SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

OTSUKA AMERICA, INC. and PHARMAVITE LLC,

Plaintiff,

-against-

CRUM & FORSTER SPECIALTY INSURANCE COMPANY

Defendant.

Index No.:

SUMMONS

TO THE ABOVE-NAMED DEFENDANT:

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer on the Plaintiffs' attorney at the address indicated below within 20 days after the service of this Summons (not counting the day of service itself), or within 30 days after service is complete if the Summons is not delivered personally to you within the State of New York; and in case of your failure to appear or answer, a judgment will be entered against you by default for the relief demanded in the complaint together with the costs of this action.

The Plaintiffs designate NEW YORK as the place of trial. This suit arises out of an insurance policy issued by Defendant. The basis of venue is the policy's designation of the "State of New York" as the exclusive venue for litigating coverage disputes arising out of that insurance policy.

Dated: January 30, 2018

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COMPLAINT FOR BREACH OF CONTRACT AND DECLARATORY JUDGMENT

Plaintiffs, OTSUKA AMERICA, INC. (hereinafter "Otsuka") and PHARMAVITE LLC (hereinafter "Pharmavite," and collectively with Otsuka, "Plaintiffs"), by and through their attorneys, hereby file this Complaint against the Defendant, CRUM & FORSTER SPECIALTY INSURANCE COMPANY (hereinafter "Crum & Forster"), and respectfully allege as follows:

INTRODUCTION

1. This is an action for declaratory judgment pursuant to CPLR § 3001, for damages for breach of contract, and for further necessary and appropriate relief.

2. At its core, this is an action against Crum & Forster for its improper denial of commercial insurance benefits under a "Product Recall Insurance for Consumable Products" Policy No. RCP103078 (hereinafter "Policy") that Otsuka purchased from Crum & Forster for a premium of nearly One Hundred Fifty Thousand Dollars ($150,000.00).

3. Pharmavite is an industry leading manufacturer of high-quality dietary supplements, including the "Nature Made" vitamin brand, and is a wholly-owned subsidiary of Otsuka.

4. Plaintiffs suffered substantial monetary losses as a result of a June 2016 recall ("2016 Recall") of certain dietary supplement products mandated by the United States Food and Drug Administration ("FDA").

5. Plaintiffs timely sought coverage from Crum & Forster under the Policy for its directly related losses, including, but not limited to, costs associated with the withdrawal, destruction, and disposal of adulterated products; lost profits; increased operating costs; and other expenses associated with the recall and third-party liabilities.

6. Plaintiffs' claim for their reasonable and necessary Loss arising from the 2016 Recall was wrongfully denied by Crum & Forster in direct contravention of the plain meaning of the terms and conditions of the Policy and controlling law.

PARTIES

7. Otsuka America, Inc. is a Delaware corporation having its principal place of business at One Embarcadero Center, Suite 2020, San Francisco, California 94111.

8. Pharmavite LLC is a California limited liability company having its principal place of business at 8510 Balboa Boulevard, Suite 100, Northridge, California 91325.

9. Upon information and belief, Defendant Crum & Forster Specialty Insurance Company is a Delaware corporation having its principal place of business at 305 Madison Avenue, Morristown, New Jersey 07960. Upon information and belief, Crum & Forster is a surplus lines carrier that conducts extensive business in New York.

JURISDICTION AND VENUE

10. This Court has jurisdiction over this action and parties pursuant to CPLR § 302(a)(1) because of the parties' respective transacting of business within this jurisdiction.

11. Jurisdiction is also proper in this Court pursuant to paragraph 4.9 CHOICE OF LAW AND FORUM of the Policy, which in relevant part provides, "The **Insurer** and the **Insured(s)** hereby expressly agree that all **Claim(s)**, **Loss(es)** and disputes will be brought and litigated in the State of New York."

12. Venue is proper pursuant to CPLR §§ 501 and 503(a) because the Policy designates the "State of New York" as the exclusive venue for litigating coverage disputes.

FACTUAL BACKGROUND

The Insurance Policy

13. Crum & Forster issued the Policy to Otsuka on or about August 5, 2015.

14. A true and correct bates-stamped copy of the Policy is attached hereto as Exhibit 1.

15. The Policy provides, pursuant to the "Named Insured Listing Endorsement," that Pharmavite is also an "Insured." *See* Ex. 1 at Bates No. OTPH0000016.

16. The Policy is a standard-form policy drafted by the insurance industry and/or contains language drafted by Crum & Forster.

17. Otsuka was obligated to, and did, pay a premium of One Hundred Forty-Two Thousand, Five Hundred Fifty Dollars ($142,550.00) as set forth in the Policy.

18. In exchange for the premium paid, Crum & Forster contractually agreed to "reimburse the [Plaintiffs] for [their] **Loss** . . . caused by or resulting from an **Insured Event** first discovered during the **Policy Period** and reported to the **Insurer** in accordance with General Conditions 4.20 (Notice of Loss)." *See* Ex. 1 at Bates No. OTPH0000007.

19. Item 3 of the Policy's Declarations lists the "**Policy Period**" as July 1, 2015 to July 1, 2016. *See* Ex. 1 at Bates No. OTPH0000005.

20. The Policy defines "**Insured Event**" as: "**Accidental Contamination**," "**Malicious Product Tampering**," "**Adverse Publicity**," and "**Governmental Recall**." *See* Ex. 1 at Bates No. OTPH0000008, as modified by the "Adverse Publicity" and "Governmental Recall" Endorsements at Bates Nos. OTPH0000024 – OTPH0000025.

21. The Policy defines "**Accidental Contamination**" as "any accidental or unintentional contamination, impairment or mislabeling of an **Insured Product(s)** or an omission of an ingredient in an **Insured Product(s)**, which occurs during or as a result of its production, preparation, processing, mixing, blending, compounding, manufacture, packaging or distribution; provided that the use or consumption of such **Insured Product(s)** has resulted in or would result in **Bodily Injury** or **Property Damage**." *See* Ex. 1 at Bates No. OTPH0000007.

22. The Policy defines "**Adverse Publicity**" as "the reporting of an actual or alleged **Accidental Contamination** during the **Policy Period** in local, regional or national media (including but not limited to radio, television, newspapers, magazines or the internet) or any governmental publication where the **Insured(s)** and the **Insured Product(s)** is specifically named." *See* Ex. 1 at Bates No. OTPH0000024.

23. The Policy defines "**Governmental Recall**" as "the recall, withdrawal, removal, recovery of possession or control, or disposal of the **Insured Product(s)** from a distributor, purchaser, or user of the **Insured Product(s)** ordered by a regularly constituted federal, state or local regulatory or administrative body because of potential **Bodily Injury** or **Property Damage** arising out of the use or consumption of the **Insured Product(s)**." *See* Ex. 1 at Bates No. OTPH0000025.

24. The Policy defines "**Loss**" as:

> [T]he following expenses or costs incurred by the **Insured(s)** directly and solely in connection with a covered **Insured Event**:

i. **Pre-Incident Costs**
ii. **Recall Costs**
iii. **Loss of Gross Profit**
iv. **Extra Expense**
v. **Replacement Costs**
vi. **Rehabilitation Expenses**
vii. **Extortion Costs**
viii. **Defense Costs**
ix. **Third Party Recall Liability**

Loss is limited to expenses or costs incurred within twelve (12) months of the **Insured(s) Event** first becoming known to the **Insured(s)**. **Loss** shall not include **Non-Incremental Costs**.

See Ex. 1 at Bates No. OTPH0000008, as modified by the "Loss of Gross Profit," "Extra Expense," "Replacement Costs," "Rehabilitation Expenses," "Extortion Costs," "Defense Costs," and the "Third Party Recall Liability" Endorsements at Bates No. OTPH0000019 – OTPH0000023, OTPH0000026.

25. The Policy then defines each of these enumerated types of "**Loss**" with its own respective definition.

26. For example, the Policy defines "**Recall Costs**" as:

[T]he reasonable costs incurred by the **Insured** for the recall, withdrawal, removal, recovery of possession or control, or disposal of such affected **Insured Product(s)** pursuant to an **Insured Event**. These costs are limited to the following:

i. The cost of newspaper, magazine or any printed advertising (whether electronic or otherwise), radio and television announcements or commercials, as well as the cost of correspondence regarding or concerning the recall.
ii. The cost of shipping the **Insured Product** from any purchaser, distributor or user to the place or places the **Insured** designates.
iii. The cost to rent additional warehouse or storage space.
iv. The cost of hiring additional person(s), other than regular employees of the **Insured**, to assist with the recall of the **Insured Product(s)**.
v. Overtime paid to regular employees, other than salaried employees, of the **Insured** for work devoted exclusively to the recall of the **Insured Product(s)**.

vi. Expenses (incl. transportation and accommodation costs) incurred by employees directly attributable to the recall of the **Insured Product(s)**.
vii. The cost of disposal of the **Insured Product(s)**, to the extent that specific methods of disposal, other than those usually employed for trash discarding or disposal, are required to avoid **Bodily Injury** or **Property Damage** as a result of such disposal.
viii. Expenses incurred to properly dispose of the unused packaging and point of purchasing marketing material of recalled **Insured Product(s)** if such packaging or material cannot be reused.
ix. The actual cost to redistribute any recalled **Insured Product(s)**.
x. Retail slotting fees and cancellation fees for any advertising and/or promotion programs, which were scheduled but were unable to be executed solely because of an **Insured Event**.
xi. Retailers' and other third party **Recall Costs** incurred during the recall of the **Insured Product(s)**.

See Ex. 1 at Bates No. OTPH0000009.

The Insured Event (i.e., The 2016 Recall)

27. On or about June 7, 2016, Pharmavite was forced to conduct a recall of certain products produced at its Opelika, Alabama, facility ("Opelika Facility").

28. The 2016 Recall resulted from certain personnel at the Opelika Facility failing to follow the required testing protocol set forth in Pharmavite's standard operating procedures.

29. Consistent with industry best practices, Pharmavite's testing protocol requires that all products that test positive on an initial "rapid test" be re-tested with a traditional "full plate test."

30. However, in a discrete number of occasions, it was determined that a quality control microbiologist at the Opelika Facility failed to perform the "full plate test" after receiving an initial "positive" result from the "rapid test." Instead, that individual performed the "rapid test" a second time, in direct violation of Pharmavite's testing protocol, and after receiving a negative result on the second "rapid test," approved the products for distribution.

31. Pharmavite discovered these violations of its testing protocol in early June 2016 during an audit conducted by its regulator, the FDA.

32. At that time, the FDA orally informed Pharmavite that the FDA believed a recall was necessary, and subsequent communications from the FDA confirmed this in writing.

33. Based on these discussions, the 2016 Recall was instituted, including issuing the standard public press release that was drafted in consultation with, and edited by, the FDA.

34. In a letter dated September 8, 2016, the FDA reviewed and approved both Pharmavite's decision to implement and the procedure used to effectuate the 2016 Recall.

35. In approving Pharmavite's execution of the 2016 Recall, FDA stated that it had

> reviewed [Pharmavite's] actions and conclude that they meet the formal definition of a "Recall." This is significant, as your actions are an alternative to a [FDA] legal action to remove your defective products from the market. The recalls will be listed in the upcoming FDA Enforcement Report.

36. In doing so, the FDA made clear that it would have issued a formal proceeding against Pharmavite and used its regulatory powers to compel a recall if Pharmavite had declined to conduct the 2016 Recall.

37. Since the 2016 Recall was announced, Pharmavite has received more than 200 complaints from consumers alleging they had suffered bodily injury as a result of consuming the affected product.

38. As a direct and proximate result of the 2016 Recall, the Plaintiffs have incurred "Loss," as that term is defined by the Policy, of approximately Nine Million Dollars ($9,000,000.00).

The Insurance Claim

39. In accordance with the timing requirements of the Policy, Plaintiffs provided contemporaneous and timely notice of the 2016 Recall to Crum & Forster.

40. Plaintiffs thereafter responded to a number of letters from Crum & Forster requesting additional information concerning the 2016 Recall.

41. Plaintiffs suffered "Loss" caused by or resulting from "Accidental Contamination" due to the accidental "contamination, impairment or mislabeling" of insured products that occurred during or as a result of the "production, preparation, processing . . . manufacture, packaging or distribution" and the use or consumption of the recalled insured products has resulted in or would result in bodily injury.

42. Plaintiffs suffered "Loss" caused by or resulting from "Adverse Publicity" due to the widespread reporting of the "Accidental Contamination" during the policy period in "local, regional or national media" and the "governmental publication where [Pharmavite] and the Insured Product(s) is specifically named."

43. Plaintiffs suffered "Loss" caused by or resulting from a "Governmental Recall" due to the "recall, withdrawal, removal, recovery of possession or control, or disposal" of the insured products "ordered by a regularly constituted federal . . . administrative body" because of "potential Bodily Injury or Property Damage" arising out of the use or consumption of the insured product.

44. Plaintiffs have satisfied all of the conditions and requirements of the Policy, including timely filing their final statement of Loss with Crum & Forster on October 5, 2017, which was well within the twenty-four month period designated by the Policy. *See* Ex. 1 at Bates No. OTPH0000013.

Crum & Forster's Erroneous Denial of Claim

45. In a letter dated February 7, 2017, Crum & Forster's outside counsel wrote to the Plaintiffs and wrongly disclaimed coverage for the 2016 Recall under the Policy's "Accidental Contamination," "Adverse Publicity," and "Governmental Recall" coverages.

46. A true and correct bates-stamped copy of Crum & Forster's declination letter is attached hereto as Exhibit 2.

47. In reaching its incorrect coverage denial, Crum & Forster ignored the plain language of its Policy and controlling New York law, choosing instead to adopt highly restrictive and questionable interpretations of the language of the Policy.

48. In a letter dated October 5, 2017, Plaintiffs' outside counsel responded to Crum & Forster's declination letter.

49. A true and correct bates-stamped copy of the Plaintiffs' response letter is attached hereto as Exhibit 3.

50. Although the Plaintiffs and Crum & Forster engaged in several months of settlement negotiations, those talks ultimately proved unsuccessful.

51. Therefore, in accordance with the terms and conditions of the Policy, Plaintiffs are filing this complaint for breach of contract and declaratory judgment within twenty-four months of submitting their final statement of Loss. *See* Ex. 1 at Bates No. OTPH0000011.

COUNT I: DECLARATORY JUDGMENT

52. The Plaintiffs repeat and re-allege all of the allegations of the preceding paragraphs as if those allegations were fully set forth herein.

53. The Policy sets forth the terms and conditions of the insurance contract between Crum & Forster and the Plaintiffs, including the Insuring Agreement and the definitions of "Accidental Contamination," "Adverse Publicity," and "Governmental Recall."

54. The Plaintiffs have not been compensated for their covered "Loss" arising out of the 2016 Recall as a result of Crum & Forster's improper interpretations of the Policy's terms and conditions and controlling case law.

55. As a result of the foregoing, an actual and justiciable controversy presently exists between the Plaintiffs and Crum & Forster regarding the meaning of the Policy and Crum & Forster's obligations to reimburse the Plaintiffs for Loss arising from the 2016 Recall.

56. The Plaintiffs are entitled to a declaration that Crum & Forster is obligated to reimburse, subject to the Policy's limit of liability, the Plaintiffs' Losses, including their reasonable and necessary expenses and lost profits that have been incurred to date.

COUNT II: BREACH OF CONTRACT

57. The Plaintiffs repeat and re-allege all of the allegations of the preceding paragraphs as if those allegations were fully set forth herein.

58. The Policy between the Plaintiffs and Crum & Forster constitutes a lawfully binding contract.

59. The Plaintiffs have satisfied all conditions precedent to coverage under the Policy, including fully paying the premium owed under the Policy.

60. The Policy sets forth the terms and conditions of the insurance contract between Crum & Forster and the Plaintiffs, including the meaning of "Accidental Contamination," "Adverse Publicity," and "Governmental Recall."

61. The Plaintiffs have suffered substantial Loss as a result of an Insured Event, triggering the "Accidental Contamination," "Adverse Publicity" and "Governmental Recall" coverage in the Policy.

62. The Plaintiffs have demanded performance under the contract.

63. Despite the plain language of the Policy set forth herein, Crum & Forster has improperly and unilaterally breached the Policy by failing to reimburse the Plaintiffs' covered Loss arising from the 2016 Recall.

64. As a direct and proximate result of Crum & Forster's breach of its obligations under the Policy, the Plaintiffs have suffered damages, and may suffer additional damages in the future.

PRAYER FOR RELIEF

WHEREFORE, for the foregoing reasons, the Plaintiffs respectfully request judgment as follows:

a. With respect to Count One, an order declaring that Crum & Forster is obligated to reimburse the Plaintiffs, subject to the Policy's limit of liability, for the Plaintiffs' Loss, including their reasonable and necessary expenses and lost profits that have been incurred to date.

b. With respect to Count Two, a ruling that Crum & Forster breached its contract with the Plaintiffs, by denying coverage under the Policy's Insuring Agreement and the definitions of "Accidental Contamination," "Adverse Publicity," and "Governmental Recall" and an order requiring Crum & Forster to pay damages to the Plaintiffs in an amount to be established at trial.

c. Any and all further relief that this Court finds appropriate, including the costs and expense of bring this action.

JURY DEMAND

Plaintiffs, OTSUKA AMERICA, INC. and PHARMAVITE LLC, request a jury trial in this proceeding.

DATED: January 30, 2018

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