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

HORIZON PHARMA, INC. and POZEN INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC.

Defendants.

Civil Action No. 3:15-cv-03327

PLAINTIFFS' DISCLOSURE OF ASSERTED CLAIMS PURSUANT TO L. PAT. R. 3.6(B)



Pursuant to Local Patent Rule 3.6(b), Plaintiffs Horizon Pharma Inc. and Pozen, Inc. (collectively, "Plaintiffs") hereby disclose the asserted claims of U.S. Patent Nos. 9,161,920 ("the '920 patent"), 9,198,888 ("the '888 patent"), and 9,220,698 ("the '698 patent") (collectively, "the asserted patents") to Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, "Mylan Defendants").

## **U.S. PATENT NO. 9,161,920**

- 1. Mylan Defendants infringed claims 1-9, 11-14 of the '920 patent under 35 U.S.C. § 271(e)(2) by filing Abbreviated New Drug Application No. 202654 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '920 patent prior to the expiration of the '920 patent.
- 2. Upon information and belief, unless enjoined by this Court, Mylan Defendants will directly infringe at least claims 1-9, 11-14 of the '920 patent (either literally or under the Doctrine of Equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling their naproxen and esomeprazole magnesium delayed-release tablet product in the United States in violation of 35 U.S.C. § 271(a).
- 3. Upon information and belief, unless enjoined by this Court, Mylan Defendants will induce the infringement of at least claims 1-9, 11-14 of the '920 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs' rights under the '920 patent and in violation of 35 U.S.C. § 271(b).



- 4. Upon information and belief, unless enjoined by this Court, Mylan Defendants will induce the infringement of at least claims 1-9, 11-14 of the '920 patent by actively and intentionally encouraging, through their label, the infringing use of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs' rights under the '920 patent and in violation of 35 U.S.C. § 271(b).
- 5. Upon information and belief, unless enjoined by this Court, Mylan Defendants will contribute to the infringement of at least claims 1-9, 11-14 of the '920 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product or equipment for the manufacture of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product in contravention of Plaintiffs' rights under the '920 patent in violation of 35 U.S.C. § 271(c).

## **U.S. PATENT NO. 9,198,888**

1. Mylan Defendants infringed claims 1-2, 4-7, and 9 of the '888 patent under 35 U.S.C. § 271(e)(2) by filing Abbreviated New Drug Application No. 202654 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '888 patent prior to the expiration of the '888 patent.



- 2. Upon information and belief, unless enjoined by this Court, Mylan Defendants will directly infringe at least claims 1-2, 4-7, and 9 of the '888 patent (either literally or under the Doctrine of Equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling their naproxen and esomeprazole magnesium delayed-release tablet product in the United States in violation of 35 U.S.C. § 271(a).
- 3. Upon information and belief, unless enjoined by this Court, Mylan Defendants will induce the infringement of at least claims 1-2, 4-7, and 9 of the '888 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs' rights under the '888 patent and in violation of 35 U.S.C. § 271(b).
- 4. Upon information and belief, unless enjoined by this Court, Mylan Defendants will induce the infringement of at least claims 1-2, 4-7, and 9 of the '888 patent by actively and intentionally encouraging, through their label, the infringing use of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs' rights under the '888 patent and in violation of 35 U.S.C. § 271(b).
- 5. Upon information and belief, unless enjoined by this Court, Mylan Defendants will contribute to the infringement of at least claims 1-2, 4-7, and 9 of the '888 patent by knowingly and intentionally selling materials and/or apparatuses, including



chemical precursors of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product or equipment for the manufacture of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product in contravention of Plaintiffs' rights under the '888 patent in violation of 35 U.S.C. § 271(c).

#### **U.S. PATENT NO. 9,220,698**

- 1. Mylan Defendants infringed claims 1-7 of the '698 patent under 35 U.S.C. § 271(e)(2) by filing Abbreviated New Drug Application No. 204470 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '698 patent prior to the expiration of the '698 patent.
  - 2. Upon information and belief, unless Mylan is enjoined by this Court, patients will directly infringe at least claims 1-7 of the '698 patent (either literally or under the Doctrine of Equivalents), upon Mylan's receipt of FDA approval, by using Mylan's naproxen and esomeprazole magnesium delayed-release tablet product in the United States in violation of 35 U.S.C. § 271(a).
- 3. Upon information and belief, unless enjoined by this Court, Mylan Defendants will induce the infringement of at least claims 1-7 of the '698 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Mylan Defendants' naproxen and esomeprazole magnesium delayed-release tablet product by others, including manufacturers, distributors, and/or consumers,



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