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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HIKMA PHARMACEUTICALS USA INC.,	:	Honorable
Plaintiff,	:	Civil Action No.
v.	:	**COMPLAINT FOR PATENT INFRINGEMENT**
INFORLIFE SA and WG CRITICAL CARE, LLC,	:	
Defendants.	:	

Plaintiff Hikma Pharmaceuticals USA Inc. ("Hikma" or "Plaintiff"), by its undersigned attorneys, brings this action for patent infringement against Defendants InfoRLife SA ("InfoRLife") and WG Critical Care, LLC ("WG Critical Care") (collectively, "Defendants"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 11,471,400 ("the '400 patent") and 12,257,342 ("the '342 patent") (collectively, the "Asserted Patents"), under the patent laws of the United States, 35 U.S.C. §§ 101 et seq., including § 271, and an action for declaratory judgment of infringement pursuant to the Declaratory Judgment Act, 28 U.S.C.

§§ 2201, et seq.

2. This action arises out of Defendants' submission of 505(b)(2) New Drug Application ("NDA") No. 215783 to the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell Phenylephrine Hydrochloride in Sodium Chloride for Injection, 0.4 mg/mL (the "InfoRLife 505(b)(2) NDA Product") prior to the expiration of the '400 and '342 patents.

3. True and correct copies of the '400 and '342 patents are attached hereto as **Exhibits A** and **B**, respectively.

THE PARTIES

4. Hikma is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

5. Hikma is the holder of NDA No. 203826 for phenylephrine hydrochloride for intravenous administration, which has been approved by the FDA.

6. Hikma currently markets IMMPHENTIV® (phenylephrine hydrochloride) injection, which was approved by the FDA in 2023.

7. Upon information and belief, InfoRLife is a Switzerland corporation, with its principal place of business at Casai, 7748 Campascio, Switzerland.

8. Upon information and belief, InfoRLife has a place of business in care of Interchem Corporation, at 120 Route 17 North, Suite 120, Paramus, New Jersey 07652.

9. Upon information and belief, Defendant WG Critical Care is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 120 Route 17 North, Paramus, New Jersey 07652.

10. Upon information and belief, Defendants acted collaboratively in the preparation and submission of 505(b)(2) NDA No. 215783.

JURISDICTION AND VENUE

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

12. This Court has personal jurisdiction over Defendants because, among other things, Defendants have committed, aided, abetted, contributed to, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and intend to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. §§ 271(a), (b), and/or (c), including in New Jersey. These acts have led and will lead to foreseeable harm and injury to Hikma. For example, on information and belief, if 505(b)(2) NDA No. 215783 is approved, Defendants intend to make, use, import, sell, and/or offer for sale the InfoRLife 505(b)(2) NDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

13. This Court has personal jurisdiction over Defendants because Defendants' contacts within this judicial district are continuous and systematic. On information and belief, InfoRLife and WG Critical Care, individually and collectively acting in concert and cooperatively, develop, manufacture, seek approval for, and sell certain FDA-approved pharmaceutical drugs that are regularly marketed, distributed, and sold in New Jersey and throughout the United States.

14. This Court also has personal jurisdiction over Defendants because Defendants have previously availed themselves of this forum by affirmatively filing counterclaims in other actions filed in this forum, including *Nevakar Injectables Inc. v. InfoRLife SA et al.*, No. 2-22-cv-06886 (D.N.J.).

15. This Court has personal jurisdiction over InfoRLife because, among other things,

InfoRLife has a place of business in New Jersey and manufactures and distributes drug products for sale throughout the United States, including in New Jersey.

16. This Court has personal jurisdiction over WG Critical Care because it is a limited liability company organized and existing under the laws of the State of New Jersey, has a principal place of business in New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey, and distributes drug products for sale throughout the United States, including in New Jersey.

17. On information and belief, Defendants directly or indirectly manufacture, market, and sell drug products throughout the United States and in this judicial district.

18. On information and belief, Defendants purposefully have conducted and continue to conduct business in this judicial district, and this judicial district is a destination of Defendants' pharmaceutical products.

19. On information and belief, InfoRLife and WG Critical Care work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in this judicial district.

20. This Court also has personal jurisdiction over Defendants because this suit arises out of and relates to their activities that are, and will be, directed to the State of New Jersey. On information and belief, Defendants have, in concert with one another, sought approval from the FDA for the InfoRLife 505(b)(2) NDA Product, and have commenced and/or will imminently commence manufacturing, marketing, and sale of the InfoRLife 505(b)(2) NDA Product that is the subject of the infringement claims in this action in the State of New Jersey and throughout the United States, including in this judicial district.

21. On information and belief, Defendants do substantial business in New Jersey,

derive substantial revenue from New Jersey, and engage in other persistent courses of conduct in New Jersey. These continuous and systematic contacts, including, but not limited to those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Defendants.

22. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

23. Venue is proper in this judicial district as to InfoRLife pursuant to 28 U.S.C. § 1391(c)(3) as it is a foreign corporation and is subject to personal jurisdiction in this judicial district.

24. Venue is proper in this judicial district as to WG Critical Care pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, upon information and belief, WG Critical Care is a limited liability company organized and existing under the laws of the State of New Jersey and is subject to personal jurisdiction in this judicial district.

BACKGROUND

25. U.S. Patent No. 11,471,400 (**Exhibit A**), titled "Phenylephrine hydrochloride ready-to-use solution," was duly and legally issued by the U.S. Patent and Trademark Office on October 18, 2022. The '400 Patent will expire on August 5, 2036. The claims of the '400 Patent are valid, enforceable, and not expired. All rights and interests in the '400 Patent are owned by and assigned to Hikma.

26. U.S. Patent No. 12,257,342 (**Exhibit B**), titled "Phenylephrine hydrochloride ready-to-use solution," was duly and legally issued by the U.S. Patent and Trademark Office on March 25, 2025. The '342 Patent will expire on August 5, 2036. The claims of the '342 Patent are valid, enforceable, and not expired. All rights and interests in the '342 Patent are owned by and assigned to Hikma.

27. IMMPHENTIV® (phenylephrine hydrochloride) is an alpha-1 adrenergic receptor agonist indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. Hikma sells IMMPHENTIV® in the United States pursuant to New Drug Application No. 203826, which was approved by the FDA in 2023.

28. Prior to IMMPHENTIV®, phenylephrine hydrochloride in injection form had been approved for marketing in the United States as a 10 mg/mL concentrated solution. At this concentration, phenylephrine hydrochloride must be diluted before administration. The inventive formulations described by the Asserted Patents provide a ready-to-use, injectable formulation of phenylephrine hydrochloride, at concentrations that can be used without further dilution, and that remain stable and active after prolonged storage. These ready-to-use formulations avoid the drawbacks associated with prior art phenylephrine solutions which require multiple dilutions prior to use, thereby increasing the overall cost and risks of contamination, over dosage, and calculation errors.

29. The Asserted Patents have been listed in connection with IMMPHENTIV® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book."

30. By letter dated June 9, 2025, and received via Federal Express on June 10, 2025 (the "Notice Letter"), Defendants notified Hikma that Defendants submitted 505(b)(2) NDA No. 215783 to the FDA for Phenylephrine Hydrochloride in Sodium Chloride for Injection, 0.4 mg/mL.

31. By submitting 505(b)(2) NDA No. 215783, Defendants have represented to the FDA that the InfoRLife 505(b)(2) NDA Product has the same active ingredient as

IMMPHENTIV®, has the same dosage forms, route of administration, and indications as IMMPHENTIV®, and is bioequivalent to IMMPHENTIV®.

32. In Defendants' Notice Letter, Defendants stated that 505(b)(2) NDA No. 215783 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the Asserted Patents and alleged that the Asserted Patents are "invalid, unenforceable and/or will not be infringed" by the InfoRLife 505(b)(2) NDA Product. The Notice Letter also informed Hikma that Defendants seek approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the InfoRLife 505(b)(2) NDA Product before the Asserted Patents expire.

33. Upon information and belief, Defendants have had knowledge of the Asserted Patents at least as of the time Defendants submitted the Paragraph IV certification in 505(b)(2) NDA No. 215783.

34. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the InfoRLife 505(b)(2) NDA Product immediately and imminently upon approval of 505(b)(2) NDA No. 215783.

35. Before the expiration of forty-five days from the date of Hikma's receipt of the Notice Letter, counsel for Hima requested samples from InfoRLife of the InfoRLife 505(b)(2) NDA Product. Counsel for InfoRLife refused to produce samples of the InfoRLife 505(b)(2) NDA Product to Hikma.

36. This action is being commenced before the expiration of forty-five days from the date of Hikma's receipt of the Notice Letter.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,213,400

37. Hikma incorporates each of the preceding paragraphs 1–36 as if fully set forth

herein.

38. Defendants' submission of 505(b)(2) NDA No. 215783 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the InfoRLife 505(b)(2) NDA Product before the expiration of the '400 Patent constituted an act of infringement of one or more claims of the '400 Patent under 35 U.S.C. § 271(e)(2)(A).

39. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the InfoRLife 505(b)(2) NDA Product prior to expiration of the '400 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '400 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

40. Upon FDA approval of 505(b)(2) NDA No. 215783, Defendants will infringe the '400 Patent by making, using, offering to sell, selling, and/or importing the InfoRLife 505(b)(2) NDA Product, and/or by actively inducing and contributing to infringement of the '400 Patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Defendants have notified Hikma of the submission of their 505(b)(2) NDA No. 215783 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the InfoRLife 505(b)(2) NDA Product before the expiration of the '400 Patent.

41. Counsel for Hikma obtained and reviewed portions of 505(b)(2) NDA No. 215783 produced by Defendants pursuant to an agreed Offer of Confidential Access. Materials provided to counsel for Hikma by Defendants support the conclusion that the InfoRLife 505(b)(2) NDA Product infringes the '400 Patent. At the very least, materials provided to counsel for Hikma by Defendants pursuant to an agreed Offer of Confidential Access are insufficient to demonstrate that the InfoRLife 505(b)(2) NDA Product does not infringe the '400 Patent.

42. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the ’400 Patent.

43. Pursuant to 28 U.S.C. § 2201, Hikma is entitled to a declaratory judgment that Defendants’ making, using, offering to sell, selling, and/or importing the InfoRLife 505(b)(2) NDA Product, including inducement thereof or contribution thereto, will infringe the ’400 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

44. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 215783 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the ’400 Patent.

45. Unless Defendants are enjoined from directly or indirectly infringing the ’400 Patent, Hikma will suffer irreparable injury. Hikma has no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 12,257,342

46. Hikma incorporates each of the preceding paragraphs 1–45 as if fully set forth herein.

47. Defendants’ submission of 505(b)(2) NDA No. 215783 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the InfoRLife 505(b)(2) NDA Product before the expiration of the ’342 Patent constituted an act of infringement of one or more claims of the ’342 Patent under 35 U.S.C. § 271(e)(2)(A).

48. Defendants’ commercial manufacture, use, offer for sale, sale, and/or importation of the InfoRLife 505(b)(2) NDA Product prior to expiration of the ’342 Patent, and Defendants’ inducement of and/or contribution to such conduct, would further infringe the ’342 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

49. Upon FDA approval of 505(b)(2) NDA No. 215783, Defendants will infringe the

'342 Patent by making, using, offering to sell, selling, and/or importing the InfoRLife 505(b)(2) NDA Product, and/or by actively inducing and contributing to infringement of the '342 Patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Defendants have notified Hikma of the submission of their 505(b)(2) NDA No. 215783 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the InfoRLife 505(b)(2) NDA Product before the expiration of the '342 Patent.

50. Counsel for Hikma obtained and reviewed portions of 505(b)(2) NDA No. 215783 produced by Defendants pursuant to an agreed Offer of Confidential Access. Materials provided to counsel for Hikma by Defendants support the conclusion that the InfoRLife 505(b)(2) NDA Product infringes the '342 Patent. At the very least, materials provided to counsel for Hikma by Defendants pursuant to an agreed Offer of Confidential Access are insufficient to demonstrate that the InfoRLife 505(b)(2) NDA Product does not infringe the '342 Patent.

51. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '342 Patent.

52. Pursuant to 28 U.S.C. § 2201, Hikma is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the InfoRLife 505(b)(2) NDA Product, including inducement thereof or contribution thereto, will infringe the '342 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

53. Upon information and belief, Defendants acted, and upon FDA approval of 505(b)(2) NDA No. 215783 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '342 Patent.

54. Unless Defendants are enjoined from directly or indirectly infringing the '342

Patent, Hikma will suffer irreparable injury. Hikma has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Hikma asks that this Court grant the following relief:

A. A judgment that the claims of the Asserted Patents are not invalid, are not unenforceable, and were infringed by Defendants' submission of 505(b)(2) NDA No. 215783 under 35 U.S.C. § 271(e)(2)(A), and that Defendants' manufacture, use, offer to sell, sale, or importation of the InfoRLife 505(b)(2) NDA Product, including inducement thereof or contribution thereto, prior to the expiration of the Asserted Patents, will infringe the Asserted Patents under 35 U.S.C. §§ 271(a), (b), and/or (c);

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of 505(b)(2) NDA No. 215783 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Hikma is or becomes entitled;

C. A declaratory judgment that Defendants' manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the InfoRLife 505(b)(2) NDA Product prior to the expiration of the Asserted Patents, would infringe the Asserted Patents under 35 U.S.C. §§ 271(a), (b), and/or (c);

D. An Order permanently enjoining Defendants, and their affiliates, subsidiaries, and/or each of their officers, agents, servants, and employees and those acting in privity or concert with Defendants, from making, using, offering to sell, selling, or importing the InfoRLife 505(b)(2) NDA Product until after the Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Hikma is or becomes entitled;

E. Damages or other monetary relief, including costs, fees, prejudgment interest,

and/or post-judgment interest, to Hikma if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of the InfoRLife 505(b)(2) NDA Product prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Hikma is or becomes entitled, as well as any damages or other monetary relief on the basis that this is an exceptional case; and

F. Such further and other relief as this Court deems proper and just.

MIDLIGE RICHTER LLC
Attorneys for Plaintiff, Hikma Pharmaceuticals USA, Inc.

By: s/ James S. Richter
James S. Richter

Dated: July 23, 2025

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in the above-captioned action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ James S. Richter
James S. Richter

Dated: July 23, 2025