the '979 Patent in the October 27, 2022 Notice Letter. Further, MTI contested infringement only as to claim 6 of the '979 Patent in its February 27, 2017 Notice Letter. If MTI had a factual or legal basis to contest infringement of the claims of the '979 Patent in light of its ANDA amendment, it was required by applicable regulations to state such a basis in the October 27, 2022 and February 27, 2017 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

63. MTI has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '979 Patent. In addition, MTI has maintained the MTI ANDA and amendments without adequate justification for asserting the '979 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products. MTI's conduct and continued pursuit of the MTI ANDA and amendments despite its infringement of the '979 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

64. On information and belief, when MTI amended its ANDA, it modified, added, removed, and altered components in the MTI ANDA Products and steps that are used in their manufacture, so as to alter the infringement analysis with respect to at least claims 1–18 of the '979 Patent, as compared with MTI's ANDA Product as described in its ANDA as of May 27, 2020.

65. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for MTI's ANDA to be a date that is not any earlier than the expiration date of the '979 Patent, including any extensions, adjustments, and exclusivities associated with the '979 Patent.

66. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing and from actively inducing or contributing to the infringement of the '979 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '979 PATENT

67. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–66 as if fully set forth herein.

68. Plaintiffs own all rights, title, and interest in and to the '979 Patent.

69. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

70. On information and belief, MTI has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, offer to sell, and sell the MTI ANDA Products prior to the expiration of the '979 Patent.

71. MTI's continued pursuit of the MTI ANDA, commercial manufacture, use, offer to sell, and sale within the United States of the MTI ANDA Products would infringe at least claims 1–18 of the '979 Patent, either literally or under the doctrine of equivalents. Accordingly, unless

enjoined by this Court, upon FDA approval of the MTI ANDA, MTI will commercially manufacture, use, offer to sell, and sell the Mylan ANDA Products within the United States and will thereby infringe one or more claims of the '979 Patent.

72. MTI did not contest infringement of any claims of the '979 Patent in the October 27, 2022 Notice Letter. Further, MTI contested infringement only as to claim 6 of the '979 Patent in its February 27, 2017 Notice Letter. If MTI had a factual or legal basis to contest infringement of the claims of the '979 Patent in light of its ANDA amendment, it was required by applicable regulations to state such a basis in the October 27, 2022 and February 27, 2017 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

73. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MTI regarding whether MTI's continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offers to sell and sale of the MTI ANDA Products will infringe one or more claims of the '979 Patent.

74. Plaintiffs should be granted a declaratory judgment that the continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offer to sell, or sale of the MTI ANDA Products would infringe one or more claims of the '979 Patent.

75. On information and belief, when MTI amended its ANDA, it modified, added, removed, and altered components in the MTI ANDA Products and steps that are used in their manufacture, so as to alter the infringement analysis with respect to at least claims 1–18 of the '979 Patent, as compared with MTI's ANDA Product as described in its ANDA as of May 27, 2020.

76. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing the '979 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships

between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III: INFRINGEMENT OF THE '980 PATENT

77. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–76 as if fully set forth herein.

78. Plaintiffs own all rights, title, and interest in and to the '980 Patent.

79. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

80. MTI has infringed at least claim 17 of the '980 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting and continuing to pursue the MTI ANDA and amendments and by submitting a Paragraph IV certification seeking FDA approval prior to the expiration of the '980 Patent.

81. MTI's commercial manufacture, use, sale, or offer for sale, in the United States of the MTI ANDA Products would directly infringe and would actively induce and contribute to infringement of the '980 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the MTI ANDA and amendments, MTI will make, use, offer to sell, or sell the MTI ANDA Products within the United States and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '980 Patent.

82. On information and belief, MTI has actual and constructive notice of the '980 Patent. MTI is aware that maintaining the MTI ANDA with the request for FDA approval prior to the expiration of the '980 Patent constitutes an act of infringement of the '980 Patent.

83. MTI did not contest infringement of any claims of the '980 Patent in the October 27, 2022 Notice Letter. Further, MTI did not contest infringement for at least claim 17 of the '980 Patent in its February 27, 2017 Notice Letter. If MTI had a factual or legal basis to contest infringement of all claims of the '980 Patent in light of its ANDA amendment, it was required by applicable regulations to state such a basis in the October 27, 2022 and February 27, 2017 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

84. MTI has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '980 Patent. In addition, MTI has maintained the MTI ANDA and amendments without adequate justification for asserting the '980 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products. MTI's conduct and continued pursuit of the MTI ANDA and amendments despite its infringement of the '980 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

85. On information and belief, when MTI amended its ANDA, it modified, added, removed, and altered components in the MTI ANDA Products and steps that are used in their manufacture, so as to alter the infringement analysis with respect to at least claim 17 of the '980 Patent, as compared with MTI's ANDA Product as described in its ANDA as of May 27, 2020.

86. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for MTI's ANDA to be a date that is not any earlier than the expiration date of the '980 Patent, including any extensions, adjustments, and exclusivities associated with the '980 Patent.

87. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing and from actively inducing or contributing to the infringement of the '980 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '980 PATENT

88. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–87 as if fully set forth herein.

89. Plaintiffs own all rights, title, and interest in and to the '980 Patent.

90. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

91. On information and belief, MTI has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, offer to sell, and sell the MTI ANDA Products prior to the expiration of the '980 Patent.

92. MTI's continued pursuit of the Mylan ANDA, commercial manufacture, use, offer to sell, and sale within the United States of the ANDA Products would infringe at least claim 17 of the '980 Patent, either literally or under the doctrine of equivalents. Accordingly, unless enjoined by this Court, upon FDA approval of the Mylan ANDA, MTI will commercially manufacture, use, offer to sell, and sell the Mylan ANDA Products within the United States and will thereby infringe one or more claims of the '980 Patent.

93. MTI did not contest infringement of any claims of the '980 Patent in the October 27, 2022 Notice Letter. Further, MTI did not contest infringement for at least claim 17 of the '980 Patent in its February 27, 2017 Notice Letter. If MTI had a factual or legal basis to contest infringement of all claims of the '980 Patent in light of its ANDA amendment, it was required by applicable regulations to state such a basis in the October 27, 2022 and February 27, 2017 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

94. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MTI regarding whether MTI's continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offers to sell and sale of the MTI ANDA Products will infringe one or more claims of the '980 Patent.

95. Plaintiffs should be granted a declaratory judgment that the continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offer to sell or sale of the MTI ANDA Products would infringe one or more claims of the '980 Patent.

96. On information and belief, when MTI amended its ANDA, it modified, added, removed, and altered components in the MTI ANDA Products and steps that are used in their manufacture, so as to alter the infringement analysis with respect to at least claim 17 of the '980 Patent, as compared with MTI's ANDA Product as described in its ANDA as of May 27, 2020.

97. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing the '980 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT V: INFRINGEMENT OF THE '589 PATENT

98. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–97 as if fully set forth herein.

99. Plaintiffs own all rights, title, and interest in and to the '589 Patent.

100. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

101. MTI has infringed at least claims 1–24 of the '589 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claims not previously adjudicated in the Actavis Action or Vermont -128 Action judgments, by submitting and continuing to pursue the MTI ANDA and amendments and by submitting a Paragraph IV certification seeking FDA approval prior to the expiration of the '589 Patent.

102. MTI's commercial manufacture, use, sale, or offer for sale, in the United States of the MTI ANDA Products would directly infringe and would actively induce and contribute to infringement of the '589 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the MTI ANDA and amendments, MTI will make, use, offer to sell, or sell the MTI ANDA Products within the United States and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '589 Patent.

103. On information and belief, MTI has actual and constructive notice of the '589 Patent. MTI is aware that maintaining the MTI ANDA with the request for FDA approval prior to the expiration of the '589 Patent constitutes an act of infringement of the '589 Patent.

104. MTI did not contest infringement of any claims of the '589 Patent in the October 27, 2022 Notice Letter. Further, MTI did not contest infringement for any claim of the '589 Patent in its July 29, 2019 Notice Letter. If MTI had a factual or legal basis to contest infringement of the claims of the '589 Patent in light of its ANDA amendment, it was required by applicable

regulations to state such a basis in the October 27, 2022 and July 29, 2019 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

105. In prior litigation involving the MTI ANDA and MTI's ANDA Products, MTI stipulated to infringement of the '589 Patent and stated that it "will not contest allegations of infringement for Claims 1-3, 4, 7, and 10-12 of the '589 patent . . . ." ECF No. 97 at 2, No. 19-cv-128-CR (D. Vt. May 13, 2020); ECF No. 98, No. 19-cv-128-CR (D. Vt. May 13, 2020) (adopting proposed stipulation without modification); ECF No. 138, No. 19-cv-128-CR (D. Vt. June 8, 2021) ("Mylan has stipulated to infringement of . . . Claims 1, 2, 3, 4, 6, 7, 10, 11, 12, 13, 14, 19, and 20 of the '589 Patent.").

106. MTI has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '589 Patent. In addition, MTI has maintained the MTI ANDA and amendments without adequate justification for asserting the '589 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products. MTI's conduct and continued pursuit of the MTI ANDA and amendments despite its infringement of the '589 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

107. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for MTI's ANDA to be a date that is not any earlier than the expiration date of the '589 Patent, including any extensions, adjustments, and exclusivities associated with the '589 Patent.

108. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '589 Patent. Plaintiffs do not have

an adequate remedy at law, and considering the balance of hardships between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '589 PATENT

109. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–108 as if fully set forth herein.

110. Plaintiffs own all rights, title, and interest in and to the '589 Patent.

111. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

112. On information and belief, MTI has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, offer to sell, and sell the MTI ANDA Products prior to the expiration of the '589 Patent.

113. MTI's continued pursuit of the Mylan ANDA, commercial manufacture, use, offer to sell, and sale within the United States of the ANDA Products would infringe at least claims 1–24 of the '589 Patent, either literally or under the doctrine of equivalents, including claims not previously adjudicated in the Actavis Action or Vermont -128 Action judgments. Accordingly, unless enjoined by this Court, upon FDA approval of the Mylan ANDA, MTI will commercially manufacture, use, offer to sell, and sell the Mylan ANDA Products within the United States and will thereby infringe one or more claims of the '589 Patent.

114. MTI did not contest infringement of any claims of the '589 Patent in the October 27, 2022 Notice Letter. Further, MTI did not contest infringement for any claim of the '589 Patent

in its July 29, 2019 Notice Letter. If MTI had a factual or legal basis to contest infringement of the claims of the '589 Patent in light of its ANDA amendment, it was required by applicable regulations to state such a basis in the October 27, 2022 and July 29, 2019 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

115. In prior litigation involving the MTI ANDA and MTI's ANDA Product, MTI stipulated to infringement of the '589 Patent and stated that it "will not contest allegations of infringement for Claims 1-3, 4, 7, and 10-12 of the '589 patent . . . ." ECF No. 97 at 2, No. 19-cv-128-CR (D. Vt. May 13, 2020); ECF No. 98, No. 19-cv-128-CR (D. Vt. May 13, 2020) (adopting proposed stipulation without modification); ECF No. 138, No. 19-cv-128-CR (D. Vt. June 8, 2021) ("Mylan has stipulated to infringement of . . . Claims 1, 2, 3, 4, 6, 7, 10, 11, 12, 13, 14, 19, and 20 of the '589 Patent.").

116. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MTI regarding whether MTI's continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offers to sell, and sale of the MTI ANDA Products will infringe one or more claims of the '589 Patent.

117. Plaintiffs should be granted a declaratory judgment that the continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offer to sell or sale of the MTI ANDA Products would infringe one or more claims of the '589 Patent.

118. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing the '589 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VII: INFRINGEMENT OF THE '174 PATENT

119. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–118 as if fully set forth herein.

120. Plaintiffs own all rights, title, and interest in and to the '174 Patent.

121. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

122. MTI has infringed at least claims 1–6 and 8–16 of the '174 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting and continuing to pursue the MTI ANDA and amendments and by submitting a Paragraph IV certification seeking FDA approval prior to the expiration of the '174 Patent.

123. MTI's commercial manufacture, use, sale, or offer for sale in the United States of the MTI ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '174 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of the MTI ANDA and amendments, MTI will make, use, offer to sell, or sell the MTI ANDA Products within the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '174 Patent.

124. On information and belief, MTI has actual and constructive notice of the '174 Patent. MTI is aware that maintaining the MTI ANDA with the request for FDA approval prior to the expiration of the '174 Patent constitutes an act of infringement of the '174 Patent.

125. MTI did not contest infringement of any claims of the '174 Patent in the October 27, 2022 Notice Letter. Further, MTI did not contest infringement of at least claims 1–6 and 8–15 in its July 29, 2019 Notice Letter. If MTI had a factual or legal basis to contest infringement of the

claims of the '174 Patent in light of its ANDA amendment, it was required by applicable regulations to state such a basis in the October 27, 2022 and July 29, 2019 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

126. In prior litigation involving the MTI ANDA and MTI's ANDA Products, MTI stipulated to infringement of the '174 Patent and stated that it "will not contest allegations of infringement for . . . Claims 1-2, 5-6 and 14-15 of the '174 Patent." ECF No. 97 at 2, No. 19-cv-128-CR (D. Vt. May 13, 2020); ECF No. 98, No. 19-cv-128-CR (D. Vt. May 13, 2020) (adopting proposed stipulation without modification); ECF No. 138, No. 19-cv-128-CR (D. Vt. June 8, 2021) ("Mylan has stipulated to infringement of . . . Claims 1, 2, 4, 5, 6, 8, 9, 14, and 15 of the '174 Patent.").

127. MTI has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '174 Patent. In addition, MTI has maintained the MTI ANDA and amendments without adequate justification for asserting the '174 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the MTI ANDA Products. MTI's conduct and continued pursuit of the MTI ANDA and amendments despite its infringement of the '174 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

128. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for MTI's ANDA to be a date that is not any earlier than the expiration date of the '174 Patent, including any extensions, adjustments, and exclusivities associated with the '174 Patent.

129. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing and from actively inducing or contributing to the infringement of the '174 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '174 PATENT

130. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–129 as if fully set forth herein.

131. Plaintiffs own all rights, title, and interest in and to the '174 Patent.

132. On information and belief, MTI submitted the MTI ANDA and amendments and continues to seek both FDA approval of the MTI ANDA and amendments and to manufacture, use, offer to sell, and sell the MTI ANDA Products before the expiration of the Neupro® Listed Patents.

133. On information and belief, MTI has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, offer to sell, and sell the MTI ANDA Products prior to the expiration of the '174 Patent.

134. MTI's continued pursuit of the Mylan ANDA, commercial manufacture, use, offer to sell, and sale within the United States of the ANDA Products would infringe at least claims 1–6 and 8–16 of the '174 Patent, either literally or under the doctrine of equivalents. Accordingly, unless enjoined by this Court, upon FDA approval of the Mylan ANDA, MTI will commercially manufacture, use, offer to sell, and sell the Mylan ANDA Products within the United States, and will thereby infringe one or more claims of the '174 Patent.

135. MTI did not contest infringement of any claims of the '174 Patent in the October 27, 2022 Notice Letter. Further, MTI further did not contest infringement of at least claims 1–6 and 8–15 in its July 29, 2019 Notice Letter. If MTI had a factual or legal basis to contest infringement of the claims of the '174 Patent in light of its ANDA amendment, it was required by applicable regulations to state such a basis in the October 27, 2022 and July 29, 2019 Notice Letters. *See* 21 C.F.R. § 314.95(c)(7).

136. In prior litigation involving the MTI ANDA and MTI's ANDA Products, MTI stipulated to infringement of the '174 Patent and stated that it "will not contest allegations of infringement for . . . Claims 1-2, 5-6 and 14-15 of the '174 Patent." ECF No. 97 at 2, No. 19-cv-128-CR (D. Vt. May 13, 2020); ECF No. 98, No. 19-cv-128-CR (D. Vt. May 13, 2020) (adopting proposed stipulation without modification); ECF No. 138, No. 19-cv-128-CR (D. Vt. June 8, 2021) ("Mylan has stipulated to infringement of . . . Claims 1, 2, 4, 5, 6, 8, 9, 14, and 15 of the '174 Patent").

137. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MTI regarding whether MTI's continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offers to sell, and sale of the MTI ANDA Products will infringe one or more claims of the '174 Patent.

138. Plaintiffs should be granted a declaratory judgment that the continued pursuit of the MTI ANDA and amendments, commercial manufacture, use, offer to sell, or sale of the MTI ANDA Products would infringe one or more claims of the '174 Patent.

139. Plaintiffs will be irreparably harmed if MTI is not enjoined from infringing the '174 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships

between Plaintiffs and MTI, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) The entry of judgment, in favor of Plaintiffs and against MTI, that MTI, through its submission and continued pursuit of ANDA No. 209982 and amendments to FDA seeking to market the MTI ANDA Products, has infringed the '979, '980, '589, and '174 Patents pursuant to 35 U.S.C. § 271(e)(2)(A);

(B) The entry of judgment, in favor of Plaintiffs and against MTI, declaring that the making, using, selling, or offering to sell the MTI ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the '979, '980, '589, and '174 Patents pursuant to 35 U.S.C. §§ 271(a), (b), and (c);

(C) The entry of a permanent injunction, enjoining MTI and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons acting in concert, participation, or in privity with MTI, and their successors or assigns, from infringing, inducing infringement of, and contributing to the infringement of any claims of the '979, '980, '589, and '174 Patents by making, using, offering for sale, selling, or importing the MTI ANDA Products in the United States;

(D) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 209982 shall be a date that is not earlier than the last expiration date of the '979, '980, '589, and '174 Patents, or any later expiration of exclusivity thereof, including any extensions or regulatory exclusivities;

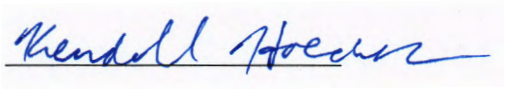
(E) An award of damages to Plaintiffs in the event that MTI engages in the commercial manufacture, use, sale, or offer to sell the Mylan ANDA Products before the expiration of the '979, '980, '589, and '174 Patents, and trebling Plaintiffs' damages award pursuant to 35 U.S.C. § 285;

(F) The entry of judgment declaring that MTI's acts render this case an exceptional case, and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(G) An award to Plaintiffs of their costs and expenses in this action; and

(H) Such other and further relief as the Court deems just and proper.

Dated at Burlington, Vermont this 12th day of December 2022.

By: 

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