IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMRING PHARMACEUTICALS INC.	:	
Plaintiff,	:	Civil Action No:
v.	:	**JURY TRIAL DEMANDED**
RUBICON RESEARCH PRIVATE LTD.	:	
Defendant.	:	

COMPLAINT

Plaintiff AMRING PHARMACEUTICALS INC. ("AMRING" or "Plaintiff"), by and through its undersigned counsel, for its Complaint against Defendant RUBICON RESEARCH PRIVATE LTD., ("RUBICON" or "Defendant"), does hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 7,947,739; 8,022,106; 8,273,795; 8,487,005; 8,791,160; 8,809,394; 8,957,113; and 9,060,939, arising under the patent laws of the United States Titles 21 and 35 of the United States Code, respectively, arising from Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 218320 to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' LYSTEDA® (tranexamic acid, 650 mg) tablets prior to the expiration of United States Patent Nos. 7,947,739; 8,022,106; 8,273,795; 8,487,005; 8,791,160; 8,809,394; 8,957,113; and 9,060,939 (collectively, the "Amring Patents" or the "patents-in-suit").

PARTIES

2. Plaintiff AMRING is a corporation organized and existing under the laws of Delaware with a principal place of business at 1205 Westlakes Drive Suite 275, Berwyn, PA 19312.

3. Upon information and belief, Defendant RUBICON is a corporation organized and existing under the laws of India, with a principal place of business at MedOne House, Plot No. B-75, Road No. 33, Wagle Estate, Thane (W) 400604, Maharashtra, India. RUBICON also maintains a Business Development and Regulatory Office located at Suite 605, Princeton Office Center II, 666 Plainsboro Road, Plainsboro, NJ 08536.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Alternatively, this Court has jurisdiction under Federal Rule of Civil Procedure 4(k)(2)(A). Venue is proper in this Court under 28 U.S.C. § 1391(c)(3) and 1400(b).

5. This Court has personal jurisdiction over RUBICON because RUBICON (1) has substantial, continuous, and systematic contacts with New Jersey; (2) has its Business Development and Regulatory Office in Plainsboro, New Jersey and therefore purposely avails itself of the rights and benefits of the State of New Jersey; (3) upon information and belief, prepared ANDA No. 218320 in its Plainsboro office and has therefore committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 218320 that has led to foreseeable harm and will lead to further foreseeable harm to AMRING; (4) intends to market, sell, and/or distribute generic versions of Plaintiff's LYSTEDA® tablets to residents of New Jersey; (4) and, upon information

and belief, enjoys substantial income from sales of its generic pharmaceutical products in New Jersey.

6. Upon information and belief, RUBICON will manufacture, market, and/or sell within the United States the generic 650 mg tranexamic acid tablets described in RUBICON's ANDA No. 218320 if FDA approval is granted. If ANDA No. 218320 is approved, the generic 650 mg tranexamic acid tablets charged with infringing the patents-in-suit would be, among other things, marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey.

7. In addition to the above reasons why RUBICON should reasonably anticipate being hailed to court in New Jersey, upon information and belief, RUBICON has previously consented to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See Metacel Pharmaceuticals LLC v. Rubicon Research Private Limited,* No. 2:21-cv-19463-EP-JRA.

PATENTS-IN-SUIT

8. AMRING is the owner by assignment of U.S. Patent No. 7,947,739 ("the '739 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and Trademark Office duly and legally issued on May 24, 2011. A true and correct copy of the '739 Patent is attached hereto as **Exhibit A**. AMRING, as assignee of the '739 Patent with respect to LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '739 Patent. The claims of the '739 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

9. AMRING is the owner by assignment of U.S. Patent No. 8,022,106 ("the '106 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and Trademark Office duly and legally issued on September 20, 2011. A true and correct copy of the '106 Patent is attached hereto as **Exhibit B**. AMRING, as assignee of the '106 Patent with respect to LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '106 Patent. The claims of the '106 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

10. AMRING is the owner by assignment of U.S. Patent No. 8,273,795 ("the '795 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and Trademark Office duly and legally issued on September 25, 2012. A true and correct copy of the '795 Patent is attached hereto as **Exhibit C**. AMRING, as assignee of the '795 Patent with respect to LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '795 Patent. The claims of the '795 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

11. AMRING is the owner by assignment of U.S. Patent No. 8,487,005 ("the '005 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and Trademark Office duly and legally issued on July 16, 2013. A true and correct copy of the '005 Patent is attached hereto as **Exhibit D**. AMRING, as assignee of the '005 Patent with respect to LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '005 Patent. The claims of the '005 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

12. AMRING is the owner by assignment of U.S. Patent No. 8,791,160 ("the '160 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and

Trademark Office duly and legally issued on July 29, 2014. A true and correct copy of the '160 Patent is attached hereto as **Exhibit E**. AMRING, as assignee of the '160 Patent with respect to LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '160 Patent. The claims of the '160 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

13. AMRING is the owner by assignment of U.S. Patent No. 8,809,394 ("the '394 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and Trademark Office duly and legally issued on August 19, 2014. A true and correct copy of the '394 Patent is attached hereto as **Exhibit F**. AMRING, as assignee of the '394 Patent with respect to LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '394 Patent. The claims of the '394 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

14. AMRING is the owner by assignment of U.S. Patent No. 8,957,113 ("the '113 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and Trademark Office duly and legally issued on February 17, 2015. A true and correct copy of the '113 Patent is attached hereto as **Exhibit G**. AMRING, as assignee of the '113 Patent with respect to LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '113 Patent. The claims of the '113 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

15. AMRING is the owner by assignment of U.S. Patent No. 9,060,939 ("the '939 Patent"), entitled "Tranexamic Acid Formulations," which the United States Patent and Trademark Office duly and legally issued on June 23, 2015. A true and correct copy of the '939 Patent is attached hereto as **Exhibit H**. AMRING, as assignee of the '939 Patent with respect to

LYSTEDA®, maintains the right to sue for and obtain equitable relief and damages for infringement of the '939 Patent. The claims of the '939 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

RUBICON'S INFRINGEMENT

16. AMRING is the holder of the New Drug Application ("NDA") No. 021753 for which the FDA granted approval for AMRING to market and sell 650 mg tranexamic acid tablets in the United States under the trade name LYSTEDA®. The formulation and dosing of LYSTEDA® is covered by the Amring Patents. The FDA's official publication of approved drugs "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") includes LYSTEDA® together with the Amring Patents.

17. By letter dated May 18, 2023 and delivered on May 19, 2023 ("the Notice Letter"), RUBICON notified AMRING that RUBICON's ANDA No. 218320 includes a certification under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv)(I) seeking approval to market 650 mg tranexamic acid tablets before the expiration of the Amring Patents with respect to AMRING's LYSTEDA® tablets ("Paragraph IV Certification"). Upon information and belief, RUBICON intends to engage in the commercial manufacture, use, and sale of the tranexamic acid tablets promptly upon receiving FDA approval to do so.

18. By filing ANDA No. 218320, RUBICON has necessarily represented to the FDA its generic tranexamic acid tablets have the same active ingredient as LYSTEDA®, have the same route of administration, dosage form, and strengths as LYSTEDA®, and are bioequivalent to LYSTEDA®.

19. Therefore, RUBICON's ANDA No. 218320, with its Paragraph IV Certification, constitutes infringement of one or more claims of United States Patent Nos. 7,947,739; 8,022,106; 8,273,795; 8,487,005; 8,791,160; 8,809,394; 8,957,113; and 9,060,939.

20. Further, RUBICON's marketing, manufacture, and sale of generic 650 mg tranexamic acid tablets, as well as the provision of dosage instructions to prescribers, would also result in infringement of the Amring Patents.

21. This Complaint is being filed before the expiration of the forty-five days from the date AMRING received the Notice Letter.

COUNT I (INFRINGEMENT OF THE '739 PATENT)

22. Each of paragraphs 1 to 21 is incorporated by reference as if fully set forth herein.

23. RUBICON's submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg tranexamic acid tablets prior to the expiration of the '739 Patent constitutes infringement of one or more claims of the '739 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

24. Upon FDA approval of RUBICON'S ANDA No. 218320, RUBICON will further infringe the '739 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

25. Upon information and belief, RUBICON had actual and constructive knowledge of the '739 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the '739 Patent.

26. If RUBICON's infringement of the '739 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '106 PATENT)

27. Each of paragraphs 1 to 26 is incorporated by reference as if fully set forth herein.

28. RUBICON's submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg tranexamic acid tablets prior to the expiration of the '106 Patent constitutes infringement of one or more claims of the '106 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

29. Upon FDA approval of RUBICON'S ANDA No. 218320, RUBICON will further infringe the '106 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

30. Upon information and belief, RUBICON had actual and constructive knowledge of the '106 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the '106 Patent.

31. If RUBICON's infringement of the '106 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III (INFRINGEMENT OF THE '795 PATENT)

32. Each of paragraphs 1 to 31 is incorporated by reference as if fully set forth herein.

33. RUBICON's submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg tranexamic acid tablets prior to the expiration of the '795 Patent constitutes infringement of one or more claims of the '795 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

34. Upon FDA approval of RUBICON'S ANDA No. 218320, RUBICON will further infringe the '795 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

35. Upon information and belief, RUBICON had actual and constructive knowledge of the '795 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the '795 Patent.

36. If RUBICON's infringement of the '795 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV (INFRINGEMENT OF THE '005 PATENT)

37. Each of paragraphs 1 to 36 is incorporated by reference as if fully set forth herein.

38. RUBICON's submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg tranexamic acid tablets prior to the expiration of the '795 Patent constitutes infringement of one or more claims of the '005 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

39. Upon FDA approval of RUBICON'S ANDA No. 218320, RUBICON will further infringe the '005 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

40. Upon information and belief, RUBICON had actual and constructive knowledge of the '005 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the '005 Patent.

41. If RUBICON's infringement of the '005 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V (INFRINGEMENT OF THE '160 PATENT)

42. Each of paragraphs 1 to 41 is incorporated by reference as if fully set forth herein.

43. RUBICON's submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg

tranexamic acid tablets prior to the expiration of the ’160 Patent constitutes infringement of one or more claims of the ‘160 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

44. Upon FDA approval of RUBICON’S ANDA No. 218320, RUBICON will further infringe the ‘160 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

45. Upon information and belief, RUBICON had actual and constructive knowledge of the ‘160 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the ‘160 Patent.

46. If RUBICON’s infringement of the ‘160 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI (INFRINGEMENT OF THE ‘394 PATENT)

47. Each of paragraphs 1 to 46 is incorporated by reference as if fully set forth herein.

48. RUBICON’s submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg tranexamic acid tablets prior to the expiration of the ’394 Patent constitutes infringement of one or more claims of the ‘394 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

49. Upon FDA approval of RUBICON'S ANDA No. 218320, RUBICON will further infringe the '394 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

50. Upon information and belief, RUBICON had actual and constructive knowledge of the '394 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the '394 Patent.

51. If RUBICON's infringement of the '394 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII (INFRINGEMENT OF THE '113 PATENT)

52. Each of paragraphs 1 to 51 is incorporated by reference as if fully set forth herein.

53. RUBICON's submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg tranexamic acid tablets prior to the expiration of the '113 Patent constitutes infringement of one or more claims of the '113 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

54. Upon FDA approval of RUBICON'S ANDA No. 218320, RUBICON will further infringe the '113 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to

providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

55. Upon information and belief, RUBICON had actual and constructive knowledge of the '113 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the '113 Patent.

56. If RUBICON's infringement of the '113 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII (INFRINGEMENT OF THE '939 PATENT)

57. Each of paragraphs 1 to 56 is incorporated by reference as if fully set forth herein.

58. RUBICON's submission of ANDA No. 218320 to obtain approval to engage in the commercial manufacture of, sale, offer for sale, importation, or use of generic 650 mg tranexamic acid tablets prior to the expiration of the '939 Patent constitutes infringement of one or more claims of the '939 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

59. Upon FDA approval of RUBICON'S ANDA No. 218320, RUBICON will further infringe the '939 Patent by making, using, offering to sell, and selling generic tranexamic acid tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others through means including but not limited to providing instruction to healthcare providers and/or patients to use the generic tranexamic acid tablets in accordance with proposed product labeling, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

60. Upon information and belief, RUBICON had actual and constructive knowledge of the '939 Patent prior to filing ANDA No. 218320 and was aware that filing said ANDA with the FDA constituted an act of infringement of the '939 Patent.

61. If RUBICON's infringement of the '939 Patent is not enjoined, AMRING will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AMRING prays that this Court grant the following relief:

a) A judgment that one or more claims of U.S. Patent Nos. 7,947,739; 8,022,106; 8,273,795; 8,487,005; 8,791,160; 8,809,394; 8,957,113; and 9,060,939 are infringed by RUBICON's submission of ANDA No. 218320, and RUBICON's making, using, offering to sell, selling in the United States, or importing into the United States generic versions of tranexamic acid 650 mg tablets will infringe one or more claims of each of the Amring Patents;

b) A judgment that each of the patents-in-suit is valid and enforceable;

c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 218320 shall be a date which is not earlier than the latest expiration date of the Amring Patents, including any extensions and/or additional periods of exclusivity to which AMRING is or becomes entitled;

d) An order preliminarily and permanently enjoining RUBICON, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States of 650 mg dosage strengths of generic tranexamic acid tablets

until after the latest expiration date of the Amring Patents, including any extensions and/or additional periods of exclusivity to which AMRING is or becomes entitled;

e) Damages or other monetary relief to AMRING if RUBICON engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of 650 mg dosage strengths of generic tranexamic acid tablets prior to the latest expiration date of the Amring Patents, including any extensions and/or additional periods of exclusivity to which AMRING is or becomes entitled;

f) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Respectfully submitted,

CAESAR RIVISE, PC

Dated: June 28, 2023

By **/s/ Douglas Panzer**

Douglas Panzer (NJ ID No. 044672006)
dpanzer@caesar.law
James J. Kozuch (PA ID No. 43600)
(To seek admission *Pro Hac Vice)*
jjkozuch@caesar.law
Allison Tramontana (PA ID No. 329108)
(To seek admission *Pro Hac Vice)*
atramontana@caesar.law
1635 Market Street
Seven Penn Center – 12th Floor
Philadelphia, PA 19103
Tel: (215) 567-2010
Fax: (215) 751-1142