IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., Plaintiff, v. ACTAVIS PLC, ACTAVIS, INC., WATSON LABORATORIES, INC., and ACTAVIS PHARMA, INC. (F/K/A WATSON PHARMA, INC.), Defendants.	CIVIL ACTION NO. 2:14-cv-188

ALLERGAN, INC.'S COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendants Actavis plc, Actavis, Inc., Watson Laboratories, Inc., ("Watson Laboratories"), and Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) ("Actavis Pharma") (collectively, the "Defendants"), Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff"), by its attorneys, alleges as follows:

The Nature of the Action

1. In this action, Allergan seeks to oppose Defendants' premature and improper triggering of the litigation process under the Drug Price Competition and Patent Term Restoration Act, as amended (the "Hatch-Waxman Act"), the statute that provides for the resolution of patent disputes over Abbreviated New Drug Applications ("ANDA") for generic drugs.

2. As will be described further below, the "receipt" of an ANDA by the U.S. Food and Drug Administration ("FDA") is a legally-defined action by the FDA, and is an event

marked by a specific written notification from the FDA to the ANDA applicant. *See* 21 C.F.R. § 314.101(b). Official receipt of an ANDA by the FDA is a prerequisite that must be satisfied before ANDA applicants like Defendants may lawfully send notification of the ANDA and a "Paragraph IV Certification" contained therein (a "Paragraph IV Notification") to a patent holder like Allergan. 21 U.S.C. § 355(j)(2)(B)(ii).

3. Such a Paragraph IV Notification, if valid, starts a statutorily defined time period in which a patent holder like Allergan must sue for patent infringement, or risk losing its rights under the Hatch-Waxman Act, including a statutory 30-month stay on ANDA approval during which time FDA cannot approve the ANDA under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3). Congress designed this stay in part to allow for the litigation of patent disputes over ANDAs before ANDA approval.

4. Defendants have submitted ANDA No. 203463 to FDA seeking approval of a generic version of Allergan's RESTASIS® product, cyclosporine ophthalmic emulsion 0.05%. RESTASIS® is an innovative and commercially successful treatment for dry eye.

5. As of the date of this complaint, ANDA No. 203463 has not been officially "received" by the FDA. Nonetheless, on January 21, 2014, Allergan received purported Paragraph IV Notifications (dated January 14, 2014 and January 15, 2014) from Defendants related to ANDA No. 203463. The purported Paragraph IV Notifications stated that one of Allergan's patents covering RESTASIS®, United States Patent No. 8,629,111 ("the '111 Patent"), is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic drug products described in Defendant's ANDA No. 203463.

6. Because, by their own admission, and FDA's confirmation, Defendants' ANDA No. 203463 has not been officially received by FDA, Defendants were not authorized to, and could not lawfully, send a Paragraph IV Notification to Allergan.

7. Defendants' premature attempt to trigger the ANDA patent litigation process is in violation of federal law. This Court should declare Defendant's purported Paragraph IV Notifications and attempts to trigger the ANDA litigation process improper and without legal effect.

8. In the alternative, because the proposed generic product, if approved, will infringe the '111 Patent, the filing of a proper ANDA containing a Paragraph IV certification and received for filing by FDA would be an act of infringement under 35 U.S.C. § 271(e)(2).

9. Accordingly, if the purported Paragraph IV Notifications received by Allergan are deemed sufficient by the Court to trigger the deadline for Allergan to sue Defendants under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3), Allergan seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and other applicable laws for Defendants' infringement of the '111 patent.

The Parties

10. Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

11. On information and belief, Actavis plc is incorporated under the laws of Ireland, with principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland and a place of business in Morris Corporate Center III 400 Interpace Parkway Parsippany, NJ 07054.

12. On information and belief, Watson Pharmaceuticals, Inc., former parent company to defendants Actavis Pharma (then known as Watson Pharma, Inc.), Watson Laboratories, and

Actavis, Inc., changed its name to Actavis, Inc. on or about January 24, 2013 as a result of Watson Pharmaceuticals, Inc.'s acquisition of Swiss-based Actavis Group on or around October 2012.

13. On information and belief, on or about October 1, 2013, and pursuant to its purpose of facilitating business between Actavis, Inc. and Warner Chilcott plc, Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.) became a wholly-owned subsidiary of parent company Actavis plc. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada with corporate headquarters at 400 Interpace Parkway, Parsippany, New Jersey 07054.

14. On information and belief, defendant Watson Laboratories is a corporation organized and existing under the laws of the State of Nevada with its principal place of business at 132 Business Center Drive, Corona, California, 92880, and having a registered office at 400 Interpace Parkway, Parsippany, New Jersey 07054.

15. On information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

16. On information and belief, on or before February 25, 2014, Watson Pharma, Inc**.** changed its name to Actavis Pharma, Inc.

17. On information and belief, Watson Laboratories and Actavis Pharma are wholly-owned subsidiaries of Actavis, Inc., which, in turn, is a wholly-owned subsidiary of Actavis plc.

Venue and Jurisdiction

18. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§

1331, 1338(a) (patent infringement). Relief is sought under 28 U.S.C §§ 2201, 2202 (declaratory judgment) for count 1, and 35 U.S.C. § 271(e)(2) for alternative count 2.

19. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

20. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including RESTASIS® (cyclosporine ophthalmic emulsion, 0.05%). Allergan employs approximately 600 individuals in Texas, more than in any other U.S. state except California.

21. This Court has personal jurisdiction over Actavis plc, Actavis, Inc., Watson Laboratories, and Actavis Pharma individually, and as Defendants collectively, by virtue of systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Allergan and the causes of action Allergan raises here, as alleged herein.

22. Specifically, this Court has personal jurisdiction over Actavis plc, Actavis, Inc., Watson Laboratories, and Actavis Pharma individually, and as Defendants collectively, either directly or through an agent, including through each other, because Defendants regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

23. On information and belief, Actavis plc is engaged in the worldwide marketing, production, and distribution of generic pharmaceutical products, including in this judicial district, through at least the actions of its wholly owned subsidiary, Actavis, Inc., and Actavis, Inc.'s subsidiaries Watson Laboratories and Actavis Pharma.

24. On information and belief, Actavis, Inc. is in the business of developing, manufacturing, and/or marketing pharmaceutical products in the United States, including in this

judicial district, through at least the actions of its subsidiaries Watson Laboratories and Actavis Pharma.

25. On information and belief, in 2013, Actavis, Inc. itself and through Actavis Pharma and/or Watson Laboratories, for the benefit of Defendants, sold approximately $1,052,980,121.72 of products in Texas, approximately $123,092,838.87 of which were sold in this judicial district.

26. On information and belief, Actavis plc, Actavis, Inc., Watson Laboratories, and Actavis Pharma operate in whole or in part from one or more shared facilities in New Jersey and California.

27. On information and belief, Watson Laboratories itself and through Actavis Pharma, Actavis plc, and Actavis, Inc., is engaged in the development, marketing, sale, and distribution of branded and generic pharmaceutical products throughout the United States, and in this judicial district.

28. On information and belief, Watson Laboratories has previously admitted to this Court that drug products of Watson Laboratories are listed on the Texas prescription drug formulary. *See Allergan, Inc. v. Watson Laboratories, Inc.*, 2:10-cv-344, D.I.17 at 3 (E.D. Tex.); *Allergan, Inc. v. Sandoz, Inc. et. al.*, 6:11-cv-441, D.I. 17 at 3 (E.D. Tex.).

29. On information and belief, Watson Laboratories previously availed itself of this forum for purposes of litigating patent disputes regarding its ANDA products. For example, Watson Laboratories has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Watson Laboratories, Inc.*, Case No. 2:10-cv-344, D.I. 17 at 13 (E.D. Tex.); *Allergan, Inc. v. Sandoz, Inc. et. al.*, 6:11-cv-441, D.I. 135 at 13 (E.D. Tex.).

30. On information and belief, Watson Laboratories, Actavis Pharma (then known as Watson Pharma), and Actavis, Inc. (then known as Watson Pharmaceuticals) has not contested personal jurisdiction in this district in at least one other litigation. *See Allergan, Inc. v. Sandoz, Inc. et. al.*, 6:11-cv-411, D.I. 135, *see, e.g.*, paras. 61-62 (E.D. Tex.).

31. On information and belief, Actavis Pharma itself and through Watson Laboratories, Actavis plc, and Actavis, Inc., is in the business of distributing and/or selling generic pharmaceutical products in the United States market, including products made by Watson Laboratories.

32. On information and belief, Actavis Pharma markets and sells generic drugs manufactured by Watson Laboratories throughout the United States, including in this judicial district.

33. On information and belief, Actavis Pharma has entered into contracts with the Texas Department of State Health Service to sell prescription drugs in Texas.

34. On information and belief, Actavis Pharma did not contest personal jurisdiction in this jurisdiction. Further, Watson Laboratories, Actavis Pharma, and Actavis, Inc. have admitted that Actavis Pharma (then known as Watson Pharma, Inc.) is a licensed drug distributor in Texas in at least one other litigation. *See Allergan, Inc. v. Sandoz, Inc. et. al.*, 6:11-cv-411, D.I. 135, *see e.g.*, paras. 64 (E.D. Tex.).

35. On information and belief, Defendants' products appear on the Preferred Drug List for the Texas Medicaid program and are available to the millions of Texans in this judicial district and throughout the State who participate in the Texas Medicaid program.

36. On information and belief, as a Medicaid participant, Defendants are required to sell products to Veteran's Administration and Public Health Services facilities, of which there

are over 200 in Texas. The Department of Veteran's Affairs Formulary lists Defendants' products as being available to its participants.

37. On information and belief, Defendants have entered into arrangements with Texas entities to have its products appear on the formulary lists of Blue Cross Blue Shield of Texas and Scott and White, two major managed care and health plan companies in Texas.

38. Upon information and belief, these Defendants are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including the generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 203463.

39. Defendants know and intend that their proposed Cyclosporine Ophthalmic Emulsion, 0.05% will be distributed and sold in the United States, including in Texas.

Factual Background

A. Background of the '111 Patent

40. The '111 Patent, entitled "Methods of Providing Therapeutic Effects Using Cyclosporine Components," issued to Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power on January 14, 2014. A true and correct copy of the '111 Patent is attached to this complaint as Exhibit 1.

41. Allergan, as assignee, owns the entire right, title, and interest in the '111 Patent.

42. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

43. In conjunction with that NDA, Allergan listed with FDA the '111 Patent, and other patents, as covering the approved formulation of RESTASIS®, or methods of using the

same. FDA has published the '111 Patent in its list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."

44. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '111 Patent.

B. The Hatch-Waxman Act is a Compromise Between the Interests of Innovator and Generic Pharmaceutical Companies and Allows for the ANDA Litigation Process Only When an ANDA is Officially Received by FDA

45. The statute governing generic drug approvals is known colloquially as the Hatch-Waxman Act. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013). It is widely understood to have been enacted by Congress as a compromise between the competing interests of innovator and generic drug companies.

46. An innovator pharmaceutical company seeking to market a new pharmaceutical drug in the United States must first obtain approval from FDA, most often by filing an NDA. *See* 21 U.S.C. § 355(a). Among other matters, the sponsor of the NDA must submit information to FDA on all patents owned or licensed by the NDA holder claiming the drug that is either the subject of the NDA or a method of using that drug. FDA then lists this patent information in the Orange Book. *See* 21 U.S.C. § 355(b)(1) and (c)(2).

47. By contrast, a generic drug company seeking to market a generic copy of a previously approved drug is not required to submit a full NDA, but need only file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug application is "abbreviated" because the company may use and take advantage of the innovator company's data and FDA's prior safety and efficacy findings by demonstrating, among other things, that the generic drug is bioequivalent to the innovator company's previously approved drug.

48. A generic drug company undertakes these activities under the Hatch-Waxman Act's "safe harbor" from patent infringement. *See* 35 U.S.C. § 271(e)(1). Under that provision, actions of the generic drug company that otherwise might infringe the patents of the innovator company—such as developing the generic copy of an innovator drug—are immune from an infringement charge.

49. This process results in an enormous cost and time savings to the generic drug company. Reliance on the innovator company's data and the ability to "free ride" on the innovator company's development saves the generic drug company countless millions of dollars and years in development and clinical research costs. One third-party source has estimated that the median cost of developing a single innovator drug is $350 million when considering all the failed efforts, and can reach a median cost of $5.5 billion per drug for those companies bringing between eight and thirteen drugs to market over the course of a decade. Matthew Herper, "The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change," www.forbes.com (last accessed on Feb. 27, 2014). By contrast, an ANDA costs a generic drug company a tiny fraction of these amounts.

50. In partial exchange for these valuable rights granted by statute to generic drug makers, Congress has put in place an intricate process for resolving patent disputes relating to generic drugs that allows an innovator company to pursue patent infringement claims before a generic company may put its product on the market. This pre-marketing patent resolution process protects both patent holders and generic applicants. This is important because, once a generic drug product is offered for sale, the market for the innovator product is typically irreparably destroyed, often within a matter of weeks. Conversely, a generic product launched "at risk" without certainty provided by a prior adjudication of non-infringement could lead to a

damages judgment that could put a generic company out of business. Thus, both innovators and generics benefit from the orderly pre-market resolution of ANDA patent infringement cases.

51. Under this process, an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the innovator drug. *See* 21 U.S.C. §355(j)(2)(A)(viii), 21 C.F.R. § 314.94(a)(12). One of the certifications that an ANDA filer may provide is known as a "Paragraph IV Certification," in which the ANDA filer states its belief that a listed patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA was submitted. *See* 21 U.S.C. § 355(j)(2)(A)(viii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

52. When an applicant submits an ANDA to FDA, FDA conducts a preliminary review of the application to ensure it is sufficiently complete to permit a substantive review. 21 C.F.R. § 314.101(b). Only after FDA notifies the applicant that its ANDA is substantially complete is the ANDA considered "received," by the FDA. *Id.* Importantly, the ANDA applicant may not send the Paragraph IV Notification before being notified by FDA that the FDA has received the ANDA. 21 U.S.C. § 355(j)(2)(B)(ii)(I); *SB Pharmco Puerto Rico, Inc. v. Mut. Pharm. Co., Inc.*, 552 F. Supp. 2d 500, 508 (E.D. Pa. 2008) *dismissed*, 318 F. App'x 897 (Fed. Cir. 2008).

53. The applicant for an ANDA with a Paragraph IV certification that has been received by FDA must provide notice to both the owner of the listed patent and the holder of the NDA for the listed drug. Known as a "Paragraph IV Notification," this letter must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid, unenforceable, and/or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

54. Upon receiving a lawful Paragraph IV Notification from an ANDA filer, the innovator company has just 45 days to file suit against the generic drug company for patent infringement, if the innovator company believes such a suit is warranted and wishes to gain all of the benefits provided under the Hatch-Waxman Act. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013); *see also* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.95(f). If suit is filed within that time frame, the approval of the generic application may be subject to a 30-month stay – i.e., FDA cannot approve the generic drug until either the litigation is resolved in favor of the generic drug company or a 30-month time period has passed, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3).

55. This notification process and 30-month stay are critical parts of the bargain underlying the Hatch-Waxman Act. They are the primary mechanism provided by Congress that gives innovator patentees such as Allergan the ability to litigate the patent infringement case before a generic product is placed on the market, thus avoiding the irreparable harm that results when the generic product is launched.

56. Although the Hatch-Waxman Act forbids such conduct, a generic drug company may nonetheless have interest in seeking to trigger the above-described litigation process and 30-month stay, prematurely. By prematurely notifying a patentee, and thus causing the innovator company to file suit sooner than would otherwise be required, the ANDA filer may be able to cause the process, including the 30-month stay, to run sooner than it otherwise would. An ANDA applicant might also believe a premature Paragraph IV Notification can provide a competitive advantage over other generic applicants by delaying other generic approvals under the so-called 180-day exclusivity period available to the first Paragraph IV ANDA filer.

57. Regardless of the motives, premature notification undermines the careful balance of Hatch-Waxman. Consequently, federal law provides for the timing of Paragraph IV Notifications that trigger the 45-day window for innovator companies to bring suit and protect their rights. The statute and regulations permit an ANDA applicant to send such notifications only after the FDA has officially "received" an ANDA, i.e., found that the ANDA "is sufficiently complete for substantive review." 21 U.S.C. §355(j)(2)(B)(ii); 21 C.F.R. § 314.95(b).

C. Acts Giving Rise to This Action

58. On or about January 21, 2014, Allergan received a first letter on Watson Laboratories letterhead described as a "Notification of Certification for U.S. Patent No. 8,629,111 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act," dated January 14, 2014 and signed by Joyce Delgaudio, Director of Regulatory Affairs. Allergan received an identical second letter (dated January 15, 2014) also on January 21, 2014. A redacted copy of the purported Paragraph IV Notifications is attached hereto as Exhibit 2.

59. On information and belief, Joyce Delgaudio is the Director of Regulatory Affairs for Actavis, Inc., and has responsibilities for both Watson Laboratories and Actavis Pharma.

60. Both purported Paragraph IV Notifications identified Brian Anderson, Esq., counsel for Actavis, Inc., as the person to whom follow-up correspondence should be directed.

61. On information and belief, Watson Laboratories sent the January 14 and 15 purported Paragraph IV Notifications for the benefit of all Defendants.

62. The January 14 and 15 purported Paragraph IV Notifications stated that Watson Laboratories had submitted ANDA No. 203463 under Section 505(j) of the FDCA, seeking approval to engage in the commercial manufacture, use, or sale of cyclosporine ophthalmic

emulsion, 0.05%--i.e., a generic version of RESTASIS®. On information and belief, Watson Laboratories submitted ANDA No. 203463 for the benefit of all Defendants.

63. The January 14 and 15 purported Paragraph IV Notification letters stated that "FDA has received" ANDA No. 203463. On information and belief, this statement was knowingly and willfully false.

64. On January 22, 2014, Actavis plc issued the press release attached hereto as Exhibit 3. That press release stated as follows, in reference to ANDA No. 203463:

> Actavis' ANDA was submitted prior to the issuance of FDA guidance related to approval of generic versions of RESTASIS® products. Following issuance of FDA guidance in June 2013, ***FDA notified Actavis' subsidiary [Watson Laboratories] that it had refused to receive the ANDA for filing***. Actavis disagrees with FDA's refusal to receive its ANDA for filing and remains in discussions with FDA concerning the filing status of its application.

(Emphasis added).

65. On February 7, 2014, counsel for Allergan, Jonathan E. Singer of Fish & Richardson, P.C., sent a letter on Allergan's behalf to Brian Anderson requesting that Defendants withdraw their purported Paragraph IV Notification in light of its prematurity, and provide all correspondence between Defendants and FDA regarding the latter's acceptance, or lack thereof, of ANDA No. 203463. That letter is attached hereto as Exhibit 4. As of the date of this complaint, Defendants have not responded to this letter.

66. On February 11, 2014, counsel for Allergan sent a letter on Allergan's behalf to FDA requesting confirmation that FDA had not received for review an ANDA from Watson for cyclosporine ophthalmic emulsion, 0.05%. On March 4, 2014, FDA sent a letter in response, attached hereto as Exhibit 5.

67. FDA's letter explains that "FDA maintains a public list of drug products for which an ANDA has been received by FDA containing a 'Paragraph IV' patent certification."

(Exhibit 5 at 2). This list, known as FDA's Paragraph IV Patent Certifications Database, is available at: http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf. The letter further explains that this list includes "the generic name of the drug product, dosage form, and strength(s) subject to a Paragraph IV certification, the name of reference listed drug (RLD), and the date on which the first ***substantially complete*** ANDA was submitted to the agency." (Exhibit 5 at 2) (emphasis added).

68. As of the date of FDA's letter, FDA's Paragraph IV Patent Certifications Database contained no listing for a substantially complete ANDA for cyclosporine ophthalmic emulsion 0.05% that contains a Paragraph IV certification, nor did it have any listing for such a product on any date before March 4, 2014.

69. FDA's March 4th letter stated that, while "Watson has submitted" an ANDA for cyclosporine ophthalmic emulsion, 0.05% for FDA review, that FDA "confirm[ed] that FDA's public list of drug products for which an ANDA has been received by FDA containing a Paragraph IV patent certification is up-to-date for this product." (Exhibit 5 at 3).

70. As of the date of the filing of this complaint, FDA's Paragraph IV Patent Certifications Database still contains no listing for a substantially complete ANDA for cyclosporine ophthalmic emulsion 0.05% that contains a paragraph IV certification. A print-out of that Database as of the date of this complaint is attached hereto as Exhibit 6.

71. Defendants' ANDA has not yet been received for review by FDA.

72. This suit is being filed within 45 days of Allergan's January 21, 2014 receipt of the purported Paragraph IV Notifications.

Count I: Declaratory Judgment of False Paragraph IV Notification

73. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

74. At the time of their purported Paragraph IV Notifications, Defendant's ANDA for Cyclosporine Ophthalmic Emulsion, 0.05% had not been received by FDA as sufficiently complete for substantive review. Absent an ANDA that has been received by FDA as sufficiently complete to permit substantive review, Defendants have no lawful basis to trigger the ANDA patent litigation process.

75. Consequently, Defendant's purported Paragraph IV Notifications to Allergan are improper, null, void, and without legal effect.

76. On information and belief, Defendants know that their purported Paragraph IV Notifications to Allergan falsely stated that FDA "has received" their ANDA.

77. An actual, substantial, and justiciable controversy exists between Defendants and Allergan regarding whether the purported Paragraph IV Notifications are null, void, and without legal effect and whether Defendants improperly triggered the ANDA litigation process.

78. The controversy concerning the validity and effectiveness of the purported Paragraph IV Notifications will cause Allergan to suffer substantial prejudice and unnecessary legal fees and other costs unless the controversy and its surrounding uncertainty are resolved by the Court.

79. Allergan is entitled to a declaration that: (1) the purported Paragraph IV Notifications are improper, null, void, and without legal effect and that Defendants were not entitled to trigger properly the Hatch-Waxman litigation process; (2) this Court has no jurisdiction over Allergan's alternative claim regarding the '111 Patent because the purported Paragraph IV Notifications are null, void, and without legal effect; (3) the Paragraph IV

Notifications did not commence the 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4) if and when FDA receives the ANDA, Defendants must serve a new Paragraph IV Notification on Allergan pursuant to 21 U.S.C. § 355(j)(2)(A)(viii); and (5) no 30-month stay will begin until Defendants send a valid Paragraph IV Notification to Allergan following FDA receipt of the ANDA for substantive review.

In the Alternative, Count II: Infringement of '111 Patent Under 35 U.S.C. § 271 (e)(2)(A)

80. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

81. Defendants submitted ANDA No. 203463 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% throughout the United States. Assuming solely for purposes of this Count that the ANDA was received by FDA as sufficiently complete for substantive review before January 14, 2014 and/or the Paragraph IV Notifications are deemed to have been properly sent to Allergan, by submitting their ANDA, Defendants have committed an act of infringement of the '111 Patent under 35 U.S.C. § 271 (e)(2)(A).

82. If the Paragraph IV Notifications are deemed sufficient by this Court to trigger the deadline for Allergan to sue Defendants under 21 U.S.C. § 355(j)(5)(B), judgment should be entered that Defendants have infringed the '111 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203463 under Section 505(j) of the FDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Defendants' proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% will constitute acts of infringement of the '111 Patent under 35 U.S.C. § 271(a) and (b).

83. Defendants have knowledge of the '111 Patent.

84. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed Cyclosporine Ophthalmic Emulsion, 0.05% will constitute an act of direct infringement of the '111 Patent.

85. The commercial offer for sale and sale of Defendants' proposed Cyclosporine Ophthalmic Emulsion, 0.05% will constitute an act of induced infringement of the '111 Patent. Defendants intend for doctors and patients to use their proposed Cyclosporine Ophthalmic Emulsion, 0.05%, which use will be direct infringement of the '111 patent.

86. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% in violation of Allergan's patent rights will cause irreparable harm to Allergan for which damages are inadequate.

Jury Trial Demand

Pursuant to Federal Rule of Civil Procedure 38(b), Allergan hereby demands a trial by jury of all issues so triable.

Prayer for Relief

Allergan respectfully requests for the following relief:

A. Declaratory Judgment for Improper Paragraph IV Notification:

1. A declaratory judgment: (1) that Defendants' Paragraph IV Notifications are improper, null, void, and without legal effect and that Defendants were not entitled to trigger the Hatch-Waxman patent litigation process; (2) that this Court has no jurisdiction over Allergan's alternative claims regarding the '111 Patent because the Paragraph IV notifications are null, void, and without legal effect; (3) the Paragraph IV Notifications did not commence the 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4)

if and when FDA accepts Defendants' ANDA, Defendants must serve a new Paragraph IV Notification on Allergan pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); and (5) no 30-month stay will begin until Defendants have sent a valid Paragraph IV Notification to Allergan following FDA acceptance for review of Defendants' ANDA; and

2. An order preliminarily and permanently enjoining Defendants: (1) to withdraw their improper and ineffective Paragraph IV Notifications; and (2) to refrain from sending any new Paragraph IV Notifications to Allergan unless and until FDA has notified Defendants that the ANDA is sufficiently complete to be deemed received for review and has been formally received by the FDA for review.

3. An award to Allergan of its reasonable attorney's fees and costs in bringing this action, including under 17 U.S.C. § 1827.

B. In the Alternative, a Finding of Infringement Under 35 U.S.C. § 271(e)(2)(A):

4. If Defendants' Paragraph IV Notification is deemed sufficient by this Court to trigger the deadline for Allergan to sue Defendants under 21 U.S.C. § 355(j)(5)(B), a judgment that Defendants have infringed the '111 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203463 under Section 505(j) of the FDCA;

5. A finding that the '111 Patent is valid and enforceable;

6. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 203463 shall be a date which is not earlier than the latest expiration date of the '111 Patent, as extended by any applicable periods of exclusivity;

7. If Defendants attempt to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of Defendants' generic product disclosed in their ANDA No. 203463 prior to the expiration of the '111 Patent, as

extended by any such periods of exclusivity, a judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284, and an accounting;

8. An order under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, their subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture use, offer to sell, or importation into the United States, of any drug product covered by the '111 Patent, including RESTASIS®;

9. An accounting for infringing sales not presented at trial and an award by the Court of any additional damages for any such infringing sales;

10. A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs; and

11. An award of any such other and further relief as the Court may deem just and proper.

Dated: March 6, 2014

Respectfully submitted,

FISH & RICHARDSON P.C.

By: /s/ Wesley Hill (by permission Jonathan E. Singer)

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COUNSEL FOR PLAINTIFF ALLERGAN, INC.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on this the 6th day of March, 2014.

/s/ Wesley Hill
Wesley Hill