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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (together, "Torrent" or "Defendants"), 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 Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.'s submission of Abbreviated New Drug Application ("ANDA") No. 213405 ("Torrent'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 Torrent Pharmaceuticals Ltd. ("TPL") is a corporation organized and existing under the laws of India, with its principal place of business at Off. Ashram Road, Ahmedabad 380009, Gujarat, India.

4. On information and belief, Defendant Torrent Pharma Inc. ("TPI") is a corporation organized and existing under the laws of Delaware, with its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920.

5. On information and belief, TPI is a wholly owned subsidiary of TPL.

The Patents-in-Suit

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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 F.

12. 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.

13. 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.

14. 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.

15. 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

16. 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.

17. 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®.

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 multiple myeloma (MM), in combination with dexamethasone.

19. 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).

20. 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.

21. 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.

Acts Giving Rise To This Suit

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

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

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

25. No earlier than May 10, 2021, TPI and TPL sent a written notice of their Paragraph IV Certification to Celgene ("Torrent's Notice Letter"). Torrent's Notice Letter alleged that the claims of the '740, '800, '217, '569, '717, '498, '095, '120, and '622 patents are invalid and/or will not be infringed by the activities described in Torrent's ANDA. Torrent's Notice Letter also informed Celgene that Torrent seeks approval to market Torrent's Proposed Products before the patents-in-suit expire. Torrent specifically directed Torrent's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

Jurisdiction and Venue

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

27. This Court has personal jurisdiction over TPI by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, TPI maintains a regular and established, physical place of business in Basking Ridge, New Jersey. On information and belief, TPI 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. 0400474439. On information and belief, TPI is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5003857. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over TPI.

On information and belief, TPI purposefully has conducted and continues to conduct business in this Judicial District.

28. On information and belief, TPI 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, TPI also prepares and/or aids in the preparation and submission of ANDAs to the FDA, including Torrent's ANDA.

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

30. On information and belief, TPI 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, TPL 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. This Court has personal jurisdiction over TPL 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, TPI, 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, TPI.

33. This Court also has personal jurisdiction over TPI and TPL 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, TPI and TPL 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.

34. In the alternative, this Court has personal jurisdiction over TPL because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Celgene's claims arise under federal law; (b) TPL is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) TPL has 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 TPL satisfies due process.

35. On information and belief, TPI and TPL 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.

36. On information and belief, each of TPI and TPL actively participated in the submission of Torrent's ANDA. On information and belief, TPI will work in privity and/or concert with TPL and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical

products, including Torrent'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.

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

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

39. On information and belief, TPI acts at the direction, and for the benefit, of TPL and is controlled and/or dominated by TPL.

40. On information and belief, TPI and TPL act, operate, and/or hold themselves out to the public as a single integrated business.

41. On information and belief, TPI and TPL have consented to or not contested personal jurisdiction in this Court and have filed counterclaims in such cases. *See, e.g.*, *Amgen Inc. v. Torrent Pharm. Ltd.*, No. 18-11156, D.I. 16 (D.N.J. Aug. 29, 2018); *Sumitomo Dainippon Pharma Co*., *Ltd., et al. v. Aurobindo Pharma Ltd.*, *et al.*, No. 18-2620, D.I. 84 (D.N.J. Apr. 12, 2018); *Takeda Pharm. Ltd.*, *et al. v. Torrent Pharm. Ltd.*, *et al.*, No. 17-3186, D.I. 12 (D.N.J. July 7, 2017).

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

Count I: Infringement of the '740 Patent

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

44. TPI and TPL's submission of their 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 Torrent'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).

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

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

47. Unless enjoined by this Court, upon FDA approval of Torrent's ANDA, TPI and TPL 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 Torrent's Proposed Products in the United States. On information and belief, upon FDA approval of Torrent's ANDA, TPI and TPL will intentionally encourage acts of direct infringement with knowledge of the '740 patent and knowledge that their acts are encouraging infringement.

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

49. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '740 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 II: Infringement of the '800 Patent

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

53. TPI and TPL's submission of their 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 Torrent'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).

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

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

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

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

58. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '800 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 III: Infringement of the '217 Patent

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

62. TPI and TPL's submission of their 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 Torrent'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).

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

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

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

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

67. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '217 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 IV: Infringement of the '569 Patent

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

71. TPI and TPL's submission of their 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 Torrent'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).

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

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

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

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

76. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '569 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 V: Infringement of the '717 Patent

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

80. TPI and TPL's submission of their 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 Torrent'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).

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

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

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

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

85. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '717 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 VI: Infringement of the '498 Patent

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

89. TPI and TPL's submission of their 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 Torrent'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).

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

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

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

93. Unless enjoined by this Court, upon FDA approval of Torrent's ANDA, TPI and TPL 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 Torrent's Proposed Products in the

United States. On information and belief, TPI and TPL have had and continue to have knowledge that Torrent'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 Torrent's Proposed Products.

94. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '498 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 VII: Infringement of the '095 Patent

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

98. TPI and TPL's submission of their 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 Torrent'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).

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

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

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

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

103. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '095 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 VIII: Infringement of the '120 Patent

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

107. TPI and TPL's submission of their 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 Torrent'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).

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

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

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

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

112. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '120 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 IX: Infringement of the '621 Patent

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

116. TPI and TPL's submission of their 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 Torrent'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).

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

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

119. Unless enjoined by this Court, upon FDA approval of Torrent's ANDA, TPI and TPL 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 Torrent's Proposed Products in the United States. On information and belief, upon FDA approval of Torrent's ANDA, TPI and TPL

will intentionally encourage acts of direct infringement with knowledge of the '621 patent and knowledge that their acts are encouraging infringement.

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

121. Celgene will be substantially and irreparably damaged and harmed if TPI and TPL's infringement of the '621 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.

Count X: Infringement of the '622 Patent

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

125. TPI and TPL's submission of their 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 Torrent'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).

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

127. Unless enjoined by this Court, upon FDA approval of Torrent's ANDA, TPI and TPL 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 Torrent's Proposed Products in the United States.

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

129. Unless enjoined by this Court, upon FDA approval of Torrent's ANDA, TPI and TPL 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 Torrent's Proposed Products in the United States. On information and belief, TPI and TPL have had and continue to have knowledge that Torrent'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 Torrent's Proposed Products.

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

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

132. 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 TPI and TPL have infringed the patents-in-suit by submitting ANDA No. 213405 with the accompanying Paragraph IV Certification and notice to Celgene of same;

(B) A Judgment that TPI and TPL have infringed, and that TPI and TPL's making, using, selling, offering to sell, or importing Torrent'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. 213405 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 TPI and TPL and their officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Torrent'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 TPI and TPL, their 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 Torrent's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that TPI and TPL, their officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, have 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 TPI and TPL their 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 Torrent'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: June 23, 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. Biocon Pharma Limited, et al.*, Civil Action No. 21-11261 (SDW)(LDW) (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals USA, Inc.,* Civil Action No. 21-10398 (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 Limited*, 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.); and *Celgene Corporation v. Mylan Pharm. Inc., et al.*, Civil Action No. 19-22231 (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 Torrent 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: June 23, 2021

By: s/ Charles M. Lizza

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