

4. Upon information and belief, Defendant Ther-Rx Corporation is a Missouri corporation having its principal place of business at 1 Corporate Woods Drive, Brigeton, MO 63044. Ther-RX is a wholly owned subsidiary of KV Pharmaceuticals responsible for marketing and selling the patented products at issue, and is a licensee of DrugTech Corporation.

NATURE OF ACTION

5. This is an action for a declaratory judgment of patent invalidity, non-infringement, unenforceability for inequitable conduct and unfair competition. Lannett seeks a declaration that patents belonging to the KV Defendants, specifically, U.S. Patent No. 6,258,846 (“the ‘846 patent”), U.S. Patent No. 6,576,666 (“the ‘666 patent”), U.S. Patent No. 7,112,609 (“the ‘609 patent”), U.S. Patent No. 6,197,329 (“the ‘329 patent”), and U.S. Patent No. 6,569,857 (“the ‘857 patent”) (collectively the “KV Patents”) are invalid and/or unenforceable. True and correct copies of the ‘846 patent, the ‘666 patent, the ‘609 patent, the ‘329 patent, and the ‘857 patent are attached hereto as Exhibits “1”, “2”, “3”, “4” and “5” respectively. Lannett also seeks a declaration that Lannett’s nutritional dietary product - Multivitamin With Mineral Capsules - does not infringe upon the KV Patents and that the KV Defendants have engaged in unfair competition and deceptive trade practices in the marketplace by preventing Lannett and others from entering the market.

6. Lannett seeks a declaration that patents licensed to the KV Defendants, specifically, U.S. Patent No. 5,516,925 (“the ‘925 patent”), and U.S. Patent No. 6,716,814 (“the ‘814 patent”) are not infringed and/or invalid. True and correct copies of the ‘925 patent and the ‘814 patent are attached hereto as Exhibits “6” and “7” respectively.

7. This action is also brought under the Clayton Act, 15 U.S.C. §§ 15 and 25, as amended, and the Sherman Act, 15 U.S.C. §§ 1 and 2, where Defendants have asserted invalid or unenforceable patents in order to inhibit competition in the marketplace.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, Title 35 of the United States Code, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and state laws regarding unfair competition and deceptive trade practices, 6 Del. C. § 2532. This Court has subject matter jurisdiction over count one (declaratory judgment of non-infringement), count two (declaratory judgment of invalidity), count three (inequitable conduct) and count four (antitrust violations) pursuant to 28 U.S.C. §§ 1331, 1367, 1338 and 2201-2202, as claims arising under the patent laws of the United States and the Declaratory Judgment Act. The Court also has subject matter jurisdiction over count five (deceptive trade practices) because count five forms part of the same case or controversy as the claims contained in counts one through five. Jurisdiction is also conferred by 28 U.S.C. § 1337, and the Clayton Act, as amended. The Court has supplemental jurisdiction over the state law claim of deceptive trade practices pursuant to 28 U.S.C. § 1367.

9. Based on information and belief, venue in this judicial district is proper under the provisions of 28 U.S.C. §§ 1391(c) and 1400(b), where the Defendants KV and DrugTech are Delaware corporations and Ther-Rx engages in significant business in, and derives significant profit within, the State of Delaware. The KV Defendants sell their PrimaCare One™ product through various pharmacies within the State of Delaware and have significant annual sales in the State of Delaware.

10. This Court also has jurisdiction over Lannett's claim for violation of the Delaware Deceptive Trade Practices Act, 6 Del. C. § 2532, pursuant to 28 U.S.C. § 1338(b) because those claims are joined with substantial and related claims under the Patent and Trademark Laws of the United States.

FACTUAL BACKGROUND

11. Lannett has plans to market its Multivitamin With Mineral Capsules, a multivitamin/mineral product containing omega-3 fatty acids for prenatal and postnatal support, within the United States. Dietary multivitamin/mineral and omega-3 fatty acid supplements are prescribed by healthcare professionals throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years.

12. The KV Patents, the '925 patent and the '814 patent prevent Lannett and other competitors from introducing their competitive multivitamin/mineral and omega-3 fatty acid supplementation products in competition with the KV Defendants' product, PrimaCare One™. There is a reasonable likelihood that the KV Defendants will assert a claim for patent infringement against Lannett once its product, Multivitamin With Mineral Capsules, enters the marketplace.

13. Lannett has a reasonable belief, based upon prior art and the patents' prosecution histories, that the KV Patents, the '925 patent and the '814 patent are invalid, non-infringed and/or unenforceable.

14. Lannett has informed the KV Defendants of its intent to market a product arguably within the scope of the KV Patents, the '925 patent and the '814 patent.

15. In light of the apparent invalidity and/or non-infringement of the KV Patents, the '925 patent and the '814 patent, Lannett has sought assurances from the KV Defendants that they will not assert these patents to block Lannett's entry into the market. The KV Defendants have failed or refused to provide such assurances. Thus, an Article III case or controversy exists between Lannett and the KV Defendants.

16. The KV Defendants are motivated to maintain their market share, which is comprised of noninfringed, invalid and/or unenforceable patents, to keep Lannett and other

competitors from entering the marketplace and to prevent the dilution of KV Defendants' market share for dietary supplement multivitamin/mineral and omega-3 fatty acid products.

COUNT ONE

Declaratory Judgment of Noninfringement

17. Lannett repeats, re-alleges and incorporates the allegations in all preceding paragraphs of this Complaint.
18. Upon information and belief, the '846 patent issued to Marc S. Hermelin, R. Saul Levinson and George Paradissis on July 10, 2001 is entitled Nutritional Supplements, and is assigned to DrugTech, a wholly-owned subsidiary of KV Pharmaceuticals.
19. Upon information and belief, the '666 patent issued to Marc S. Hermelin, R. Saul Levinson and George Paradissis on June 10, 2003 is entitled Nutritional Supplements, and is assigned to DrugTech, a wholly owned subsidiary of KV Pharmaceuticals.
20. Upon information and belief, the '609 patent issued to Marc S. Hermelin, R. Saul Levinson and George Paradissis on September 26, 2006 is entitled Nutritional Supplements, and is assigned to DrugTech, a wholly owned subsidiary of KV Pharmaceuticals.
21. Upon information and belief, the '329 patent issued to Marc S. Hermelin, Mitchell I. Kirschner, and R. Saul Levinson on March 6, 2001 is entitled Anti-nausea Compositions and Methods, and is assigned to DrugTech, a wholly owned subsidiary of KV Pharmaceuticals.
22. Upon information and belief, the '857 patent issued to Marc S. Hermelin and R. Saul Levinson on May 27, 2003 is entitled Dietary Supplements, and is assigned to DrugTech, a wholly owned subsidiary of KV Pharmaceuticals.

23. Upon information and belief, the '925 patent issued to Mark Pedersen and H. DeWayne Ashmead on May 14, 1996 is entitled Amino Acid Chelates Having Improved Platability, is assigned to Albion International, Inc., and is licensed to KV Pharmaceuticals for use in PrimaCare One™.

24. Upon information and belief, the '814 patent issued to Clayton Ericson and H. DeWayne Ashmead on April 6, 2004 is entitled Enhancing Solubility of Iron Amino Acid Chelates and Iron Proteinates, is assigned to Albion International, Inc., and is licensed to KV Pharmaceuticals for use in PrimaCare One™.

25. The KV Defendants have failed to comply with the requirements of Sections 102 and 103 of Title 35 of the United States Code, and other relevant sections of Title 35.

26. Thus, Lannett has not infringed upon, and will not infringe upon the KV Patents, the '925 patent and '814 patent by making, using, offering to sell or selling its Multivitamin With Mineral Capsules in the United States, or importing such a product into the United States.

27. Based on the foregoing, an actual and justiciable controversy exists between Lannett and the KV Defendants with respect to the KV Patents, the '925 patent and the '814 patent.

COUNT TWO

Declaratory Judgment of Invalidity

28. Lannett repeats, re-alleges and incorporates the allegations in all preceding paragraphs of this Complaint.

29. Upon information and belief, the KV Patents are invalid based upon prior art and the patents' prosecution histories.

30. The KV Patents are invalid for failure to comply with the requirements of sections 102 and 103 of Title 35 of the United States Code, and other relevant sections of Title 35.

31. The KV Patents are invalid. Thus, Lannett has not, is not and will not infringe upon the KV Patents by making, using, offering to sell or selling its Multivitamin With Mineral Capsules in the United States, or by importing such a product into the United States.

32. The KV Patents are invalid. Therefore, Lannett has not induced or contributed to, and is not inducing or contributing to, infringement of the KV Patents and will not induce or contribute to infringement of the KV patents by making, using, offering to sell or selling its Multivitamin With Mineral Capsules in the United States, or by importing such a product into the United States.

COUNT THREE

Inequitable Conduct

33. Lannett repeats, re-alleges and incorporates the allegations in all preceding paragraphs of this Complaint.

34. Upon information and belief, the '609 patent is unenforceable based upon the KV Defendants' inequitable conduct and the patent's prior art and prosecution history.

35. The '609 patent was filed on June 10, 2003, and issued on September 26, 2006.

36. The '609 patent is a continuation-in-part of the '666 patent, which is a continuation-in-part of the '846 patent. In other words, these three patents constitute a family of patents that claim the KV Defendants' product, PrimaCare One™.

37. Defendants filed a continuation application for the '609 patent on December 26, 2004 as U.S. Application Serial No. 11/021,344 ("the '344 Continuation Application"). The '344 Continuation Application was filed almost two years before the issuance of the '609 patent on September 26, 2006, and more than one year after the filing date of the '609 patent on June 10, 2003.

38. On July 12, 2005, Gary J. Connell, Esquire (“Mr. Connell”) of Sheridan Ross, P.C., on behalf of an undisclosed client, filed a third-party submission with the United States Patent and Trademark Office (“USPTO”) stating that European Patent Application EP 0 705 539 A2 (“the ‘539 Application”), which was published on April 10, 1996, is material to the patentability of the ‘344 Continuation Application. A true and correct copy of the third-party submission is attached hereto as Exhibit 8. The disclosure reveals that the KV Patents are invalid and/or unenforceable.

39. Mr. Connell also mailed a copy of the third-party submission to counsel for the KV Defendants on July 12, 2005. Thus, the KV Defendants and their counsel were aware that the ‘539 Application was prior art for the ‘344 Continuation Application.

40. Mr. Connell’s actions clearly demonstrate a desire on the part of his client to invalidate the KV Defendants’ dietary supplement patents via an administrative procedure through the USPTO in order to enter the dietary supplement market dominated exclusively by the KV Defendants.

41. This administrative proceeding has been pending before the USPTO since July 12, 2005, but a decision has not been issued. However, the proceeding has prevented the continued prosecution of a fourth patent application for the KV Defendants’ product, PrimaCare One™. As a result, the KV Defendants have been able to maintain their market share and effectively prevent the entry of other competitors into the marketplace.

42. On July 12, 2005, Mr. Connell mailed a copy of the third-party submission to counsel for the KV Defendants. The ‘609 patent was issued on September 26, 2006. Thus, the KV Defendants knew or should have known that the ‘539 Application was prior art to the ‘609 patent about fourteen (14) months prior to issuance of the ‘609 patent.

43. The '539 Application is material to the patentability of the '344 Continuation Application, and therefore it is also material to the patentability of the '609 patent.

44. During the prosecution of the '609 patent, the KV Defendants, with knowledge of the '539 Application, did not disclose the reference to the USPTO as a prior art reference.

45. On October 4, 2005, during the prosecution of the '609 patent, the KV Defendants responded to a Non-final Office Action from the USPTO.

46. In its written response to the USPTO on October 4, 2005, the KV Defendants were aware of '539 Application but failed to disclose it as prior art. In fact, in their written response, the KV Defendants represented that the "pending claims 53-60 are patentable as written. A notice of allowance is thereby respectfully requested." See Written Response of the KV Defendants dated October 4, 2005 at p. 10, ¶ 3 attached hereto as Exhibit 9. Therefore, the KV Defendants asserted that the application was patentable with full knowledge that they had not disclosed the '539 Application to the USPTO.

47. On February 21, 2006, USPTO Examiner Jennifer Kim and Primary Examiner Sheng Jun Wang conducted a personal interview of Sarah Vaz (Reg # 34,747), a representative for the KV Defendants, in furtherance of the prosecution of what would eventually issue as the '609 patent. During this interview, the KV Defendants were aware that the '539 Application was material prior art, but did not disclose the reference to the USPTO examiners.

48. On March 10, 2006, the KV Defendants submitted an amendment after a Final Office Action to the USPTO in furtherance of the prosecution of what would eventually issue as the '609 patent. The KV Defendants again stated that the "application is in condition for allowance". See Amendment After Final Office Action at p. 4, ¶ 1 attached hereto as Exhibit 10. However, the KV Defendants knew that they had not disclosed the '539 Application to the USPTO Examiner as a material prior art reference to the patentability of the '609 patent.

49. On June 13, 2006, the KV Defendants paid the issue fee to the USPTO in furtherance of the prosecution of what would eventually issue as the '609 patent.

50. The KV Defendants, however, had a duty of disclosure to reveal all prior art information material to patentability to the USPTO during the prosecution of the '609 patent.

51. The duty of disclosure arises from case law and the Code of Federal Regulations governing patent procurement. See 37 C.F.R. §§ 1.56, 1.97 and 1.98.

52. The duty to disclose information material to patentability exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. See 37 C.F.R. § 1.56.

53. The Defendants made affirmative statements to the USPTO that the application to eventually issue as the '609 patent was patentable, while intentionally withholding the '539 Application, which was material to patentability of the '609 patent.

54. The '609 patent is unenforceable. Therefore, Lannett has not infringed upon, and is not infringing upon any claims of the '609 patent, and will not infringe upon any claims of this patent by making, using, offering to sell or selling its Multivitamin With Mineral Capsules, or importing such a product into the United States.

55. Moreover, Lannett has not induced or contributed to, and is not inducing or contributing to, the infringement of any claims of the '609 patent, and will not induce or contribute to the infringement of any claims of this patent, by making, using, offering to sell or selling its Multivitamin With Mineral Capsules in the United States, or importing such a product into the United States.

COUNT FOUR

Anti-Trust Violations

56. Lannett repeats, re-alleges and incorporates the allegations in all preceding paragraphs of this Complaint.

57. Upon information and belief, the KV Defendants have obtained and maintained monopoly power in the relevant market for the multivitamin/mineral product containing omega-3 fatty acids for prenatal and postnatal support. The relevant geographic market for this product is the United States.

58. Upon information of belief, the KV Defendants knew or should have known that the KV Patents are invalid and/or unenforceable, in light of the '539 Application.

59. The KV Defendants pursued issuance of the '609 patent with the USPTO and allowed the USPTO to issue the '609 patent despite knowledge of the existence of invalidating prior art. Moreover, the KV Defendants have taken no steps to correct defects in the '846 patent and the '666 patent.

60. Furthermore, upon information and belief, the KV Defendants have not taken any steps to address the prior art issue in the pending '344 Continuation Application currently before the USPTO, despite the undeniable conclusion that there is a third party adversely affected by the pending application and the KV Patents.

61. Defendants have obtained and maintained their market power through acquisition and maintenance of their fraudulently-procured '609 patent, as well as their invalid '846 and '666 patents.

62. In light of the apparent and undeniable invalidity of the '846 patent, the '666 patent and the '609 patent, Lannett has requested assurances from the KV Defendants that they will not assert their facially invalid patents to block Lannett's entry into the market. The KV

Defendants have failed or refused to provide such assurances. Therefore, an Article III case or controversy exists between Lannett and the KV Defendants.

63. As a result of the KV Defendants' anticompetitive conduct, Lannett stands to lose substantial sales of its Multivitamin With Mineral Capsules for prenatal and postnatal support. This injury is a competitive injury of the sort that the antitrust laws were intended to prevent because Lannett and the KV Defendants directly compete in the marketing and sale to end-users of multivitamin/mineral products containing omega-3 fatty acids. In addition, Lannett was forced to hire counsel and bring the instant action to obtain redress for the KV Defendants' unlawful and anticompetitive conduct.

64. The KV Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by unlawfully obtaining and maintaining market power in the relevant market by use of threats to enforce patents that the KV Defendants knew were invalid and/or procured fraudulently. Section 4 of the Clayton, 15 U.S.C. § 15(a), authorizes private suits for damages based upon violations of the Sherman Act.

65. As the result of the KV Defendants' unlawful and anticompetitive conduct described above, Lannett has suffered economic injury.

COUNT FIVE

Violation of Deceptive Trade Practices Act

66. Lannett repeats, re-alleges and incorporates the allegations in all preceding paragraphs of this Complaint.

67. Upon information and belief, the KV Defendants knew or should have known that the '609 patent is invalid and/or unenforceable, especially in light of the '539 Application.

68. The KV Defendants have, and continue to represent, in the course of their business, that PrimaCare One™ is covered by the '609 patent, when the KV Defendants knew or should have known that this patent was invalid and/or unenforceable.

69. The KV Defendants have, and continue to advertise that PrimaCare One™ is covered by the '609 patent, when the KV Defendants knew or should have known that this patent was invalid and/or unenforceable.

70. Upon information and belief, and in the course of their business, as alleged above, the KV Defendants' conduct violates 6 Del. C. § 2532.

71. The KV Defendants' conduct violates 6 Del. C. § 2532 and unfairly interferes with Lannett's ability to compete with the KV Defendants on the merits of their products.

72. Because the KV Defendants' conduct violates 6 Del. C. § 2532, Lannett has suffered and will continue to suffer economic injury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court order the following relief:


- A. Declare that the Multivitamin With Mineral Capsules sold by Lannett Company Inc. does not infringe upon the claims of the '846 patent, the '666 patent, the '609 patent, the '925 patent, the '329 patent, the '857 patent, and the '814 patent;
- B. Declare that the claims of the '846 patent, the '666 patent, the '609 patent, the '329 patent and the '857 patent issued to the KV Defendants are invalid;
- C. Declare that the claims of the '609 patent issued to the KV Defendants are unenforceable; and
- D. Award such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Lannett hereby demands a trial by jury on all issues.

Respectfully Submitted,

FOX ROTHSCHILD LLP

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Lannett Company Inc.

Date: June 10, 2008

SEALED DOCUMENT

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

LANNETT COMPANY, INC.,	:	
	:	CIVIL ACTION
Plaintiff,	:	NO. 08-338 (JJF)
	:	
v.	:	
	:	
KV PHARMACEUTICAL COMPANY,	:	
Ther-Rx Corp., and Drugtech Corp.,	:	
	:	
Defendants.	:	
<hr/>		
KV PHARMACEUTICAL COMPANY,	:	
Ther-Rx Corp., and Drugtech Corp.,	:	
	:	
Counterclaim-Plaintiffs,	:	
	:	
v.	:	
	:	
LANNETT COMPANY, INC.,	:	
	:	
Counterclaim-Defendant.	:	

**ANSWER AND AFFIRMATIVE DEFENSES OF
LANNETT COMPANY, INC., IN RESPONSE TO COUNTERCLAIM**

Plaintiff/Counterclaim-Defendant, Lannett Company, Inc. (“Lannett”), by and through its attorneys, Fox Rothschild LLP, hereby Answers the Counterclaim filed by Defendants/Counterclaim-Plaintiffs, KV Pharmaceutical Company, Ther-Rx Corp., and Drugtech Corp. (collectively, “Ther-Rx”) as follows:

1. Admitted.
2. Admitted.
3. Admitted.
4. Admitted.

JURISDICTION AND VENUE

5. Denied as a conclusion of law to which no response is required.

6. Admitted in part, denied in part. It is admitted only that Lannett is a Delaware corporation. The remaining averments are denied as a conclusion of law to which no response is required.

7. Denied as a conclusion of law to which no response is required.

ALLEGATIONS APPLICABLE TO ALL COUNTS

8. Admitted in part, denied in part. It is admitted only that U.S. Patent No. 6,258,846 (“the ‘846 Patent”) was issued on July 10, 2001. The remaining averments are denied as a conclusion of law to which no response is required. To the extent that the remaining averments contained in this Paragraph constitute averments of fact, they are denied.

9. Admitted in part, denied in part. It is admitted only that U.S. Patent No. 6,576,666 (“the ‘666 Patent”) was issued on June 10, 2003. The remaining averments are denied as a conclusion of law to which no response is required. To the extent that the remaining averments contained in this Paragraph constitute averments of fact, they are denied.

10. Admitted in part, denied in part. It is admitted only that U.S. Patent No. 7,112,609 (“the ‘609 Patent”) was issued on September 26, 2006. The remaining averments are denied as a conclusion of law to which no response is required. To the extent that the remaining averments contained in this Paragraph constitute averments of fact, they are denied.

11. Denied.

12. Admitted in part, denied in part. It is admitted only that Lannett has imported into the United States, offered for sale in the United States, and sold in the United States, a product it describes as a Multivitamin with Minerals capsules, which is a multivitamin/mineral product

containing, inter alia, omega-3 fatty acids (the “Lannett Product”). It is further denied that the Lannett Product is an “Infringing Product” or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx.

13. Admitted in part, denied in part. It is admitted only that the Lannett Product is a prescription product of the type often referred to as a prenatal supplement, and that the Lannett Product is intended for use by pregnant women, women trying to get pregnant, and women who have already given birth, especially those who are nursing their babies. It is denied that the Lannett Product is an “Infringing Product” or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx.

14. Admitted in part, denied in part. It is admitted only that Ther-Rx has used the “PrimaCare®” mark in connection with the pre-natal and post-natal supplements for women. The remaining averments of this Paragraph are denied.

15. Admitted in part, denied in part. It is admitted only that Ther-Rx has used the “PrimaCare® ONE” mark in connection with the pre-natal and post-natal supplements for women. The remaining averments of this Paragraph are denied.

16. Denied.

17. Denied.

18. Denied.

19. Denied.

20. Denied.

21. Denied.

22. Denied.

23. Denied.

24. Admitted.

25. Admitted.

26. Denied.

27. Denied.

28. Admitted in part, denied in part. It is admitted only that copies of registration certificates are attached to Ther-Rx's Counterclaim as Exhibit "D." The remaining averments are denied as a conclusion of law to which no response is required. To the extent that the remaining averments contained in this Paragraph constitute averments of fact, they are denied.

29. Denied as a conclusion of law to which no response is required.

30. Denied as a conclusion of law to which no response is required.

31. Admitted in part, denied in part. It is admitted that Lannett had knowledge as to the existence of Ther-Rx's marks, "PrimaCare®" and "PrimaCare® ONE." It is further admitted that a label on the Lannett Product read "Compare to the active ingredients in PrimaCare® ONE* *Registered trademark of Ther-Rx Corp." solely for the purpose of comparative advertising, which is entirely appropriate under the law. It is denied that the Lannett Product is an "Infringing Product" or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx. The remaining averments in this Paragraph are denied.

32. Admitted in part, denied in part. It is admitted only that on or about June 10, 2008, Lannett began to sell, offer for sale and distribute the Lannett Product in the United States commerce, as a generic version of PrimaCare ® ONE. It is denied that the Lannett Product is an "Infringing Product" or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx.

33. Admitted in part, denied in part. It is admitted only that from June 10, 2008, to June 24, 2008, Lannett advertised, marketed, promoted, offered for sale, sold and distributed the Lannett Product in the United States commerce, with a label on the Lannett Product that read “Compare to the active ingredients in PrimaCare® ONE* *Registered trademark of Ther-Rx Corp.” solely for the purpose of comparative advertising, which is entirely appropriate under the law. By way of further response, as of June 27, 2008, Lannett changed the labeling on the Lannett Product and, as a result, no Lannett Products sold or distributed after June 24, 2008 contain any reference to “PrimaCare ®” or “PrimaCare® ONE.” It is denied that the Lannett Product is an “Infringing Product” or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx.

34. Admitted in part, denied in part. It is admitted only that from June 10, 2008, to June 24, 2008, a label near the top of the Lannett Product sold or distributed read “Compare to the active ingredients in PrimaCare® ONE* *Registered trademark of Ther-Rx Corp.,” which reference was made solely for the purpose of comparative advertising, which is entirely appropriate under the law. It is further admitted that the term “PrimaCare® ONE” on the label of the Lannett Product was written in red ink, appeared in an italics font, contained an uppercase “C” in the term “PrimaCare,” and contained all uppercase letters for the word “ONE.” By way of further response, as of June 27, 2008, Lannett changed the labeling on the Lannett Product and, as a result, no Lannett Products sold or distributed after June 24, 2008 contain any reference to “PrimaCare®” or “PrimaCare® ONE.” It is denied that the Lannett Product was an “Infringing Product” at any time, or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx. The remaining averments in this Paragraph, including the graphic size of the labels shown in the Paragraph, are denied.

35. Admitted in part, denied in part. It is admitted only that from June 10, 2008, to June 24, 2008, a label near the top of the Lannett Product sold or distributed read “Compare to the active ingredients in PrimaCare® ONE* *Registered trademark of Ther-Rx Corp.,” which reference was made solely for the purpose of comparative advertising, which is entirely appropriate under the law. It is denied that the phrase “Compare to the active ingredients in” was provided in much smaller print than the phrase “PrimaCare® ONE.” By way of further response, as of June 27, 2008, Lannett changed the labeling on the Lannett Product and, as a result, no Lannett Products sold or distributed after June 24, 2008 contain any reference to “PrimaCare®” or “PrimaCare® ONE.” It is further denied that the Lannett Product was an “Infringing Product” at any time, or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx.

36. Admitted in part, denied in part. It is admitted only that the phrase “Compare to the active ingredients in” found on the label of the Lannett Product sold or distributed from June 10, 2008, to June 24, 2008, was written in purple ink and was on an angle compared to the phrase “PrimaCare® ONE.” By way of further response, as of June 27, 2008, Lannett changed the labeling on the Lannett Product and, as a result, no Lannett Products sold or distributed after June 24, 2008 contain any reference to “PrimaCare®” or “PrimaCare® ONE.” It is denied that the Lannett Product was an “Infringing Product” at any time, or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx. The remaining averments in this Paragraph are denied.

37. Admitted. By way of further answer, Lannett’s use of the “PrimaCare® ONE” mark was solely for the purpose of comparative advertising, which is entirely appropriate under

the law, and it was not necessary that Ther-Rx authorize, approve, sponsor or endorse any of Lannett's products or the use of said mark.

38. Admitted in part, denied in part. It is admitted that Ther-Rx's "PrimaCare® ONE" product and the Lannett Product both come in a purple gel capsule. It is denied that the Lannett Product is an "Infringing Product" or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx.

39. Denied as a conclusion of law to which no further response is required. To the extent that this Paragraph contains averments of fact, they are denied.

40. Denied.

41. Denied.

42. Denied. By way of further answer, as of June 24, 2008, Lannett changed the labeling on the Lannett Product and, as a result, no Lannett Products produced after June 24, 2008 contain any reference to "PrimaCare ®" or "PrimaCare® ONE."

43. Admitted in part, denied in part. It is admitted that on the package insert for the Lannett Product, Lannett has placed an asterisk next to its listing for "Vitamin C (as calcium ascorbate and calcium threonate*)," and that the corresponding asterisk reads "Compare to Ester-C®, a patented pharmaceutical grade material consisting of calcium ascorbate and calcium threonate. Ester-C® is a licensed trademark of Zila Nutraceuticals, Inc." It is denied that the Lannett Product is an "Infringing Product" or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx or any other third party, including but not limited to Zila Nutraceuticals, Inc.

44. Denied.

45. Admitted in part, denied in part. It is admitted only that the Lannett Product does not contain Ester-C® brand of Vitamin C, although it does contain Vitamin C (as calcium ascorbate and calcium threonate). It is denied that the Lannett Product is an “Infringing Product” or that Lannett has infringed any patent, trademark or other interest held by Ther-Rx or any other third party. The remaining averments contained in this Paragraph are denied.

46. Denied.

47. Denied.

FIRST CAUSE OF ACTION

Infringement of U.S. Patent 6,258,846

48. Lannett incorporates by reference Paragraphs 1 through 47 of this Answer, above, as if set forth at length herein.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

SECOND CAUSE OF ACTION

Infringement of U.S. Patent 6,576,666

54. Lannett incorporates by reference Paragraphs 1 through 53 of this Answer, above, as if set forth at length herein.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

THIRD CAUSE OF ACTION

Infringement of U.S. Patent 7,112,609

60. Lannett incorporates by reference Paragraphs 1 through 59 of this Answer, above, as if set forth at length herein.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

FOURTH CAUSE OF ACTION

Federal Trademark Infringement

66. Lannett incorporates by reference Paragraphs 1 through 65 of this Answer, above, as if set forth at length herein.

67. Denied.

68. Denied as a conclusion of law to which no response is required.

69. Denied.

70. Denied.

71. Denied.

FIFTH CAUSE OF ACTION

**False Designation of Origin, False Description and False Representation,
Unfair Competition and False Advertising (Federal)**

72. Lannett incorporates by reference Paragraphs 1 through 71 of this Answer, above, as if set forth at length herein.

73. Denied.

74. Denied as a conclusion of law to which no response is required.

75. Denied.

76. Denied.

SIXTH CAUSE OF ACTION

**Trademark Infringement, Unfair Competition,
False Advertising and Misappropriation (Common Law)**

77. Lannett incorporates by reference Paragraphs 1 through 76 of this Answer, above, as if set forth at length herein.

78. Denied.

79. Denied as a conclusion of law to which no response is required.

80. Denied.

81. Denied.

WHEREFORE, Plaintiff/Counterclaim-Defendant, Lannett Company, Inc., demands that judgment be entered in its favor and against Defendants/Counterclaim-Plaintiffs, KV Pharmaceutical Company, Ther-Rx Corp., and Drugtech Corp.

AFFIRMATIVE DEFENSES

Lannett, for its separate affirmative defenses to the Counterclaims of Ther-Rx, states and alleges as follows:

First Affirmative Defense

Ther-Rx fails to state, in whole or in part, claims upon which relief can be granted.

Second Affirmative Defense

Ther-Rx's claims are barred and/or limited for the reasons set forth in Lannett's Amended Complaint, which is incorporated by reference as if set forth fully herein.

Third Affirmative Defense

The '846 Patent, the '666 Patent, and the '609 Patent (collectively, the "Ther-Rx Patents") are invalid and/or unenforceable based upon prior art and obviousness of the subject matter of said patents, and as a result of Ther-Rx's failure to comply with Sections 102 and 103 of Title 35 of the United States Code and other relevant sections of Title 35. Specifically, the Ther-Rx Patents are invalid at least in light of the European published patent application number EP 0 705 539 ("the '539 Publication"), either alone or in combination with PCT International published patent application number WO 1997/48392 ("the '392 Publication").

Fourth Affirmative Defense

The Ther-Rx Patents are invalid and/or unenforceable based on the inequitable conduct of Ther-Rx.

Fifth Affirmative Defense

Lannett has not infringed the Ther-Rx Patents.

Sixth Affirmative Defense

Ther-Rx's marks "PrimaCare®" and "PrimaCare® ONE" are invalid, unenforceable and void.

Seventh Affirmative Defense

The claims of Ther-Rx are barred, in whole or in part, because Lannett's use, if any, of the "PrimaCare®" and "PrimaCare® ONE" marks is considered fair use.

Eighth Affirmative Defense

The claims of Ther-Rx are barred, in whole or in part, because the phrases "Compare to the active ingredients in PrimaCare® ONE* *Registered trademark of Ther-Rx Corp." found on the Lannett Product, were used solely for the purpose of comparative and/or descriptive advertising, which is entirely reasonable and appropriate under the law.

Ninth Affirmative Defense

As of June 24, 2008, Lannett changed the labeling on the Lannett Product and, as a result, no Lannett Products produced after June 24, 2008 contain any reference to "PrimaCare ®" or "PrimaCare® ONE."

Tenth Affirmative Defense

Ther-Rx lacks standing to assert a claim based on the use by Lannett of the following statement in the packaging insert for the Lannett Product: "Vitamin C (as calcium ascorbate and calcium threonate*) *Compare to Ester-C®, a patented pharmaceutical grade material consisting of calcium ascorbate and calcium threonate. Ester-C® is a licensed trademark of Zila Nutraceuticals, Inc."

Eleventh Affirmative Defense

The claims of Ther-Rx are barred, in whole or in part, because there is no likelihood of confusion between Ther-Rx's mark and the Lannett Product.

Twelfth Affirmative Defense

Lannett has not made any false or misleading statements as to its own products or those of another.

Thirteenth Affirmative Defense

There has been no actual deception by Lannett, nor is there a tendency that the packaging for the Lannett Product will deceive a substantial portion of the intended audience.

Fourteenth Affirmative Defense

The claims of Ther-Rx are barred, in whole or in part, because Lannett has at all times acted in a manner that was proper, reasonable, lawful, and in good faith.

Fifteenth Affirmative Defense

The claims of Ther-Rx are barred, in whole or in part, because Ther-Rx's alleged damages, the existence of which is expressly denied, were caused by the acts and omissions of individuals or entities over whom Lannett had or has no control or right to control, including but not limited to Ther-Rx.

Sixteenth Affirmative Defense

The claims of Ther-Rx are barred, in whole or in part, because Ther-Rx failed to mitigate its damages, the existence of which is expressly denied.

Seventeenth Affirmative Defense

The claims of Ther-Rx are barred, in whole or in part, by the doctrine of unclean hands.

Eighteenth Affirmative Defense

Plaintiff's claims are barred by the doctrine of estoppel.

Nineteenth Affirmative Defense

Plaintiff's claims are barred by the doctrine of waiver.

Twentieth Affirmative Defense

Lannett reserves the right to amend or add such additional separate affirmative defenses that may become available during discovery or at trial and conform any such additional defenses that it may have to the evidence as permitted by Fed.R.Civ.P. 15(b).

WHEREFORE, Plaintiff/Counterclaim-Defendant, Lannett Company, Inc., requests that judgment be entered in its favor and against Defendants/Counterclaim-Plaintiffs, KV Pharmaceutical Company, Ther-Rx Corp., and Drugtech Corp.

/s/ Sophia Siddiqui

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CERTIFICATE OF SERVICE

I hereby certify that on July 7, 2008, I caused to be served via email the foregoing documents and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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