IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC. and CIPLA LTD.,	)	
Plaintiffs,	)	
	)	C.A. No. 14-1453-LPS
v.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Meda Pharmaceuticals Inc. ("Meda") and Cipla Ltd. ("Cipla") (collectively, "Plaintiffs"), by their attorneys, hereby 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, against defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"). This action relates to Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 207712 to the U.S. Food and Drug Administration ("FDA"). ANDA No. 207712 seeks approval to market a 137 mcg strength azelastine hydrochloride and 50 mcg strength fluticasone propionate combination nasal spray ("Generic Product")—a generic version of Plaintiff Meda's proprietary DYMISTA® drug product—before the expiration of Plaintiff Cipla's U.S. Patent Nos. 8,163,723 ("the '723 patent"), 8,168,620 ("the '620 patent"), and 9,259,428 ("the '428 patent"), all of which cover the DYMISTA® drug product, and for all of which Meda is the exclusive licensee in the United States.

PARTIES

2. Meda is a corporation organized and existing under the laws of Delaware, and having its principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873-4120.

3. Cipla is a publicly held company organized and existing under the laws of India, and having a registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India.

4. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, and having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of Delaware, and having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing and selling generic drug products. As part of its business, upon information and belief, Apotex Inc., directly or through agents (including Apotex Corp.), regularly files ANDAs with 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, Apotex Inc., directly or through agents (including Apotex Corp.), regularly files 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, Apotex Inc.'s 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 filed by Apotex.

7. Upon information and belief, Apotex Inc. manufactures drug products for the purpose of sale within the United States, including in Delaware, by Apotex Corp.

8. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. that serves as Apotex Inc.'s United States sales agent and distributor, and sells and offers for sale Apotex Inc.'s drug products throughout the United States, including in Delaware. Upon information and belief, Apotex Inc. derives substantial revenue from services or things used or consumed in the State of Delaware. Apotex Inc. has stated on its website that "Apotex Inc. serves a marketplace of over 115 countries, and is committed to the growth on a global basis through affiliates such as Apotex Corp. in the United States of America."

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. Apotex Corp. is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, Apotex Corp. is a Delaware corporation with a registered agent in Delaware (The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801); it is registered with the Delaware Board of Pharmacy as a

"Distributor/Manufacturer CSR" and "Pharmacy – Wholesale" pursuant to 24 Del. C. § 2540; it is in the business of marketing drug products, which it distributes and sells throughout the United States, including in Delaware; it derives substantial revenue from services or things used and/or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; and, upon receiving FDA approval, it intends to offer to sell and sell the Generic Product described in ANDA No. 207712 in the United States, including in Delaware.

12. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other reasons, upon information and belief, Apotex Inc. has had persistent and continuous contacts with this judicial district. It is in the business of manufacturing drug products which it manufactures, distributes, sells and/or offers to sell, primarily through Apotex Corp., throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in the State of 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, filed 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. 207712 in the United States, including in Delaware; upon receiving FDA approval, it intends to offer to sell and sell, primarily through Apotex Corp., a Delaware corporation, the Generic Product described in ANDA No. 207712 throughout the United States, including in Delaware; and Apotex Corp., acting as Apotex Inc.'s agent and/or alter ego, regularly does and solicits business in Delaware and is engaged in a persistent, continuous and systematic course of

conduct in Delaware in which it distributes, sells, and offers to sell Apotex Inc.'s drug products in Delaware and derives substantial revenue from services or things used or consumed in the State of Delaware on behalf of Apotex Inc.

13. By letter dated October 20, 2014, Apotex sent notice of its ANDA submission and Paragraph IV certification to Meda and Cipla ("the Notice Letter"), affirmatively challenging the validity and infringement of the '723 and '620 patents. Meda and Cipla's receipt of the Notice Letter triggered the 45-day statutory deadline for Meda and Cipla to initiate an infringement lawsuit that would invoke the automatic 30-month stay of FDA approval of ANDA No. 207712 in accordance with the Hatch-Waxman framework. 35 U.S.C. § 355(j)(5)(B)(iii). Apotex's submission of ANDA No. 207712 with Paragraph IV certifications to the '723 and '620 patents and its 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. Apotex, therefore, has purposefully directed its activities towards the State of 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, Apotex reasonably anticipated being haled into court in Delaware.

14. Apotex's Notice Letter listed the law firm of Wilson Sonsini Goodrich & Rosati P.C. ("WSGR") as the agent in the United States authorized to accept service of process for Apotex Inc. relating to ANDA 207712, which is the subject of the present action. WSGR maintains an office in Delaware, at 222 Delaware Avenue, Suite 800, Wilmington, Delaware, 19801.

15. Upon information and belief, Apotex Corp. and Apotex Inc. have on multiple occasions consented to personal jurisdiction in patent infringement actions in this District,

including in *Aventis Pharma S.A. and Sanofi-Aventis U.S., LLC v. Apotex Inc. and Apotex Corp.*, No. 08-cv-00496-GMS (D. Del.); *The Proctor & Gamble Company and Hoffmann-La Roche, Inc. v. Apotex, Inc. and Apotex Corp.*, No. 09-cv-00143-LPS (D. Del.); *Pronova Biopharma Norge AS v. Apotex Corp. and Apotex Inc.*, No. 09-00304-SLR-MPT (D. Del.); *Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. v. Apotex Inc. and Apotex Corp.*, No. 09-cv-00470 (D. Del.); *Warner Chilcott Company, LLC and Hoffman-La Roche, Inc. v. Apotex Inc. and Apotex Corp.*, No. 10-cv-01111-LPS (D. Del.); *Pfizer Inc. et al. v. Apotex, Inc. and Apotex Corp.*, No. 11-cv-606-GMS (D. Del.); *Senju Pharmaceutical Co., Ltd. et al. v. Apotex Inc. and Apotex Corp.*, 12-cv-0159-SLR; *Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 12-cv-00809-SLR (D. Del.); *Bristol-Myers Squibb Co. v. Apotex Inc. and Apotex Corp.*, No. 14-00351-RGA (D. Del.); and most recently when they answered a complaint for infringement and asserted counterclaims on September 12, 2014 in *Aptalis Pharmatech, Inc. and Ivax International GMBH v. Apotex Inc. and Apotex Corp.*, No. 14-cv-01038-DED (D. Del.).

16. Upon information and belief, Apotex Inc. and Apotex Corp. have availed themselves of the legal protections of the State of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including in *Aventis-Pharma S.A. and Sanofi-Aventis U.S., LLC v. Apotex Inc. and Apotex Corp.*, No. 08-cv-00496-GMS (D. Del.); *The Procter & Gamble Company and Hoffmann-La Roche, Inc. v. Apotex Inc. and Apotex Corp.*, No. 09-cv-00143-LPS (D. Del.); *Pronova Biopharma Norge AS v. Apotex Corp. and Apotex Inc.*, No. 09-00304-SLR-MPT (D. Del.); *Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. v. Apotex Inc. and Apotex Corp.*, No. 09-cv-00470 (D. Del.); *Warner Chilcott Company, LLC and Hoffman-La Roche, Inc. v. Apotex Inc. and Apotex Corp.*, No. 10-cv-01111-LPS (D. Del.); *Pfizer Inc. et al. v. Apotex, Inc. and Apotex Corp.*, No. 11-cv-606-GMS (D. Del.); *Senju*

Pharmaceutical Co., Ltd. et al. v. Apotex Inc. and Apotex Corp., 12-cv-0159-SLR; *Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 12-cv-00809-SLR (D. Del.); *Bristol-Myers Squibb Co. v. Apotex Inc. and Apotex Corp.*, No. 14-00351-RGA (D. Del.); and most recently, on September 12, 2014 in *Aptalis Pharmatech, Inc. and Ivax International GmbH v. Apotex Inc. and Apotex Corp.*, No. 14-cv-01038-DED (D. Del.).

REGULATORY REQUIREMENTS FOR
APPROVAL OF NEW AND GENERIC DRUGS

17. 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.

18. 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 entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

19. 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.

20. 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

21. On April 24, 2012, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,163,723, titled "Combination of Azelastine and Steroids." The Orange Book presently shows that the '723 patent's term ends on August 29, 2023. A true and correct copy of the '723 patent is attached hereto as **Exhibit A**.

22. On May 1, 2012, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,168,620, also titled "Combination of Azelastine and Steroids." The Orange Book shows that the '620 patent's term ends on February 24, 2026. A true and correct copy of the '620 patent is attached hereto as **Exhibit B**.

23. On February 16, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,259,428, titled "Combination of Azelastine and Fluticasone for Nasal Administration." The '428 patent's term ends on June 13, 2023. A true and correct copy of the '428 patent is attached hereto as **Exhibit C**.

24. Plaintiff Cipla is the owner of the '723, '620, and '428 patents.

25. Plaintiff Meda is the exclusive licensee of the '723, '620, and '428 patents in the United States, pursuant to an exclusive license agreement between Meda and Cipla, of the right to make, use, and sell certain pharmaceutical preparations containing azelastine hydrochloride

and fluticasone propionate to treat seasonal allergic rhinitis. Pursuant to that exclusive license, Meda currently markets an azelastine hydrochloride and fluticasone propionate combination nasal spray in the United States under the trademark DYMISTA®. The DYMISTA® product and the conditions of use for which DYMISTA® is approved fall within the claims of the '723, '620, and '428 patents.

26. As exclusive licensee, Meda has the right to enforce the '723, '620, and the '428 patents.

MEDA'S APPROVED DRUG PRODUCT: DYMISTA®

27. Meda holds NDA No. 202236, which covers the DYMISTA® (137 mcg azelastine hydrochloride and 50 mcg fluticasone propionate) nasal spray. The FDA approved NDA No. 202236 on May 1, 2012, allowing Meda to market DYMISTA® throughout the United States for the treatment of seasonal allergic rhinitis ("SAR").

28. The FDA lists the '723 and '620 patents in the Orange Book in connection with NDA No. 202236 because each individually claims the drug composition or methods for using the approved drug product. 21 U.S.C. § 355(b)(1). The '428 patent will be added to the Orange Book in connection with NDA No. 202236 within 30 days of issuance. 21 U.S.C. § 314.53(d)(3).

APOTEX'S ANDA

29. By Notice Letter dated October 20, 2014, Apotex notified Meda and Cipla that it had submitted ANDA No. 207712 and a Paragraph IV certification under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for a Generic Product purportedly bioequivalent to Meda's DYMISTA® product.

30. The Notice Letter states that Apotex seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Generic Product before the expiration of the '723 and '620 patents.

31. By filing ANDA No. 207712, Apotex has necessarily represented to the FDA that its Generic Product has the same active ingredients as Meda's DYMISTA®, and is bioequivalent to DYMISTA®.

32. The product and the conditions of use for which Apotex seeks approval in ANDA No. 207712 fall within one or more of the claims of the '723, '620, and '428 patents. If approved, the importation, manufacture, sale, offer for sale and/or use of Apotex's Generic Product would infringe one or more claims of the '723, '620, and '428 patents.

33. In its Notice Letter, Apotex states that ANDA No. 207712 contains a "Paragraph IV certification" asserting that the '723 and '620 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Apotex's Generic Product. However, Apotex's Notice Letter fails to disclose non-infringement positions for claims 1-4, 7, 8, 10-18, and 20-28 of the '723 patent and claims 1-13, 15-18, 21, 22, 24-26, 28-31, 33, and 35-47 of the '620 patent.

34. The original Complaint was initially filed on December 2, 2014, within 45 days from the date Meda and Cipla received the Notice Letter. 35 U.S.C. § 355(j)(5)(B)(iii).

35. Upon review of ANDA No. 207712, Meda and Cipla allege that Apotex's Generic Product as described in ANDA No. 207712 would infringe one or more claims of the '428 patent.

COUNT I: INFRINGEMENT OF THE '723 PATENT

36. Meda and Cipla reallege paragraphs 1 to 35 above as if fully set forth herein.

37. Apotex's submission of ANDA No. 207712 infringes one or more claims of the '723 patent under 35 U.S.C. § 271(e)(2)(A).

38. Upon information and belief, if the FDA approves Apotex's ANDA No. 207712, Apotex will further infringe one or more claims of the '723 patent by making, using, offering to sell, and selling its Generic Product in the United States and/or importing such sprays 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.

39. If Apotex's marketing and sale of its Generic Product before the expiration of the '723 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '723 PATENT

40. Meda and Cipla reallege paragraphs 1 to 39 above as if fully set forth herein.

41. These claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

42. There is an actual case and controversy between Meda and Cipla on the one side, and Apotex 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.

43. Apotex has 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.

44. Apotex's actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

45. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of the '723 patent.

46. Unless Apotex is enjoined from infringing, inducing infringement and contributing to the infringement of, the '723 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III: INFRINGEMENT OF THE '620 PATENT

47. Meda and Cipla reallege paragraphs 1 to 46 above as if fully set forth herein.

48. Apotex's submission of ANDA No. 207712 infringes one or more claims of the '620 patent under 35 U.S.C. § 271(e)(2)(A).

49. Upon information and belief, if the FDA approves Apotex's ANDA No. 207712, Apotex will further infringe one or more claims of the '620 patent by making, using, offering to sell, and selling its Generic Product in the United States and/or importing such sprays 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. If Apotex's marketing and sale of its Generic Product before the expiration of the '620 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '620 PATENT

51. Meda and Cipla reallege paragraphs 1 to 50 above as if fully set forth herein.

52. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case and controversy between Meda and Cipla on the one side, and Apotex 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. Apotex has 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. Apotex's actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

56. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of the '620 patent.

57. Unless Apotex is enjoined from infringing, inducing infringement and contributing to the infringement of, the '620 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT V: INFRINGEMENT OF THE '428 PATENT

58. Meda and Cipla reallege paragraphs 1 to 57 above as if fully set forth herein.

59. Apotex's submission of ANDA No. 207712 infringes one or more claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

60. Upon information and belief, if the FDA approves Apotex's ANDA No. 207712, Apotex will further infringe one or more claims of the '428 patent by making, using, offering to sell, and selling its Generic Product in the United States and/or importing such sprays 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.

61. If Apotex's marketing and sale of its Generic Product before the expiration of the '428 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '428 PATENT

62. Meda and Cipla reallege paragraphs 1 to 61 above as if fully set forth herein.

63. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

64. There is an actual case and controversy between Meda and Cipla on the one side, and Apotex 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.

65. Apotex has 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.

66. Apotex's actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

67. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of the '428 patent.

68. Unless Apotex is enjoined from infringing, inducing infringement and contributing to the infringement of, the '428 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Meda and Cipla respectfully request that this Court grant the following relief:

A. A judgment that Apotex has infringed valid and enforceable claims of the ’723, ’620, and ’428 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. 207712 not be earlier than the latest of the expiration dates of the ’723, ’620, and ’428 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

C. A judgment declaring that Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of the Generic Product for which approval is sought in ANDA No. 207712 would constitute infringement of the ’723, ’620, and ’428 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 Apotex and its 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. 207712, or any generic azelastine hydrochloride and fluticasone propionate combination nasal spray product that infringes or induces or contributes to the infringement of the ’723, ’620, and ’428 patents, until expiration of those patents;

E. A declaration under 28 U.S.C. § 2201 that if Apotex, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all 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 Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '723, '620, and '428 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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