UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

RUBICON RESEARCH PRIVATE LIMITED, Plaintiff, v. KARTHA PHARMACEUTICALS INC., and MANOJ BABU MAZHUVANCHERIL, Defendants.	Civil Action No. _____ *Document Electronically Filed*

VERIFIED COMPLAINT FOR DAMAGES, INJUNCTIVE, AND OTHER RELIEF

Rubicon Research Private Limited ("Rubicon"), by and through their counsel, allege for their Complaint against Defendants Kartha Pharmaceuticals, Inc. ("Kartha") and Manoj Babu Mazhuvancheril ("Mazhuvancheril") (collectively "Defendants"), as follows:

NATURE OF THE CASE

1. This is a blatant case of trade secrets theft by Defendant Kartha and its principal, Defendant Manoj Babu Mazhuvancheril. In 2013, Defendants started providing agency and consulting services to third-party Zakłady Farmaceutyczne Polpharma SA ("Polpharma"), which manufactures pharmaceutical ingredients that it supplies to its customers, including Rubicon. Defendants were Polpharma's authorized U.S. representative with the Food and Drug Administration ("FDA"), and, in this capacity, had access to extensive amounts of confidential and trade secret information belonging to Rubicon.

2. More specifically, Defendants had access to the technical specifications for the active pharmaceutical ingredient ("API") Rubicon uses to manufacture its baclofen products that are unique to Rubicon and that were the result of years of Rubicon's research and development efforts, including the technical specifications for Rubicon's 5 mg strength of baclofen.

3. The information concerning Rubicon's 5 mg dose is particularly valuable because Rubicon was the first applicant—generic or branded—to receive FDA approval to sell baclofen in a 5 mg strength. Indeed, until April 2020, Rubicon was the only company approved to sell baclofen 5 mg, and Rubicon has become the market leader in the sales and distribution of this product.

4. In October 2019, Defendants through Polpharma were personally introduced to Rubicon. During this introductory meeting, Polpharma, Defendants, and Rubicon discussed confidential raw material supply, volume, and pricing for various products, including baclofen. The parties also discussed market insights, as is common between supplier and customer, but would never have been discussed if Rubicon knew Defendants could become a competitor.

5. Defendants, not disclosing that it had planned to seek approval from the FDA to sell baclofen, showed specific interest in Rubicon's baclofen program and asked many questions about it, including the genesis of Rubicon's unique idea for introducing a 5 mg strength, the regulatory pathway for this approval, and Rubicon's expected marketing strategy and consequent volume share on the 5 mg strength. As a result of this discussion and subsequent communications thereafter, Defendants also had information about the projected market outlook for this product long before any such data would be publicly available.

6. Unbeknownst to Rubicon and Polpharma, at this same time, Defendants were surreptitiously preparing to seek approval from the FDA to sell baclofen in 5 mg, 10 mg, and 20 mg dosages in direct competition with Rubicon. With intimate knowledge of Rubicon's trade secrets regarding the development, validation, regulatory approval, market introduction and commercial potential of baclofen products, Defendants prepared and filed an application to manufacture baclofen products that was quickly approved by the FDA in March 2021, despite the fact that this was Defendants' first approval from the FDA to sell any drug product.

7. As a result of the FDA's approval of Defendants' baclofen application and Rubicon's investigation, Rubicon is informed and believes that Kartha will commercialize its competing baclofen drug products using Rubicon's confidential and proprietary trade secrets, actions that will irreparably harm Rubicon if not enjoined.

8. In light of these actions, Rubicon has no choice but to bring this action to prevent Kartha from unfairly competing and improperly usurping Rubicon's significant investment in baclofen products.

THE PARTIES

9. Plaintiff Rubicon is a private limited company incorporated under the Companies Act, 1956 of the Republic of India bearing Corporate Identification Number (CIN) U73100MH1999PTC119744 and with its registered office at MedOne House, B75, Road No 33, Wagle Estate, Thane (West), Maharashtra 400604, India.

10. Third-Party Zakłady Farmaceutyczne Polpharma SA ("Polpharma") is a corporation organized under the laws of Poland with its principal place of business in Starogard Gdanski, Poland.

11. Rubicon is informed and believes that defendant Kartha Pharmaceuticals Inc. is incorporated in North Carolina and has its principal place of business at 12208 Summer Breeze Court, Charlotte, North Carolina.

12. Kartha Pharmaceuticals Inc. is the successor entity to Kartha Pharmaceutics, LLC.

13. Rubicon is informed and believes that defendant Manoj Babu Mazhuvancheril is a resident of Charlotte, North Carolina. Mazhubancheril is Kartha's President and Chief Executive Officer of Kartha.

14. Rubicon is informed and believes that the Defendants were the agents, servants, and employees of each other, and were acting within the course and scope of their authority as

such agents, servants, and employees and with the permission and consent of each of them at all relevant times alleged herein. In particular, Rubicon is informed and believes that Defendant Mazhuvancheril has acted and is presently acting as the agent and/or employee of Kartha and working on its behalf.

JURISDICTION AND VENUE

15. This action arises under the Defend Trade Secrets Act of 2016, 18 U.S.C. §§ 1836, *et seq*. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, and has supplemental jurisdiction over the state law claims alleged in this Complaint pursuant to 28 U.S.C. § 1367.

16. This Court has personal jurisdiction over Defendants because each of them is domiciled in or has its principal place of business in Charlotte, North Carolina.

17. As is further set forth herein, a substantial part of the events or omissions giving rise to the claims alleged in this Complaint occurred and have a direct effect in this District. Venue therefore lies in the United States District Court for the Western District of North Carolina pursuant to 28 U.S.C. § 1391(b)(2).

GENERAL ALLEGATIONS

A. Rubicon Obtains ANDA Approval for Baclofen.

18. Rubicon is a pharmaceutical company focused on developing high quality products using innovative technologies for the global market, including the United States. Rubicon develops and manufactures over two dozen different finished drug products. One of its most profitable and important products is baclofen, which is used to treat spasticity and concomitant pain, clonus, and muscular rigidity in people with multiple sclerosis or with spinal cord injuries.

19. To market a generic version of any previously-approved drug product in the United States, a generic pharmaceutical company must file an abbreviated new drug application

("ANDA") with the United States Food and Drug Administration ("FDA") that shows the product's chemical and biological equivalence to a previously-approved drug product (known as the "reference listed drug" or "RLD"). *Id*. (citing 21 U.S.C. § 355(j)(2)(A)). This well-established regulatory pathway establishes the safety and efficacy of generic drugs.

20. To gain approval, the FDA must be satisfied that the finished drug product manufactured by the generic pharmaceutical company contains the same active ingredient, employs the same route of administration (*e.g.*, oral or injected), is in the same dosage form and the same strength, and "ha[s] the same therapeutic effect" as the branded equivalent on which the ANDA is based. 21 U.S.C. § 355(j)(2)(A)(i)-(iv).

21. To make these showings, generic pharmaceutical companies must submit scores of information and data about the drug and describe in detail how it will be manufactured. ANDA applications typically include sections on chemistry, manufacturing and controls ("CMC"), clinical/bioequivalence studies, quality aspects of the drug substance and the drug product, non-clinical study reports, and references to scientific publications. The ANDA application also must include the ingredients used to manufacture the drug and, specifically, very detailed information about the API, such as its particle size distribution and the location from where it is sourced. The ANDA application also includes information on how the drug maintains its stability (or efficacy) over time when stored in certain conditions. To obtain this data, the ANDA applicant must submit the results of stability testing that it conducted on the finished drug product that it has actually manufactured. This requirement means that the generic pharmaceutical company must manufacture batches of the finished drug product, and then conduct testing on the drug product as it is stored over time.

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