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and Hetero USA, Inc.*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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SYMED LABS LIMITED AND HETERO	:	
USA, INC.	:	CIVIL ACTION NO.
	:	
Plaintiffs	:	
	:	
v.	:	
	:	
AMNEAL PHARMACEUTICALS LLC	:	
AND RAKS PHARMA PRIVATE	:	
LIMITED,	:	
	:	
Defendants	:	
	:	
-----X		

COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiffs Symed Labs Limited (“Symed”) and Hetero USA, Inc. (“Hetero”) (collectively “Plaintiffs”), by and through their undersigned attorneys, for their complaint against Defendants Amneal Pharmaceuticals LLC (“Amneal”) and Raks Pharma Private Limited (“Raks”) (collectively “Defendants”), allege as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 101, *et seq.* This action arises out of Defendants’ infringement of Plaintiffs’ U.S. Patent Nos. 7,351,824 (the “824 patent”) and 7,429,661 (the “661 patent”) by Defendants’ unauthorized manufacture, use, importation, offer for sale, and/or sale in the United States of

linezolid tablets containing novel intermediates claimed in the '824 and '661 patents and used in the synthesis of the antibiotic linezolid.

THE PARTIES

2. Symed is a company organized and existing under the laws of India, having a principal place of business at 8-2-293/174/3, B.N.Reddy Colony, Road No. 14, Banjara Hills, Hyderabad-500 034, Telangana, India. Symed is a leading developer of processes for the manufacture of active pharmaceutical ingredients, and Symed markets its active pharmaceutical ingredients throughout the world.

3. Hetero is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

4. Symed and Hetero are engaged in the business of developing and bringing to market affordable medicines in a wide range of therapeutic areas.

5. On information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey 08807.

6. On information and belief, Raks is a company organized and existing under the laws of India, having a principal place of business at Plot No.: 68, Survey No.: 60, 62 & 63, J.N. Pharma City, E- Bonangi Revenue Village, Parawada Mandal, Andhra Pradesh, Visakhapatnam 531021 India.

7. On information and belief, Raks is an affiliate and/or wholly owned subsidiary of Amneal.

8. On information and belief, Raks acts at the direction of and for the benefit of Amneal, and Raks is controlled by Amneal.

9. On information and belief, Amneal and Raks collaborate with respect to the development, regulatory approval, manufacture, marketing, sale and/or distribution of pharmaceutical products. On further information and belief, Amneal and Raks are agents of each other and act in concert in the preparation and submission of applications for FDA approval to market pharmaceutical products in the United States, and in the manufacture, marketing, sale and/or distribution of the FDA approved pharmaceutical products in the United States, including in the State of New Jersey.

10. On information and belief, Raks is the holder of DMF No. 26042, which sets forth a process for the manufacture of linezolid active pharmaceutical ingredient (“API”).

11. On information and belief, Amneal and Raks acted collaboratively in the preparation and submission of ANDA No. 204536 for linezolid 600 mg. tablets, and ANDA No. 204536, under a letter of authorization from Raks, references and relies upon Raks’ DMF No. 26042 for a description of the supposed process for manufacturing the linezolid API to be formulated into the linezolid tablets. On further information and belief, Amneal and Raks caused ANDA No. 204536 to be submitted to the FDA for approval to market linezolid 600 mg. tablets in the United States, and ANDA No 204536 was approved on December 21, 2015.

12. On information and belief, Amneal and Raks collaborate in the manufacture, marketing, distribution, importation, offer for sale, and/or sale in the United States, including in the State of New Jersey, of linezolid 600 mg. tablets pursuant to approved ANDA No. 204536 referencing Raks’ DMF No. 26042.

JURISDICTION AND VENUE

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

14. This Court has personal jurisdiction over Defendants. On information and belief, Defendants have continuous and systematic contacts with the State of New Jersey, regularly and continuously conduct business in the State of New Jersey, have purposely availed themselves of the privilege of doing business in the State of New Jersey, have derived substantial revenue from the sale of linezolid tablets and other pharmaceutical products in the State of New Jersey, and have infringed and continue to infringe Plaintiffs' '824 and '661 patents in the State of New Jersey.

15. On information and belief, Amneal maintains a regular and established place of business in the State of New Jersey and is registered to do business in the State of New Jersey.

16. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing and selling pharmaceutical drug products, including generic drugs, which Defendants manufacture, distribute, market and sell throughout the United States, including in the State of New Jersey.

17. Amneal regularly engages in patent infringement litigation concerning pharmaceutical products in the District of New Jersey, has admitted or has not contested personal jurisdiction and venue of the Court in prior District of New Jersey actions, and has purposely availed itself of the rights and benefits of this Court by asserting claims and counterclaims in this judicial district including, for example, Symbio Labs Ltd. *et al.* v. Amneal Pharmaceuticals LLC, Case No. 2:15-cv-08307; Sucampo AG *et al.* v. Amneal Pharmaceuticals

LLC, Case. No. 3:17-cv-02577; and AstraZeneca Pharmaceuticals LP *et al.* v. Amneal Pharmaceuticals LLC, Case No. 1:17-cv-01968.

18. On information and belief, Amneal and Raks operate as a single integrated business. The Amneal website notes that the “company’s expanding operations in India are an integral part of Amneal’s R&D and manufacturing capabilities and expertise”, at <http://www.amneal.com.international//>.

19. Venue is proper in this district for Amneal pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Amneal maintains a regular and established place of business in New Jersey, and has committed acts of infringement of the ‘824 and ‘661 patents in New Jersey, and Amneal is subject to personal jurisdiction in this judicial district.

20. Venue is proper in this district for Raks pursuant to 28 U.S.C. §§ 1391(c)(3) because, *inter alia*, Raks is a foreign company organized and existing under the laws of the Republic of India, and Raks is subject to personal jurisdiction in this judicial district.

**PLAINTIFFS’ PATENTS
AND LINEZOLID DRUG PRODUCT**

21. Linezolid, the chemical name for N-[[[(5-S)-3-[3-fluoro-4-(4-morpholinyl)-2-5-oxo-5-oxazolidinyl]methyl]acetamide, is a synthetic antibiotic used to combat serious Gram-positive bacterial infections that are resistant to conventional antibiotics. Linezolid is active against most Gram-positive bacteria that cause disease, including streptococci, vancomycin-resistant enterococci (VRE), and methicillin-resistant *Staphylococcus aureus* (MRSA). Because of its efficacy in treating tuberculosis in patients with multidrug resistant and extensively drug-resistant disease, the World Health Organization includes linezolid on its List of Essential Medicines.

22. In the solid state, the compound linezolid can exist in different crystalline forms, or polymorphs. Linezolid is also a chiral compound. Of the S and R enantiomers, only the S enantiomer of linezolid is biologically active.

23. The first two isolated polymorphic forms of linezolid were identified as Form I and Form II linezolid. Symed thereafter invented and patented a new polymorphic form of linezolid, designated as Form III linezolid, as well as processes for making Form III linezolid. Form III linezolid exhibits superior physical properties to the Form I and Form II linezolid polymorphs.

24. There are currently three ongoing patent litigations in this Court brought by Plaintiffs against Amneal and two other defendants for infringement of Plaintiffs' patent covering Form III linezolid, U.S. Patent No. 7,714,128, entitled "Crystalline Form of Linezolid", issued on May 11, 2010.

25. Early processes for the preparation of linezolid API were associated with many drawbacks including, *inter alia*, the use of expensive, highly flammable, explosive and corrosive reagents that were "difficult to handle" in commercial scale operations; hazardous solvents; extremely low reaction temperatures; slow and expensive purifications; and cumbersome procedures. Seeking a safer, less complicated, and less expensive method for making linezolid, Symed invented novel, simpler, commercially viable, industrially advantageous and far more economical processes for making linezolid, as well as novel intermediates for use in these processes.

26. Symed has sought and obtained patents for its linezolid process innovations, including the novel processes and novel process intermediates used to synthesize linezolid API.

27. The '824 patent entitled "Process for the Preparation of Linezolid and Related Compounds" was duly and lawfully issued on April 1, 2008. A true and correct copy of the '824 patent is attached as Exhibit A. The '824 patent is valid and enforceable.

28. The claims of the '824 patent are directed to novel compounds of a particular chemical formula useful as intermediates in the synthesis of linezolid. Claim 1 of the '824 patent is directed to the general chemical formula of these novel intermediate compounds, and dependent claims 2 and 3 of the '824 patent are directed to particular embodiments of the formula of claim 1, including N-[3-Chloro-2-(R)-hydroxypropyl]-3-fluoro-4-morpholinyl aniline (hereinafter referred to as "CHFA"). CHFA is disclosed in the '824 patent at col. 7, lines 53-59, and col. 9, lines 16-21.

29. The '661 patent, entitled "Intermediates for Linezolid and Related Compounds", was duly and lawfully issued on September 30, 2008. A true and correct copy of the '661 patent is attached hereto as Exhibit B. The '661 patent is valid and enforceable.

30. The claims of the '661 patent are directed to novel compounds of a particular chemical formula useful as intermediates in the synthesis of linezolid and its precursors, and to novel processes for making linezolid using the novel intermediates. Claim 64 of the '661 patent is directed to the general chemical formula of these novel intermediate compounds and dependent claims 65 and 66 are directed to particular embodiments of the formula of claim 64, including N-[3-Phthalimido-2-(R)-hydroxypropyl]-3-flouro-4-morpholinyl aniline (hereinafter referred to as "PHPFMA"). PHPFMA is disclosed in the '661 patent at col. 7, lines 62-67, and col. 8, lines 17-22, and line 64 through col. 9, line 4.

31. Plaintiffs are the assignees of the '824 and '661 patents, and own the entire right, title and interest in each of the patents.

32. Symed markets and sells linezolid API made using the process intermediates CHFA and PHPFMA claimed in the '824 and '661 patents, and Plaintiffs market and sell linezolid products formulated from Symed's linezolid API throughout the world including in the United States.

33. Defendants are well aware of the patents in suit. Amneal has had actual notice of the patents in suit. On or about June 2, 2015, Plaintiffs advised Amneal in written correspondence of Symed's ownership of patents relating to linezolid API, as well as methods of manufacture of linezolid and the intermediates used in the processes for the manufacture of linezolid, including the '824 and '661 patents.

34. On information and belief, Raks has had actual notice of the patents in suit. On or about January 30, 2015, Plaintiffs advised Raks in written correspondence of Symed's ownership of patents relating to linezolid API, as well as methods of manufacture of linezolid and the intermediates used in the processes for the manufacture of linezolid, including the '824 and '661 patents.

35. On information and belief, Defendants have submitted or caused to be submitted ANDA No. 204536 to the FDA under 21 U.S.C. § 355(j) to obtain approval to manufacture and market the linezolid tablets described therein in the United States. On further information and belief, ANDA No. 204536 for linezolid tablets was approved on December 21, 2015, and ANDA No. 204536 references and relies upon Raks' DMF No. 26042 for the supposed process for manufacturing the linezolid API used in the linezolid tablets.

36. On information and belief, Defendants make, use, offer for sale and/or sell in the United States, including the State of New Jersey, and/or import into the United States, including the State of New Jersey, linezolid tablets containing CHFA, a compound claimed in at least one

claim of the '824 patent, and PHPFMA, a compound claimed in at least one claim of the '661 patent.

COUNT I
(Direct Infringement of the '824 Patent)

37. Plaintiffs repeat, reallege, and incorporate by reference the allegations contained in paragraphs 1 through 36 as if fully set forth herein.

38. On information and belief, Defendants have infringed and continue to infringe one or more claims of the '824 patent in violation of 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, through the commercial manufacture, use, importation, offer for sale and/or sale in the United States of linezolid tablets and linezolid API containing CHFA or its equivalent, and through the use of CHFA, or its equivalent, in Defendants' manufacture of linezolid API and linezolid tablets.

39. On information and belief, based on analysis of Defendants' linezolid tablets sold in the United States, CHFA is present in Defendants' linezolid tablets.

40. The CHFA in Defendants' linezolid tablets is an embodiment of compounds claimed in claims 1, 2 and 3 of the '824 patent, and CHFA meets each and every limitation of claims 1, 2 and 3 of the '824 patent.

41. On information and belief, Defendants have had actual notice of the '824 patent, and Defendants' infringement of the '824 patent has been and continues to be willful and deliberate, entitling Plaintiffs to increased damages under 35 U.S.C. § 284.

42. Plaintiffs have suffered and will continue to suffer irreparable harm as a result of Defendants' unlawful conduct unless enjoined by the Court. Plaintiffs have no adequate remedy at law.

43. This case is exceptional, and Plaintiffs are entitled to attorney fees under 35 U.S.C. § 285.

COUNT II
(Direct Infringement of the '661 Patent)

44. Plaintiffs repeat, reallege, and incorporate by reference the allegations contained in paragraphs 1 through 43 as if fully set forth herein.

45. On information and belief, Defendants have infringed and continue to infringe one or more claims of the '661 patent in violation of 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, through the commercial manufacture, use, importation, offer for sale and/or sale in the United States of linezolid tablets and linezolid API containing PHPFMA or its equivalent, and through the use of PHPFMA, or its equivalent, in Defendants' manufacture of linezolid API and linezolid tablets.

46. On information and belief, based on analysis of Defendants' linezolid tablets sold in the United States, PHPFMA is present in Defendants' linezolid tablets

47. The PHPFMA in Defendants' tablets is an embodiment of compounds claimed in claims 64, 65 and 66 of the '661 patent, and PHPFMA meets each and every limitation of claims 64, 65 and 66 of the '661 patent.

48. On information and belief, Defendants have had actual notice of the '661 patent, and Defendants' infringement of the '661 patent has been and continues to be willful and deliberate, entitling Plaintiffs to increased damages under 35 U.S.C. § 284.

49. Plaintiffs have suffered and will continue to suffer irreparable harm as a result of Defendants' unlawful conduct unless enjoined by the Court. Plaintiffs have no adequate remedy at law.

50. This case is exceptional, and Plaintiffs are entitled to attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Symed and Hetero respectfully request the following relief:

- a) The entry of judgment in favor of Plaintiffs that Defendants have infringed the '824 and '661 patents under 35 U.S.C. § 271(a);
- b) A preliminary and permanent injunction against Defendants enjoining and restraining Defendants and each of them from manufacturing, using, offering for sale, or selling within the United States, or importing into the United States, the infringing linezolid products and intermediates until after the expiration of the '824 and '661 patents;
- c) An award of damages to Plaintiffs adequate to compensate for Defendants' infringement of the '824 and '661 patents including lost profits, but not less than a reasonable royalty, and that such damages be trebled pursuant to 35 U.S.C. § 284;
- d) A judgment that this is an exceptional case and awarding Plaintiffs their attorney fees in this action pursuant to 35 U.S.C. § 285;
- e) Costs and expenses in this action; and
- f) Such other and further relief as the Court deems just and proper.

JURY DEMAND

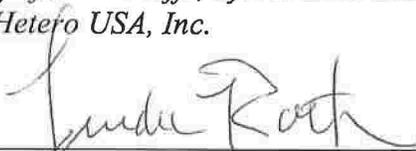
Plaintiffs demand a trial by jury for all claims so triable.

September 6, 2018

Respectfully submitted,

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and Hetero USA, Inc.*

By: _____



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