IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CLARUS THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Civil Action No. _____
LIPOCINE INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Clarus Therapeutics, Inc. ("Plaintiff" or "Clarus"), by its undersigned attorneys, brings this action against Defendant Lipocine Inc. ("Defendant" or "Lipocine"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising from Lipocine's filing of a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval to market an oral testosterone pharmaceutical product prior to the expiration of United States Patent No. 8,828,428 ("the '428 patent"), which is owned by Clarus.

THE PARTIES

2. Plaintiff Clarus Therapeutics, Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 555 Skokie Boulevard, Suite 340, Northbrook, Illinois 60062.

3. Clarus is in the business of, among other activities, developing pharmaceutical products containing testosterone esters, *e.g.*, testosterone undecanoate, for oral delivery.

4. Upon information and belief, Defendant Lipocine Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 675 Arapeen Drive, Suite 202, Salt Lake City, Utah 84108.

5. Upon information and belief, Lipocine is in the business of, among other activities, developing pharmaceutical products for oral delivery, including pharmaceutical products containing testosterone esters, *e.g.*, testosterone undecanoate, for oral delivery.

6. Clarus and Lipocine are direct competitors. Clarus and, upon information and belief, Lipocine, are each in the business of, *inter alia*, developing pharmaceutical products containing testosterone esters for oral delivery, and each has filed an NDA with the FDA seeking approval of a pharmaceutical product containing a testosterone ester, *e.g.*, testosterone undecanoate, for oral delivery.

THE CLARUS NDA PRODUCT (REXTORO™)

7. Clarus has filed an NDA ("the Clarus NDA") with the FDA seeking approval to market an oral testosterone undecanoate formulation throughout the United States, including in the State of Delaware.

8. The Clarus NDA was accepted for filing by the FDA on January 3, 2014, and is currently pending at the FDA.

THE LIPOCINE ORAL TESTOSTERONE PRODUCT (LPCN 1021) AND THE LIPOCINE NDA WHICH SEEKS APPROVAL FOR LPCN 1021

9. Upon information and belief, Lipocine has developed an oral testosterone formulation referred to by Lipocine as LPCN 1021.

10. Upon information and belief, Lipocine filed an NDA ("the Lipocine NDA") on LPCN 1021 ("the Lipocine NDA Product") with the FDA on or about August 27, 2015.

11. Upon information and belief, the Lipocine NDA seeks approval to manufacture, market, offer for sale and/or sell the Lipocine NDA Product throughout the United States, including in the State of Delaware.

12. Upon information and belief, the Lipocine NDA Product contains a testosterone ester.

13. Upon information and belief, the Lipocine NDA Product contains testosterone undecanoate.

14. Upon information and belief, the Lipocine NDA Product contains 10% to 20% w/w testosterone undecanoate.

15. Upon information and belief, the Lipocine NDA Product contains a lipophilic surfactant.

16. Upon information and belief, the Lipocine NDA Product contains an ingredient that is the equivalent of a lipophilic surfactant.

17. Upon information and belief, the Lipocine NDA Product contains a monoglyceride of a fatty acid or a di-glyceride of a fatty acid.

18. Upon information and belief, the Lipocine NDA Product contains glyceryl monolinoleate.

19. Upon information and belief, the Lipocine NDA Product contains an ingredient that is the equivalent of glyceryl monolinoleate.

20. Upon information and belief, the Lipocine NDA Product contains Maisine.

21. Upon information and belief, the Lipocine NDA Product contains an ingredient that is the equivalent of Maisine.

22. Upon information and belief, the Lipocine NDA Product contains polyoxyl 40 hydrogenated castor oil.

23. Upon information and belief, the Lipocine NDA Product contains Cremophor RH40.

24. Upon information and belief, the Lipocine NDA Product contains an ingredient that is the equivalent of: (i) Cremophor RH40 or (ii) polyoxyl 40 hydrogenated castor oil.

25. Upon information and belief, the Lipocine NDA Product contains polyethylene glycol.

26. Upon information and belief, the Lipocine NDA Product contains polyethylene glycol ("PEG") with an average molecular weight of about 200 to about 1000 g/mol.

27. Upon information and belief, the Lipocine NDA Product contains PEG 8000.

28. Upon information and belief, the Lipocine NDA Product contains an ingredient that is the equivalent of PEG 8000.

29. Upon information and belief, the Lipocine NDA Product is free of ethanol.

30. Upon information and belief, the Lipocine NDA Product does not contain ethanol.

31. Upon information and belief, the Lipocine NDA does not identify ethanol as a substance that will be used in the manufacture of the Lipocine NDA Product.

32. Upon information and belief, the Lipocine NDA does not identify ethanol as an excipient (ingredient) in the Lipocine NDA Product.

33. Upon information and belief, the Lipocine NDA does not identify ethanol as an excipient (ingredient) of the Lipocine NDA Product in the proposed label.

34. Upon information and belief, and pursuant to a Lipocine September 2015 Corporate Presentation (as reported in Lipocine's Form 8-K dated August 31, 2015), the Lipocine NDA contained information demonstrating that the Lipocine NDA Product:

(a) "Met FDA primary efficacy endpoint targets in all data sets in pivotal Phase 3 clinical study";

(b) "Completed the 52 week safety extension arm," and was "well tolerated, [there being] no cardiac, hepatic, gastrointestinal or drug related SAEs, and [having an] overall AE profile comparable to Androgel 1.62%"; and

(c) Completed a "successful food study" with "consistent and predictable T levels not sensitive to meal fat levels."

35. Upon information and belief, and pursuant to a Lipocine September 2015 Corporate Presentation (as reported in Lipocine's Form 8-K dated August 31, 2015), Lipocine reported that it had "successfully completed [a] Pre-NDA meeting" with FDA, and that "no additional studies [are] required for filing [the Lipocine NDA]."

36. Upon information and belief, and as reported by Lipocine in its August 11, 2015, Form 10-Q (for the Quarterly Period ended June 30, 2015), Lipocine states that "[i]n the near term, we anticipate that our expenses will increase as we: prepare for commercial manufacturing agreement for LPCN 1021 *** conduct market research, market analytics and other activities in preparation of commercial launch of LPCN 1021 . . . ."

37. Upon information and belief, and as reported by Lipocine in Exhibit 99.1 to its September 29, 2015, 8-K Statement, Lipocine states that it anticipates receiving a "NDA 74-day letter" for the Lipocine NDA in "November 2015."

38. A 74-day letter is issued by the FDA, and advises an NDA applicant, *inter alia*, that its NDA has been accepted for filing, confirms the action date, confirms standard versus priority review, and identifies any preliminary deficiencies in the NDA.

39. Upon information and belief, and as reported by Lipocine in a press release dated October 29, 2015, Lipocine received a communication from the FDA indicating that the FDA has accepted the Lipocine NDA for filing. According to Lipocine, the "acceptance by the FDA of the [Lipocine] NDA indicates that the application is sufficiently complete to permit substantive review."

40. Upon information and belief, and pursuant to a Lipocine September 2015 Corporate Presentation (as reported in Lipocine's Form 8-K dated August 31, 2015), Lipocine expects its FDA Prescription Drug User Fee Act ("PDUFA") date to be "June 2016."

41. Upon information and belief, this June 2016 date is the end of the 10-month time period established under PDUFA for FDA review of an NDA, in this case, the end of the review period for the Lipocine NDA. Upon information and belief, while this 10-month review period is a target for the FDA, the FDA can announce a decision on the approval status of an NDA prior to the PDUFA date.

42. Upon information and belief, Lipocine currently expects FDA approval of the Lipocine NDA, is preparing for the commercial launch of the Lipocine NDA Product, and will commercially launch the Lipocine NDA Product in the United States upon receipt of FDA approval of the Lipocine NDA.

JURISDICTION AND VENUE

43. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

44. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its status as a Delaware corporation, having availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district, and

through its intent to market and sell the Lipocine NDA Product, if approved, to residents of this judicial district.

45. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENT-IN-SUIT

46. On September 9, 2014, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '428 patent entitled "Pharmaceutical Delivery Systems For Hydrophobic Drugs And Compositions Comprising Same" which discloses and claims, *inter alia,* oral formulations containing testosterone undecanoate.

47. The '428 patent will expire no earlier than April 14, 2026.

48. From the time of its issue to date, all right, title and interest in and to the '428 patent has been assigned to Clarus. Clarus is the owner of the '428 patent with the right to sue for injunctive relief and damages for the infringement of that patent. A true and correct copy of the '428 patent is attached hereto as Exhibit A.

COUNT FOR DECLARATION OF INFRINGEMENT OF U.S. PATENT 8,828,428

49. There currently exists an actual case or controversy which permits this Court to entertain Clarus' request for declaratory relief consistent with Article III of the United States Constitution. A judicial declaration is necessary to determine the parties' respective rights relative to the '428 patent.

50. Lipocine's commercial manufacture, use, offer to sell, or sale of the Lipocine NDA Product within the United States, or importation of the Lipocine NDA Product into the United States, during the term of the '428 patent, would infringe claims 1-4 of the '428 patent under 35 U.S.C. § 271(a).

51. Lipocine is seeking FDA approval of the Lipocine NDA, and to market the Lipocine NDA Product, prior to the expiration of the ‘428 patent.

52. Lipocine has made, and will continue to make, substantial preparation in the United States to commercially manufacture, offer to sell, sell and/or import the Lipocine NDA Product prior to the expiration of the ’428 patent.

53. Clarus is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Lipocine NDA Product prior the expiration of the ’428 patent would constitute infringement of claims 1-4 of the ’428 patent.

54. Clarus will be substantially and irreparably harmed, and will have no adequate remedy at law, if Lipocine is not enjoined from infringing the ’428 patent by commercially manufacturing, offering to sell, or selling in the United States, and/or importing into the United States, the Lipocine NDA Product prior to the expiration of the ’428 patent.

PRAYER FOR RELIEF

WHEREFORE, Clarus Therapeutics, Inc. prays for a judgment in its favor against Defendant Lipocine Inc., and respectfully requests the following relief:

A. A judgment declaring that Defendant will infringe one or more claims of the ’428 patent with the Lipocine NDA Product;

B. A declaration that Defendant’s commercial manufacture, use, offer for sale, or sale of the Lipocine NDA Product within the United States, or importation of the Lipocine NDA Product into the United States, prior to the expiration of the ’428 patent (inclusive of any extensions), would constitute an act of infringement of the ’428 patent;

C. A preliminary and permanent injunction enjoining Defendant, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from commercially manufacturing, using, offering to sell, or

selling the Lipocine NDA Product within the United States, or importing the Lipocine NDA Product into the United States, prior to the expiration of the '428 patent, inclusive of any extensions;

D. An order enjoining Defendant from obtaining FDA approval of the Lipocine NDA prior to the expiration date of the '428 patent, inclusive of any extensions;

E. An award of damages, together with interest, for any commercial manufacture, use, offer for sell, or sale of the Lipocine NDA Product within the United States, or importation of the Lipocine NDA Product into the United States, prior to the expiration of the '428 patent, inclusive of any extensions;

F. A finding that this is an exceptional case under 35 U.S.C. § 285, and an award of Clarus' attorneys' fees;

G. An award of Clarus' costs and expenses in this action; and

H. Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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