IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SPECTRUM PHARMACEUTICALS, INC. and TOPOTARGET UK LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
FRESENIUS KABI USA, LLC, FRESENIUS KABI USA, INC., and FRESENIUS KABI ONCOLOGY LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Spectrum Pharmaceuticals, Inc. ("Spectrum") and TopoTarget UK Ltd. ("TopoTarget UK") (collectively, "Plaintiffs"), by way of their Complaint against Defendants Fresenius Kabi USA, LLC ("Fresenius LLC"), Fresenius Kabi USA, Inc. ("Fresenius Inc."), and Fresenius Kabi Oncology Ltd. ("Fresenius Oncology") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent Nos. 6,888,027 (the "'027 patent") and U.S. Patent No. 8,835,501 (the "'501 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(a-c, e-g), and for a declaratory judgment of infringement of the '027 and '501 patents under 28 U.S.C. §§ 2201 and 2202. This action arises out of Fresenius LLC's submission of Abbreviated New Drug Application ("ANDA") No. 211485 seeking approval to manufacture, use and/or sell a generic version of the pharmaceutical product BELEODAQ® (belinostat) for intravenous injection (500 mg vials) ("Defendants'

ANDA product") prior to the expiration of the '027 and '501 patents. Plaintiffs seek injunctive relief against infringement, attorneys' fees, and any other relief the Court deems just and proper.

PARTIES

2. Spectrum is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at 11500 South Eastern Avenue, Suite 240, Henderson, Nevada 89052. Spectrum is engaged in the business of research, development, manufacture, and sale of pharmaceutical products.

3. TopoTarget UK is a corporation organized and existing under the laws of the United Kingdom. Its principal place of business is located at 7200 The Quorum, Oxford Business Park, North Garsington Road, Oxford, OX4 2JZ, United Kingdom.

4. Upon information and belief, Defendant Fresenius LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Upon information and belief, Fresenius LLC is a wholly-owned subsidiary of Fresenius Inc.

5. Upon information and belief, Defendant Fresenius Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

6. Upon information and belief, Defendant Fresenius Oncology is a corporation organized and existing under the laws of India, having a principal place of business at D-35, Industrial Area, Kalyani, District Nadia, West Bangal – 741 235, India.

7. Upon information and belief, Fresenius LLC, Fresenius Inc., and Fresenius Oncology collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, Defendants

are agents of one another and/or operate in concert as integrated parts of the same business group.

8. Upon information and belief, Fresenius LLC caused ANDA No. 211485 to be submitted to FDA and seeks FDA approval of ANDA No. 211485.

9. Upon information and belief, Fresenius Inc. and Fresenius Oncology are agents or affiliates of Fresenius LLC, and are acting as agents of Fresenius LLC with respect to ANDA No. 211485.

10. Upon information and belief, Fresenius Oncology holds Drug Master File ("DMF") No. 32260 for belinostat.

11. Upon information and belief, Defendants regularly act in concert to transact business throughout the United States and within Delaware, including but not limited to marketing, distribution, sales, and/or offers to sell generic drugs.

JURISDICTION AND VENUE

12. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

13. This Court has jurisdiction over Fresenius LLC because, *inter alia*, upon information and belief, Fresenius LLC is a Delaware company, is registered with the Delaware Department of State, Division of Corporations to do business in Delaware under file number 4373141, and has a registered agent for service of process in this judicial district (Corporation Service Company). Upon information and belief, Fresenius LLC directly or indirectly manufactures, imports, markets, and sells generic drugs throughout the United States, including

Delaware, and Delaware would be a destination of Defendants' ANDA product. Upon information and belief, Fresenius LLC acted in concert with and/or with the assistance of Fresenius Inc. and Fresenius Oncology to file ANDA No. 211485. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA product in the United States, including in Delaware, upon approval of ANDA No. 211485, and will derive substantial revenue from the use or consumption of Defendants' ANDA product in the State of Delaware.

14. This Court has jurisdiction over Fresenius Inc. because, *inter alia*, upon information and belief, Fresenius Inc. is a Delaware corporation, is registered with the Delaware Department of State, Division of Corporations to do business as a domestic corporation in Delaware under file number 4373132, and has a registered agent for service of process in this judicial district (Corporation Service Company). Upon information and belief, Fresenius Inc. directly or indirectly manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA product. Upon information and belief, Fresenius Inc. acted in concert with and/or with the assistance of Fresenius LLC and Fresenius Oncology to file ANDA No. 211485. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA product in the United States, including in Delaware, upon approval of ANDA No. 211485, and will derive substantial revenue from the use or consumption of Defendants' ANDA product in the State of Delaware.

15. This Court has jurisdiction over Fresenius Oncology because, *inter alia*, upon information and belief, Fresenius Oncology directly or indirectly manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware

would be a destination of Defendants' ANDA product. Upon information and belief, Fresenius Oncology acted in concert with and/or with the assistance of Fresenius LLC and Fresenius Inc. to file ANDA No. 211485. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA product in the United States, including in Delaware, upon approval of ANDA No. 211485, and will derive substantial revenue from the use or consumption of Defendants' ANDA product in the State of Delaware.

16. In the alternative, this Court has jurisdiction over Fresenius Oncology because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Fresenius Oncology because, *inter alia*, this action arises from actions of Fresenius Oncology directed toward Delaware, and because Fresenius Oncology has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Fresenius Oncology regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Fresenius Oncology derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

17. This Court also has jurisdiction over Fresenius LLC, Fresenius Inc., and Fresenius Oncology because, *inter alia*, upon information and belief, Fresenius LLC, Fresenius Inc., and Fresenius Oncology have previously been sued in this jurisdictional district without objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See, e.g.*, *Pharmacyclics LLC et al.*

v. Fresenius Kabi USA, LLC et al., Civil Action No. 18-192-CFC (D. Del.); *Onyx Therapeutics, Inc. v. Fresenius Kabi USA, LLC*, Civil Action No. 16-1012-LPS (D. Del.); *Teva Pharmaceuticals International GmbH v. Fresenius Kabi USA, LLC*, Civil Action No. 17-1201-CFC (D. Del.); *Astellas Pharma Inc. v. Fresenius Kabi USA, LLC*, Civil Action No. 15-080-LPS (D. Del.).

18. Venue is proper in this district for Fresenius LLC under 28 U.S.C. § 1400(b) because, *inter alia*, Fresenius LLC is a limited liability company organized and existing under the laws of the State of Delaware.

19. Venue is proper in this district for Fresenius Inc. under 28 U.S.C. § 1400(b) because, *inter alia*, Fresenius Inc. is a corporation organized and existing under the laws of the State of Delaware.

20. Venue is proper in this district for Fresenius Oncology under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Fresenius Oncology is a corporation organized and existing under the laws of India, and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

BELEODAQ®

21. Spectrum is the holder of an approved New Drug Application ("NDA") No. 206256 for BELEODAQ®, which the U.S. Food and Drug Administration ("FDA") approved on July 3, 2014.

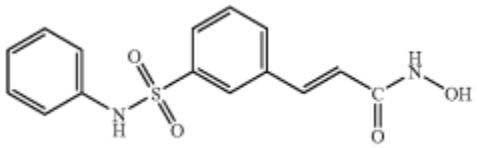
22. BELEODAQ® is a medication marketed and sold by Spectrum as lyophilized powder in single-dose, 500 mg vials for reconstitution and intravenous injection. Spectrum received FDA approval to market BELEODAQ® (belinostat) to treat relapsed or refractory peripheral T-cell lymphoma ("PTCL").

23. PTCL is a sub-type of non-Hodgkin's lymphoma (blood cancer) that develops from mature-stage white blood cells called T-cells, and results when these T-cells grow

abnormally. PTCL accounts for around 10 to 15% of non-Hodgkin's lymphoma, and its global incidence is estimated at 12,000 cases each year.

24. Belinostat is the active ingredient in BELEODAQ®. Belinostat is an inhibitor of histone deacetylase ("HDAC'), an enzyme involved in gene expression and cell growth. Belinostat works to inhibit the activity of HDAC to induce cell cycle-arrest and/or apoptosis of transformed T-cells.

25. Belinostat can be referred to by the chemical names N-hydroxy-3-(3-phenyl-sulfamoyl-phenyl)-acrylamide or (2E)-*N*-hydroxy-3-[3-(phenylsulfamoyl)phenyl]prop-2-enamide, and has the following chemical structure:



26. BELEODAQ® was granted Orphan Drug Exclusivity for treatment of patients with relapsed or refractory PTCL.

27. BELEODAQ®, its active pharmaceutical ingredient belinostat, and its method of use are covered by one or more of the claims of the '027 and '501 patents, which are both listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for NDA No. 206256.

THE PATENTS-IN-SUIT

28. On May 3, 2005, the '027 patent, titled "Carbamic Acid Compounds Comprising a Sulfonamide Linkage as HDAC Inhibitors," was issued by the United States Patent and Trademark Office ("PTO"). A true and correct copy of the '027 patent is attached as Exhibit A.

29. The claims of the ’027 patent are directed to compounds that inhibit HDAC activity, including belinostat, compositions comprising said compounds, and methods of, *inter alia*, inhibiting cell proliferation using said compounds.

30. On September 16, 2014, the ’501 patent, titled “Pharmaceutical Formulations of HDAC Inhibitors,” was issued by the PTO. A true and correct copy of the ’501 patent is attached as Exhibit B.

31. The claims of the ’501 patent are directed to pharmaceutical compositions comprising HDAC inhibitors, including belinostat, packaging (IV, infusion bag, vial, or ampule) for said compositions, and kits comprising said compositions and instructions for use.

32. The ’027 and ’501 patents are owned by TopoTarget UK.

33. Spectrum has an exclusive license to both the ’027 patent and the ’501 patent in the United States, with the right to sue for infringement of the ’027 patent and the ’501 patent.

FRESENIUS LLC’S ANDA NO. 211485

34. Plaintiffs received a letter dated August 21, 2018 from Fresenius LLC notifying Plaintiffs that Fresenius LLC had submitted ANDA No. 211485 to the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) seeking approval to commercially manufacture, use, sell, and/or import Defendants’ ANDA product prior to the expiration of the ’027 and ’501 patents.

35. According to applicable regulations, the purpose of Fresenius LLC’s August 21, 2018 letter was to notify Plaintiffs that ANDA No. 211485 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (“Paragraph IV Certification”) alleging that the claims of the ’027 and ’501 patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants’ ANDA product.

36. Included in the August 21, 2018 letter was a detailed statement of the factual and legal basis for Fresenius LLC's Paragraph IV Certification, alleging that the claims of the '027 and '501 patents were either invalid as obvious under 35 U.S.C. § 103 or would not be infringed by Defendants' ANDA product.

37. Upon information and belief, Defendants were aware of both the '027 patent and the '501 patent when Fresenius LLC notified Plaintiffs of its Paragraph IV Certification regarding the '027 and '501 patents.

38. Plaintiffs commenced this action within 45 days of receipt of Fresenius LLC's August 21, 2018 letter.

COUNT I
INFRINGEMENT OF THE '027 PATENT

39. Plaintiffs incorporate and reallege paragraphs 1-38 above, as if set forth specifically here.

40. Upon information and belief, Fresenius LLC submitted ANDA No. 211485 to the FDA under the provisions of 21 U.S.C. § 355(j).

41. Upon information and belief, Fresenius LLC's ANDA No. 211485 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product (generic belinostat in 500 mg vials for intravenous injection) before the expiration of the '027 patent.

42. Plaintiffs received a letter from Fresenius LLC dated August 21, 2018, purporting to be a Notice of Certification for ANDA No. 211485 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

43. Fresenius LLC's August 21, 2018 letter states that the active ingredient in Defendants' ANDA product for which it seeks approval is belinostat.

44. Upon information and belief, Fresenius LLC has made and included in its ANDA a Paragraph IV Certification stating that, in its opinion, the ’027 patent is invalid, unenforceable and/or not infringed.

45. Fresenius LLC’s submission of ANDA No. 211485 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants’ ANDA product prior to the expiration of the ’027 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

46. Defendants’ commercial manufacture, use, sale, and/or importation of Defendants’ ANDA product would infringe and actively induce and/or contribute to infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’027 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 211485, Defendants will make, use, offer to sell, or sell Defendants’ ANDA product within the United States, or will import Defendants’ ANDA product into the United States, and will thereby infringe and induce and/or contribute to the infringement of one or more claims of the ’027 patent.

47. Defendants had actual knowledge of the ’027 patent prior to Fresenius LLC’s submission of ANDA No. 211485, and were aware that the filing of ANDA No. 211485 with the request for FDA approval prior to the expiration of the ’027 patent would constitute an act of infringement of the ’027 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants’ ANDA product will not infringe and induce and/or contribute to the infringement of the ’027 patent.

48. Fresenius LLC's Detailed Statement in its August 21, 2018 letter lacks any sufficient contention that Defendants' ANDA product will not infringe, induce and/or contribute to the infringement of one or more claims of the '027 patent.

49. On information and belief, Fresenius LLC's statement of the factual and legal bases for its opinions regarding invalidity of the '027 patent lacks an objective good faith basis in either the facts or the law. This case is exceptional.

50. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '027 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, injunctive relief is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '027 PATENT

51. Plaintiffs incorporate and reallege paragraphs 1-50 above, as if set forth specifically here.

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

53. Upon information and belief, if ANDA No. 211485 is approved, Defendants' ANDA product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

54. Upon information and belief, Defendants know that health care professionals or patients will use Defendants' ANDA product in accordance with the labeling sought by ANDA No. 211485, and Defendants will therefore infringe and induce and/or contribute to the

infringement of one or more claims of the ’027 patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

55. Upon information and belief, Defendants’ infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants’ ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 211485. Any such conduct before the ’027 patent expires will infringe and induce and/or contribute to the infringement of one or more claims of the ’027 patent under one or more of 35 U.S.C. §§ 271 (a), (b), (c), (f), and (g).

56. There is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the ’027 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

57. Plaintiffs will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

58. 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 ’501 PATENT

59. Plaintiffs incorporate and reallege paragraphs 1-58 above, as if set forth specifically here.

60. Upon information and belief, Fresenius LLC submitted ANDA No. 211485 to the FDA under the provisions of 21 U.S.C. § 355(j).

61. Upon information and belief, Fresenius LLC's ANDA No. 211485 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product (generic belinostat in 500 mg vials for intravenous injection) before the expiration of the '501 patent.

62. Plaintiffs received a letter from Fresenius LLC dated August 21, 2018, purporting to be a Notice of Certification for ANDA No. 211485 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

63. Fresenius LLC's August 21, 2018 letter states that the active ingredient in Defendants' ANDA product for which it seeks approval is belinostat. Fresenius LLC's letter further states that Defendants' ANDA product contains lyophilized belinostat (an HDAC inhibitor) and L-arginine, and is intended for intravenous administration after reconstitution with sterile water for injection, and further dilution with sterile 0.9% sodium chloride for injection.

64. Upon information and belief, Fresenius LLC has made and included in its ANDA a Paragraph IV Certification stating that, in its opinion, the '501 patent is invalid, unenforceable and/or not infringed.

65. Fresenius LLC's submission of ANDA No. 211485 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product prior to the expiration of the '501 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

66. Defendants' commercial manufacture, use, sale, and/or importation of Defendants' ANDA product would infringe and actively induce and/or contribute to infringement, either literally or under the doctrine of equivalents, of one or more claims of the '501 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No.

211485, Defendants will make, use, offer to sell, or sell Defendants' ANDA product within the United States, or will import Defendants' ANDA product into the United States, and will thereby infringe and induce and/or contribute to the infringement of one or more claims of the '501 patent.

67. Defendants had actual knowledge of the '501 patent prior to Fresenius LLC's submission of ANDA No. 211485, and were aware that the filing of ANDA No. 211485 with the request for FDA approval prior to the expiration of the '501 patent would constitute an act of infringement of the '501 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA product will not infringe and induce and/or contribute to the infringement of the '501 patent.

68. Fresenius LLC's Detailed Statement in its August 21, 2018 letter lacks any sufficient contention that Defendants' ANDA product will not infringe, induce and/or contribute to the infringement of one or more claims of the '501 patent.

69. On information and belief, Fresenius LLC's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '501 patent lacks an objective good faith basis in either the facts or the law. This case is exceptional.

70. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '501 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, injunctive relief is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '501 PATENT

71. Plaintiffs incorporate and reallege paragraphs 1-70 above, as if set forth specifically here.

72. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. Upon information and belief, if ANDA No. 211485 is approved, Defendants' ANDA product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

74. Upon information and belief, Defendants know that health care professionals or patients will use Defendants' ANDA product in accordance with the labeling sought by ANDA No. 211485, and Defendants will therefore infringe and induce and/or contribute to the infringement of one or more claims of the '501 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

75. Upon information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 211485. Any such conduct before the '501 patent expires will infringe and induce and/or contribute to the infringement of one or more claims of the '501 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

76. There is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '501 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

77. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

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

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '027 patent and the '501 patent were infringed by Fresenius LLC's submission of ANDA No. 211485 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA product prior to the expiration of the '027 and '501 patents will constitute an act of infringement of the '027 and '501 patents;

B. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendants' ANDA product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '027 patent and the '501 patent;

C. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, Defendants' ANDA product until after the expiration of the '027 patent and the '501 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. An order under 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of ANDA No. 211485 shall be a date that is not earlier than the later of the expiration dates of the ’027 and ’501 patents, inclusive of any extensions;

E. A declaration under 28 U.S.C. § 2201 that if 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, engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in ANDA No. 211485, it will constitute an act of direct and/or indirect infringement of the ’027 patent and the ’501 patent;

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA product, or any product that infringes the ’027 patent and the ’501 patent, or induces or contributes to such conduct, prior to the expiration of the ’027 patent and the ’501 patent, or any later expiration of exclusivity for the ’027 patent and the ’501 patent, including any extensions or regulatory exclusivities;

G. A declaration that this is an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and awarding Plaintiffs’ costs, expenses, and disbursements in this action, including reasonable attorney fees; and

H. An award of such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Jeffrey J. Lyons (#6437)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jlyons@mnat.com

Attorney for Spectrum Pharmaceuticals, Inc. and TopoTarget UK Ltd.

OF COUNSEL:

William E. Solander
Michael E. Furrow
Kathryn E. Easterling
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

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