IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC., Plaintiffs, v. UNICHEM INC. (a/k/a UNICHEM LABORATORIES, LTD.) and UNICHEM PHARMACEUTICALS (USA), INC. Defendants.	Civil Action No.: _____

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer AG (Bayer AG and BIP are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Unichem, Inc. (a/k/a Unichem Laboratories, Ltd.), of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' XARELTO® products prior to the expiration of, *inter alia*, U.S. Patent Nos. 7,157,456 and 9,539,218.

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Unichem

5. Upon information and belief, Defendant Unichem, Inc., which according to counsel for Unichem, Inc. is also known as Unichem Laboratories, Ltd. ("Unichem India"), is a corporation organized under the laws of India, having a principal place of business and corporate office in India, with a registered office at Unichem Bhavan, Prabhat Estate off S.V. Road, Jogeshwari (West) Mumbai 400102, Maharashtra, India, and a "corporate office" at Unichem Laboratories Centre of Excellence, Plot Nos. 12 to 14, Pilerne Industrial Estate, Pilerne, Bardez, Goa 403511.

6. Upon information and belief, Defendant Unichem Pharmaceuticals (USA), Inc. ("Unichem USA") is a corporation organized under the laws of the State of New Jersey and has its principal place of business at 777 Terrace Avenue, Suite 102, Hasbrouck Heights, New Jersey 07604.

7. Upon information and belief, Unichem USA is a wholly-owned subsidiary of Unichem India, and is controlled and dominated by Unichem India.

8. Upon information and belief, Unichem India is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, upon information and belief, Unichem India, acting in concert with Unichem USA, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as part of these ANDAs, Unichem India, acting in concert with Unichem USA, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. Upon information and belief, Unichem India and Unichem USA acted in concert to prepare and submit ANDA No. 214342 for Unichem India's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Unichem's ANDA Products").

10. Upon information and belief, Unichem India and Unichem USA are agents of one another, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Unichem's ANDA Products at issue.

11. Upon information and belief, following any FDA approval of ANDA No. 214342, Unichem India and Unichem USA will act in concert to market, distribute, offer for sale, and sell Unichem's ANDA Products throughout the United States and within New Jersey. These entities—Unichem India and Unichem USA—are hereafter collectively referred to as "Unichem."

12. Upon information and belief, following any FDA approval of ANDA No. 214342, Unichem knows and intends that Unichem's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States, including in New Jersey.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over each of Unichem India and Unichem USA because, among other things, upon information and belief: (1) Unichem India, acting in concert with Unichem USA, has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Unichem's ANDA Products in the United States, including in New Jersey; and (2) Unichem India and Unichem USA, acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Unichem's ANDA Products in the United States, including in New Jersey, upon approval of ANDA No. 214342, and will derive substantial revenue from the use or consumption of Unichem's ANDA Products in the State of New Jersey. Upon information and belief, if ANDA No. 214342 is approved, the generic Unichem products charged with infringing the '456 and '218 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in New

Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

16. If Unichem India's connections with New Jersey are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Unichem India is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Unichem in New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2). Relatedly, Unichem India in the Unichem Notice Letter (defined below) provided an agent for service "[p]ursuant to 21 C.F.R. 314.95(c)(9)," which applies "[i]f the applicant does not reside or have a place of business in the United States."

17. This court also has personal jurisdiction over Unichem USA because, upon information and belief, Unichem USA is incorporated in New Jersey, has its principal place of business in New Jersey, and has a registered agent for service of process in this judicial district.

18. Upon information and belief, Unichem India and Unichem USA have consented to jurisdiction in New Jersey in a prior case arising out of the filing of an ANDA.

VENUE

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

20. Venue is proper in this district for Unichem India pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Unichem India is a private limited company organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

21. Venue is proper in this district for Unichem USA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Unichem USA is a corporation organized and existing

under the laws of the State of New Jersey and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

22. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT); (iii) for the treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; (v) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; and (vi) in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). XARELTO® is available as tablets in 2.5 mg, 10 mg, 15 mg, and 20 mg dosage strengths.

23. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

The ’456 Patent

24. United States Patent No. 7,157,456 (“the ’456 patent”), entitled “Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation,” was duly and legally issued on January 2, 2007. The ’456 patent is attached as Exhibit A.

25. As set forth in greater detail in the ’456 patent, the claims of the ’456 patent, incorporated by reference herein, cover the compound rivaroxaban, pharmaceutical compositions containing rivaroxaban, methods of using rivaroxaban, and processes for preparing rivaroxaban.

26. BIP is the assignee of the ’456 patent.

27. Bayer AG is an exclusive licensee under the ’456 patent.

28. Janssen is an exclusive sublicensee under the ’456 patent.

29. Pursuant to 21 U.S.C. § 355, the ’456 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with XARELTO®.

The ’218 Patent

30. U.S. Patent No. 9,539,218 (“the ’218 patent”), entitled “Prevention and Treatment of Thromboembolic Disorders,” was duly and legally issued on January 10, 2017. The ’218 patent is attached as Exhibit B.

31. As set forth in greater detail in the ’218 patent, the claims of the ’218 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, claim 1 recites, “A method of treating a thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke.”

32. BIP is the assignee of the ’218 patent.

33. Bayer AG is an exclusive licensee under the ’218 patent.

34. Janssen is an exclusive sublicensee under the ’218 patent.

35. Pursuant to 21 U.S.C. § 355, the ’218 patent is listed in the Orange Book in connection with XARELTO® tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

Infringement by Unichem

36. By letter dated March 17, 2020, but not sent until March 23, 2020, at the earliest, (the "Unichem Notice Letter"), Unichem India notified BIP and Janssen, among others, that Unichem India had submitted to the FDA ANDA No. 214342 for Unichem's ANDA Products. These products are generic versions of XARELTO®.

37. In the Unichem Notice Letter, Unichem stated that Unichem's ANDA Products contain rivaroxaban.

38. Upon information and belief, Unichem India is the holder of DMF 32374 for rivaroxaban.

39. In the Unichem Notice Letter, Unichem stated that the dosage form of Unichem's ANDA Products is tablets. Upon information and belief, the dosage form of Unichem's ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

40. Upon information and belief, the proposed labeling for Unichem's ANDA Products directs the use of Unichem's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT); (iii) for the treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; and (v) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. Upon information and belief, the proposed labeling for Unichem's ANDA Products further directs the use of Unichem's ANDA Products in a manner that

satisfies the "no more than once daily for at least five consecutive days" requirement of claim 1 of the '218 patent.

41. Upon information and belief, the manufacture, use (including in accordance with and as directed by Unichem's proposed labeling for Unichem's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Unichem's ANDA Products will infringe at least claim 16 of the '456 patent and at least claim 1 of the '218 patent.

42. In the Unichem Notice Letter, Unichem indicated that, in connection with its ANDA No. 214342, Unichem had filed Paragraph IV Certifications with respect to each of the '456 and '218 patents.

43. The purpose of ANDA No. 214342 was to obtain approval under the Food Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Unichem's ANDA Products with their proposed labeling prior to the expiration of the '456 and '218 patents.

44. Unichem intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Unichem's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 214342, *i.e.*, prior to the expiration of the '456 and '218 patents.

45. Unichem has knowledge of the claims of the '456 and '218 patents. Notwithstanding this knowledge, Unichem has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Unichem's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 214342. Upon information and belief, by such activities, Unichem specifically intends infringement of the '456 and '218 patents.

46. Upon information and belief, Unichem plans and intends to, and will, actively induce infringement of the ’456 and ’218 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

47. Upon information and belief, Unichem knows that Unichem’s ANDA Products are especially made or adapted for use in infringing the ’456 and ’218 patents, and that Unichem’s ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Unichem plans and intends to, and will, contribute to infringement of the ’456 and ’218 patents immediately and imminently upon approval of ANDA No. 214342.

48. The foregoing actions by Unichem constitute and/or will constitute infringement of the ’456 and ’218 patents, active inducement of infringement of the ’456 and ’218 patents, and/or contribution to the infringement by others of the ’456 and ’218 patents.

49. An actual case or controversy exists between Plaintiffs and Unichem with respect to infringement of each of the ’456 and ’218 patents.

50. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Unichem Notice Letter (not earlier than March 24, 2020).

COUNT I
(Infringement of the ’456 Patent)

51. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

52. Unichem’s submission of ANDA No. 214342 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Unichem’s ANDA Products was an act of infringement of the ’456 patent under 35 U.S.C. § 271(e)(2).

53. Upon information and belief, Unichem has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Unichem's ANDA Products with their proposed labeling prior to the expiration of the '456 patent.

54. Unichem intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Unichem's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 214342, *i.e.*, prior to the expiration of the '456 patent.

55. The foregoing actions by Unichem constitute and/or will constitute infringement of the '456 patent, active inducement of infringement of the '456 patent, and/or contribution to the infringement by others of the '456 patent.

56. Unless Unichem is enjoined from infringing the '456 patent, actively inducing infringement of the '456 patent, and contributing to the infringement by others of the '456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '218 Patent)

57. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

58. Unichem's submission of ANDA No. 214342 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Unichem's ANDA Products was an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2).

59. Upon information and belief, Unichem has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or

import Unichem's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

60. Unichem intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Unichem's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 214342, *i.e.*, prior to the expiration of the '218 patent.

61. The foregoing actions by Unichem constitute and/or will constitute infringement of the '218 patent, active inducement of infringement of the '218 patent, and/or contribution to the infringement by others of the '218 patent.

62. Unless Unichem is enjoined from infringing the '218 patent, actively inducing infringement of the '218 patent, and contributing to the infringement by others of the '218 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Unichem has infringed the '456 patent;

(b) A judgment that Unichem has infringed the '218 patent;

(c) A judgment ordering that the effective date of any FDA approval for Unichem to make, use, offer for sale, sell, market, distribute, or import Unichem's ANDA Products, or any product or compound which infringes or the use of which infringes the '456 patent, be no earlier than the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment ordering that the effective date of any FDA approval for Unichem to make, use, offer for sale, sell, market, distribute, or import Unichem's ANDA

Products, or any product or compound the use of which infringes the ’218 patent, be no earlier than the expiration date of the ’218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Unichem, and all persons acting in concert with Unichem, from making, using, selling, offering for sale, marketing, distributing, or importing Unichem’s ANDA Products, or any product or compound that infringes or the use of which infringes the ’456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A preliminary and permanent injunction enjoining Unichem, and all persons acting in concert with Unichem, from making, using, selling, offering for sale, marketing, distributing, or importing Unichem’s ANDA Products, or any product or compound the use of which infringes the ’218 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A declaration that this is an exceptional case and an award of attorneys’ fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(h) An award of Plaintiffs’ costs and expenses in this action; and

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

Dated: May 1, 2020

s/ Keith J. Miller

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned, attorney of record for Plaintiffs, hereby certifies that to the best of my knowledge and based upon the information available to me, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding, except for *Bayer Intellectual Property GmbH, et al. v. Taro Pharmaceuticals, et al.*, 1:17-cv-00462 (D. Del.) and *Bayer Intellectual Property GmbH, et al. v. InvaGen Pharmaceuticals Inc.*, 1:17-cv-00812 (D. Del.).

Dated: May 1, 2020

By: *s/ Keith J. Miller*

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