IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

INTENDIS, INC. and DOW PHARMACEUTICAL SCIENCES, INC. Plaintiffs, v. RIVER'S EDGE PHARMACEUTICALS, LLC. Defendant.	Civ. Act. No. _____

COMPLAINT

Plaintiffs Intendis, Inc. and Dow Pharmaceutical Sciences, Inc. for their Complaint herein, aver and allege as follows:

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.

THE PARTIES

2. Plaintiff Intendis, Inc. ("Intendis") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 36 Columbia Road, Morristown, NJ 07962. Intendis is an exclusive licensee of the patent in suit identified in paragraph 11 below and is the holder of New Drug Application ("NDA") No. 21844 for the desonide gel medication, which it markets in the United States under the trade name Desonate.®

3. Plaintiff Dow Pharmaceutical Sciences, Inc. ("Dow") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1330 Redwood Way, Petaluma, CA 94954. Dow is the owner of the patent in suit identified in paragraph 11 below.

4. Upon information and belief, Defendant River's Edge Pharmaceuticals, LLC ("River's Edge") is a limited liability company organized and existing under the laws of the State of Florida, having a principal place of business at 5400 Laurel Springs Parkway, Building 500, Suit 504, Suwanee, GA 30024.

JURISDICTION AND VENUE

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

6. On May 18, 2011, Plaintiffs filed a complaint against River's Edge in the District of New Jersey. *See Intendis, Inc. et al. v. River's Edge Pharmaceuticals, Inc. et al.* ("the New Jersey Action").

7. Plaintiffs contend, upon information and belief, that jurisdiction and venue for this action are proper in the District of New Jersey.

8. Under the Hatch-Waxman Act, to perfect Plaintiff's right to a statutory 30-month stay of US. Food and Drug Administration ("FDA") approval of Abbreviated New Drug Application ("ANDA") No. 202470, Plaintiffs are required to bring suit within 45 days of April 5, 2011. *See e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.95(f). On May 18, 2011, Plaintiffs filed the New Jersey Action in the District of New Jersey. The allegations in the Complaint in that action are substantially identical to this Complaint. Although Plaintiffs' choice of forum is the District of New Jersey, because River's Edge may challenge jurisdiction in that district, Plaintiffs are filing the present Complaint to ensure that suit has been timely commenced, regardless of how the Court may later resolve motions challenging jurisdiction or venue in New Jersey, if River's Edge were to bring such a motion. If River's Edge does not challenge jurisdiction in New Jersey, Plaintiffs will immediately dismiss this action.

9. This Court has personal jurisdiction over River's Edge because River's Edge is a resident of and has a principal place of business in this Judicial District.

10. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENT IN SUIT AND NDA NO. 21844

11. Plaintiff Dow is the lawful owner of all right, title and interest in United States Patent No. 6,387,383 entitled "TOPICAL LOW-VISCOSITY GEL COMPOSITION" ("the '383 patent"), including the right to sue and to recover for past infringement thereof. Plaintiff Intendis is an exclusive licensee of the '383 patent from Dow, with the right to enforce the '383 patent. A copy of the '383 patent is attached hereto as Exhibit A, which was duly and legally issued on May 14, 2002, naming Gordon J. Dow, Robert W. Lathrop and Debra A. Dow as the inventors.

12. The '383 patent is listed in the FDA's "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering Desonate®, which is the subject of NDA No. 21844. Intendis is the NDA holder of NDA No. 21844.

RIVER'S EDGE'S ANDA

13. Upon information and belief, River's Edge submitted Abbreviated New Drug Application No. 202470 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of a generic Desonide Gel, 0.05% formulation ("the ANDA product") based on the Reference Listed Drug ("RLD") Desonate®, which is the subject of approved NDA No. 21844, before the expiration of the '383 patent.

14. Upon information and belief, ANDA No. 202470 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that "the ANDA formulation does not infringe the '383 patent."

15. Upon information and belief, nevertheless the ANDA product is covered by one or more claims of the '383 patent.

16. In letters dated March 15 and/or March 16, 2011 ("paragraph IV letters") addressed to Intendis GmbH and Dow, counsel Hultquist IP, on behalf of a "client," indicated that an ANDA for the ANDA product was filed with the FDA and such product did not infringe the '383 patent. Counsel did not identify River's Edge as the ANDA applicant in either of these letters.

17. On April 5, 2011, counsel for Intendis contacted Hultquist IP by telephone. During that call, Hultquist IP identified River's Edge as the ANDA applicant.

18. For purposes of 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.95(f), Intendis received the paragraph IV letters on April 5, 2011.

19. By letter dated April 12, 2011, Intendis and River's Edge, *inter alia*, clarified that Intendis received the paragraph IV letters on April 5, 2011 and that the 45 day period set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.95(f) commenced on April 5, 2011.

20. All conditions precedent to the assertion of the claims in this Complaint have been satisfied or waived.

COUNT I
PATENT INFRINGEMENT

21. Plaintiffs incorporate by reference as if fully set forth herein the averments and allegations contained within Paragraphs 1-20, above.

22. River's Edge's submission of ANDA No. 202470 is an act of infringement of the '383 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, the commercial sale, offer for sale, use, and/or manufacture of the ANDA product would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '383 patent.

24. Upon information and belief, River's Edge has been aware of the existence of the '383 patent, and has no reasonable basis for believing that the commercial sale, offer for sale, use, and/or manufacture of the ANDA product will not infringe, contribute to the infringement of, and/or induce the infringement of the '383 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

25. The acts of infringement by River's Edge set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that River's Edge has infringed the '383 patent, and that the commercial sale, offer for sale, use, and/or manufacture of the ANDA product described in ANDA No. 202470 would infringe, induce infringement of, and/or contribute to the infringement of the '383 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202470, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '383 patent plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., River's Edge, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '383 patent;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

This 19th day of May, 2011

Respectfully submitted,

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