UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

APOTHECUS PHARMACEUTICAL CORP., Plaintiff, - against - PHARMASOL CORPORATION, Defendant.	21 cv. 867 COMPLAINT Plaintiff requests a trial by jury.

Plaintiff Apothecus Pharmaceutical Corp., by its attorney, Stanley K. Shapiro, Esq., complaining of defendant, alleges as follows:

The Parties

1. Plaintiff Apothecus Pharmaceutical Corp. ("Apothecus") is a New York corporation, with principal executive office at 220 Townsend Square, Oyster Bay, County of Nassau, State of New York, engaged in the business of developing, manufacturing, marketing and commercially distributing certain over-the-counter health care products under its brand name "VCF".

2. On information and belief, defendant Pharmasol Corporation ("Pharmasol"), is a Delaware corporation, with principal executive office in the Commonwealth of Massachusetts, at One Norfolk Avenue, South Easton, Massachusetts. On information and belief, Phamasol regularly does and solicits business, and derives substantial revenue from goods used or consumed in New York.

3. At all relevant times, defendant Pharmasol held itself out as and was a contract manufacturer for pharmaceutical products subject to FDA regulation. In particular,

Pharmasol was engaged by plaintiff as a contract manufacturer of one of plaintiff's products, contracting to supply goods and services for Apothecus in New York.

Jurisdiction and Venue

4. Federal jurisdiction is predicated on diversity of citizenship, 28 U.S.C. § 1332. This action is of a civil nature involving, exclusive of interest and costs, a sum in excess of $75,000. The matter in controversy herein is wholly between citizens of different States.

5. Venue is appropriate in this district pursuant to 28 U.S.C. §1391(a)(2) or (3), in that defendant resides out of New York, and is subject to long arm jurisdiction in New York for this action pursuant to NY CPLR 302.

As and for a First Cause of Action
(Breach of Contract)

6. For more than twenty-five years and continuously through and until November 2019, plaintiff held proprietary rights and trade marks to and developed, manufactured and commercially distributed under its proprietary VCF brand name several vaginal contraceptive health care products, sold over-the-counter in pharmacies throughout the United States and Canada, including since about 1996, a VCF brand vaginal contraceptive foam in an aerosol spray container (the "Product") under plaintiff's brand name.

7. Pharmasol held itself out as a contract manufacturer, qualified with expertise to manufacture aerosol pharmaceutical products subject to FDA regulation. Pharmasol's website represents itself as having "significant expertise and a thorough understanding of aerosols"; and proclaims that its "state of the art cGMP facilities" are "designed and constructed to provide optimum efficiency, safety and regulatory compliance" for the manufacture and packaging of aerosols, liquids and semi-solids.

8. Sometime prior to 2017, plaintiff arranged with Pharmasol to serve as a contract manufacturer of Apothecus' product vaginal contraceptive foam packaged in a 0.6 oz. aerosol spray container under Plaintiff's VCF label and trade name (the "Product").

9. In January 2017, plaintiff and defendant entered a written contract , denominated Quality Agreement Commercial Product (the "Quality Agreement"), for the manufacture and testing of the Product, including quality inspection and quality assurance, between defendant Pharmasol as "Supplier" and plaintiff Apothecus as "Client". (A copy of the Quality Agreement is annexed hereto as Exhibit 1, and incorporated herein.)

10. The Quality Agreement set forth quality management obligations upon Phamasol, for its manufacture of the Product as contract manufacturer for Apothecus. which Pharmasol breached, causing Apothecus to incur substantial damages.

11. Under the terms of the Quality Agreement Pharmasol was obliged to conduct operations in compliance with current Good Manufacturing Practices ("cGMP") regulations and other applicable FDA regulations (Quality Agreement Section 4.1.1).

12. The Quality Agreement specified that "PHARMASOL will ensure that Product(s) are manufactured and tested in strict compliance with current US Federal Good Manufacturing Practices (GMP) (US 21 CFR parts 210 and 211 for the manufacture of finished medicinal product) as applicable" (Quality Agreement Section 4.2.3).

13. On information and belief, the Pharmasol's manufacturing facility ("Pharmasol Plant") where it manufactured and tested the Product under the contract with plaintiff, was inspected by the FDA in July and August 2018.

14. Under the terms of the Quality Agreement, Pharmasol was obliged to notify Apothecus within three business days of receipt of any notice of inspection by the FDA;

and Pharmasol was obligated to notify Apothecus within one day of any regulatory authority request of product samples, batch documentation, or other information related to the Product. Under the Quality Agreement, Pharmasol was obligated to notify on daily basis of any regulatory findings or violations, and must obtain duplicate copies of records for Apothecus.

15. Pharmasol failed to notify Apothecus of the July and August 2018 inspections of the Pharmasol Plant, and failed to notify Apothecus of requests made by the FDA with respect to the Product. Pharmasol also failed to notify Apothecus of the regulatory findings issued by the FDA with respect to the inspections.

16. Under the Quality Agreement, Pharmasol was obliged to provide Apothecus, for review and comment, a copy of any Pharmasol response to any regulatory authority involving the Product, no less than five business days prior to submission of the response to the regularity authority.

17. Pharmasol failed to provide Apothecus with copies of any of its responses to the FDA.

18. In or about March 2019, the FDA, Division of Pharmaceutical Quality Operations, issued a Warning Letter to Pharmasol finding that Pharmasol failed to comply with cGMP with respect to the manufacture and testing of the Product. The Warning Letter to Pharmasol in March 2019 summarized the FDA's findings of violations.

19. The FDA inspection of Pharmasol uncovered significant violations by Pharmasol of current Good Manufacturing Practice regulations for finished pharmaceuticals effecting the Product.

20. The FDA reported in its Warning Letter to Pharmasol, that because Pharmasol's methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to cGMP, Pharmasol's drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

21. The FDA Warning Letter detailed specific violations observed by the FDA investigators relating to Pharmasol performance of manufacturing and testing of the Product delivered under contract for Apothecus.

22. The Quality Agreement required Pharmasol to notify Apothecus within one business day of receipt of any warning letters from any regulatory agency that relates to the Product (Section 4.2.4).

23. Yet, Pharmasol failed to notify Apothecus of the FDA Warning Letter after Pharmasol's receipt of that letter in March 2019.

24. Pharmasol concealed the FDA regulatory inspections and letters from Apothecus.

25. The FDA found that Pharmasol violated federal regulations (21 CFR 211.192) by failing to thoroughly investigate unexplained discrepancy or failure of the batch or any of its components to meet specifications, in respect to two batches of the Product, Lots 31560 and 31561.

26. In July 2017, Pharmasol found that the Product, Vaginal Conception Foam 0.6 oz., Lots 31560 and 31561 were found Out-of-Specification ("OOS") as samples were found leaking (Lab OOS #17-042, 7/12/17). (Out-of-Specification results for elevated leak rate for the two lots of the Product are documented (reference Laboratory OOS# 17-042).)

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.