IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANACOR PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., ENCUBE ETHICALS PVT. LTD., GLASSHOUSE PHARMACEUTICALS LIMITED CANADA, and FLATWING PHARMACEUTICALS, LLC,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Anacor Pharmaceuticals, Inc. ("Anacor"), by its attorneys, for its Complaint, alleges as follows:

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 each Defendant's filing of an Abbreviated New Drug Applications ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Kerydin® (TAVABOROLE) TOPICAL SOLUTION, 5% ("Kerydin"), prior to the expiration of U.S. Patent No. 9,459,938 ("the '938 patent"); U.S. Patent No. 9,566,289 ("the '289 patent"); U.S. Patent No. 9,566,290 ("the '290 patent"); and U.S. Patent No. 9,572,823 ("the '823 patent"). These four patents are referred to collectively herein as "the patents-in-suit."

2. Lupin Limited notified Anacor by letter dated September 4, 2018 ("Lupin's Notice Letter") that it had submitted to the FDA ANDA No. 212168 ("Lupin's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or

sale of a generic tavaborole topical solution ("Lupin's ANDA Product") prior to the expiration of the patents-in-suit.

3. Encube Ethicals Pvt. Ltd. ("Encube") notified Anacor by letters dated September 4, 2018, and September 11, 2018 ("Encube's Notice Letters") that it had submitted to the FDA ANDA No. 211297 ("Encube's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic tavaborole topical solution ("Encube's ANDA Product") prior to the expiration of the patents-in-suit.

4. Glasshouse Pharmaceuticals Limited Canada ("Glasshouse") notified Anacor by letter dated September 6, 2018 ("Glasshouse's Notice Letter") that it had submitted to the FDA ANDA No. 212116 ("Glasshouse's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic tavaborole topical solution ("Glasshouse's ANDA Product") prior to the expiration of the patents-in-suit.

5. FlatWing Pharmaceuticals, LLC ("FlatWing") notified Anacor by letter dated September 7, 2018 ("FlatWing's Notice Letter") that it had submitted to the FDA ANDA No. 211963 ("FlatWing's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic tavaborole topical solution ("FlatWing's ANDA Product") prior to the expiration of the patents-in-suit.

6. Lupin's Notice Letter, Encube's Notice Letters, Glasshouse's Notice Letter, and FlatWing's Notice Letter are collectively referred to herein as "Defendants' Notice Letters." Lupin's ANDA, Encube's ANDA, Glasshouse's ANDA, and FlatWing's ANDA are collectively referred to herein as "Defendants' ANDAs." Lupin's ANDA Product, Encube's ANDA Product, Glasshouse's ANDA Product, and FlatWing's ANDA Product, are collectively referred to herein as "Defendants' ANDA Products."

7. Upon information and belief, Defendants' ANDA Products are all drug products that are generic versions of Kerydin, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

8. Plaintiff Anacor is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 235 East 42nd Street, New York, New York 10017.

9. Upon information and belief, defendant Lupin Limited is a corporation organized and existing under the laws of India, with a principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Lupin Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

10. Upon information and belief, defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

11. Upon information and belief, Lupin Pharmaceuticals is an indirect, wholly-owned subsidiary of Lupin Limited. Lupin Limited and Lupin Pharmaceuticals are collectively referred to herein as "Lupin."

12. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals acted in concert to prepare and submit Lupin's ANDA to the FDA.

13. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals know and intend that upon approval of Lupin's ANDA, Lupin Limited will manufacture Lupin's ANDA Product and Lupin Pharmaceuticals will directly or indirectly market, sell, and distribute Lupin's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Lupin's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Lupin Pharmaceuticals participated in, assisted, and cooperated with Lupin Limited in the acts complained of herein.

14. Upon information and belief, following any FDA approval of Lupin's ANDA, Lupin Limited and Lupin Pharmaceuticals will act in concert to distribute and sell Lupin's ANDA Product throughout the United States, including within Delaware.

15. Upon information and belief, defendant Encube is a corporation organized and existing under the laws of India, with a principal place of business at Unit 24, Steelmade Industrial Estate, Andheri (E), Mumbai, 400 069 India. Upon information and belief, Encube is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

16. Upon information and belief, Encube prepared and submitted Encube's ANDA to the FDA.

17. Upon information and belief, Encube knows and intends that upon approval of Encube's ANDA, Encube will manufacture and directly or indirectly market, sell, and distribute Encube's ANDA Product throughout the United States, including in Delaware.

18. Upon information and belief, following any FDA approval of Encube's ANDA, Encube will distribute and sell Encube's ANDA Product throughout the United States, including within Delaware.

19. Upon information and belief, defendant Glasshouse is a corporation organized and existing under the laws of Canada, with a principal place of business at 2145 Meadowpine Blvd., Mississauga, Ontario L5N 658 Canada. Upon information and belief, Glasshouse is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

20. Upon information and belief, Glasshouse prepared and submitted Glasshouse's ANDA to the FDA.

21. Upon information and belief, Glasshouse knows and intends that upon approval of Glasshouse's ANDA, Glasshouse will manufacture and directly or indirectly market, sell, and distribute Glasshouse's ANDA Product throughout the United States, including in Delaware.

22. Upon information and belief, following any FDA approval of Glasshouse's ANDA, Glasshouse will distribute and sell Glasshouse's ANDA Product throughout the United States, including within Delaware.

23. Upon information and belief, defendant FlatWing is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at 833 W 15th Pl., Unit 901, Chicago, Illinois 60608-1429. Upon information and belief,

FlatWing is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

24. Upon information and belief, FlatWing prepared and submitted FlatWing's ANDA to the FDA.

25. Upon information and belief, FlatWing knows and intends that upon approval of FlatWing's ANDA, FlatWing will manufacture and directly or indirectly market, sell, and distribute FlatWing's ANDA Product throughout the United States, including in Delaware.

26. Upon information and belief, following any FDA approval of FlatWing's ANDA, FlatWing will distribute and sell FlatWing's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

27. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

28. This Court has personal jurisdiction over each of the Defendants.

Lupin

29. Lupin Limited is subject to personal jurisdiction in Delaware because, among other things, Lupin Limited, itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Lupin Limited, itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the

State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Lupin Limited is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Lupin Pharmaceuticals and therefore the activities of Lupin Pharmaceuticals in this jurisdiction are attributed to Lupin Limited.

30. Lupin Pharmaceuticals is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Lupin Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Lupin Pharmaceuticals develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Anacor's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

31. Lupin has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

32. Upon information and belief, Lupin, with knowledge of the Hatch-Waxman Act process, directed the Notice Letter to, *inter alia*, Anacor, an entity incorporated in Delaware, and alleged in the Notice Letter that Anacor's patents are invalid. Upon information and belief, Lupin knowingly and deliberately challenged Anacor's patent rights, and knew when it did so that it was triggering a forty-five day period for Anacor to bring an action for patent infringement under the Hatch-Waxman Act.

33. Because Anacor is a corporation incorporated in Delaware, Anacor suffers injury and consequences from Lupin's filing of Lupin's ANDA, challenging Anacor's patent rights, in Delaware. Upon information and belief, Lupin knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Lupin has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending the Notice Letter to Anacor, a Delaware corporation, that it would be sued in Delaware for patent infringement.

34. In addition, this Court has personal jurisdiction over Lupin because Lupin Limited and Lupin Pharmaceuticals regularly engage in patent litigation concerning FDA-approved branded drug products in this District, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *H. Lundbeck A/S v. Lupin Limited*, No. 18-090, D.I. 11 (D. Del. Mar. 22, 2018) (Lupin Limited and Lupin Pharmaceuticals); *Omeros Corp. v. Lupin Limited*, No. 17-803, D.I. 9 (D. Del. Aug. 23, 2017) (Lupin Limited); *Bayer Intellectual Prop. GmbH v. Lupin Limited*, No. 17-1047, D.I. 9 (D. Del. Aug. 22, 2017) (Lupin Limited and Lupin Pharmaceuticals); *Bristol-Myers Squibb Co. v. Lupin Limited*, No. 17-378, D.I. 8 (D. Del. May 4, 2017) (Lupin Limited); *ViiV Healthcare Co. v. Lupin Limited*, No. 17-315,

D.I. 8 (D. Del. Apr. 17, 2017) (Lupin Limited and Lupin Pharmaceuticals); *Astellas Pharma Inc. v. Lupin Limited*, No. 16-908, D.I. 20 (D. Del. Jan. 17, 2017) (Lupin Limited and Lupin Pharmaceuticals); *Arena Pharm., Inc. v. Lupin Limited*, No. 16-887, D.I. 12 (Jan. 11, 2017) (Lupin Limited and Lupin Pharmaceuticals).

35. Upon information and belief, if Lupin's ANDA is approved, Lupin will directly or indirectly manufacture, market, sell, and/or distribute Lupin's ANDA Product within the United States, including in Delaware, consistently with Lupin's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Lupin regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Lupin's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Lupin's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Anacor's patents in the event that Lupin's ANDA Product is approved before the patents expire.

36. Upon information and belief, Lupin derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Lupin and/or for which Lupin Limited or Lupin Pharmaceuticals is the named applicant on approved ANDAs. Upon information and belief, various products for which Lupin Limited or Lupin Pharmaceuticals is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

Encube

37. Encube is subject to personal jurisdiction in Delaware because, among other things, Encube has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

38. Upon information and belief, Encube, with knowledge of the Hatch-Waxman Act process, directed the Notice Letter to, *inter alia*, Anacor, an entity incorporated in Delaware, and alleged in the Notice Letter that Anacor's patents are invalid. Upon information and belief, Encube knowingly and deliberately challenged Anacor's patent rights, and knew when it did so that it was triggering a forty-five day period for Anacor to bring an action for patent infringement under the Hatch-Waxman Act.

39. Because Anacor is a corporation incorporated in Delaware, Anacor suffers injury and consequences from Encube's filing of Encube's ANDA, challenging Anacor's patent rights, in Delaware. Upon information and belief, Encube knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware.

40. Upon information and belief, if Encube's ANDA is approved, Encube will directly or indirectly manufacture, market, sell, and/or distribute Encube's ANDA Product within the United States, including in Delaware. Upon information and belief, Encube's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Anacor's patents in the event that Encube's ANDA Product is approved before the patents expire.

Glasshouse

41. Glasshouse is subject to personal jurisdiction in Delaware because, among other things, Glasshouse has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

42. Upon information and belief, Glasshouse, with knowledge of the Hatch-Waxman Act process, directed the Notice Letter to, *inter alia*, Anacor, an entity incorporated in Delaware, and alleged in the Notice Letter that Anacor's patents are invalid. Upon information and belief, Glasshouse knowingly and deliberately challenged Anacor's patent rights, and knew when it did so that it was triggering a forty-five day period for Anacor to bring an action for patent infringement under the Hatch-Waxman Act.

43. Because Anacor is a corporation incorporated in Delaware, Anacor suffers injury and consequences from Glasshouse's filing of Glasshouse's ANDA, challenging Anacor's patent rights, in Delaware. Upon information and belief, Glasshouse knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware.

44. Upon information and belief, if Glasshouse's ANDA is approved, Glasshouse will directly or indirectly manufacture, market, sell, and/or distribute Glasshouse's ANDA Product within the United States, including in Delaware. Upon information and belief, Glasshouse's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Anacor's patents in the event that Glasshouse's ANDA Product is approved before the patents expire.

FlatWing

45. FlatWing is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. FlatWing is a limited liability company organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware.

46. Upon information and belief, FlatWing, with knowledge of the Hatch-Waxman Act process, directed the Notice Letter to, *inter alia*, Anacor, an entity incorporated in Delaware, and alleged in the Notice Letter that Anacor's patents are invalid. Upon information and belief, FlatWing knowingly and deliberately challenged Anacor's patent rights, and knew when it did so that it was triggering a forty-five day period for Anacor to bring an action for patent infringement under the Hatch-Waxman Act.

47. Because Anacor is a corporation incorporated in Delaware, Anacor suffers injury and consequences from FlatWing's filing of FlatWing's ANDA, challenging Anacor's patent rights, in Delaware. Upon information and belief, FlatWing knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware.

48. Upon information and belief, if FlatWing's ANDA is approved, FlatWing will directly or indirectly manufacture, market, sell and/or distribute FlatWing's ANDA Product within the United States, including in Delaware. Upon information and belief, if FlatWing's ANDA is approved, FlatWing will directly or indirectly market and distribute FlatWing's ANDA Product in Delaware. Upon information and belief, FlatWing's ANDA Product will be

prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Anacor's patents in the event that FlatWing's ANDA Product is approved before the patents expire.

VENUE

49. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Limited is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

50. Venue is proper in this district for Lupin Pharmaceuticals pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

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

52. Venue is proper in this district for Glasshouse pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Glasshouse is a corporation organized and existing under the laws of Canada and is subject to personal jurisdiction in this judicial district.

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

THE PATENTS-IN-SUIT

54. Anacor incorporates each of the preceding paragraphs 1–53 as if fully set forth herein.

55. The inventors named on each of the patents-in-suit are Stephen J. Baker, Tsutomu Akama, Vincent S. Hernandez, Karin M. Hold, Kirk Maples, Jacob J. Plattner, Virginia Sanders, Yong-Kang Zhang, Gregory T. Fieldson, and James J. Leyden (collectively, "the Named Inventors").

56. The '938 patent, entitled "Boron-Containing Small Molecules" (Exhibit A hereto), was duly and legally issued on January 24, 2017, to Anacor, as assignee of the Named Inventors.

57. The '938 patent claims, *inter alia*, a method of treating a *Tinea unguium* infection of a toenail of a human, the method comprising topically administering to the toenail of the human a pharmaceutical composition comprising 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof in an amount sufficient to treat the infection, wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole.

58. The '938 patent claims, *inter alia*, a method of treating a *Tinea unguium* infection of a toenail of a human, the method comprising topically administering to the toenail of the human a pharmaceutical composition comprising 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof in an amount sufficient to treat the infection, wherein the *Tinea unguium* infection is due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*, and wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole.

59. The ’938 patent claims, *inter alia*, a method of treating a *Tinea unguium* infection of a toenail of a human, the method comprising topically administering to the toenail of the human a pharmaceutical composition comprising 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof in an amount sufficient to treat the infection, wherein the *Tinea unguium* infection is due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*, wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole, and wherein the pharmaceutical composition further comprises ethanol and propylene glycol.

60. The ’289 patent, entitled “Boron-Containing Small Molecules” (Exhibit B hereto), was duly and legally issued on February 14, 2017, to Anacor, as assignee of the Named Inventors.

61. The ’289 patent claims, *inter alia*, a pharmaceutical formulation comprising 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benoxaborole, or a pharmaceutically acceptable salt thereof, a solvent system, and a chelating agent; wherein the 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole, or a pharmaceutically acceptable salt thereof, is present in a concentration of about 5% w/w.

62. The ’289 patent claims, *inter alia*, a pharmaceutical formulation comprising about 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benoxaborole, or a pharmaceutically acceptable salt thereof, propylene glycol, ethanol, and ethylene diamine tetraacetic acid (EDTA) or a pharmaceutically acceptable salt thereof.

63. The ’289 patent claims, *inter alia*, a pharmaceutical formulation comprising about 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benoxaborole, or a pharmaceutically acceptable salt thereof, propylene glycol, ethanol, and ethylene diamine

tetraacetic acid (EDTA) or a pharmaceutically acceptable salt thereof; wherein the formulation is suitable for the treatment of onychomycosis of a toenail due to *Trichophyton rubrum* or *Trichophyton mentagrophytes* by topical application of the formulation to the toenail.

64. The ’289 patent claims, *inter alia*, a pharmaceutical formulation comprising about 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benoxaborole, or a pharmaceutically acceptable salt thereof, propylene glycol, ethanol, and ethylene diamine tetraacetic acid (EDTA) or a pharmaceutically acceptable salt thereof; wherein the ethylene diamine tetraacetic acid (EDTA) or a pharmaceutically acceptable salt thereof, is present in a concentration of from about 0.005% to about 2.0% w/w.

65. The ’289 patent claims, *inter alia*, a pharmaceutical formulation comprising about 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benoxaborole, or a pharmaceutically acceptable salt thereof, propylene glycol, ethanol, and ethylene diamine tetraacetic acid (EDTA) or a pharmaceutically acceptable salt thereof; wherein the ethylene diamine tetraacetic acid (EDTA) or a pharmaceutically acceptable salt thereof, is present in a concentration of from about 0.005% to about 2.0% w/w; wherein the formulation is suitable for the treatment of onychomycosis of a toenail due to *Trichophyton rubrum* or *Trichophyton mentagrophytes* by topical application of the formulation to the toenail.

66. The ’290 patent, entitled “Boron-Containing Small Molecules” (Exhibit C hereto), was duly and legally issued on February 14, 2017, to Anacor, as assignee of the Named Inventors.

67. The ’290 patent claims, *inter alia*, a method of treating a human having onychomycosis of a toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising topically administering to the toenail a pharmaceutical composition

comprising an amount of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, effective to inhibit an aminoacyl tRNA synthetase in the *Trichophyton rubrum* or *Trichophyton mentagrophytes*; wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof.

68. The '290 patent claims, *inter alia*, a method of treating a human having onychomycosis of a toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising topically administering to the toenail a pharmaceutical composition comprising an amount of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, effective to inhibit an aminoacyl tRNA synthetase in the *Trichophyton rubrum* or *Trichophyton mentagrophytes*; wherein the aminoacyl tRNA synthetase is leucyl tRNA synthetase; and wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof.

69. The '290 patent claims, *inter alia*, a method of treating a human having onychomycosis of a toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising topically administering to the toenail a pharmaceutical composition comprising an amount of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, effective to inhibit an aminoacyl tRNA synthetase in the *Trichophyton rubrum* or *Trichophyton mentagrophytes*; wherein the aminoacyl tRNA synthetase is leucyl tRNA synthetase; wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a

pharmaceutically acceptable salt thereof; and wherein the pharmaceutical composition further comprises ethanol and propylene glycol.

70. The '290 patent claims, *inter alia*, a method of treating a human having onychomycosis of a toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising topically administering to the toenail a pharmaceutical composition comprising an amount of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, effective to inhibit an aminoacyl tRNA synthetase in the *Trichophyton rubrum* or *Trichophyton mentagrophytes*; wherein the aminoacyl tRNA synthetase is leucyl tRNA synthetase; wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical composition further comprises ethanol and propylene glycol; and wherein the administering of the pharmaceutical composition occurs once a day.

71. The '290 patent claims, *inter alia*, a method of treating a human having onychomycosis of a toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising topically administering to the toenail a pharmaceutical composition comprising an amount of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, effective to inhibit an aminoacyl tRNA synthetase in the *Trichophyton rubrum* or *Trichophyton mentagrophytes*; wherein the aminoacyl tRNA synthetase is leucyl tRNA synthetase; wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical composition further

comprises ethanol and propylene glycol; and wherein the method inhibits leucyl tRNA synthetase in *Trichophyton rubrum*.

72. The ’290 patent claims, *inter alia*, a method of treating a human having onychomycosis of a toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising topically administering to the toenail a pharmaceutical composition comprising an amount of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, effective to inhibit an aminoacyl tRNA synthetase in the *Trichophyton rubrum* or *Trichophyton mentagrophytes*; wherein the aminoacyl tRNA synthetase is leucyl tRNA synthetase; wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical composition further comprises ethanol and propylene glycol; and wherein the method inhibits leucyl tRNA synthetase in *Trichophyton mentagrophytes*.

73. The ’823 patent, entitled “Boron-Containing Small Molecules” (Exhibit D hereto), was duly and legally issued on February 14, 2017, to Anacor, as assignee of the Named Inventors.

74. The ’823 patent claims, *inter alia*, a method of delivering a compound, in a human, from a dorsal layer of a nail plate to a nail bed to treat onychomycosis caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising contacting the dorsal layer of the nail plate with a pharmaceutical composition comprising a compound that penetrates the nail plate, the compound being 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, thereby treating onychomycosis due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*; wherein the pharmaceutical composition

is in the form of a topical solution comprising 5% w/w of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole, and wherein the pharmaceutical composition further comprises ethanol and propylene glycol.

75. Anacor owns each of the patents-in-suit.

76. Kerydin, and methods of using Kerydin, are covered by one or more claims of each of the patents-in-suit, and each of the patents-in-suit has been listed in connection with Kerydin in the FDA's Orange Book.

77. Anacor will be substantially and irreparably damaged by infringement of the patents-in-suit.

COUNT I – LUPIN'S INFRINGEMENT OF THE PATENTS-IN-SUIT

78. Anacor incorporates each of the preceding paragraphs 1–77 as if fully set forth herein.

79. In Lupin's Notice Letter, Lupin notified Anacor of the submission of Lupin's ANDA to the FDA. The purpose of that submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's ANDA Product prior to the expiration of the patents-in-suit.

80. In its Notice Letter, Lupin also notified Anacor that, as part of its ANDA, Lupin had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to each of the patents-in-suit. Upon information and belief, Lupin submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that each of the patents-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product.

81. Lupin's ANDA Product, and the use of Lupin's ANDA Product, are covered by one or more claims of each of the patents-in-suit, including at least the following: claims 3 and 5–6 of the '938 patent; claims 10 and 12–15 of the '289 patent; claims 2, 5–6, 8, and 11–12 of the '290 patent; and claim 2 of the '823 patent.

82. In its Notice Letter, Lupin did not contest infringement of the '938 patent, the '290 patent, the '823 patent, or claims 1–5 or 7–15 of the '289 patent.

83. Lupin has knowledge of the each of the patents-in-suit.

84. Lupin's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product before the expiration of the patents-in-suit was an act of infringement of those patents under 35 U.S.C. § 271(e)(2)(A).

85. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product immediately and imminently upon approval of its ANDA.

86. The manufacture, use, sale, offer for sale, or importation of Lupin's ANDA Product would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 81.

87. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Lupin's ANDA Product in accordance with, and as directed by Lupin's proposed product labeling would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 81.

88. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the patents-in-suit when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

89. Upon information and belief, Lupin knows that Lupin's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the patents-in-suit, that Lupin's ANDA Product is not a staple article or commodity of commerce, and that Lupin's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Lupin plans and intends to, and will, contribute to infringement of the patents-in-suit immediately and imminently upon approval of Lupin's ANDA.

90. Notwithstanding Lupin's knowledge of the claims of the patents-in-suit, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Lupin's ANDA Product with its product labeling following upon FDA approval of Lupin's ANDA prior to the expiration of the patents-in-suit.

91. The foregoing actions by Lupin constitute and/or will constitute infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and contribution to the infringement by others of the patents-in-suit.

92. Upon information and belief, Lupin has acted with full knowledge of the patents-in-suit and without a reasonable basis for believing that it would not be liable for infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and/or contribution to the infringement by others of the patents-in-suit.

93. Unless Lupin is enjoined from infringing the patents-in-suit, actively inducing infringement of the patents-in-suit, and contributing to the infringement by others of the patents-in-suit, Anacor will suffer irreparable injury. Anacor has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT BY LUPIN OF THE PATENTS-IN-SUIT

94. Anacor incorporates each of the preceding paragraphs 1–93 as if fully set forth herein.

95. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Anacor on the one hand and Lupin on the other regarding Lupin's infringement, active inducement of infringement, and contribution to the infringement by others of the patents-in-suit.

96. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Lupin's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the patents-in-suit, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents.

COUNT III – ENCUBE'S INFRINGEMENT OF THE PATENTS-IN-SUIT

97. Anacor incorporates each of the preceding paragraphs 1–96 as if fully set forth herein.

98. In Encube's Notice Letters, Encube notified Anacor that it had submitted Encube's ANDA to the FDA. The purpose of the submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Encube's ANDA Product prior to the expiration of the patents-in-suit.

99. In its Notice Letter, Encube also notified Anacor that, as part of its ANDA, Encube had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to each of the patents-in-suit. Upon information and belief, Encube submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that each of the patents-in-suit is invalid,

unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Encube's ANDA Product.

100. Encube's ANDA Product, and the use of Encube's ANDA Product, are covered by one or more claims of each of the patents-in-suit, including at least the following: claims 3 and 5–6 of the '938 patent; claims 10 and 12–15 of the '289 patent; claims 2, 5–6, 8, and 11–12 of the '290 patent; and claim 2 of the '823 patent.

101. In its Notice Letter, Encube did not contest infringement of the patents-in-suit.

102. Encube has knowledge of the each of the patents-in-suit.

103. Encube's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product before the expiration of the patents-in-suit was an act of infringement of those patents under 35 U.S.C. § 271(e)(2)(A).

104. Upon information and belief, Encube will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product immediately and imminently upon approval of its ANDA.

105. The manufacture, use, sale, offer for sale, or importation of Encube's ANDA Product would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 100.

106. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Encube's ANDA Product in accordance with, and as directed by Encube's proposed product labeling would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 100.

107. Upon information and belief, Encube plans and intends to, and will, actively induce infringement of the patents-in-suit when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

108. Upon information and belief, Encube knows that Encube's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the patents-in-suit, that Encube's ANDA Product is not a staple article or commodity of commerce, and that Encube's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Encube plans and intends to, and will, contribute to infringement of the patents-in-suit immediately and imminently upon approval of Encube's ANDA.

109. Notwithstanding Encube's knowledge of the claims of the patents-in-suit, Encube has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Encube's ANDA Product with its product labeling following upon FDA approval of Encube's ANDA prior to the expiration of the patents-in-suit.

110. The foregoing actions by Encube constitute and/or will constitute infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and contribution to the infringement by others of the patents-in-suit.

111. Upon information and belief, Encube has acted with full knowledge of the patents-in-suit and without a reasonable basis for believing that it would not be liable for infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and/or contribution to the infringement by others of the patents-in-suit.

112. Unless Encube is enjoined from infringing the patents-in-suit, actively inducing infringement of the patents-in-suit, and contributing to the infringement by others of the patents-in-suit, Anacor will suffer irreparable injury. Anacor has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT BY ENCUBE OF THE PATENTS-IN-SUIT

113. Anacor incorporates each of the preceding paragraphs 1–112 as if fully set forth herein.

114. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Anacor on the one hand and Encube on the other regarding Encube's infringement, active inducement of infringement, and contribution to the infringement by others of the patents-in-suit.

115. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Encube's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the patents-in-suit, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents.

COUNT V – GLASSHOUSE'S INFRINGEMENT OF THE PATENTS-IN-SUIT

116. Anacor incorporates each of the preceding paragraphs 1–115 as if fully set forth herein.

117. In Glasshouse's Notice Letter, Glasshouse notified Anacor that it had submitted Glasshouse's ANDA to the FDA. The purpose of the submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Glasshouse's ANDA Product prior to the expiration of the patents-in-suit.

118. In its Notice Letter, Glasshouse also notified Anacor that, as part of its ANDA, Glasshouse had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to each of the patents-in-suit. Upon information and belief, Glasshouse submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that each of the patents-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Glasshouse's ANDA Product.

119. Glasshouse's ANDA Product, and the use of Glasshouse's ANDA Product, are covered by one or more claims of each of the patents-in-suit, including at least the following: claims 3 and 5–6 of the '938 patent; claims 10 and 12–15 of the '289 patent; claims 2, 5–6, 8, and 11–12 of the '290 patent; and claim 2 of the '823 patent.

120. In its Notice Letter, Glasshouse did not contest infringement of the '938 patent, the '290 patent, the '823 patent, or claims 1–5 or 7–15 of the '289 patent.

121. Glasshouse has knowledge of each of the patents-in-suit.

122. Glasshouse's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product before the expiration of the patents-in-suit was an act of infringement of those patents under 35 U.S.C. § 271(e)(2)(A).

123. Upon information and belief, Glasshouse will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product immediately and imminently upon approval of its ANDA.

124. The manufacture, use, sale, offer for sale, or importation of Glasshouse's ANDA Product would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 119.

125. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Glasshouse's ANDA Product in accordance with, and as directed by Glasshouse's proposed product labeling would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 119.

126. Upon information and belief, Glasshouse plans and intends to, and will, actively induce infringement of the patents-in-suit when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

127. Upon information and belief, Glasshouse knows that Glasshouse's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the patents-in-suit, that Glasshouse's ANDA Product is not a staple article or commodity of commerce, and that Glasshouse's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Glasshouse plans and intends to, and will, contribute to infringement of the patents-in-suit immediately and imminently upon approval of Glasshouse's ANDA.

128. Notwithstanding Glasshouse's knowledge of the claims of the patents-in-suit, Glasshouse has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Glasshouse's ANDA Product with its product labeling following upon FDA approval of Glasshouse's ANDA prior to the expiration of the patents-in-suit.

129. The foregoing actions by Glasshouse constitute and/or will constitute infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and contribution to the infringement by others of the patents-in-suit.

130. Upon information and belief, Glasshouse has acted with full knowledge of the patents-in-suit and without a reasonable basis for believing that it would not be liable for infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and/or contribution to the infringement by others of the patents-in-suit.

131. Unless Glasshouse is enjoined from infringing the patents-in-suit, actively inducing infringement of the patents-in-suit, and contributing to the infringement by others of the patents-in-suit, Anacor will suffer irreparable injury. Anacor has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT BY GLASSHOUSE OF THE PATENTS-IN-SUIT

132. Anacor incorporates each of the preceding paragraphs 1–131 as if fully set forth herein.

133. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Anacor on the one hand and Glasshouse on the other regarding Glasshouse's infringement, active inducement of infringement, and contribution to the infringement by others of the patents-in-suit.

134. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Glasshouse's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the patents-in-suit, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents.

COUNT VII – FLATWING'S INFRINGEMENT OF THE PATENTS-IN-SUIT

135. Anacor incorporates each of the preceding paragraphs 1–134 as if fully set forth herein.

136. In FlatWing's Notice Letter, FlatWing notified Anacor that it had submitted FlatWing's ANDA to the FDA. The purpose of the submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of FlatWing's ANDA Product prior to the expiration of the patents-in-suit.

137. In its Notice Letter, FlatWing also notified Anacor that, as part of its ANDA, FlatWing had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to each of the patents-in-suit. Upon information and belief, FlatWing submitted its ANDA to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that each of the patents-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of FlatWing's ANDA Product.

138. FlatWing's ANDA Product, and the use of FlatWing's ANDA Product, are covered by one or more claims of each of the patents-in-suit, including at least the following: claims 3 and 5–6 of the '938 patent; claims 10 and 12–15 of the '289 patent; claims 2, 5–6, 8, and 11–12 of the '290 patent; and claim 2 of the '823 patent.

139. In its Notice Letter, FlatWing did not contest infringement of the patents-in-suit.

140. FlatWing has knowledge of the each of the patents-in-suit.

141. FlatWing's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product before the expiration of the patents-in-suit was an act of infringement of those patents under 35 U.S.C. § 271(e)(2)(A).

142. Upon information and belief, FlatWing will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Product immediately and imminently upon approval of its ANDA.

143. The manufacture, use, sale, offer for sale, or importation of FlatWing's ANDA Product would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 138.

144. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of FlatWing's ANDA Product in accordance with, and as directed by FlatWing's proposed product labeling would infringe one or more claims of each of the patents-in-suit, including at least the claims listed in above paragraph 138.

145. Upon information and belief, FlatWing plans and intends to, and will, actively induce infringement of the patents-in-suit when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

146. Upon information and belief, FlatWing knows that FlatWing's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the patents-in-suit, that FlatWing's ANDA Product is not a staple article or commodity of commerce, and that FlatWing's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, FlatWing plans and intends to, and

will, contribute to infringement of the patents-in-suit immediately and imminently upon approval of FlatWing's ANDA.

147. Notwithstanding FlatWing's knowledge of the claims of the patents-in-suit, FlatWing has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import FlatWing's ANDA Product with its product labeling following upon FDA approval of FlatWing's ANDA prior to the expiration of the patents-in-suit.

148. The foregoing actions by FlatWing constitute and/or will constitute infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and contribution to the infringement by others of the patents-in-suit.

149. Upon information and belief, FlatWing has acted with full knowledge of the patents-in-suit and without a reasonable basis for believing that it would not be liable for infringement of the patents-in-suit; active inducement of infringement of the patents-in-suit; and/or contribution to the infringement by others of the patents-in-suit.

150. Unless FlatWing is enjoined from infringing the patents-in-suit, actively inducing infringement of the patents-in-suit, and contributing to the infringement by others of the patents-in-suit, Anacor will suffer irreparable injury. Anacor has no adequate remedy at law.

COUNT VIII– DECLARATORY JUDGMENT OF INFRINGEMENT BY FLATWING OF THE PATENTS-IN-SUIT

151. Anacor incorporates each of the preceding paragraphs 1–150 as if fully set forth herein.

152. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Anacor on the one hand and FlatWing on the other regarding FlatWing's infringement, active inducement of infringement, and contribution to the infringement by others of the patents-in-suit.

153. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of FlatWing's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the patents-in-suit, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents.

WHEREFORE, Anacor requests the following relief:

(a) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Lupin's submission to the FDA of Lupin's ANDA;

(b) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Encube's submission to the FDA of Encube's ANDA;

(c) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Glasshouse's submission to the FDA of Glasshouse's ANDA;

(d) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by FlatWing's submission to the FDA of FlatWing's ANDA;

(e) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Defendants' ANDA Products, or any other drug product that infringes or the use of which infringes one or more of the patents-in-suit, be not earlier than the latest of the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A preliminary and permanent injunction enjoining Defendants, and all persons acting in concert with Defendants, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' ANDA Products, or any other drug product covered by or whose use is covered by one or more of the patents-in-suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Defendants' ANDA Products, or any other drug product which is covered by or whose use is covered by one-or-more of the patents-in-suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents;

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

(i) Costs and expenses in this action; and

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

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October 17, 2018