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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, and ALEMBIC PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against Defendants Alembic Pharmaceuticals Limited ("Alembic Ltd."), Alembic Global Holding SA ("Alembic Global"), and Alembic Pharmaceuticals, Inc. ("Alembic Inc.") (collectively, "Alembic"), alleges as follows:

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 Alembic's submission of Abbreviated New Drug Application ("ANDA") No. 216260 ("Alembic's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell,

and/or sell generic versions of Celgene's Revlimid® drug products prior to the expiration of United States Patent Nos. 7,465,800 (the "'800 patent"), 7,855,217 (the "'217 patent"), 7,968,569 (the "'569 patent"), 8,530,498 (the "'498 patent"), 8,648,095 (the "'095 patent"), 9,101,621 (the "'621 patent"), and 9,101,622 (the "'622 patent") (collectively, "the patents-in-suit"), all owned by Celgene.

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.

3. On information and belief, Defendant Alembic Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390 003, Gujarat, India.

4. On information and belief, Defendant Alembic Global is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

5. On information and belief, Alembic Global is a wholly-owned subsidiary of Alembic Ltd.

6. On information and belief, Defendant Alembic Inc. is a Delaware Corporation having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

7. On information and belief, Alembic Inc. is a wholly-owned subsidiary of Alembic Global.

The Patents-in-Suit

8. On December 16, 2008, the United States Patent and Trademark Office ("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." A copy of the '800 patent is attached hereto as Exhibit A.

9. On December 21, 2010, the USPTO duly and lawfully issued the '217 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione." A copy of the '217 patent is attached hereto as Exhibit B.

10. 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." A copy of the '569 patent is attached hereto as Exhibit C.

11. 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." A copy of the '498 patent is attached hereto as Exhibit D.

12. 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." A copy of the '095 patent is attached hereto as Exhibit E.

13. 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." A copy of the '621 patent is attached hereto as Exhibit F.

14. 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." A copy of the '622 patent is attached hereto as Exhibit G.

The Revlimid® Drug Product

15. 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. 021880), which it sells under the trade name Revlimid®. 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.

16. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Revlimid®.

17. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® for the treatment of, *inter alia*, adult patients with multiple myeloma (MM), in combination with dexamethasone.

18. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® for the treatment of, *inter alia*, adult patients with MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).

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

Jurisdiction and Venue

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

21. This Court has personal jurisdiction over Alembic Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Alembic Inc. maintains a regular and established, physical place of business in Bridgewater, New Jersey. On information and belief, Alembic Inc. also maintains a regular and established, physical place of business in Bedminster, New Jersey.

22. On information and belief, Alembic Inc. 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. 101031141. On information and belief, Alembic Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5004785. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Alembic Inc. On information and belief, Alembic Inc. purposefully has conducted and continues to conduct business in this Judicial District.

23. On information and belief, Alembic Inc. 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, Alembic Inc. also prepares and/or aids in the preparation and submission of ANDAs to the FDA, including Alembic's ANDA.

24. On information and belief, this Judicial District is a likely destination for the generic drug products described in Alembic's ANDA.

25. On information and belief, Alembic Ltd.'s 2020-2021 Annual Report reports a research-and-development facility in New Jersey. *See* Alembic Pharmaceuticals Limited Annual Report 2020-21, https://www.alembicpharmaceuticals.com/wp-content/uploads/2021/06/Alembic%20Pharmaceuticals%20Limited-Annual%20Report-2020-21.pdf (last visited November 18, 2021) at 2, 4, 14.

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

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

28. This Court also has personal jurisdiction over Alembic Inc., Alembic Ltd., and Alembic Global because, *inter alia*, they have committed an act of patent infringement under 35

U.S.C. § 271(e)(2), including sending notice of the ANDA submission to Celgene in the State of New Jersey. On information and belief, Alembic Inc., Alembic Ltd., and Alembic Global intend 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.

29. On information and belief, Alembic Inc. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

30. On information and belief, Alembic Ltd. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

31. On information and belief, Alembic Global derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

32. In the alternative, this Court has personal jurisdiction over Alembic Ltd. and Alembic Global because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Celgene's claims arise under federal law; (b) Alembic Ltd. and Alembic Global are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Alembic Ltd. and Alembic Global have sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing,

importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alembic Ltd. and Alembic Global satisfies due process.

33. On information and belief, Alembic Inc., Alembic Ltd., and Alembic Global work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

34. On information and belief, each of Alembic Inc., Alembic Ltd., and Alembic Global actively participated in the submission of Alembic's ANDA. On information and belief, Alembic Inc. will work in privity and/or concert with Alembic Ltd., Alembic Global, and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Alembic's Proposed Products, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

35. On information and belief, Alembic Inc. intends to benefit directly if Alembic's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Alembic's ANDA.

36. On information and belief, Alembic Ltd. intends to benefit directly if Alembic's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Alembic's ANDA.

37. On information and belief, Alembic Global intends to benefit directly if Alembic's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Alembic's ANDA.

38. On information and belief, Alembic Inc. acts on behalf, at the direction, and for the benefit, of Alembic Ltd. and Alembic Global, and is controlled and/or dominated by Alembic Ltd. and Alembic Global, including with respect to Alembic's ANDA.

39. On information and belief, Alembic Global acts on behalf, at the direction, and for the benefit, of Alembic Ltd., and is controlled and/or dominated by Alembic Ltd., including with respect to Alembic's ANDA.

40. On information and belief, Alembic Inc., Alembic Ltd., and Alembic Global hold themselves out to the public as a single integrated business.

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

Acts Giving Rise To This Suit

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

43. On information and belief, following FDA approval of Alembic's ANDA, Alembic will make, use, sell, or offer to sell Alembic's Proposed Products throughout the United States, or import such generic products into the United States.

44. On information and belief, in connection with the submission of its ANDA as described above, Alembic provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Alembic's Paragraph IV Certification"), alleging that the claims of the '800, '217, '569, '498, '095, and '622 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Alembic's ANDA.

45. No earlier than October 7, 2021, Alembic sent a written notice of its Paragraph IV Certification to Celgene ("Alembic's Notice Letter"). Alembic's Notice Letter alleged that the claims of the '800, '217, '569, '498, '095, and '622 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Alembic's ANDA. Alembic's Notice Letter also informed Celgene that Alembic seeks approval to market Alembic's Proposed Products before the patents-in-suit expire. Alembic specifically directed Alembic's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

Count I: Infringement of the '800 Patent

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

47. Alembic's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alembic'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).

48. There is a justiciable controversy between the parties hereto as to the infringement of the '800 patent.

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

50. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic 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 Alembic's Proposed Products in the United States. On information and belief, upon FDA approval of Alembic's ANDA, Alembic will intentionally encourage acts of direct infringement with knowledge of the '800 patent and knowledge that its acts are encouraging infringement.

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

52. Celgene will be substantially and irreparably damaged and harmed if Alembic's infringement of the '800 patent is not enjoined.

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

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

Count II: Infringement of the '217 Patent

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

56. Alembic's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alembic's Proposed Products, prior to the expiration of the '217 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. There is a justiciable controversy between the parties hereto as to the infringement of the '217 patent.

58. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic will infringe one or more claims of the '217 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Alembic's Proposed Products in the United States.

59. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic will induce infringement of one or more claims of the '217 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Alembic's Proposed Products in the United States. On information and belief, upon FDA approval of Alembic's ANDA, Alembic will intentionally encourage acts of direct infringement with knowledge of the '217 patent and knowledge that its acts are encouraging infringement.

60. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic will contributorily infringe one or more claims of the '217 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Alembic's Proposed Products in the United States. On information and belief, Alembic has had and continues to have knowledge

that Alembic's Proposed Products are especially adapted for a use that infringes one or more claims of the '217 patent and that there is no substantial non-infringing use for Alembic's Proposed Products.

61. Celgene will be substantially and irreparably damaged and harmed if Alembic's infringement of the '217 patent is not enjoined.

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

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

Count III: Infringement of the '569 Patent

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

65. Alembic's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alembic'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).

66. There is a justiciable controversy between the parties hereto as to the infringement of the '569 patent.

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

68. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic 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 Alembic's Proposed Products in the United States. On information and belief, upon FDA approval of Alembic's ANDA, Alembic will intentionally encourage acts of direct infringement with knowledge of the '569 patent and knowledge that its acts are encouraging infringement.

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

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

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

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

Count IV: Infringement of the '498 Patent

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

74. Alembic's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alembic'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).

75. There is a justiciable controversy between the parties hereto as to the infringement of the '498 patent.

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

77. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic 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 Alembic's Proposed Products in the United States. On information and belief, upon FDA approval of Alembic's ANDA, Alembic will intentionally encourage acts of direct infringement with knowledge of the '498 patent and knowledge that its acts are encouraging infringement.

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

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

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

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.

Count V: Infringement of the '095 Patent

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

83. Alembic's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alembic'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).

84. There is a justiciable controversy between the parties hereto as to the infringement of the '095 patent.

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

86. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic 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 Alembic's Proposed Products in the United States. On information and belief, upon FDA approval of Alembic's ANDA, Alembic will intentionally encourage acts of direct infringement with knowledge of the '095 patent and knowledge that its acts are encouraging infringement.

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

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

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

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

Count VI: Infringement of the '621 Patent

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

92. Alembic's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alembic'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).

93. There is a justiciable controversy between the parties hereto as to the infringement of the '621 patent.

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

95. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic 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 Alembic's Proposed Products in the United States. On information and belief, upon FDA approval of Alembic's ANDA, Alembic will intentionally encourage acts of direct infringement with knowledge of the '621 patent and knowledge that its acts are encouraging infringement.

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

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

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

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

Count VII: Infringement of the '622 Patent

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

101. Alembic's submission of its ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale,

offer for sale, or importation into the United States of Alembic'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).

102. There is a justiciable controversy between the parties hereto as to the infringement of the '622 patent.

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

104. Unless enjoined by this Court, upon FDA approval of Alembic's ANDA, Alembic 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 Alembic's Proposed Products in the United States. On information and belief, upon FDA approval of Alembic's ANDA, Alembic will intentionally encourage acts of direct infringement with knowledge of the '622 patent and knowledge that its acts are encouraging infringement.

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Alembic has infringed the patents-in-suit by submitting ANDA No. 216260 with the accompanying Paragraph IV Certification and notice to Celgene of same;

(B) A Judgment that Alembic has infringed, and that Alembic's making, using, selling, offering to sell, or importing Alembic's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 216260 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Alembic and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Alembic's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Alembic, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any solid forms of lenalidomide, compositions, or methods claimed in the patents-in-suit, or from actively inducing or contributing to the

infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Alembic, its officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, has committed any acts with respect to the solid forms of lenalidomide, compositions, or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Alembic, its officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

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

Dated: November 18, 2021

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned *Celgene Corporation v. Hikma Pharmaceuticals USA, Inc.*, Civil Action No. 21-10398 (D.N.J.) and *Celgene Corporation v. Lupin Ltd.*, Civil Action No. 20-8570 (SDW)(LDW) (D.N.J.) are related to the matter in controversy because the matter in controversy involves the same plaintiff and some of the same patents, and because Alembic is seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 18, 2021

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