IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACERTA PHARMA B.V., ACERTA PHARMA LLC, and ASTRAZENECA PHARMACEUTICALS LP,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Pharmacyclics LLC ("Plaintiff" or "Pharmacyclics") hereby asserts the following claims for patent infringement against Defendants Acerta Pharma B.V. ("Acerta Netherlands"), Acerta Pharma LLC ("Acerta USA"), and AstraZeneca Pharmaceuticals LP ("AstraZeneca") (collectively "Defendants" or "Acerta"), and alleges as follows:

INTRODUCTION

1. Pharmacyclics has invested substantial resources in discovering, identifying, and developing new compounds and drugs for human treatment. One group of compounds discovered by Pharmacyclics is a novel class of small molecules that covalently bind to a protein called Bruton's tyrosine kinase ("BTK"), thereby irreversibly inhibiting BTK's activity.

2. BTK is a key signaling molecule in the pathway that leads to B-cell growth and maturation following activation of the B-cell receptor. Abnormalities in the B-cell receptor signaling pathway can lead to uncontrolled cell growth and cause cancers of the blood and bone marrow.

3. Pharmacyclics obtained U.S. patents directed to its novel class of BTK inhibitors and to methods of using these BTK inhibitors. Among these patents are U.S. Patent Nos.

9,079,908 ("the '908 patent"), 9,139,591 ("the '591 patent"), and 9,556,182 ("the '182 patent") (collectively, "the Patents-in-Suit"), which are asserted in this action.

4. After creating its novel class of BTK inhibitors, Pharmacyclics developed IMBRUVICA® (ibrutinib), a first-in-class drug that irreversibly inhibits BTK's enzymatic activity. In November 2013, the United States Food and Drug Administration ("FDA") approved IMBRUVICA® to treat mantle cell lymphoma ("MCL"), a type of non-Hodgkin's lymphoma.

5. In 2014, IMBRUVICA® received FDA approval for the treatment of chronic lymphocytic leukemia ("CLL") for patients who received at least one prior therapy. IMBRUVICA® was subsequently approved for additional indications, including CLL/small lymphocytic lymphoma ("SLL"), Waldenström's macroglobulinemia, the treatment of patients with marginal zone lymphoma ("MZL") who require systemic therapy and have received at least one prior anti-CD20-based therapy, and chronic graft versus host disease after failure of one or more lines of systemic therapy ("cGVHD"). For MZL and cGVHD, IMBRUVICA® represents the first FDA approved treatment specifically for patients with these respective indications.

6. Acerta has obtained approval to market a different BTK inhibitor, acalabrutinib, from the class of compounds invented by Pharmacyclics. Pharmacyclics brings this patent infringement action to compensate Pharmacyclics for the damage that Acerta has and will cause and for any equitable relief that the Court deems appropriate.

NATURE OF THE ACTION

7. This is an action for patent infringement under the laws of the United States, 35 U.S.C. § 100, *et seq.*

THE PARTIES

8. Plaintiff Pharmacyclics LLC is a limited liability company organized and existing under the laws of Delaware with its principal place of business at 999 East Arques Avenue,

Sunnyvale, California 94085. Pharmacyclics LLC is a wholly-owned subsidiary of AbbVie Inc., a Delaware corporation which has its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064-6400.

9. On information and belief, defendant Acerta Netherlands is a corporation organized and existing under the laws of the Netherlands, having a principal place of business at Kloosterstraat 9, 5349 AB Oss, The Netherlands.

10. On information and belief, defendant Acerta USA is a limited liability company organized and existing under the laws of Delaware with its principal place of business at 2200 Bridge Parkway, Suite 101, Redwood City, California 94065. On information and belief, Acerta USA is in the business of, among other things, manufacturing, marketing and selling pharmaceutical products in the United States, including in the District of Delaware, and conducts business throughout the United States.

11. On information and belief, defendant Acerta USA is a wholly-owned subsidiary of defendant Acerta Netherlands. On information and belief, Acerta USA conducts activities as the agent of Acerta Netherlands in the District of Delaware.

12. On information and belief, defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, P.O. Box 15437, Wilmington, Delaware 19850.

THE PATENTS-IN-SUIT

13. On July 14, 2015, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 9,079,908, entitled "Inhibitors of Bruton's tyrosine kinase." The inventors of the '908 Patent are Lee Honigberg, Erik J. Verner, Joseph J. Buggy, David J. Loury, Wei Chen, and Zhengying Pan. Pharmacyclics is the assignee of the '908 patent. A copy of the '908 patent is attached hereto as Exhibit A.

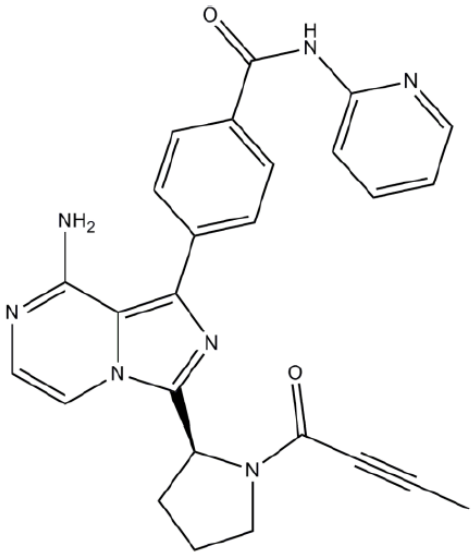
14. On September 22, 2015, the PTO issued U.S. Patent No. 9,139,591, entitled "Inhibitors of Bruton's tyrosine kinase." The inventors of the '591 patent are Lee Honigberg, Erik J. Verner, Joseph J. Buggy, David J. Loury, Wei Chen, and Zhengying Pan. Pharmacyclics is the assignee of the '591 patent. A copy of the '591 patent is attached hereto as Exhibit B.

15. On January 31, 2017, the PTO issued U.S. Patent No. 9,556,182, entitled "Inhibitors of Bruton's tyrosine kinase." The inventors of the '182 patent are Lee Honigberg, Erik J. Verner, Joseph J. Buggy, David J. Loury, Wei Chen, and Zhengying Pan. Pharmacyclics is the assignee of the '182 patent. A copy of the '182 patent is attached hereto as Exhibit C.

ACERTA'S CALQUENCE® (ACALABRUTINIB) PRODUCT

16. On information and belief, on June 13, 2017, Acerta Netherlands, working in conjunction with Acerta USA, submitted a New Drug Application ("NDA") to the FDA seeking approval to sell CALQUENCE® (acalabrutinib).

17. The active ingredient in CALQUENCE® (acalabrutinib) is acalabrutinib, which has the following structure:



18. On October 31, 2017, the FDA approved CALQUENCE® (acalabrutinib) for the treatment of adults with MCL who have received at least one prior therapy. The approved label

states that CALQUENCE® (acalabrutinib) will be distributed by AstraZeneca "[u]nder license of Acerta Pharma B.V." AstraZeneca sent a press release to the CLL Society stating that "CALQUENCE will be available to patients immediately." Acalabrutinib Receives US FDA Accelerated Approval, https://cllsociety.org/2017/10/acalabrutinib-fda-accelerated-approval/ (last accessed on November 1, 2017).

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

20. This Court has personal jurisdiction over Acerta USA because Acerta USA is a limited liability company organized and existing under the laws of Delaware.

21. This Court has personal jurisdiction over Acerta Netherlands because this action arises from actions of Acerta Netherlands directed towards Delaware. As indicated on the label for CALQUENCE® (acalabrutinib), Acerta Netherlands has licensed AstraZeneca, a Delaware entity with its principal place of business in Delaware, to distribute CALQUENCE® (acalabrutinib). The label for CALQUENCE® (acalabrutinib) lists "Wilmington, DE 19850" as the location for AstraZeneca's distribution of CALQUENCE® (acalabrutinib) and states that AstraZeneca's distribution is "[u]nder license" of Acerta Netherlands.

22. This Court also has personal jurisdiction over Acerta Netherlands because, *inter alia*, Acerta Netherlands intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Pharmacyclics in Delaware. For example, on information and belief, Acerta Netherlands will work in concert with Acerta USA and AstraZeneca to make, use, import, sell, and/or offer for sale CALQUENCE® (acalabrutinib) in Delaware, prior to the expiration of the Patents-in-Suit, thereby causing injury to Pharmacyclics in Delaware.

23. In the alternative, this Court has jurisdiction over Acerta Netherlands because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Pharmacyclics's claims arise under federal law; (b) Acerta Netherlands is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Acerta Netherlands has sufficient contacts with the United States as a whole, including, but not limited to, participating in the preparation and submission of the NDA for CALQUENCE® (acalabrutinib) to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Acerta Netherlands satisfies due process.

24. This Court has personal jurisdiction over AstraZeneca because AstraZeneca is a limited partnership organized and existing under the laws of Delaware.

25. Venue as to Acerta USA and AstraZeneca is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) because Acerta USA and AstraZeneca are Delaware entities. Venue as to Acerta Netherlands is proper in this judicial district under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Acerta Netherlands is subject to personal jurisdiction in this Judicial District, as set forth above.

COUNT I
INFRINGEMENT OF THE '908 PATENT

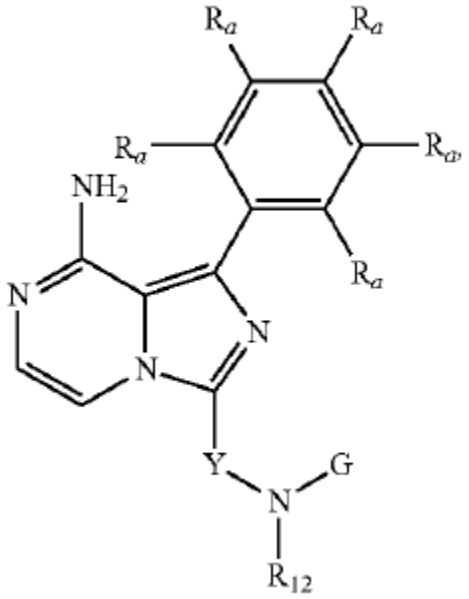
26. Pharmacyclics realleges and incorporates by reference each of the allegations set forth in paragraphs 1 through 25.

27. Upon information and belief, during the term of the '908 patent, Acerta has made, used, sold, offered for sale and/or imported CALQUENCE® (acalabrutinib).

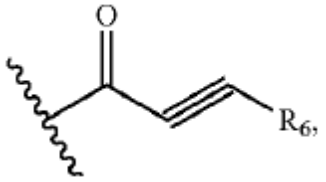
28. Acerta's manufacture, use, offer to sell, or sale of CALQUENCE® (acalabrutinib) within the United States, or importation of CALQUENCE® (acalabrutinib) into the United States, during the term of the '908 patent, infringes at least claims 1, 10, 12, 16, and 17 of the

'908 patent under 35 U.S.C. § 271(a).

29. Specifically, claims 1, 10, 12, 16, and 17 of the '908 patent all recite the following general chemical formula:



Claims 1, 10, 12, 16, and 17 of the '908 patent each permit R_a to be H or $–L_a–$(substituted or unsubstituted heteroaryl) wherein L_a is –C(O)NH. Claims 1, 10, 12, 16, and 17 of the '908 patent each permit Y and R_{12} taken together to be a 5-membered heterocyclic ring and G to be:



Claims 1, 10, 12, 16, and 17 of the '908 patent each permit R_6 to be a lower alkyl. Accordingly, CALQUENCE® (acalabrutinib) infringes at least claims 1, 10, 12, 16, and 17 of the '908 patent.

30. On information and belief, Acerta's sale, offer for sale, and distribution of CALQUENCE® (acalabrutinib) includes labeling that instructs patients to orally administer a therapeutically effective amount of CALQUENCE® (acalabrutinib) to humans.

31. The use of CALQUENCE® (acalabrutinib) by patients directly infringes at least claims 1, 10, 12, 16, and 17 of the '908 patent under 35 U.S.C. § 271(a).

32. On information and belief, this infringing use of CALQUENCE® (acalabrutinib) is at Acerta's behest, and with its intent, knowledge, and encouragement, and Acerta will actively induce, encourage, contribute to, aid, and abet this administration with knowledge that it is in contravention of the '908 patent. On information and belief, CALQUENCE® (acalabrutinib) has no substantial noninfringing uses.

33. As a result, Acerta is liable under 35 U.S.C. §§ 271(b) and/or (c) for inducing and/or contributing to infringement of the '908 patent by patients who use CALQUENCE® (acalabrutinib).

34. In addition, Acerta Netherlands is liable under 35 U.S.C. §§ 271(b) and/or (c) for inducing and/or contributing to infringement of the '908 patent by Acerta USA and/or AstraZeneca by aiding and abetting Acerta USA's and/or AstraZeneca's making, using, selling, offering for sale, and/or importing CALQUENCE® (acalabrutinib) in or into the United States.

35. Pharmacyclics has been damaged by Acerta's infringement of the '908 patent. Pharmacyclics has a right to recover from Acerta the damages sustained by Pharmacyclics as a result of Acerta's wrongful acts.

36. Acerta's infringement has been deliberate and willful, which permits Pharmacyclics to seek enhanced damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. On information and belief, Acerta has knowledge of the '908 patent. Acerta's infringement of the '908 patent has been with full and complete knowledge of the '908 patent and its applicability to CALQUENCE® (acalabrutinib) without a good faith belief that the '908 patent is invalid or not infringed.

37. Pharmacyclics has no adequate remedy at law to redress Acerta's infringement of the '908 patent.

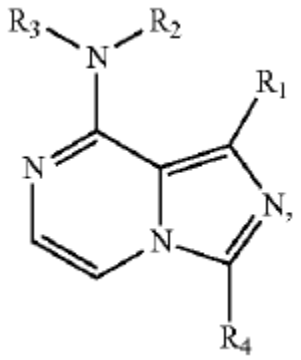
COUNT II
INFRINGEMENT OF THE '591 PATENT

38. Pharmacyclics realleges and incorporates by reference each of the allegations set forth in 1 through 37.

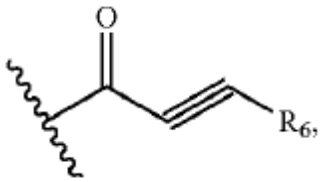
39. Upon information and belief, during the term of the '591 patent, Acerta has made, used, sold, offered for sale and/or imported CALQUENCE® (acalabrutinib).

40. Acerta's manufacture, use, offer to sell, or sale of CALQUENCE® (acalabrutinib) within the United States, or importation of CALQUENCE® (acalabrutinib) into the United States, during the term of the '591 patent, infringes at least claims 1, 2, 3, 19, and 20 of the '591 patent under 35 U.S.C. § 271(a).

41. Specifically, claims 1, 2, 3, 19, and 20 of the '591 patent all recite the following general chemical formula:



Claims 1, 2, 3, 19, and 20 of the '591 patent each permit R_1 to be L_2–(substituted aryl) where L_2 is a bond. Claims 1, 2, 3, 19, and 20 of the '591 patent each permit R_2 and R_3 to be hydrogen. Claims 1, 2, 3, 19, and 20 of the '591 patent each permit R_4 to be L_3–X–L_4–G where L_3–X–L_4 is a nitrogen containing heterocyclic ring and G to be:



Claims 1, 2, 3, 19, and 20 of the ’591 patent each permit R_6 to be a lower alkyl. Accordingly, CALQUENCE® (acalabrutinib) infringes at least claims 1, 2, 3, 19, and 20 of the ’591 patent.

42. On information and belief, Acerta’s sale, offer for sale, and distribution of CALQUENCE® (acalabrutinib) includes labeling that instructs patients to orally administer a therapeutically effective amount of CALQUENCE® (acalabrutinib) to humans.

43. The use of CALQUENCE® (acalabrutinib) by patients directly infringes at least claims 1, 2, 3, 19, and 20 of the ’591 patent under 35 U.S.C. § 271(a).

44. On information and belief, this infringing use of CALQUENCE® (acalabrutinib) is at Acerta’s behest, and with its intent, knowledge, and encouragement, and Acerta will actively induce, encourage, contribute to, aid, and abet this administration with knowledge that it is in contravention of the ’591 patent. On information and belief, CALQUENCE® (acalabrutinib) has no substantial noninfringing uses.

45. As a result, Acerta is liable under 35 U.S.C. §§ 271(b) and/or (c) for inducing and/or contributing to infringement of the ’591 patent by patients who use CALQUENCE® (acalabrutinib).

46. In addition, Acerta Netherlands is liable under 35 U.S.C. §§ 271(b) and/or (c) for inducing and/or contributing to infringement of the ’591 patent by Acerta USA and/or AstraZeneca by aiding and abetting Acerta USA’s and/or AstraZeneca’s making, using, selling, offering for sale, and/or importing CALQUENCE® (acalabrutinib) in or into the United States.

47. Pharmacyclics has been damaged by Acerta’s infringement of the ’591 patent.

Pharmacyclics has a right to recover from Acerta the damages sustained by Pharmacyclics as a result of Acerta's wrongful acts.

48. Acerta's infringement has been deliberate and willful, which permits Pharmacyclics to seek enhanced damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. On information and belief, Acerta has knowledge of the '591 patent. Acerta's infringement of the '591 patent has been with full and complete knowledge of the '591 patent and its applicability to CALQUENCE® (acalabrutinib) without a good faith belief that the '591 patent is invalid or not infringed.

49. Pharmacyclics has no adequate remedy at law to redress Acerta's infringement of the '591 patent.

COUNT III
INFRINGEMENT OF THE '182 PATENT

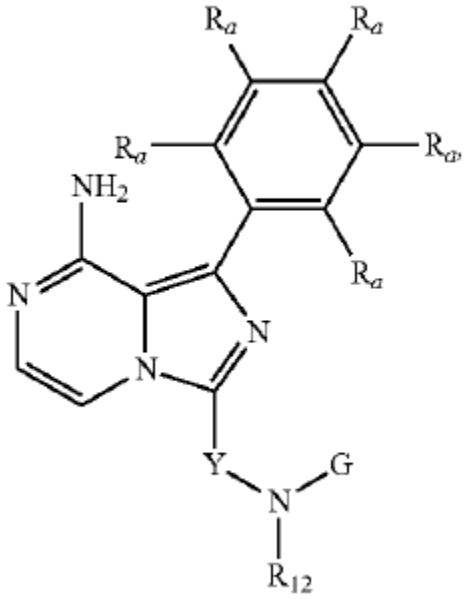
50. Pharmacyclics realleges and incorporates by reference each of the allegations set forth in 1 through 49.

51. Upon information and belief, during the term of the '182 patent, Acerta has made, used, sold, offered for sale and/or imported CALQUENCE® (acalabrutinib). Upon information and belief, during the term of the '182 patent, patients have used CALQUENCE® (acalabrutinib) to treat MCL.

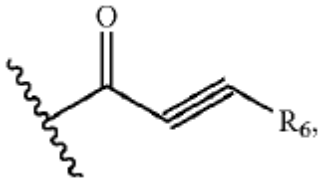
52. Acerta's commercial manufacture, use, offer to sell, or sale of CALQUENCE® (acalabrutinib) within the United States, or importation of CALQUENCE® (acalabrutinib) into the United States and subsequent use by patients of CALQUENCE® (acalabrutinib) to treat MCL, during the term of the '182 patent, infringes at least claims 1, 6, 8, 17, 19 and 20 of the '182 patent under 35 U.S.C. § 271(a).

53. Specifically, claims 1, 6, 8, 17, 19 and 20 of the '182 patent all recite the follow-

ing general chemical formula:



Claims 1, 6, 8, 17, 19 and 20 of the '182 patent each permit R_a to be H or $–L_a–$(substituted or unsubstituted heteroaryl) wherein L_a is –C(O)NH. Claims 1, 6, 8, 17, 19 and 20 of the '182 patent each permit Y and R_{12} taken together to be a 5-membered heterocyclic ring and G to be:



Claims 1, 6, 8, 17, 19 and 20 of the '182 patent each permit R_6 to be a lower alkyl. Accordingly, when used to treat MCL, CALQUENCE® (acalabrutinib) infringes at least claims 1, 6, 8, 17, 19 and 20 of the '182 patent.

54. On information and belief, Acerta's sale, offer for sale, and distribution of CALQUENCE® (acalabrutinib) includes labeling indicating that it has been approved by FDA to treat MCL, a B-cell proliferative disorder. The labeling also instructs patients to administer a therapeutically effective amount of CALQUENCE® (acalabrutinib) to humans to treat MCL. On

information and belief, Acerta specifically intends that CALQUENCE® (acalabrutinib) be used to treat MCL.

55. The use by patients of CALQUENCE® (acalabrutinib) to treat MCL directly infringes at least claims 1, 6, 8, 17, 19 and 20 of the '182 patent under 35 U.S.C. § 271(a).

56. On information and belief, this infringing use of CALQUENCE® (acalabrutinib) is at Acerta's behest, and with its intent, knowledge, and encouragement, and Acerta will actively induce, encourage, contribute to, aid, and abet this administration with knowledge that it is in contravention of the '182 patent. On information and belief, CALQUENCE® (acalabrutinib) has no substantial noninfringing uses, and Acerta knows CALQUENCE® (acalabrutinib) is especially made or especially adapted for use in infringement of the '182 patent.

57. As a result, Acerta is liable under 35 U.S.C. §§ 271(b) and/or (c) for inducing and/or contributing to infringement of the '182 patent by patients who use CALQUENCE® (acalabrutinib).

58. In addition, Acerta Netherlands is liable under 35 U.S.C. §§ 271(b) and/or (c) for inducing and/or contributing to infringement of the '182 patent by Acerta USA by aiding and abetting Acerta USA's making, using, selling, offering for sale and/or importing CALQUENCE® (acalabrutinib) in or into the United States.

59. Pharmacyclics has been damaged by Acerta's infringement of the '182 patent. Pharmacyclics has a right to recover from Acerta the damages sustained by Pharmacyclics as a result of Acerta's wrongful acts.

60. Acerta's infringement has been deliberate and willful, which permits Pharmacyclics to seek enhanced damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. On information and belief, Acerta has knowledge

of the ’182 patent. Acerta’s infringement of the ’182 patent has been with full and complete knowledge of the ’182 patent and its applicability to CALQUENCE® (acalabrutinib) without a good faith belief that the ’182 patent is invalid or not infringed.

61. Pharmacyclics has no adequate remedy at law to redress Acerta’s infringement of the ’182 patent.

JURY DEMAND

62. Pharmacyclics requests a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Pharmacyclics respectfully requests:

1. A judgment that the ’908, ’591, and ’182 patents are infringed by Acerta’s manufacture, offers to sell, sales, and uses within the United States, and importation into the United States, of CALQUENCE® (acalabrutinib);

2. A judgment that Acerta’s manufacture, offers to sell, sales, and uses within the United States, and importation into the United States, of CALQUENCE® (acalabrutinib) has induced and contributed to the infringement of the ’908, ’591, and ’182 patents by others;

3. An order granting any equitable relief that the Court deems appropriate;

4. An accounting of all damages sustained by Pharmacyclics as a result of Acerta’s infringing activities;

5. Actual damages together with prejudgment interest;

6. That Acerta’s infringement be deemed willful and that Pharmacyclics be awarded enhanced damages under 35 U.S.C. § 284;

7. That the case be found exceptional under 35 U.S.C. § 285 and that Pharmacyclics be awarded its attorneys’ fees;

8. Costs and expenses in this action; and

9. Such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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