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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD., Defendants.	)	C.A. No. 2:18-cv-08519 (Filed Electronically)

DEFENDANTS ZYDUS PHARMACEUTICALS (USA) INC. AND CADILA HEALTHCARE LIMITED'S ANSWER AND AFFIRMATIVE DEFENSES

Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Limited ("Cadila") (together, "Defendants") for their Answer and Affirmative Defenses to the Complaint of Celgene Corporation ("Plaintiff") state as follows:

All averments not expressly admitted are denied.

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Zydus's filing of an Abbreviated New Drug Application ("ANDA") No. 210154 ("Zydus's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Celgene's 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID® drug products prior to the expiration of United States Patent Nos. 7,977,357 (the "'357 patent"), 8,193,219 (the "'219 patent"), and 8,431,598 (the "'598 patent"), all owned by Celgene (collectively, "the patents-in-suit").

ANSWER: The allegations in paragraph 1 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted Abbreviated New Drug Application ("ANDA") No. 210154 to the United States Food and Drug Administration ("FDA") to obtain approval to engage in the commercial manufacture, use, or sale of lenalidomide capsules, 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg. Defendants further admit that Plaintiff's Complaint purports to be a civil action alleging infringement of U.S. Patent Nos. 7,977,357 ("the '357 patent"), 8,193,219 ("the '219 patent"), and 8,431,598 ("the '598 patent") (collectively, "the patents-in-suit") pursuant to Title 35 of the United States Code. Defendants deny that this Court has subject matter jurisdiction over Plaintiff's claims regarding the patents-in-suit. Defendants further deny that Defendants have infringed any valid claim of the patents-in-suit. Defendants deny all other allegations in paragraph 1.

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions, including cancer. Celgene is a world leader in the treatment of many such diseases. Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in the first, second, and third sentences of paragraph 2 and therefore deny them. Upon information and belief, Defendants admit that Plaintiff is a corporation

organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901. Defendants deny all other allegations of paragraph 2.

3. On information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

ANSWER: Admitted.

4. On information and belief, Defendant Cadila Healthcare Limited is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, Gujarat, India.

ANSWER: Admitted.

5. On information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila.

ANSWER: Admitted.

The Patents-in-Suit

6. On July 12, 2011, the USPTO duly and lawfully issued the '357 patent, entitled, "Polymorphic Forms of 3-(4- amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '357 patent is attached hereto as Exhibit A.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '357 patent is attached to the Complaint as Exhibit A. Defendants further admit that Exhibit A is titled "Polymorphic Forms of 3-(4- amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" and lists July 12, 2011 as the date of patent. Defendants further admit that Plaintiff is listed as the assignee on the face of the patent and that Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller are listed as inventors on the face of the patent. Defendants deny all other allegations of paragraph 6.

7. On June 5, 2012, the USPTO duly and lawfully issued the '219 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '219 patent is attached hereto as Exhibit B.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '219 patent is attached to the Complaint as Exhibit B. Defendants further admit that Exhibit B is titled "Polymorphic Forms of 3-(4- amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" and lists June 5, 2012 as the date of patent. Defendants further admit that Plaintiff is listed as the assignee on the face of the patent and that Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller are listed as inventors on the face of the patent. Defendants deny all other allegations of paragraph 7.

8. On April 30, 2013, the USPTO duly and lawfully issued the '598 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" to Celgene as assignee of the inventor Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '598 patent is attached hereto as Exhibit C.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '598 patent is attached to the Complaint as Exhibit C. Defendants further admit that Exhibit C is titled "Polymorphic Forms of 3-(4- amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" and lists April 30, 2013 as the date of patent. Defendants further admit that Plaintiff is listed as the assignee on the face of the patent and that Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller are listed as inventors on the face of the patent. Defendants deny all other allegations of paragraph 8.

The REVLIMID® Drug Product

9. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for lenalidomide capsules (NDA No. 21-880), which it sells under the trade name REVLIMID®. REVLIMID® is an FDA-approved medication used for the treatment of certain forms of cancer, including multiple myeloma (MM), in combination with dexamethasone. The claims of the patents-in-suit cover, *inter alia*, solid forms of lenalidomide and pharmaceutical compositions containing those solid forms.

ANSWER: Defendants admit that New Drug Application ("NDA") No. 021880, for lenalidomide capsules, 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg, is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"), which also lists the product's proprietary name as Revlimid® and "Celgene Corp" as the applicant holder. Defendants further admit that the February 22, 2017 label for Revlimid® states:

----------INDICATIONS AND USAGE----------

REVLIMID is a thalidomide analogue indicated for the treatment of patients with:

- Multiple myeloma (MM), in combination with dexamethasone (1.1).
- MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT) (1.1).
- Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities (1.2).
- Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib (1.3).

Limitations of Use:

- REVLIMID is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials (1.4).

The third sentence of paragraph 9 states legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that the third sentence accurately and completely recites the limitations of the claims recited in the patents-in-suit and, therefore, deny the allegations in the third sentence. Defendants deny all other allegations in paragraph 9.

Jurisdiction and Venue

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

ANSWER: The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that this Court has subject matter jurisdiction over Plaintiff's claims regarding the patents-in-suit. Defendants deny all other allegations in paragraph 10.

11. This Court has personal jurisdiction over Zydus USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Zydus USA's principal place of business is in Pennington, New Jersey. On information and belief, Zydus USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business I.D. No. 0100915422. On information and belief, Zydus USA is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003171. On information and belief, Zydus USA purposefully has conducted and continues to conduct business in this Judicial District. On information and belief, Zydus USA is a corporation organized and existing under the laws of the State of New Jersey. By virtue of its incorporation in New Jersey, this Court has personal jurisdiction over Zydus USA.

ANSWER: The allegations in the first and seventh sentences in paragraph 11 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Zydus USA in this case and solely as they apply to the proposed products described in ANDA No. 210154. Defendants admit the allegations in the second, third, fourth, fifth, and sixth sentences in paragraph 11. Defendants deny all other allegations in paragraph 11.

12. On information and belief, Zydus USA is in the business of, among other things, manufacturing, marketing, offering for sale, selling, and importing pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. This Judicial District is a likely destination for the generic drug product described in Zydus's ANDA. On information and belief, Zydus USA also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: Defendants admit that Zydus USA imports pharmaceutical products, including generic pharmaceutical products, into the United States, and that Zydus USA sells

pharmaceutical products, including generic pharmaceutical products, in the United States, including the State of New Jersey. Defendants further admit that Zydus USA submits ANDAs to the FDA. Defendants deny all other allegations in paragraph 12.

13. This Court has personal jurisdiction over Cadila Healthcare Limited because, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Zydus Pharmaceuticals (USA) Inc., a company incorporated in New Jersey, with its principal place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Zydus Pharmaceuticals (USA) Inc.

ANSWER: The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent an answer is required, Cadila does not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Cadila in this case and solely as they apply to the proposed products described in ANDA No. 210154. Defendants admit that Cadila develops and manufactures pharmaceutical products, including pharmaceutical products sold in the United States; that Zydus USA sells pharmaceutical products in the United States, including pharmaceutical products manufactured by Cadila; and that Zydus USA is incorporated in New Jersey, with its principal place of business in New Jersey. Defendants deny all other allegations in paragraph 13.

14. This Court has personal jurisdiction over Zydus because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Zydus intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

ANSWER: The allegations in paragraph 14 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. Defendants admit that

Zydus USA transmitted letters dated February 27, 2017 to Plaintiff ("Zydus USA's February 27, 2017 letter") at addresses in New Jersey notifying Plaintiff that Zydus USA submitted ANDA No. 210154 to FDA. Defendants deny all other allegations in paragraph 14.

15. Zydus Cadila's Annual Report 2015-16 states that "US is the world's largest pharmaceutical market, both for branded and generic drugs, accounting for around one third of the global market," and that "[t]he Company is present in the [US] generic pharmaceuticals market through its wholly owned subsidiary, Zydus Pharmaceuticals (USA) Inc." Cadila Healthcare Limited Annual Report 2015-16 ("Zydus Cadila 2015-16 Annual Report" (https://zyduscadila.com/wp-content/uploads/2016/07/annual_report_15_16.pdf, last visited April 24, 2018) at 9). The Zydus Cadila 2015-16 Annual Report further states that "the Company is ranked amongst the top 10 generics companies in the US based on prescriptions." *Id*. The Zydus Cadila 2015-16 Annual Report further states that "[t]he Company launched 3 new products in the US market during the year," and that "[i]n terms of ANDA filings, 30 more ANDAs were filed with the USFDA during the year, taking the cumulative number of ANDA filings to 269." *Id.* at 10. The Zydus Cadila 2015-16 Annual Report further states that "[g]oing forward, the Company's focus will continue to be on launching complex, difficult-to-make oral solids and formulations of other dosage forms like injectables, nasals, creams and ointments in order to enhance its share in the US generics market." *Id.*

ANSWER: Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. Defendants admit that the language quoted in paragraph 15 appears in portions of Cadila's Annual Report 2015-16, but deny that the allegations accurately and completely recite the complete contents of Cadila's Annual Report 2015-16. Defendants deny all other allegations in paragraph 15.

16. Zydus Cadila's Annual Report 2016-17 states that "[the] US is the world's largest pharmaceutical market, both for branded and generic drugs, accounting for around forty percent of the global market," that "[t]he Company is present in the generic pharmaceuticals market in the US," and that "Zydus Pharmaceuticals (USA) Inc., the wholly-owned subsidiary of the Company spearheads its operations in the US." Cadila Healthcare Limited Annual Report 2016-17 ("Zydus Cadila 2016-17 Annual Report" (https://zyduscadila.com/wp-content/uploads/2017/07/Annual-Report-CHL-2016-2017.pdf, last visited April 24, 2018) at 20). The Zydus Cadila 2016-17 Annual Report further states that "[t]he Company is the ninth largest generic player in the US in terms of prescriptions with approximately 3% market share." *Id*. The Zydus Cadila 2016-17 Annual Report further states that "[t]he Company launched 15 new products in the US market during the year," and that "[i]n terms of ANDA filings, over 45 ANDAs were filed with the USFDA during the year, taking the cumulative number of ANDA filings to over 305." *Id.*

ANSWER: Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. Defendants admit that the language quoted in paragraph 16 appears in portions of Cadila's Annual Report 2016-17, but deny that the allegations accurately and completely recite the complete contents of Cadila's Annual Report 2016-17. Defendants deny all other allegations in paragraph 16.

17. Zydus Pharmaceuticals (USA) Inc.'s website, http://www.zydususa.com/who-is-zydus/, states that Zydus Pharmaceuticals (USA) Inc. "is the U.S. division of Cadila Healthcare." (last visited April 24, 2018.)

ANSWER: Admitted.

18. On information and belief, Zydus USA and Zydus Cadila work in concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: The allegations in paragraph 18 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submits ANDAs to FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed pharmaceutical products, including products to be manufactured by Cadila, and that

Zydus USA sells pharmaceutical products in the United States, including products manufactured by Cadila. Defendants deny all other allegations in paragraph 18.

19. On information and belief, Zydus USA acts at the direction, and for the benefit, of Zydus Cadila, and is controlled and/or dominated by Zydus Cadila.

ANSWER: The allegations in paragraph 19 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 19.

20. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited, in addition to not contesting personal jurisdiction for purposes of this dispute, have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g.*, *Celgene Corporation v. Zydus Pharmaceuticals (USA) Inc.*, No. 17-2528 (SDW)(LDW); *Helsinn Healthcare S.A. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila)*, No. 16-4239 (MLC)(DEA); *AstraZeneca AB, et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (dba Zydus Cadila)*, No. 15-7415 (MLC)(TJB); *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 14-7272 (SDW)(LDW); *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 14-7252 (JBS)(KMW); *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 14-3168 (JBS)(KMW).

ANSWER: Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that: in *Celgene Corporation v. Zydus Pharmaceuticals (USA) Inc.*, No. 17-2528 (SDW)(LDW) (D.N.J.), Defendants asserted counterclaims and stated that "Zydus USA does not contest personal jurisdiction in this Court solely for [Celgene's] claims against Zydus USA in this case and solely as they apply to the proposed products described in ANDA No. 210154" and that "Cadila does not contest personal jurisdiction in this Court solely for [Celgene's] claims against Cadila in this case and solely as they apply to the proposed products described in ANDA No. 210154"; in *Helsinn Healthcare S.A. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare*

Ltd. (d/b/a Zydus Cadila), No. 16-4239 (MLC)(DEA) (D.N.J.), Defendants asserted counterclaims and stated that "Defendants do not contest personal jurisdiction in this Court solely for the purposes of [Helsinn's] claims against Defendants in this case and solely as they apply to the proposed product described in [the ANDA at issue in that case]"; in *AstraZeneca AB, et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (dba Zydus Cadila)*, No. 15-7415 (MLC)(TJB) (D.N.J.), Defendants asserted counterclaims and stated that "Defendants do not contest personal jurisdiction in this Court solely for purposes of [AstraZeneca's] claims against Defendants in this case and solely as they apply to the proposed product described in [the ANDA at issue in that case]"; in *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 14-7272 (SDW)(LDW) (D.N.J.), Defendants asserted counterclaims and stated that "Defendants do not contest personal jurisdiction in this Court solely for purposes of [Supernus's] claims against Defendants in this case and solely as they apply to the proposed product described in [the ANDA at issue in that case]"; in *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 14-7252 (JBS)(KMW) (D.N.J.), Defendants asserted counterclaims and stated that "Defendants do not contest personal jurisdiction in this Court solely for purposes of Otsuka's claims against Defendants in this case"; and in *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 14-3168 (JBS)(KMW) (D.N.J.), Defendants asserted counterclaims and stated that "Defendants do not contest personal jurisdiction in this Court solely for purposes of Otsuka's claims against Defendants in this case." Defendants deny all other allegations in paragraph 20.

21. Zydus Pharmaceuticals (USA) Inc. has also admitted that it is subject to personal jurisdiction in this Judicial District. *See, e.g.*, *Takeda Pharm. Co. Ltd., et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 10-1723 (Answer to Complaint, Dkt. No. 29, ¶ 12; Answer to Amended Complaint, Dkt. No. 99, ¶ 12).

ANSWER: Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in *Takeda Pharm. Co. Ltd., et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 10-1723, Defendants asserted counterclaims and stated that "Zydus is subject to personal jurisdiction in this district." Defendants deny all other allegations in paragraph 21.

22. Cadila Healthcare Limited has also admitted that it is subject to personal jurisdiction in this Judicial District. *See, e.g.*, *Takeda Pharm. Co. Ltd., et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 10-1723 (Answer to Complaint, Dkt. No. 29, ¶¶ 13, 18; Answer to Amended Complaint, Dkt. No. 99, ¶¶ 13, 18).

ANSWER: Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that in *Takeda Pharm. Co. Ltd., et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 10-1723, Defendants asserted counterclaims and stated that "Cadila is subject to personal jurisdiction for purposes of this action." Defendants deny all other allegations in paragraph 22.

23. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited have further availed themselves of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g.*, *Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. v. Gilead Scis., Inc.*, No. 14-7080 (FLW)(LHG). Zydus Pharmaceuticals (USA) Inc. has further availed itself of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g.*, *Zydus Pharms. USA, Inc. v. Eli Lilly and Co.*, No. 10-5584 (DMC)(JAD).

ANSWER: Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. Defendants admit that they have previously initiated litigation in this judicial district in *Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. v. Gilead Scis., Inc.*, No. 14-7080 (FLW)(LHG) (D.N.J.). Defendants admit that Zydus USA has previously initiated litigation in this judicial district in *Zydus Pharms. USA, Inc. v. Eli Lilly and Co.*, No. 10-5584 (DMC)(JAD) (D.N.J.). Defendants deny all other allegations in paragraph 23.

24. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: The allegations in paragraph 24 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 210154. Defendants deny all other allegations in paragraph 24.

Acts Giving Rise to This Suit

25. Pursuant to Section 505 of the FFDCA, Zydus filed Zydus's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of lenalidomide capsules 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg ("Zydus's Proposed Products"), before the patents-in-suit expire.

ANSWER: The allegations in Paragraph 25 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted

ANDA No. 210154 to FDA to obtain approval to engage in the commercial manufacture, use, or sale of the proposed products described in ANDA No. 210154. Defendants deny all other allegations in paragraph 25.

26. On information and belief, following FDA approval of Zydus's ANDA, Zydus USA and Zydus Cadila will work in concert with one another to make, use, sell, or offer to sell Zydus's Proposed Products throughout the United States, or import such generic products into the United States.

ANSWER: The allegations in paragraph 26 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 210154 to FDA to obtain approval to engage in the commercial manufacture, use, or sale of the proposed products described in ANDA No. 210154 to be manufactured by Cadila. Defendants deny all other allegations in paragraph 26.

27. On information and belief, in connection with the filing of its ANDA as described above, Zydus provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Zydus's Paragraph IV Certification"), alleging that the claims of United States Patent Nos. 7,465,800 (the "'800 patent"), 7,855,217 (the "'217 patent"), 7,968,569 (the "'569 patent"), 8,530,498 (the "'498 patent"), 8,648,095 (the "'095 patent"), 9,101,621 (the "'621 patent"), and 9,101,622 (the "'622 patent") are invalid, unenforceable, and/or will not be infringed by the activities described in Zydus's ANDA.

ANSWER: Defendants admit that ANDA No. 210154 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") U.S. Patent Nos. 7,465,800, 7,855,217, 7,968,569, 8,530,498, 8,648,095, 9,101,621, and 9,101,622 (collectively, "the Orange Book Patents") are invalid, unenforceable, and/or will not be infringed by the proposed products described in ANDA No. 210154. Defendants deny all other allegations in paragraph 27.

28. No earlier than February 27, 2017, Zydus sent written notice of its Paragraph IV Certification to Celgene ("Zydus's Notice Letter"). Zydus's Notice Letter alleged that the claims of the '800, '217, '569, '498, '095, '621, and '622 patents are invalid and/or will not be infringed by the activities described in Zydus's ANDA. Zydus's Notice Letter also informed Celgene that Zydus seeks approval to market Zydus's Proposed Products before the '800, '217, '569, '498, '095, '621, and '622 patents expire. Zydus specifically directed Zydus's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Defendants admit that Zydus USA transmitted Zydus USA's February 27, 2017 letter to Plaintiff, at addresses including a location in Summit, New Jersey, notifying Plaintiff that Zydus USA submitted ANDA No. 210154 to FDA under 21 U.S.C. § 355(j)(2)(B)(ii). Defendants admit that Zydus USA's February 27, 2017 letter states that ANDA No. 210154 included Paragraph IV certifications with respect to the Orange Book Patents and that Zydus USA seeks approval to engage in the commercial manufacture, use, or sale of the proposed products described in ANDA No. 210154. Defendants deny all other allegations in paragraph 28.

Count I: Infringement of the '357 Patent

29. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants repeat and re-allege their answers to each of the preceding paragraphs 1 to 28, as if fully set forth herein.

30. Zydus, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's Proposed Products, prior to the expiration of the '357 patent.

ANSWER: The allegations of paragraph 30 state legal conclusions to which no answer is required. To the extent an answer is required, denied.

31. Zydus's ANDA has been pending before the FDA since at least February 27, 2017, the date that Zydus sent Zydus's Notice Letter to Celgene.

ANSWER: Admitted.

32. Zydus's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's Proposed Products, prior to the expiration of the '357 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

33. There is a justiciable controversy between the parties hereto as to the infringement of the '357 patent.

ANSWER: Denied.

34. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe one or more claims of the '357 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States.

ANSWER: Denied.

35. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will induce infringement of one or more claims of the '357 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement with knowledge of the '357 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

36. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '357 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States. On information and belief, Zydus has had and continues to have knowledge that Zydus's Proposed Products are especially adapted for a use that infringes one or more claims of the '357 patent and that there is no substantial non-infringing use for Zydus's Proposed Products.

ANSWER: Denied.

37. Celgene will be substantially and irreparably damaged and harmed if Zydus's infringement of the '357 patent is not enjoined.

ANSWER: Denied.

38. Celgene does not have an adequate remedy at law.

ANSWER: Denied.

39. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count II: Infringement of the '219 Patent

40. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants repeat and re-allege their answers to each of the preceding paragraphs 1 to 39, as if fully set forth herein.

41. Zydus, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's Proposed Products, prior to the expiration of the '219 patent.

ANSWER: The allegations of paragraph 41 state legal conclusions to which no answer is required. To the extent an answer is required, denied.

42. Zydus's ANDA has been pending before the FDA since at least February 27, 2017, the date that Zydus sent Zydus's Notice Letter to Celgene.

ANSWER: Admitted.

43. Zydus's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's Proposed Products, prior to the expiration of the '219 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

44. There is a justiciable controversy between the parties hereto as to the infringement of the '219 patent.

ANSWER: Denied.

45. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe one or more claims of the '219 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States.

ANSWER: Denied.

46. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will induce infringement of one or more claims of the '219 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement with knowledge of the '219 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

47. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '219 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States. On information and belief, Zydus has had and continues to have knowledge that Zydus's Proposed Products are especially adapted for a use that infringes one or more claims of the '219 patent and that there is no substantial non-infringing use for Zydus's Proposed Products.

ANSWER: Denied.

48. Celgene will be substantially and irreparably damaged and harmed if Zydus's infringement of the '219 patent is not enjoined.

ANSWER: Denied.

49. Celgene does not have an adequate remedy at law.

ANSWER: Denied.

50. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count III: Infringement of the '598 Patent

51. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants repeat and re-allege their answers to each of the preceding paragraphs 1 to 50, as if fully set forth herein.

52. Zydus, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's Proposed Products, prior to the expiration of the '598 patent.

ANSWER: The allegations of paragraph 52 state legal conclusions to which no answer is required. To the extent an answer is required, denied.

53. Zydus's ANDA has been pending before the FDA since at least February 27, 2017, the date that Zydus sent Zydus's Notice Letter to Celgene.

ANSWER: Admitted.

54. Zydus's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's Proposed Products, prior to the expiration of the '598 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

55. There is a justiciable controversy between the parties hereto as to the infringement of the '598 patent.

ANSWER: Denied.

56. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe one or more claims of the '598 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States.

ANSWER: Denied.

57. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will induce infringement of one or more claims of the '598 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement with knowledge of the '598 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

58. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '598 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Zydus's Proposed Products in the United States. On information and belief, Zydus has had and continues to have knowledge that Zydus's Proposed Products are especially adapted for a use that infringes one or more claims of the '598 patent and that there is no substantial non-infringing use for Zydus's Proposed Products.

ANSWER: Denied.

59. Celgene will be substantially and irreparably damaged and harmed if Zydus's infringement of the '598 patent is not enjoined.

ANSWER: Denied.

60. Celgene does not have an adequate remedy at law.

ANSWER: Denied.

61. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Prayer for Relief

Defendants deny that Plaintiff is entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited aver and assert the following Affirmative Defenses to Plaintiff Celgene Corporation's Complaint.

First Affirmative Defense:
Noninfringement of U.S. Patent No. 7,977,357

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed lenalidomide capsules, 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg dosage, that are described in ANDA No. 210154 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of U.S. Patent No. 7,977,357 ("the '357 patent").

Second Affirmative Defense:
Invalidity of U.S. Patent No. 7,977,357

Upon information and belief, the claims of the '357 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

Third Affirmative Defense:
Noninfringement of U.S. Patent No. 8,193,219

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed products described in ANDA No. 210154 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of U.S. Patent No. 8,193,219 ("the '219 patent").

Fourth Affirmative Defense:
Invalidity of U.S. Patent No. 8,193,219

Upon information and belief, the claims of the '219 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

Fifth Affirmative Defense:
Noninfringement of U.S. Patent No. 8,431,598

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed products described in ANDA No. 210154 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of U.S. Patent No. 8,431,598 ("the '598 patent").

Sixth Affirmative Defense:
Invalidity of U.S. Patent No. 8,431,598

Upon information and belief, the claims of the '598 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

Seventh Affirmative Defense:
Prosecution History Estoppel

Plaintiff's claims are barred in whole or in part by the doctrine of prosecution history estoppel. Under the doctrine of prosecution history estoppel, Plaintiff cannot use the doctrine of equivalents to reclaim claim scope surrendered during prosecution.

Eighth Affirmative Defense:
Laches

Plaintiff's claims are barred in whole or in part by the doctrine of laches because Plaintiffs unreasonably and inexcusably delayed asserting infringement of U.S. Patent Nos. 7,977,357, 8,193,219, and 8,431,598 in earlier-filed litigation in order to delay resolution of all patent litigation relating to ANDA No. 210154.

Reservation of Defenses

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may

now exist or become available later as a result of discovery and further factual investigation during this litigation.

July 9, 2018

Respectfully submitted,

s/ Paul B. Sudentas
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Attorneys for Defendants
Zydus Pharmaceuticals (USA) Inc. and
Cadila Healthcare Limited

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Rule 11.2, I hereby certify that the within action is the subject of *Celgene Corporation v. Zydus Pharmaceuticals (USA) Inc.*, No. 17-2528 (SDW)(LDW) (D.N.J.) pending in this Court.

s/ Paul B. Sudentas
Paul B. Sudentas

CERTIFICATE OF SERVICE

I hereby certify that on July 9, 2018 a copy of the foregoing document was filed electronically with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to counsel of record via the electronic filing system.

Respectfully submitted,

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