

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

1474971 Ontario Ltd.

PLAINTIFF

vs.

**Allergan, Inc.; Allergan Sales, LLC; and
Actavis, plc.**

DEFENDANTS

Case No. _____

Request for Jury Trial

COMPLAINT FOR PATENT INFRINGEMENT
OF U.S. PATENT NO.: 6,806,251

Plaintiff, by and through its attorneys, Amin Talati & Upadhye, LLC, for its complaint for patent infringement against Defendants, Allergan, Inc.; Allergan Sales, LLC; and Actavis, plc. allege:

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. Plaintiff alleges that Defendants infringe U.S. Patent No.: 6,806,251 (the '251 patent) particularly under 35 U.S.C. §271(a), (b), and (c) relating to Botox(R) injections.
2. 1474971 Ontario Ltd. ("Plaintiff") is a limited company organized under the laws of the Province of Ontario. It has an operating address at 2177 Burnhamthorpe Road West, Suite 1309, Mississauga, Ontario, Canada.
3. Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2525 Dupont Drive, Irvine, California, 92612.
4. Allergan Sales, LLC, is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California, 92612.
5. On information and belief, Actavis plc is incorporated under the laws of Ireland,

with principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland and a place of business in Morris Corporate Center III, 400 Interpace Parkway Parsippany, NJ 07054.

5. Allergan, Inc.; Allergan Sales, LLC; and Actavis plc are collectively referred to hereinafter as "Allergan."

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§1391 and 1400(b).

7. This Court has personal jurisdiction over Allergan because its affiliations with the State of Illinois are so continuous and systematic as to render it essentially at home in this forum.

8. For the Allergan, Inc. and Allergan Sales LLC defendants, upon information and belief, the defendants maintain a nationwide sales force to actively market its drug products and maintain part of such sales force within the State of Illinois.

9. Allergan designed, developed, manufactured, tested, marketed, promoted, distributed, and sold Botox. In doing so, Allergan placed the product in the stream of commerce in Illinois and throughout the United States. Allergan has received, and will continue to receive, substantial benefits and income through its activities within the State of Illinois. Allergan authorized the actions attributed to it herein through its officers, directors, and managing agents.

10. At all times relevant alleged herein, Defendant Allergan was in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising, distributing, selling, and/or introducing into interstate commerce, either directly or indirectly, through third parties or related entities, the prescription drug Botox. These actions occurred wholly or in part in the State of Illinois.

11. At all times relevant herein, Defendant Allergan designed, developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold Botox in interstate commerce and in Chicago, Illinois. Allergan conducted substantial business at this location in Chicago, Illinois, advertised Botox in this city, and received substantial compensation and profits from sales of Botox in this city.

12. Upon information and belief, at all times relevant herein, Allergan, by and through its employees, agents, affiliates, subsidiaries, and representatives, were involved in developing, designing, testing, manufacturing, and/or marketing Botox. Many of these activities occurred in the State of Illinois.

13. Defendant Allergan developed, designed, manufactures, and markets and injectable pharmaceutical known as Botox. Botox is Defendant Allergan's name for Botulinum Toxin Type A. Botulinum toxin is the most potent neurotoxin known to man. It is several hundred times stronger than cyanide. It has been researched by the United States Government as a biological weapon, and is considered to be one of the most toxic substances on earth. Though dangerous, Allergan has U.S. FDA approval to market Botox in the United States, which includes sales in the State of Illinois.

14. The Allergan Defendants have purposefully availed themselves of the jurisdiction of this court or have waived any jurisdictional defects by participating in many actions in this court. For example, the Allergan Defendants have been involved in patent infringement matters (*Simonian v. Allergan, Inc.*, 10-cv-02414) and in non-patent matters (*Rosenstern v. Allergan, Inc.*, 13-cv-4416).

15. The Allergan Defendants themselves, or by and through an affiliate, are registered to do business in the State of Illinois (see, Illinois Secretary of State Registration No.: 66269353).

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

17. On information and belief, Actavis, Inc. is in the business of developing, manufacturing, and/or marketing pharmaceutical products in the United States, including in this judicial district, through at least the actions of its subsidiaries Watson Laboratories and Actavis Pharma.

18. The Actavis defendants conduct nationwide business, including in this District. One or more of the Actavis defendants have been involved in patent litigation in this District (*In Re Nebivolol*, 12-cv-05026).

19. The Actavis defendant itself, or by and through an affiliate, is registered to do business in the State of Illinois (see, Illinois Secretary of State Registration No.: 04094549; 61718753).

20. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Defendants.

THE PATENT-IN-SUIT

21. On 19 Oct. 2004, the U.S. Patent and Trademark Office duly and legally issued the '251 patent, entitled a "Method of Treating Pain". A true and correct copy of the '251 patent is attached hereto as Exhibit A. The claims of the '251 patent are valid and enforceable. The '251 patent is owned by the Plaintiff. Plaintiff has the right to sue for and obtain equitable relief and damages for infringement of the '251 patent.

NOTICE AND INFRINGEMENT BY DEFENDANTS

22. Plaintiff incorporates each of the preceding Paras. 1-21 as if fully set forth herein.

23. In June 2011, by letter from the law firm of Falconeri Munro and Tucci, the letter informed Allergan that it was falsely claiming ownership of the '251 patent in the commercial marketplace. Allergan, as early as June 2011, was on notice of the existence of the '251 patent. The letter, though, does not threaten Allergan with infringement of the '251 patent.

24. The '251 patent contains 10 claims of which claims 1 and 10 are independent. Claims 1 and 10 are reproduced here:

1 CLAIM.

1. A method of treating a disorder associated with spinal compression comprising administering an effective dose of botulinum toxin directly and solely to the intrinsic muscles of a patient in need of such therapy.

10. A method of treating spinal compression comprising penetrating the skin with an acupuncture needle, advancing the acupuncture needle between two vertebrae to provide a mechanical release of the spinal muscles, introducing an injection syringe containing botulinum toxin, and injecting the toxin directly and solely into the intrinsic muscles.

25. Allergan has infringed, and on information and belief is still infringing, the '251 patent either by directly performing the patented methods or by actively inducing others to perform one or more of the patented methods, and Allergan will continue to do so unless enjoined by this Court.

26. Allergan has actively induced health care practitioners to perform the patented methods by providing education, coaching, training, whether by documentation or in-person, on how to perform the patented methods. Health care practitioners then perform one or more of the patented methods.

27. Upon information and belief, Allergan has actively induced health care practitioners to perform the patented methods by providing education, coaching, training, whether by documentation or in-person, on how to perform the patented methods, particularly by providing Botox to the practitioner, showing how to perform the Botox injection, assisting the practitioner in the injection by providing advice about the location and depth of the injection, and answering any questions about the procedure the practitioner may have.

28. For example, it is believed that an Allergan sales representative coached a practitioner on the use of Botox as claimed in the patent. The practitioner was advised to inject 2 cc of normal saline into a Botox vial for reconstitution. Then 1 cc of the solution was drawn into a 1 cc syringe. The Allergan sales representative guided the practitioner to inject into the spinal area to treat a condition in the infringing manner.

29. Botox is not approved by the FDA to treat back pain, and therefore this use was a so-called "off-label" use of the product.

30. Upon information and belief, Allergan has a corporate plan to illegally promote the off-label use of Botox by physicians. This plan includes encouraging physicians to use Botox for a wide variety of indications and never identifying in any meaningful fashion which are approved by the FDA, including in the infringing manner. Allergan created and funded organizations such as the Neurotoxin Institute to promote Botox for off-label uses, including in an infringing manner. Allergan's sales representatives were specifically trained to refer doctors to the online neurotoxin education organization and to distribute "Awareness Cards," with the website's information on them, to all doctors during sales calls. Similarly, Allergan has established and funded an organization known as WE MOVE for the express purpose of promoting off-label use of its products. WE MOVE, at the direction of Allergan, has published numerous online and printed materials which encourage the off-label use of Botox including use in the infringing manner. Allergan also has funded and/or ghost-written numerous medical articles touting the benefits of Botox for off-label uses including back pain. Additionally, Allergan sales representatives and other employees encourage off-label use by sponsoring Allergan dinners, Botox talks and Botox demonstrations for injecting physicians. Finally, Allergan encourages off-label use by teaching injecting physicians and their staff how to get reimbursed for these non-approved uses by third-party payers. Allergan recently plead guilty to off-label promotion and agreed to pay \$600 million in civil and criminal penalties to the United States government.

31. Upon information and belief, a significant effort is undertaken by Allergan to induce practitioners to inject effective amounts of Botox into the spinal regions for the treatment of back pain, particularly into the intrinsic muscles to treat back pain. Such actions actively induce a practitioner to use Botox in an directly infringing manner.

32. Upon information and belief, the FDA approved uses of therapeutic Botox (as opposed to cosmetic uses of Botox) are for rare medical conditions.

33. Upon information and belief, Allergan records high levels of sales from therapeutic uses of Botox but those sales levels do not correlate to rarity of the FDA approved sales conditions. Much of the sales are for FDA unapproved uses, including infringing uses.

34. Because Defendants have known about the existence of the '251 patent since at least as early as June 2011 but have continued the infringing conduct in reckless disregard to the rights conferred, such infringing activities have been and continue to be recklessly and willfully infringing the '251 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court grant the following relief:

1. A judgment that one or more claims of the '251 patent is not invalid, is enforceable and is infringed by Allergan's activities and that such activities infringe one or more claims of the '251 patent.
2. An order pursuant to 35 U.S.C. § 283 for all equitable relief available to the Plaintiff.
3. An order permanently enjoining Defendants, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States any product that violates the rights conferred by the '251 patent, until after the expiration date of the '251 patent, including any extensions and/or additional periods of exclusivity to which Plaintiff is or become entitled.
4. Damages or other monetary relief to Plaintiff, including triple damages for willful and reckless infringement.
5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. §284 and/or 285, including but not limited to an award of costs and expenses and a declaration that this case was exceptional.

Amin Talati & Upadhye, LLC

/s/ Shashank Upadhye
Shashank Upadhye
Joseph Cwik

Date: April 16, 2015

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