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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION **Plaintiff,** **v.** **HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, and HETERO USA, INC.,** **Defendant.**	**Civil Action No. 2:20-cv-14389-SDW-LDW** **ANSWER TO FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

DEFENDANTS HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, AND HETERO USA, INC'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero"), by their undersigned attorneys, for their Answer to the First Amended Complaint for Patent Infringement filed by Plaintiff Celgene Corporation ("Celgene" or "Plaintiff"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations in Plaintiff's First Amended Complaint except those expressly admitted below.

ALLEGATIONS CONCERNING THE 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 Hetero's filing of Abbreviated New Drug Application ("ANDA") No. 212414 ("Hetero's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Celgene's Revlimid® drug products prior to the expiration of United States Patent Nos. 7,189,740 ("the '740 patent"), 7,465,800 ("the '800 patent"), 7,968,569 ("the '569 patent"), 7,977,357 ("the '357 patent"), 8,193,219 ("the '219 patent") 8,404,717 ("the '717 patent"), 8,530,498 ("the '498 patent"), 8,648,095 ("the '095 patent"), 9,056,120 ("the '120 patent"), 9,101,621 ("the '621 patent"), and 9,101,622 ("the '622 patent") (collectively, "the patents-in-suit"), owned by Celgene.

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Celgene's Complaint purports to assert an action for patent infringement based on Hetero's filing of Abbreviated New Drug Application ("ANDA") No. 212414 seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market generic a lenalidomide product. Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

ALLEGATIONS CONCERNING 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. Celgene is a world leader in the treatment of many such diseases, including cancer. 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: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 2 of the Complaint and, therefore, denies all allegations.

3. On information and belief, Defendant Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500018, Telangana, India.

ANSWER: Admitted.

4. On information and belief, Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

ANSWER: Admitted.

5. On information and belief, Hetero Unit-V is a division of Hetero Labs.

ANSWER: Admitted.

6. On information and belief, Defendant Hetero Drugs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500018, Telangana, India.

ANSWER: Admitted.

7. On information and belief, Defendant Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

ANSWER: Admitted.

8. On information and belief, Hetero Labs is the parent corporation of Hetero USA.

ANSWER: Admitted.

9. On information and belief, Hetero USA is the U.S. regulatory agent of Hetero Unit-V with respect to ANDA No. 212414.

ANSWER: Admitted.

ALLEGATIONS CONCERNING THE PATENTS-IN-SUIT

10. On March 13, 2007, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '740 patent, entitled "Methods of Using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the Treatment and Management of Myelodysplastic Syndromes," to Celgene as assignee. A copy of the '740 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '740 patent is attached to the Complaint as Exhibit A; that the '740 patent is entitled "Methods of Using 3-(4-amino-oxo-1,3- dihydro-isoindol-2-yl)-piperidine-2,6-dione for the Treatment and Management of Myelodysplastic Syndromes"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '740 patent. Hetero denies that the '740 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 10 of the Complaint.

11. On December 16, 2008, the USPTO duly and lawfully issued the '800 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee. A copy of the '800 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '800 patent is attached to the Complaint as Exhibit B; that the '800 patent is entitled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '800 patent. Hetero denies that the '800 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 10 of the Complaint.

12. On June 28, 2011, the USPTO duly and lawfully issued the '569 patent, entitled "Methods For Treatment of Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee. A copy of the '569 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '569 patent is attached to the Complaint as Exhibit C; that the '569 patent is entitled "Methods For Treatment of Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2- yl)-piperidine-2,6-dione"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '569 patent. Hetero denies that the '569 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 11 of the Complaint.

13. On July 12, 2011, the United States Patent and Trademark Office ("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. A copy of the '357 patent is attached hereto as Exhibit D.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '357 patent is attached to the Complaint as Exhibit D; that the '357 patent is entitled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '357 patent. Hetero denies that the '357 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 13 of the Complaint.

14. 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. A copy of the '219 patent is attached hereto as Exhibit E.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '219 patent is attached to the Complaint as Exhibit E; that the '219 patent is entitled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '219patent. Hetero denies that the '219 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 14 of the Complaint.

15. On March 26, 2013, the USPTO duly and lawfully issued the '717 patent, entitled "Methods of Treating Myelodysplastic Syndromes Using Lenalidomide," to Celgene as assignee. A copy of the '717 patent is attached hereto as Exhibit F.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '717 patent is attached to the Complaint as Exhibit E that the '717 patent is entitled "Methods of Treating

Myelodysplastic Syndromes Using Lenalidomide"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '717 patent. Hetero denies that the '717 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 15 of the Complaint.

16. On September 10, 2013, the USPTO duly and lawfully issued the '498 patent, entitled "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione," to Celgene as assignee. A copy of the '498 patent is attached hereto as Exhibit G.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '498 patent is attached to the Complaint as Exhibit G; that the '498 patent is entitled "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydroisoindol- 2-yl)piperidine-2,6-dione"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '498 patent. Hetero denies that the '498 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 16 of the Complaint.

17. On February 11, 2014, the USPTO duly and lawfully issued the '095 patent, entitled "Methods For Treating Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione In Combination With Proteasome Inhibitor," to Celgene as assignee. A copy of the '095 patent is attached hereto as Exhibit H.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '095 patent is attached to the Complaint as Exhibit H; that the '095 patent is entitled "Methods For Treating Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydroisoindol- 2-yl)-piperidine-2,6-dione In

Combination With Proteasome Inhibitor"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '095 patent. Hetero denies that the '095 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 17 of the Complaint.

18. On June 16, 2015, the USPTO duly and lawfully issued the '120 patent, entitled "Methods of Treating Myelodysplastic Syndromes with a Combination Therapy Using Lenalidomide and Azacitidine," to Celgene as assignee. A copy of the '120 patent is attached hereto as Exhibit I.

ANSWER: Paragraph 18 contains legal conclusions to which on answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '120 patent is attached to the Complaint as Exhibit I; that the '120 patent is entitled "Methods of Treating Myelodysplastic Syndromes with a Combination Therapy Using Lenalidomide and Azacitidine"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '120 patent. Hetero denies that the '120 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 18 of the Complaint.

19. On August 11, 2015, the USPTO duly and lawfully issued the '621 patent, entitled "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione After Stem Cell Transplantation," to Celgene as assignee. A copy of the '621 patent is attached hereto as Exhibit J.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '621 patent is attached to the Complaint as Exhibit J; that the '621 patent is entitled "Methods For Treating

Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydro-isoindol- 2-yl)-piperidine-2,6-dione After Stem Cell Transplantation"; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '621 patent. Hetero denies that the '621 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 19 of the Complaint.

20. On August 11, 2015, the USPTO duly and lawfully issued the '622 patent, entitled "Methods For Treating Newly Diagnosed Multiple Myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione In Combination With Dexamethasone," to Celgene as assignee. A copy of the '622 patent is attached hereto as Exhibit K.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '622 patent is attached to the Complaint as Exhibit H; that the '622 patent is entitled "Methods For Treating Newly Diagnosed Multiple Myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione In Combination With Dexamethasone"; that the issue date identified on the cover of the '622 patent is August 11, 2015; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '622 patent. Hetero denies that the '622 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 20 of the Complaint.

ALLEGATIONS CONCERNING THE REVLIMID® DRUG PRODUCT

21. 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®.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies New Drug Application ("NDA") No. 021880 in connection with REVLIMID® (lenalidomide) capsules, and further identifies "CELGENE CORP" as the holder of NDA No. 021880. All remaining allegations are denied.

22. The claims of the patents-in-suit cover, *inter alia*, solid forms of lenalidomide, pharmaceutical compositions containing lenalidomide, and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required, and on that basis, Hetero denies the allegations of paragraph 22.

23. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '740, '800, '569, '717, '498, '095, '120, '621, and '622 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to REVLIMID®.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required, and on that basis, Hetero denies the allegations of paragraph 23. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the '740,

'800, '569, '717, '498, '095, '120, '621, and '622 patents in connection with New Drug Application ("NDA") No. 021880. All remaining allegations are denied.

24. The labeling for REVLIMID® instructs and encourages physicians, pharmacists, and other healthcare workers and patients to administer REVLIMID® according to one or more of the methods claimed in the patents-in-suit.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero states that the labeling for REVLIMID® speaks for itself. Hetero denies the remaining allegations of Paragraph 24.

ALLEGATIONS CONCERNING JURISDICTION AND VENUE

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

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required, and on that basis, Hetero denies the allegations of paragraph 25.

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

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District.

27. This Court has personal jurisdiction over Hetero USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Hetero USA's principal place of business is in Piscataway, New Jersey. On information and belief, Hetero 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 Id. No. 0400362826. On

information and belief, Hetero USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050. On information and belief, Hetero USA purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Hetero USA.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction in this District for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 27.

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

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 28.

29. This Court has personal jurisdiction over Hetero Labs, Hetero Drugs, and Hetero Unit-V because, *inter alia*, they: (1) have purposefully availed themselves of the privilege of doing business in New Jersey, including directly or indirectly through their subsidiary, agent, and/or alter ego, Hetero USA, a company with its principal place of business in New Jersey; and maintain 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, Hetero USA.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 29.

30. This Court has personal jurisdiction over Hetero 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, Hetero 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: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 30.

31. On information and belief, Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs 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: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court,

Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 31.

32. On information and belief, Hetero USA acts at the direction, and for the benefit, of Hetero Labs, Hetero Unit-V, and Hetero Drugs, and is controlled and/or dominated by Hetero Labs, Hetero Unit-V, and Hetero Drugs.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 32.

33. On information and belief, Hetero USA has a regular and established, physical place of business in New Jersey.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 33.

34. On information and belief, Hetero Drugs, Hetero Labs, Hetero Unit-V, and Hetero USA operate as a single integrated business. On information and belief, Hetero Drugs and Hetero Labs share common corporate directors.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court,

Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 34.

35. On information and belief, Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g.*, *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 19-15449 (SDW)(LDW) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited, et al*., Civil Action No. 19-5797 (ES)(MAH) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited*, et al., Civil Action No. 18-17463 (SDW)(LDW) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 18-14111 (ES)(MAH) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387 (ES)(MAH) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, Civil Action No. 15-161 (JBS)(KMW) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Drugs); *AstraZeneca AB, et al. v. Hetero USA Inc.*, et al., Civil Action No. 16-2442 (RMB)(JS) (D.N.J.) (Hetero USA and Hetero Labs); and *BTG Int'l Ltd., et al. v. Actavis Labs. FL, Inc., et al.*, Civil Action No. 15-5909 (KM)(JBC) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V).

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that it has previously been sued in this Judicial District, and solely to conserve the resources of the parties and the Court, Hetero does not contest

personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 35.

36. On information and belief, Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs have all previously been sued in this Judicial District and have not challenged venue. See, e.g., *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 19-15449 (SDW)(LDW) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 19-5797 (ES)(MAH) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited, et al*., Civil Action No. 18-17463 (SDW)(LDW) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited, et al*., Civil Action No. 18-14111 (ES)(MAH) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs); *Celgene Corporation v. Hetero Labs Limited, et al*., Civil Action No. 17-3387 (ES)(MAH) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs).

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that it has previously been sued in this Judicial District, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction for the limited purpose of this action only. Hetero denies all remaining allegations of Paragraph 36.

ALLEGED ACTS

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

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that it submitted an ANDA to the FDA seeking approval to engage in the commercial manufacture, use, and sale of lenalidomide capsules, 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg, as soon as legally permissible, and that its ANDA satisfied all applicable legal, statutory, and regulatory requirements for filing. Hetero denies all remaining allegations of Paragraph 37.

38. On information and belief, following FDA approval of Hetero's ANDA, Defendants Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA will work in concert with one another to make, use, offer for sale, or sell Hetero's Proposed Products throughout the United States, or import such generic products into the United States.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 38.

39. On information and belief, in connection with the filing of its ANDA as described above, Hetero provided written certifications to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Hetero's Paragraph IV Certifications"), alleging that the claims of the '740, '800, '569, '717, '498, '095, '120, '621, and '622 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA

ANSWER: Hetero admits that its ANDA contained Paragraph IV Certification as to '740, '800, '569, '717, '498, '095, '120, '621, and '622 patents. Hetero denies all remaining allegations of Paragraph 39.

40. No earlier than November 9, 2018, Hetero sent written notice of its first Paragraph IV Certification to Celgene ("Hetero's First Notice Letter"). Hetero's First Notice Letter alleged that the claims of the '800 patent are invalid and/or will not be infringed by the activities described

in Hetero's ANDA. Hetero's First Notice Letter also informed Celgene that Hetero seeks approval to market Hetero's Proposed Products before the '800 patent expires. Hetero specifically directed Hetero's First Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Hetero admits to sending Hetero's Notice Letter dated November 9, 2018, to Celgene Corporation in Summit, New Jersey, alleging that the claims of certain patents are invalid and/or will not be infringed by the activities described in Hetero's ANDA and seeking approval to engage in the commercial manufacture, use, and sale for the product described therein as soon as legally permissible. All other allegations of Paragraph 40 are denied.

41. On December 20, 2018, within 45 days of receiving Hetero's First Notice Letter, Celgene filed suit against Hetero in this Judicial District in connection with Hetero's ANDA. *See Celgene Corp. v. Hetero Labs Limited, et al.*, No. 18-17463 at D.I. 1 (D.N.J. Dec. 20, 2018).

ANSWER: Admitted.

42. No earlier than June 3, 2019, Hetero sent written notice of its second Paragraph IV Certification to Celgene ("Hetero's Second Notice Letter"). Hetero's Second Notice Letter alleged that the claims of the '740, '569, '717, '498, '095, '120, '621, and '622 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA. Hetero's Second Notice Letter also informed Celgene that Hetero seeks approval to market Hetero's Proposed Products before the '740, '569, '717, '498, '095, '120, '621, and '622 patents expire. Hetero specifically directed Hetero's Second Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Hetero admits to sending a notice letter dated June 3, 2019, to Celgene Corporation in Summit, New Jersey, alleging that the claims of certain patents are invalid and/or

will not be infringed by the activities described in Hetero's ANDA and seeking approval to engage in the commercial manufacture, use, and sale for the product described therein as soon as legally permissible. All other allegations of Paragraph 42 are denied

43. On July 16, 2019, within 45 days of receiving Hetero's Second Notice Letter, Celgene filed suit against Hetero in this Judicial District in connection with Hetero's ANDA. *See Celgene Corp. v. Hetero Labs Limited, et al.*, No. 19-15449 at D.I. 1 (D.N.J. Jul. 16, 2019).

ANSWER: Admitted.

COUNT I: ALLEGED INFRINGEMENT OF THE '740 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraph 1-43, as if fully set forth herein.

45. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '740 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 45.

46. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '740 patent.

ANSWER: Admitted.

47. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '740 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 47. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

48. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '740 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '740 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 48. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

49. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '740 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '740 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 49. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

50. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '740 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

52. 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: ALLEGED INFRINGEMENT OF THE '800 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraphs 1-52, as if fully set forth herein.

54. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '800 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 54.

55. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '800 patent.

ANSWER: Admitted.

56. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '800 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 56. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

57. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '800 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '800 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 57 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 57. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

58. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '800 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's

Proposed Products are especially adapted for a use that infringes one or more claims of the '800 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 58 Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

59. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '800 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.

COUNT III: ALLEGED INFRINGEMENT OF THE '569 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraphs 1-61, as if fully set forth herein.

63. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '569 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 63.

64. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '569 patent.

ANSWER: Admitted.

65. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '569 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 65. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

66. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '569 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '569 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 66. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

67. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '569 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '569 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 67. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

68. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '569 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

70. 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 IV: ALLEGED INFRINGEMENT OF THE '357 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraph 1-70, as if fully set forth herein.

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

ANSWER: Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 73.

73. Hetero's ANDA has been pending before the FDA since at least November 9, 2018, the date that Hetero sent Hetero's Notice Letter to Celgene.

ANSWER: Hetero's admits that its ANDA has been pending before the FDA since at least November 9, 2018.

74. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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). Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 74.

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

ANSWER: Admitted.

76. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Products in the United States.

ANSWER: Paragraph 76 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 76. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

77. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '357 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 77. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

78. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero'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 Hetero's Proposed Products.

ANSWER: Paragraph 78 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 78. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

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

ANSWER: Denied.

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

ANSWER: Denied.

81. 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 V: ALLEGED INFRINGEMENT OF THE '219 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraphs 1-82, as if fully set forth herein.

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

ANSWER: Paragraph 83 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 83.

84. Hetero's ANDA has been pending before the FDA since at least November 9, 2018, the date that Hetero sent Hetero's Notice Letter to Celgene.

ANSWER: Hetero's admits that its ANDA has been pending before the FDA since at least November 9, 2018.

85. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 85 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 85. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(e)(2)(A).

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

ANSWER: Admitted.

87. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Products in the United States.

ANSWER: Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 87. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

88. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '219 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 88 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 88. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

89. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero'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 Hetero's Proposed Products.

ANSWER: Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 89. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c)

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

ANSWER: Denied.

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

ANSWER: Denied

92. 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 VI: ALLEGED INFRINGEMENT OF THE '717 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraphs 1-92, as if fully set forth herein.

94. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '717 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 94 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 94.

95. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '717 patent.

ANSWER: Admitted.

96. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '717 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 96 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 96. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

97. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '717 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '717 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 97. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

98. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '717 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '717 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 98 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 98. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

99. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '717 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

101. 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 VII: ALLEGED INFRINGEMENT OF THE '498 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraphs 1-101, as if fully set forth herein.

103. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '498 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 103 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 103.

104. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '498 patent.

ANSWER: Admitted.

105. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '498 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 105 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 105. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

106. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '498 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '498 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 106 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 106. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

107. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '498 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '498 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 107. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

108. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '498 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

110. 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 VIII: ALLEGED INFRINGEMENT OF THE '095 PATENT

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

ANSWER: Hetero incorporates its answer to Paragraphs 1-110, as if fully set forth herein.

112. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '095 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 112 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 112.

113. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '095 patent.

ANSWER: Admitted.

114. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '095 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 114. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

115. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '095 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '095 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 115. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

116. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '095 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '095 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 116. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

117. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '095 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

119. 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 IX: ALLEGED INFRINGEMENT OF THE '120 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraph 1-119, as if fully set forth herein.

121. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '120 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 121 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 121.

122. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '120 patent.

ANSWER: Admitted.

123. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '120 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 123 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 123. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

124. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '120 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '120 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 124 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 124. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

125. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '120 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '120 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 125 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 125. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

126. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '120 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

128. 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 X: ALLEGED INFRINGEMENT OF THE '621 PATENT

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

ANSWER: Hetero incorporates its answer to Paragraphs 1-128, as if fully set forth herein.

130. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '621 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 130 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 130.

131. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '621 patent.

ANSWER: Hetero denies the allegations of paragraph 131.

132. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '621 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 132 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 132. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

133. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '621 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '621 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 133 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 133. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

134. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '621 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '621 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 134 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 134. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

135. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '621 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

137. 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 XI: ALLEGED INFRINGEMENT OF THE '622 PATENT

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

ANSWER: Hetero incorporates its answers to Paragraphs 1-137, as if fully set forth herein.

139. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '622 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 139 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 139.

140. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '622 patent.

ANSWER: Admitted.

141. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '622 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 141 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 141. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

142. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '622 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '622 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 142 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 142. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

143. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '622 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '622 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 143 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 143. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

144. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '622 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

146. 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.

CELGENE'S PRAYER FOR RELIEF

Hetero denies that Plaintiff is entitled to any of the relief sought in its prayer for relief, or to any other relief whatsoever.

HETERO'S DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the First Amended Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Hetero avers and asserts the following separate defenses to the First Amended Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '740 PATENT)

The claims of the '740 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '740 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '740 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '740 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '740 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '800 PATENT)

The claims of the '800 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '800 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '800 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '800 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '800 Patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '569 PATENT)

The claims of the '569 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '569 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '569 Patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '569 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '569 Patent.

TENTH SEPARATE DEFENSE
(INVALIDITY OF THE '357 PATENT)

The claims of the '357 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

ELEVENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '357 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '357 patent.

TWELFTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '357 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '357 patent.

THIRTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '219 PATENT)

The claims of the '219 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '219 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '219 patent.

FIFTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '219 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '219 patent.

SIXTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '717 PATENT)

The claims of the '717 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SEVENTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '717 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '717 Patent.

EIGHTTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '717 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '717 Patent.

NINETEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '498 PATENT)

The claims of the '498 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

TWENTIETH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '498 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '498 Patent.

TWENTY-FIRST SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '498 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '498 Patent.

TWENTY-SECOND SEPARATE DEFENSE
(INVALIDITY OF THE '095 PATENT)

The claims of the '095 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

TWENTY-THIRD SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '095 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '095 Patent.

TWENTY-FOURTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '095 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '095 Patent.

TWENTY-FIFTH SEPARATE DEFENSE
(INVALIDITY OF THE '120 PATENT)

The claims of the '120 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

TWENTY-SIXTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '120 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '120 Patent.

TWENTY-SEVENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '120 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '120 Patent.

TWENTY-EIGHTH SEPARATE DEFENSE
(INVALIDITY OF THE '621 PATENT)

The claims of the '621 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

TWENTY-NINTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '621 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '621 Patent.

THIRTIETH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '621 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '621 Patent.

THIRTY-FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '622 PATENT)

The claims of the '622 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

THIRTY-SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '622 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '622 Patent.

THIRTY-THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '622 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212414 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '622 Patent.

THIRTY-FOURTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

THIRTY-FIFTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

The Court lacks subject matter jurisdiction over any and all claims asserted.

THIRTY-SIXTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiff fails to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Hetero reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

WHEREFORE, Hetero requests that Celgene's First Amended be dismissed with prejudice and that Hetero be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

HETERO'S COUNTERCLAIMS

Defendants Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero"), through counsel, hereby submit the following Counterclaims against Plaintiff Celgene Corporation ("Celgene" or "Plaintiff").

PARTIES

1. On information and belief, Celgene is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

2. Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India.

3. Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar - 509301, Andhra Pradesh, India.

4. Hetero Unit-V is a division of Hetero Labs.

5. Hetero Drugs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India.

6. Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

NATURE OF THE ACTION

7. Hetero seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 7,189,740 ("the '740 patent"), 7,465,800 ("the '800 patent"), 7,968,569 ("the '569 patent"), 7,977,357 ("the '357 patent"), 8,193,219 ("the '219 patent") 8,404,717 ("the '717 patent"), 8,530,498 ("the '498 patent"), 8,648,095 ("the '095 patent"), 9,056,120 ("the '120 patent"), 9,101,621 ("the '621 patent"), and 9,101,622 ("the '622 patent") (collectively, "the patents-in-suit"), are invalid and/or not infringed.

JURISDICTION AND VENUE

8. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Celgene because, among other reasons, Celgene subjected itself to the jurisdiction of this Court by filing its complaint here.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Celgene's choice of forum.

11. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the patents-in-suit.

BACKGROUND

12. Celgene filed its First Amended Complaint in this case alleging infringement of the patents-in-suit. There is now is an actual and justiciable controversy between Hetero and Celgene as to whether Hetero's Proposed Products infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of patents-in-suit.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '740 PATENT

13. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

14. There is an actual, substantial, continuing, and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '740 patent.

15. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '740 patent is not infringed by Hetero's ANDA or the products or activities described therein.

16. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '740 patent and is not liable for such infringement.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '740 PATENT

17. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

18. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '740 patent are invalid.

19. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '740 patent are invalid.

20. Hetero is entitled to a declaration that all claims of the '740 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT III: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '800 PATENT

21. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

22. There is an actual, substantial, continuing, and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '800 patent.

23. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '800 patent is not infringed by Hetero's ANDA or the products or activities described therein.

24. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '800 patent and is not liable for such infringement.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '800 PATENT

25. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

26. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '800 patent are invalid.

27. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '800 patent are invalid.

28. Hetero is entitled to a declaration that all claims of the '800 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT V: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '569 PATENT

29. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

30. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '569 patent.

31. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '569 patent is not infringed by Hetero's ANDA or the products or activities described therein.

32. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '569 patent and is not liable for such infringement.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '569 PATENT

33. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

34. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '569 patent are invalid.

35. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '569 patent are invalid.

36. Hetero is entitled to a declaration that all claims of the '569 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT VII
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '357 PATENT)

37. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

38. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '357 patent.

39. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '357 patent is not infringed by Hetero's ANDA or the products or activities described therein.

40. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '357 patent and is not liable for such infringement.

COUNT VIII
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '357 PATENT)

41. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

42. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '357 patent are invalid.

43. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '357 patent are invalid.

44. Hetero is entitled to a declaration that all claims of the '357 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT IX
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '219 PATENT)

45. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

46. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '219 patent.

47. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '219 patent is not infringed by Hetero's ANDA or the products or activities described therein.

48. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '219 patent and is not liable for such infringement.

COUNT X
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '219 PATENT)

49. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

50. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '219 patent are invalid.

51. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '219 patent are invalid.

52. Hetero is entitled to a declaration that all claims of the '219 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT XI: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '717 PATENT

53. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

54. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '717 patent.

55. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '717 patent is not infringed by Hetero's ANDA or the products or activities described therein.

56. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '717 patent and is not liable for such infringement.

COUNT XII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '717 PATENT

57. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

58. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '717 patent are invalid.

59. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '717 patent are invalid.

60. Hetero is entitled to a declaration that all claims of the '717 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT XIII: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '498 PATENT

61. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

62. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use,

offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '498 patent.

63. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '498 patent is not infringed by Hetero's ANDA or the products or activities described therein.

64. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '498 patent and is not liable for such infringement.

COUNT XIV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '498 PATENT

65. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

66. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '498 patent are invalid.

67. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '498 patent are invalid.

68. Hetero is entitled to a declaration that all claims of the '498 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT XV: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '095 PATENT

69. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

70. There is an actual, substantial, continuing, and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '095 patent.

71. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '095 patent is not infringed by Hetero's ANDA or the products or activities described therein.

72. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '095 patent and is not liable for such infringement.

COUNT XVI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '095 PATENT

73. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

74. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '095 patent are invalid.

75. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '095 patent are invalid.

76. Hetero is entitled to a declaration that all claims of the '095 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT XVII: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '120 PATENT

77. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

78. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '120 patent.

79. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '120 patent is not infringed by Hetero's ANDA or the products or activities described therein.

80. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '120 patent and is not liable for such infringement.

COUNT XVIII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '120 PATENT

81. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

82. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '120 patent are invalid.

83. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '120 patent are invalid.

84. Hetero is entitled to a declaration that all claims of the '120 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT XIX: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '621 PATENT

85. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

86. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '621 patent.

87. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '621 patent is not infringed by Hetero's ANDA or the products or activities described therein.

88. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '621 patent and is not liable for such infringement.

COUNT XX: DECLARATORY JUDGMENT OF INVALIDITY OF THE '621 PATENT

89. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

90. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the '621 patent are invalid.

91. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '621 patent are invalid.

92. Hetero is entitled to a declaration that all claims of the '621 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity

COUNT XXI: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '622 PATENT

93. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

94. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's Proposed Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '622 patent.

95. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '622 patent is not infringed by Hetero's ANDA or the products or activities described therein.

96. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '622 patent and is not liable for such infringement.

COUNT XXII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '622 PATENT

97. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

98. There is an actual, substantial, continuing and justiciable controversy between Celgene and Hetero regarding whether the claims of the ’622 patent are invalid.

99. Hetero incorporates by reference Hetero’s Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the ’622 patent are invalid.

100. Hetero is entitled to a declaration that all claims of the ’622 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity

PRAYER FOR RELIEF

WHEREFORE, Hetero requests that the Court enter judgment in its favor and against Celgene as follows:

A. Dismissing Plaintiffs’ First Amended and entering judgment in favor of Hetero on all of Plaintiff’s claims.

B. Declaring that the filing of Hetero’s ANDA has not infringed, and does not infringe, any valid and enforceable claims of the patents-in-suit;

C. Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of Hetero’s Proposed Products do not, and will not, infringe any valid and enforceable claims of the patents-in-suit;

D. Declaring that the claims of the patents-in-suit are invalid and/or unenforceable;

E. Awarding Hetero its costs and expenses in this action;

F. Declaring this an exceptional case in favor of Hetero and a

G. warding Hetero its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

H. Awarding such other and further relief as this Court deems just and proper.

January 26, 2021

By: */s/ Eric I. Abraham*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on January 26, 2021, the foregoing was served on counsel of record for Plaintiffs via CM/ECF.

HILL WALLACK LLP

/s/ Eric I. Abraham
Eric I. Abraham

Dated: January 26, 2021