UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SEATTLE CHILDREN'S HOSPITAL, NOVARTIS AG, NOVARTIS VACCINES AND DIAGNOSTICS, INC., and NOVARTIS PHARMACEUTICALS CORPORATION Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs, Seattle Children's Hospital (formerly known as Children's Hospital and Regional Medical Center, formerly known as Children's Hospital and Medical Center) ("Children's"), Novartis AG, Novartis Vaccines and Diagnostics, Inc., and Novartis Pharmaceuticals Corporation (collectively, "Novartis"), for their Complaint against defendants Teva Parenteral Medicines, Inc. ("Teva Parenteral"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Industries") allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.* This action relates to Teva Parenteral's Abbreviated New Drug Application ("ANDA") No. 91-589 submitted to the United

States Food and Drug Administration (the "FDA") to market a generic version of Novartis' Tobramycin Inhalation Solution (TOBI®), which is indicated for the management of cystic fibrosis ("CF") patients with *Pseudomonas aeruginosa* ("*P. aeruginosa*").

The Parties

2. Children's is a non-profit corporation organized and existing under the laws of the State of Washington and has its principal place of business at 4800 Sand Point Way NE, Seattle, Washington 98105.

3. Novartis Pharmaceutical Corporation is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

4. Novartis Vaccines and Diagnostics is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 4560 Horton Street, Emeryville, CA 94608.

5. Novartis AG is a corporation organized and existing under the laws of Switzerland and has its principal place of business at Lichtstrasse 35, 4056 Basel, Switzerland.

6. Upon information and belief, Teva Parenteral is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 17 Hughes, Irvine, California 92618. Upon information and belief, Teva Parenteral is a wholly-owned subsidiary of Teva USA.

7. Upon information and belief, Defendant Teva USA is a Delaware corporation, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA is engaged in the manufacture and sale of pharmaceutical products. Upon information and belief, Teva USA, itself and through its

wholly-owned subsidiary and agent Defendant Teva Parenteral, manufactures and/or distributes generic drugs for sale and use in this judicial district and throughout the United States at the direction, under the control, and for the benefit of Teva Industries.

8. Upon information and belief, Defendant Teva Industries is an Israeli corporation, having a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. Upon information and belief, Teva Industries manufactures bulk pharmaceutical products. Upon information and belief, Teva Industries established Defendant Teva Pharmaceuticals USA, Inc. and Defendant Teva Parenteral Medicines, Inc., for the purposes of distributing, marketing, and selling its generic drug products in this judicial district and throughout the United States.

9. Upon information and belief, Teva Industries owns 100% of the ownership and voting interest in Teva USA.

10. Upon information and belief, Teva USA is controlled and/or dominated by Teva Industries.

11. Upon information and belief, Teva Parenteral is controlled and/or dominated by Teva Industries and Teva USA.

12. Upon information and belief, Teva Industries conducts its North American operations, in part, through Teva USA.

Jurisdiction And Venue

13. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202.

14. Teva Parenteral is subject to personal jurisdiction in this judicial district because it is a Delaware corporation and, on information and belief, it regularly and continuously

transacts business within the State of Delaware, including, but not limited to, the regular sale of pharmaceutical products within the State of Delaware.

15. Teva USA is subject to personal jurisdiction in this judicial district because it is a Delaware corporation, and, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, the regular sale of pharmaceutical products within the State of Delaware.

16. Teva Industries is subject to personal jurisdiction in this judicial district because, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, directing the operations and management of Teva USA as well as shipping pharmaceuticals to Teva USA from locations outside the United States for distribution by Teva USA within the United States generally, and within this judicial district specifically.

17. Upon information and belief, Teva Parenteral is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with Teva USA and Teva Industries for the purposes of manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware, and in seeking FDA approval to conduct such activities.

18. Upon information and belief, Teva Parenteral, Teva USA, and Teva Industries collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) within the United States generally, and the State of Delaware specifically.

19. Upon information and belief, Teva Parenteral acts as an agent of Teva USA and Teva Industries with respect to the acts complained of herein.

20. Upon information and belief, the acts of Teva Parenteral complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of, and in part, for the benefit of Teva USA and Teva Industries.

21. Teva Parenteral's and Teva USA's acts and contacts with this judicial district are attributable to Teva Industries for jurisdictional purposes.

22. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

The Patent-In-Suit

23. United States Letters Patent Nos. 5,508,269 entitled "Aminoglycoside Formulation for Aerosolization" (the "'269 patent"), a copy of which is attached hereto as Exhibit A, was duly issued by the United States Patent and Trademark Office on April 16, 1996 to inventors Arnold L. Smith, Bonnie W. Ramsey, and Alan B. Montgomery.

24. Children's, Novartis Vaccines and Diagnostics, Inc., and Novartis Pharmaceuticals Corporation are the lawful owners of the '269 patent by assignment of all right, title and interest in and to the '269 patent.

25. The '269 patent claims, *inter alia*, aerosol formulations containing an aminoglycoside, including tobramycin, and methods of using such formulations for the treatment of patients suffering from endobronchial infections, including *P. aeruginosa* infection.

The TOBI® Drug Product

26. Novartis Pharmaceuticals Corporation holds an approved New Drug Application (No. 50-753) for Tobramycin Inhalation Solution, which it markets and sells under the registered trademark TOBI®.

27. Pursuant to 21 U.S.C. § 355(b)(1) and attendant regulations, the '269 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") with respect to TOBI®.

Acts Giving Rise to this Action

28. By letter dated October 27, 2009, Teva Parenteral notified Children's and Novartis AG that it had filed ANDA No. 91-589 with the FDA seeking approval to market Tobramycin Inhalation Solution, USP, 300 mg/5mL ("Teva's ANDA Product") prior to the expiration of the '269 patent. Teva Parenteral's letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) "of the factual and legal bases for Teva's opinion that the '269 patent is not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva's product."

29. Upon information and belief, Teva Parenteral, Teva USA, and Teva Industries collaborated in the research, development, preparation and filing of ANDA No. 91-589 for Teva's ANDA Product.

30. Upon information and belief, pursuant to Section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)), Teva Parenteral filed with the FDA ANDA No. 91-589 seeking approval to engage in the commercial manufacture, use and sale of Teva's ANDA Product. On information and belief, Teva Parenteral stated to the FDA in its ANDA that

Teva's ANDA Product is qualitatively and quantitatively the same as Novartis' approved TOBI® product.

31. Upon information and belief, Teva Parenteral's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of Teva's ANDA Product prior to expiration of the '269 patent.

32. Upon information and belief, Teva Parenteral's ANDA No. 91-589 contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) stating that in Teva Parenteral's opinion the '269 patent is invalid or unenforceable or would not be infringed by the manufacture, use or sale of Teva's ANDA Product.

33. Upon information and belief, Teva Parenteral, Teva USA, and Teva Industries were aware of the '269 patent when ANDA 91-589 was filed containing the Paragraph IV certification.

34. Teva Parenteral's filing of ANDA No. 91-589 constitutes infringement of one or more of the claims of the '269 patent under 35 U.S.C. § 271(e)(2).

35. Upon information and belief, Teva USA and Teva Industries have also infringed, induced or contributed to and will infringe, induce or contribute to infringement of one or more claims of the '269 patent by acting in concert and actively aiding, abetting, encouraging, and inducing Teva Parenteral to (1) file ANDA No. 91-589 for Tobramycin Inhalation Solution, (2) prepare to sell Teva's ANDA Product pursuant to that ANDA and (3) upon FDA approval, to sell Teva's ANDA Product which will result in direct infringement of one or more claims of the '269 patent.

36. Teva Parenteral's commercial manufacture, use, offer to sell or sale of Teva's ANDA Product for management of CF patients with *P. aeruginosa* would constitute

infringement of the ’269 patent under 35 U.S.C. § 271. Teva Parenteral’s ANDA and Teva Parenteral's intention to engage in the commercial manufacture, use, offer to sell or sale of Teva’s ANDA Product upon receiving FDA approval prior to expiration of the ’269 patent create an actual and justiciable controversy with respect to infringement of the ’269 patent.

37. Upon FDA approval of Teva Parenteral’s ANDA, Teva Parenteral will infringe the '269 patent by making, using, offering to sell, and selling Teva’s ANDA Product in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

38. Upon information and belief, Teva Parenteral has undertaken substantial activities directed toward engaging in infringement, contributory infringement and active inducement of infringement of the ’269 patent by making substantial preparations for making, using, and selling or authorizing to sell without authority from plaintiffs, Teva’s ANDA Product for the management of CF patients with *P. aeruginosa*.

39. Upon information and belief, Teva Parenteral, Teva USA and Teva Industries had notice of the ’269 patent and Teva Parenteral’s filing of ANDA No. 91-589 with its Paragraph IV certification makes this case exceptional.

40. Upon information and belief, Teva Parenteral, Teva USA, and Teva Industries had notice of the '269 patent and if any of them engage in the commercial manufacture, use, offer to sell or sale of Teva's ANDA product prior to the expiration of the '269 patent, such conduct would constitute willful and deliberate infringement.

41. Plaintiffs will be substantially and irreparably damaged and harmed if Teva Parenteral’s infringement is not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

A. A judgment declaring that Teva Parenteral, Teva USA and Teva Industries have infringed, and that Teva Parenteral, Teva USA and Teva Industries making, using, selling, offering to sell or importing Teva's ANDA Product described in ANDA No. 91-589 will constitute infringement, contributory infringement and actively inducing infringement of the '269 patent;

B. A judgment providing that the effective date of any FDA approval for Teva Parenteral to make, use, sell, offer for sale, or import Teva's ANDA Product described in ANDA No. 91-589 be no earlier than the date on which the '269 patent expires or any later expiration of exclusivity to which Plaintiffs are or become entitled;

C. A judgment permanently enjoining Teva Parenteral, Teva USA and Teva Industries, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporation., other business entities and all other persons acting in concert, participation or privity with them, their successors and assigns, from infringing, contributorily infringing or inducing others to infringe the '269 patent;

D. If Teva Parenteral, Teva USA and/or Teva Industries engages in the commercial manufacture, use, offer to sell or sale of Teva's ANDA Product prior to the expiration of the '269 patent, a judgment awarding plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest.

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E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: December 10, 2009

RESPECTFULLY SUBMITTED,
MCCARTER & ENGLISH, LLP

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