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

ALLERGAN, INC.,

Plaintiff,

V.

SANDOZ, INC., HI-TECH PHARMACAL CO., LUPIN LTD., LUPIN PHARMACEUTICALS INC., WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC., and WATSON PHARMA, INC.

Defendants.

C.A. No. 6:11-cv-441 (MHS)

Consolidated Action

ALLERGAN'S AMENDED COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendants Sandoz, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., Hi-Tech Pharmacal Co., Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., and Watson Pharma, Inc. ("Defendants"), Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff"), by its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 5,688,819 ("the '819 patent"), 7,851,504 ("the '504 patent"), 8,278,353 ("the '353 patent"), 8,299,118 ("the '118 patent"), 8,309,605 ("the '605 patent), and 8,338,479 ("the '479 patent") under 35 U.S.C. § 271(e)(2) and for a declaratory judgment of infringement under 28 U.S.C. § 2201-02 and 35 U.S.C. § 271(a), (b), and (c).

The Parties

2. 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.

- 3. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including Lumigan®. Allergan employs approximately 600 individuals in Texas, more than in any other U.S. state except California.
- 4. On information and belief, defendant Sandoz, Inc. ("Sandoz") is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.
- 5. On information and belief, Lupin Ltd. is a corporation organized under the laws of India with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India.
- 6. On information and belief, Lupin Ltd. is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing generic drugs throughout the United States, including in this judicial district, through operating subsidiaries including Lupin Pharmaceuticals.
- 7. On information and belief, Lupin Pharmaceuticals Inc. ("Lupin Pharmaceuticals"), a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the Commonwealth of Virginia, with its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.
- 8. On information and belief, Lupin Pharmaceuticals is in the business of offering for sale and selling generic drugs throughout the United States, including in this judicial district, and regularly acts as Lupin Ltd.'s U.S. agent on filings with the FDA. Lupin Ltd. and Lupin Pharmaceuticals are referred to collectively as "Lupin."

- 9. On information and belief, and consistent with their prior practice, Lupin Pharmaceuticals is the U.S. agent for Lupin Ltd.'s Abbreviated New Drug Application ("ANDA") No. 202911 (defined below). Lupin Pharmaceuticals has admitted to being Lupin Ltd.'s U.S. agent for ANDAs in multiple actions, including, among others, *Astrazeneca AB et al. v. Lupin Ltd. & Lupin Pharmaceuticals Inc.*, Civil Action No. 3:11-cv-4275-JAP-DEA (D.N.J.). On information and belief, and consistent with their prior practice, Lupin Ltd. and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA No. 202911. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals actively participated in the preparation of ANDA No. 202911 and both entities submitted ANDA No. 202911 to the FDA.
- approval of ANDA No. 202911, Lupin Ltd. and Lupin Pharmaceuticals will act in concert to distribute and sell Lupin's proposed generic product, Bimatoprost Ophthalmic Solution, 0.01%, throughout the United States, including in Texas. On information and belief, following FDA approval of ANDA 202911, Lupin Ltd. and Lupin Pharmaceuticals know and intend that Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% will be distributed and sold in the United States, including in Texas.
- 11. On information and belief, Hi-Tech Pharmacal Co. ("Hi-Tech") is a corporation incorporated under the laws of the State of Delaware, having a place of business at 369 Bayview Avenue, Amityville, NY 11701.
- 12. On information and belief, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California 92880.

- 13. On information and belief, Watson Pharmaceuticals, both directly and through its subsidiaries, is engaged in the development, marketing, sale, and distribution of brand and generic pharmaceutical products throughout the United States, included Texas.
- 14. On information and belief, Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California 92880.
- 15. On information and belief, Watson Laboratories is a wholly-owned subsidiary of defendant Watson Pharmaceuticals, and the two share at least some common officers and directors.
- 16. On information and belief, Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 360 Mount Hemble Avenue, Morristown, New Jersey 07962.
- 17. On information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two share at least some common officers. Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are collectively referred to as "Watson."
- 18. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma 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 Bimatoprost Ophthalmic Solution, 0.01% described in ANDA No. 203748 (defined below).
- 19. Watson knows and intends that its proposed Bimatoprost Ophthalmic Solution,0.01% will be distributed and sold in the United States, including in Texas.

Venue and Jurisdiction

- 20. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.
 - 21. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

A. Personal Jurisdiction over Sandoz

- 22. This Court has personal jurisdiction over Sandoz by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein.
- 23. Specifically, this Court has personal jurisdiction over Sandoz because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.
- 24. On information and belief, Sandoz has indicated that it is subject to personal jurisdiction in any judicial district in which it conducts business.
- 25. On information and belief, Sandoz is a licensed wholesale distributor of prescription drugs in Texas, and sells over 180 products in Texas.
- 26. On information and belief, in 2010 Sandoz sold over \$1 billion of products in Texas, over \$70 million of which were sold in this judicial district.
- 27. On information and belief, from 2007 to 2010, Sandoz sold over \$3 billion of products in Texas, over \$230 million of which were sold in this judicial district. On information and belief, Sandoz's sales in Texas during this period were higher than its sales in any other U.S. state except California.
- 28. On information and belief, numerous Sandoz over-the-counter products are available for purchase at pharmacies throughout Texas and in this judicial district.

- 29. On information and belief, Sandoz has entered into contracts with the State of Texas related to sales of prescription drugs. For example, on information and belief Sandoz has signed a Supplemental Rebate Agreement with the State of Texas and is classified as a "Preferred Generic Manufacturer" in the Texas Medicaid program.
- 30. On information and belief, Sandoz 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.
- 31. On information and belief, Sandoz sells products to hundreds of Veterans Administration and Public Health Services facilities throughout Texas through the Texas Medicaid program.
- 32. On information and belief, Sandoz has entered into arrangements with Texas entities to have its products appear on the formulary lists of major managed care and health plan companies in Texas, including Blue Cross Blue Shield Texas and the Scott and White formulary list.
- 33. On information and belief, Sandoz has entered into arrangements with Novation, LLC, a 25,000 member contracting services organization based in Irving, Texas, to make Sandoz products available to Novation's member network.
- 34. On information and belief, Sandoz has entered into arrangements with pharmaceutical wholesalers, including AmeriSource Bergen Co., Cardinal Health, and McKesson Co., which distribute Sandoz products to pharmacies throughout Texas, including in this judicial district.

- 35. On information and belief, AmeriSource Bergen Co. operates a large distribution center in this judicial district in Roanoke, Texas, where Sandoz products bound for this district and locations throughout Texas are warehoused prior to distribution.
- 36. On information and belief, Sandoz has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Sandoz has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Sandoz Inc.*, Case No. 09-cv-97 (E.D. Tex.).

B. Personal Jurisdiction over Lupin

- 37. This Court has personal jurisdiction over Lupin by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein.
- 38. Specifically, this Court has personal jurisdiction over Lupin because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.
- 39. On information and belief, Lupin Pharmaceuticals is registered to do business in Texas. On information and belief, Lupin Ltd. does business in Texas through Lupin Pharmaceuticals, its wholly-owned subsidiary and agent.
- 40. On information and belief, Lupin Pharmaceuticals is a licensed wholesale distributor of prescription drugs in Texas, and sells at least twenty-eight products in this judicial district.
- 41. On information and belief, Lupin Ltd., through its agent Lupin Pharmaceuticals, sold over \$1.2 billion of products in Texas, over \$77 million of which were sold in this judicial district.

- 42. On information and belief, Lupin Ltd., through its agent Lupin Pharmaceuticals, sold over \$2.6 billion of products in Texas, over \$168 million of which were sold in this judicial district.
- 43. On information and belief, various Lupin products appear on the Formulary Index of the Texas CHIP/Medicaid Vendor Drug Program, which provides services for over 4,000 Texas pharmacies.
- 44. On information and belief, Lupin 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.
- 45. On information and belief, Lupin has entered into arrangements with Texas entities to have its products appear on the formulary list of BlueCross BlueShield Texas, a major managed care and health plan.
- 46. On information and belief, Lupin has authorized numerous customers in Texas to distribute both Lupin branded and generic products, including AmerisourceBergen Drug Corp., Cardinal Health, Inc., Caremark LLC, McKesson Corp., MWI Veterinary Supply Inc., NLS Animal Health, and Walgreen Co.

C. Personal Jurisdiction over Hi-Tech

- 47. This Court has personal jurisdiction over Hi-Tech by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein.
- 48. Specifically, this Court has personal jurisdiction over Hi-Tech because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

- 49. On information and belief, Hi-Tech markets, offers for sale, and sells products to customers, including wholesalers, retail chains, chain drugstores, distributors, mail order houses, and managed care organizations in various states throughout the United States, including Texas, and it offers those products to customers in this judicial district.
- 50. On information and belief, Hi-Tech's products are available for purchase by residents of this judicial district in at least Target.
- 51. On information and belief, Hi-Tech is a licensed wholesale distributor of prescription drugs in Texas, and sells over 80 products in Texas.
- 52. On information and belief, in 2011, Hi-Tech sold over \$76 million of products in Texas, over \$3.5 million of which were sold in this judicial district. On information and belief, Hi-Tech's sales in Texas over this period were higher than any other state in the United States except California.
- 53. On information and belief, from 2009-2011 Hi-Tech sold over \$176 million of products in Texas, over \$9 million of which were sold in this judicial district.
- 54. On information and belief, Hi-Tech has entered into contracts with the Texas Department of State Health Service to sell prescription drugs in Texas.
- 55. On information and belief, Hi-Tech's 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.
- 56. On information and belief, as a Medicaid participant, Hi-Tech is required to sell products to Veterans Administration and Public Health Services facilities, of which there are over 200 in Texas. The Department of Veteran Affairs formulary lists Hi-Tech products as being available to its participants.

- 57. On information and belief, Hi-Tech has 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.
- 58. On information and belief, Hi-Tech lists AmeriSource Bergen Co. ("ABC"), Cardinal, and McKesson as three of its customers in its SEC filings, all of which distribute products throughout Texas. One of ABC's largest distribution centers is located in the Eastern District in Roanoke, Texas.
- 59. On information and belief, Hi-Tech previously admitted that it markets and sells products in Texas in *Coria Labs, Ltd. v. Hi-Tech Pharmacal Co., Inc.,* Case No. 07-ca-0734 (W.D. Tex.).
- 60. On information and belief, Hi-Tech has previously availed itself of this forum for purposes of litigating its patent disputes regarding its ANDA products. For example, Hi-Tech has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Sandoz Inc. & Hi-Tech Pharmacal Co., Inc.*, Case No. 09-cv-182 (E.D. Tex.).

D. Personal Jurisdiction over Watson

- 61. This Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma by virtue of their systematic and continuous contacts with this jurisdiction, as alleged herein, and because of the injury to Allergan and the causes of action Allergan raises here, as alleged herein.
- 62. Specifically, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma because they, either directly or through an agent, including each other, 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.

- 63. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma 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 Bimatoprost Ophthalmic Solution, 0.01% described in ANDA No. 203748.
- 64. On information and belief, Watson Pharma is a licensed drug distributor in Texas, and sells over 380 products in Texas.
- 65. On information and belief, Watson Pharma markets and sells generic drugs manufactured by Watson Laboratories throughout the United States, including this judicial district.
- 66. On information and belief, in 2011, Watson Pharma sold over \$1.06 billion of products in Texas, over \$62.88 million of which were sold in this judicial district.
- 67. On information and belief, from 2008 to 2010, Watson Pharma sold over \$2.5 billion of products in Texas, over \$151.76 million of which were sold in this judicial district.
- 68. On information and belief, Watson has entered into contracts with the Texas Department of State Health Service to sell prescription drugs in Texas.
- 69. On information and belief, Watson's 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.
- 70. On information and belief, as a Medicaid participant, Watson is required to sell products to Veterans Administration and Public Health Services facilities, of which there are over 200 in Texas. The Department of Veteran Affairs Formulary lists Watson products as being available to its participants.

- 71. On information and belief, Watson has 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.
- 72. On information and belief, Watson Laboratories previously admitted to this Court that it markets and sells products in Texas, including in this judicial district. *See Allergan, Inc. v. Watson Laboratories, Inc.*, Case No. 2:10-cv-344, D.I. 17 (E.D. Tex.).
- 73. On information and belief, Watson Laboratories has previously availed itself of this forum for purposes of litigating its 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 (E.D. Tex.).

Background

- 74. The '819 patent, entitled "Cyclopentane Heptanoic Acid, 2-Cycloalkyl or Arylalkyl Derivatives as Therapeutic Agents," issued to David F. Woodward, Steven W. Andrews, Robert M. Burk, and Michael E. Garst on November 18, 1997. A copy of the '819 patent is attached to this complaint as Exhibit A.
 - 75. Allergan, as assignee, owns the entire right, title, and interest in the '819 patent.
- 76. The '504 patent, entitled "Enhanced Bimatoprost Ophthalmic Solution," issued to Chin-Ming Chang, James N. Chang, Rhett M. Schiffman, R. Scott Jordan, and Joan-En Chang-Lin on December 14, 2010. A copy of the '504 patent is attached to this complaint as Exhibit B.
 - 77. Allergan, as assignee, owns the entire right, title, and interest in the '504 patent.
- 78. The '353 patent, entitled "Enhanced Bimatoprost Ophthalmic Solution," issued to Chin-Ming Chang, James N. Chang, Rhett M. Schiffman, R. Scott Jordan, and Joan-En Chang-Lin on October 2, 2012. A copy of the '353 patent is attached to this complaint as Exhibit C.

- 79. Allergan, as assignee, owns the entire right, title, and interest in the '353 patent.
- 80. The '118 patent, entitled "Enhanced Bimatoprost Ophthalmic Solution," issued to Chin-Ming Chang, James N. Chang, Rhett M. Schiffman, R. Scott Jordan, and Joan-En Chang-Lin on October 30, 2012. A copy of the '118 patent is attached to this complaint as Exhibit D.
 - 81. Allergan, as assignee, owns the entire right, title, and interest in the '118 patent.
- 82. The '605 patent, entitled "Enhanced Bimatoprost Ophthalmic Solution," issued to Chin-Ming Chang, James M. Chang, Rhett M. Schiffman, R. Scott Jordan, and Joan-En Chang-Lin on November 13, 2012. A copy of the '605 patent is attached to this complaint as Exhibit E.
 - 83. Allergan, as assignee, owns the entire right, title, and interest in the '605 patent.
- 84. The '479 patent, entitled "Enhanced Bimatoprost Ophthalmic Solution," issued to Chin-Ming Chang, James N. Chang, Rhett M. Schiffman, R. Scott Jordan, and Joan-En Chang-Lin on December 25, 2012. A copy of the '479 patent is attached to this complaint as Exhibit F.
 - 85. Allergan, as assignee, owns the entire right, title, and interest in the '479 patent.
- 86. Allegan is the holder of an approved New Drug Application ("NDA") No. 22-184 for bimatoprost ophthalmic solution 0.01% sold under the Lumigan® trademark.
- 87. In conjunction with that NDA, Allergan listed with the United States Food and Drug Administration ("FDA") the '819 patent, the '504 patent, and U.S. Patent Nos. 6,403,649 ("the '649 patent") and 8,017,655 ("the '655 patent"), which covered the approved 0.01% formulation of Lumigan®. Allergan subsequently listed the '353, '118, '605, and '479 patents with the FDA after each of those patents issued. The FDA has published, or in the case of the '479 patent will publish, these patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

¹ The '649 patent expired on September 21, 2012. The '655 patent expired on November 27, 2012.

- 88. Lumigan® 0.01% and/or methods of using Lumigan® 0.01% are covered by at least one claim of each of the '819, '649, '504, '655, '353, '118, '605, and '479 patents.
 - A. Acts Giving Rise to This Action for Sandoz's Infringement of the Patent-in-Suit
- 89. On or about July 15, 2011, Plaintiff received a letter, dated July 11, 2011, signed on behalf of Sandoz by Bernadette Attinger, Director of Regulatory Affairs.
- 90. The July 11, 2011 letter stated that Sandoz had submitted an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Bimatoprost Ophthalmic Solution, 0.01%, a generic version of Allergan's Lumigan® 0.01% product, prior to expiration of the '504 and '819 patents. The ANDA Number for Sandoz's application is 203056.
- 91. The July 11, 2011 letter stated that the '504 and '819 patents are invalid and/or will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01%. The July 11, 2011 letter did not discuss the '649 patent. The '649 patent has now expired.
- 92. Attached to the July 11, 2011 letter was a statement of the factual and legal bases for Sandoz's certifications under 21 CFR § 314.95 that the '504 and '819 patents are invalid, or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 93. The '353, '118, '605, and '479 patents had not issued at the time Sandoz submitted its certifications under section 505(j) of the FDCA.
- 94. On information and belief, Sandoz became aware of the '353, '118, '605, and '479 patents no later than the dates on which they were listed in the Orange Book as patents

covering the approved formulation of Allergan's Lumigan® 0.01% product, or in the case of the '479 patent as of the date of issuance, December 25, 2012.

- 95. On information and belief, Sandoz has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Lumigan® 0.01% product prior to patent expiry.
- 96. Sandoz's actions, including, but not limited to, the development of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% and the filing of an ANDA with Paragraph IV certifications as to the '504 and '819 patents, indicate a refusal to change the course of its action in the face of acts by Plaintiff.
- 97. In filing its ANDA No. 203056, Sandoz has requested the FDA's approval to market a generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.
- 98. On information and belief, Sandoz continues to seek approval of ANDA No. 203056 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Ophthalmic Solution, 0.01%.
- 99. On information and belief, following FDA approval of its ANDA No. 203056, Sandoz will sell the approved generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.
 - B. Acts Giving Rise to This Action for Lupin's Infringement of the Patent-in-Suit
- 100. On or about October 4, 2011, Plaintiff received a letter, dated September 30, 2011, signed on behalf of Lupin Ltd. by William A. Rakoczy, outside counsel for Lupin Ltd.
- 101. The September 30, 2011 letter stated that Lupin Ltd. had submitted an ANDA under section 505(j) of the FDCA, seeking approval to engage in the commercial manufacture,

use, importation, sale, or offer for sale of Bimatoprost Ophthalmic Solution, 0.01%, a generic version of Allergan's Lumigan® 0.01% product, prior to expiration of the '504 patent. The ANDA Number for this application is 202911.

- 102. On information and belief, Lupin Pharmaceuticals is designated as Lupin Ltd.'sU.S. agent on ANDA No. 202911, as it has been on numerous ANDAs in the past.
- 103. Lupin Ltd.'s September 30, 2011 letter stated that the '504 patent is invalid and/or will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 104. Attached to the September 30, 2011 letter was a statement of the factual and legal bases for Lupin Ltd.'s certifications under 21 CFR § 314.95 that the '504 patent is invalid, or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01%. No such statement was attached to the September 30, 2011 letter regarding the '819, '649, or '655 patents.
- 105. Lupin Ltd. has filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) as to the '819, '649, and '655 patents, and based on representation from Lupin's counsel, Allergan understands that Lupin has no intention of selling a product made under ANDA No. 202911 prior to the expiration of the '819, '649, or '655 patents. The '649 and '655 patents have now expired.
- 106. The '353, '118, '605, and '479 patents had not issued at the time Lupin Ltd. submitted its certification under section 505(j) of the FDCA.
- 107. On information and belief, Lupin became aware of the '353, '118, '605, and '479 patents no later than the dates on which they were listed in the Orange Book as patents covering

the approved formulation of Allergan's Lumigan® 0.01% product, or in the case of the '479 patent as of the date of issuance, December 25, 2012.

- 108. Lupin has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Lumigan® 0.01% product prior to patent expiry.
- 109. Lupin's actions, including, but not limited to, the development of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% and the filing of an ANDA with a Paragraph IV certification as to the '504 patent, indicate a refusal to change the course of its action in the face of acts by Plaintiff.
- 110. In filing ANDA No. 202911, Lupin Ltd. and Lupin Pharmaceuticals have requested the FDA's approval to market a generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.
- 111. On information and belief, Lupin continues to seek approval of ANDA No. 202911 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Ophthalmic Solution, 0.01%.
- 112. On information and belief, following FDA approval of its ANDA No. 202911, Lupin will sell the approved generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.
 - C. Acts Giving Rise to This Action for Hi-Tech's Infringement of the Patent-in-Suit
- 113. On or about January 3, 2012, Plaintiff received a letter, dated December 23, 2011, signed on behalf of Hi-Tech by Joanne Curri, Director of Regulatory Affairs.
- 114. The December 23, 2011 letter stated that Hi-Tech had submitted an ANDA under section 505(j) of the FDCA, seeking approval to engage in the commercial manufacture, use,

importation, sale, or offer for sale of Bimatoprost Ophthalmic Solution, 0.01%, a generic version of Allergan's Lumigan® 0.01% product, prior to expiration of the '504 patent. The ANDA Number for Hi-Tech's application is 203604.

- 115. The December 23, 2011 letter stated that the '504 patent is invalid and/or will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01%. The December 23, 2011 letter did not discuss the '649 patent, the '819 patent, or the '655 patent.
- 116. Attached to the December 23, 2011 letter was a statement of the factual and legal bases for Hi-Tech's certifications under 21 CFR § 314.95 that the '504 patent is invalid, or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 117. On or around January 25, 2012, Hi-Tech sent a letter to Allergan counsel confirming that Hi-Tech filed a paragraph IV certification only as to the '504 patent and not as to the '649 patent, the '819 patent, or the '655 patent. Hi-Tech confirmed in this letter that Hi-Tech has no present intention of selling a product made under ANDA No. 203604 prior to the expiration of the '649, '819, and '655 patents. The '649 and '655 patents have now expired.
- 118. The '353, '118, '605, and '479 patents had not issued at the time Hi-Tech submitted its certification under section 505(j) of the FDCA.
- 119. On information and belief, Hi-Tech became aware of the '353, '118, '605, and '479 patents no later than the dates on which they were listed in the Orange Book as patents covering the approved formulation of Allergan's Lumigan® 0.01% product, or in the case of the '479 patent as of the date of issuance, December 25, 2012.

- 120. On information and belief, Hi-Tech has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Lumigan® 0.01% product prior to patent expiry.
- 121. Hi-Tech's actions, including, but not limited to, the development of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% and the filing of an ANDA with a Paragraph IV certification as to the '504 patent, indicate a refusal to change the course of its action in the face of acts by Plaintiff.
- 122. In filing its ANDA No. 203604, Hi-Tech has requested the FDA's approval to market a generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.
- 123. On information and belief, Hi-Tech continues to seek approval of ANDA No. 203604 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Ophthalmic Solution, 0.01%.
- 124. On information and belief, following FDA approval of its ANDA No. 203604, Hi-Tech will sell the approved generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.
 - D. Acts Giving Rise to This Action for Watson's Infringement of the Patent-in-Suit
- 125. On or about March 1, 2012, Plaintiff received a letter, dated February 29, 2012, signed on behalf of Watson Laboratories by Joyce Delgaudio, Executive Director, Regulatory Affairs.
- 126. The February 29, 2012 letter stated that Watson Laboratories had submitted an ANDA under §§ 505(j)(1) and (2)(A) of the FDCA, seeking approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Bimatoprost Ophthalmic

Solution, 0.01%, a generic version of Allergan's Lumigan® 0.01% product, prior to expiration of the '504 patent. The ANDA Number for this application is 203748.

- 127. The February 29, 2012 letter stated that the '504 patent is invalid and/or will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01%. The February 29, 2012 letter did not discuss the '819 patent, the '649 patent, or the '655 patent.
- bases for Watson Laboratories' certifications under 21 CFR § 314.95 that the '504 patent is invalid, or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01%. No such statement was attached to the February 29, 2012 letter regarding the '819 patent, the '649 patent, or the '655 patent. Watson Laboratories later confirmed that it certified in connection with ANDA No. 203748 under 21 U.S.C. § 355(j)(2)(A)(vii)(III) and 21 C.F.R. 314.94(a)(12)(i)(A)(3) that the sale of any product made under ANDA No. 203748 will not begin until after the expiration date of the '819 patent. The '649 and '655 patents have now expired.
- 129. The '353, '118, '605, and '479 patents had not issued at the time Watson Laboratories submitted its certification under section 505(j) of the FDCA.
- 130. On information and belief, Watson became aware of the '353, '118, '605, and '479 patents no later than the dates on which they were listed in the Orange Book as patents covering the approved formulation of Allergan's Lumigan® 0.01% product, or in the case of the '479 patent as of the date of issuance, December 25, 2012.

- 131. On information and belief, Watson has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Lumigan® 0.01% product prior to patent expiry.
- 132. Watson's actions, including, but not limited to, the development of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% and the filing of an ANDA with a Paragraph IV certification as to the '504 patent, indicate a refusal to change the course of its action in the face of acts by Plaintiff.
- 133. In filing its ANDA No. 203748, Watson has requested the FDA's approval to market a generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.
- 134. On information and belief, Watson continues to seek approval of ANDA No. 203748 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Ophthalmic Solution, 0.01%.
- 135. On information and belief, following FDA approval of its ANDA No. 203748, Watson will sell the approved generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.

Count I

(Infringement of the '504 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 136. Paragraphs 1 to 135 are incorporated herein as set forth above.
- 137. Sandoz submitted ANDA No. 203056 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the

United States. By submitting this application, Sandoz has committed an act of infringement of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

- 138. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '504 patent.
- 139. On information and belief, Sandoz became aware of the '504 patent no later than when it submitted ANDA No. 203056 to the FDA, in which it identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.
- 140. On information and belief, Sandoz knew or should have known that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.
- 141. On information and belief, Sandoz knew or should have known that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '504 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '504 patent.
- 142. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count II

(Infringement of the '819 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 143. Paragraphs 1 to 142 are incorporated herein as set forth above.
- 144. Sandoz submitted ANDA No. 203056 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the '819 patent under 35 U.S.C. § 271(e)(2)(A).
- 145. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '819 patent.
- 146. On information and belief, Sandoz became aware of the '819 patent no later than when it submitted ANDA No. 203056 to the FDA, in which it identified the '819 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.
- 147. On information and belief, Sandoz knew or should have known that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '819 patent.
- 148. On information and belief, Sandoz knew or should have known that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '819 patent, is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '819 patent.

149. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count III

(Infringement of the '353 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 150. Paragraphs 1 to 149 are incorporated herein as set forth above.
- 151. Sandoz submitted ANDA No. 203056 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the '353 patent under 35 U.S.C. § 271(e)(2)(A).
- 152. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '353 patent.
- 153. On information and belief, Sandoz became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 154. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '353 patent.
- 155. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted

for use in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '353 patent.

156. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count IV

(Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(a) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 157. Paragraphs 1 to 156 are incorporated herein as set forth above.
- 158. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 159. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 160. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '353 patent.
- 161. On information and belief, Sandoz will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost

 Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203056.
 - 162. The foregoing actions by Sandoz will constitute infringement of the '353 patent.
 - 163. Sandoz will commit those acts of infringement without license or authorization.

- 164. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01% by Sandoz will infringe the '353 patent.
- 165. Unless Sandoz is enjoined from infringing the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 166. On information and belief, Sandoz became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 167. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 168. Sandoz's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 169. On information and belief, Sandoz has acted, and will continue to act, with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for infringing the '353 patent.
- 170. On information and belief, despite having actual notice of the '353 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to infringe the '353 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count V

(Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

171. Paragraphs 1 to 170 are incorporated herein as set forth above.

- 172. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 173. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 174. Sandoz has actual knowledge of the '353 patent.
- 175. On information and belief, Sandoz became aware of the '353 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 176. On information and belief, Sandoz has acted with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '353 patent.
- 177. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '353 patent.
- 178. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '353 patent.
- 179. On information and belief, Sandoz will encourage another's infringement of the '353 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '353 patent.

- 180. Sandoz's acts of infringement will be done with knowledge of the '353 patent and with the intent to encourage infringement.
- 181. The foregoing actions by Sandoz will constitute active inducement of infringement of the '353 patent.
- 182. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 183. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 184. On information and belief, Sandoz knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 185. The foregoing actions by Sandoz will constitute contributory infringement of the '353 patent.
- 186. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the '353 patent when ANDA No. 203056 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 187. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Sandoz will induce and/or contribute to infringement of the '353 patent.

- 188. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '353 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 189. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 190. On information and belief, despite having actual notice of the '353 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '353 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count VI

(Infringement of the '118 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 191. Paragraphs 1 to 190 are incorporated herein as set forth above.
- 192. Sandoz submitted ANDA No. 203056 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the '118 patent under 35 U.S.C. § 271(e)(2)(A).
- 193. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '118 patent.

- 194. On information and belief, Sandoz became aware of the '118 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 195. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '118 patent.
- 196. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '118 patent.
- 197. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count VII

(Declaratory Judgment of Infringement of the '118 Patent Under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 198. Paragraphs 1 to 197 are incorporated herein as set forth above.
- 199. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 200. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 201. Sandoz has actual knowledge of the '118 patent.
- 202. On information and belief, Sandoz became aware of the '118 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 203. On information and belief, Sandoz has acted with full knowledge of the '118 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '118 patent.
- 204. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '118 patent.
- 205. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '118 patent.
- 206. On information and belief, Sandoz will encourage another's infringement of the '118 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '118 patent.
- 207. Sandoz's acts of infringement will be done with knowledge of the '118 patent and with the intent to encourage infringement.

- 208. The foregoing actions by Sandoz will constitute active inducement of infringement of the '118 patent.
- 209. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 210. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 211. On information and belief, Sandoz knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 212. The foregoing actions by Sandoz will constitute contributory infringement of the '118 patent.
- 213. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the '118 patent when ANDA No. 203056 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 214. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Sandoz will induce and/or contribute to infringement of the '118 patent.
- 215. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce

and/or contribute to infringement of the '118 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 216. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the '118 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 217. On information and belief, despite having actual notice of the '118 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '118 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count VIII

(Infringement of the '605 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 218. Paragraphs 1 to 217 are incorporated herein as set forth above.
- 219. Sandoz submitted ANDA No. 203056 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the '605 patent under 35 U.S.C. § 271(e)(2)(A).
- 220. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '605 patent.
- 221. On information and belief, Sandoz became aware of the '605 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 222. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '605 patent.
- 223. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '605 patent.
- 224. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count IX

(Declaratory Judgment of Infringement of the '605 Patent Under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 225. Paragraphs 1 to 224 are incorporated herein as set forth above.
- 226. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 227. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 228. Sandoz has actual knowledge of the '605 patent.

- 229. On information and belief, Sandoz became aware of the '605 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 230. On information and belief, Sandoz has acted with full knowledge of the '605 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '605 patent.
- 231. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '605 patent.
- 232. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '605 patent.
- 233. On information and belief, Sandoz will encourage another's infringement of the '605 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '605 patent.
- 234. Sandoz's acts of infringement will be done with knowledge of the '605 patent and with the intent to encourage infringement.
- 235. The foregoing actions by Sandoz will constitute active inducement of infringement of the '605 patent.
- 236. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted

for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 237. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 238. On information and belief, Sandoz knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 239. The foregoing actions by Sandoz will constitute contributory infringement of the '605 patent.
- 240. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the '605 patent when ANDA No. 203056 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 241. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Sandoz will induce and/or contribute to infringement of the '605 patent.
- 242. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '605 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 243. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the '605 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 244. On information and belief, despite having actual notice of the '605 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '605 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count X

(Infringement of the '479 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 245. Paragraphs 1 to 244 are incorporated herein as set forth above.
- 246. Sandoz submitted ANDA No. 203056 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the '479 patent under 35 U.S.C. § 271(e)(2)(A).
- 247. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '479 patent.
- 248. On information and belief, Sandoz became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 249. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost

Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '479 patent.

- 250. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '479 patent.
- 251. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XI

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(a) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 252. Paragraphs 1 to 251 are incorporated herein as set forth above.
- 253. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 254. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 255. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '479 patent.

- 256. On information and belief, Sandoz will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203056.
 - 257. The foregoing actions by Sandoz will constitute infringement of the '479 patent.
 - 258. Sandoz will commit those acts of infringement without license or authorization.
- 259. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01% by Sandoz will infringe the '479 patent.
- 260. Unless Sandoz is enjoined from infringing the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 261. On information and belief, Sandoz became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 262. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Sandoz's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 263. Sandoz's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 264. On information and belief, Sandoz has acted, and will continue to act, with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for infringing the '479 patent.
- 265. On information and belief, despite having actual notice of the '479 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to infringe the '479 patent in disregard

of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XII

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 266. Paragraphs 1 to 265 are incorporated herein as set forth above.
- 267. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 268. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 269. Sandoz has actual knowledge of the '479 patent.
- 270. On information and belief, Sandoz became aware of the '479 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 271. On information and belief, Sandoz has acted with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '479 patent.
- 272. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '479 patent.
- 273. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '479 patent.

- 274. On information and belief, Sandoz will encourage another's infringement of the '479 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '479 patent.
- 275. Sandoz's acts of infringement will be done with knowledge of the '479 patent and with the intent to encourage infringement.
- 276. The foregoing actions by Sandoz will constitute active inducement of infringement of the '479 patent.
- 277. On information and belief, Sandoz knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 278. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 279. On information and belief, Sandoz knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 280. The foregoing actions by Sandoz will constitute contributory infringement of the '479 patent.
- 281. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the '479 patent when ANDA No. 203056 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

- 282. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Sandoz will induce and/or contribute to infringement of the '479 patent.
- 283. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '479 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 284. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 285. On information and belief, despite having actual notice of the '479 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '479 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XIII

(Infringement of the '504 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 286. Paragraphs 1 to 135 are incorporated herein as set forth above.
- 287. Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, submitted ANDA No. 202911 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this

application, Lupin Ltd. and Lupin Pharmaceuticals committed an act of infringement of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

- 288. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '504 patent.
- 289. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals became aware of the '504 patent no later than the date on which they jointly submitted ANDA No. 202911 to the FDA, in which they identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.
- 290. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals know or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.
- 291. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals know or should know that their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '504 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '504 patent.
- 292. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XIV

(Declaratory Judgment of Infringement of the '504 Patent Under 35 U.S.C. § 271(a) and/or (b) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 293. Paragraphs 1 to 135 and 286 to 292 are incorporated herein as set forth above.
- 294. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 202911.
- 295. The manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '504 patent.
- 296. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals intend to, and will, actively induce infringement of the '504 patent when ANDA No. 202911 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 297. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals became aware of the '504 patent no later than the date on which they jointly submitted ANDA No. 202911 to the FDA, in which they identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.
- 298. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals know or should know that their commercial manufacture, use, offer for sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.

- 299. The foregoing actions by Lupin Ltd. and Lupin Pharmaceuticals constitute and/or will constitute infringement of the '504 patent and active inducement of infringement of the '504 patent.
- 300. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Allergan on the one hand and Lupin Ltd. and Lupin Pharmaceuticals on the other hand regarding Lupin Ltd. and Lupin Pharmaceuticals' infringement of the '504 patent and active inducement of infringement of the '504 patent.
- 301. Allergan is entitled to a judgment declaring that the foregoing actions by Lupin Ltd. and Lupin Pharmaceuticals constitute and/or will constitute infringement of the '504 patent and active inducement of infringement of the '504 patent.
- 302. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals have acted with full knowledge of the '504 patent and without a reasonable basis for believing that they would not be liable for infringing the '504 patent and actively inducing the infringement of the '504 patent.
- 303. Unless Lupin Ltd. and Lupin Pharmaceuticals are enjoined from infringing the '504 patent and actively inducing infringement of the '504 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Count XV

(Infringement of the '353 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 304. Paragraphs 1 to 135 and 286 to 303 are incorporated herein as set forth above.
- 305. Lupin submitted ANDA No. 202911 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Lupin has committed an act of infringement of the '353 patent under 35 U.S.C. § 271(e)(2)(A).

- 306. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '353 patent.
- 307. On information and belief, Lupin became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 308. On information and belief, Lupin knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '353 patent.
- 309. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '353 patent.
- 310. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XVI

(Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(a) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 311. Paragraphs 1 to 135 and 286 to 310 are incorporated herein as set forth above.
- 312. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 313. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 314. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '353 patent.
- 315. On information and belief, Lupin will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 202911.
 - 316. The foregoing actions by Lupin will constitute infringement of the '353 patent.
 - 317. Lupin will commit those acts of infringement without license or authorization.
- 318. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% by Lupin will infringe the '353 patent.
- 319. Unless Lupin is enjoined from infringing the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 320. On information and belief, Lupin became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 321. On information and belief, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 322. Lupin's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 323. On information and belief, Lupin has acted, and will continue to act, with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for infringing the '353 patent.
- 324. On information and belief, despite having actual notice of the '353 patent, Lupin continues to willfully, wantonly, and deliberately prepare to infringe the '353 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XVII

(Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(b) and (c) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 325. Paragraphs 1 to 135 and 286 to 324 are incorporated herein as set forth above.
- 326. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 327. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 328. Lupin has actual knowledge of the '353 patent.

- 329. On information and belief, Lupin became aware of the '353 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 330. On information and belief, Lupin has acted with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '353 patent.
- 331. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '353 patent.
- 332. On information and belief, Lupin knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '353 patent.
- 333. On information and belief, Lupin will encourage another's infringement of the '353 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '353 patent.
- 334. Lupin's acts of infringement will be done with knowledge of the '353 patent and with the intent to encourage infringement.
- 335. The foregoing actions by Lupin will constitute active inducement of infringement of the '353 patent.
- 336. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use

in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 337. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 338. On information and belief, Lupin knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 339. The foregoing actions by Lupin will constitute contributory infringement of the '353 patent.
- 340. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the '353 patent when ANDA No. 202911 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 341. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Lupin will induce and/or contribute to infringement of the '353 patent.
- 342. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '353 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 343. Unless Lupin is enjoined from actively inducing and contributing to the infringement of the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 344. On information and belief, despite having actual notice of the '353 patent, Lupin continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '353 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XVIII

(Infringement of the '118 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 345. Paragraphs 1 to 135 and 286 to 344 are incorporated herein as set forth above.
- 346. Lupin submitted ANDA No. 202911 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Lupin has committed an act of infringement of the '118 patent under 35 U.S.C. § 271(e)(2)(A).
- 347. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '118 patent.
- 348. On information and belief, Lupin became aware of the '118 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 349. On information and belief, Lupin knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost

Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '118 patent.

- 350. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '118 patent.
- 351. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XIX

(Declaratory Judgment of Infringement of the '118 Patent Under 35 U.S.C. § 271(b) and (c) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 352. Paragraphs 1 to 135 and 286 to 351 are incorporated herein as set forth above.
- 353. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 354. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 355. Lupin has actual knowledge of the '118 patent.
- 356. On information and belief, Lupin became aware of the '118 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan 0.01%.

- 357. On information and belief, Lupin has acted with full knowledge of the '118 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '118 patent.
- 358. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '118 patent.
- 359. On information and belief, Lupin knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '118 patent.
- 360. On information and belief, Lupin will encourage another's infringement of the '118 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '118 patent.
- 361. Lupin's acts of infringement will be done with knowledge of the '118 patent and with the intent to encourage infringement.
- 362. The foregoing actions by Lupin will constitute active inducement of infringement of the '118 patent.
- 363. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 364. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 365. On information and belief, Lupin knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 366. The foregoing actions by Lupin will constitute contributory infringement of the '118 patent.
- 367. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the '118 patent when ANDA No. 202911 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 368. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Lupin will induce and/or contribute to infringement of the '118 patent.
- 369. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '118 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 370. Unless Lupin is enjoined from actively inducing and contributing to the infringement of the '118 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

371. On information and belief, despite having actual notice of the '118 patent, Lupin continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '118 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XX

(Infringement of the '605 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 372. Paragraphs 1 to 135 and 286 to 371 are incorporated herein as set forth above.
- 373. Lupin submitted ANDA No. 202911 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Lupin has committed an act of infringement of the '605 patent under 35 U.S.C. § 271(e)(2)(A).
- 374. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '605 patent.
- 375. On information and belief, Lupin became aware of the '605 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 376. On information and belief, Lupin knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '605 patent.

- 377. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '605 patent.
- 378. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXI

(Declaratory Judgment of Infringement of the '605 Patent Under 35 U.S.C. § 271(b) and (c) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 379. Paragraphs 1 to 135 and 286 to 378 are incorporated herein as set forth above.
- 380. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 381. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 382. Lupin has actual knowledge of the '605 patent.
- 383. On information and belief, Lupin became aware of the '605 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 384. On information and belief, Lupin has acted with full knowledge of the '605 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '605 patent.
- 385. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '605 patent.
- 386. On information and belief, Lupin knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '605 patent.
- 387. On information and belief, Lupin will encourage another's infringement of the '605 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '605 patent.
- 388. Lupin's acts of infringement will be done with knowledge of the '605 patent and with the intent to encourage infringement.
- 389. The foregoing actions by Lupin will constitute active inducement of infringement of the '605 patent.
- 390. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 391. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 392. On information and belief, Lupin knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 393. The foregoing actions by Lupin will constitute contributory infringement of the '605 patent.
- 394. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the '605 patent when ANDA No. 202911 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 395. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Lupin will induce and/or contribute to infringement of the '605 patent.
- 396. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '605 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 397. Unless Lupin is enjoined from actively inducing and contributing to the infringement of the '605 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

398. On information and belief, despite having actual notice of the '605 patent, Lupin continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '605 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXII

(Infringement of the '479 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 399. Paragraphs 1 to 135 and 286 to 398 are incorporated herein as set forth above.
- 400. Lupin submitted ANDA No. 202911 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Lupin has committed an act of infringement of the '479 patent under 35 U.S.C. § 271(e)(2)(A).
- 401. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '479 patent.
- 402. On information and belief, Lupin became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 403. On information and belief, Lupin knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '479 patent.

- 404. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '479 patent.
- 405. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXIII

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(a) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 406. Paragraphs 1 to 135 and 286 to 405 are incorporated herein as set forth above.
- 407. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 408. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 409. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '479 patent.
- 410. On information and belief, Lupin will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 202911.

- 411. The foregoing actions by Lupin will constitute infringement of the '479 patent.
- 412. Lupin will commit those acts of infringement without license or authorization.
- 413. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% by Lupin will infringe the '479 patent.
- 414. Unless Lupin is enjoined from infringing the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 415. On information and belief, Lupin became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 416. On information and belief, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 417. Lupin's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 418. On information and belief, Lupin has acted, and will continue to act, with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for infringing the '479 patent.
- 419. On information and belief, despite having actual notice of the '479 patent, Lupin continues to willfully, wantonly, and deliberately prepare to infringe the '479 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXIV

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(b) and (c) by Lupin's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 420. Paragraphs 1 to 135 and 286 to 419 are incorporated herein as set forth above.
- 421. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 422. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 423. Lupin has actual knowledge of the '479 patent.
- 424. On information and belief, Lupin became aware of the '479 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 425. On information and belief, Lupin has acted with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '479 patent.
- 426. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '479 patent.
- 427. On information and belief, Lupin knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '479 patent.
- 428. On information and belief, Lupin will encourage another's infringement of the '479 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '479 patent.

- 429. Lupin's acts of infringement will be done with knowledge of the '479 patent and with the intent to encourage infringement.
- 430. The foregoing actions by Lupin will constitute active inducement of infringement of the '479 patent.
- 431. On information and belief, Lupin knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 432. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 433. On information and belief, Lupin knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 434. The foregoing actions by Lupin will constitute contributory infringement of the '479 patent.
- 435. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the '479 patent when ANDA No. 202911 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 436. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic

Bimatoprost Ophthalmic Solution, 0.01% by Lupin will induce and/or contribute to infringement of the '479 patent.

- 437. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '479 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 438. Unless Lupin is enjoined from actively inducing and contributing to the infringement of the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 439. On information and belief, despite having actual notice of the '479 patent, Lupin continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '479 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXV

(Infringement of the '504 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 440. Paragraphs 1 to 135 are incorporated herein as set forth above.
- 441. Hi-Tech submitted ANDA No. 203604 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

- 442. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '504 patent.
- 443. On information and belief, Hi-Tech became aware of the '504 patent no later than when it submitted ANDA No. 203604 to the FDA, in which it identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.
- 444. On information and belief, Hi-Tech knew or should have known that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.
- 445. On information and belief, Hi-Tech knew or should have known that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '504 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '504 patent.
- 446. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXVI

(Infringement of the '353 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

447. Paragraphs 1 to 135 and 440 to 446 are incorporated herein as set forth above.

- 448. Hi-Tech submitted ANDA No. 203604 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement of the '353 patent under 35 U.S.C. § 271(e)(2)(A).
- 449. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '353 patent.
- 450. On information and belief, Hi-Tech became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 451. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '353 patent.
- 452. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '353 patent.

453. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXVII

(Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(a) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 454. Paragraphs 1 to 135 and 440 to 453 are incorporated herein as set forth above.
- 455. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 456. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 457. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '353 patent.
- 458. On information and belief, Hi-Tech will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203604.
 - 459. The foregoing actions by Hi-Tech will constitute infringement of the '353 patent.
 - 460. Hi-Tech will commit those acts of infringement without license or authorization.
- 461. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01% by Hi-Tech will infringe the '353 patent.

- 462. Unless Hi-Tech is enjoined from infringing the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 463. On information and belief, Hi-Tech became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 464. On information and belief, Hi-Tech has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 465. Hi-Tech's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 466. On information and belief, Hi-Tech has acted, and will continue to act, with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for infringing the '353 patent.
- 467. On information and belief, despite having actual notice of the '353 patent, Hi-Tech continues to willfully, wantonly, and deliberately prepare to infringe the '353 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXVIII

(Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(b) and (c) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 468. Paragraphs 1 to 135 and 440 to 467 are incorporated herein as set forth above.
- 469. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 470. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 471. Hi-Tech has actual knowledge of the '353 patent.
- 472. On information and belief, Hi-Tech became aware of the '353 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 473. On information and belief, Hi-Tech has acted with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '353 patent.
- 474. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '353 patent.
- 475. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '353 patent.
- 476. On information and belief, Hi-Tech will encourage another's infringement of the '353 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '353 patent.
- 477. Hi-Tech's acts of infringement will be done with knowledge of the '353 patent and with the intent to encourage infringement.

- 478. The foregoing actions by Hi-Tech will constitute active inducement of infringement of the '353 patent.
- 479. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 480. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 481. On information and belief, Hi-Tech knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 482. The foregoing actions by Hi-Tech will constitute contributory infringement of the '353 patent.
- 483. On information and belief, Hi-Tech intends to, and will, actively induce and contribute to the infringement of the '353 patent when ANDA No. 203604 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 484. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Hi-Tech will induce and/or contribute to infringement of the '353 patent.
- 485. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce

and/or contribute to infringement of the '353 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 486. Unless Hi-Tech is enjoined from actively inducing and contributing to the infringement of the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 487. On information and belief, despite having actual notice of the '353 patent, Hi-Tech continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '353 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXIX

(Infringement of the '118 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 488. Paragraphs 1 to 135 and 440 to 487 are incorporated herein as set forth above.
- 489. Hi-Tech submitted ANDA No. 203604 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement of the '118 patent under 35 U.S.C. § 271(e)(2)(A).
- 490. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '118 patent.
- 491. On information and belief, Hi-Tech became aware of the '118 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 492. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '118 patent.
- 493. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '118 patent.
- 494. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXX

(Declaratory Judgment of Infringement of the '118 Patent Under 35 U.S.C. § 271(b) and (c) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 495. Paragraphs 1 to 135 and 440 to 494 are incorporated herein as set forth above.
- 496. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 497. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 498. Hi-Tech has actual knowledge of the '118 patent.

- 499. On information and belief, Hi-Tech became aware of the '118 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 500. On information and belief, Hi-Tech has acted with full knowledge of the '118 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '118 patent.
- 501. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '118 patent.
- 502. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '118 patent.
- 503. On information and belief, Hi-Tech will encourage another's infringement of the '118 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '118 patent.
- 504. Hi-Tech's acts of infringement will be done with knowledge of the '118 patent and with the intent to encourage infringement.
- 505. The foregoing actions by Hi-Tech will constitute active inducement of infringement of the '118 patent.
- 506. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted

for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 507. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 508. On information and belief, Hi-Tech knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 509. The foregoing actions by Hi-Tech will constitute contributory infringement of the '118 patent.
- 510. On information and belief, Hi-Tech intends to, and will, actively induce and contribute to the infringement of the '118 patent when ANDA No. 203604 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 511. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Hi-Tech will induce and/or contribute to infringement of the '118 patent.
- 512. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '118 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 513. Unless Hi-Tech is enjoined from actively inducing and contributing to the infringement of the '118 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 514. On information and belief, despite having actual notice of the '118 patent, Hi-Tech continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '118 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXXI

(Infringement of the '605 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 515. Paragraphs 1 to 135 and 440 to 514 are incorporated herein as set forth above.
- 516. Hi-Tech submitted ANDA No. 203604 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement of the '605 patent under 35 U.S.C. § 271(e)(2)(A).
- 517. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '605 patent.
- 518. On information and belief, Hi-Tech became aware of the '605 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 519. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost

Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '605 patent.

- 520. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '605 patent.
- 521. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXXII

(Declaratory Judgment of Infringement of the '605 Patent Under 35 U.S.C. § 271(b) and (c) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 522. Paragraphs 1 to 135 and 440 to 521 are incorporated herein as set forth above.
- 523. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 524. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 525. Hi-Tech has actual knowledge of the '605 patent.
- 526. On information and belief, Hi-Tech became aware of the '605 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 527. On information and belief, Hi-Tech has acted with full knowledge of the '605 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '605 patent.
- 528. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '605 patent.
- 529. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '605 patent.
- 530. On information and belief, Hi-Tech will encourage another's infringement of the '605 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '605 patent.
- 531. Hi-Tech's acts of infringement will be done with knowledge of the '605 patent and with the intent to encourage infringement.
- 532. The foregoing actions by Hi-Tech will constitute active inducement of infringement of the '605 patent.
- 533. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 534. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 535. On information and belief, Hi-Tech knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 536. The foregoing actions by Hi-Tech will constitute contributory infringement of the '605 patent.
- 537. On information and belief, Hi-Tech intends to, and will, actively induce and contribute to the infringement of the '605 patent when ANDA No. 203604 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 538. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Hi-Tech will induce and/or contribute to infringement of the '605 patent.
- 539. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '605 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 540. Unless Hi-Tech is enjoined from actively inducing and contributing to the infringement of the '605 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

541. On information and belief, despite having actual notice of the '605 patent, Hi-Tech continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '605 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXXIII

(Infringement of the '479 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 542. Paragraphs 1 to 135 and 440 to 541 are incorporated herein as set forth above.
- 543. Hi-Tech submitted ANDA No. 203604 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement of the '479 patent under 35 U.S.C. § 271(e)(2)(A).
- 544. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '479 patent.
- 545. On information and belief, Hi-Tech became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 546. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '479 patent.

- 547. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '479 patent.
- 548. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXXIV

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(a) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 549. Paragraphs 1 to 135 and 440 to 548 are incorporated herein as set forth above.
- 550. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 551. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 552. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '479 patent.
- 553. On information and belief, Hi-Tech will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203604.

- 554. The foregoing actions by Hi-Tech will constitute infringement of the '479 patent.
- 555. Hi-Tech will commit those acts of infringement without license or authorization.
- 556. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01% by Hi-Tech will infringe the '479 patent.
- 557. Unless Hi-Tech is enjoined from infringing the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 558. On information and belief, Hi-Tech became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 559. On information and belief, Hi-Tech has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Hi-Tech's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 560. Hi-Tech's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 561. On information and belief, Hi-Tech has acted, and will continue to act, with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for infringing the '479 patent.
- 562. On information and belief, despite having actual notice of the '479 patent, Hi-Tech continues to willfully, wantonly, and deliberately prepare to infringe the '479 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXXV

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(b) and (c) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 563. Paragraphs 1 to 135 and 440 to 562 are incorporated herein as set forth above.
- 564. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 565. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 566. Hi-Tech has actual knowledge of the '479 patent.
- 567. On information and belief, Hi-Tech became aware of the '479 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 568. On information and belief, Hi-Tech has acted with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '479 patent.
- 569. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '479 patent.
- 570. On information and belief, Hi-Tech knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '479 patent.
- 571. On information and belief, Hi-Tech will encourage another's infringement of the '479 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '479 patent.

- 572. Hi-Tech's acts of infringement will be done with knowledge of the '479 patent and with the intent to encourage infringement.
- 573. The foregoing actions by Hi-Tech will constitute active inducement of infringement of the '479 patent.
- 574. On information and belief, Hi-Tech knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 575. The commercial manufacture, use, sale, offer for sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 576. On information and belief, Hi-Tech knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 577. The foregoing actions by Hi-Tech will constitute contributory infringement of the '479 patent.
- 578. On information and belief, Hi-Tech intends to, and will, actively induce and contribute to the infringement of the '479 patent when ANDA No. 203604 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 579. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic

Bimatoprost Ophthalmic Solution, 0.01% by Hi-Tech will induce and/or contribute to infringement of the '479 patent.

- 580. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '479 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 581. Unless Hi-Tech is enjoined from actively inducing and contributing to the infringement of the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 582. On information and belief, despite having actual notice of the '479 patent, Hi-Tech continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '479 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XXXVI

(Infringement of the '504 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 583. Paragraphs 1 to 135 are incorporated herein as set forth above.
- 584. Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, acting jointly, submitted ANDA No. 203748 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) for approval to engage in the commercial manufacture, use, or sale of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have committed an act of infringement of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

- 585. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '504 patent.
- 586. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma became aware of the '504 patent no later than the date on which they jointly submitted ANDA No. 203748 to the FDA, in which they identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.
- 587. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.
- 588. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXXVII

(Declaratory Judgment of Infringement of the '504 Patent Under 35 U.S.C. § 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 589. Paragraphs 1 to 135 and 583 to 588 are incorporated herein as set forth above.
- 590. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203748.

- 591. The manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '504 patent.
- 592. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma intend to, and will, actively induce infringement of the '504 patent when ANDA No. 203748 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 593. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma became aware of the '504 patent no later than the date on which they jointly submitted ANDA No. 203748 to the FDA, in which they identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.
- 594. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.
- 595. The foregoing actions by Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma constitute and/or will constitute infringement of the '504 patent and active inducement of infringement of the '504 patent.
- 596. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Allergan on the one hand and Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma on the other hand regarding Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma's infringement of the '504 patent and active inducement of infringement of the '504 patent.

- 597. Allergan is entitled to a judgment declaring that the foregoing actions by Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma constitute and/or will constitute infringement of the '504 patent and active inducement of infringement of the '504 patent.
- 598. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have acted with full knowledge of the '504 patent and without a reasonable basis for believing that they would not be liable for infringing the '504 patent and actively inducing the infringement of the '504 patent.
- 599. Unless Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are enjoined from infringing the '504 patent and actively inducing infringement of the '504 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Count XXXVIII

(Infringement of the '353 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 600. Paragraphs 1 to 135 and 583 to 599 are incorporated herein as set forth above.
- 601. Watson submitted ANDA No. 203748 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Watson has committed an act of infringement of the '353 patent under 35 U.S.C. § 271(e)(2)(A).
- 602. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '353 patent.

- 603. On information and belief, Watson became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 604. On information and belief, Watson knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '353 patent.
- 605. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '353 patent.
- 606. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XXXIX

- (Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(a) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)
- 607. Paragraphs 1 to 135 and 583 to 606 are incorporated herein as set forth above.
- 608. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 609. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 610. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '353 patent.
- 611. On information and belief, Watson will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203748.
 - 612. The foregoing actions by Watson will constitute infringement of the '353 patent.
 - 613. Watson will commit those acts of infringement without license or authorization.
- 614. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01% by Watson will infringe the '353 patent.
- 615. Unless Watson is enjoined from infringing the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 616. On information and belief, Watson became aware of the '353 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 617. On information and belief, Watson has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Watson's proposed Bimatoprost Ophthalmic Solution, 0.01%.

- 618. Watson's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 619. On information and belief, Watson has acted, and will continue to act, with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for infringing the '353 patent.
- 620. On information and belief, despite having actual notice of the '353 patent, Watson continues to willfully, wantonly, and deliberately prepare to infringe the '353 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XL

(Declaratory Judgment of Infringement of the '353 Patent Under 35 U.S.C. § 271(b) and (c) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 621. Paragraphs 1 to 135 and 583 to 620 are incorporated herein as set forth above.
- 622. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 623. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 624. Watson has actual knowledge of the '353 patent.
- 625. On information and belief, Watson became aware of the '353 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 626. On information and belief, Watson has acted with full knowledge of the '353 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '353 patent.
- 627. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '353 patent.
- 628. On information and belief, Watson knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '353 patent.
- 629. On information and belief, Watson will encourage another's infringement of the '353 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '353 patent.
- 630. Watson's acts of infringement will be done with knowledge of the '353 patent and with the intent to encourage infringement.
- 631. The foregoing actions by Watson will constitute active inducement of infringement of the '353 patent.
- 632. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '353 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 633. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 634. On information and belief, Watson knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '353 patent.
- 635. The foregoing actions by Watson will constitute contributory infringement of the '353 patent.
- 636. On information and belief, Watson intends to, and will, actively induce and contribute to the infringement of the '353 patent when ANDA No. 203748 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 637. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Watson will induce and/or contribute to infringement of the '353 patent.
- 638. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '353 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 639. Unless Watson is enjoined from actively inducing and contributing to the infringement of the '353 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

640. On information and belief, despite having actual notice of the '353 patent, Watson continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '353 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XLII

(Infringement of the '118 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 641. Paragraphs 1 to 135 and 583 to 640 are incorporated herein as set forth above.
- 642. Watson submitted ANDA No. 203748 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Watson has committed an act of infringement of the '118 patent under 35 U.S.C. § 271(e)(2)(A).
- 643. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '118 patent.
- 644. On information and belief, Watson became aware of the '118 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 645. On information and belief, Watson knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '118 patent.

- 646. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '118 patent.
- 647. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XLII

(Declaratory Judgment of Infringement of the '118 Patent Under 35 U.S.C. § 271(b) and (c) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 648. Paragraphs 1 to 135 and 583 to 647 are incorporated herein as set forth above.
- 649. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 650. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 651. Watson has actual knowledge of the '118 patent.
- 652. On information and belief, Watson became aware of the '118 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 653. On information and belief, Watson has acted with full knowledge of the '118 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '118 patent.
- 654. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '118 patent.
- 655. On information and belief, Watson knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '118 patent.
- 656. On information and belief, Watson will encourage another's infringement of the '118 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '118 patent.
- 657. Watson's acts of infringement will be done with knowledge of the '118 patent and with the intent to encourage infringement.
- 658. The foregoing actions by Watson will constitute active inducement of infringement of the '118 patent.
- 659. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '118 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 660. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 661. On information and belief, Watson knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '118 patent.
- 662. The foregoing actions by Watson will constitute contributory infringement of the '118 patent.
- 663. On information and belief, Watson intends to, and will, actively induce and contribute to the infringement of the '118 patent when ANDA No. 203748 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 664. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Watson will induce and/or contribute to infringement of the '118 patent.
- 665. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '118 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 666. Unless Watson is enjoined from actively inducing and contributing to the infringement of the '118 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

667. On information and belief, despite having actual notice of the '118 patent, Watson continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '118 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XLIII

(Infringement of the '605 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 668. Paragraphs 1 to 135 and 583 to 667 are incorporated herein as set forth above.
- 669. Watson submitted ANDA No. 203748 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Watson has committed an act of infringement of the '605 patent under 35 U.S.C. § 271(e)(2)(A).
- 670. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '605 patent.
- 671. On information and belief, Watson became aware of the '605 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 672. On information and belief, Watson knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '605 patent.

- 673. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '605 patent.
- 674. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XLIV

(Declaratory Judgment of Infringement of the '605 Patent Under 35 U.S.C. § 271(b) and (c) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 675. Paragraphs 1 to 135 and 583 to 674 are incorporated herein as set forth above.
- 676. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 677. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 678. Watson has actual knowledge of the '605 patent.
- 679. On information and belief, Watson became aware of the '605 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.

- 680. On information and belief, Watson has acted with full knowledge of the '605 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '605 patent.
- 681. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '605 patent.
- 682. On information and belief, Watson knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '605 patent.
- 683. On information and belief, Watson will encourage another's infringement of the '605 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '605 patent.
- 684. Watson's acts of infringement will be done with knowledge of the '605 patent and with the intent to encourage infringement.
- 685. The foregoing actions by Watson will constitute active inducement of infringement of the '605 patent.
- 686. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '605 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 687. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 688. On information and belief, Watson knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '605 patent.
- 689. The foregoing actions by Watson will constitute contributory infringement of the '605 patent.
- 690. On information and belief, Watson intends to, and will, actively induce and contribute to the infringement of the '605 patent when ANDA No. 203748 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 691. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% by Watson will induce and/or contribute to infringement of the '605 patent.
- 692. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '605 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 693. Unless Watson is enjoined from actively inducing and contributing to the infringement of the '605 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

694. On information and belief, despite having actual notice of the '605 patent, Watson continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '605 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XLV

(Infringement of the '479 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 695. Paragraphs 1 to 135 and 583 to 694 are incorporated herein as set forth above.
- 696. Watson submitted ANDA No. 203748 to the 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 Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Watson has committed an act of infringement of the '479 patent under 35 U.S.C. § 271(e)(2)(A).
- 697. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '479 patent.
- 698. On information and belief, Watson became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 699. On information and belief, Watson knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce and contribute to the actual infringement of the '479 patent.

- 700. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '479 patent.
- 701. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XLVI

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(a) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 702. Paragraphs 1 to 135 and 583 to 701 are incorporated herein as set forth above.
- 703. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 704. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 705. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of one or more claims of the '479 patent.
- 706. On information and belief, Watson will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203748.

- 707. The foregoing actions by Watson will constitute infringement of the '479 patent.
- 708. Watson will commit those acts of infringement without license or authorization.
- 709. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01% by Watson will infringe the '479 patent.
- 710. Unless Watson is enjoined from infringing the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 711. On information and belief, Watson became aware of the '479 patent no later than the date on which that patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 712. On information and belief, Watson has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Watson's proposed Bimatoprost Ophthalmic Solution, 0.01%.
- 713. Watson's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.
- 714. On information and belief, Watson has acted, and will continue to act, with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for infringing the '479 patent.
- 715. On information and belief, despite having actual notice of the '479 patent, Watson continues to willfully, wantonly, and deliberately prepare to infringe the '479 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count XLVII

(Declaratory Judgment of Infringement of the '479 Patent Under 35 U.S.C. § 271(b) and (c) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

- 716. Paragraphs 1 to 135 and 583 to 715 are incorporated herein as set forth above.
- 717. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 718. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
 - 719. Watson has actual knowledge of the '479 patent.
- 720. On information and belief, Watson became aware of the '479 patent no later than the date on which the patent was listed in the Orange Book as one of the patents covering the approved formulation of Lumigan® 0.01%.
- 721. On information and belief, Watson has acted with full knowledge of the '479 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '479 patent.
- 722. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will induce the actual infringement of the '479 patent.
- 723. On information and belief, Watson knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '479 patent.
- 724. On information and belief, Watson will encourage another's infringement of the '479 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% which is covered by certain claims of the '479 patent.

- 725. Watson's acts of infringement will be done with knowledge of the '479 patent and with the intent to encourage infringement.
- 726. The foregoing actions by Watson will constitute active inducement of infringement of the '479 patent.
- 727. On information and belief, Watson knows or should know that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '479 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 728. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 729. On information and belief, Watson knows or should know that its offer for sale, sale, and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will contribute to the actual infringement of the '479 patent.
- 730. The foregoing actions by Watson will constitute contributory infringement of the '479 patent.
- 731. On information and belief, Watson intends to, and will, actively induce and contribute to the infringement of the '479 patent when ANDA No. 203748 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 732. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic

Bimatoprost Ophthalmic Solution, 0.01% by Watson will induce and/or contribute to infringement of the '479 patent.

- 733. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, which will actively induce and/or contribute to infringement of the '479 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 734. Unless Watson is enjoined from actively inducing and contributing to the infringement of the '479 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 735. On information and belief, despite having actual notice of the '479 patent, Watson continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '479 patent in disregard to Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Jury Trial Demand

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

Prayer for Relief

Allergan respectfully prays for the following relief:

a. That judgment be entered that Sandoz has infringed the '504, '819, '353, '118, '605, and '479 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203056 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the

United States, of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute acts of infringement of the '504, '819, '353, '118, '605, and '479 patents;

- b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Sandoz's ANDA No. 203056 shall be a date which is not earlier than the latest expiration date of the '504, '819, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity;
- c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '504, '819, '353, '118, '605 and/or '479 patents;
- d. That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '353, '118, '605, and '479 patents;
- e. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's generic product disclosed in its ANDA No. 203056 prior to the expiration of the '504, '819, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity, a preliminary injunction be entered enjoining such conduct;

- f. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's generic product disclosed in its ANDA No. 203056 prior to the expiration of the '504, '819, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity, 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;
- g. That judgment be entered declaring that Sandoz will infringe the '353, '118, '605, and '479 patents and will actively induce infringement of the '353, '118, '605, and '479 patents if and when it engages in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's generic product disclosed in its ANDA No. 203056 prior to the expiration of the '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity;
- h. That a declaration be issued under 28 U.S.C. § 2201 that if Sandoz, its officers, agents, servants, employees, licensees, representative, and attorneys, and all other persons acting or attempting to act in concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, it will constitute acts of infringement of the '353, '118, '605, and '479 patents;
- i. That judgment be entered that Lupin Ltd. and Lupin Pharmaceuticals have infringed the '504, '353, '118, '605, and '479 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202911 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 Lupin's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute acts of infringement of the '504, '353, '118, '605, and '479 patents;

- j. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Lupin's ANDA No. 202911 shall be a date which is not earlier than the latest expiration date of the '504, '353, '118, '605, and/or '479 patents, as extended by any applicable periods of exclusivity;
- k. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Lupin Ltd. and Lupin Pharmaceuticals, their 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 sale within the United States, or importation into the United States, of any drug product covered by the '504, '353, '118, '605, and '479 patents;
- 1. That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Lupin Ltd. and Lupin Pharmaceuticals, their 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 sale within the United States, or importation into the United States, of any drug product covered by the '504, '353, '118, '605, and '479 patents;
- m. That if Lupin Ltd. or Lupin Pharmaceuticals attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Lupin's generic product disclosed in its ANDA No. 202911 prior to the expiration of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity, a preliminary injunction be entered enjoining such conduct;
- n. That if Lupin Ltd. or Lupin Pharmaceuticals attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Lupin's generic product disclosed in its

ANDA No. 202911 prior to the expiration of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity, 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;

- o. That judgment be entered declaring that Lupin Ltd. and Lupin Pharmaceuticals will infringe the '504, '353, '118, '605, and '479 patents and will actively induce infringement of the '504, '353, '118, '605, and '479 patents if and when the engage in the commercial manufacture, use, offer for sale, sale, or importation of Lupin's generic product disclosed in their ANDA No. 202911 prior to the expiration of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity;
- p. That a declaration be issued under 28 U.S.C. § 2201 that if Lupin Ltd. and Lupin Pharmaceuticals, their officers, agents, servants, employees, licensees, representative, and attorneys, and all other persons acting or attempting to act in concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, it will constitute acts of infringement of the '504, '353, '118, '605, and '479 patents;
- q. That judgment be entered that Hi-Tech has infringed the '504, '353, '118, '605, and '479 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203604 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 Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute acts of infringement of the '504, '353, '118, '605, and '479 patents;

- r. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Hi-Tech's ANDA No. 203604 shall be a date which is not earlier than the latest expiration date of the '504, '353, '118, '605, and/or '479 patents, as extended by any applicable periods of exclusivity;
- s. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Hi-Tech, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '504, '353, '118, '605, and '479 patents;
- t. That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Hi-Tech, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '353, '118, '605, and '479 patents;
- u. If Hi-Tech attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Hi-Tech's generic product disclosed in its ANDA No. 203604 prior to the expiration of the '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity, a preliminary injunction be entered enjoining such conduct;
- v. If Hi-Tech attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Hi-Tech's generic product disclosed in its ANDA No. 203604 prior to the expiration of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods

of exclusivity, 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;

- w. That judgment be entered declaring that Hi-Tech will infringe the '353, '118, '605, and '479 patents and will actively induce infringement of the '353, '118, '605, and '479 patents if and when it engages in the commercial manufacture, use, offer for sale, sale, or importation of Hi-Tech's generic product disclosed in its ANDA No. 203604 prior to the expiration of the '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity;
- x. That a declaration be issued under 28 U.S.C. § 2201 that if Hi-Tech, its officers, agents, servants, employees, licensees, representative, and attorneys, and all other persons acting or attempting to act in concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, it will constitute acts of infringement of the '353, '118, '605, and '479 patents;
- y. That judgment be entered that Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have infringed the '504, '353, '118, '605, and '479 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203748 under 21 U.S.C. §§ 355(j)(1) and (2)(A), and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01% will constitute acts of infringement of the '504, '353, '118, '605, and '479 patents;
- z. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Watson's ANDA No. 203748 shall be a date which is not earlier than the

latest expiration date of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity;

- aa. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, their 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 sale within the United States, or importation into the United States, of any drug product covered by the '504, '353, '118, '605, and '479 patents;
- bb. That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, their 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 sale within the United States, or importation into the United States, of any drug product covered by the '504, '353, '118, '605, and '479 patents;
- cc. If Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Watson's generic product disclosed in its ANDA No. 203748 prior to the expiration of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity, a preliminary injunction be entered enjoining such conduct;
- dd. If Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Watson's

generic product disclosed in its ANDA No. 203748 prior to the expiration of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity, 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;

- ee. That judgment be entered declaring that Watson will infringe the '504, '353, '118, '605, and '479 patents and will actively induce infringement of the '504, '353, '118, '605, and '479 patents if and when it engages in the commercial manufacture, use, offer for sale, sale, or importation of Watson's generic product disclosed in its ANDA No. 203748 prior to the expiration of the '504, '353, '118, '605, and '479 patents, as extended by any applicable periods of exclusivity;
- ff. That a declaration be issued under 28 U.S.C. § 2201 that if Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, their officers, agents, servants, employees, licensees, representative, and attorneys, and all other persons acting or attempting to act in concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Ophthalmic Solution, 0.01%, it will constitute acts of infringement of the '504, '353, '118, '605, and '479 patents;
- gg. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs;
- hh. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and
 - ii. That this Court award such other and further relief as it may deem just and proper.

Dated: January 4, 2013 Respectfully submitted,

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