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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAXTER HEALTHCARE CORP. and CYDEX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

PH HEALTH LTD., PAR HEALTH USA, ENDO USA, INC., ENDO OPERATIONS LIMITED, and ENDO, INC.,

Defendants.

Civil Action No. 3:25-15120

COMPLAINT FOR PATENT INFRINGEMENT

Document Electronically Filed

COMPLAINT

Plaintiffs Baxter Healthcare Corp. ("Baxter") and CyDex Pharmaceuticals, Inc. ("CyDex") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants PH Health Ltd. ("PHL"), Par Health USA ("PH USA," and together with PHL, "Par Health"), Endo USA, Inc. ("Endo USA"), Endo Operations Limited ("EOL,") and Endo, Inc. (together with Endo USA and EOL, "Endo") (all defendants collectively, "Par" or "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Defendants of Abbreviated New Drug Application ("ANDA") No. 219703 ("Par's ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of the commercial pharmaceutical product NEXTERONE® (amiodarone HCl) Premixed Injection for intravenous use, submitted under New Drug Application ("NDA") No. 022325, prior to the expiration of United States Patent No. 7,635,773 ("the '773 patent") (attached as Exhibit A hereto) that is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for NEXTERONE®. Defendants notified Plaintiffs that they had submitted Par's ANDA by a letter dated July 16, 2025 ("Notice Letter"). On information and belief, Defendants submitted Par's ANDA which seeks approval to market its generic version of NEXTERONE® (Amiodarone Hydrochloride Injection, 150 mg/100 mL (1.5 mg/mL)) ("Defendants' ANDA Product") prior to the expiration of the '773 patent. On information and belief, if Par's ANDA is approved by FDA, Defendants' ANDA Product will be marketed as a competing product to NEXTERONE®.

THE PARTIES

2. Plaintiff Baxter is a corporation organized and existing under the laws of the State of Delaware, with offices at One Baxter Parkway, Deerfield, Illinois 60015.

3. Plaintiff CyDex is a corporation organized and existing under the laws of the State of Delaware, with offices at 3911 Sorrento Valley Blvd, Suite 110, San Diego, California 92121.

4. Baxter is the holder of New Drug Application No. 022325 for NEXTERONE® (amiodarone HCl) Premixed Injection for intravenous use, which has been approved as an antiarrhythmic agent for treatment and prophylaxis of ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy.

5. Baxter's NEXTERONE® is sold and marketed in the United States under FDA approval of NDA No. 022325.

6. On information and belief, defendant PHL is a company organized and existing under the laws of Ireland with offices located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, D04 H9P8, Ireland. On information and belief, PHL is a wholly-owned subsidiary of EOL and a wholly-owned indirect subsidiary of Endo, Inc.

7. On information and belief, defendant PH USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 9 Great Valley Parkway, Malvern, Pennsylvania 19355. On information and belief, defendant PH USA is a wholly-owned subsidiary of Endo USA and a wholly-owned indirect subsidiary of Endo, Inc.

8. On information and belief, defendant EOL is a company organized and existing under the laws of Ireland with offices located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, D04 H9P8, Ireland. Upon information and belief, EOL is a wholly-owned indirect subsidiary of Endo, Inc.

9. On information and belief, EOL is an affiliate of defendant Endo USA which is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 9 Great Valley Parkway, Malvern, Pennsylvania 19355. On information and belief, Endo USA is a wholly-owned indirect subsidiary of Endo, Inc.

10. On information and belief, Endo USA maintains a regular and established place of business at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677.

11. On information and belief, defendant Endo, Inc. is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 9 Great Valley Parkway, Malvern, Pennsylvania 19355. On information and belief, Endo, Inc. is a publicly-traded company that has no parent corporation and is the only publicly-traded company that owns 10% or more of the stock of EOL, Endo USA, PHL, and PH USA.

12. On information and belief, Endo Inc. maintains a regular and established place of business at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677.

13. On information and belief, Defendants are in the business of, *inter alia*, developing, manufacturing, marketing, distributing, and directly and/or indirectly selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

14. On information and belief, following any approval of Par's ANDA, Defendants will act in concert to distribute and sell Defendants' ANDA Product throughout the United States, including within New Jersey.

15. On information and belief, following any approval of Par's ANDA, Defendants intend to benefit directly if Par's ANDA is approved by participating in the development,

regulatory approval, marketing, manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

JURISDICTION AND VENUE

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

17. This Court has personal jurisdiction over Defendants under Fed. R. Civ. P. 4(k)(1), Fed. R. Civ. P. 4(k)(2), and N.J. Ct. R. 4:4-4.

18. This Court has personal jurisdiction over the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States. For example, on information and belief, by and through PHL, Defendants prepared and submitted Par's ANDA to FDA in New Jersey. Further, on information and belief, following approval of Par's ANDA, Defendants will make, use, import, sell, and/or offer for sale Defendants' ANDA Product in the United States, including in New Jersey, prior to the expiration of the '773 patent.

19. This Court has personal jurisdiction over PHL because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) PHL is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) PHL has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over PHL satisfies due process.

20. In the alternative, this Court has personal jurisdiction over PHL at least because, among other things, PHL has purposely availed itself of the benefits and protections of New Jersey

laws such that it should reasonably anticipate being haled into court here. On information and belief: (i) PHL sent the Notice Letter containing a paragraph IV patent certification regarding Par's ANDA No. 219703, signed by Gina R. Gencarelli, Executive Director of Intellectual Property at Endo, located in New Jersey at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677; (ii) PHL is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) PHL is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) PHL has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) PHL has purposefully directed its activities at residents and corporate entities within the State of New Jersey; (vi) the claims set forth herein as to PHL arise out of or relate to those activities; (vii) PHL's contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; (viii) it is reasonable and fair for this Court to exercise personal jurisdiction over PHL; (ix) if Par's ANDA receives final approval, Defendants' ANDA Product will be marketed and distributed by PHL in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. In addition, PHL is subject to personal jurisdiction in New Jersey because, upon information and belief, it is controlled by Endo, and therefore, the activities of Endo in this jurisdiction are attributed to PHL.

21. This Court has personal jurisdiction over PH USA at least because, among other things, PH USA has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being haled into court here. On information and belief: (i) PH USA is listed as the agent authorized to accept service of process in the Notice Letter regarding Par's ANDA No. 219703; (ii) the Notice Letter was signed by Gina R. Gencarelli,

Executive Director of Intellectual Property at Endo, located in New Jersey at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677; (iii) PH USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iv) PH USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0451303144; (v) PH USA is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (vi) PH USA has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (vii) PH USA has purposefully directed its activities at residents and corporate entities within the State of New Jersey; (viii) the claims set forth herein as to PH USA arise out of or relate to those activities; (ix) PH USA's contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; (x) it is reasonable and fair for this Court to exercise personal jurisdiction over PH USA; and (xi) if Par's ANDA receives final approval, Defendants' ANDA Product will be marketed and distributed by PH USA in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. In addition, PH USA is subject to personal jurisdiction in New Jersey because, upon information and belief, it is controlled by Endo, and therefore, the activities of Endo in this jurisdiction are attributed to PH USA.

22. This Court has personal jurisdiction over Endo USA at least because, among other things, Endo USA has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being haled into court here. On information and belief: (i) the Notice Letter containing a paragraph IV patent certification regarding Par's ANDA No. 219703 was sent on Endo letterhead by Gina R. Gencarelli, Executive Director of Intellectual

Property at Endo, located in New Jersey at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677; (ii) Endo USA maintains a regular place of business in New Jersey located at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677; (iii) Endo USA maintains a manufacturing facility in New Jersey located at 8 Clarke Drive, Cranbury, New Jersey 08512; (iv) Endo USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (v) Endo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0451072158; (vi) Endo USA is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer and wholesaler" with Registration Number 5006471; (vii) Endo USA is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (viii) Endo USA has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (ix) if Par's ANDA receives final approval, Defendants' ANDA Product will be marketed and distributed by Endo USA in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

23. This Court has personal jurisdiction over EOL because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) EOL is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) EOL has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over EOL satisfies due process.

24. In the alternative, this Court has personal jurisdiction over EOL at least because, among other things, EOL has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being haled into court here. On information and belief: (i) the Notice Letter containing a paragraph IV patent certification regarding Par's ANDA No. 219703 was sent on Endo letterhead by Gina R. Gencarelli, Executive Director of Intellectual Property at Endo, located in New Jersey at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677; (ii) EOL is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) EOL is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) EOL has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) EOL has purposefully directed its activities at residents and corporate entities within the State of New Jersey; (vi) the claims set forth herein as to EOL arise out of or relate to those activities; (vii) EOL's contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; (viii) it is reasonable and fair for this Court to exercise personal jurisdiction over EOL; (ix) if Par's ANDA receives final approval, Defendants' ANDA Product will be marketed and distributed by EOL in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

25. This Court has personal jurisdiction over Endo, Inc. at least because, among other things, Endo, Inc. has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being haled into court here. On information and belief: (i) the Notice Letter containing a paragraph IV patent certification regarding Par's ANDA No. 219703 was sent on Endo letterhead by Gina R. Gencarelli, Executive Director of Intellectual

Property at Endo, located in New Jersey at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677; (ii) Endo Inc. maintains a regular place of business in New Jersey located at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677; (iii) Endo, Inc. is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iv) Endo, Inc. is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (v) Endo, Inc. has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (vi) Endo, Inc. has purposefully directed its activities at residents and corporate entities within the State of New Jersey; (vii) the claims set forth herein as to Endo, Inc. arise out of or relate to those activities; (viii) Endo, Inc.'s contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; (ix) it is reasonable and fair for this Court to exercise personal jurisdiction over Endo, Inc.; (x) if Par's ANDA receives final approval, Defendants' ANDA Product will be marketed and distributed by Endo, Inc. in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

26. On information and belief, PHL intends to benefit directly if Par's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

27. On information and belief, PH USA intends to benefit directly if Par's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

28. On information and belief, Endo USA intends to benefit directly if Par's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of

Defendants' ANDA Product.

29. On information and belief, EOL intends to benefit directly if Par's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

30. On information and belief, Endo, Inc. intends to benefit directly if Par's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product.

31. On information and belief, Defendants acted collaboratively in the preparation and submission of Par's ANDA to FDA. On information and belief, Defendants work in privity and in concert with respect to regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including Defendants' ANDA Product, throughout the United States, including in this Judicial District, prior to the expiration of the '773 patent.

32. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if Par's ANDA receives final approval, Defendants' ANDA Product will be manufactured, sold, distributed, and/or used by Defendants in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

33. On information and belief, Defendants' acts of preparing and filing Par's ANDA and directing notice of their ANDA submission to Plaintiffs are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Defendants' ANDA Product before the expiration of the '773 patent throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an essential and expected part of an ANDA filer's business, Defendants reasonably anticipate being sued in New Jersey.

34. Par's ANDA filing implicating the '773 patent directly relates to this litigation and is substantially connected with this Judicial District because it reliably and non-speculatively predicts Defendants' intent to market and sell Defendants' ANDA Product in this Judicial District.

35. Defendants have taken the significant step of applying to FDA for approval to engage in future activities—including the marketing of Defendants' ANDA Product—which, upon information and belief, will be purposefully directed at this Judicial District.

36. On information and belief, Defendants will market Defendants' ANDA Product in New Jersey upon receiving final FDA approval of Par's ANDA.

37. On information and belief, Defendants have thus been, and continue to be, joint actors in the drafting, submission, approval, and maintenance of Par's ANDA and intend to benefit from Par's ANDA upon receiving final FDA approval.

38. For the reasons described above, among others, the filing of Par's ANDA was suit-related conduct with a substantial connection to New Jersey and this District, the exercise of personal jurisdiction over Defendants does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Defendants.

39. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

40. Baxter Healthcare Corp. is the holder of NDA No. 022325, which was approved by FDA for the manufacture and sale of NEXTERONE®. NEXTERONE ® is the trade name for amiodarone HCl Premixed Injection for intravenous use and is approved as an antiarrhythmic agent indicated for treatment and prophylaxis of VF and hemodynamically unstable VT in patients refractory to other therapy.

41. On December 24, 2008, FDA approved NEXTERONE® (amiodarone HCl)

Injection for intravenous use (50 mg/mL).

42. On November 16, 2010, FDA approved Supplemental New Drug Application (sNDA) for NEXTERONE® (amiodarone HCl) Premixed Injection for intravenous use (150 mg/100 ml and 360 mg/200 ml) (NDA 022325/S-001). Baxter is the holder of NDA No. 022325/S-001.

43. Baxter launched NEXTERONE® as the first and only ready-to-use premixed intravenous (IV) bag version of amiodarone in the United States in June 2011.

44. Pursuant to 21 U.S.C. § 355(b)(1), the '773 patent is listed in the Orange Book as covering the NEXTERONE® product.

45. CyDex is the assignee of the '773 patent.

46. CyDex entered into the License Agreement and a companion Supply Agreement with Prism Pharmaceuticals, Inc. ("Prism") for the development and sale of NEXTERONE®.

47. Baxter acquired Prism in 2011, thereby becoming the owner of all of Prism's rights, title and interest in and to NEXTERONE®, including ownership of NDA 022325.

48. Baxter holds exclusive rights to certain CyDex-owned patents and intellectual property, including the '773 patent, to develop, market, manufacture, make, have made, use, distribute, commercialize, sell, offer to sell, import and export Captisol-enabled® Amiodarone and all formulations for all uses in humans and animals.

49. The '773 patent, titled "SULFOALKYL ETHER CYCLODEXTRIN COMPOSITIONS" was duly and legally issued on December 22, 2009 to CyDex. The '773 patent is generally directed to sulfoalkyl ether cyclodextrin compositions.

50. On information and belief, pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), Defendants have prepared, submitted,

and filed with FDA, and FDA has received, Par's ANDA, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Defendants' ANDA Product before the expiration of the '773 patent throughout the United States, including in this Judicial District.

51. On information and belief, Defendants will market and distribute Defendants ANDA Product throughout the United States, if approved.

52. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(7)(i)–(ii).

53. PHL sent the Notice Letter to Baxter and CyDex purporting to provide notification that Par's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the '773 patent.

54. On information and belief, Defendants jointly developed Defendants' ANDA Product and jointly sought approval from FDA to sell Defendants' ANDA Product throughout the United States, including within this Judicial District.

55. On information and belief, Defendants jointly prepared and submitted Par's

ANDA and are jointly prosecuting and maintaining Par's ANDA.

56. There is an actual case or controversy between the parties regarding Defendants' liability for their infringement of the '773 patent.

57. This action is being filed within 45 days of Plaintiffs' receipt of Par's Notice Letter.

58. On information and belief, the Notice Letter does not disclose any invalidity contentions or opinions for the '773 patent.

59. On information and belief, the Notice Letter does not disclose any unenforceability contentions for the '773 patent.

60. On information and belief, the Notice Letter does not provide a full and detailed explanation of Defendants' factual and legal basis of noninfringement, invalidity and/or unenforceability for any claim of any patent for which Defendants have made a paragraph IV certification.

FIRST COUNT
(Infringement of the '773 Patent by Defendants)

61. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

62. On information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of Defendants' ANDA Product.

63. On information and belief, in connection with Par's ANDA, Defendants submitted a paragraph IV certification to the '773 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product before the expiration of the '773 patent.

64. On information and belief, Defendants will commercially manufacture, sell, offer

for sale, and/or import Defendants' ANDA Product upon FDA approval of Par's ANDA.

65. On information and belief, as of the date of the Notice Letter, Defendants were aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

66. The inclusion of a paragraph IV certification to the '773 patent in Par's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Product before the expiration of the '773 patent is an act of infringement by Defendants of one or more claims of the '773 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, literally or under the doctrine of equivalents, including by inducement and/or contributory infringement.

67. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' ANDA Product that is the subject of Par's ANDA will infringe one or more claims of the '773 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

68. On information and belief, Defendants are aware of the existence of the '773 patent at least because the '773 patent is listed in the FDA's Orange Book for Baxter's NEXTERONE® drug product. On information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringement of the '773 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

69. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

i. A judgment declaring that the ’773 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to FDA and filing of Par’s ANDA with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Par’s ANDA was an act of infringement of the ’773 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Par’s ANDA prior to the expiration of the ’773 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of Par’s ANDA shall be no earlier than the date on which the ’773 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of Par’s ANDA until the expiration of the ’773 patent including any regulatory extensions;

vi. A judgment awarding Plaintiffs damages or other monetary relief, pursuant to

35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Par's ANDA that infringes the '773 patent;

vii. A judgment declaring that infringement of the '773 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Par's ANDA that infringes the '773 patent;

viii. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys' fees and costs;

ix. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: August 29, 2025
Newark, New Jersey

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