IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
ROXANE LABORATORIES, INC. and BOEHRINGER INGELHEIM ROXANE, INC.,	)	Civil Action No. _____
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Meda Pharmaceuticals Inc. ("Meda"), for its Complaint against defendants Roxane Laboratories, Inc. ("Roxane Labs") and Boehringer Ingelheim Roxane, Inc. ("BI-Roxane") (collectively, "Roxane Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the Roxane Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 207243 to the U.S. Food and Drug Administration ("FDA"). ANDA No. 207243 seeks approval to market an azelastine hydrochloride nasal spray (0.15%, 205.5 mcg per spray) ("Generic Product")—a generic version of Meda's proprietary ASTEPRO® drug product—before the expiration of Meda's U.S. Patent Nos. 8,071,073 ("the '073 patent") and 8,518,919 ("the '919 patent"), both of which cover the ASTEPRO® drug product.

PARTIES

2. Meda is a corporation organized and existing under the laws of Delaware, having its principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873.

3. Upon information and belief, Roxane Labs is a corporation organized and existing under the laws of Nevada, having its principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

4. Upon information and belief, BI-Roxane is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1809 Wilson Road, Columbus, Ohio 43228, and having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington Delaware 19801. Upon information and belief, BI-Roxane is also registered to do business in Delaware (Del. Bus. Lic. No. 1999202390).

5. Upon information and belief, the Roxane Defendants are in the business of manufacturing, marketing, and selling generic drug products. As part of their business, upon information and belief, the Roxane Defendants, directly or through agents, regularly submit ANDAs to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as part of these ANDAs, the Roxane Defendants, directly or through agents, regularly file certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV certification") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of the U.S. patents that cover them. Upon information and belief, the Roxane Defendants' ordinary business operations include litigating and filing claims in the courts of the United States, including the United States District Court for the District of Delaware, regarding the infringement, validity, and/or enforceability of

United States patents that cover or are alleged to cover generic drug products that are the subject of ANDAs submitted by the Roxane Defendants.

6. Upon information and belief, BI-Roxane is the manufacturing arm and supply-chain affiliate for Roxane Labs and manufactures pharmaceutical products for Roxane Labs including, among other things, azelastine hydrochloride nasal sprays. According to Roxane Labs' website, Roxane Labs "is the research and development, sales and marketing arm of [Roxane Labs' parent company] Boehringer Ingelheim's multisource pharmaceutical business." *See* https://www.roxane.com/about_roxane.html. Further, "Boehringer Ingelheim Roxane, Inc. [BI-Roxane]… is the manufacturing arm for … Roxane Laboratories, Inc." *Id.* And upon information and belief, upon approval of ANDA No. 207243, BI-Roxane will manufacture the Generic Product for sale and marketing by Roxane Labs within the United States, including within Delaware.

7. Upon information and belief, the Roxane Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware.

8. On information and belief, Roxane Labs and BI-Roxane have their principal places of business at the same address in Columbus, Ohio and share common officers, directors, Managing Directors, and employees. And on information and belief, Roxane Labs and BI-Roxane operate under common corporate policies.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.,* and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

11. Roxane Labs is subject to personal jurisdiction in Delaware because, among other reasons, upon information and belief, Roxane Labs has had persistent and continuous contacts with this judicial district. It is in the business of developing drug products which it manufactures, distributes, sells, and/or offers to sell throughout the United States, by itself or through agents such as BI-Roxane, including in Delaware; it derives substantial revenue from services or things used or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated ANDA cases without contesting jurisdiction in this District, including by availing itself of this forum by filing counterclaims; it has, directly or through an agent, submitted an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product described in ANDA No. 207243 in the United States, including in Delaware; upon receiving FDA approval, upon information and belief, it intends to offer to sell and sell the Generic Product described in ANDA No. 207243 throughout the United States, including in Delaware.

12. By letter dated May 5, 2015, Roxane Labs notified Meda that Roxane Labs submitted ANDA No. 207243 with Paragraph IV certifications to the '073 and '919 patents ("Notice Letter"), affirmatively challenging the validity and infringement of the '073 and '919 patents. Meda's receipt of the Notice Letter triggered the 45-day statutory deadline for Meda to initiate an infringement lawsuit that would invoke the automatic 30-month stay of FDA approval of ANDA No. 207243 in accordance with the Hatch-Waxman framework. 35 U.S.C. § 355(j)(5)(B)(iii). Roxane Lab's submission of ANDA No. 207243 with Paragraph IV

certifications to the '073 and '919 patents and Roxane Lab's act of sending the Notice Letter are tortious acts with real and injurious consequences giving rise to this infringement action. And because Meda is a Delaware corporation, these injuries and consequences are suffered in Delaware. Defendants, therefore, have purposefully directed their activities towards Delaware, where Meda is incorporated. And because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Defendants reasonably anticipated being haled into court in Delaware.

13. Upon information and belief, Roxane Labs has on multiple occasions consented to personal jurisdiction in patent infringement actions in this District, including in *Genzyme Corp. v. Roxane Labs., Inc.*, 1:09-cv-00567-GMS (D. Del.); *Genzyme Corp. v. Roxane Labs., Inc.*, 1:10-cv-00627-GMS (D. Del.); *Abbott Labs., et al. v. Roxane Labs., Inc.*, 1:10-cv-00998-GMS (D. Del.); *GlaxoSmithKline LLC (f/k/a SmithKline Beecham Corp.) v. Roxane Labs., Inc., et al.*, 1:11-cv-00542-RGA (D. Del.); *Abbott Labs. v. Roxane Labs., Inc.*, 1:12-cv-00457-RGA (D. Del.); *OSI Pharms. LLC, et al., v. Roxane Labs., Inc.*, 1:12-cv-00465-SLR (D. Del.); *Pfizer Inc., et al., v. Roxane Labs., Inc., et al.*, 1:12-cv-00813-SLR (D. Del.); *Pfizer Inc., et al., v. Zydus Pharms. USA Inc., et al.*, 1:12-cv-00808-SLR (D. Del.); *OSI Pharms. LLC, et al., v. Roxane Labs., Inc.*, 1:12-cv-01669-SLR (D. Del.); *Eisai Co. Ltd., et. al. v. Roxane Labs., Inc.*, 1:13-cv-01284-LPS (D. Del.); *Novartis Pharms., et al. v. Roxane Labs., Inc.*, 1:13-cv-01973-GMS (D. Del.); *Teijin Ltd., et al. v. Roxane Labs., Inc.*, 1:14-cv-00189-SLR (D. Del.); *Acorda Therapeutics, Inc., et al. v. Roxane Labs., Inc.*, 1:14-cv-00922-LPS (D. Del.); *Novartis Pharms., et al. v. Roxane Labs., Inc.*, 1:14-cv-01196-RGA (D. Del.); *Endo Pharms. Inc., et al., v. Roxane Labs., Inc.*, 1:14-cv-01387-RGA (D. Del.); *Novartis Pharms. Corp., et al. v. Roxane Labs., Inc.*, 1:14-cv-01508-RGA (D. Del.); *Eisai Co., Ltd., et al. v. Roxane Labs., Inc.*, 1:14-cv-01511-LPS

(D. Del.); and most recently when it answered a complaint for infringement on February 19, 2015, in *Novartis Pharms. Corp., et al. v. Roxane Labs., Inc.*, 1:15-cv-00128-RGA (D. Del.).

14. Upon information and belief, Roxane Labs has availed itself of the legal protections of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including in *Abbott Labs., et al. v. Roxane Labs., Inc.*, 1:10-cv-00998-GMS (D. Del.); *GlaxoSmithKline LLC (f/k/a SmithKline Beecham Corp.) v. Roxane Labs., Inc., et al.*, 1:11-cv-00542-RGA (D. Del.); *Abbott Labs. v. Roxane Labs., Inc.*, 1:12-cv-00457-RGA (D. Del.); *Pfizer Inc., et al., v. Roxane Labs., Inc., et al.*, 1:12-cv-00813-SLR (D. Del.); *Pfizer Inc., et al., v. Zydus Pharms. USA Inc., et al.*, 1:12-cv-00808-SLR (D. Del.); *Eisai Co. Ltd., et. al. v. Roxane Labs., Inc.*, 1:13-cv-01284-LPS (D. Del.); *Novartis Pharms., et al. v. Roxane Labs., Inc.*, 1:13-cv-01973-GMS (D. Del.); *Teijin Ltd., et al. v. Roxane Labs., Inc.*, 1:14-cv-00189-SLR (D. Del.); and *Eisai Co., Ltd., et al. v. Roxane Labs., Inc.*, 1:14-cv-01511-LPS (D. Del.).

15. This Court has personal jurisdiction over BI-Roxane. On information and belief, BI-Roxane is a corporation organized and existing under the laws of Delaware, and has designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

16. On information and belief, BI-Roxane is the manufacturing arm and supply-chain affiliate for Roxane Labs and manufactures pharmaceutical products including, among other things, azelastine hydrochloride nasal sprays.

17. BI-Roxane is subject to personal jurisdiction in Delaware because, among other reasons, upon information and belief, it is incorporated in the State of Delaware. Additionally, upon information and belief, BI-Roxane has had persistent and continuous contacts with this judicial district. It is in the business of developing drug products which it manufactures,

distributes, sells, and/or offers to sell, by itself or through agents such as Roxane Labs, throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; it has, directly or through an agent, submitted an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product described in ANDA No. 207243 in the United States, including in Delaware.

18. Upon information and belief, BI-Roxane has on multiple occasions consented to personal jurisdiction in patent infringement actions in this District, including in *Pfizer Inc., et al., v. Roxane Labs., Inc., et al.*, 1:12-cv-00813-SLR (D. Del.); *Acorda Therapeutics, Inc., et al. v. Roxane Labs., Inc., et al.*, 1:14-cv-00922-LPS (D. Del.); and *Novartis Pharms. Corp., et al. v. Roxane Labs., Inc., et al.*, 1:14-cv-01196-RGA (D. Del.).

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

19. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules FDA follows when considering whether to approve the marketing of pharmaceutical drugs.

20. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several aspects. One provision requires innovator drug companies to submit patent information to FDA "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, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA publishes the

submitted patent information in a publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

21. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called "reference drugs") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file what is referred to as an ANDA under 21 U.S.C. § 355(j). When filing an ANDA, generic drug companies are required to review the patent information that FDA lists in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to the same. One such certification is the Paragraph IV certification, where the generic drug company seeks FDA approval to market its generic drug products prior to patent expiration by stating in its ANDA that the Orange Book-listed patents are purportedly "invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

PATENTS-IN-SUIT

22. On December 6, 2011, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,071,073, titled "Compositions Comprising Azelastine and Methods of Use Thereof." The Orange Book presently shows that the '073 patent's term ends on June 4, 2028. A true and correct copy of the '073 patent is attached hereto as **Exhibit A.**

23. On August 27, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,518,919, also titled "Compositions Comprising Azelastine and Methods of Use Thereof." The Orange Book shows that the '919 patent's term ends on November 22, 2025. A true and correct copy of the '919 patent is attached hereto as **Exhibit B.**

24. Meda is the owner of the '073 and '919 patents and has the right to make, use, and sell certain pharmaceutical preparations containing azelastine hydrochloride to treat allergic and non-allergic vasomotor rhinitis. Meda currently markets an azelastine hydrochloride nasal spray in the United States under the trademark ASTEPRO®. The ASTEPRO® product and the conditions of use for which ASTEPRO® is approved fall within the claims of the '073 and '919 patents.

MEDA'S APPROVED DRUG PRODUCT: ASTEPRO®

25. Meda holds NDA No. 022371, which covers the ASTEPRO® (205.5 mcg of azelastine hydrochloride) nasal spray. The FDA approved NDA No. 022371 on August 31, 2009, allowing Meda to market ASTEPRO® throughout the United States for the treatment of seasonal and perennial allergic rhinitis.

26. The FDA lists the '073 and '919 patents in the Orange Book in connection with NDA No. 022371 because each patent individually claims the drug composition or methods for using the approved drug product. 21 U.S.C. § 355(b)(1).

ANDA No. 207243

27. By Notice Letter dated May 5, 2015, Roxane Labs notified Meda that Roxane Labs submitted ANDA No. 207243 with Paragraph IV certifications under Section 505(j) of the FFDCA (21 U.S.C. § 355(j)) for the Generic Product, which is purportedly bioequivalent to Meda's ASTEPRO® product.

28. The Notice Letter states that ANDA No. 207243 seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Generic Product before the expiration of the '073 and '919 patents.

29. By submitting ANDA No. 207243, Roxane Labs has necessarily represented to the FDA that the Generic Product has the same active ingredients as Meda's ASTEPRO® and is bioequivalent to ASTEPRO®.

30. The product and the conditions of use for which Roxane Labs seeks approval in ANDA No. 207243 fall within one or more of the claims of the '073 and '919 patents. If approved, the importation, manufacture, sale, offer for sale, and/or use of the Generic Product would infringe one or more claims of the '073 and '919 patents.

31. In the Notice Letter, Roxane Labs states that ANDA No. 207243 contains a "Paragraph IV certification" asserting that the '073 and '919 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Generic Product.

32. Upon information and belief, BI-Roxane manufactured the Generic Product relied upon in ANDA No. 207243 to purportedly demonstrate bioequivalence to Meda's ASTEPRO® product. And upon information and belief, BI-Roxane participated in operations related to preparing ANDA No. 207243 and contributed employees to the preparation of ANDA No. 207243. Further, upon information and belief, if ANDA No. 207243 is approved by FDA the Generic Product will be manufactured on behalf of Roxane Labs by BI-Roxane for sale by Roxane Labs within the United States, including within Delaware.

33. This Complaint is being filed within 45 days from the date Meda received the Notice Letter. 35 U.S.C. § 355(j)(5)(B)(iii).

COUNT I: INFRINGEMENT OF THE '073 PATENT

34. Meda realleges paragraphs 1 to 33 above as if fully set forth herein.

35. The Roxane Defendants' submission of ANDA No. 207243 infringes one or more claims of the '073 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, if the FDA approves ANDA No. 207243, the Roxane Defendants will further infringe one or more claims of the '073 patent by manufacturing, using, offering to sell, and selling the Generic Product in the United States and/or importing the Generic Product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

37. Unless the Roxane Defendants' manufacture, marketing, and sale of the Generic Product before the expiration of the '073 patent is enjoined, Meda will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '073 PATENT

38. Meda realleges paragraphs 1 to 37 above as if fully set forth herein.

39. Meda's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

40. There is an actual case and controversy between Meda on the one side, and the Roxane Defendants on the other, creating a justiciable case and controversy for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

41. The Roxane Defendants have made, and will continue to make, substantial preparations in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Generic Products.

42. The Roxane Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Meda.

43. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product before the '073 patent expires will constitute direct infringement and/or contribute to and/or actively induce the infringement by others of the '073 patent.

44. On information and belief, BI-Roxane actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 207423 to the FDA, while knowing of the '073 patent.

45. The submission of ANDA No. 207423 by the Roxane Defendants through Roxane Labs constituted direct infringement of the '073 patent under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), BI-Roxane induced the infringement of the '073 patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 207423 to the FDA and knowing that the submission of ANDA No. 207423 would constitute direct infringement of the '073 patent. BI-Roxane's knowing and purposeful activities of causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 207423, while knowing that its submission would constitute direct infringement, constitute induced infringement of the '073 patent.

46. Unless the Roxane Defendants are enjoined from directly and indirectly infringing the '073 patent, Meda will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III: INFRINGEMENT OF THE '919 PATENT

47. Meda realleges paragraphs 1 to 46 above as if fully set forth herein.

48. The Roxane Defendants' submission of ANDA No. 207243 infringes one or more claims of the '919 patent under 35 U.S.C. § 271(e)(2)(A).

49. Upon information and belief, if the FDA approves ANDA No. 207243, the Roxane Defendants will further infringe one or more claims of the '919 patent by manufacturing, using, offering to sell, and selling the Generic Product in the United States and/or importing the

Generic Product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

50. Unless the Roxane Defendants' manufacture, marketing, and sale of the Generic Product before the expiration of the '919 patent is enjoined, Meda will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '919 PATENT

51. Meda realleges paragraphs 1 to 50 above as if fully set forth herein.

52. Meda's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case and controversy between Meda on the one side, and Defendants on the other, creating a justiciable case and controversy for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

54. The Roxane Defendants have made, and will continue to make, substantial preparations in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Generic Products.

55. The Roxane Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Meda.

56. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product before the '919 patent expires will constitute direct infringement and/or contribute to and/or actively induce the infringement by others of the '919 patent.

57. On information and belief, BI-Roxane actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 207423 to the FDA, while knowing of the '919 patent.

58. The submission of ANDA No. 207423 by the Roxane Defendants through Roxane Labs constituted direct infringement of the '919 patent under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), BI-Roxane induced the infringement of the '919 patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 207423 to the FDA and knowing that the submission of ANDA No. 207423 would constitute direct infringement of the '919 patent. BI-Roxane's knowing and purposeful activities of causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 207423, while knowing that its submission would constitute direct infringement, constitute induced infringement of the '919 patent.

59. Unless the Roxane Defendants are enjoined from directly and indirectly infringing the '919 patent, Meda will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Meda respectfully requests that this Court grant the following relief:

A. A judgment that the Roxane Defendants have infringed valid and enforceable claims of the '073 and '919 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 207243 not be earlier than the latest of the expiration dates of the '073 and '919 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

C. A judgment declaring that the Roxane Defendants' manufacture, use, sale, offer for sale, or importation into the United States of the Generic Product for which approval is

sought in ANDA No. 207243 would constitute infringement of the '073 and '919 patents, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. A permanent injunction enjoining the Roxane Defendants and their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the Generic Product for which approval is sought in ANDA No. 207243, or any generic azelastine hydrochloride nasal spray product that infringes or induces or contributes to the infringement of the '073 or '919 patents, until expiration of those patents;

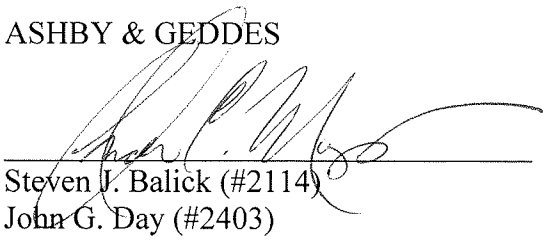
E. A declaration under 28 U.S.C. § 2201 that if the Roxane Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Generic Product prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '073 and '919 patents;

F. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

G. An award of costs and expenses in this action; and

H. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES



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