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

HORIZON MEDICINES LLC and NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD.,

Defendants.

Civil Action No. 15-cv-03324 (SRC) (CLW)

THIRD AMENDED COMPLAINT FOR PATENT INFRINGEMENT

JURY TRIAL DEMANDED

Plaintiffs Horizon Medicines LLC and Nuvo Pharmaceuticals (Ireland) Designated Activity Company (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Horizon Medicines LLC ("Horizon") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015.

2. Plaintiff Nuvo Pharmaceuticals (Ireland) Designated Activity Company ("Nuvo") is a corporation operating and existing under the laws of Ireland, with its principal place of business at 88 Harcourt Street, Dublin 2, DO2 DK18.

3. On information and belief, Defendant Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at 107 College Road East, Princeton, NJ 08540.

4. On information and belief, Defendant Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500 034.

5. On information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd.

BACKGROUND

The NDA

6. Horizon is the holder of New Drug Application ("NDA") No. 022511 for VIMOVO® (naproxen and esomeprazole magnesium) Delayed-Release Tablets, in 375 mg

(naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

7. VIMOVO® Delayed-Release Tablets are prescription drugs approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO® Delayed-Release Tablets.

The Patents-in-Suit

8. United States Patent No. 8,858,996 ("the '996 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 14, 2014. The claims of the '996 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen and methods comprising administration of the aforementioned compositions. A true and correct copy of the '996 patent is attached as Exhibit A.

9. Nuvo owns the '996 patent by assignment. Horizon is Nuvo's exclusive licensee under the '996 patent. The '996 patent will expire on May 31, 2022.

10. The '996 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

11. United States Patent No. 9,161,920 ("the '920 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 20, 2015. The claims of the '920 patent are directed to methods of administering a pharmaceutical composition in unit dose form comprising naproxen and esomeprazole. A true and correct copy of the '920 patent is attached as Exhibit B.

12. Nuvo owns the '920 patent by assignment. Horizon is Nuvo's exclusive licensee under the '920 patent. The '920 patent will expire on May 31, 2022.

13. The '920 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

The ANDA

14. On information and belief, Defendants filed ANDA No. 204206 ("ANDA II") with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and sale in the United States of naproxen and esomeprazole magnesium delayed-release tablets containing 375 mg or 500 mg of naproxen and 20.71 mg esomeprazole magnesium ("ANDA II Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

15. By letter dated November 20, 2012 (the "ANDA II Notice Letter"), Defendants notified AstraZeneca AB and Pozen that Defendants had filed ANDA No. 204206 seeking approval to market the ANDA II Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

16. On information and belief, ANDA II received final approval on February 18, 2020.

17. On February 27, 2020, Defendants issued a press release entitled, "Dr. Reddy's Laboratories announces the first generic launch of Naproxen and Esomeprazole Magnesium Delayed-Release Tablets in the U.S. Market." Exhibit C.

18. On information and belief, Defendants are now making, using, offering to sell, and/or selling the ANDA II Product within the United States.

JURISDICTION AND VENUE

19. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

20. On information and belief, Defendants have been and are engaging in activities directed toward infringement of the '996 and '920 patents (collectively, the "patents-in-suit") by, inter alia, submitting to the FDA ANDA No. 204206, receiving final approval to market the ANDA II Product, and launching the ANDA II Product at risk.

21. Defendants' ANDA II Notice Letter states Defendants' intention to seek FDA approval to market a generic version of the VIMOVO® product before the expiration of the patents-in-suit.

22. There is an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '996 and '920 patents.

23. On information and belief, Dr. Reddy's Inc. is a corporation organized and existing under the laws of the State of New Jersey. By virtue of its incorporation in New Jersey, this Court has personal jurisdiction over Dr. Reddy's Inc.

24. On information and belief, Defendants are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing pharmaceutical products.

25. On information and belief, Dr. Reddy's Ltd., either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

26. On information and belief, Dr. Reddy's Inc., with the assistance and/or at the direction of Dr. Reddy's Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

27. On information and belief, Defendants acted in concert to develop the ANDA II Product and to seek approval from the FDA to sell the ANDA II Product throughout the United States, including within this judicial district.

28. On information and belief, both Dr. Reddy's Ltd. and Dr. Reddy's Inc. participated in the preparation and/or filing of ANDA No. 204206.

29. On information and belief and as stated in the ANDA II Notice Letter, the FDA received ANDA No. 204206 from Dr. Reddy's Ltd. and Dr. Reddy's Inc.

30. In their ANDA II Notice Letter, Defendants stated that the name and address of their agent in the United States authorized to accept service of process for Defendants for purposes of an infringement action based upon the ANDA II Notice Letter is Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807.

31. By naming Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 as their agent in the ANDA II Notice Letter, Defendants have consented to jurisdiction in the State of New Jersey for this action.

32. On information and belief, by virtue of, inter alia, Dr. Reddy's Ltd.'s relationship with Dr. Reddy's Inc. in connection with the preparation and/or filing of ANDA No. 204206; Dr. Reddy's Ltd.'s designation of Lee Banks, Dr. Reddy's Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 as its agent for service of process; and the sales-related activities of Defendants in New Jersey, including but not limited to the substantial, continuous, and

systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has personal jurisdiction over Dr. Reddy's Ltd.

33. On information and belief, Defendants have previously been sued in this district and have not challenged personal jurisdiction. See, e.g., Wyeth LLC v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., Civ. Action No. 3:10-cv-04551-FLW-DEA (D.N.J.); Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., Civ. Action No. 2:09-cv-04638-GEB-MCA (D.N.J.); Sepracor, Inc. v. Teva Pharm. USA, Inc., et al., Civ. Action No. 2:09-cv-01302-DMC-MF (D.N.J.); Hoffman-La Roche Inc. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., Civ. Action No. 2:08-cv-04055-SRC-MAS (D.N.J.); AstraZeneca AB et al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., Civil Action No. 3:08-cv-00328-JAP-TJB (D.N.J.); and AstraZeneca AB et al. v. Dr. Reddy's Labs, Inc. and Dr. Reddy's Labs., Ltd., Civil Action Nos. 3:11-cv-02317-JAP-DEA (D.N.J.) and 3:13-cv-00091-JAP-DEA (D.N.J.).

34. On information and belief, both Defendants Dr. Reddy's Ltd. and Dr. Reddy's Inc. have admitted that each is subject to personal jurisdiction in this district. See, e.g., AstraZeneca UK Ltd. and AstraZeneca Pharms. LP v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., 3:08-cv-03237-MLC-TJB (D.N.J.), Answer to Complaint, ¶ 8 (July 11, 2008); AstraZeneca AB et al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., 3:11-cv-02317-JAP-DEA (D.N.J.), Answer to Second Amended Complaint, ¶ 29.

35. On information and belief, Defendants have availed themselves of the jurisdiction of this Court by initiating litigation in this district. See, e.g., Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. Eli Lilly & Co., Civ. Action No. 3:09-0192-GEB-LHG (D.N.J.); and Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. AstraZeneca AB et al., Civil Action No. 3:08-cv-02496-JAP-TJB (D.N.J.).

36. On information and belief, Defendants are making, using, offering to sell, and/ or selling the ANDA II Product throughout the United States, including within this judicial district.

37. On information and belief, by virtue of, inter alia, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 204206, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

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

COUNT I
(INFRINGEMENT OF THE '996 PATENT UNDER 35 U.S.C. § 271(e)(2))

39. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint as if fully set forth herein.

40. The '996 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

41. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '996 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

42. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, inter alia, certification by the ANDA applicant that the subject patent in the Orange Book, here the '996 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that

the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, inter alia, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of 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."

43. On information and belief, Defendants were aware of the statutory provisions and regulations referred to above when they served the ANDA II Notice Letter regarding certain patents.

44. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204206 seeking, inter alia, FDA final approval prior to the expiration of the '996 patent. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204206 before the '996 patent expires.

45. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA II Product infringes the '996 patent.

46. Defendants have infringed, either literally or under the doctrine of equivalents, the '996 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204206 and seeking approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug claimed in the '996 patent before the expiration of the '996 patent.

47. On information and belief, Defendants' ANDA II Product includes an enteric coated naproxen core and an immediate release esomeprazole magnesium layer surrounding the

core and therefore contains the pharmaceutical composition patented in the '996 patent, is a material for use in practicing the methods patented in the '996 patent, constitutes a material part of the inventions of the '996 patent, is especially made or especially adapted for use in an infringement of the '996 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA II Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA II Product will be used in contravention of Plaintiffs' rights under the '996 patent.

48. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '996 patent under 35 U.S.C. § 271(e)(2).

49. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II
(INFRINGEMENT OF THE '996 PATENT UNDER 35 U.S.C. § 271 (a), (b), and/or (c))

50. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint as if fully set forth herein.

51. On information and belief, Defendants have infringed the '996 Patent, pursuant to 35 U.S.C. § 271 (a), (b), or (c), by engaging in the commercial manufacture, use, offer to sell, sale, or importation of the ANDA II Product prior to the expiration of the '996 Patent.

52. Defendants have had knowledge of and notice of the '996 patent and their infringement before the filing of this complaint. At a minimum, Defendants have had knowledge of and notice of the '996 patent and its infringement since at least, and through, the filing and service of the original complaint in this action and despite this knowledge continue to commit infringing acts.

53. Defendants have engaged and continue to engage in acts of infringement by building inventory of the ANDA II Product for commercial sale within the United States. In addition, on or about February 27, 2020, Defendants commercially launched the ANDA II Product (a therapeutic equivalent generic version of Vimovo®) at risk in the United States, offering the drug for sale, selling the drug, and filling orders for the drug, without regard to the '996 Patent. Defendants' acts of infringement have been a deliberate, willful, and objectively reckless disregard of one or more valid and enforceable patent claims of the '996 Patent.

54. On information and belief, Defendants' ANDA II Product includes an enteric coated naproxen core and an immediate release esomeprazole magnesium layer surrounding the core and therefore contains the pharmaceutical composition patented in the '996 patent, is a material for use in practicing the methods patented in the '996 patent, constitutes a material part of the inventions of the '996 patent, is especially made or especially adapted for use in an infringement of the '996 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA II Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA II Product will be used in contravention of Plaintiffs' rights under the '996 patent.

55. Defendants' infringement of the '996 patent has injured Plaintiffs in their business and property rights. Defendants' infringement has cause Plaintiffs to suffer lost sales, lost market share, price erosion, lost opportunities, and other harm. Plaintiffs are entitled to recover monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial. Defendants' infringement of the '996 patent has caused irreparable harm to Plaintiffs and will continue to cause such harm unless and until Defendants' infringing activities are enjoined by this Court.

56. Defendants' infringement of the '996 patent has been and is deliberate and willful and constitutes egregious misconduct.

57. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
(INFRINGEMENT OF THE '920 PATENT UNDER 35 U.S.C. § 271(e)(2))

58. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint as if fully set forth herein.

59. The '920 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

60. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '920 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

61. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, inter alia, certification by the ANDA applicant that the subject patent in the Orange Book, here the '920 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, inter alia, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of 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."

62. On information and belief, Defendants were aware of the statutory provisions and regulations referred to above when they served the ANDA II Notice Letter regarding certain patents.

63. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204206 seeking, inter alia, FDA final approval prior to the expiration of the '920 patent. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204206 before the '920 patent expires.

64. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA II Product infringes the '920 patent.

65. Defendants have infringed, either literally or under the doctrine of equivalents, the '920 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204206 and seeking approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug claimed in the '920 patent before the expiration of the '920 patent.

66. On information and belief, Defendants' ANDA II Product includes an enteric coated naproxen core and an immediate release esomeprazole magnesium layer surrounding the core and therefore contain the pharmaceutical composition patented in the '920 patent, is a material for use in practicing the methods patented in the '920 patent, constitutes a material part of the inventions of the '920 patent, is especially made or especially adapted for use in an infringement of the '920 patent, and is not a staple article or commodity of commerce suitable for substantial

noninfringing use. On information and belief, Defendants are aware that the ANDA II Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA II Product will be used in contravention of Plaintiffs' rights under the '920 patent.

67. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '920 patent under 35 U.S.C. § 271(e)(2).

68. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV
(INFRINGEMENT OF THE '920 PATENT UNDER 35 U.S.C. § 271 (a), (b), and/or (c))

69. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint as if fully set forth herein.

70. On information and belief, Defendants have infringed the '920 Patent, pursuant to 35 U.S.C. § 271 (a), (b), or (c), by engaging in the commercial manufacture, use, offer to sell, sale, or importation of the ANDA II Product prior to the expiration of the '920 Patent.

71. Defendants have had knowledge of and notice of the '920 patent and their infringement before the filing of this complaint. At a minimum, Defendants have had knowledge of and notice of the '920 patent and its infringement since at least, and through, the filing and service of the Second Amended Complaint in this action and despite this knowledge continue to commit infringing acts.

72. Defendants have engaged and continue to engage in acts of infringement by building inventory of the ANDA II Product for commercial sale within the United States. In addition, on or about February 27, 2020, Defendants commercially launched the ANDA II Product (a therapeutic equivalent generic version of Vimovo®) at risk in the United States, offering the

drug for sale, selling the drug, and filling orders for the drug, without regard to the '920 Patent. Defendants' acts of infringement have been a deliberate, willful, and objectively reckless disregard of one or more valid and enforceable patent claims of the '920 Patent.

73. On information and belief, Defendants' ANDA II Product includes an enteric coated naproxen core and an immediate release esomeprazole magnesium layer surrounding the core and therefore contains the pharmaceutical composition patented in the '920 patent, is a material for use in practicing the methods patented in the '920 patent, constitutes a material part of the inventions of the '920 patent, is especially made or especially adapted for use in an infringement of the '920 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA II Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA II Product will be used in contravention of Plaintiffs' rights under the '920 patent.

74. Defendants' infringement of the '920 patent has injured Plaintiffs in their business and property rights. Defendants' infringement has cause Plaintiffs to suffer lost sales, lost market share, price erosion, lost opportunities, and other harm. Plaintiffs are entitled to recover monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial. Defendants' infringement of the '920 patent has caused irreparable harm to Plaintiffs and will continue to cause such harm unless and until Defendants' infringing activities are enjoined by this Court.

75. Defendants' infringement of the '920 patent has been and is deliberate and willful and constitutes egregious misconduct.

76. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '996 and '920 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 204206 by Defendants infringes one or more claims of the '996 and '920 patents under 35 U.S.C. § 271(e)(2)(A);

C. A judgment that the use, sale, offer for sale, manufacture in the United States and/or importation into the United States by Defendants of the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204206 infringes one or more claims of the '996 and '920 patents under 35 U.S.C. § 271(a), (b), (c);

D. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 204206 shall be no earlier than the expiration date of the '996 and '920 patents or any later exclusivity to which Plaintiffs are or become entitled;

E. An order permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204206 no earlier than the expiration date of the '996 and '920 patents or any later exclusivity to which Plaintiffs are or become entitled;

F. An award of damages pursuant to 35 U.S.C. § 284 plus pre-judgment and post-judgment interest on such damages;

G. An award to Plaintiffs of their costs and reasonable expenses to the fullest extent permitted by law;

H. A determination that Defendants' infringement of the '996 and '920 patents has been willful, and an award of enhanced damages, up to and including trebling of the damages awarded to Plaintiffs;

I. Attorneys' fees in this action pursuant to 35 U.S.C. § 285; and

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

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: June 17, 2020

Respectfully submitted,

By: */s/ John E. Flaherty*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing THIRD AMENDED COMPLAINT were caused to be served on June 17, 2020, by electronic mail and/or the ECF system upon all counsel of record.

By: /s/ John E. Flaherty
John E. Flaherty