IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IGI LABORATORIES, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
MALLINCKRODT, LLC, MALLINCKRODT, INC., and NUVO RESEARCH INC.,	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff IGI Laboratories, Inc. ("IGI"), for its Declaratory Judgment Complaint against Defendants Mallinckrodt, LLC, Mallinckrodt, Inc. (collectively, "Mallinckrodt") and Nuvo Research Inc. ("Nuvo") (all defendants collectively referred to as "Defendants") states and alleges as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent Nos. 8,217,078 ("the '078 patent") and 8,546,450 ("the '450 patent") so that IGI can bring its generic diclofenac sodium topical solution 1.5% to market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and allow the public to enjoy the benefits of generic competition for Defendants' brand product.

2. This case is related to at least two other cases pending in this Court including *Mallinckrodt LLC, et al. v. Apotex Inc., et al.*, Case No. 1:12-cv-01087-RGA, and *Mallinckrodt LLC, et al. v. Taro Pharmaceutical Industries Ltd., et al.*, Case No. 1:13-cv-00494-RGA

(collectively "related actions") because this case and the related actions involve the same '078 patent and generic versions of Defendants' brand product, Pennsaid®.

THE PARTIES

3. Plaintiff IGI Laboratories, Inc. is an entity organized under the laws of the State of Delaware and has a principal place of business at 105 Lincoln Avenue, Buena, NJ 08310.

4. On information and belief, Defendant Mallinckrodt, LLC is organized and existing under the laws of the State of Delaware and has regular and established places of business at 675 McDonnell Blvd., Hazelwood, MO 63402 and in Delaware.

5. On information and belief, Defendant Mallinckrodt, Inc. is organized and existing under the laws of the State of Delaware and has regular and established places of business at 675 McDonnell Blvd., Hazelwood, MO 63402 and in Delaware.

6. On information and belief, Defendant Nuvo Research Inc. is organized and existing under the laws of Ontario, Canada, having a principal place of business at 7560 Airport Road, Unit 10, Mississauga, Ontario L4T 4H4 Canada.

JURISDICTION AND VENUE

7. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., based upon an actual controversy between the parties to declare that IGI does not infringe the '078 and '450 patents and is free upon FDA approval to commercially manufacture, use, market, sell, offer to sell and/or import its diclofenac sodium topical solution 1.5% product as described in IGI's Abbreviated New Drug Application ("ANDA").

8. In particular, this Complaint arises under and this Court has jurisdiction pursuant to 21 U.S.C. § 355 (j)(4)(C)(i) and 35 U.S.C. § 271(e)(5), which grant an ANDA applicant the right to bring a declaratory judgment action for noninfringement against the patent holder and New Drug Application holder when: (1) those holders have not first brought an infringement action against the ANDA applicant within 45 days after receiving a notice pursuant to 21 U.S.C. § 355(j)(2)(B) from the applicant; and (2) the notice included an Offer of Confidential Access to the Application in accordance with 21 U.S.C. § 355 (j)(4)(C)(i)(III).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Mallinckrodt, LLC and Mallinckrodt, Inc. because they are organized and existing under the laws of the State of Delaware.

11. This Court has personal jurisdiction over Nuvo because Nuvo has engaged in continuous and systematic contacts with the State of Delaware, including having availed itself of the rights and benefits of Delaware law by filing at least two lawsuits in this Court alleging infringement of the ’078 patent.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because, among other things, Mallinckrodt, LLC and Mallinckrodt, Inc. reside in this district.

DEFENDANTS’ NDA FOR PENNSAID®

13. On information and belief, Mallinckrodt, Inc. is the current owner of New Drug Application (“NDA”) No. N020947. On November 4, 2009, the FDA approved Mallinckrodt, Inc.’s NDA No. N020947 for the manufacture and sale of diclofenac sodium topical solution 1.5% under the trade name Pennsaid®.

14. As part of the regulatory process for obtaining approval of the NDA for Pennsaid®, Mallinckrodt, Inc. was required by the FDA to submit a proposed label for the drug. The label for Pennsaid® instructs physicians and patients about the FDA-approved indications and usage of Pennsaid®. Attached hereto as **Exhibit A** is the current FDA-approved label for Pennsaid®.

15. The Pennsaid® label shows that the only FDA-approved indication for Pennsaid® is "the treatment of signs and symptoms of osteoarthritis of the knee(s)."

16. Pennsaid® has not been approved by the FDA as safe and effective for any indications or uses other than "the treatment of signs and symptoms of osteoarthritis of the knee(s)."

THE PATENTS-IN-SUIT

17. On July 10, 2012, the United States Patent and Trademark Office ("PTO") issued the '078 patent, entitled "Treatment of Pain with Topical Diclofenac." The '078 patent is directed to methods of treatment involving the use of topical diclofenac on the knee and a second topical medication on the same knee during a course of treatment. A copy of the '078 patent is attached hereto as **Exhibit B**.

18. On October 1, 2013, the PTO issued the '450 patent, entitled "Treatment of pain with topical diclofenac compounds." The '450 patent is directed to methods of treatment involving the use of topical diclofenac on the knee and either the application of a second topical medication on the same knee or the administration of an oral NSAID during a course of treatment. A copy of the '450 patent is attached hereto as **Exhibit C**.

19. On information and belief, Nuvo is the assignee and owner of the '078 and '450 patents.

20. On information and belief, Mallinckrodt, LLC is the exclusive licensee under the ’078 and ’450 patents with respect to Pennsaid®.

21. In connection with the NDA for Pennsaid®, Defendants listed the ’078 and ’450 patents in the FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations”, which is commonly known as the “Orange Book.”

22. According to the Orange Book, the ’078 patent will expire on July 10, 2029 and the ’450 patent will expire on August 9, 2030.

23. The claims of the ’078 and ’450 patents, however, do not cover the only FDA-approved indication for diclofenac sodium topical solution 1.5%.

24. Indeed, the FDA has not approved diclofenac sodium topical solution 1.5% as safe and effective under 21 U.S.C. § 355 for any of the uses claimed in ’078 and ’450 patents.

25. Specifically, the FDA has not approved as safe and effective the combination therapy of applying diclofenac sodium topical solution 1.5% to the knee of a patient to treat osteoarthritis and subsequently applying a second different topical NSAID to the same knee during a course of treatment with the diclofenac solution.

26. The FDA has not approved as safe and effective the combination therapy of applying diclofenac sodium topical solution 1.5% to the knee of a patient to treat osteoarthritis and subsequently applying a topical corticosteroid to the same knee during a course of treatment with the diclofenac solution.

27. The FDA has not approved as safe and effective the combination therapy of applying diclofenac sodium topical solution 1.5% to the knee of a patient to treat osteoarthritis of the knee and the administration of an oral NSAID.

28. The FDA has not approved as safe and effective the combination therapy of applying diclofenac sodium topical solution 1.5% to the knee of a patient to treat osteoarthritis of the knee and subsequently applying a sunscreen or insect repellant during a course of treatment with the diclofenac solution.

IGI'S ANDA

29. IGI submitted ANDA No. 202769 to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of diclofenac sodium topical solution 1.5% before the expiration of the '078 and '450 patents. The diclofenac sodium topical solution 1.5% described in IGI's ANDA is herein referred to as the "IGI Product."

30. Pursuant 21 U.S.C. §355(j)(4)(G), the proposed IGI Product label will be the same as the Pennsaid® label except that the listed producer and/or manufacturer will be different.

31. IGI's ANDA seeks FDA approval to market the IGI Product only for "the treatment of signs and symptoms of osteoarthritis of the knee(s)."

32. IGI does not seek FDA approval for any other uses including any combination therapy involving the application of the IGI product and either the administration of an oral NSAID or a second topical agent during a course of treatment with the IGI Product.

33. The use of diclofenac sodium topical solution 1.5% alone for "the treatment of signs and symptoms of osteoarthritis of the knee(s)" does not infringe any claims of the '078 or '450 patents.

34. The proposed IGI Product label does not promote, encourage, instruct or induce anyone to administer or apply a second oral or topical agent in addition to the application of diclofenac sodium topical solution 1.5% during a course of treatment.

35. The use of diclofenac sodium topical solution 1.5% alone and without the administration or application of second oral or topical agent is a common and regular use of the product.

36. In connection with IGI's ANDA and pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), IGI made paragraph IV certifications to the '078 and '450 patents, certifying that the those patents are invalid, unenforceable and/or will not be infringed by IGI's Product.

37. On October 24, 2013, IGI sent the patent owner, Nuvo, and the NDA holder, Mallinckrodt, Inc., a letter ("Notice Letter") pursuant 21 U.S.C. § 355(j)(2)(B)(ii) notifying them that IGI submitted ANDA No. 202769 to the FDA with paragraph IV certifications to the '078 and '450 patents.

38. As required by 21 U.S.C. § 355(j)(2)(B)(ii), the Notice Letter contained a detailed statement of the factual and legal basis for IGI's paragraph IV certifications.

39. Pursuant to 21 U.S.C. § 355(j)(5)(c)(i)(III), the Notice Letter was accompanied by an Offer of Confidential Access ("OCA") offering to disclose certain information in IGI's ANDA to Defendants.

40. Mallinckrodt, Inc. and Nuvo received the Notice Letter on or before October 30, 2013.

41. After receiving the Notice Letter, Defendants' counsel asked for and received IGI's proposed product label pursuant to the OCA.

42. Defendants' did not bring a civil action for patent infringement against IGI within 45 days of receiving the Notice Letter.

43. Upon a final judgment that the '078 and '450 patents are not infringed by IGI's Product, the FDA can approve IGI's ANDA unless any regulatory barriers remain at the time of the judgment.

44. Unless IGI obtains a judgment of noninfringement as to the '078 and '450 patents, IGI faces potential infringement liability when it commercially markets the IGI Product. Only a declaratory judgment of noninfringement from this Court will provide IGI with certainty regarding the '078 and '450 patents and allow IGI to bring its generic product to market without concern for potential liability and damages.

COUNT I

Declaratory Judgment of Non-infringement of the '078 Patent

45. IGI realleges and incorporates by reference the allegations of Paragraphs 1-44.

46. This Declaratory Judgment Action arises under the Patent Laws of the United States, 35 U.S.C. § 1, et seq., including § 271(e)(5); the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and Food, Drug and Cosmetic Act 21 U.S.C. et seq., including § 355(j)(4)(C).

47. A present, genuine and justiciable controversy exists between Defendants and IGI regarding, among other things, the issue of whether IGI's commercial manufacture, use, sale, offer to sell and/or importation of IGI's Product would infringe the '078 patent.

48. IGI's commercial manufacture, use, sale, offer to sell and/or importation of the IGI Product will not infringe the '078 patent, directly or indirectly.

49. IGI is entitled to a declaration that the commercial manufacture, use, sale, offer to sell and/or importation of the IGI Product would not infringe the ’078 patent, directly or indirectly.

COUNT II

Declaratory Judgment of Non-infringement of the ’450 Patent

50. IGI realleges and incorporates by reference the allegations of Paragraphs 1-49.

51. This Declaratory Judgment Action arises under the Patent Laws of the United States, 35 U.S.C. § 1, et seq., including § 271(e)(5); the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and Food, Drug and Cosmetic Act 21 U.S.C. et seq., including § 355(j)(4)(C).

52. A present, genuine and justiciable controversy exists between Defendants and IGI regarding, among other things, the issue of whether IGI’s commercial manufacture, use, sale, offer to sell and/or importation of IGI’s Product would infringe the ’450 patent.

53. IGI’s commercial manufacture, use, sale, offer to sell and/or importation of the IGI Product will not infringe the ’450 patent, directly or indirectly.

54. IGI is entitled to a declaration that the commercial manufacture, use, sale, offer to sell and/or importation of the IGI Product would not infringe the ’450 patent, directly or indirectly.

* * * * *

PRAYER FOR RELIEF

WHEREFORE, IGI prays for judgment against Defendants:

A. Declaring that the ’078 patent is not infringed by IGI;

B. Declaring that the ’450 patent is not infringed by IGI;

C. Declaring that this case is exceptional under 35 U.S.C. § 285 and awarding IGI its attorneys' fees, costs and expenses in this action; and

D. Awarding such other and further relief as this Court may deem just and equitable.

Respectfully submitted,

SEITZ ROSS ARONSTAM & MORITZ LLP

/s/ Benjamin J. Schladweiler

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Dated: December 19, 2013