IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

Civil Action No. 1:21-CV-817

PFIZER INC., WARNER-LAMBERT COMPANY LLC, and PF PRISM IMB B.V. Plaintiffs, v. SYNTHON PHARMACEUTICALS, INC., SYNTHON B.V., and SYNTHON INTERNATIONAL HOLDING B.V. Defendants.	**COMPLAINT**

Pfizer Inc., Warner-Lambert Company LLC, and PF PRISM IMB B.V. (collectively "Pfizer") file this Complaint for patent infringement against Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. (collectively, "Synthon"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Synthon's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (palbociclib) tablets, 75 mg, 100 mg, and 125 mg, prior to the

expiration of U.S. Patent No. 11,065,250 ("the '250 patent").

2. Synthon Pharmaceuticals, Inc. notified Pfizer by letter dated September 8, 2021 ("Synthon's Notice Letter") that it had submitted to the FDA ANDA No. 215570 ("Synthon's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic palbociclib tablets, 75mg, 100 mg, and 125 mg ("Synthon's ANDA Products") prior to the expiration of the patent-in-suit.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 212436 for the manufacture and sale of palbociclib tablets, 75 mg, 100 mg and 125 mg, which has been approved by the FDA.

4. Plaintiff Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

6. Upon information and belief, defendant Synthon International Holding B.V.

is a corporation organized and existing under the law of the Netherlands, having a business address at Microweg 22, P.O. Box. 7071, 6503 GN Nijmegan, the Netherlands. Upon information and belief, Synthon International Holding B.V. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various Synthon entities, including Synthon Pharmaceuticals, Inc.

7. Upon information and belief, defendant Synthon B.V. is a corporation organized and existing under the law of the Netherlands, having a business address at Microweg 22, P.O. Box. 7071, 6503 GN Nijmegan, the Netherlands. Upon information and belief, Synthon B.V. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various Synthon entities, including Synthon Pharmaceuticals, Inc.

8. Upon information and belief, defendant Synthon Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 1007 Slater Road, Suite 150, Durham, North Carolina 27703. Upon information and belief, Synthon Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, Synthon Pharmaceuticals, Inc. and Synthon B.V. are subsidiaries of Synthon International Holding B.V.

10. Upon information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V.,

and Synthon International Holding B.V. acted in concert to prepare and submit Synthon's ANDA to the FDA.

11. Upon information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. know and intend that upon approval of Synthon's ANDA, Synthon Pharmaceuticals, Inc., Synthon B.V., and/or Synthon International Holding B.V. will manufacture, market, sell, and distribute Synthon's ANDA Products throughout the United States, including in North Carolina and in this judicial district. On information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Synthon's ANDA Products, and enter into agreements that are nearer than arm's length. Upon information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. participated, assisted, and cooperated in carrying out the acts complained of herein.

12. Upon information and belief, following any FDA approval of Synthon's ANDA, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. will act in concert to distribute and sell Synthon's ANDA Products throughout the United States, including within North Carolina and within this judicial district.

JURISDICTION

13. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

14. Synthon International Holding B.V. is subject to personal jurisdiction in North Carolina and in this judicial district because, among other things, Synthon International Holding B.V., itself and through its subsidiaries Synthon B.V. and Synthon Pharmaceuticals, Inc., has purposefully availed itself of the benefits and protections of North Carolina's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Synthon International Holding B.V., itself and through its subsidiaries Synthon B.V. and Synthon Pharmaceuticals, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of North Carolina and in this judicial district, and therefore transacts business within the State of North Carolina and in this judicial district, and/or has engaged in systematic and continuous business contacts within the State of North Carolina and within this judicial district. In addition, Synthon International Holding B.V. is subject to personal jurisdiction in North Carolina and in this judicial district because, upon information and belief, it controls Synthon Pharmaceuticals, Inc. and Synthon B.V., and therefore the activities of Synthon Pharmaceuticals, Inc. and Synthon B.V. in this jurisdiction are attributed to Synthon International Holding B.V.

15. Synthon B.V. is subject to personal jurisdiction in North Carolina and in this judicial district because, among other things, Synthon International Holding B.V., itself and through other Synthon entities, including Synthon Pharmaceuticals, Inc., has purposefully availed itself of the benefits and protections of North Carolina's laws such

that it should reasonably anticipate being haled into court here. Upon information and belief, Synthon B.V., itself and through other Synthon entities, including Synthon Pharmaceuticals, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of North Carolina and in this judicial district, and therefore transacts business within the State of North Carolina and in this judicial district, and/or has engaged in systematic and continuous business contacts within the State of North Carolina and within this judicial district. Upon information and belief, Synthon B.V. previously has been sued in this judicial district, did not challenge venue or the Court's personal jurisdiction over it, and/or availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes under the Hatch-Waxman Act. *See Celgene Corp. v. Synthon Pharmaceuticals, Inc. et al.*, C.A. No. 1:18-cv-00540-LCB-JEP, ECF No. 6, pp. 13-23. In addition, Synthon B.V. is subject to personal jurisdiction in North Carolina and in this judicial district because, upon information and belief, it directs and coordinates the activities of Synthon Pharmaceuticals, Inc., and therefore the activities of Synthon Pharmaceuticals, Inc. in this jurisdiction are attributed to Synthon B.V.

16. Synthon Pharmaceuticals, Inc. is subject to personal jurisdiction in North Carolina and in this judicial district because, among other things, it has purposely availed itself of the benefits and protections of North Carolina's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Synthon

Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of North Carolina and is registered to conduct business within the State of North Carolina. Synthon Pharmaceuticals, Inc. is therefore subject to general jurisdiction in the State of North Carolina. Upon information and belief, Synthon Pharmaceuticals, Inc. also has a principal place of business within this judicial district. Upon information and belief, Synthon Pharmaceuticals, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of North Carolina and in this judicial district, and therefore transacts business within the State of North Carolina and within this judicial district related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of North Carolina and within this judicial district. Upon information and belief, Synthon Pharmaceuticals, Inc. previously has been sued in this judicial district, did not challenge venue or the Court's personal jurisdiction over it, and/or availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes under the Hatch-Waxman Act. *See Celgene Corp. v. Synthon Pharmaceuticals, Inc. et al.*, C.A. No. 1:18-cv-00540-LCB-JEP, ECF No. 6, at ¶ 17, pp. 13-23.

17. Synthon has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent

litigation arising from the process contemplated by the Hatch-Waxman Act.

18. Upon information and belief, Synthon, with knowledge of the Hatch-Waxman Act process, directed Synthon's Notice Letter to Pfizer, and alleged in Synthon's Notice Letter that the patent-in-suit is not infringed. Upon information and belief, Synthon knowingly and deliberately challenged Pfizer's patent rights, and knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

19. Upon information and belief, if Synthon's ANDA is approved, Synthon will directly or indirectly manufacture, market, sell, and/or distribute Synthon's ANDA Products within the United States, including in North Carolina and in this judicial district, consistent with Synthon's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, following any FDA approval of ANDA No. 215570, Synthon knows and intends that Synthon's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within this judicial district. Upon information and belief, Synthon regularly does business in North Carolina and in this judicial district, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in North Carolina and in this judicial district. Upon information and belief, Synthon's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in North Carolina and in this

judicial district. Upon information and belief, Synthon's ANDA Products will be prescribed by physicians practicing in North Carolina and in this judicial district, dispensed by pharmacies located within North Carolina and in this judicial district, and used by patients in North Carolina and in this judicial district. Each of these activities would have a substantial effect within North Carolina and within this judicial district and would constitute infringement of the patent-in-suit in the event that Synthon's ANDA Products are approved before the patent-in-suit expires.

20. Upon information and belief, Synthon derives substantial revenue from generic pharmaceutical products that are used and/or consumed within North Carolina and in this judicial district, and which are manufactured by Synthon Pharmaceuticals, Inc. and/or for which Synthon Pharmaceuticals, Inc., Synthon B.V., or Synthon International Holding B.V. is the named applicant on approved ANDAs. Upon information and belief, various products for which Synthon Pharmaceuticals, Inc., Synthon B.V., or Synthon International Holding B.V. is the named applicant on approved ANDAs are available at retail pharmacies in North Carolina and in this judicial district.

21. Alternatively, if Synthon International Holding B.V.'s or Synthon B.V.'s connections with North Carolina and/or this judicial district, including its connections with Synthon Pharmaceuticals, Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Synthon International Holding B.V. and Synthon B.V. are not subject to jurisdiction in any state's courts of general jurisdiction, and exercising

jurisdiction over Synthon International Holding B.V. and Synthon B.V. in this judicial district is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

VENUE

22. Venue is proper in this district as to Synthon International Holding B.V. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Synthon International Holding B.V. is a company organized and existing under the laws of the Netherlands and is subject to personal jurisdiction in this judicial district.

23. Venue is proper in this district as to Synthon B.V. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Synthon B.V. is a company organized and existing under the laws of the Netherlands and is subject to personal jurisdiction in this judicial district.

24. Venue is proper in this district as to Synthon Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Synthon Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of North Carolina and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

25. IBRANCE®, which contains palbociclib, is approved for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer.

26. Upon information and belief, Synthon's ANDA Products are a generic version

of IBRANCE®.

27. Synthon's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to Synthon's ANDA. The offer, however, was subject to various unreasonably restrictive conditions. In an exchange of correspondence, counsel for Plaintiffs and counsel for Synthon discussed the terms of Synthon's Offer of Confidential Access, though the parties were unable to agree on terms under which Pfizer could review internal documents, data, and/or samples relevant to infringement, which are not publicly available, on reasonable confidentiality terms.

28. Plaintiffs are filing this Complaint within forty-five days of receipt of Synthon's Notice Letter.

COUNT I - INFRINGEMENT OF THE '250 PATENT

29. Pfizer incorporates each of the preceding paragraphs as if fully set forth herein.

30. The inventors named on the '250 patent are Fady Makram Louiz Ibrahim, Matthew Patrick Mullarney, Ravi M. Shanker, Barbara Rodriguez Spong, and Jian Wang.

31. The '250 patent, entitled "Solid Dosage Forms of Palbociclib" (attached as Exhibit A), was duly and legally issued on July 20, 2021.

32. Pfizer is the owner and assignee of the '250 patent.

33. The '250 patent claims, *inter alia*, a tablet formulation consisting of palbociclib and other inactive ingredients as recited in claim 1 of the '250 patent.

34. IBRANCE® is covered by one or more claims of the ’250 patent, including claim 1 of the ’250 patent, and the ’250 patent has been listed in connection with IBRANCE® in the FDA’s Orange Book.

35. In Synthon’s Notice Letter, Synthon notified Pfizer of the submission of Synthon’s ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Synthon’s ANDA Products prior to the expiration of the ’250 patent.

36. In Synthon’s Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’250 patent. Upon information and belief, Synthon submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’250 patent will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Synthon’s ANDA Products.

37. According to Synthon’s Notice Letter, Synthon’s ANDA Products contain palbociclib. Upon information and belief, Synthon’s ANDA Products contain palbociclib in an amount that satisfies literally and/or by equivalents the palbociclib limitation of claim of 1 of the ’250 patent.

38. Upon information and belief, Synthon’s ANDA Products contain inactive

ingredients that satisfy, literally and/or by equivalents, the limitations of claim 1 concerning materials other than palbociclib that are contained in the claimed formulation. Synthon's Notice Letter did not contest that Synthon's ANDA Products literally and/or by equivalents satisfy various of the limitations of claim 1 of the '250 patent.

39. Upon information and belief, Synthon's ANDA Products and the use of Synthon's ANDA Products in accordance with their proposed labeling are covered literally and/or under the doctrine of equivalents by one or more claims of the '250 patent, including at least claim 1 of the '250 patent.

40. In Synthon's Notice Letter, Synthon did not contest the validity of any claim of the '250 patent.

41. Synthon's submission of Synthon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products before the expiration of the '250 patent was an act of infringement of the '250 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Synthon will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Synthon's ANDA Products immediately and imminently upon approval of its ANDA.

43. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '250 patent, including at least claim 1

of the ’250 patent.

44. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon’s ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’250 patent, including at least claims 1 of the ’250 patent.

45. Upon information and belief, Synthon plans and intends to, and will, actively induce infringement of the ’250 patent when Synthon’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Synthon’s activities will be done with knowledge of the ’250 patent and specific intent to infringe that patent.

46. Notwithstanding Synthon’s knowledge of the claims of the ’250 patent, Synthon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Synthon’s ANDA Products with their product labeling following FDA approval of Synthon’s ANDA prior to the expiration of the ’250 patent.

47. The foregoing actions by Synthon constitute and/or will constitute infringement of the ’250 patent and active inducement of infringement of the ’250 patent.

48. Upon information and belief, Synthon has acted with full knowledge of the ’250 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’250 patent and active inducement of infringement of the ’250 patent.

49. Pfizer will be substantially and irreparably damaged by infringement of the

’250 patent.

50. Unless Synthon is enjoined from infringing the ’250 patent and actively inducing infringement of the ’250 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’250 PATENT

51. Pfizer incorporates each of the preceding paragraphs as if fully set forth herein.

52. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Synthon on the other regarding Synthon’s infringement and active inducement of infringement of the ’250 patent.

53. The ’250 patent claims, *inter alia*, a tablet formulation consisting of palbociclib and other inactive ingredients as recited in claim 1 of the ’250 patent.

54. IBRANCE® is covered by one or more claims of the ’250 patent, including claim 1 of the ’250 patent, and the ’250 patent has been listed in connection with IBRANCE® in the FDA’s Orange Book.

55. In Synthon’s Notice Letter, Synthon notified Pfizer of the submission of Synthon’s ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale,

sale and/or importation of Synthon's ANDA Products prior to the expiration of the '250 patent.

56. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '250 patent. Upon information and belief, Synthon submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '250 patent will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products.

57. According to Synthon's Notice Letter, Synthon's ANDA Products contain palbociclib. Upon information and belief, Synthon's ANDA Products contain palbociclib in an amount that satisfies literally and/or by equivalents the palbociclib limitation of claim of 1 of the '250 patent.

58. Upon information and belief, Synthon's ANDA Products contain inactive ingredients that satisfy, literally and/or by equivalents, the limitations of claim 1 concerning materials other than palbociclib that are contained in the claimed formulation. Synthon's Notice Letter did not contest that Synthon's ANDA Products literally and/or by equivalents satisfy various of the limitations of claim 1 of the '250 patent.

59. Upon information and belief, Synthon's ANDA Products and the use of Synthon's ANDA Products in accordance with their proposed labeling are covered literally

and/or under the doctrine of equivalents by one or more claims of the ’250 patent, including at least claim 1 of the ’250 patent.

60. In Synthon’s Notice Letter, Synthon did not contest the validity of any claim of the ’250 patent.

61. Synthon’s submission of Synthon’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon’s ANDA Products before the expiration of the ’250 patent was an act of infringement of the ’250 patent under 35 U.S.C. § 271(e)(2)(A).

62. Upon information and belief, Synthon will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Synthon’s ANDA Products immediately and imminently upon approval of its ANDA.

63. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon’s ANDA Products would infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’250 patent, including at least claim 1 of the ’250 patent.

64. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon’s ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’250 patent, including at least claims 1 of the ’250 patent.

65. Upon information and belief, Synthon plans and intends to, and will, actively

induce infringement of the ’250 patent when Synthon’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Synthon’s activities will be done with knowledge of the ’250 patent and specific intent to infringe that patent.

66. Notwithstanding Synthon’s knowledge of the claims of the ’250 patent, Synthon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Synthon’s ANDA Products with their product labeling following FDA approval of Synthon’s ANDA prior to the expiration of the ’250 patent.

67. The foregoing actions by Synthon constitute and/or will constitute infringement of the ’250 patent and active inducement of infringement of the ’250 patent.

68. Upon information and belief, Synthon has acted with full knowledge of the ’250 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’250 patent and active inducement of infringement of the ’250 patent.

69. Pfizer will be substantially and irreparably damaged by infringement of the ’250 patent.

70. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Synthon’s ANDA Products with its proposed labeling, or any other Synthon drug product that is covered by or whose use is covered by the ’250 patent, will infringe and induce the infringement of the ’250 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that the patent-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Synthon's submission to the FDA of Synthon's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Synthon's ANDA Products, or any other drug product that infringes or the use of which infringes the patent-in-suit, be not earlier than the latest of the expiration dates of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Synthon and all persons acting in concert with Synthon, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Synthon's ANDA Products, or any other drug product covered by or whose use is covered by the patent-in-suit, prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Synthon's ANDA Products, or any other drug product which is covered by or whose use is covered by the patent-in-suit, prior to the expiration of said patent, will infringe and induce the infringement of said patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

This, the 21st day of October, 2021.

/s/ Allison Mullins
Allison Mullins
N.C. State Bar No. 23430
L. Cooper Harrell
N.C. State Bar No. 27875
TURNING POINT LITIGATION
MULLINS DUNCAN HARRELL & RUSSELL PLLC
300 North Greene Street, Suite 2000
Greensboro, NC 27401
Telephone: 336-645-3320
Facsimile: 336-645-3330
amullins@turningpointlit.com
charrell@turningpointlit.com

OF COUNSEL:

David I. Berl
Christopher J. Mandernach
Seth R. Bowers
Michael Xun Liu
Kevin Hoagland-Hanson
Andrew L. Hoffman
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiffs