**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF INDIANA**
**INDIANAPOLIS DIVISION**

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| ELI LILLY AND COMPANY et al.,<br>Plaintiffs,<br><br>v.<br><br>PERRIGO COMPANY et al.,<br>Defendants. | Case No. 1:13-CV-0851-SEB-DKL |

**SECOND CONSOLIDATED AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Eli Lilly and Company ("Lilly"), Eli Lilly Export S.A., and Acrux DDS Pty Ltd. ("Acrux") file this Amended Complaint for patent infringement against Perrigo Company and Perrigo Israel Pharmaceuticals Ltd. (collectively, "the Perrigo Defendants"), Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc. and referred to herein as "Watson Laboratories"), and Amneal Pharmaceuticals LLC ("Amneal") under 35 U.S.C. § 271. This patent action concerns the pharmaceutical drug product Axiron®.

**THE PARTIES**

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business

of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Eli Lilly Export S.A. is a Swiss corporation that has its corporate office at 16 Chemin des Coquelicots, The Air Centre, 1214 Vernier/Geneva, Switzerland. Eli Lilly Export S.A. is a wholly owned subsidiary of Lilly.

3. Acrux is an Australian corporation that has its corporate offices and principal place of business at 103-113 Stanley Street, West Melbourne VIC 3003, Australia. Acrux is engaged in the development and commercialization of pharmaceutical products for sale throughout the world.

4. Perrigo Company is a Michigan corporation with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Company is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States.

5. Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli corporation with its principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel. Perrigo Israel is a wholly-owned subsidiary of Perrigo Company.

6. Perrigo Israel is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States in concert with its parent company Perrigo Company and related companies.

7. Watson Laboratories is a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories is a pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products

for sale in the State of Indiana and throughout the United States in concert with its parent company Actavis, Inc. and related companies, including Actavis Pharma, Inc. ("Actavis Pharma"). Watson Laboratories and Actavis Pharma are wholly owned subsidiaries of Actavis, Inc. Watson Laboratories, Actavis Pharma and Actavis, Inc. are collectively referred to herein as "Actavis."

8. Amneal is a Delaware corporation with its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863. Amneal is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States.

## NATURE OF THE ACTION

9. This is an action for infringement of U.S. Patent Nos. 6,299,900 ("the '900 patent); 6,818,226 ("the '226 patent"); 6,923,983 ("the '983 patent"); 8,071,075 ("the '075 patent"); 8,419,307 ("the '307 patent"); 8,435,944 ("the '944 patent"); 8,177,449 ("the '449 patent"); 8,807,861 ("the '861 patent"); and 8,993,520 ("the '520 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 204255 submitted in the name of Perrigo Israel to the U.S. Food and Drug Administration ("FDA"), ANDA No. 205328 submitted in the name of Watson Laboratories, and ANDA No. 206998 submitted in the name of Amneal for approval to market a generic version of Lilly's Axiron® (testosterone) product, which constitutes an action of infringement under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

## SUBJECT MATTER JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

**PERSONAL JURISDICTION OVER THE PERRIGO DEFENDANTS**

13. The Court has personal jurisdiction over the Perrigo Defendants because they regularly and continuously transact business within the State of Indiana. The Perrigo Defendants market and sell pharmaceutical products throughout the United States, including the State of Indiana. The Perrigo Defendants derive substantial revenue from Indiana drug sales and have availed themselves of the privilege of conducting business within the State of Indiana.

14. According to the website for Perrigo Company and its subsidiaries (collectively, "Perrigo"), "Perrigo develops, manufactures and distributes over-the-counter (OTC) and generic prescription ($R_x$) pharmaceuticals, infant formulas, nutritional products, dietary supplements and active pharmaceutical ingredients (API). The Company is the world's largest manufacturer of OTC pharmaceutical products for the store brand market. The Company's primary markets and locations of logistics operations have evolved over the years to include the United States . . . ."

15. Perrigo's 2012 Annual Report states that Perrigo "operates through several wholly owned subsidiaries," including Perrigo Israel. As described in its Annual Report, Perrigo has "four reportable segments, aligned primarily by type of product: Consumer Healthcare, Nutritionals, $R_x$ Pharmaceuticals and API." Perrigo's Annual Report explains that "[e]ach of these business segments share Research & Development ("R&D"), Supply Chain, Information Technology, Finance, Human Resources, Legal and Quality services, all of which are directed out of the Company's headquarters in Allegan, Michigan."

16. Perrigo Israel is part of Perrigo's $R_x$ pharmaceuticals segment.

17. According to Perrigo's 2012 Annual Report, "[t]he Consumer Healthcare segment currently markets over 2,100 store brand products, with over 9,000 stock-keeping units ("SKUs"), to over 800 customers." In addition, for the Consumer Healthcare segment, "[t]he

Company's U.S.-based customers are major national and regional retail drug, supermarket and mass merchandise chains, including Wal-Mart, CVS, Walgreens, Kroger, Target, Dollar General, Rite Aid, Sam's Club and Costco, and major wholesalers, including McKesson, Cardinal Health and AmerisourceBergen."

18. According to Perrigo's 2012 Annual Report, "[t]he $R_x$ Pharmaceuticals segment develops, manufactures and markets a portfolio of generic prescription drugs for the U.S. market. The Company defines this portfolio as predominantly 'extended topical' and specialty as it encompasses a broad array of topical dosage forms such as creams, ointments, lotions, gels, shampoos, foams, suppositories, sprays, liquids, suspensions, solutions and powders. The portfolio also includes select controlled substances, injectables, hormones, oral liquids and oral solid dosage forms." The 2012 Annual Report further states that "[t]he $R_x$ Pharmaceuticals segment currently markets approximately 400 generic prescription products, with almost 1,000 SKUs, to approximately 300 customers." In addition, for the $R_x$ Pharmaceuticals segment, "[t]he Company's U.S.-based customers are major wholesalers, including Cardinal Health, McKesson and AmerisourceBergen, as well as national and regional retail drug, supermarket and mass merchandise chains, including Walgreens, Wal-Mart, CVS, Rite Aid, Kroger and Safeway. Generic prescription drugs are sold to the consumer through the pharmacy counter of predominantly the same retail outlets as OTC pharmaceuticals and nutritional products."

19. A wholly owned subsidiary of Perrigo Company, Perrigo Sales Corporation (515 Eastern Avenue, Allegan, MI 40910), has been granted a Certificate of Authority from the Indiana Secretary of State.

20. Perrigo Company, directly or through related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Perrigo Company in Indiana on the basis of general jurisdiction.

21. Perrigo Company, either directly or through wholesalers, sells products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Perrigo Company derives substantial revenue from these sales.

22. Perrigo Israel, directly or in concert with related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Perrigo Israel in Indiana on the basis of general jurisdiction.

23. Perrigo Israel develops and manufactures pharmaceutical products for the United States market, including the State of Indiana. These products include cetirizine tablets and syrup, clobetasol foam, halobetasol ointment and cream, imiquimod cream, and mesalamine rectal suspension enema, which are all among Perrigo's major pharmaceutical products, according to Perrigo's 2012 Annual Report. Perrigo Israel, directly, through wholesalers, or in concert with related companies, sells products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Perrigo Israel derives substantial revenue from these sales.

24. Perrigo Company acts as the agent and official submitter to the FDA of Perrigo Israel's ANDA No. 204255 at issue in this case. Perrigo Company participated in the preparation and submission of ANDA No. 204255 and will benefit directly and indirectly upon the approval of ANDA No. 204255.

**PERSONAL JURISDICTION OVER WATSON LABORATORIES**

25. The Court has personal jurisdiction over Watson Laboratories because it regularly and continuously transacts business within the State of Indiana. Watson Laboratories markets

and sells pharmaceutical products throughout the United States, including the State of Indiana. Watson Laboratories derives substantial revenue from Indiana drug sales and has availed itself of the privilege of conducting business within the State of Indiana.

26. According to the website for Actavis, Inc. and its subsidiaries, Actavis "is a global, integrated specialty pharmaceutical company focused on developing, manufacturing and distributing generic, brand and biosimilar products."

27. According to Actavis's 2012 Annual Report Form 10-K ("Actavis's 2012 Annual Report"), "On October 31, 2012, Watson Pharmaceuticals, Inc. completed the acquisition of the Actavis Group. On January 24, 2013, the Company was renamed Actavis, Inc." The 2012 Annual Report further states that "[f]ollowing the renaming of Watson Pharmaceuticals, Inc. to Actavis, Inc. efforts are underway to change the underlying 'Watson' subsidiary and legal entity names to an 'Actavis' name. This process is expected to continue to roll out throughout the year."

28. According to Actavis's 2012 Annual Report, "[t]he Company operates in three business segments: Actavis Pharma; Actavis Specialty Brands; and Anda Distribution (also known as 'Anda')."

29. According to Actavis's 2012 Annual Report, the "United States of America ('U.S.') remains our largest commercial market and represented approximately 81% of total net revenues for 2012. As of December 31, 2012, we marketed approximately 250 generic pharmaceutical product families and over 40 brand pharmaceutical products in the U.S. and distributed approximately 11,450 stock-keeping units ('SKUs') through our Anda Distribution Division."

30. The 2012 Annual Report further states: "[i]n the U.S., we predominantly market our generic products to various drug wholesalers, mail order, government and national retail drug

and food store chains utilizing a small team of sales and marketing professionals. We sell our generic prescription products primarily under the 'Watson Laboratories', 'Watson Pharma' and 'Actavis Pharma' labels, and our over-the-counter generic products under private label."

31. According to Actavis's 2012 Annual Report: "[i]n our Actavis Pharma and Actavis Specialty Brand operations, we sell our generic and brand pharmaceutical products primarily to drug wholesalers, retailers and distributors, including national retail drug and food store chains, hospitals, clinics, mail order, government agencies and managed healthcare providers such as health maintenance organizations and other institutions. In our Anda Distribution business, we distribute generic and certain select brand pharmaceutical products to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains, physicians' offices and buying groups."

32. According to Actavis's 2012 Annual Report, "[o]ur Anda Distribution business primarily distributes generic and selected brand pharmaceutical products, vaccines, injectables and over-the-counter medicines to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains and physicians' offices. Additionally, we sell to members of buying groups, which are independent pharmacies that join together to enhance their buying power. We believe that we are able to effectively compete in the distribution market, and therefore optimize our market share, based on three critical elements: (i) competitive pricing, (ii) high levels of inventory for approximately 11,450 SKUs for responsive customer service that includes, among other things, next day delivery to the entire U.S., and (iii) well established telemarketing relationships with our customers, supplemented by our electronic ordering capabilities. While we purchase most of the approximate 11,450 SKUs in our Anda Distribution operations from third party manufacturers, we also distribute our own products and

our collaborative partners' products. We are the only U.S. pharmaceutical company that has meaningful distribution operations with direct access to independent pharmacies."

33. Upon information and belief, Watson Pharmaceuticals, Actavis Pharma, and/or Actavis, Inc. share common officers and directors.

34. Watson Laboratories, directly or through related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Watson Laboratories in Indiana on the basis of general jurisdiction.

35. Watson Laboratories develops and manufactures pharmaceutical products for sale throughout the United States, including the State of Indiana. Watson Laboratories, either directly or through wholesalers, sells pharmaceutical products to national and regional retail drug, supermarket, and/or mass merchandise chains in Indiana, and Watson Laboratories derives substantial revenue from these sales.

36. As further evidence of personal jurisdiction over Watson Laboratories, Watson Laboratories, has been sued for patent infringement in this district and has not contested personal jurisdiction. (*See* C.A. No. 1:11-cv-00786.) In addition, Watson Laboratories has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in a lawsuit filed in this Court. (*See* C.A. No. 1:11-cv-00786.)

37. Watson Laboratories acts as the agent and official submitter to the FDA of ANDA No. 205328 at issue in this case. Actavis, Inc. and Actavis Pharma participated in the preparation and submission of ANDA No. 205328 and will benefit directly and indirectly upon the approval of ANDA No. 205328.

**PERSONAL JURISDICTION OVER AMNEAL**

38. The Court has personal jurisdiction over Defendant Amneal because it regularly and continuously transacts business within the State of Indiana. Amneal markets and sells

pharmaceutical products throughout the United States, including the State of Indiana. Amneal maintains a broad distributorship network within Indiana. Amneal derives substantial revenue from Indiana drug sales and has availed itself of the privilege of conducting business within the State of Indiana.

39. According to the website for Amneal, "Amneal sells over 12 billion units of medication annually in the U.S. alone." In fact, "Amneal's primary distribution facility allows it to service customers in every corner of the U.S. in an expeditious, accurate and dependable fashion." Amneal boasts on its website that because it is "[s]trategically located in close proximity to the UPS hub and within the Central Time Zone, Amneal is able to provide one-day ground delivery to more than 75% of the American population."

40. Upon information and belief, Amneal Pharmaceuticals currently sells significant quantities of generic drug products in the state of Indiana. Those products include, for example, generic versions of Percocet®, Ultracet®, and Neurontin®. A list of generic products manufactured and sold by Amneal Pharmaceuticals in the United States can be found at http://prd03.apsiva.net/amneal/#/.

41. According to the website for Amneal, "Amneal proudly sells directly to warehousing chains, wholesalers/distributors and mail order operations in order to make its quality products available to all levels of retail pharmacy including independently owned, regional chains and cooperatives."

42. On information and belief, Amneal has directly entered into a distribution agreement with an Indiana wholesale distributor. According to the website for Amneal, Amneal lists A.F. Hauser, Inc. as an authorized distributor of its products. On information and belief, A.F. Hauser, Inc. is located at 4401 East U.S. Hwy. 30, Valparaiso, Indiana 46383.

43. On information and belief Amneal has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Amneal filed counterclaims for declaratory judgment in the Southern District of Indiana. *Eli Lilly and Company et al. v. Accord Healthcare, Inc. USA. et al.*, No. 1:14-cv-389-SEB-TAB (S.D.Ind.).

44. Amneal has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Amneal in Indiana on the basis of general jurisdiction.

45. Amneal, either directly or through wholesalers, sells products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Amneal derives substantial revenue from these sales.

46. Amneal develops and manufactures pharmaceutical products for the United States market, including the State of Indiana.

47. Amneal prepared and submitted ANDA No. 206998 and will benefit from the approval of ANDA No. 206998.

## FACTUAL BACKGROUND

### A. Axiron®

48. Lilly is the holder of approved New Drug Application ("NDA") No. 022504 for the manufacture and sale of testosterone metered transdermal solution, 30mg/1.5mL used to treat males for conditions associated with a deficiency or absence of endogenous testosterone. Lilly markets and sells testosterone metered transdermal solution, 30mg/1.5mL under the trade name Axiron®. Axiron® was approved by the FDA on November 23, 2010.

**B. The ’900 Patent**

49. United States Patent No. 6,299,900 (“the ’900 patent”) entitled “Dermal Penetration Enhancers and Drug Delivery Systems Involving Same,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on October 9, 2001. The ’900 patent claims, *inter alia*, a transdermal drug delivery system that comprises at least one physiologically active agent and at least one dermal penetration enhancer. The ’900 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”) in connection with Axiron®. A true and correct copy of the ’900 patent is attached as Exhibit A. Acrux is the owner of the ’900 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’900 patent. Eli Lilly Export S.A. has licensed its rights in the ’900 patent to Lilly.

**C. The ’226 Patent**

50. United States Patent No. 6,818,226 (“the ’226 patent”), entitled “Dermal Penetration Enhancers and Drug Delivery Systems Involving Same,” was duly and legally issued by the PTO on November 16, 2004. The ’226 patent claims, *inter alia*, a transdermal drug delivery system that comprises at least one physiologically active agent and at least one dermal penetration enhancer. The ’226 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’226 patent is attached as Exhibit B. Since its date of issue, Acrux has been, and continues to be, the owner of the ’226 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’226 patent. Eli Lilly Export S.A. has licensed its rights in the ’226 patent to Lilly.

**D. The ’983 Patent**

51. United States Patent No. 6,923,983 (“the ’983 patent”), entitled “Transdermal Delivery of Hormones,” was duly and legally issued by the PTO on August 2, 2005. The ’983 patent claims, *inter alia*, a transdermal drug delivery system comprising a therapeutically effective amount of a hormone and at least one dermal penetration enhancer. The ’983 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’983 patent is attached as Exhibit C. Since its date of issue, Acrux has been, and continues to be, the owner of the ’983 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’983 patent. Eli Lilly Export S.A. has licensed its rights in the ’983 patent to Lilly.

**E. The ’075 Patent**

52. United States Patent No. 8,071,075 (“the ’075 patent”), entitled “Dermal Penetration Enhancers and Drug Delivery Systems Involving the Same,” was duly and legally issued by the PTO on December 6, 2011. The ’075 patent claims, *inter alia*, a transdermal drug delivery system comprising a therapeutically effective amount of testosterone and at least one dermal penetration enhancer. The ’075 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’075 patent is attached as Exhibit D. Since its date of issue, Acrux has been, and continues to be, the owner of the ’075 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’075 patent. Eli Lilly Export S.A. has licensed its rights in the ’075 patent to Lilly.

**F. The ’307 Patent**

53. United States Patent No. 8,419,307 (“the ’307 patent”), entitled “Spreading Implement,” was duly and legally issued by the PTO on April 16, 2013. The ’307 patent claims, *inter alia*, a method of increasing the testosterone blood level of a person in need thereof

comprising applying a liquid pharmaceutical composition that contains testosterone. The '307 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '307 patent is attached as Exhibit E. Since its date of issue, Acrux has been, and continues to be, the owner of the '307 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '307 patent. Eli Lilly Export S.A. has licensed its rights in the '307 patent to Lilly.

**G. The '944 Patent**

54. United States Patent No. 8,435,944 ("the '944 patent"), entitled "Method and Composition for Transdermal Drug Delivery," was duly and legally issued by the PTO on May 7, 2013. The '944 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male comprising applying a transdermal drug delivery composition that contains testosterone. The '944 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '944 patent is attached as Exhibit F. Since its date of issue, Acrux has been, and continues to be, the owner of the '944 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '944 patent. Eli Lilly Export S.A. has licensed its rights in the '944 patent to Lilly.

**H. The '449 Patent**

55. United States Patent No. 8,177,449 ("the '449 patent"), entitled "Spreading Implement," was duly and legally issued by the PTO on May 15, 2012. The '449 patent claims, *inter alia*, a method of transdermal administration of a physiologically active agent. A true and correct copy of the '449 patent is attached as Exhibit G. Since its date of issue, Acrux has been, and continues to be, the owner of the '449 patent. Eli Lilly Export S.A. is the exclusive licensee

worldwide for all uses of Axiron® under the ’449 patent. Eli Lilly Export S.A. has licensed its rights in the ’449 patent to Lilly.

**I. The ’861 Patent**

56. United States Patent No. 8,807,861 (“the ’861 patent”), entitled “Spreading Implement,” was duly and legally issued by the PTO on August 19, 2014. The ’861 patent claims, *inter alia*, a method of transdermal administration of a physiologically active agent. A true and correct copy of the ’861 patent is attached as Exhibit H. Since its date of issue, Acrux has been, and continues to be, the owner of the ’861 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’861 patent. Eli Lilly Export S.A. has licensed its rights in the ’861 patent to Lilly.

**J. The ’520 Patent**

57. United States Patent No. 8,993,520 (“the ’520 patent”), entitled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the PTO on March 31, 2015. The ’520 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male comprising applying to at least one axilla of the subject, without occlusion by a patch device, a transdermal drug delivery composition that contains testosterone. The ’520 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’520 patent is attached as Exhibit G. Since its date of issue, Acrux has been, and continues to be, the owner of the ’520 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’520 patent. Eli Lilly Export S.A. has licensed its rights in the ’520 patent to Lilly.

**K. The Perrigo Defendants' ANDA No. 204255**

58. The Perrigo Defendants filed or caused to be filed with the FDA ANDA No. 204255 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "Testosterone Metered Transdermal Solution, 30mg/1.5mL" ("Perrigo's Generic Product") in the United States before the expiration of the '944, '307, '449, '861, and '520 patents.

59. Perrigo Company and Perrigo Israel acted in concert to prepare and submit ANDA No. 204255.

60. The Perrigo Defendants amended ANDA No. 204255 to contain certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '944, '307, '449, and '861 patents are invalid, unenforceable, and/or would not be infringed by Perrigo's Generic Product.

61. The Perrigo Defendants sent or caused to be sent to Lilly a letter dated September 7, 2012 ("Perrigo's September 7, 2012, Notice Letter"), notifying Lilly that the Perrigo Defendants' ANDA No. 204255 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '449 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Perrigo's September 7, 2012, Notice Letter states: "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '449 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA."

62. The Perrigo Defendants sent or caused to be sent to Lilly a letter dated April 16, 2013 ("Perrigo's April 16, 2013, Notice Letter"), notifying Lilly that the Perrigo Defendants' ANDA No. 204255 includes a paragraph IV certification to obtain approval to engage in the

commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '307 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Perrigo's April 16, 2013, Notice Letter states: "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '307 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA."

63. The Perrigo Defendants sent or caused to be sent to Lilly a letter dated May 9, 2013 ("Perrigo's May 9, 2013, Notice Letter"), notifying Lilly that the Perrigo Defendants' ANDA No. 204255 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '944 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Perrigo's May 9, 2013, Notice Letter states: "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '944 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA."

64. The Perrigo Defendants sent or caused to be sent to Lilly a letter dated October 23, 2014, ("Perrigo's October 23, 2014, Notice Letter"), notifying Lilly that the Perrigo Defendants' ANDA No. 204255 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '861 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Perrigo's October 23, 2014, Notice Letter states: "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '861 . . . patent[ is] invalid, unenforceable, and/or

will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA."

65. The submission of ANDA No. 204255 to the FDA constitutes infringement by the Perrigo Defendants of the '944, '307, '449, '861, and '520 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Perrigo's Generic Product would infringe the '944, '307, '449, '861, and '520 patents under 35 U.S.C. § 271(a), (b), and/or (c).

66. The Perrigo Defendants know and intend that physicians will prescribe and patients will take Perrigo's Generic Product for which approval is sought in ANDA No. 204255 and therefore, will infringe at least one claim of the patents in suit.

67. The Perrigo Defendants had knowledge of the patents-in-suit and by their promotional activities associated with Perrigo's Generic Product, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the patents in suit either literally or under the doctrine of equivalents.

68. The Perrigo Defendants plan to make, use, sell, offer to sell and/or import Perrigo's Generic Product for uses that will infringe the patents in suit. Perrigo's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

69. Plaintiffs commenced this action within 45 days of receiving Perrigo's April 16, 2013, Notice Letter, Perrigo's May 9, 2013, Notice Letter, and Perrigo's October 23, 2014, Notice Letter.

**L. Watson Laboratories' ANDA No. 205328**

70. Watson Laboratories filed or caused to be filed with the FDA ANDA No. 205328 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "Testosterone Topical Solution, for Topical Use, 30 mg of Testosterone per Pump Actuation"

("Watson Laboratories' Generic Product") in the United States before the expiration of the '900, '226, '983, '075, '307, '944, '449, '861, and '520 patents.

71. Watson Laboratories, Actavis, Inc., and Actavis Pharma acted in concert to prepare and submit ANDA No. 205328.

72. ANDA No. 205328 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '900, '226, '983, '075, '307, '944, and '861 patents are invalid, unenforceable, and/or would not be infringed by Watson Laboratories' Generic Product.

73. Watson Laboratories sent to Lilly and Acrux a letter dated October 4, 2013 ("the October 4, 2013, Notice Letter"), notifying Lilly and Acrux that Watson Laboratories' ANDA No. 205328 includes paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of Watson Laboratories' Generic Product before the expiration of the '900, '226, '983, '075, '307, and '944 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Watson Laboratories' Notice Letter states: "[Watson Laboratories] alleges, and has certified to FDA, that in [Watson Laboratories'] opinion and to the best of its knowledge, the '900, '226, '983, '075, '397, and '944 patent claims are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in [Watson Laboratories'] ANDA."

74. Watson Laboratories sent to Lilly and Acrux a letter dated March 30, 2015 ("March 30, 2015, Notice Letter"), notifying Lilly and Acrux that Watson Laboratories' ANDA No. 205328 includes paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of Watson Laboratories' Generic Product before the expiration of the '861 patent and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Watson

Laboratories' Notice Letter states: "[Watson Laboratories] alleges, and has certified to FDA, that in [Watson Laboratories'] opinion and to the best of its knowledge, the claims of the . . . '861 patent[ ] are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in [Watson Laboratories'] ANDA."

75. The Notice Letters purported to include an "Offer of Confidential Access" to Lilly and Acrux to ANDA No. 205328. Under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(5)(III), restrictions to an Offer of Confidential Access must serve the purpose of protecting trade secrets and other confidential business information. Actavis's Offer of Confidential Access restricted disclosure to outside counsel only and required that such counsel (a) not be involved in patent prosecution matters, either formally or informally, for Lilly or Acrux without limitation as to time or subject matter, and (b) not be involved in any FDA counseling, litigation or other work before or involving the FDA, without limitation as to time or subject matter. Actavis's offer was also restricted to certain unspecified information from its ANDA.

76. The proposed terms of Actavis's Offer of Confidential Access did not allow Acrux or Lilly in-house litigation team members who do not engage in patent prosecution relating to Axiron® or development of Axiron®, and who are crucial decision makers in the process of filing any infringement action, access to the necessary information with which to assess many of the details of Actavis's proposed generic copy of Axiron®. Actavis's proposed restrictions to other work performed by those having access to the ANDA were not directed to the purpose of protecting trade secrets and other confidential business information. Therefore, Actavis's Offer of Confidential Access was not on reasonable terms.

77. Lilly's and Acrux's outside counsel had a series of discussions with Actavis in an attempt to reach agreement on the terms and conditions of the Offer for Confidential Access; however, the parties did not reach agreement. Lilly and Acrux could not agree to all of the restrictions Actavis continued to place on its Offer of Confidential Access that were above and beyond those found in a reasonable protective order or as would be necessary to protect confidential business information, and Actavis did not provide Lilly or Acrux access to any portion of Watson Laboratories' ANDA.

78. The submission of ANDA No. 205328 to the FDA constitutes infringement by Watson Laboratories of the '900, '226, '983, '075, '307, '944, '449, '861, and '520 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Watson Laboratories' Generic Product would infringe the '900, '226, '983, '075, '307, '944, '449,'861, and '520 patents under 35 U.S.C. § 271(a), (b), and/or (c).

79. Watson Laboratories knows and intends that physicians will prescribe and patients will take Watson Laboratories' Generic Product for which approval is sought in ANDA No. 205328 and therefore, will infringe at least one claim of the patents-in-suit.

80. Watson Laboratories had knowledge of the patents-in-suit and by their promotional activities associated with Watson Laboratories' Generic Product, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the patents-in-suit either literally or under the doctrine of equivalents.

81. Watson Laboratories plans to make, use, sell, offer to sell, and/or import Watson Laboratories' Generic Product for uses that will infringe the patents-in-suit. Watson Laboratories' Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

82. Plaintiffs commenced this action within 45 days of receiving Watson Laboratories' October 4, 2013, and March 30, 2015, Notice Letters.

**M. Amneal's ANDA No. 206998**

83. Amneal filed or caused to be filed with the FDA ANDA No. 206998 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "Testosterone Topical Solution, 30mg/1.5mL" ("Amneal's Generic Product") in the United States before the expiration of the '944, '307,'449,'861, and '520 patents.

84. Amneal's ANDA No. 206998 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '944, '307,'861, and '520 patents are invalid, unenforceable, and/or would not be infringed by Amneal's Generic Product.

85. Amneal sent to Plaintiffs a letter dated October 29, 2014 ("October 9, 2014, Notice Letter"), notifying Plaintiffs that its ANDA No. 206998 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Amneal's Generic Product before the expiration of the '944, '307, and '861 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Amneal's Notice Letter states that it: "submitted to the FDA, and the FDA has received, an Abbreviated New Drug Application ("ANDA") that contains data from bioavailability or bioequivalence studies for, and which seeks approval to engage in the commercial manufacture, use, and/or sale of, Testosterone Topical Solution, 30mg/1.5mL, before the expiration of the Orange Book Listed Patents."

86. Amneal sent or caused to be sent to Lilly a letter dated April 20, 2015 ("April 20, 2015, Notice Letter"), notifying Lilly that the Amneal's ANDA No. 206998 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '520 patent, and providing information

pursuant to 21 U.S.C. § 355(j)(2)(B). Amneal's April 20, 2015, Notice Letter "identifies the Orange Book Listed Patent ['520], as being unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 206998 has been submitted by AMNEAL."

87. The submission of ANDA No. 206998 to the FDA constitutes infringement by Defendant of the '944, '307, '449, '861, and '520 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Amneal's Generic Product would infringe the '944, '307, '449,' 861, and '520 patents under 35 U.S.C. § 271(a), (b), and/or (c).

88. Defendant knows and intends that physicians will prescribe and patients will take Amneal's Generic Product for which approval is sought in ANDA No. 206998 and therefore, will infringe at least one claim of the patents-in-suit.

89. Defendant had knowledge of the patents-in-suit and by its promotional activities and proposed Generic product, knew or should know that it will aid and abet another's direct infringement of at least one of the claims of the patents-in-suit either literally or under the doctrine of equivalents.

90. Defendant plans to make, use, sell, offer to sell and/or import their Generic Product for uses that will infringe the patents-in-suit. Amneal's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

91. Plaintiffs commenced this action within 45 days of receiving Amneal's October 29, 2014, and April 20, 2015, Notice Letters.

## COUNTS AGAINST PERRIGO

### COUNT I. FOR PATENT INFRINGEMENT
**(Direct Infringement of U.S. Patent No. 8,435,944)**

92. Plaintiffs incorporate by reference and reallege Paragraphs 1-91 above as though fully restated herein.

93. Pursuant to 35 U.S.C. § 271(e)(2), the Perrigo Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by the Perrigo Defendants.

94. If ANDA No. 204255 is approved by the FDA, the Perrigo Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271.

95. Unless the Perrigo Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by the Perrigo Defendants' infringement of the '944 patent. Plaintiffs do not have an adequate remedy at law.

### COUNT II. FOR PATENT INFRINGEMENT
**(Inducement To Infringe U.S. Patent No. 8,435,944)**

96. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 95 above as though fully restated herein.

97. The Perrigo Defendants have knowledge of the '944 patent.

98. Upon FDA approval of ANDA No. 204255, the Perrigo Defendants will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that their acts are encouraging infringement.

**COUNT III. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,435,944)**

99. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 98 above as though fully restated herein.

100. If ANDA No. 204255 is approved, the Perrigo Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

101. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '944 patent.

102. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

**COUNT IV. FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 8,419,307)**

103. Plaintiffs incorporate by reference and reallege Paragraphs 1-102 above as though fully restated herein.

104. Pursuant to 35 U.S.C. § 271(e)(2), the Perrigo Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by the Perrigo Defendants.

105. If ANDA No. 204255 is approved by the FDA, the Perrigo Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '307 patent under 35 U.S.C. § 271.

106. Unless the Perrigo Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by the Perrigo Defendants' infringement of the '307 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT V. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,419,307)**

107. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 109 above as though fully restated herein.

108. The Perrigo Defendants have knowledge of the '307 patent.

109. Upon FDA approval of ANDA No. 204255, the Perrigo Defendants will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that their acts are encouraging infringement.

**COUNT VI. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,419,307)**

110. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 109 above as though fully restated herein.

111. If ANDA No. 204255 is approved, the Perrigo Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

112. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '307 patent.

113. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

**COUNT VII. FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 8,177,449)**

114. Plaintiffs incorporate by reference and reallege Paragraphs 1-113 above as though fully restated herein.

115. Pursuant to 35 U.S.C. § 271(e)(2), the Perrigo Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by the Perrigo Defendants.

116. If ANDA No. 204255 is approved by the FDA, the Perrigo Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 patent under 35 U.S.C. § 271.

117. Unless the Perrigo Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by the Perrigo Defendants' infringement of the '449 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT VIII. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,177,449)**

118. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 117 above as though fully restated herein.

119. The Perrigo Defendants have knowledge of the '449 patent.

120. Upon FDA approval of ANDA No. 204255, the Perrigo Defendants will intentionally encourage acts of direct infringement of the '449 patent by others, with knowledge that their acts are encouraging infringement.

**COUNT IX. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,177,449)**

121. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 120 above as though fully restated herein.

122. If ANDA No. 204255 is approved, the Perrigo Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

123. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '449 patent.

124. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

**COUNT X. FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 8,807,861)**

125. Plaintiffs incorporate by reference and reallege Paragraphs 1-124 above as though fully restated herein.

126. Pursuant to 35 U.S.C. § 271(e)(2), the Perrigo Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '861 patent was an act of infringement of the '861 patent by the Perrigo Defendants.

127. If ANDA No. 204255 is approved by the FDA, the Perrigo Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '861 patent under 35 U.S.C. § 271.

128. Unless the Perrigo Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by the Perrigo Defendants' infringement of the '861 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XI. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,807,861)**

129. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 128 above as though fully restated herein.

130. The Perrigo Defendants have knowledge of the '861 patent.

131. Upon FDA approval of ANDA No. 204255, the Perrigo Defendants will intentionally encourage acts of direct infringement of the '861 patent by others, with knowledge that their acts are encouraging infringement.

**COUNT XII. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,807,861)**

132. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 131 above as though fully restated herein.

133. If ANDA No. 204255 is approved, the Perrigo Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

134. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '861 patent.

135. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

**COUNT XIII. FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 8,993,520)**

136. Plaintiffs incorporate by reference and reallege Paragraphs 1-135 above as though fully restated herein.

137. Pursuant to 35 U.S.C. § 271(e)(2), the Perrigo Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by the Perrigo Defendants.

138. If ANDA No. 204255 is approved by the FDA, the Perrigo Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '520 patent under 35 U.S.C. § 271.

139. Unless the Perrigo Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by the Perrigo Defendants' infringement of the '520 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XIV. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,993,520)**

140. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 139 above as though fully restated herein.

141. The Perrigo Defendants have knowledge of the '520 patent.

142. Upon FDA approval of ANDA No. 204255, the Perrigo Defendants will intentionally encourage acts of direct infringement of the '520 patent by others, with knowledge that their acts are encouraging infringement.

**COUNT XV. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,993,520)**

143. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 142 above as though fully restated herein.

144. If ANDA No. 204255 is approved, the Perrigo Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

145. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '520 patent.

146. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

**COUNT XVI. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,435,944)**

147. Plaintiffs incorporate by reference and reallege Paragraphs 1-146 above as though fully restated herein.

148. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act,

28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

149. The Perrigo Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. The Perrigo Defendants' Generic Product has no substantial non-infringing uses.

150. The Perrigo Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '944 patent.

151. The Perrigo Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

152. The Perrigo Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

153. The Perrigo Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '944 patent.

154. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '944 patent.

155. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

156. There is a justiciable case or controversy between Plaintiffs and the Perrigo Defendants regarding whether the Perrigo Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '944 patent.

157. If the Perrigo Defendants' infringement of the '944 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XVII. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,419,307)**

158. Plaintiffs incorporate by reference and reallege Paragraphs 1-157 above as though fully restated herein.

159. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

160. The Perrigo Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. The Perrigo Defendants' Generic Product has no substantial non-infringing uses.

161. The Perrigo Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '307 patent.

162. The Perrigo Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

163. The Perrigo Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '307 patent under 35 U.S.C. § 271(a), (b), and/or (c).

164. The Perrigo Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '307 patent.

165. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '307 patent.

166. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

167. There is a justiciable case or controversy between Plaintiffs and the Perrigo Defendants regarding whether the Perrigo Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '307 patent.

168. If the Perrigo Defendants' infringement of the '307 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XVIII. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,177,449)**

169. Plaintiffs incorporate by reference and reallege Paragraphs 1-168 above as though fully restated herein.

170. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

171. The Perrigo Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. The Perrigo Defendants' Generic Product has no substantial non-infringing uses.

172. The Perrigo Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '449 patent.

173. The Perrigo Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

174. The Perrigo Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '449 patent under 35 U.S.C. § 271(a), (b), and/or (c).

175. The Perrigo Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '449 patent.

176. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '449 patent.

177. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

178. There is a justiciable case or controversy between Plaintiffs and the Perrigo Defendants regarding whether the Perrigo Defendants' commercial manufacture, use, sale, offer

for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '449 patent.

179. If the Perrigo Defendants' infringement of the '449 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XIX. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,807,861)**

180. Plaintiffs incorporate by reference and reallege Paragraphs 1-179 above as though fully restated herein.

181. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

182. The Perrigo Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. The Perrigo Defendants' Generic Product has no substantial non-infringing uses.

183. The Perrigo Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '861 patent.

184. The Perrigo Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

185. The Perrigo Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '861 patent under 35 U.S.C. § 271(a), (b), and/or (c).

186. The Perrigo Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '861 patent.

187. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '861 patent.

188. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

189. There is a justiciable case or controversy between Plaintiffs and the Perrigo Defendants regarding whether the Perrigo Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '861 patent.

190. If the Perrigo Defendants' infringement of the '861 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XX. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,993,520)**

191. Plaintiffs incorporate by reference and reallege Paragraphs 1-190 above as though fully restated herein.

192. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

193. The Perrigo Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. The Perrigo Defendants' Generic Product has no substantial non-infringing uses.

194. The Perrigo Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '520 patent.

195. The Perrigo Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

196. The Perrigo Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '520 patent under 35 U.S.C. § 271(a), (b), and/or (c).

197. The Perrigo Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '520 patent.

198. The Perrigo Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '520 patent.

199. The Perrigo Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

200. There is a justiciable case or controversy between Plaintiffs and the Perrigo Defendants regarding whether the Perrigo Defendants' commercial manufacture, use, sale, offer

for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '520 patent.

201. If the Perrigo Defendants' infringement of the '520 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

## COUNTS AS TO WATSON LABORATORIES

### COUNT XXI. FOR PATENT INFRINGEMENT
**(Direct Infringement of U.S. Patent No. 6,299,900)**

202. Plaintiffs incorporate by reference and reallege Paragraphs 1-201 above as though fully restated herein.

203. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories' submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories' Generic Product before expiration of the '900 patent was an act of infringement of the '900 patent by Watson Laboratories.

204. If ANDA No. 205328 is approved by the FDA, Watson Laboratories' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories' Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '900 patent under 35 U.S.C. § 271.

205. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '900 patent. Plaintiffs do not have an adequate remedy at law.

### COUNT XXII. FOR PATENT INFRINGEMENT
**(Inducement to Infringe U.S. Patent No. 6,299,900)**

206. Plaintiffs incorporate by reference and reallege Paragraphs 1-205 above as though fully restated herein.

207. Watson Laboratories has knowledge of the '900 patent.

208. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the ’900 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XXIII. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 6,299,900)**

209. Plaintiffs incorporate by reference and reallege Paragraphs 1-208 above as though fully restated herein.

210. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories’ Generic Product.

211. Watson Laboratories has had and continues to have knowledge that Watson Laboratories’ Generic Product is especially adapted for a use that infringes the ’900 patent.

212. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories’ Generic Product.

**COUNT XXIV. FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 6,818,226)**

213. Plaintiffs incorporate by reference and reallege Paragraphs 1-212 above as though fully restated herein.

214. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories’ submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories’ Generic Product before expiration of the ’226 patent was an act of infringement of the ’226 patent by Watson Laboratories.

215. If ANDA No. 205328 is approved by the FDA, Watson Laboratories’ commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories’ Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the ’226 patent under 35 U.S.C. § 271.

216. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '226 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XXV. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 6,818,226)**

217. Plaintiffs incorporate by reference and reallege Paragraphs 1-216 above as though fully restated herein.

218. Watson Laboratories has knowledge of the '226 patent.

219. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the '226 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XXVI. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 6,818,226)**

220. Plaintiffs incorporate by reference and reallege Paragraphs 1-219 above as though fully restated herein.

221. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories' Generic Product.

222. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '226 patent.

223. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

**COUNT XXVII. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 6,923,983)**

224. Plaintiffs incorporate by reference and reallege Paragraphs 1-223 above as though fully restated herein.

225. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories' submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories' Generic Product before expiration of the '983 patent was an act of infringement of the '983 patent by Watson Laboratories.

226. If ANDA No. 205328 is approved by the FDA, Watson Laboratories' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories' Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '983 patent under 35 U.S.C. § 271.

227. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '983 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XXVIII. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 6,923,983)**

228. Plaintiffs incorporate by reference and reallege Paragraphs 1-227 above as though fully restated herein.

229. Watson Laboratories has knowledge of the '983 patent.

230. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the '983 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XXIX. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 6,923,983)**

231. Plaintiffs incorporate by reference and reallege Paragraphs 1-230 above as though fully restated herein.

232. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories' Generic Product.

233. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '983 patent.

234. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

**COUNT XXX. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,071,075)**

235. Plaintiffs incorporate by reference and reallege Paragraphs 1-234 above as though fully restated herein.

236. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories' submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories' Generic Product before expiration of the '075 patent was an act of infringement of the '075 patent by Watson Laboratories.

237. If ANDA No. 205328 is approved by the FDA, Watson Laboratories' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories' Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '075 patent under 35 U.S.C. § 271.

238. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '075 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XXXI. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe of U.S. Patent No. 8,071,075)**

239. Plaintiffs incorporate by reference and reallege Paragraphs 1-238 above as though fully restated herein.

240. Watson Laboratories has knowledge of the '075 patent.

241. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the ’075 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XXXII. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,071,075)**

242. Plaintiffs incorporate by reference and reallege Paragraphs 1-241 above as though fully restated herein.

243. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories’ Generic Product.

244. Watson Laboratories has had and continues to have knowledge that Watson Laboratories’ Generic Product is especially adapted for a use that infringes the ’075 patent.

245. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories’ Generic Product.

**COUNT XXXIII. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,419,307)**

246. Plaintiffs incorporate by reference and reallege Paragraphs 1-245 above as though fully restated herein.

247. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories’ submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories’ Generic Product before expiration of the ’307 patent was an act of infringement of the ’307 patent by Watson Laboratories.

248. If ANDA No. 205328 is approved by the FDA, Watson Laboratories’ commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories’ Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the ’307 patent under 35 U.S.C. § 271.

249. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '307 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XXXIV. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 8,419,307)**

250. Plaintiffs incorporate by reference and reallege Paragraphs 1-249 above as though fully restated herein.

251. Watson Laboratories has knowledge of the '307 patent.

252. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XXXV. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,419,307)**

253. Plaintiffs incorporate by reference and reallege Paragraphs 1-252 above as though fully restated herein.

254. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories' Generic Product.

255. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '307 patent.

256. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

**COUNT XXXVI. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,435,944)**

257. Plaintiffs incorporate by reference and reallege Paragraphs 1-256 above as though fully restated herein.

258. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories' submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories' Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Watson Laboratories.

259. If ANDA No. 205328 is approved by the FDA, Watson Laboratories' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories' Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271.

260. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '944 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XXXVII. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 8,435,944)**

261. Plaintiffs incorporate by reference and reallege Paragraphs 1-260 above as though fully restated herein.

262. Watson Laboratories has knowledge of the '944 patent.

263. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XXXVIII. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,435,944)**

264. Plaintiffs incorporate by reference and reallege Paragraphs 1-263 above as though fully restated herein.

265. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories' Generic Product.

266. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '944 patent.

267. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

**COUNT XXXIX. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,177,449)**

268. Plaintiffs incorporate by reference and reallege Paragraph 1-267 above as though fully restated herein.

269. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories' submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories' Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by Watson Laboratories.

270. If ANDA No. 205328 is approved by the FDA, Watson Laboratories' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories' Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 patent under 35 U.S.C. § 271.

271. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '449 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XL. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 8,177,449)**

272. Plaintiffs incorporate by reference and reallege Paragraphs 1-271 above as though fully restated herein.

273. Watson Laboratories has knowledge of the '449 patent.

274. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the ’449 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XLI. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,177,449)**

275. Plaintiffs incorporate by reference and reallege Paragraphs 1-274 above as though fully restated herein.

276. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories’ Generic Product.

277. Watson Laboratories has had and continues to have knowledge that Watson Laboratories’ Generic Product is especially adapted for a use that infringes the ’449 patent.

278. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories’ Generic Product.

**COUNT XLII. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,807,861)**

279. Plaintiffs incorporate by reference and reallege Paragraph 1-278 above as though fully restated herein.

280. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories’ submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories’ Generic Product before expiration of the ’861 patent was an act of infringement of the ’861 patent by Watson Laboratories.

281. If ANDA No. 205328 is approved by the FDA, Watson Laboratories’ commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories’ Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the ’861 patent under 35 U.S.C. § 271.

282. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '861 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XLIII. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 8,807,861)**

283. Plaintiffs incorporate by reference and reallege Paragraphs 1-282 above as though fully restated herein.

284. Watson Laboratories has knowledge of the '861 patent.

285. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the '861 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XLIV. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,807,861)**

286. Plaintiffs incorporate by reference and reallege Paragraphs 1-285 above as though fully restated herein.

287. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories' Generic Product.

288. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '861 patent.

289. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

**COUNT XLV. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,993,520)**

290. Plaintiffs incorporate by reference and reallege Paragraphs 1-289 above as though fully restated herein.

291. Pursuant to 35 U.S.C. § 271(e)(2), Watson Laboratories' submission of ANDA No. 205328 to the FDA seeking approval of Watson Laboratories' Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by Watson Laboratories.

292. If ANDA No. 205328 is approved by the FDA, Watson Laboratories' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Watson Laboratories' Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '520 patent under 35 U.S.C. § 271.

293. Unless Watson Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Watson Laboratories' infringement of the '520 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XLVI. FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 8,993,520)**

294. Plaintiffs incorporate by reference and reallege Paragraphs 1-293 above as though fully restated herein.

295. Watson Laboratories has knowledge of the '520 patent.

296. Upon FDA approval of ANDA No. 205328, Watson Laboratories will intentionally encourage acts of direct infringement of the '520 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT XLVII. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,993,520)**

297. Plaintiffs incorporate by reference and reallege Paragraphs 1-296 above as though fully restated herein.

298. If ANDA No. 205328 is approved, Watson Laboratories intends to and will offer to sell, sell, or import into the United States Watson Laboratories' Generic Product.

299. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '520 patent.

300. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

**COUNT XLVIII. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 6,299,900)**

301. Plaintiffs incorporate by reference and reallege Paragraphs 1-300 above as though fully restated herein.

302. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

303. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

304. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '900 patent.

305. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

306. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '900 patent under 35 U.S.C. § 271(a), (b), and/or (c).

307. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '900 patent.

308. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '900 patent.

309. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

310. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '900 patent.

311. If Watson Laboratories' infringement of the '900 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XLIX. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 6,818,226)**

312. Plaintiffs incorporate by reference and reallege Paragraphs 1-311 above as though fully restated herein.

313. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

314. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

315. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '226 patent.

316. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

317. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '226 patent under 35 U.S.C. § 271(a), (b), and/or (c).

318. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '226 patent.

319. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '226 patent.

320. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

321. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer

for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '226 patent.

322. If Watson Laboratories' infringement of the '226 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT L. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 6,923,983)**

323. Plaintiffs incorporate by reference and reallege Paragraphs 1-322 above as though fully restated herein.

324. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

325. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

326. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '983 patent.

327. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

328. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '983 patent under 35 U.S.C. § 271(a), (b), and/or (c).

329. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '983 patent.

330. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '983 patent.

331. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

332. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '983 patent.

333. If Watson Laboratories' infringement of the '983 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LI. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,071,075)**

334. Plaintiffs incorporate by reference and reallege Paragraphs 1-333 above as though fully restated herein.

335. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

336. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

337. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '075 patent.

338. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

339. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '075 patent under 35 U.S.C. § 271(a), (b), and/or (c).

340. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '075 patent.

341. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '075 patent.

342. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

343. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer

for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '075 patent.

344. If Watson Laboratories' infringement of the '075 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LII. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,419,307)**

345. Plaintiffs incorporate by reference and reallege Paragraphs 1-344 above as though fully restated herein.

346. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

347. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

348. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '307 patent.

349. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

350. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '307 patent under 35 U.S.C. § 271(a), (b), and/or (c).

351. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '307 patent.

352. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '307 patent.

353. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

354. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '307 patent.

355. If Watson Laboratories' infringement of the '307 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LIII. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,435,944)**

356. Plaintiffs incorporate by reference and reallege Paragraphs 1-355 above as though fully restated herein.

357. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

358. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

359. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '944 patent.

360. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

361. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

362. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '944 patent.

363. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '944 patent.

364. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

365. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer

for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '944 patent.

366. If Watson Laboratories' infringement of the '944 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LIV. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,177,449)**

367. Plaintiffs incorporate by reference and reallege Paragraphs 1-366 above as though fully restated herein.

368. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

369. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

370. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '449 patent.

371. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

372. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '449 patent under 35 U.S.C. § 271(a), (b), and/or (c).

373. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '449 patent.

374. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '449 patent.

375. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

376. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '449 patent.

377. If Watson Laboratories' infringement of the '449 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LV. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,807,861)**

378. Plaintiffs incorporate by reference and reallege Paragraphs 1-377 above as though fully restated herein.

379. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

380. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

381. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '861 patent.

382. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

383. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '861 patent under 35 U.S.C. § 271(a), (b), and/or (c).

384. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '861 patent.

385. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '861 patent.

386. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

387. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer

for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '861 patent.

388. If Watson Laboratories' infringement of the '861 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LVI. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,993,520)**

389. Plaintiffs incorporate by reference and reallege Paragraphs 1-388 above as though fully restated herein.

390. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

391. Watson Laboratories submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Watson Laboratories' Generic Product in the United States. Watson Laboratories' Generic Product has no substantial non-infringing uses.

392. Watson Laboratories has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Watson Laboratories' Generic Product prior to expiration of the '520 patent.

393. Watson Laboratories intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Watson Laboratories' Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

394. Watson Laboratories' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Watson Laboratories' Generic Product would infringe one or more claims of the '520 patent under 35 U.S.C. § 271(a), (b), and/or (c).

395. Watson Laboratories' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Watson Laboratories' Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '520 patent.

396. Watson Laboratories has had and continues to have knowledge that Watson Laboratories' Generic Product is especially adapted for a use that infringes the '520 patent.

397. Watson Laboratories has had and continues to have knowledge that there is no substantial non-infringing use for Watson Laboratories' Generic Product.

398. There is a justiciable case or controversy between Plaintiffs and Watson Laboratories regarding whether Watson Laboratories' commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson Laboratories' Generic Product according to ANDA No. 205328 would infringe one or more claims of the '520 patent.

399. If Watson Laboratories' infringement of the '520 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

## COUNTS AS TO AMNEAL

### COUNT LVII. FOR PATENT INFRINGEMENT
**(Direct Infringement of U.S. Patent No. 8,435,944)**

400. Plaintiffs incorporate by reference and reallege Paragraphs 1-399 above as though fully restated herein.

401. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendant.

402. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271.

403. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '944 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT LVIII. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,435,944)**

404. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 403 above as though fully restated herein.

405. Defendant has knowledge of the '944 patent.

406. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT LIX. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,435,944)**

407. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 406 above as though fully restated herein.

408. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

409. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '944 patent.

410. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

**COUNT LX. FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 8,419,307)**

411. Plaintiffs incorporate by reference and reallege Paragraphs 1-410 above as though fully restated herein.

412. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by Defendant.

413. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '307 patent under 35 U.S.C. § 271.

414. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '307 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT LXI. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,419,307)**

415. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 414 above as though fully restated herein.

416. Defendant has knowledge of the '307 patent.

417. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT LXII. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,419,307)**

418. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 417 above as though fully restated herein.

419. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

420. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '307 patent.

421. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

**COUNT LXIII. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,177,449)**

422. Plaintiffs incorporate by reference and reallege Paragraphs 1-421 above as though fully restated herein.

423. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by Defendant.

424. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 patent under 35 U.S.C. § 271.

425. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '449 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT LXIV. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,177,449)**

426. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 425 above as though fully restated herein.

427. Defendant has knowledge of the '449 patent.

428. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '449 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT LXV. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,177,449)**

429. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 428 above as though fully restated herein.

430. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

431. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '449 patent.

432. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

**COUNT LXVI. FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 8,807,861)**

433. Plaintiffs incorporate by reference and reallege Paragraphs 1-432 above as though fully restated herein.

434. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '861 patent was an act of infringement of the '861 patent by Defendant.

435. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '861 patent under 35 U.S.C. § 271.

436. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '861 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT LXVII. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,807,861)**

437. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 436 above as though fully restated herein.

438. Defendant has knowledge of the '861 patent.

439. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '861 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT LXVIII. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,807,861)**

440. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 439 above as though fully restated herein.

441. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

442. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '861 patent.

443. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

**COUNT LXIX. FOR PATENT INFRINGEMENT**
**(Infringement of U.S. Patent No. 8,993,520)**

444. Plaintiffs incorporate by reference and reallege Paragraphs 1-443 above as though fully restated herein.

445. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by Defendant.

446. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '520 patent under 35 U.S.C. § 271.

447. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '520 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT LXX. FOR PATENT INFRINGEMENT**
**(Inducement To Infringe U.S. Patent No. 8,993,520)**

448. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 447 above as though fully restated herein.

449. Defendant has knowledge of the '520 patent.

450. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '520 patent by others, with knowledge that its acts are encouraging infringement.

**COUNT LXXI. FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,993,520)**

451. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 450 above as though fully restated herein.

452. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

453. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '520 patent.

454. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

**COUNT LXXII. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,435,944)**

455. Plaintiffs incorporate by reference and reallege Paragraphs 1-454 above as though fully restated herein.

456. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

457. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

458. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '944 patent.

459. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

460. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic Product would infringe one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

461. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Amneal's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '944 patent.

462. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '944 patent.

463. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

464. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '944 patent.

465. If Defendant's infringement of the '944 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LXXIII. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,419,307)**

466. Plaintiffs incorporate by reference and reallege Paragraphs 1-465 above as though fully restated herein.

467. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

468. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

469. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '307 patent.

470. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

471. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic Product would infringe one or more claims of the '307 patent under 35 U.S.C. § 271(a), (b), and/or (c).

472. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Amneal's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '307 patent.

473. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '307 patent.

474. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

475. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '307 patent.

476. If Defendant's infringement of the '307 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LXXIV. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,177,449)**

477. Plaintiffs incorporate by reference and reallege Paragraphs 1-476 above as though fully restated herein.

478. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

479. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

480. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '449 patent.

481. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

482. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic Product would infringe one or more claims of the '449 patent under 35 U.S.C. § 271(a), (b), and/or (c).

483. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Amneal's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '449 patent.

484. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '449 patent.

485. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

486. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '449 patent.

487. If Defendant's infringement of the '449 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LXXV. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,807,861)**

488. Plaintiffs incorporate by reference and reallege Paragraphs 1-487above as though fully restated herein.

489. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

490. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

491. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '861 patent.

492. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

493. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic Product would infringe one or more claims of the '861 patent under 35 U.S.C. § 271(a), (b), and/or (c).

494. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Amneal's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '861 patent.

495. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '861 patent.

496. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

497. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '861 patent.

498. If Defendant's infringement of the '861 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT LXXVI. FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,993,520)**

499. Plaintiffs incorporate by reference and reallege Paragraphs 1-498 above as though fully restated herein.

500. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

501. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

502. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '520 patent.

503. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

504. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Amneal's Generic Product would infringe one or more claims of the '520 patent under 35 U.S.C. § 271(a), (b), and/or (c).

505. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Amneal's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '520 patent.

506. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '520 patent.

507. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

508. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '520 patent.

509. If Defendant's infringement of the '520 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

a) United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; 8,435,944; 8,177,449; 8,807,861; and 8,993,520 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), the Perrigo Defendants infringed United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; 8,807,861; and 8,993,520 by submitting ANDA No. 204255 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Perrigo's Generic Product prior to expiration of said patents;

c) The Perrigo Defendants' threatened acts of commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Perrigo's Generic Product prior to the expiration of United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; 8,807,861; and 8,993,520 would constitute infringement of said patents;

**d)** The effective date of any FDA approval of Perrigo's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 8,435,944; 8,419,307;

8,177,449; 8,807,861; and 8,993,520 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

**e)** The Perrigo Defendants, and all persons acting in concert with the Perrigo Defendants shall be enjoined from commercially manufacturing, using, offering for sale, or selling Perrigo's Generic Product within the United States, or importing Perrigo's Generic Product into the United States, until the expiration of United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; 8,807,861; and 8,993,520, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

**f)** Under 35 U.S.C. § 271(e)(2)(A), Watson Laboratories infringed United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; 8,435,944; 8,177,449; 8,807,861; and 8,993,520 by submitting ANDA No. 205328 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Watson Laboratories' Generic Product prior to expiration of said patents;

**g)** Watson Laboratories' threatened acts of commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Watson Laboratories' Generic Product prior to the expiration of United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; 8,435,944; 8,177,449; 8,807,861; and 8,993,520 would constitute infringement of said patents;

**h)** The effective date of any FDA approval of Watson Laboratories' Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; 8,435,944; 8,177,449; 8,807,861; and 8,993,520, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

**i)** Watson Laboratories, and all persons acting in concert with Watson Laboratories shall be enjoined from commercially manufacturing, using, offering for sale, or selling Watson Laboratories' Generic Product within the United States, or importing Watson Laboratories' Generic Product into the United States, until the expiration of United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; 8,435,944; 8,177,449; 8,807,861; and 8,993,520 in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

j) Under 35 U.S.C. § 271(e)(2)(A), Amneal infringed United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; 8,807,861; and 8,993,520 by submitting ANDA No. 204255 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Perrigo's Generic Product prior to expiration of said patents;

k) Amneal's threatened acts of commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Amneal's Generic Product prior to the expiration of United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; 8,807,861; and 8,993,520 would constitute infringement of said patents;

l) The effective date of any FDA approval of Amneal's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 8,435,944; 8,419,307;

8,177,449; 8,807,861; and 8,993,520 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

m) Amneal, and all persons acting in concert with Amneal, shall be enjoined from commercially manufacturing, using, offering for sale, or selling Perrigo's Generic Product within the United States, or importing Perrigo's Generic Product into the United States, until the expiration of United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; 8,807,861; and 8,993,520, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

n) This is an exceptional case and Plaintiffs should be awarded their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

o) Plaintiffs are entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

p) Plaintiffs are entitled to any further and additional relief that this Court deems just and proper.

Respectfully submitted,

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By: */s/ Laura P. Masurovsky*

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