**IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION**

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| SCHERING CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>APOTEX INC. and APOTEX CORP.,<br><br>Defendants. | Civil Action No. _____ |

**COMPLAINT FOR PATENT INFRINGEMENT**

For its complaint, Plaintiff Schering Corporation alleges as follows:

**PARTIES**

1. Schering Corporation ("Schering") is a New Jersey corporation with its principal place of business at 3070 US Highway 22, Branchburg, New Jersey 08876.

2. On information and belief, Defendant Apotex Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9.

3. On information and belief, Defendant Apotex Corp. ("Apotex USA") regularly transacts business in Illinois and is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, Apotex USA is the United States subsidiary of Apotex.

5. On information and belief, Apotex conducts business operations in the United States, including in the State of Illinois, through Apotex USA.

## JURISDICTION AND VENUE

6. This action arises under the Patent Statute of the United States of America, Title 35, United States Code, and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Apotex because its agent for service of process with respect to commencement of this patent infringement action resides in this judicial district. Apotex has authorized William A. Rakoczy of Rakozcy Molino Mazzochi Siwik LLP, located at 6 West Hubbard Street, Suite 500, Chicago, Illinois 60654, to act as its agent for service of process with respect to commencement of this patent infringement action.

8. This Court has personal jurisdiction over Apotex USA because Apotex USA resides in this judicial district and engages in continuous and systematic contacts with the State of Illinois and this district.

9. Apotex USA has previously submitted to the jurisdiction of this Court in several cases and has previously availed itself of the Northern District of Illinois by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. On information and belief, Apotex USA markets and sells drug products in the United States manufactured by Apotex, following any FDA approval, including in this judicial District. Apotex USA maintains offices in this judicial District and has invested in significant research and development facilities in this judicial District.

11. Apotex USA's acts and continuous contacts with the State of Illinois, as an agent for Apotex, are also attributable to Apotex for jurisdictional purposes.

12. For all the reasons set forth above, this Court has personal jurisdiction over Apotex and Apotex USA.

13. Venue is proper in this Court for this action under at least Title 29, United States Code § 1391(b) and (c).

**BACKGROUND**

14. On November 17, 1998, United States Letters Patent No. 5,837,699 (the '699 patent), entitled USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES, duly and legally issued to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen. The '699 patent is currently scheduled to expire on January 27, 2014. The '699 patent discloses and claims novel pharmaceutical compositions of mometasone furoate, as well as novel methods for treating diseases of the upper airway passages, including allergic or nonallergic rhinitis, with these compositions. A copy of the '699 patent is attached to this Complaint as Exhibit 1.

15. On October 3, 2000, United States Letters Patent No. 6,127,353 (the '353 patent), entitled MOMETASONE FUROATE MONOHYDRATE, PROCESS FOR MAKING SAME AND PHARMACEUTICAL COMPOSITIONS, duly and legally issued to Pui-Ho Yen, Charles Eckhart, Teresa Etlinger, and Nancy Levine. The '353 patent is currently scheduled to expire on October 3, 2017. The '353 patent discloses and claims novel form(s) of mometasone furoate monohydrate (also designated 9α,21-dichloro-16α-methyl-1,4-pregnadiene-11β,17α-diol-3,20-dione-17-(2'-furoate) monohydrate) and novel pharmaceutical compositions thereof. A copy of the '353 patent is attached to this Complaint as Exhibit 2.

16. On April 20, 2004, United States Letters Patent No. 6,723,713 (the '713 patent), entitled USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES, duly and legally issued to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen. The '713 patent is

currently scheduled to expire on January 27, 2014. The '713 patent discloses and claims novel pharmaceutical compositions of mometasone furoate, as well as novel methods for treating diseases of the upper airway passages, including allergic rhinitis, with these compositions. A copy of the '713 patent is attached to this Complaint as Exhibit 3.

17. Schering is the owner through assignment of the '699, '353, and '713 patents, and Schering-Plough Corporation is the owner of an approved New Drug Application for mometasone furoate monohydrate metered nasal spray (NDA No. 20-762) that is sold under the trademark Nasonex®.

18. Schering Nasonex® nasal spray is extremely successful and is widely used in Illinois, the United States, and throughout the world to treat diseases of the upper airways, including allergic and nonallergic rhinitis.

19. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the United States Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA). Schering has listed the '699, '353, and '713 patents in the Orange Book for Nasonex® nasal spray.

20. On information and belief, Apotex has filed an Abbreviated New Drug Application with the FDA for generic mometasone furoate nasal spray, 50 mcg (ANDA No. 91-161). Apotex's ANDA No. 91-161 allegedly contains a certification under Title 21, United States Code § 355(j)(2)(A)(vii)(IV) and Title 21, Code of Federal Regulations, § 314.95, that each of the '699, '353, and '713 patents are "invalid, unenforceable, or will not be infringed." Notice of that certification, but not the certification, was transmitted to Schering and Schering-

Plough Corporation on or after November 6, 2009, and received by Schering on or after November 9, 2009.

21. Apotex has refused to make ANDA No. 91-161 or samples of its proposed generic copy of Nasonex® nasal spray available to Schering under reasonable conditions that would allow evaluation before the filing of this Complaint.

22. Upon information and belief, Apotex's proposed generic copy would contain mometasone furoate in such a form that would infringe the '353 patent.

23. Upon information and belief, Apotex's proposed generic copy represents a composition that is intended to be used in a manner that would infringe the '699 and '713 patents.

24. On information and belief, Apotex filed ANDA No. 91-161 because both Apotex and its U.S. subsidiary, Apotex USA, seek to enter the lucrative intranasal mometasone furoate market that Nasonex® nasal spray has created with its beneficial and advantageous treatments for diseases of the upper airways, including allergic and nonallergic rhinitis.

25. On information and belief, Apotex USA actively and knowingly aided and abetted Apotex's filing of ANDA No. 91-161 and would be involved in any manufacturing, marketing, sale, and/or distribution of Apotex's proposed generic copies of Nasonex® nasal spray in the United States.

**COUNT I**

26. Each of the preceding paragraphs 1 – 25 is incorporated as if fully set forth herein.

27. On information and belief, Apotex filed ANDA No. 91-161 to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '699 patent, before the expiration of the '699 patent. On

information and belief, Apotex has committed an act of infringement under Title 35, United States Code § 271(e)(2)(A).

28. On information and belief, when Apotex filed ANDA No. 91-161 seeking approval to market generic mometasone furoate nasal spray before the expiration of the '699 patent, Apotex was aware of the existence of the '699 patent and that the filing of ANDA No. 91-161 constituted an act of infringement of that patent.

29. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '699 patent.

**COUNT II**

30. Each of the preceding paragraphs 1 – 29 is incorporated as if fully set forth herein.

31. On information and belief, when Apotex USA actively and knowingly aided and abetted Apotex with its drafting and/or filing of ANDA No. 91-161, Apotex USA was aware of the '699 patent and knew that Apotex's filing of ANDA No. 91-161 constituted an act of infringement.

32. On information and belief, Apotex USA has committed an act of infringement under Title 35, United States Code § 271(b).

33. On information and belief, Apotex USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '699 patent.

**COUNT III**

34. Each of the preceding paragraphs 1 – 25 is incorporated as if fully set forth herein.

35. On information and belief, Apotex filed ANDA No. 91-161 to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of a drug product which

is claimed in the ’353 patent, before the expiration of the ’353 patent. On information and belief, Apotex has committed an act of infringement under Title 35, United States Code § 271(e)(2)(A).

36. On information and belief, when Apotex filed ANDA No. 91-161 seeking approval to market generic mometasone furoate nasal spray before the expiration of the ’353 patent, Apotex was aware of the existence of the ’353 patent and that the filing of ANDA No. 91-161 constituted an act of infringement of that patent.

37. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the ’353 patent.

**COUNT IV**

38. Each of the preceding paragraphs 1 – 25 and 34 – 37 is incorporated as if fully set forth herein.

39. On information and belief, when Apotex USA actively and knowingly aided and abetted Apotex with its drafting and/or filing of ANDA No. 91-161, Apotex USA was aware of the ’353 patent and knew that Apotex’s filing of ANDA No. 91-161 constituted an act of infringement.

40. On information and belief, Apotex USA has committed an act of infringement under Title 35, United States Code § 271(b).

41. On information and belief, Apotex USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the ’353 patent.

**COUNT V**

42. Each of the preceding paragraphs 1 – 25 is incorporated as if fully set forth herein.

43. On information and belief, Apotex filed ANDA No. 91-161 to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of a drug product the

use of which is claimed in the '713 patent, before the expiration of the '713 patent. On information and belief, Apotex has committed an act of infringement under Title 35, United States Code § 271(e)(2)(A).

44. On information and belief, when Apotex filed ANDA No. 91-161 seeking approval to market generic mometasone furoate nasal spray before the expiration of the '713 patent, Apotex was aware of the existence of the '713 patent and that the filing of ANDA No. 91-161 constituted an act of infringement of that patent.

45. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '713 patent.

**COUNT VI**

46. Each of the preceding paragraphs 1 – 25 and 42 – 45 is incorporated as if fully set forth herein.

47. On information and belief, when Apotex USA actively and knowingly aided and abetted Apotex with its drafting and/or filing of ANDA No. 91-161, Apotex USA was aware of the '713 patent and knew that Apotex's filing of ANDA No. 91-161 constituted an act of infringement.

48. On information and belief, Apotex USA has committed an act of infringement under Title 35, United States Code § 271(b).

49. On information and belief, Apotex USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '713 patent.

**REQUESTED RELIEF**

WHEREFORE, Plaintiff Schering respectfully seeks the following relief:

a. That judgment be entered that Defendant Apotex has infringed the ’699, ’353, and ’713 patents by submitting ANDA No. 91-161;

b. That judgment be entered that Defendant Apotex USA has infringed the ’699, ’353, and ’713 patents through actively and knowingly aiding and abetting Apotex’s drafting and/or filing of ANDA 91-161;

c. That a permanent injunction be issued under Title 35, United States Code § 271(e) restraining or enjoining Defendants Apotex and Apotex USA, their officers, agents or attorneys or employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any chemical entity, therapeutic composition, and/or method of use covered by the ’699, ’353, and ’713 patents for the full terms thereof, including the applicable pediatric exclusivities, and from inducing or contributing to such activities;

d. That an order be issued under Title 35, United States Code § 271(e)(4)(A) that the effective date of any approval of ANDA No. 91-161 be a date which is not earlier than the expiration date of the last to expire of the asserted patents, including the applicable pediatric exclusivity;

e. That this is an exceptional case under Title 35, United States Code § 285 and that judgment be entered for costs and reasonable attorney fees to be awarded to Schering; and

f. That this Court award such other and further relief as the Court may deem proper and just under the circumstances.

Dated: December 22, 2009

Respectfully submitted,

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