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Attorneys for Plaintiff
SCHERING CORPORATION

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORPORATION Plaintiff, v. SANDOZ INC. Defendant.	CIVIL ACTION NO.:____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Schering Corp., by way of Complaint against Sandoz Inc., alleges as follows:

THE PARTIES

1. Schering Corp. ("Schering") is a corporation organized and existing under the laws of the state of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Schering is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

2. Schering is a wholly owned subsidiary of Merck & Co., Inc.

3. On information and belief, Sandoz Inc. ("Sandoz") is a corporation organized and existing under the laws of the state of Colorado, having a principal place of business at 506 Carnegie Center Drive, Suite 400, Princeton, New Jersey 08540.

4. On information and belief, Sandoz is in the business of developing and manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Sandoz because of its continuous and systematic contacts with the state of New Jersey.

7. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and/or 28 U.S.C. § 1400(b).

SCHERING'S NDAs AND ASSERTED PATENTS

8. Schering filed New Drug Application ("NDA") Nos. 022003 and 022027, by which the U.S. Food and Drug Administration ("FDA") granted approval for an oral suspension including 40 mg/mL of the active ingredient posaconazole. The posaconazole oral suspension described in NDA Nos. 022003 and 022027 is approved for the prophylaxis of invasive Aspergillus and Candida fungal infections in immunocompromised patients at high risk of developing those infections, and for the treatment of oropharyngeal candidiasis. Posaconazole oral suspension, 40 mg/mL, is sold by Schering under the tradename "NOXAFIL®".

9. Schering is the owner of U.S. Patent Nos. 5,661,151 (the "'151 patent"), 5,703,079 (the "'079 patent"), and 6,958,337 (the "'337 patent") (collectively, the "Schering patents"), which are attached as Exhibits A, B, and C, respectively.

10. Pursuant to 21 U.S.C. § 355(b)(1), Schering has submitted information concerning the Schering patents to the FDA in connection with its NDA Nos. 022003 and 022027, identifying them as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

SANDOZ'S ANDA AND NOTICE LETTER

11. By letter ("Notice Letter") dated March 17, 2011, and received by Schering on March 23, 2011, Sandoz gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 202481 to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use and sell posaconazole oral suspension, 40 mg/mL (the "Sandoz Generic Product"), prior to the expiration of the Schering patents.

12. In the Notice Letter, Sandoz informed Schering that its ANDA contained a "Paragraph IV Certification" that each of the Schering patents is invalid and/or will not be infringed by the manufacture, use, offer for sale and sale of the Sandoz Generic Product.

13. This complaint for patent infringement is being filed before the expiration of forty-five days from the date Schering received the Sandoz Notice Letter.

COUNT I – INFRINGEMENT OF '151 PATENT

14. Schering realleges, as if fully set forth herein, the averments contained in paragraphs 1-13.

15. The '151 patent discloses and claims chemical compounds, including the posaconazole compound, pharmaceutical compositions comprising those compounds, and methods of treating and/or preventing fungal infections comprising the administration of an antifungally effective amount of those compounds.

16. Because Sandoz's ANDA seeks approval to engage in the commercial manufacture, use, or sale of a drug which is claimed in the '151 patent and the use of which is claimed in the '151 patent before its expiration, Sandoz has infringed the '151 patent under 35 U.S.C. § 271(e)(2)(A).

17. Upon FDA approval of Sandoz's ANDA, Sandoz will further infringe the '151 patent under 35 U.S.C. §§ 271(a), (b) and/or (c) by making, using, offering to sell, and selling Sandoz's Generic Product in the United States, by actively inducing infringement by others, and/or by contributorily infringing the patent, unless enjoined by this Court.

18. Schering will be substantially and irreparably harmed if Sandoz's infringement of the '151 patent is not enjoined. Schering does not have an adequate remedy at law.

19. Schering is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Sandoz's ANDA be a date that is not earlier than the July 19, 2019, expiration date of the '151 patent, or the date of any later expiration of exclusivity to which Schering is or becomes entitled.

20. Upon information and belief, Sandoz was aware of the existence of the '151 patent and was aware that the filing of its ANDA and certification with respect to the '151 patent constituted an act of infringement of that patent.

21. This case is an exceptional one, and Schering is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT II – INFRINGEMENT OF '079 PATENT

22. Schering realleges, as if fully set forth herein, the averments contained in paragraphs 1-21.

23. The '079 patent discloses and claims genuses of chemical compounds that include the posaconazole compound, pharmaceutical compositions comprising those compounds, and methods of treating and/or preventing fungal infections comprising the administration of an antifungally effective amount of those compounds.

24. Because Sandoz's ANDA seeks approval to engage in the commercial manufacture, use, or sale of a drug which is claimed in the '079 patent and the use of which is claimed in the '079 patent before its expiration, Sandoz has infringed the '079 patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon FDA approval of Sandoz's ANDA, Sandoz will further infringe the '079 patent under 35 U.S.C. §§ 271(a), (b) and/or (c) by making, using, offering to sell, and

selling Sandoz's Generic Product in the United States, by actively inducing infringement by others, and/or by contributorily infringing the patent, unless enjoined by this Court.

26. Schering will be substantially and irreparably harmed if Sandoz's infringement of the '079 patent is not enjoined. Schering does not have an adequate remedy at law.

27. Schering is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Sandoz's ANDA be a date that is not earlier than the August 26, 2014, expiration date of the '079 patent, or the date of any later expiration of exclusivity to which Schering is or becomes entitled.

28. Upon information and belief, Sandoz was aware of the existence of the '079 patent and was aware that the filing of its ANDA and certification with respect to the '079 patent constituted an act of infringement of that patent.

29. This case is an exceptional one, and Schering is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT III – INFRINGEMENT OF '337 PATENT

30. Schering realleges, as if fully set forth herein, the averments contained in paragraphs 1-29.

31. Claims 4-7 of the '337 patent claim posaconazole in crystalline Form III, pharmaceutical compositions comprising posaconazole in crystalline Form III, and methods of treating and/or preventing fungal infections comprising administering an antifungally effective amount of posaconazole in crystalline Form III.

32. Sandoz's Notice Letter states that the Sandoz Generic Product "does not contain . . . Form III crystalline polymorph."

33. As set forth below, Sandoz has prevented Schering from evaluating the accuracy of Sandoz's assertion that its Generic Product "does not contain . . . Form III crystalline polymorph." Accordingly, Schering herein alleges that the filing of Sandoz's ANDA infringed the '337 patent under 35 U.S.C. § 271(e)(2)(A), and that the commercial manufacture, use, offer for sale, and sale of the Sandoz Generic Product prior to the expiration of the '337 patent would infringe the '337 patent under 35. U.S.C. §§ 271(a), (b) and/or (c).

34. The Offer of Confidential Access included with Sandoz's Notice Letter was unreasonable on its face, for example, by prohibiting any of Schering's in-house litigation attorneys from having access to Sandoz's confidential materials. Since March 25, 2011, Sandoz has failed and, upon information and belief, has willfully refused to respond to numerous telephone calls, e-mails, and letters from Schering's outside counsel attempting to negotiate a mutually agreeable Offer of Confidential Access. As a result of this conduct on the part of Sandoz, Schering has not received any part of Sandoz's ANDA, or samples of Sandoz's Generic Product or the active pharmaceutical ingredient used in that product.

35. Schering is not aware of any other means of obtaining information regarding Sandoz's Generic Product within the 45-day statutory period. In the absence of such information, Schering resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that Sandoz's Generic Product, or the use or manufacture of that product, falls within the scope of one or more of Claims 4-7 of the '337 patent.

36. Schering will be substantially and irreparably harmed if Sandoz's infringement of the '337 patent is not enjoined. Schering does not have an adequate remedy at law.

37. Schering is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Sandoz's ANDA be a date that is not earlier than the October 5, 2018, expiration date of the '337 patent, or the date of any later expiration of exclusivity to which Schering is or becomes entitled.

38. On information and belief, Sandoz was aware of the existence of the '337 patent and was aware that the filing of its ANDA and certification with respect to the '337 patent constituted an act of infringement of that patent.

39. This case is an exceptional one, and Schering is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

40. Schering requests that:

a. Judgment be entered that Sandoz has infringed the '151, '079 and '337 patents by submitting ANDA No. 202481;

b. Judgment be entered that this is an exceptional case, and that Schering is entitled to its reasonable attorney fees pursuant to 35 U.S.C. § 285;

c. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Sandoz, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or

importation into the United States, of drug compounds claimed in or the use of which is claimed in the '151, '079 and '337 patents;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 202481 be a date which is not earlier than the later of July 19, 2019, the expiration date of the '151 patent, August 26, 2014, the expiration date of the '079 patent, October 5, 2018, the expiration date of the '337 patent, or the date of any later expiration of exclusivity to which Schering is or becomes entitled; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: May 4, 2011

Respectfully submitted,

By: s/Sheila F. McShane

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