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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>CELGENE CORPORATION,</p> <p>Plaintiff,</p> <p>v.</p> <p>HIKMA PHARMACEUTICALS USA, INC.,</p> <p>Defendant.</p>	<p>Civil Action No. _____</p> <p>COMPLAINT FOR PATENT INFRINGEMENT</p> <p>(Filed Electronically)</p>
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Plaintiff Celgene Corporation (“Celgene”), by its undersigned attorneys, for its Complaint against Defendant Hikma Pharmaceuticals USA, Inc. (“Defendant” or “Hikma”), 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 Hikma’s submission of Abbreviated New Drug Application (“ANDA”) No. 213103 (“Hikma’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. 7,189,740 (“the ’740 patent”), 7,465,800 (“the ’800 patent”),

7,855,217 (“the ’217 patent”), 7,968,569 (“the ’569 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”), 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 Hikma is a Delaware corporation, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

The Patents-in-Suit

4. 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,” to Celgene as assignee. A copy of the ’800 patent is attached hereto as Exhibit A.

5. 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,” to Celgene as assignee. A copy of the ’217 patent is attached hereto as Exhibit B.

6. 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.

7. 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 D.

8. 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 E.

9. 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-dihydroisoindol-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 F.

10. 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 G.

11. On March 13, 2007, the 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 H.

12. 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 I.

13. 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 J.

The Revlimid® Drug Product

14. 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.

15. 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®.

16. 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.

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 MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).

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 transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities.

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 Hikma by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Hikma 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, Hikma has purposefully conducted and continues to conduct business in this Judicial District, including the purposeful sale and distribution of drug products. This Judicial District is a likely destination for the generic drug products described in Hikma's ANDA.

22. On information and belief, Hikma derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s)

used in various generic pharmaceutical products sold throughout the United States, including in this Judicial District.

23. On information and belief, Hikma maintains a physical place of business in at least Berkeley Heights, New Jersey. Hikma's website states that its "US Headquarters" is located at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. *See* <https://www.hikma.com/contact/us-locations/> (last visited, April 28, 2021).

24. On information and belief, Hikma 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. 100487525 and is registered as a manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5002130.

25. On information and belief, Hikma participated in the preparation and/or submission of ANDA No. 213103 and, as described below, provided notice of its ANDA submission in New Jersey.

26. This Court also has personal jurisdiction over Hikma because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), including by sending notice of the ANDA submission to Celgene in the State of New Jersey. On information and belief, Hikma 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.

27. On information and belief, Hikma has previously been sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Celgene Corp. v. West-Ward Pharm. Int'l Ltd., et al.*, Civil Action No. 18-13477 (D.N.J.) (SDW)(LDW).

28. Hikma has further availed itself of the jurisdiction of this Court by previously asserting counterclaims in this jurisdiction. *See, e.g., Celgene Corp. v. West-Ward Pharm. Int'l Ltd., et al.*, Civil Action No. 18-13477 (D.N.J.) (SDW)(LDW).

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

Acts Giving Rise To This Suit

30. Pursuant to Section 505 of the FFDCA, Hikma submitted Hikma'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 ("Hikma's Proposed Products"), before the patents-in-suit expire.

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

32. On information and belief, in connection with the submission of its ANDA as described above, Hikma provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Hikma's Paragraph IV Certification"), alleging that the claims of the '740, '800, '217, '569, '717, '498, '095, '120, and '622 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Hikma's ANDA.

33. No earlier than March 15, 2021, Hikma sent a written notice of its Paragraph IV Certification to Celgene ("Hikma's March 15 Notice Letter") focusing on the 25 mg dosage strength of Hikma's Proposed Products. No earlier than April 1, 2021, Hikma sent a written notice of its Paragraph IV Certification to Celgene ("Hikma's April 1 Notice Letter") (together with Hikma's March 15 Notice Letter, "Hikma's Notice Letters") focusing on the 2.5 mg, 5 mg,

10 mg, 15 mg, and 20 mg dosage strengths of Hikma's Proposed Products. Hikma's Notice Letters alleged that the claims of the '740, '800, '217, '569, '717, '498, '095, '120, and '622 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Hikma's ANDA. Hikma's Notice Letters also informed Celgene that Hikma seeks approval to market Hikma's Proposed Products before the patents-in-suit expire. Hikma specifically directed Hikma's Notice Letters to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

Count I: Infringement of the '740 Patent

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

35. Hikma'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 Hikma'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).

36. There is a justiciable controversy between the parties hereto as to the infringement of the '740 patent.

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

38. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the

United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '740 patent and knowledge that its acts are encouraging infringement.

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

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

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

42. 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 '800 Patent

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

44. Hikma'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 Hikma'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).

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

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

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

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

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

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

51. 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 '217 Patent

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

53. Hikma'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 Hikma'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).

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

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

56. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '217 patent and knowledge that its acts are encouraging infringement.

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

Hikma'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 Hikma's Proposed Products.

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

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

60. 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 '569 Patent

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

62. Hikma'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 Hikma'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).

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

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

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

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

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

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

69. 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 '717 Patent

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

71. Hikma'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 Hikma'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).

72. There is a justiciable controversy between the parties hereto as to the infringement of the '717 patent.

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

74. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '717 patent and knowledge that its acts are encouraging infringement.

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

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

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

78. 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 '498 Patent

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

80. Hikma'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 Hikma'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).

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

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

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

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

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

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

87. 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 '095 Patent

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

89. Hikma'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 Hikma'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).

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

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

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

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

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

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

96. 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 VIII: Infringement of the '120 Patent

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

98. Hikma'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 Hikma'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).

99. There is a justiciable controversy between the parties hereto as to the infringement of the '120 patent.

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

101. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 Hikma's Proposed Products in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '120 patent and knowledge that its acts are encouraging infringement.

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

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

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

105. 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 IX: Infringement of the '621 Patent

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

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

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

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

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

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

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

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

114. 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 X: Infringement of the '622 Patent

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

116. Hikma'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 Hikma'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).

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

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

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

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

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

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

123. 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 Hikma has infringed the patents-in-suit by submitting ANDA No. 213103 with the accompanying Paragraph IV Certification and notice to Celgene of same;

(B) A Judgment that Hikma has infringed, and that Hikma's making, using, selling, offering to sell, or importing Hikma'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. 213103 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 Hikma 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 Hikma'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 Hikma, 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 Hikma's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Hikma, 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 Hikma, 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 Hikma'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: April 28, 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. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 21-1734 (SDW)(LDW) (D.N.J.); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 20-14389 (SDW)(LDW) (D.N.J.); *Celgene Corporation v. Lupin Ltd.*, Civil Action No. 20-8570 (SDW)(LDW) (D.N.J.); *Celgene Corporation v. Aurobindo Pharma, Ltd., et al.*, Civil Action No. 20-315 (SDW)(LDW) (D.N.J.); *Celgene Corporation v. Mylan Pharm. Inc., et al.*, Civil Action No. 19-22231 (SDW)(LDW) (D.N.J.); and *Celgene Corporation v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 18-11630 (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 Hikma 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: April 28, 2021

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