IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and DOW PHARMACEUTICAL SCIENCES, INC.,	§	
Plaintiffs,	§	**CIVIL ACTION NO. _____**
v.	§	
SEEGPHARM S.A.,	§	
Defendant.	§	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GALDERMA LABORATORIES, L.P., GALDERMA S.A., and DOW PHARMACEUTICAL SCIENCES, INC. (collectively, "Plaintiffs") file this Complaint for patent infringement against Defendant SEEGPHARM S.A. ("SEEGPharm" or "Defendant") as follows:

PARTIES

1. Galderma Laboratories, L.P. ("Galderma L.P.") is a Texas limited partnership with its principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. Galderma L.P. is the exclusive beneficial holder of rights to market MetroGel® (1% metronidazole topical gel) under FDA approval of New Drug Application No. 21789 (the "NDA"), approved June 30, 2005, and is the owner of this NDA. Galderma L.P. has the exclusive right from Galderma S.A. to sell and offer to sell MetroGel® in the United States. MetroGel® is used for the treatment of rosacea.

2. Galderma S.A. is a Swiss company with its principal place of business at World Trade Center, Avenue de Gratta-Paille 2, 1018 Lausanne, Switzerland. Galderma S.A. and/or its affiliates are involved in the research, development, marketing, and sale of pharmaceutical products.

3. Plaintiff Dow Pharmaceutical Sciences, Inc. ("Dow") is a Delaware corporation with its principal place of business at 1330 Redwood Way, Petaluma, California 94954. As part of its business, Dow is involved in the research and development of pharmaceutical products. Dow is the current owner of U.S. Patent No. 6,881,726 (the "'726 Patent") and U.S. Patent No. 7,348,317 (the "'317 Patent"). A copy of the '726 Patent is attached as Exhibit "A." A copy of the '317 Patent is attached as Exhibit "B." Dow has licensed the '726 Patent and '317 Patent to Galderma S.A.

4. SEEGPharm S.A. is a Swiss company with its principal place of business at Via Trevano 15, CH-6904 Lugano, Switzerland. SEEGPharm may be served with process under Federal Rule of Civil Procedure 4(h)(2) and 4(f)(1) through the Central Authority under the Hague Service Convention by forwarding two copies of the Summons and this Complaint to: Tribunale di appello, Rogatorie Internazionali, Via Pretorio 16, 6901 Lugano, Switzerland.

JURISDICTION AND VENUE

5. This is a complaint for patent infringement. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

6. This Court has personal jurisdiction over SEEGPharm because SEEGPharm sells products for distribution throughout the United States and regularly conducts business in the State of Texas. SEEGPharm also submitted the ANDA (an act of infringement under 35 U.S.C.

§ 271(e)(2)) for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV Certification")—the acts which give rise to the instant litigation—with knowledge that Galderma L.P. would be injured by such actions in this district, and delivered its Paragraph IV Certification to Galderma L.P. in this district. SEEGPharm intends to sell the infringing product in or for distribution in this district upon approval by the FDA. SEEGPharm has thus purposefully targeted its conduct to cause harm in the State of Texas and this district.

7. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement (*i.e.*, SEEGPharm's submission of the ANDA and issuance of the Paragraph IV Certification) purposefully targeting a resident of this district (*i.e.*, Galderma L.P.). Further, venue is proper in this district because 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this district as the only proper venue in which SEEGPharm could file suit seeking a declaration of non-infringement in connection with the ANDA.

BACKGROUND FACTS

A. The '726 Patent

8. On April 19, 2005, the USPTO issued the '726 Patent, entitled "Aqueous Compositions Containing Metronidazole," to Dow, the assignee of the named inventors, Yunik Chang and Gordon Dow. Dow is the current owner of the '726 Patent.

9. Dow granted Galderma S.A. an exclusive license under the '726 Patent and to make, distribute, market, sell, and use the inventions disclosed in the '726 Patent. Galderma's exclusive license includes the right to grant sublicenses, and the right to enforce the '726 Patent.

10. The '726 Patent is valid, enforceable, and has not expired.

B. The ˈ317 Patent

11. On March 25, 2008, the USPTO issued the ˈ317 Patent, entitled, "Aqueous Compositions Containing Metronidazole," to Dow, the assignee of the named inventors, Yunik Chang and Gordon Dow. Dow is the current owner of the ˈ317 Patent.

12. Dow granted Galderma S.A. an exclusive license under the ˈ317 Patent and to make, distribute, market, sell, and use the inventions disclosed in the ˈ317 Patent. Galderma's exclusive license includes the right to grant sublicenses, and the right to enforce the ˈ317 Patent.

13. The ˈ317 Patent is valid, enforceable, and has not expired.

C. MetroGel®

14. Galderma L.P. is the owner of New Drug Application ("NDA") No. 21789. On June 30, 2005, Galderma L.P. obtained FDA Approval to market MetroGel®. The ˈ726 Patent and ˈ317 Patent are listed in the FDA publication entitled, "Approved Drug Products With Therapeutic Equivalence Evaluations" (known as the "Orange Book") as covering MetroGel® (1% metronidazole gel).

15. Galderma S.A. has granted Galderma L.P. the exclusive right to sell and offer for sale MetroGel® in the United States.

D. SEEGPharm's Infringement

16. SEEGPharm is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

17. Prior to July 15, 2016, SEEGPharm decided to file an application seeking FDA approval to sell a generic version of MetroGel®.

18. SEEGPharm submitted Abbreviated New Drug Application No. 209023 (the "ANDA") seeking approval to engage in the commercial manufacture, use, and sale of generic

1% metronidazole topical gel (the "Accused Product" or "Infringing Product") prior to the expiration of the ʹ726 Patent and ʹ317 Patent.

19. The Accused Product that is the subject of the ANDA will directly and indirectly infringe one or more claims of the ʹ726 Patent and ʹ317 Patent.

20. On or about July 15, 2016, SEEGPharm sent a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas, Galderma S.A., and Dow. Through the Certification Letter, SEEGPharm first notified Plaintiffs that SEEGPharm had filed the ANDA with the FDA relating to the Accused Product, and that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in SEEGPharmʹs opinion, the claims of the ʹ726 Patent and ʹ317 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of the Accused Product.

21. The Paragraph IV Certification Letter was not accompanied by an offer of confidential access that would permit Plaintiffs access to the ANDA. To date, SEEGPharm has refused to offer Plaintiffs access to the ANDA.

22. Plaintiffs do not have access to information that would allow Plaintiffs to confirm that SEEGPharmʹs proposed generic version of MetroGel® infringes one or more claims of the ʹ726 Patent and ʹ317 Patent.

23. Plaintiffs do not have other means of obtaining information regarding SEEGPharmʹs proposed generic product. In the absence of such information, Plaintiffs must resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm infringement and to present to the Court evidence that SEEGPharmʹs proposed generic version of MetroGel® falls within the scope of one or more claims of the ʹ726 Patent and ʹ317 Patent.

24. Plaintiffs have commenced this action within 45 days of the date that they received the Certification Letter.

25. SEEGPharm intends to continue seeking approval of the ANDA from the FDA, and to engage in the commercial manufacture, marketing, and sale of the Accused Product (including commercial marketing and sale of the Accused Product in the State of Texas and this District), in the event that the FDA approves the ANDA.

COUNT I:
INFRINGEMENT OF U.S. PATENT NO. 6,881,726

26. Plaintiffs incorporate paragraphs 1 through 25 above by reference as if fully set forth herein.

27. The ˈ726 Patent is valid, enforceable, and has not expired.

28. SEEGPharm's submission of the ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of the Accused Product, prior to the expiration of the '726 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

29. The Accused Product and/or its use as directed infringes one or more of the claims of the ˈ726 Patent. Under 35 U.S.C. § 271(e)(2)(A), SEEGPharm infringed the ˈ726 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ˈ726 Patent.

30. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, SEEGPharm's ANDA must include information showing that the Accused Product (1) contains the same active ingredients as MetroGel® [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as MetroGel® [21 U.S.C. §

355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as MetroGel® [21 U.S.C. § 355(j)(2)(A)(iv)].

31. As such, under 35 U.S.C. § 271(e)(2)(A), SEEGPharm has infringed the '726 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '726 Patent.

32. As a result of SEEGPharm's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '726 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '726 Patent.

33. Plaintiffs will be substantially and irreparably harmed by SEEGPharm's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

34. As a result of SEEGPharm's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining SEEGPharm and all those in privity with or acting in concert with SEEGPharm from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '726 Patent, or from otherwise infringing or inducing the infringement of the '726 Patent.

COUNT II:
INFRINGEMENT OF U.S. PATENT NO. 7,348,317

35. Plaintiffs incorporate paragraphs 1 through 34 above by reference as if fully set forth herein.

36. The '317 Patent is valid, enforceable, and has not expired.

37. SEEGPharm's submission of the ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of the Accused Product, prior to

the expiration of the '317 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

38. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, SEEGPharm's ANDA must include information showing that the Accused Product (1) contains the same active ingredients as MetroGel® [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as MetroGel® [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as MetroGel® [21 U.S.C. § 355(j)(2)(A)(iv)].

39. As such, under 35 U.S.C. § 271(e)(2)(A), SEEGPharm has infringed the '317 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '317 Patent.

40. As a result of SEEGPharm's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '317 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '317 Patent.

41. Plaintiffs will be substantially and irreparably harmed by SEEGPharm's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

42. As a result of SEEGPharm's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining SEEGPharm and all those in privity with or acting in concert with SEEGPharm from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '317 Patent, or from otherwise infringing or inducing the infringement of the '317 Patent.

DEMAND FOR JURY TRIAL

In the event SEEGPharm commercially manufactures, uses, sells, offers to sell, or imports the Accused Product prior to trial, Plaintiffs demand trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

(A) A declaration that SEEGPharm's commercial manufacture, use, offer for sale, or sale in, or importation into the United States of the Accused Product prior to the date of the expiration of the '726 Patent and '317 Patent, including any patent extensions and any additional periods of exclusivity, would constitute infringement of such patents in violation of Plaintiffs' patent rights;

(B) A declaration, pursuant to 35 U.S.C. § 271(e)(2)(A), that SEEGPharm has infringed the '726 Patent and '317 Patent by submitting the ANDA to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell in, or import into the United States the Accused Product prior to the expiration of such patents, including any patent extensions and any additional periods of exclusivity, and that the Accused Product infringes such patents;

(C) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the Accused Product described in the ANDA is not to be earlier than the date of the expiration of the '726 Patent and '317 Patent, including any patent extensions and any additional periods of exclusivity;

(D) A permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and (D), and 35 U.S.C. § 283, enjoining SEEGPharm and its officers, agents, servants, employees, privies, and

others acting for, on behalf of, or in concert with any of them, from commercially manufacturing, using, selling, or offering to sell the Accused Product within the United States; importing the Accused Product into the United States; or otherwise infringing or inducing the infringement of the ˈ726 Patent and ˈ317 Patent, prior to the date of the expiration of such patents, including any patent extensions and any additional periods of exclusivity;

(E) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, as a result of SEEGPharmˈs infringement, to the extent there has been any commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Accused Product prior to the date of the expiration of the ˈ726 Patent and ˈ317 Patent, including any patent extensions and any additional periods of exclusivity; and

(F) Such other and further relief as this Court may deem just and proper.

Dated: August 29, 2016

Respectfully submitted,

/s/ Michael C. Wilson

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