UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE HARTZ MOUNTAIN CORPORATION, Plaintiff, v. CHANELLE PHARMACEUTICALS MANUFACTURING LIMITED, Defendant.	Civil Action No. **COMPLAINT AND JURY DEMAND**

Plaintiff Hartz Mountain Corporation ("Hartz"), by and through its attorneys, alleges as and for its Complaint against defendant, Chanelle Pharmaceuticals Manufacturing Limited ("Chanelle"), as follows:

SUMMARY O F CLAIMS

These claims each arise from Chanelle's numerous breaches of a January 10, 2003 non-exclusive Confidential License and Supply Agreement (the "Agreement") between the parties. Under the Agreement, Chanelle was required to manufacture and package certain veterinary pharmaceutical products in compliance with all applicable regulations promulgated by the United States Food & Drug Administration ("USFDA"). The subject veterinary products were intended to be sold in, among other places, the United States. The Agreement resulted from Chanelle's representations that it: (1) could comply with the Food, Drug and Cosmetic Act, 21 U.S.C. §§300, et seq., (the "FDA Act"), and the regulations promulgated thereunder, and (2) that it developed and owned a unique technology that would allow three otherwise incompatible pet pharmaceutical products to be safely combined in one product. Each of these representations was false, and resulted in numerous breaches of the Agreement by Chanelle, damaging Hartz.

JURISDICTION AND VENUE

1. This Court has jurisdiction over Hartz's claims pursuant to 28 U.S.C. §1332 as it involves parties with diverse citizenship, and the amount in controversy exceeds $75,000.

2. Venue is proper in this District pursuant to 28 U.S.C. §1391(a) and (d).

THE PARTIES

3. Plaintiff Hartz is a Corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 400 Plaza Drive, Secaucus, New Jersey.

4. Hartz develops, produces, markets and sells, both domestically and internationally, a variety of quality pet products including, but not limited to, veterinary medicines subject to licensing and registration by the USFDA and other relevant licensing or registering agencies.

5. Defendant Chanelle is a Corporation organized and existing under the laws of Ireland, with its principal place of business at Athenry Road, Loughrea, County Galway, Ireland.

6. Chanelle develops, manufactures, packages and sells, among other products, veterinary pharmaceuticals subject to regulation under the FDA Act.

FACTS

7. In or about late 2002, Chanelle represented to Hartz that Chanelle had developed and owned a process technology that would allow a pet heart worm product, ivermectin, to be safely combined in one product with two separate and incompatible heartworm pharmaceuticals, praziquantel and pyrantel.

8. Chanelle represented that its technology, an aqueous granular encapsulation technology ("AGE"), was stable, and that it could produce specific products subject to regulations promulgated by the USFDA Center for Veterinary Medicine ("FDA/CVM").

9. Based upon these representations, on January 10, 2003, Hartz entered into the Agreement.

Chanelle's Obligations Under The Agreement

10. Chanelle agreed to "manufacture, package and sell to Hartz Allheart, Prazitel, Zantel, Zerofen, and Cat Wormer (collectively, the "Veterinary Products").

11. The contents and manufacture of the Veterinary Products produced are regulated under the FDA Act.

12. The Veterinary Products are manufactured pursuant to commercial Good Manufacturing Practices ("cGMP"). The requirements for cGMP are set forth in 21 C.F.R. parts 210 and 211.

13. The failure to adhere to cGMP in all aspects relating to the manufacturing process would cause the resulting Veterinary Products to become adulterated and unusable.

14. The Agreement required Chanelle to manufacture and package the Veterinary Products pursuant to, among other specifications, "cGMP and other requirements of any of the Regulatory Agencies and the Registrations."

15. Under the Agreement, Chanelle was responsible for compliance with all applicable FDA/CVM requirements regarding the manufacture and quality assurance of the Veterinary Products.

16. Chanelle expressly represented and warranted that "it, and its manufacturers, agents and Affiliates shall comply with all laws, rules and regulations applicable to the manufacture of the [Veterinary Products], including, without limitation, the FDA Act and cGMP."

17. Chanelle was required by the Agreement to, at its expense, complete all required manufacturing process validations necessary to register the Veterinary Products with FDA/CVM.

18. In or about late October or early November, 2003, Chanelle provided to Hartz "specifications" for the Veterinary Products that did not describe the AGE technology.

19. Thereafter, Chanelle suddenly and without prior discussion with Hartz changed the basic specifications and workings of AGE technology.

20. The changed technology encompassed a non-aqueous granular encapsulation technology (the "NAGE technology"). The explanation given to Hartz for this change from AGE technology to NAGE technology related to the continuing problems and concerns with the stability with products using AGE technology.

21. Later, Chanelle indicated that the NAGE technology, unlike AGE technology, would require the expenditure of substantial additional sums including new buildings, equipment and other facilities.

22. Chanelle requested Hartz to pay for all or most of these substantial additional sums to support the NAGE technology.

23. Hartz was concerned that the NAGE technology also suffered the same stability problems as AGE technology.

24. Chanelle commenced six month stability tests on products produced using NAGE technology.

25. Hartz requested that the stability data be audited by a third party auditor. Initially, Chanelle cancelled the scheduled stability test audit. Later, Chanelle allowed the audit of the stability tests.

26. The audit was completed and showed that the Chanelle facilities and practices were not in compliance with applicable USFDA regulations and also indicated potential issues with the stability of the NAGE technology product.

27. During this process to find a stable technology, an inventor of the AGE technology and NAGE technology, Vinay Tripathi, left Chanelle and claimed ownership of both the AGE technology and NAGE technology.

28. After Tripathi's resignation, Chanelle was unable to engineer a replacement technology that would meet the regulatory requirements of the FDA/CVM.

The Hartz Audit

29. Under the Agreement, Hartz retained the right to hire, at its own cost, consultants and/or advisors and inspectors to visit, review, copy and inspect the Chanelle manufacturing facilities and records in order to confirm Chanelle's compliance with, among other regulations, cGMP.

30. Pursuant to the Agreement, between December 20 and 23, 2004, a representative of Hartz and a consultant retained by Hartz visited Chanelle's drug formulation facilities in Loughrea, Ireland.

31. The purpose of the visit was to audit a stability study being performed by Chanelle relating to the Veterinary Products.

32. The objections of the audit were to ascertain whether the stability study being performed by Chanelle complied with USFDA's Good Laboratory Practices for Non-Clinical Laboratory studies (21 C.F.R. Part 58), and to determine whether the results of the stability study were usable in judging the behavior of the test articles and storage under the conditions employed.

33. Among the audit's key findings were that Chanelle had not complied with its obligations under the Agreement because:

a. the study being conducted by Chanelle is not submissible to the USFDA as part of an NADA because it uses as test substances developmental rather than commercial products; and

b. the Chanelle study does not comply with the USFDA's good laboratory practices for non-clinical laboratory studies. (21 C.F.R. Part 58)

Hartz's Termination of the Agreement

34. The Agreement provides that if USFDA approval of the Veterinary Products was not obtained by Chanelle by January 1, 2005, then Hartz had the right to unilaterally terminate the Agreement:

> Deadline for U.S. Registrations: The Parties Agreement that each of the respective products shall be registered pursuant to the deadlines of U.S. registrations as set forth in Schedule 3. In the event any product is not registered with its U.S. registration by the deadline for U.S. registration for such product, Hartz shall have the right to terminate this Agreement with respect to such product only.

35. Chanelle failed to obtain appropriate registrations for any of the Veterinary Products by January 1, 2005.

36. By letter dated January 21, 2005, Hartz exercised its right to terminate the Agreement.

COUNT I

BREACH OF CONTRACT-PRODUCT DEVELOPMENT, REGULATORY COMPLIANCE AND PRICING

37. Hartz repeats each of the allegations set forth in Paragraphs 1 through 36.

38. Hartz has performed each of its obligations under the Agreement.

39. Chanelle has failed to fulfill its obligations under the Agreement including, but not limited, to obligations relating to product development, regulatory compliance and pricing.

40. As a result of Chanelle's numerous breaches of the Agreement, Hartz has been and continues to be damaged.

COUNT II

BREACH OF IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

41. Hartz repeats each of the allegations set forth in Paragraphs 1 through 40.

42. Chanelle failed to perform under its agreement with Hartz in good faith, thereby breaching the covenant of good faith and fair dealing implicit in all contracts.

43. As a direct and proximate result of Chanelle's breach, Hartz has been damaged.

COUNT III

NEGLIGENT MISREPRESENTATION

44. Hartz repeats each of the allegations set forth in Paragraphs 1 through 43.

45. Prior to entering into the Agreement, Chanelle represented to Hartz that it would utilize agreed upon AGE technology to develop all the Veterinary Products, when in fact NAGE technology was utilized because of the stability problems with the AGE technology. Hartz specifically relied upon and signed the final agreement based on the stability and use of the AGE technology.

46. Chanelle further represented to Hartz that it was and would continue to comply with the terms of the Agreement regarding compliance with all USFDA regulations, including cGMPs, when in reality, Chanelle could not comply with these regulations.

47. Chanelle represented that it owned both of the AGE technology and later the NAGE technology. Vinay Tripathi, formerly associated with Chanelle, asserted and continues

to assert that he is the sole inventor and owner of both the AGE technology and the NAGE technology.

48. Each of the representations was false.

49. Hartz relied on each of the representations to its detriment.

COUNT IV

BREACH OF CONTRACT—PATENT PROSECUTION

50. Hartz repeats each of the allegations set forth in Paragraphs 1 through 49.

51. Chanelle is required to cause its co-inventors of AGE technology and NAGE technology, Michael Burke and Vinay Tripathi, to cooperate, sign documents and assist with the filing, application and prosecution of patent applications therefor.

52. Chanelle has refused to cause such individuals to cooperate, sign documents assist with the filing, application and prosecution of all of the patent applications therefor but only some of same, despite repeated requests by Hartz to do so in compliance with the Agreement.

53. Chanelle has failed to fulfill its obligations under the Agreement including, but not limited to obligations relating to patent prosecution.

54. As a result of Chanelle's numerous breaches of the Agreement, Hartz has been and continues to be damaged.

WHEREFORE Plaintiff Hartz prays for Judgment awarding Hartz:

(a) compensatory damages arising out of Chanelle's breach of the Agreement;

(b) compensatory damages arising out of Chanelle's negligent misrepresentations;

(c) its attorneys fees and costs;

(d) pre-judgment and post-judgment interest on any award; and

(f) such other relief as the Court deems just.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Hartz hereby demands a jury trial on all issues so triable.

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