UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE HARTZ MOUNTAIN CORPORATION,	:	C.A. No.: 2:05-cv-02488-WJM-RJH
Plaintiff,	:	
v.	:	
CHANELLE PHARMACEUTICALS MANUFACTURING LIMITED,	:	
Defendant.	:	

DEFENDANT CHANELLE PHARMACEUTICALS MANUFACTURING, LIMITED'S ANSWER TO THE COMPLAINT

Defendant Chanelle Pharmaceuticals Manufacturing, Limited ("Chanelle"), by and through its undersigned counsel, hereby responds to the Complaint of plaintiff The Hartz Mountain Corporation ("Hartz"), as follows:

RESPONSE TO PLAINTIFF'S "SUMMARY OF CLAIMS"

The allegations in plaintiff's Summary of Claims ("Summary") constitute legal conclusions, to which no responsive pleading is required. Chanelle demands strict proof of such allegations during discovery and at trial. By way of further answer, the allegations in the Summary are based on and relate to a Confidential License and Supply Agreement ("CL&S Agreement), which is a writing that speaks for itself. Chanelle therefore denies Hartz's characterization of the CL&S Agreement.

JURISDICTION AND VENUE

1. Denied. Chanelle denies the allegations in paragraph 1 as legal conclusions, to which no responsive pleading is required. Chanelle demands strict proof of such allegations during discovery and at trial.

2. Denied. Chanelle denies the allegations in paragraph 2 as legal conclusions, to which no responsive pleading is required. Chanelle demands strict proof of such allegations during discovery and at trial.

3. Admitted in part, denied in part. Chanelle admits that Hartz has a place of business at 400 Plaza Drive, Secaucus, New Jersey. Chanelle lacks sufficient knowledge and information to form a belief as to the remaining allegations in this paragraph, and therefore denies the same and demands strict proof during discovery and at trial.

4. Admitted. On information and belief, Chanelle admits the allegations in paragraph 4.

5. Admitted.

6. Admitted in part, denied in part. Chanelle admits that it develops, manufactures, packages and sells, among other products, veterinary pharmaceuticals subject to European Union ("EU") regulation. Chanelle denies that its products are subject to regulation under the FDA Act.

7. Admitted in part, denied in part. Chanelle admits that, in or about early 2002, Chanelle and Hartz discussed the possibility of working together on several of Chanelle's products including, but not limited to, triple therapy anthelmintic, which was initially referred to as Allheart, and later became known as TTA ("Allheart/TTA"). Chanelle admits that it informed Hartz that Allheart/TTA combined a pet heartworm product – Ivermectin – in one product with two separate heartworm pharmaceuticals – Praziquantel and Pyrantel. Chanelle denies that it informed Hartz that it was utilizing an aqueous granulation encapsulation technology, or "AGE technology" as alleged in the Complaint. On the contrary, although Chanelle admits that it represented to Hartz that it was utilizing an aqueous technology that could produce

Allheart/TTA, at no time prior to the execution of the CL&S Agreement did Chanelle describe the technology as being an "aqueous granular encapsulation technology," nor did Chanelle refer to its process technology as "AGE technology." In addition, prior to entering into the CL&S Agreement, Chanelle specifically informed Hartz that it had produced only two trial batches of Allheart/TTA. Moreover, Hartz was fully aware that Chanelle did not place Allheart/TTA on stability until in or about July, 2002. Indeed, Chanelle did not provide Hartz with any stability data until February, 2003. At that time, Chanelle provided Hartz with three months stability data for all of the pharmaceutical products listed in the CL&S Agreement (the "Products"). Chanelle denies all the remaining allegations in this paragraph.

8. Denied. Chanelle denies the allegations in this paragraph in that it made no specific representations to Hartz, prior to entering into the CL&S Agreement, regarding the process technology that it utilized to manufacture any of the Products. By way of further answer, Chanelle specifically denies that it referred to the process technology as "aqueous granular encapsulation technology" or "AGE technology" at that time, and denies that it made representations regarding the stability of the process technology used to manufacture any of the Products including, but not limited to, the two trial batches of Allheart/TTA. It should also be noted that "stability" relates to a particular product, not the process technology used to manufacture that product. In addition, prior to entering into the CL&S Agreement, Chanelle specifically informed Hartz that it had produced only two ***trial*** batches of Allheart/TTA. Moreover, Hartz was fully aware that Chanelle did not place Allheart/TTA on stability until in or about July, 2002. Indeed, Chanelle did not provide Hartz with any stability data until February, 2003. At that time, Chanelle provided Hartz with three months stability data for all of the Products listed in the CL&S Agreement. Chanelle further denies that it represented to Hartz that

it could produce specific products subject to regulations promulgated by the USFDA Center for Veterinary Medicine ("FDA/CVM"), or that it had FDA approval with respect to the "AGE technology." On the contrary, both prior to and at the time the parties entered into the CL&S Agreement, Chanelle indicated only that its facilities were EU cGMP approved. Thus, Chanelle specifically informed Hartz that additional investment from Hartz would be necessary for Chanelle to obtain FDA cGMP approval, and Hartz agreed to provide such investment when it entered into the CL&S Agreement.

9. Admitted in part, denied in part. Chanelle admits only that Chanelle and Hartz entered into the CL&S Agreement, which is dated January 10, 2003. As to the allegation that Hartz entered into the Agreement based upon certain "representations" of Chanelle, Chanelle lacks sufficient knowledge and information to form a belief as to the truth of the allegations, and therefore denies the same and demands strict proof during discovery and at trial. By way of further answer, Section 19.10 of the CL&S Agreement provides that "[t]here are no understandings, agreements, representations or warranties, express or implied, with respect to the subject matter hereof except as expressly set forth in this Agreement." In other words, all representations made by either Chanelle or Hartz, with respect to the subject matter of the CL&S Agreement, were contained in the CL&S Agreement.

10. Denied. Chanelle denies the allegations in paragraph 10 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial.

11. Admitted in part, denied in part. Chanelle denies the allegations in paragraph 11 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that

speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial. By way of further answer, Chanelle admits that the Products were to be regulated ultimately under the FDA Act, but only ***after*** certain clinical trials were conducted, and ***after*** Chanelle's facilities were approved by the FDA. Moreover, Hartz knew, either before or at the time it entered into the CL&S Agreement, that Chanelle's facilities were not FDA cGMP compliant, and that it was likely that Hartz would be required to fund necessary upgrades of Chanelle's plant and/or equipment, in order to obtain such approval from the FDA. In addition, Hartz knew or should have known, prior to entering into the CL&S Agreement, that pilot batches of the Products, which formed part of a New Animal Drug Application ("NADA") or an Abbreviated New Animal Drug Application ("ANADA"), were not required to be manufactured in an FDA-approved facility, but, rather, could be manufactured in an EU cGMP approved facility.

12. Admitted in part, denied in part. Chanelle denies the allegations in paragraph 12 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial. By way of further answer, Chanelle denies that "cGMP" is an acronym for "***commercial*** Good Manufacturing Practices." On the contrary, as set forth in section 1.5 of the CL&S Agreement, cGMP is an acronym for ***current*** Good Manufacturing Practices. Chanelle admits that ***commercial*** batches of the Products were to be manufactured pursuant to FDA cGMP. Chanelle further admits that Hartz specifically knew or should have known, prior to entering into the CL&S Agreement, that ***pilot*** batches of the Products would be manufactured pursuant to EU cGMP; Hartz knew that Chanelle's facilities were not FDA cGMP compliant; and, Hartz knew that it was likely that it

would need to fund necessary upgrades to Chanelle's plant and/or equipment, in order to receive cGMP approval from the FDA for the Products. In fact, the CL&S Agreement specifically addresses Hartz's obligation to reimburse Chanelle for any such upgrades.

13. Admitted in part, denied in part. Chanelle denies the allegations in paragraph 13 as legal conclusions, to which no responsive pleading is required. By way of further answer, Chanelle admits the allegations in this paragraph only to the extent that the allegations relate to commercial batches of the Products. Chanelle denies the allegations to the extent that the allegations relate to pilot batches of the Products. Indeed, Hartz specifically knew or should have known, prior to entering into the CL&S Agreement, that pilot batches of the Products would be manufactured pursuant to EU cGMP; Hartz knew that Chanelle's facilities were not FDA cGMP compliant; and, Hartz knew that it was likely that Hartz would need to fund necessary upgrades to Chanelle's plant and/or equipment in order to achieve cGMP approval from the FDA for the Products. In fact, the CL&S Agreement specifically addresses Hartz's obligation to reimburse Chanelle for any such upgrades.

14. Admitted in part, denied in part. Chanelle denies the allegations in paragraph 14 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial. By way of further answer, Chanelle admits the allegations in this paragraph only to the extent that such allegations relate to commercial batches of the Products. Chanelle denies the allegations in this paragraph to the extent that the allegations relate to pilot batches of the Products. Indeed, Hartz specifically knew or should have known, prior to entering into the CL&S Agreement, that pilot batches of the Products would be manufactured pursuant to EU cGMP; Hartz knew that Chanelle's facilities

were not FDA cGMP compliant; and, Hartz knew that it was likely that Hartz would need to fund necessary upgrades to Chanelle's plant and/or equipment, in order to achieve cGMP approval from the FDA for the Products. In fact, the CL&S Agreement specifically addresses Hartz's obligation to reimburse Chanelle for any such upgrades.

15. Denied. Chanelle denies the allegations in paragraph 15 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial. To the extent the allegations relate to Chanelle's purported obligations under the CL&S Agreement, Chanelle further denies the allegations in this paragraph as legal conclusions, to which no responsive pleading is required. By way of further answer, Hartz specifically knew or should have known, prior to entering into the CL&S Agreement, that pilot batches of the Products would be manufactured pursuant to EU cGMP; Hartz knew that Chanelle's facilities were not FDA cGMP compliant; and, Hartz knew that it was likely that Hartz would need to fund necessary upgrades to Chanelle's plant and/or equipment, in order to achieve cGMP approval from the FDA for the Products. In fact, the CL&S Agreement specifically addresses Hartz's obligation to reimburse Chanelle for any such upgrades.

16. Denied. Chanelle denies the allegations in paragraph 16 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies Hartz's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial.

17. Denied. Chanelle denies the allegations in paragraph 17 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle

therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial. By way of further answer, the section of the CL&S Agreement cited to in this paragraph actually provides that Chanelle "shall use commercially reasonable efforts, at its expense to complete manufacturing process validation for the Products with FDA/CVM and all other similar agencies in the Territory (the 'Regulatory Agencies') particularly cGMP status." That same section provides that "[i]f additional investment is required for plant and equipment to achieve cGMP validation from the FDA only, Hartz will reimburse CHANELLE for required investments either in the cost of goods until equipment is paid or an advance from Hartz which could then be used against purchases of the Products." In fact, subsequent to the signing of the CL&S Agreement and Hartz's inspection of the Chanelle facilities, Hartz agreed initially to advance Chanelle funds to be used to achieve cGMP approval from the FDA. Hartz subsequently reneged on that promise and communicated with other parties (prior to terminating the CL&S Agreement with Chanelle) in an attempt to manufacture the Allheart/TTA without Chanelle's participation.

18. Admitted in part, denied in part. Chanelle denies the allegations in paragraph 18 in that the allegations are based on and relate to "specifications," which are comprised of one or more writings that speak for themselves. Chanelle therefore denies plaintiff's purported characterization of the "specifications," and demands strict proof of such allegations at trial. Chanelle admits only that, on or about October 24, 2003, Chanelle provided Hartz with a draft Manufacturing Work Order for a pilot batch for *one* of the Products in the CL&S Agreement – Allheart/TTA – which utilized non-aqueous granulation process technology. Moreover, contrary to Hartz's allegations, the non-aqueous technology did not utilize an "encapsulation" component.

By way of further answer, the process technology for the other Products remained aqueous granulation technology.

19. Admitted in part, denied in part. Chanelle denies the allegations in this paragraph in that the allegations are based on and relate to certain "specifications," which are writings that speak for themselves. Chanelle therefore denies plaintiff's characterization of the specifications and demands strict proof of the same during discovery and at trial. By way of further answer, Chanelle denies that it "suddenly and without prior discussion with Hartz changed the basic specifications and workings of the AGE technology." On the contrary, Hartz and Chanelle specifically discussed the "pros and cons" of using non-aqueous granulation technology, versus aqueous granulation technology, for Allheart/TTA only. In this regard, with respect to commercial-scale batches of Allheart/TTA, Chanelle admits that it advised that non-aqueous granulation technology may be more appropriate than aqueous granulation technology. In addition, after a representative of Hartz visited Chanelle's facilities in November, 2003, to discuss the "pros and cons" of using non-aqueous granulation technology, Hartz agreed that Chanelle should proceed with the same, and Hartz subsequently approved a Manufacturing Work Order for non-aqueous granulation technology.

20. Admitted in part, denied in part. Chanelle admits only that the technology discussed between Chanelle and Hartz encompassed a non-acqueous granulation technology. Chanelle denies the remaining allegations in this paragraph regarding the "explanation" given by Chanelle for non-aqueous granulation technology. On the contrary, with respect to commercial-scale batches of Allheart/TTA, Chanelle advised that non-aqueous technology may be more appropriate than aqueous granulation technology. In addition, after a representative of Hartz visited Chanelle's facilities in November, 2003, to review the non-aqueous granulation

technology, Hartz agreed that Chanelle should proceed with the same, and Hartz subsequently approved a Manufacturing Work Order for non-aqueous granulation technology.

21. Admitted in part, denied in part. Chanelle denies that ***it*** "indicated that the NAGE technology, ***unlike AGE technology***, would require the expenditure of substantial additional sums including new buildings, equipment and other facilities." Chanelle admits that it informed Hartz, prior to entering into the CL&S Agreement, that it was likely that Chanelle would require additional funds from Hartz, in order to obtain cGMP approval from the FDA to manufacture commercial-scale batches of the Products. Chanelle further admits that the requirement of new buildings, equipment and other facilities (including the projected costs of the same), were based on recommendations from inspections conducted by employees and/or consultants of Hartz – not Chanelle. Moreover, the Hartz employees and/or consultants indicated that the buildings, equipment and other facilities were necessary to obtain cGMP approval from the FDA. Finally, as per the terms of the CL&S Agreement, Hartz was well aware that additional investment would likely be required for Chanelle to achieve FDA cGMP approval, and was well aware that it was obligated to provide the same.

22. Admitted in part, denied as stated. Chanelle admits only that it requested that Hartz provide it with funds so that Chanelle could achieve cGMP approval from the FDA, as was Hartz's obligation under the CL&S Agreement. By way of further answer, Hartz knew that the expenditures applied to the manufacturing process for all of the Products, was not solely dependant on the process technology utilized for Allheart/TTA, and was necessary for Chanelle to comply with, and/or achieve, FDA cGMP. Indeed, the recommendations for new buildings, equipment and other facilities (including the projected costs of the same) were based on inspections conducted by employees and/or consultants of Hartz – not Chanelle.

23. Denied. Chanelle denies the allegations in paragraph 23 in that the allegations are based on information in the exclusive possession of Hartz. By way of further answer, Chanelle lacks sufficient knowledge and information to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same and demands strict proof of such allegations during discovery and at trial.

24. Admitted in part, denied in part. Chanelle admits only that it commenced stability testing on three strengths of Allheart/TTA, in or about March, 2004. The product was placed on stability according to a Chanelle-Hartz protocol under ICH conditions, *i.e.*, accelerated conditions (40º Celsius/75% RH), for six months, and real time conditions (25º Celsius/60%), for 60 months. The remaining allegations in this paragraph are denied.

25. Admitted.

26. Admitted in part, denied in part. Chanelle denies that Hartz audited the ***manufacturing facility*** on December 20-22, 2004. Chanelle admits that Hartz had previously inspected Chanelle's manufacturing facility in June, 2003 and March, 2004. Chanelle admits that, during the December 2004 time period referenced above, Hartz audited the stability data for Allheart/TTA and a generic product that combined Ivermectin with Pyrantel Pamoate ("DTA"). Chanelle further admits that the audit encompassed documentation and procedures associated with the stability testing of Allheart/TTA and DTA, the Laboratory, and the stability storage chambers. Chanelle denies the allegations in this paragraph to the extent that the audit is comprised of various writings, which speak for themselves. Chanelle therefore denies plaintiff's characterization of the audit, and demands strict proof of the same during discovery and at trial. Chanelle further denies the allegations in this paragraph in that Hartz refused to share the findings or results of the audit with Chanelle. During the audit, however, Hartz's representatives

repeatedly advised Chanelle's representatives that all information regarding the data and systems reviewed was satisfactory.

27. Admitted in part, denied in part. Chanelle admits only that a former employee and/or contractor of Chanelle, Vinay Tripathi ("Tripathi"), terminated his relationship with Chanelle during the time period that the parties were performing under the CL&S Agreement. As to the allegation that Tripathi has claimed ownership of the aqueous granulation technology or the non-aqueous granulation technology, Chanelle lacks sufficient knowledge and information to form a belief as to the truth of the allegations, and therefore denies the same and demands strict proof of such allegations during discovery and at trial.

28. Admitted in part, denied in part. Chanelle denies the allegations in this paragraph to the extent that the allegations relate to the time period ***after*** Hartz purported to terminate the CL&S Agreement, by letter dated January 21, 2005. Chanelle admits that it was unable to satisfy the regulatory requirements of the FDA/CVM prior to the time that Hartz purported to terminate the CL&S Agreement. By way of further answer, Chanelle was unable to meet the registration deadlines because Hartz refused to provide Chanelle with the necessary investment for Chanelle's facilities to achieve cGMP approval from the FDA, and because Hartz failed to disclose in a timely fashion all material information regarding the registration of DTA. Indeed, although DTA ***was not*** one of the Products included in the CL&S Agreement, and although Hartz met with the FDA in May, 2003, and was advised allegedly that it had to register DTA before it could register Allheart/TTA, Hartz did not fully disclose this information to Chanelle (including the minutes from the meeting with the FDA) until March, 2004. By that time (if not several months before), Hartz knew or should have known that the registration date for Allheart/TTA, as set forth in the CL&S Agreement, could not be met by Chanelle. Moreover,

even though Hartz now blames Chanelle for the failure to register any of the Products, in fact, Chanelle provided Hartz with three months stability data for Allheart/TTA, DTA, and Fenbendazole (identified in the CL&S Agreement as "Zerofen") so that Hartz could conduct clinical trials, which were required by the FDA. Hartz, however, failed to conduct any such clinical trials on these products, as was its responsibility and obligation under the CL&S Agreement.

29. Denied. Chanelle denies the allegations in paragraph 29 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial.

30. Admitted in part, denied in part. Chanelle admits that a Hartz consultant, Dr. David Brookman ("Brookman"), and a Hartz employee, Ian Cottrell ("Cottrell"), visited Chanelle's facilities in Loughrea, Ireland, on December 20, 21 and 22, 2004. To the extent that the allegations in this paragraph are based on or relate to the CL&S Agreement, Chanelle denies such allegations, as they relate to a writing, which speaks for itself.

31. Admitted in part, denied in part. Chanelle denies that the purpose of the visit by Brookman and Cottrell to Chanelle's facilities was to audit a stability study being performed by Chanelle related to "the Veterinary Products." Chanelle admits that Brookman and Cottrell audited the stability data for Allheart/TTA, which was one of the Products identified in the CL&S Agreement. By way of further answer, the audit also included data for DTA, which was not part of the CL&S Agreement, but was, according to Hartz (based on its meeting with the FDA), required to be registered first in order to obtain FDA approval of Allheart/TTA. Chanelle denies that Hartz's audit team requested stability data for any of the other Products identified in

the CL&S Agreement. In fact, even though Chanelle advised that it had three months stability data on Fenbendazole (identified in the CL&S Agreement as "Zerofen"), Hartz did not request an audit of such data.

32. Admitted in part, denied in part. Chanelle denies the allegations in paragraph 32 in that the allegations are based on and relate to the audit, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the audit, and demands strict proof of the same during discovery and at trial. By way of further answer, Chanelle denies Hartz's characterization of the objectives of the audit as "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 data were usable in judging the behavior of the test articles and storage under the conditions employed." Chanelle admits that the objectives of the audit were to assess the stability of products that had been subjected to stability tests in an EU approved cGMP facility, against a stability protocol designed to meet USFDA requirements (and approved by Hartz), as well as with respect to the principles of USFDA's Good Laboratory Practices for Non-Clinical Laboratory studies (21 C.F.R. Part 58).

33. Denied. Chanelle denies the allegations in paragraph 33 in that the allegations are based on and relate to the audit, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the audit, and demands strict proof of such allegations during discovery and at trial. Chanelle further denies the allegations to the extent the allegations constitute legal conclusions, to which no responsive pleading is required. By way of further answer, Chanelle denies the allegations in this paragraph in that Hartz refused to disclose to Chanelle the findings or results of the audit. Moreover, during the audit, Brookman and Cottrell

repeatedly advised Chanelle representatives that all information regarding the data and systems reviewed was satisfactory.

34. Denied. Chanelle denies the allegations in paragraph 34 in that the allegations are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement, and demands strict proof of such allegations during discovery and at trial.

35. Admitted in part, denied in part. Chanelle admits that it did not obtain registrations for any of the Products by January 1, 2005. Chanelle denies the allegations to the extent that Hartz is suggesting that Chanelle breached the CL&S Agreement by failing to obtain such registrations, or that Chanelle was solely responsible for obtaining the registrations. On the contrary, Hartz's conduct contributed to the fact that the registrations were not obtained by January 1, 2005. Indeed, based on its meeting with the FDA in May, 2003, during which the FDA instructed allegedly that DTA had to be registered before it would approve Allheart/TTA, Hartz knew or should have known that Chanelle would not be able to obtain the registrations by January 1, 2005. Moreover, contrary to its obligations under the CL&S Agreement, Hartz refused to provide Chanelle with the appropriate funds for Chanelle to construct and/or update its plant and equipment to achieve cGMP approval from the FDA. Finally, even though Chanelle provided Hartz with three months stability data for Allheart/TTA, DTA, and Fenbendazole (identified in the CL&S Agreement as "Zerofen"), Hartz failed to conduct the necessary clinical studies on these products, as was its responsibility under the CL&S Agreement.

36. Admitted in part, denied in part. Chanelle admits only that Hartz purported to terminate the CL&S Agreement, via a letter dated January 21, 2005. The remaining allegations in this paragraph are denied as legal conclusions, to which no responsive pleading is required.

By way of further answer, the allegations in this paragraph are denied in that the allegations are based on and relate to a letter and the CL&S Agreement, which are writings that speak for themselves. Chanelle therefore denies plaintiff's characterization of the writings, and demands strict proof of the same during discovery and at trial.

COUNT I
BREACH OF CONTRACT -- PRODUCT DEVELOPMENT,
REGULATORY COMPLIANCE AND PRICING

37. The allegations in this paragraph do not require a responsive pleading. By way of further answer, Chanelle incorporates by reference the responses in paragraphs 1 through 36 above, as if fully set forth at length herein.

38. Denied. Chanelle denies the allegations in paragraph 38 as legal conclusions, to which no responsive pleading is required.

39. Denied. Chanelle denies the allegations in paragraph 39 as legal conclusions, to which no responsive pleading is required.

40. Denied. Chanelle denies the allegations in paragraph 40 as legal conclusions, to which no responsive pleading is required.

COUNT II
BREACH OF IMPLIED COVENANT OF
GOOD FAITH AND FAIR DEALING

41. The allegations in this paragraph do not require a responsive pleading. By way of further answer, Chanelle incorporates by reference the responses in paragraphs 1 through 40 above, as if fully set forth at length herein.

42. Denied. Chanelle denies the allegations in paragraph 42 as legal conclusions, to which no responsive pleading is required.

43. Denied. Chanelle denies the allegations in paragraph 43 as legal conclusions, to which no responsive pleading is required.

COUNT III
NEGLIGENT MISREPRESENTATION

44. The allegations in this paragraph do not require a responsive pleading. By way of further answer, Chanelle incorporates by reference the responses in paragraphs 1 through 43 above, as if fully set forth at length herein.

45. Denied. Chanelle denies that, prior to entering into the CL&S Agreement, it made any specific representations regarding the process technology that was to be used to manufacture the Products. In particular, Chanelle denies that it stated that it would utilize agreed upon "AGE technology" to develop all of the Products. Notwithstanding the foregoing, and although not specifically discussed at that time, Chanelle admits that it intended to use aqueous granulation technology to manufacture all of the Products. With respect to Allheart/TTA, the aqueous granulation involved the following steps:

1. Lot A – granulation of Ivermectin into granules;
2. Lot B – granulation of Pyrantel into granules;
3. Lot C – granulation of Praziquantel into granules and then spraying it with a coat of eudragit; and
4. Dry-mixing the three lots together.

As noted above, however, prior to entering into the CL&S Agreement, Chanelle did not disclose to Hartz the specifics of the technology to be used to manufacture any of the Products. In addition, although Chanelle admits that, with respect to commercial-scale batches of Allheart/TTA, it later advised that non-aqueous granulation technology would be more appropriate than the aqueous granulation technology, Hartz expressly approved the use of non-

aqueous granulation technology for Allheart/TTA. Finally, although Chanelle lacks sufficient knowledge and information to form a belief as to Hartz's contention regarding "reliance" on the "stability" of the "AGE technology" when it entered into the CL&S Agreement, stability refers to a product, not the technology used to manufacture the Products, and Chanelle specifically denies that it made any representations regarding the stability of Allheart/TTA (which is the only Product focused on by Hartz in its Complaint), prior to entering into the CL&S Agreement. In fact, Chanelle specifically informed Hartz that it had produced only two trial batches of Allheart/TTA, and Hartz was fully aware that Chanelle did not place Allheart/TTA on stability until in or about July, 2002. Moreover, Chanelle did not provide Hartz with any stability data until February, 2003. At that time, Chanelle provided Hartz with three months stability data for all of the pharmaceutical products listed in the CL&S Agreement (the "Products").

46. Denied. Chanelle denies the allegations in paragraph 46 as legal conclusions, to which no responsive pleading is required. By way of further answer, Hartz specifically knew or should have known, prior to entering into the CL&S Agreement, that pilot batches of the Products would be manufactured pursuant to EU cGMP, and that it was likely that Hartz would need to make an additional investment in Chanelle's facilities and/or equipment, in order to achieve cGMP approval from the FDA. In fact, the CL&S Agreement specifically addressed Hartz's obligation to reimburse Chanelle for investments necessary to achieve cGMP approval from the FDA. Thus, based on the terms of the CL&S Agreement and Hartz's own conduct, Chanelle denies Hartz's contention that it believed Chanelle's facilities were FDA cGMP compliant when it signed the CL&S Agreement.

47. Admitted in part, denied in part. Chanelle admits that it informed Hartz, prior to entering into the CL&S Agreement, that it utilized a technology that could combine a pet heartworm product – Ivermectin – in one product with two separate heartworm pharmaceuticals

– Praziquantel and Pyrantel. Chanelle further admits that it later advised Hartz that it had developed a non-aqueous granulation technology to be used for the production of Allheart/TTA only. As to the allegation that Tripathi contends that he is the sole inventor and owner of these technologies, Chanelle lacks sufficient knowledge and information to form a belief as to the truth of such allegations, and therefore denies same and demands strict proof of such allegations during discovery and at trial.

48. Denied. Chanelle denies the allegations in paragraph 48 as legal conclusions, to which no responsive pleading is required. Strict proof of the same is demanded during discovery and at trial.

49. Denied. Chanelle denies the allegations in paragraph 49 as legal conclusions, to which no responsive pleading is required. Strict proof of the same is demanded during discovery and at trial.

COUNT IV
BREACH OF CONTRACT -- PATENT PROSECUTION

50. The allegations in this paragraph do not require a responsive pleading. By way of further answer, Chanelle incorporates by reference the responses in paragraphs 1 through 49 above, as if fully set forth at length herein.

51. Denied. Chanelle denies the allegations in paragraph 51 as legal conclusions, to which no responsive pleading is required. By way of further answer, the allegations in this paragraph are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's purported characterization of the CL&S Agreement and any obligations that Chanelle may have thereunder, and demands strict proof of the same at trial.

52. Denied. Chanelle denies the allegations in paragraph 52 in that the allegations are based on and relate to Chanelle's alleged obligations under the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's purported characterization of the CL&S Agreement and any obligations that Chanelle may have thereunder, and demands strict proof of the same during discovery and at trial.

53. Denied. Chanelle denies the allegations in paragraph 53 as legal conclusions, to which no responsive pleading is required. By way of further answer, the allegations in this paragraph are based on and relate to the CL&S Agreement, which is a writing that speaks for itself. Chanelle therefore denies plaintiff's characterization of the CL&S Agreement and any obligations of Chanelle thereunder, and demands strict proof of the same during discovery and at trial.

54. Denied. Chanelle denies the allegations in paragraph 54 as legal conclusions, to which no responsive pleading is required. By way of further answer, Chanelle lacks sufficient knowledge and information to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same, and demands strict proof of such allegations during discovery and at trial.

WHEREFORE, defendant Chanelle Pharmaceuticals Manufacturing, Limited respectfully requests that the Court enter judgment in its favor and against plaintiff The Hartz Mountain Corporation, together with its attorneys' fees and costs of suit, and such other relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of contract in Counts I, II and IV of the Complaint are barred, in whole or in part, by plaintiff's own breach of, or failure to comply with, its obligations under the CL&S Agreement.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of contract in Counts I, II and IV of the Complaint are barred, in whole or in part, in that Chanelle did not breach any of its obligations under the CL&S Agreement.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claim for negligent misrepresentation in Count III of the Complaint is barred, in whole or in part, by the integration clause in the CL&S Agreement.

FIFTH AFFIRMATIVE DEFENSE

To the extent plaintiff's claims in the Complaint are based on the alleged failure of Chanelle to obtain appropriate registrations for the Products by January 1, 2005, such claims are barred, in whole or in part, by plaintiff's failure to provide Chanelle with the necessary investment for Chanelle to achieve cGMP approval from the FDA.

SIXTH AFFIRMATIVE DEFENSE

To the extent plaintiff's claims in the Complaint are based on the alleged failure of Chanelle to obtain appropriate registrations for the Products by January 1, 2005, such claims are barred, in whole or in part, by plaintiff's failure to disclose to Chanelle all material information

concerning FDA requirements for the registration of the Products including, but not limited to, DTA.

SEVENTH AFFIRMATIVE DEFENSE

To the extent plaintiff's claims in the Complaint are based on the alleged failure of Chanelle to obtain appropriate registrations for the Products by January 1, 2005, such claims are barred, in whole or in part, because the FDA advised allegedly that Allheart/TTA could not be registered until a generic drug – DTA – was registered, and DTA was not a part of the CL&S Agreement or any amendment to the same.

EIGHTH AFFIRMATIVE DEFENSE

To the extent plaintiff's claims in the Complaint are based on the alleged failure of Chanelle to obtain appropriate registrations for the Products by January 1, 2005, such claims are barred, in whole or in part, because Hartz failed to disclose to Chanelle all material information obtained by it during its meeting with the FDA in May, 2003, concerning the registration of DTA. Indeed, although Hartz informed Chanelle that the parties were required to register DTA, Hartz did not disclose the exact reasons for doing so, nor did it provide Chanelle with the actual minutes from the May, 2003 meeting with the FDA, until March, 2004. Hartz therefore knew or should have known that Chanelle would not be able to meet the registration dates set forth in the CL&S Agreement.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims for damages are barred, in whole or in part, because Chanelle did not proximately cause plaintiff's damages.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's claims for damages are barred and/or extinguished in that the damages suffered by Chanelle, as a result of plaintiff's breach of its obligations under the CL&S Agreement, exceed plaintiff's alleged damages.

ELEVENTH AFFIRMATIVE DEFENSE

To the extent that the Court determines that plaintiff has suffered damages, Chanelle is entitled to a set-off against such damages in the amount of damages Chanelle suffered as a result of plaintiff's misconduct or breach of its obligations under the CL&S Agreement.

TWELFTH AFFIRMATIVE DEFENSE

To the extent that the Court determines that plaintiff has suffered damages, Chanelle is entitled to a set-off against such damages in the amount of damages Chanelle has suffered as a result of Chanelle's detrimental reliance on Hartz's promise and/or representation to fund an upgrade of Chanelle's plant and/or equipment.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that the Court determines that plaintiff has suffered damages, plaintiff's damages are limited to those damages specifically set forth in the CL&S Agreement.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, in that plaintiff's damages, if any, were caused by the conduct of entities or individuals not within the control of Chanelle.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, in that plaintiff's damages, if any, were caused by events or factors not within the control of Chanelle.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, in that plaintiff's damages, if any, were caused by its own acts and/or omissions.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that plaintiff claims that it was entitled to terminate the CL&S Agreement because Chanelle misrepresented the cost to upgrade Chanelle's plant and/or equipment, in order to achieve cGMP approval from the FDA, such claims are barred, in whole or in part, because it was Hartz's employee and/or consultant that made such recommendations and Hartz was obligated to fund such upgrades to achieve FDA approval.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine of unclean hands.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent that Hartz breached the CL&S Agreement by disclosing confidential information of Chanelle to third parties.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine of waiver.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by its failure to mitigate its alleged damages.

Respectfully submitted,

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s/ John C. Barnoski

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Dated: October 19, 2005

CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of October 2005, a copy of Defendant's Answer to the Complaint was served electronically and by first-class mail, postage prepaid, to counsel of record as follows:

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COZEN O'CONNOR

s/ John C. Barnoski
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