IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV, Plaintiffs, v. HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC, and WEST-WARD COLUMBUS INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPNV"), (collectively "Plaintiffs" or "Janssen"), for their Complaint against Defendants Hikma Pharmaceuticals PLC ("Hikma UK"); Hikma Pharmaceuticals USA Inc. ("Hikma USA"), and West-Ward Columbus Inc. ("WWCI") (collectively, "Hikma" or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 10,869,844 (the "'844 Patent"), United States Patent No. 11,173,134 (the "'134 Patent"), United States Patent No. 11,311,500 (the "'500 Patent"), and United States Patent No. 11,446,260 (the "'260 Patent").

2. This action relates to the submission of Abbreviated New Drug Application ("ANDA") No. 217976 by Hikma to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of JPI's Spravato® brand products prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents.

THE PARTIES

3. JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. JPNV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.

5. On information and belief, Hikma UK is a corporation organized and existing under the laws of the United Kingdom, having a place of business at 1 New Burlington Place, Mayfair, London, W1S 2HR, United Kingdom.

6. On information and belief, Hikma USA is a corporation organized and existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. Upon information and belief, Hikma USA is an agent or affiliate of WWCI and a wholly owned subsidiary of Hikma UK.

7. On information and belief, WWCI is a corporation organized and existing under the laws of Delaware, having a place of business at 1809 Wilson Road, Columbus, OH 43228. Upon information and belief, WWCI is an agent or affiliate of Hikma USA and a wholly owned subsidiary of Hikma UK.

8. On information and belief, Hikma UK, Hikma USA, and WWCI are pharmaceutical companies that develop, manufacture, market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of Delaware and throughout the United States.

9. Upon information and belief, Hikma UK, Hikma USA, and WWCI are acting in concert to develop, manufacture, market, and/or distribute generic pharmaceutical

products, including the proposed generic version of Spravato® described in ANDA No. 217976, for sale in the state of Delaware and throughout the United States.

10. On information and belief, Hikma UK, Hikma USA, and WWCI hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products, including the proposed generic version of Spravato® described in ANDA No. 217976, in Delaware and throughout the United States.

11. On information and belief, Hikma UK, Hikma USA, and WWCI are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 217976.

12. On information and belief, Hikma USA, together with its affiliates and/or agents Hikma UK and WWCI, prepared and filed the Hikma ANDA No. 217976 that is at issue in this patent infringement suit.

13. On information and belief, Hikma USA is acting on behalf of itself and on behalf of Hikma UK and WWCI with respect to ANDA No. 217976.

JURISDICTION AND VENUE

14. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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

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

Hikma Pharmaceuticals PLC ("Hikma UK")

17. This Court has personal jurisdiction over Hikma UK because, *inter alia*, Hikma UK has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 217976, Hikma UK will, directly or through its affiliates, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Spravato® brand products in the United States, including in Delaware, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents.

18. Exercising personal jurisdiction over Hikma UK in this District is reasonable given Hikma UK's contacts in this District and the interest of this District in resolving disputes related to products to be sold herein.

19. This Court also has personal jurisdiction over Hikma UK because Hikma UK has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Hikma UK regularly and continuously transacts business within Delaware, either directly or through affiliates that it controls (including Hikma USA and WWCI), including by selling pharmaceutical products in Delaware. On information and belief, Hikma UK derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

20. On information and belief, Hikma UK, either directly or indirectly through its agents and/or affiliates Hikma USA and WWCI, is in the business of formulating,

manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

21. This Court also has personal jurisdiction over Hikma UK because, *inter alia*, this action arises from the actions of Hikma UK directed toward Delaware, either directly or through Hikma USA and/or WWCI. For example, counsel for Hikma UK's wholly owned subsidiary Hikma USA sent a letter dated April 18, 2023 to JPI stating that Hikma USA had submitted ANDA No. 217976 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Spravato® brand products prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents. If Hikma USA succeeds in obtaining FDA approval, Hikma UK would sell its proposed generic versions of JPI's Spravato® brand products in Delaware and other states, either directly or through its affiliates, causing injury to Plaintiffs in Delaware.

22. In the alternative, this Court has personal jurisdiction over Hikma UK because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

23. Venue in this District is proper for Hikma UK under 28 U.S.C. § 1391(c)(3), including because Hikma UK is a foreign corporation and is subject to personal jurisdiction in this District, as alleged herein. In addition, as alleged herein and on information and belief, Hikma UK will commit further acts of infringement in this District and continuously transacts business in this District either directly or indirectly through its agents and/or affiliates Hikma USA and WWCI.

24. Hikma UK has conceded that venue is proper over Hikma UK in patent cases in this Judicial District and has consented to or did not contest the jurisdiction of this Court in at least the following District of Delaware actions: *Forest Labs., LLC v. Hikma Pharms. LLC*

et al., Civil Action No. 14-1266, D.I. 16 (D. Del. Oct. 2, 2014) and *Takeda Pharms. U.S.A., Inc. v. Hikma Pharms. USA, Inc. et al.*, Civil Action No. 14-1268, D.I. 137 (D. Del. Oct. 3, 2014).

Hikma Pharmaceuticals USA Inc. ("Hikma USA")

25. This Court has personal jurisdiction over Hikma USA because, *inter alia*, Hikma USA is incorporated in Delaware, and because Hikma USA has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 217976, Hikma USA will, directly or through its affiliates, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Spravato® brand products in the United States, including in Delaware, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents.

26. Exercising personal jurisdiction over Hikma USA in this District is reasonable given Hikma USA's contacts in this District and the interest of this District in resolving disputes related to products to be sold herein.

27. This Court also has personal jurisdiction over Hikma USA because Hikma USA has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware, including by incorporating in Delaware. On information and belief, Hikma USA regularly and continuously transacts business within Delaware, either directly or through its affiliates, including by selling pharmaceutical products in Delaware. On information and belief, Hikma USA derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

28. On information and belief, Hikma USA has substantial, continuous and systematic contacts with Delaware, is organized under the laws of Delaware, has appointed a registered agent in Delaware for receipt of service of process, and is registered as a pharmaceutical wholesaler in Delaware (License No. 2022873627).

29. On information and belief, Hikma USA, either directly or indirectly through its agents and/or affiliates Hikma UK and WWCI, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

30. This Court also has personal jurisdiction over Hikma USA because, *inter alia*, this action arises from the actions of Hikma USA directed toward Delaware, either directly or through Hikma UK and/or WWCI. For example, Hikma USA's counsel sent a letter dated April 18, 2023 to JPI stating that Hikma USA had submitted ANDA No. 217976 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Spravato® brand products prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents. If Hikma USA succeeds in obtaining FDA approval, Hikma USA would sell its proposed generic versions of JPI's Spravato® brand products in Delaware and other states, either directly or through its affiliates, causing injury to Plaintiffs in Delaware.

31. Venue in this District is proper for Hikma USA under 28 U.S.C. § 1400(b) because Hikma USA is incorporated under the laws of Delaware.

32. Hikma USA has conceded that venue is proper over Hikma USA in patent cases in this Judicial District and has consented to or did not contest the jurisdiction of this Court in at least the following District of Delaware actions: *Astellas US LLC et al. v. Hikma Pharms.*

USA, Inc. et al., Civil Action No. 21-1785, D.I. 9 (D. Del. Dec. 22, 2021) and *Novo Nordisk Inc. et al. v. Hikma Pharms. USA Inc.*, Civil Action No. 21-1783, D.I. 8 (D. Del. Dec. 21, 2021).

West-Ward Columbus Inc. ("WWCI")

33. On information and belief, WWCI, either directly or indirectly through Hikma, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

34. This Court has personal jurisdiction over WWCI because, *inter alia,* WWCI is incorporated in Delaware, and because WWCI has committed an act of patent infringement under 35 U.S.C. §271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 217976, WWCI will, directly or through its affiliates, including Hikma UK and Hikma USA, distribute the proposed generic versions of JPI's Spravato® brand products described in ANDA No. 217976 in the United States, including in Delaware, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents.

35. Exercising personal jurisdiction over WWCI in this District is reasonable given WWCI's contacts in this District and the interest of this District in resolving disputes related to products to be sold herein.

36. This Court also has personal jurisdiction over WWCI because WWCI has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware, including by incorporating in Delaware. On information and belief, WWCI regularly and continuously transacts business within Delaware,

either directly or through its affiliates, including by selling pharmaceutical products in Delaware. On information and belief, WWCI derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

37. On information and belief, WWCI has substantial, continuous and systematic contacts with Delaware, is organized under the laws of Delaware, and has appointed a registered agent in Delaware for receipt of service of process.

38. On information and belief, WWCI, either directly or indirectly through its agents and/or affiliates Hikma UK and Hikma USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

39. This Court also has personal jurisdiction over WWCI because, *inter alia*, this action arises from the actions of WWCI directed toward Delaware, either directly or through Hikma UK and/or Hikma USA. For example, Hikma USA's counsel sent a letter dated April 18, 2023 to JPI stating that Hikma USA had submitted ANDA No. 217976 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Spravato® brand products prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents. If Hikma USA succeeds in obtaining FDA approval, Hikma would sell its proposed generic versions of JPI's Spravato® brand products in Delaware and other states, either directly or through its affiliates and/or agents including WWCI, causing injury to Plaintiffs in Delaware.

40. Venue in this District is proper for WWCI under 28 U.S.C. § 1400(b) because WWCI is incorporated under the laws of Delaware.

THE PATENTS-IN-SUIT

41. On December 22, 2020, the '844 Patent, titled "Methods for the Treatment of Depression" was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the '844 Patent. A copy of the '844 Patent is attached as Exhibit A.

42. On November 16, 2021, the '134 Patent, titled "Methods for the Treatment of Depression" was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the '134 Patent. A copy of the '134 Patent is attached as Exhibit B.

43. On April 26, 2022, the '500 Patent, titled "Methods for the Treatment of Depression" was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the '500 patent. A copy of the '500 Patent is attached as Exhibit C.

44. On September 20, 2022, the '260 Patent, titled "Pharmaceutical Composition of S-Ketamine Hydrochloride" was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the '260 Patent. A copy of the '260 Patent is attached as Exhibit D.

45. JPI holds approved NDA No. 211243 for esketamine nasal spray, which is prescribed and sold under the trademark Spravato®.

46. Pursuant to 21 U.S.C. § 355(b)(1), the '134, '844, '500, and '260 Patents are listed in the United States FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering JPI's Spravato® brand esketamine nasal spray products.

COUNT I:
INFRINGEMENT OF THE '844 PATENT BY
HIKMA'S ANDA FOR SPRAVATO®

47. Plaintiffs re-allege paragraphs 1-46 as if fully set forth herein.

48. An actual controversy exists between the parties as to whether Hikma's proposed sale of its generic esketamine nasal spray products infringes at least claims 1-11, 13-16, and 19-30 of the '844 Patent.

49. By letter dated April 18, 2023 ("Hikma Notice Letter"), Hikma notified Plaintiffs that it had submitted ANDA No. 217976 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Hikma Notice Letter stated that ANDA No. 217976 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of Delaware, of generic esketamine nasal spray products prior to the expiration of certain Orange Book listed patents. ANDA No. 217976 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '844 Patent.

50. ANDA No. 217976 includes a Paragraph IV Certification that the claims of the '844 Patent are invalid, unenforceable, and/or not infringed.

51. Upon information and belief, the Hikma Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

52. The Hikma Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Hikma's Notice Letter.

53. The Hikma Notice Letter purports to include a Notice of Certification for ANDA No. 217976 under 21 C.F.R. § 314.95(c)(6) as to the '844 Patent. The Hikma Notice

Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '844 Patent.

54. Hikma has actual knowledge of the '844 Patent, as shown by the Hikma Notice Letter.

55. On information and belief, Hikma's proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least claims 1-11, 13-16, and 19-30 of the '844 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

56. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Hikma has infringed at least claims 1-11, 13-16, and 19-30 of the '844 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 217976 seeking approval to manufacture, use, import, offer to sell or sell Hikma's proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '844 Patent. Upon information and belief, the products described in ANDA No. 217976 would infringe, either literally or under the doctrine of equivalents, at least claims 1-11, 13-16, and 19-30 of the '844 Patent under 35 U.S.C. § 271(e)(2)(A).

57. On information and belief, physicians and/or patients will directly infringe at least claims 1-11, 13-16, and 19-30 of the '844 Patent by use of Hikma's proposed generic versions of Janssen's Spravato® brand products upon approval.

58. On information and belief, upon approval, Hikma will take active steps to encourage the use of Hikma's proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Hikma's generic products will be used by physicians and/or patients in a manner that infringes at least claims 1-11, 13-16, and

19-30 of the '844 Patent for the pecuniary benefit of Hikma. Pursuant to 21 C.F.R. § 314.94, Hikma is required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets the elements of at least claims 1-11, 13-16, and 19-30 of the '844 Patent. Hikma specifically intends its generic esketamine nasal spray products to be used according to its proposed labeling in a manner that infringes at least claims 1-11, 13-16, and 19-30 of the '844 Patent. Upon information and belief, Hikma will thus induce the infringement of at least claims 1-11, 13-16, and 19-30 of the '844 Patent.

59. On information and belief, if the FDA approves ANDA No. 217976, WWCI, together with its affiliates and/or agents Hikma UK and Hikma USA, will be involved in the manufacture and/or sale of the product that is the subject of ANDA No. 217976 that infringes at least claims 1-11, 13-16, and 19-30 of the '844 Patent.

60. On information and belief, if the FDA approves ANDA No. 217976, Hikma will sell or offer to sell its proposed generic products specifically labeled for use in practicing at least claims 1-11, 13-16, and 19-30 of the '844 Patent, wherein Hikma's proposed generic products are a material part of the claimed invention, wherein Hikma knows that physicians will prescribe and patients will use Hikma's proposed generic products in accordance with the instructions and/or label provided by Hikma in practicing at least claims 1-11, 13-16, and 19-30 of the '844 Patent, and wherein Hikma's generic esketamine nasal spray products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Hikma's proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes at least claims 1-11, 13-16, and 19-30 of the '844 Patent. On information and belief, Hikma will thus contribute to the infringement of the '844 Patent.

61. On information and belief, the actions described in this Complaint relating to Hikma's ANDA No. 217976 were done by and for the benefit of Hikma.

62. Plaintiffs will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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

COUNT II:
INFRINGEMENT OF THE '134 PATENT BY
HIKMA'S ANDA FOR SPRAVATO®

64. Plaintiffs re-allege paragraphs 1-46 as if fully set forth herein.

65. An actual controversy exists between the parties as to whether Hikma's proposed sale of its generic esketamine nasal spray products infringes claims 1-30 of the '134 Patent.

66. By letter dated April 18, 2023, Hikma notified Plaintiffs that it had submitted ANDA No. 217976 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Hikma Notice Letter stated that ANDA No. 217976 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of Delaware, of generic esketamine nasal spray products prior to the expiration of certain Orange Book listed patents. ANDA No. 217976 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '134 Patent.

67. ANDA No. 217976 includes a Paragraph IV Certification that the claims of the '134 Patent are invalid, unenforceable, and/or not infringed.

68. Upon information and belief, the Hikma Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

69. The Hikma Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Hikma's Notice Letter.

70. The Hikma Notice Letter purports to include a Notice of Certification for ANDA No. 217976 under 21 C.F.R. § 314.95(c)(6) as to the '134 Patent. The Hikma Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '134 Patent.

71. Hikma has actual knowledge of the '134 Patent, as shown by the Hikma Notice Letter.

72. On information and belief, Hikma's proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, claims 1-30 of the '134 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

73. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Hikma has infringed claims 1-30 of the '134 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 217976 seeking approval to manufacture, use, import, offer to sell or sell Hikma's proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '134 Patent. Upon information and belief, the products described in ANDA No. 217976 would infringe, either literally or under the doctrine of equivalents, claims 1-30 of the '134 Patent under 35 U.S.C. § 271(e)(2)(A).

74. On information and belief, physicians and/or patients will directly infringe claims 1-30 of the '134 Patent by use of Hikma's proposed generic versions of Janssen's Spravato® brand products upon approval.

75. On information and belief, upon approval, Hikma will take active steps to encourage the use of Hikma's proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Hikma's generic products will be used by physicians and/or patients in a manner that infringes claims 1-30 of the '134 Patent, for the pecuniary benefit of Hikma. Pursuant to 21 C.F.R. § 314.94, Hikma is required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets claims 1-30 of the '134 Patent. Hikma specifically intends its generic esketamine nasal spray products to be used according to its proposed labeling in a manner that infringes claims 1-30 of the '134 Patent. Upon information and belief, Hikma will thus induce the infringement of claims 1-30 of the '134 Patent.

76. On information and belief, if the FDA approves ANDA No. 217976, WWCI, together with its affiliates and/or agents Hikma UK and Hikma USA, will be involved in the manufacture and/or sale of the product that is the subject of ANDA No. 217976 that infringes claims 1-30 of the '134 Patent.

77. On information and belief, if the FDA approves ANDA No. 217976, Hikma will sell or offer to sell its proposed generic products specifically labeled for use in practicing claims 1-30 of the '134 Patent, wherein Hikma's proposed generic products are a material part of the claimed invention, wherein Hikma knows that physicians will prescribe and patients will use Hikma's proposed generic products in accordance with the instructions and/or label provided by Hikma in practicing claims 1-30 of the '134 Patent, and wherein Hikma's

generic esketamine nasal spray products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Hikma's proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes claims 1-30 of the '134 Patent. On information and belief, Hikma will thus contribute to the infringement of the '134 Patent.

78. On information and belief, the actions described in this Complaint relating to Hikma's ANDA No. 217976 were done by and for the benefit of Hikma.

79. Plaintiffs will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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

COUNT III:
INFRINGEMENT OF THE '500 PATENT BY
HIKMA'S ANDA FOR SPRAVATO®

81. Plaintiffs re-allege paragraphs 1-46 as if fully set forth herein.

82. An actual controversy exists between the parties as to whether Hikma's proposed sale of its generic esketamine nasal spray products infringes claims 1-22 of the '500 Patent.

83. By letter dated April 18, 2023, Hikma notified Plaintiffs that it had submitted ANDA No. 217976 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Hikma Notice Letter stated that ANDA No. 217976 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of Delaware, of generic esketamine nasal spray products prior to the expiration of certain Orange Book listed patents.

ANDA No. 217976 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '500 Patent.

84. ANDA No. 217976 includes a Paragraph IV Certification that the claims of the '500 Patent are invalid, unenforceable, and/or not infringed.

85. Upon information and belief, the Hikma Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

86. The Hikma Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Hikma's Notice Letter.

87. The Hikma Notice Letter purports to include a Notice of Certification for ANDA No. 217976 under 21 C.F.R. § 314.95(c)(6) as to the '500 Patent. The Hikma Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '500 Patent.

88. Hikma has actual knowledge of the '500 Patent, as shown by the Hikma Notice Letter.

89. On information and belief, Hikma's proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, claims 1-22 of the '500 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

90. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Hikma has infringed claims 1-22 of the '500 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 217976 seeking approval to manufacture, use, import, offer to sell or sell Hikma's

proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '500 Patent. Upon information and belief, the products described in ANDA No. 217976 would infringe, either literally or under the doctrine of equivalents, claims 1-22 of the '500 Patent under 35 U.S.C. § 271(e)(2)(A).

91. On information and belief, physicians and/or patients will directly infringe claims 1-22 of the '500 Patent by use of Hikma's proposed generic versions of Janssen's Spravato® brand products upon approval.

92. On information and belief, upon approval, Hikma will take active steps to encourage the use of Hikma's proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Hikma's generic products will be used by physicians and/or patients in a manner that infringes claims 1-22 of the '500 Patent for the pecuniary benefit of Hikma. Pursuant to 21 C.F.R. § 314.94, Hikma is required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets the elements of claims 1-22 of the '500 Patent. Hikma specifically intends its generic esketamine nasal spray products to be used according to its proposed labeling in a manner that infringes claims 1-22 of the '500 Patent. Upon information and belief, Hikma will thus induce the infringement of claims 1-22 of the '500 Patent.

93. On information and belief, if the FDA approves ANDA No. 217976, WWCI, together with its affiliates and/or agents Hikma UK and Hikma USA, will be involved in the manufacture and/or sale of the product that is the subject of ANDA No. 217976 that infringes claims 1-22 of the '500 Patent.

94. On information and belief, if the FDA approves ANDA No. 217976, Hikma will sell or offer to sell its proposed generic products specifically labeled for use in

practicing claims 1-22 of the '500 Patent, wherein Hikma's proposed generic products are a material part of the claimed invention, wherein Hikma knows that physicians will prescribe and patients will use Hikma's proposed generic products in accordance with the instructions and/or label provided by Hikma in practicing claims 1-22 of the '500 Patent, and wherein Hikma's generic esketamine nasal spray products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Hikma's proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes claims 1-22 of the '500 Patent. On information and belief, Hikma will thus contribute to the infringement of the '500 Patent.

95. On information and belief, the actions described in this Complaint relating to Hikma's ANDA No. 217976 were done by and for the benefit of Hikma.

96. Plaintiffs will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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

COUNT IV:
INFRINGEMENT OF THE '260 PATENT BY
HIKMA'S ANDA FOR SPRAVATO®

98. Plaintiffs re-allege paragraphs 1-46 as if fully set forth herein.

99. An actual controversy exists between the parties as to whether Hikma's proposed sale of its generic esketamine nasal spray products infringes at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent.

100. By letter dated April 18, 2023, Hikma notified Plaintiffs that it had submitted ANDA No. 217976 to the FDA under § 505(j) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355(j)). The Hikma Notice Letter stated that ANDA No. 217976 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of Delaware, of generic esketamine nasal spray products prior to the expiration of certain Orange Book listed patents. ANDA No. 217976 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '260 Patent.

101. ANDA No. 217976 includes a Paragraph IV Certification that the claims of the '260 Patent are invalid, unenforceable, and/or not infringed.

102. Upon information and belief, the Hikma Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

103. The Hikma Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Hikma's Notice Letter.

104. The Hikma Notice Letter purports to include a Notice of Certification for ANDA No. 217976 under 21 C.F.R. § 314.95(c)(6) as to the '260 Patent. The Hikma Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '260 Patent.

105. Hikma has actual knowledge of the '260 Patent, as shown by the Hikma Notice Letter.

106. On information and belief, Hikma's proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the

doctrine of equivalents, at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

107. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Hikma has infringed at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 217976 seeking approval to manufacture, use, import, offer to sell or sell Hikma's proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '260 Patent. Upon information and belief, the products described in ANDA No. 217976 would infringe, either literally or under the doctrine of equivalents, at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent under 35 U.S.C. § 271(e)(2)(A).

108. On information and belief, physicians and/or patients will directly infringe at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent by use of Hikma's proposed generic versions of Janssen's Spravato® brand products upon approval.

109. On information and belief, upon approval, Hikma will take active steps to encourage the use of Hikma's proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Hikma's generic products will be used by physicians and/or patients in a manner that infringes at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent for the pecuniary benefit of Hikma. Pursuant to 21 C.F.R. § 314.94, Hikma is required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets the elements of at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent. Hikma specifically intends its generic esketamine nasal spray products to be used according to its proposed labeling in a manner that infringes at least claims 1-3, 6-19, 22,

25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent. Upon information and belief, Hikma will thus induce the infringement of at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent.

110. On information and belief, if the FDA approves ANDA No. 217976, WWCI, together with its affiliates and/or agents Hikma UK and Hikma USA, will be involved in the manufacture and/or sale of the product that is the subject of ANDA No. 217976 that infringes at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent.

111. On information and belief, if the FDA approves ANDA No. 217976, Hikma will sell or offer to sell its proposed generic products specifically labeled for use in practicing at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent, wherein Hikma's proposed generic products are a material part of the claimed invention, wherein Hikma knows that physicians will prescribe and patients will use Hikma's proposed generic products in accordance with the instructions and/or label provided by Hikma in practicing at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent, and wherein Hikma's generic esketamine nasal spray products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Hikma's proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes at least claims 1-3, 6-19, 22, 25-26, 31-43, 46-58, 61, 64-65, and 70-75 of the '260 Patent. On information and belief, Hikma will thus contribute to the infringement of the '260 Patent.

112. On information and belief, the actions described in this Complaint relating to Hikma's ANDA No. 217976 were done by and for the benefit of Hikma.

113. Plaintiffs will be irreparably harmed by Hikma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Hikma has infringed at least one claim of the '844, '134, '500, and '260 Patents through Hikma's submission of ANDA No. 217976 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Hikma's proposed generic versions of JPI's Spravato® brand products identified in this Complaint in the United States before the latest of the expiration dates of the '844, '134, '500, and '260 Patents;

B. Enter judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Hikma's commercial manufacture use, offer for sale, or sale within the United States, or importation into the United States of Hikma's proposed generic versions of JPI's Spravato® brand products identified in this Complaint, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents, constitutes infringement of one or more claims of the '844, '134, '500, and '260 Patents under 35 U.S.C. § 271(a), (b), or (c);

C. Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 217976 be a date that is not earlier than the latest of the expiration dates of the '844, '134, '500, and '260 Patents, or such later date as the Court may determine;

D. Order that Hikma, its affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Hikma, are preliminarily and

permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling Hikma's proposed generic versions of JPI's Spravato® brand products identified in this Complaint, and any other product that infringes or contributes to the infringement of the '844, '134, '500, and '260 Patents, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents, or such later date as the Court may determine;

E. If Hikma engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic versions of JPI's Spravato® brand products identified in this Complaint prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents, a Judgment awarding damages to Plaintiffs resulting from such infringement with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorneys' fees; and

G. Award such further and other relief that the Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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