David E. De Lorenzi
Charles H. Chevalier
Christine A. Gaddis
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4611
ddelorenzi@gibbonslaw.com
cchevalier@gibbonslaw.com
cgaddis@gibbonslaw.com

Of Counsel:
George F. Pappas
Kevin B. Collins
Alexander Trzeciak
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
Tel: (202) 662-6000

Alexa Hansen
COVINGTON & BURLING LLP
One Front Street
San Francisco, California 94111-5356
Tel: (415) 591-7035

Attorneys for Plaintiff
Merck Sharp & Dohme Corp.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., **Plaintiff,** v. **SANDOZ INC.,** **Defendant.**	**Civil Action No. 20-cv-783** **(Filed Electronically)**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp. ("Merck" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendant Sandoz Inc. ("Sandoz" or "Defendant"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 202481 (hereinafter, "Sandoz's ANDA"), filed by and for the benefit of Sandoz with the United States Food and Drug Administration ("FDA"). Through Sandoz's ANDA, Sandoz seeks approval to market a generic version of NOXAFIL® (posaconazole, oral suspension 40 mg/mL) (hereinafter, "Sandoz's Infringing ANDA Product"), prior to the expiration of Merck's United States Patent No. 8,263,600 ("the '600 Patent" or "the Patent-in-Suit").

THE PARTIES

2. Merck is a global healthcare company committed to improving the health and well-being around the world. Merck is in the business of manufacturing and bringing to market innovative medicines and technologies. Merck is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

3. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271, for infringement of the Patent-in-Suit.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

6. This Court has personal jurisdiction over Defendant Sandoz because, on information and belief, Sandoz is a corporation with a principal place of business in New Jersey. This Court also has personal jurisdiction over Defendant Sandoz because, *inter alia*, on information and belief, Sandoz has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell Sandoz's Infringing ANDA Product in the State of New Jersey upon approval of ANDA No. 202481.

7. On information and belief, Sandoz is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within the State of New Jersey, through its own actions and through the actions of its agents and subsidiaries, from which Sandoz derives a substantial portion of its revenue.

8. On information and belief, Sandoz, through its own actions and through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of ANDA No. 202481, continues to engage in seeking FDA approval of this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Sandoz's Infringing ANDA Product throughout the United States, including within the State of New Jersey, and stands to benefit from the approval of ANDA No. 202481.

9. On information and belief, Sandoz, through its own actions and through the actions of its agents and subsidiaries, prepared and submitted ANDA No. 202481 with a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

10. On information and belief, following FDA approval of ANDA No. 202481, Sandoz intends to market, offer to sell, sell, or distribute Sandoz's Infringing ANDA Product throughout the United States and within the State of New Jersey, that will, as explained below, infringe upon Merck's rights in the Patent-in-Suit protecting its NOXAFIL® products. On information and belief, following FDA approval of ANDA No. 202481, Sandoz knows and intends that Sandoz's Infringing ANDA Product will be marketed, used, distributed, offered for sale, or sold in the United States and within the State of New Jersey.

11. On information and belief, Sandoz is registered to do business in the State of New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

12. Sandoz has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, *Celgene Corp. v. Sandoz Inc.*, No. 18-11026, D.I. 18 (D.N.J. Sept. 25, 2018); *Allergan Sales, LLC et al. v. Sandoz, Inc. et al.*, No. 17-cv-10129, D.I. 18 (D.N.J. Dec. 19, 2017); *Boehringer Ingelheim Pharm., Inc. et al. v. Sandoz Inc.*, No. 17-cv-08825, D.I. 14 (D.N.J. Jan. 23, 2018); *Mitsubishi Tanabe Pharma Corp. et al. v. MSN Labs. Pvt. Ltd. et al.*, No. 17-cv-05302, D.I. 28 (D.N.J. Nov. 17, 2017). Sandoz has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

13. This Court also has personal jurisdiction over Sandoz at least because, *inter alia*, (a) Sandoz has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's Infringing ANDA Product in the United States, including in the State of New Jersey; (b) Sandoz, through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell Sandoz's Infringing ANDA Product in the United States, including in the State of New Jersey and to residents of this Judicial District, upon approval of ANDA No. 202481, and will derive substantial revenue from the use or consumption of Sandoz's Infringing ANDA Product in the State of New Jersey; and (c) Sandoz has purposefully availed itself of the privilege of doing business in the State of New Jersey by placing goods into the stream of commerce for distribution throughout the United States and within the State of New Jersey, and/or by selling, directly or through its agents, pharmaceutical products in the State of New Jersey. On information and belief, if ANDA No. 202481 is approved, Sandoz's Infringing ANDA Product charged with infringing the Patent-in-Suit would, *inter alia*, be marketed, distributed, offered for sale, or sold in the State of New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

14. This Court also has personal jurisdiction over Sandoz because Sandoz has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Merck, a corporation headquartered in the State of New Jersey that manufactures NOXAFIL® drug products for sale and use throughout the United States, including in this Judicial District. On information and belief, Sandoz filed ANDA No. 202481 with a Paragraph IV Certification, which was

purposefully directed to the State of New Jersey, where Merck is located. As a result, the consequences of Sandoz's actions were, and will be, suffered in the State of New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in the State of New Jersey. At the time Sandoz sent notice of the Paragraph IV Certification, it was reasonably foreseeable that Sandoz would be sued within 45 days in this Judicial District, where Merck is located. On information and belief, Sandoz's actions will injure Merck by displacing at least some, if not all, of Merck's sales of NOXAFIL® drug products in this Judicial District, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of NOXAFIL® drug products in this Judicial District.

15. On information and belief, Sandoz has also engaged in substantial, systematic, and continuous contacts with New Jersey that satisfy due process and confer personal jurisdiction over Sandoz in New Jersey.

16. At least because, on information and belief, Sandoz has a principal place of business in New Jersey and has committed acts of infringement in New Jersey, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b).

MERCK'S PATENT AND APPROVED NOXAFIL® DRUG PRODUCTS

17. Merck makes and sells NOXAFIL® (posaconazole, oral suspension, 40 mg/mL) to treat adult patients prophylactically for invasive *Aspergillus* and *Candida* infections (Indication 1.1), as well as for the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole (Indication 1.2). The active ingredient in NOXAFIL® is posaconazole. In addition to oral suspension, 40 mg/mL, NOXAFIL® is also sold in delayed-release tablet (100 mg) and injection (18 mg/mL) formulations. A true and correct copy of the prescribing information for Merck's NOXAFIL® is attached as Exhibit A.

18. Merck, formerly Schering Plough Corporation, holds New Drug Application ("NDA") No. 022003, under which FDA approved the marketing of NOXAFIL® on September 15, 2006, as well as NDA No. 022027, which is directed to a particular indication of NOXAFIL®.

19. The Patent-in-Suit is listed in *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "*Orange Book*") in connection with NDA No. 022003.

20. Merck, as the assignee, owns the entire right, title, and interest in the Patent-in-Suit. Merck has the right to enforce this Patent.

21. The '600 Patent is entitled, "Antifungal Composition with Enhanced Bioavailability." The '600 Patent was duly and legally issued on September 11, 2012. The *Orange Book* presently shows that the '600 Patent's term ends on April 1, 2022. A true and correct copy of the '600 Patent is attached as Exhibit B.

SANDOZ'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

22. On information and belief, Sandoz has submitted or caused to be submitted ANDA No. 202481 to FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the posaconazole oral suspension described therein, as a purported generic version of NOXAFIL®, prior to the expiration of the Patent-in-Suit.

23. On information and belief, Sandoz's Infringing ANDA Product is oral suspension at 40 mg/mL of posaconazole.

24. On information and belief, FDA has not yet approved ANDA No. 202481.

25. Merck received a Notice of Paragraph IV Certification from Sandoz dated December 13, 2019 ("Notice Letter"). The Notice Letter represented that Sandoz had submitted

to FDA ANDA No. 202481 with a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the products described in ANDA No. 202481, before the expiration of the patent listed in the *Orange Book* for NOXAFIL®. Hence, Sandoz's purpose in submitting ANDA No. 202481 is to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz's Infringing ANDA Product before the expiration of the Patent-in-Suit.

26. The Notice Letter states that the Paragraph IV Certification in ANDA No. 202481 alleges that the Patent-in-Suit is invalid, unenforceable, or would not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz's Infringing ANDA Product.

27. The Notice Letter contained a purported detailed statement of the factual and legal basis for Sandoz's opinion that the Patent-in-Suit is purportedly invalid, unenforceable, or not infringed by the manufacture, use, offer for sale, sale, or importation into the United States of Sandoz's Infringing ANDA Product ("Paragraph IV Statement").

28. On information and belief, Sandoz, through its own actions and through the actions of its agents and subsidiaries, has assisted with and participated in the preparation and submission of ANDA No. 202481, has provided material support to the preparation and submission of ANDA No. 202481, and intends to support the further prosecution of ANDA No. 202481.

29. On information and belief, if FDA approves ANDA No. 202481, Sandoz will manufacture, offer to sell, or sell Sandoz's Infringing ANDA Product within the United States,

including within the State of New Jersey, or will import Sandoz's Infringing ANDA Product into the United States, including New Jersey.

30. On information and belief, if FDA approves ANDA No. 202481, Sandoz will actively induce or contribute to the manufacture, use, offer to sell, sale, or importation of Sandoz's Infringing ANDA Product in the United States.

31. Merck brings this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of the Notice Letter. *See* 21 U.S.C. § 355(c)(3)(C).

COUNT 1
INFRINGEMENT OF THE '600 PATENT

32. Merck states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

33. On information and belief, Sandoz has submitted or caused the submission of ANDA No. 202481 to FDA and continues to seek FDA approval of ANDA No. 202481.

34. Sandoz has infringed the '600 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202481 with a Paragraph IV Certification and seeking FDA approval of ANDA No. 202481 prior to the expiration of the '600 Patent.

35. The '600 Patent includes claims that recite liquid suspensions comprising micronized posaconazole, Polysorbate 80, a buffer system, thickening agents, and a liquid carrier.

36. On information and belief, Sandoz's Infringing ANDA Product is a liquid suspension comprising micronized posaconazole, Polysorbate 80, a buffer system, thickening agents, and a liquid carrier.

37. Sandoz's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Sandoz's Infringing ANDA Product would

directly infringe, or would actively induce or contribute to infringement of the ’600 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 202481, Sandoz will make, use, offer for sale, or sell Sandoz’s Infringing ANDA Product within the United States, or will import Sandoz’s Infringing ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the ’600 Patent. *See id.*

38. On information and belief, upon FDA approval of ANDA No. 202481, Sandoz, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Sandoz’s Infringing ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Sandoz’s Infringing ANDA Product. On information and belief, Sandoz will also knowingly and intentionally accompany Sandoz’s Infringing ANDA Product with a product label and product insert that will include instructions for using or administering Sandoz’s Infringing ANDA Product.

39. On information and belief, the product label and product insert accompanying Sandoz’s Infringing ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for NOXAFIL®, attached as Exhibit A, and which, if followed, will infringe the ’600 Patent. Accordingly, Sandoz will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Sandoz’s Infringing ANDA Product to directly infringe one or more claims of the ’600 Patent. In addition, on information and belief, Sandoz will encourage acts of direct infringement with knowledge of the ’600 Patent and knowledge that it is encouraging infringement.

40. Sandoz had actual and constructive notice of the ’600 Patent prior to amending Sandoz’s ANDA and was aware that the submission of an ANDA with a request for FDA approval prior to the expiration of the ’600 Patent would constitute an act of infringement of the ’600 Patent. Sandoz had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Sandoz’s Infringing ANDA Product would not contribute to, or induce, the infringement of the ’600 Patent.

41. Sandoz’s Paragraph IV Statement in the Notice Letter lacks any sufficient contention that Sandoz’s Infringing ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the ’600 Patent.

42. On information and belief, Sandoz filed ANDA No. 202481 without adequate justification for asserting the ’600 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz’s Infringing ANDA Product. Sandoz’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’600 Patent renders this case “exceptional” under 35 U.S.C. § 285.

43. Merck will be irreparably harmed if Sandoz is not enjoined from infringing, and from actively inducing and contributing to the infringement of the ’600 Patent. Merck does not have an adequate remedy at law, and considering the balance of hardships between Merck and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 2
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’600 PATENT

44. Merck states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

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

46. The '600 Patent includes claims that recite liquid suspensions comprising micronized posaconazole, Polysorbate 80, a buffer system, thickening agents, and a liquid carrier.

47. On information and belief, Sandoz's Infringing ANDA Product is a liquid suspension comprising micronized posaconazole, Polysorbate 80, a buffer system, thickening agents, and a liquid carrier.

48. On information and belief, if Sandoz's ANDA is approved, Sandoz's Infringing ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, or will be imported into the United States, including the State of New Jersey, by or through Sandoz and its affiliates. Sandoz will therefore directly infringe one or more claims of the '600 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

49. On information and belief, Sandoz knows that healthcare professionals or patients will use Sandoz's Infringing ANDA Product in accordance with the labeling sought by Sandoz's ANDA. On information and belief, the product label and product insert accompanying Sandoz's Infringing ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for NOXAFIL®, attached as Exhibit A, and which, if followed, will infringe the '600 Patent. Sandoz will therefore contribute to, or induce, the infringement of one or more claims of the '600 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

50. On information and belief, Sandoz's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's Infringing ANDA Product complained of herein, will begin immediately after the FDA approves Sandoz's ANDA. Any such conduct before the '600 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '600 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

51. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Merck and Sandoz concerning liability for the infringement of the '600 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

52. Merck will be substantially and irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

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

REQUEST FOR RELIEF

WHEREFORE, Merck respectfully requests the following relief:

(a) The entry of a judgment, in favor of Merck and against Sandoz, that Sandoz's submission of ANDA No. 202481 to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, Sandoz's Infringing ANDA Product before the expiration of the Patent-in-Suit was an act of infringement of one or more claims of the Patent-in-Suit under 35 U.S.C. § 271(e)(2)(A);

(b) The entry of a declaratory judgment, in favor of Merck and against Sandoz, declaring that Sandoz's commercial manufacture, use, offer for sale, or sale in the United States,

or importation into the United States, Sandoz's Infringing ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the Patent-in-Suit by Sandoz under one or more of 35 U.S.C. § 271(a), (b), and (c);

(c) The entry of a judgment declaring that the Patent-in-Suit remain valid and enforceable;

(d) The entry of an injunction enjoining Sandoz and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Sandoz, and their successors or assigns, from commercially manufacturing, using, offering to sell, or selling Sandoz's Infringing ANDA Product within the United States, or importing Sandoz's Infringing ANDA Product into the United States, or inducing or contributing to such conduct, until the last of the expiration date of the Patent-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Merck is or becomes entitled;

(e) The entry of an injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Sandoz and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Sandoz, and their successors or assigns, from commercially manufacturing, using, offering to sell, or selling Sandoz's Infringing ANDA Product within the United States, or importing Sandoz's Infringing ANDA Product into the United States, or inducing or contributing to such conduct, until the last of the expiration date of the Patent-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Merck is or becomes entitled;

(f) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 202481 shall be a date that is not earlier than the last of the expiration date of the Patent-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Merck is or becomes entitled;

(g) A declaration under 28 U.S.C. § 2201 that if Sandoz, its officers, directors, agents, servants, employees, representatives, attorneys, parents, subsidiaries, affiliates, other related business entities, or other persons or entities acting or attempting to act in concert, participation, or in privity with Sandoz, or acting on Sandoz's behalf, engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, Sandoz's Infringing ANDA Product, then it will constitute an act of direct or indirect infringement of the Patent-in-Suit;

(h) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Sandoz engages in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's Infringing ANDA Product, or any product that infringes the Patent-in-Suit, or induces or contributes to such conduct, prior to the expiration of such patent, including any extensions or regulatory exclusivities;

(i) The entry of judgment declaring that Sandoz's acts render this case an exceptional case and awarding Merck its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(j) An award to Merck of its costs and expenses in this action; and

(k) Such other and further relief this Court deems just and proper.

Dated: January 23, 2020

By: s/ Charles H. Chevalier

David E. De Lorenzi
Charles H. Chevalier
Christine A. Gaddis
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4611
ddelorenzi@gibbonslaw.com
cchevalier@gibbonslaw.com
cgaddis@gibbonslaw.com

Attorneys for Plaintiff
Merck Sharp & Dohme Corp.

OF COUNSEL:

George F. Pappas
Kevin B. Collins
Alexander Trzeciak
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
Tel: (202) 662-6000

Alexa Hansen
COVINGTON & BURLING LLP
Salesforce Tower
415 Mission Street, Suite 5400
San Francisco, CA 94105
Tel: (415) 591-7035