

**IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION**

SOLUTEX, N.A. LLC,

Plaintiff,

v.

DESIGNS FOR HEALTH, INC., INNOVA
SOFTGEL, LLC D/B/A/ KD NUTRA, and
K.D. PHARMA BEXBACH L.L.C.

Defendants.

Case No. 3:20-cv-00800-MMH-JBT

Patent Case

Jury Trial Demanded

**PLAINTIFF’S FIRST AMENDED COMPLAINT FOR
PATENT INFRINGEMENT AND JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 15(a)(2), the Court’s April 14, 2021 Order amending the Scheduling Order (Dkt. 38), and the Court’s April 20, 2021 Order (Dkt. 40), Plaintiff Solutex N.A. LLC, (“Solutex”), by and through its attorneys, files this First Amended Complaint for Patent Infringement against Defendants Designs for Health Inc. (“DFH”), Innova Softgel, LLC d/b/a KD Nutra (“Innova”), and K.D. Pharma Bexbach L.L.C. (“KD Pharma”) (collectively, “Defendants”), stating as follows:¹

THE PARTIES

1. Plaintiff Solutex is a Delaware limited liability company with its principal place of business located at 200 East First St., Ste. 104, Winston-Salem, N. C. 27101.

¹ On April 8, 2020, Solutex, DHF, and Innova jointly moved to amend the Scheduling Order, including to extend the deadline to amend the pleadings and to add parties to April 16, 2021. *See* Dkt. 37. Before making that request, the parties discussed Solutex’s plans to amend the complaint and add KD Pharma to this case. KD Pharma is a related company to Innova and is already involved in this case. The joint motion was drafted by counsel for both sides, and explains: “Solutex plans to amend its complaint (and has informed opposing counsel of its plans) to include an additional party affiliated with [Innova] . . . Business principals of the soon-to-be added party are already aware of the case, and have been active in the settlement discussions on behalf of Innova and Designs for Health, Inc.” *Id.*, ¶ 4. Accordingly, DHF and Innova have given their consent, *see* FRCP 15(a)(2), and Solutex timely filed on April 16.

2. On information and belief, Defendant DFH is a corporation organized and existing under the laws of the State of Florida with its principal place of business located at 14 Commerce Boulevard, Palm Coast, Florida, 32164. On information and belief, DFH is authorized to do business in Florida, does business in the State of Florida and this District, and may be served with process through its registered agent for service of process, Northwest Registered Agent LLC, 7901 4th Street North, Suite 300, St. Petersburg, Florida 33702.

3. On information and belief, Defendant Innova is a Delaware limited liability company with its principal place of business located at 14193 SW 119th Avenue, Miami, Florida 33186. On information and belief, Innova is authorized to do business in Florida, does business in the State of Florida and this District, and may be served with process through its registered agent for service of process, Scott Woodruff, President, 14193 SW 119th Avenue, Miami, Florida 33186.

4. On information and belief, Defendant KD Pharma is a limited liability company organized and existing under the laws of Germany with its principal place of business located in Bexbach, Germany. On information and belief, KD Pharma is authorized to do business in Florida, does business in the State of Florida and this District, and may be served with process through Innova (which, is listed as KD Pharma's registered agent).

5. On information and belief, Innova and KD Pharma are related or associated corporations, including that Innova promotes itself as a "KD Pharma Group Company."

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., including but not limited to 35 U.S.C. §§ 271 and 281.

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendant DFH because, on information and belief, DFH is organized and existing under the laws of the State of Florida, DFH is headquartered and has a principal place of business in this District, and DFH has solicited and transacted business in this District, including business directly related to the patent infringement claims asserted in this action.

9. This Court has personal jurisdiction over Defendants Innova and KD Pharma because, on information and belief, both are registered to conduct business in the State of Florida, both have regularly and systematically conducted and solicited business in the State of Florida and this District, including business directly related to the patent infringement claims, asserted in this action, and both have established minimum contacts with this forum such that the exercise of jurisdiction over Innova and KD Pharma would not offend traditional notions of fair play and substantial justice.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (d) and 1400(b) because, on information and belief, Defendants are organized and/or registered to conduct business in the State of Florida and have regularly and systematically conducted and solicited business in the State of Florida and this District; Defendants are subject to personal jurisdiction in this District; and, a substantial part of the events or omissions giving rise to the claims asserted in this action occurred in this District. Specifically, on information and belief, Defendants have committed acts giving rise to this action in this District, including the manufacture, use, sale, offer for sale, and/or importation into the United States of the infringing products at issue herein.

FACTUAL BACKGROUND

Solutex, Specialized Proresolving Mediators, and the Asserted Patents

11. Solutex is a leading manufacturer and supplier of fish oil concentrations containing omega-3 fatty acids and certain derivatives of omega-3 fatty acids known as Specialized Proresolving Mediators or “SPMs.” Omega-3 fatty acids are essential fats that people need to survive. But unlike other essential fats, the body cannot make omega-3 fatty acids on its own; they must be obtained from food. The best food source of omega-3 fatty acids is fish, especially “fatty” or oily fish like salmon, tuna, sardines, anchovies, mackerel, and trout. Other food sources include vegetable oils, nuts, and leafy vegetables.

12. The two main omega-3 fatty acids in fish are: eicosapentaenoic acid (“EPA”) and docosahexaenoic acid (“DHA”). Years of research shows that EPA and DHA help to prevent inflammation and that people with higher levels of EPA and DHA in their blood and tissue generally see various health benefits, including improved cardiovascular health. Consequently, EPA and DHA are the active ingredients in most fish oil supplements sold in the US today.

13. More recently, attention has shifted to SPMs, which play more specific roles in the inflammatory process. While the research is still developing, there is a growing body of research that fish oil concentrations enriched with SPMs (or the precursors of SPMs recited in the asserted claims in this action) may provide even greater health benefits than EPA and DHA alone. Solutex is at the front of this transition and, based on foundational work involving SPMs, owns a portfolio of patents covering fish oil concentrations enriched with SPMs and SPM precursors.

14. United States Patent No. 10,568,858 (“the ’858 Patent”), entitled “Oils with Anti-Inflammatory Activity Containing Natural Specialized Proresolving Mediators and their Precursors,” was filed on May 9, 2013 and issued to Solutex on February 25, 2020. The ’858

Patent discloses and claims, among other things, fish oil concentrations (or “fractionates”) comprising SPMs or SPM precursors. Claim 1 is exemplary and recites:

A fish oil fractionate comprising 18-HEPE ethyl ester, 17-HDHA ethyl ester, 10-HDHA ethyl ester, 4-HDHA ethyl ester and 14-HDHA ethyl ester,

wherein the 17-HDHA ethyl ester is present in an amount of at least 100 mg/L, and

wherein the fractionate has anti-inflammatory or resolution stimulating activity.

A true and correct copy of the '858 Patent is attached as Exhibit A.

15. United States Patent No. 10,653,703 (“the '703 Patent”), entitled “Compositions Comprising Omega-3 Fatty Acids, 17-HDHA and 18-HEPE and Methods of Using Same,” was filed on September 6, 2016 and issued to Solutex on May 19, 2020. The '703 Patent discloses and claims, among other things, compositions comprising SPM precursors. Claim 1 is exemplary and recites:

A composition comprising:

omega-3 fatty acids present in an amount of about 20% to about 95%, by weight, of the composition; and

17-hydroxy-4Z,7Z,10Z,13Z,15E,19Z-docosahexaenoic acid (“17-HDHA”), 14-hydroxy-4Z,7Z,10Z,12E,16Z,19Z-docosahexaenoic acid (“14-HDHA”), and 18-hydroxy-5Z,8Z,11Z,14Z,16E-eicosapentaenoic acid (“18-HEPE”), wherein the 18-HEPE is present in an amount of 0.02% to about 1%, by weight, of the composition.

A true and correct copy of the '703 patent is attached as Exhibit B.

16. Solutex is the owner and assignee of all rights, title, and interest in and to the '858 and '703 Patents.

17. On information and belief, Defendants make, use, sell, offer for sale and/or import into the United States products infringing one or more claims of the '858 and/or '703 Patent -- including, at least, Claim 1 of both Patents (shown above).

The Infringing SPM Supreme Product (Sold by DFH and Made by Innova)

18. Defendant DFH offers for sale and/or sells in the United States a fish-oil dietary supplement marketed as “SPM Supreme.” DFH contracts with Defendant Innova to encapsulate, bottle, and label the SPM Supreme product sold by DFH in the United States. *See* Dkt. 23, ¶10. The SPM Supreme products are sold in bottles containing 60 softgels.



19. The SPM Supreme product is marketed on DFH’s website as “a combination of three highly potent ‘specialized pro-resolving mediators’ designed to help support the body’s natural ability to respond to physical challenges and ‘resolve’ the initial steps in the natural inflammatory process.” A printout from DFH’s website describing the “SPM Supreme” product is attached as Exhibit C.

20. The listed ingredients (shown below) of the SPM Supreme product are: Active Fractionated Marine Lipid Concentrate; olive oil; bovine gelatin, glycerine, purified water, natural lemon flavor, and tocotrienols.

Supplement Facts		
Serving Size 1 softgel		
Amount Per Serving	% Daily Value	
Calories	5	
Total Fat	0.5 g	1%*
Active Fractionated Marine Lipid Concentrate	300 mg	†
[standardized to 150 mcg Total Pro-Resolving Mediators (PRMs) - 18-hydroxyeicosapentaenoic acid (18-HEPE), 17-hydroxydocosahexaenoic acid (17-HDHA) and 14-hydroxydocosahexaenoic acid (14-HDHA)]		
*Percent Daily Values are based on a 2,000 calorie diet.		
†Daily Value not established.		

Other Ingredients: Olive oil, bovine gelatin, glycerine, purified water, natural lemon flavor, DeltaGold® tocotrienols.

Contains fish (anchovy, squid, sardine, mackerel, and herring).

See Exhibit C. The SPM Supreme product is “standardized” to include certain SPM precursors, including 18-HEPE, 17-HDHA, and 14-HDHA. *See id.* Based on product testing, it also includes 10-HDHA and 4-HDHA.

21. Based on product testing (and other documents produced in the action), the SPM Supreme product includes (a) omega-3 fatty acids in an amount of about 20% to about 95%, by weight, of the composition, (b) 18-HEPE in an amount of 0.02% to about 1%, by weight, of the composition, and (c) 17-HDHA ethyl ester in an amount of at least 100 mg/L.

22. On information and belief, DFH and Innova had knowledge of the ’858 Patent since its issuance on or about February 25, 2020.

23. On information and belief, DFH and Innova had knowledge of the ’703 Patent since its issuance on or about May 19, 2020.

The Infringing Concentrate (Sold by KD Pharma and Used by DFH and/or Innova)

24. Defendant KD Pharma makes the Active Fractionated Marine Lipid Concentrate (the “Concentrate”) used in the SPM Supreme product.

25. On information and belief, KD Pharma sells and/or offers to sell the Concentrate in the United States, including that: KD Pharma contracts with DFH and/or Innova in the United States to sell the Concentrate; DFH and/or Innova order, invoice, and initiate or make payment to purchase the Concentrate in the United States; KD Pharma delivers the Concentrate to DFH and/or Innova in the United States; DFH and/or Innova use the Concentrate to make the SPM Supreme product in the United States; and, KD Pharma knows that DFH and/or Innova will use the Concentrate to make and sell the SPM Supreme product.

26. On information and belief (including documents produced in the action), the Concentrate includes (a) each of the SPM precursors 18-HEPE, 17-HDHA, 14-HDHA, 10-HDHA, and 4-HDHA, (b) omega-3 fatty acids in an amount of about 20% to about 95%, by weight, of the composition, (c) 18-HEPE in an amount of 0.02% to about 1%, by weight, of the composition, and (d) 17-HDHA ethyl ester in an amount of at least 100 mg/L.

27. On information and belief, KD Pharma had knowledge of the '858 Patent since its issuance on or about February 25, 2020.

28. On information and belief, KD Pharma had knowledge of the '703 Patent since its issuance on or about May 19, 2020.

COUNT I INFRINGEMENT OF THE '858 PATENT
(Against DFH)

29. Solutex incorporates by reference Paragraphs 2, 14-26.

30. DFH has infringed and is currently infringing one or more claims of the '858 Patent in violation of 35 U.S.C. § 271(a), including but not limited to Claim 1, by, among other things, making, having made, using, importing, offering to sell and/or selling in the United States products that embody the patented invention, including, the SPM Supreme product made with the Concentrate.

31. Each of the SPM Supreme product and Concentrate include (a) the SPM precursors 18-HEPE, 17-HDHA, 14-HDHA, 10-HDHA, and 4-HDHA, and (b) 17-HDHA ethyl ester in an amount of at least 100 mg/L.

32. On information and belief, DFH's infringement of the '858 Patent has been willful and intentional because DFH had prior knowledge of the '858 Patent yet continues to infringe the patent by committing the acts described above.

33. DFH's infringement of the '858 Patent has caused and will continue to cause Solutex both monetary damage and irreparable harm for which it has no adequate remedy at law.

34. Unless this Court enjoins DFH's infringing conduct, Solutex will continue to be irreparably harmed by DFH's infringement of the '858 Patent.

COUNT II INFRINGEMENT OF THE '858 PATENT
(Against Innova)

35. Solutex incorporates by reference Paragraphs 3-5, 14-26.

36. Innova has infringed and is currently infringing one or more claims of the '858 Patent in violation of 35 U.S.C. § 271(a), including but not limited to Claim 1, by, among other things, making, having made, using, importing, offering to sell and/or selling in the United States products that embody the patented invention, including, the SPM Supreme product made with the Concentrate.

37. Each of the SPM Supreme product and Concentrate include (a) the SPM precursors 18-HEPE, 17-HDHA, 14-HDHA, 10-HDHA, and 4-HDHA, and (b) 17-HDHA ethyl ester in an amount of at least 100 mg/L.

38. On information and belief, Innova's infringement of the '858 Patent has been willful and intentional because Innova had prior knowledge of the '858 Patent yet continues to infringe the patent by committing the acts described above.

39. Innova's infringement of the '858 Patent has caused and will continue to cause Solutex both monetary damage and irreparable harm for which it has no adequate remedy at law.

40. Unless this Court enjoins Innova's infringing conduct, Solutex will continue to be irreparably harmed by Innova's infringement of the '858 Patent.

COUNT III INFRINGEMENT OF THE '858 PATENT
(Against KD Pharma)

41. Solutex incorporates by reference Paragraphs 3-5, 14-17, 24-28.

42. KD Pharma has infringed and is currently infringing one or more claims of the '858 Patent in violation of 35 U.S.C. § 271(a), including but not limited to Claim 1, by, among other things, offering to sell and/or selling in the United States products that embody the patented invention, including, the Concentrate.

43. The Concentrate includes (a) the SPM precursors 18-HEPE, 17-HDHA, 14-HDHA, 10-HDHA, and 4-HDHA, and (b) 17-HDHA ethyl ester in an amount of at least 100 mg/L.

44. On information and belief, KD Pharma's infringement of the '858 Patent has been willful and intentional because Innova had prior knowledge of the '858 Patent yet continues to infringe the patent by committing the acts described above.

45. KD Pharma's infringement of the '858 Patent has caused and will continue to cause Solutex both monetary damage and irreparable harm for which it has no adequate remedy at law.

46. Unless this Court enjoins KD Pharma's infringing conduct, Solutex will continue to be irreparably harmed by KD Pharma's infringement of the '858 Patent.

COUNT IV INFRINGEMENT OF THE '703 PATENT
(Against DFH)

47. Solutex incorporates by reference Paragraphs 2, 14-26.

48. DFH has infringed and is currently infringing one or more claims of the '703 Patent in violation of 35 U.S.C. § 271(a), including but not limited to Claim 1, by, among other things, making, having made, using, importing, offering to sell and/or selling in the United States products that embody the patented invention, including, the SPM Supreme product made with the Concentrate.

49. Each of the SPM Supreme product and Concentrate include (a) 18-HEPE, 17-HDHA, and 14-HDHA, (b) omega-3 fatty acids in an amount of about 20% to about 95%, by weight, of the composition, (c) 18-HEPE in an amount of 0.02% to about 1%, by weight.

50. On information and belief, DFH's infringement of the '703 Patent has been willful and intentional because DFH had prior knowledge of the '703 Patent yet continues to infringe the patent by committing the acts described above.

51. DFH's infringement of the '703 Patent has caused and will continue to cause Solutex both monetary damage and irreparable harm for which it has no adequate remedy at law.

52. Unless this Court enjoins DFH's infringing conduct, Solutex will continue to be irreparably harmed by DFH's infringement of the '703 Patent.

COUNT V INFRINGEMENT OF THE '703 PATENT
(Against Innova)

53. Solutex incorporates by reference Paragraphs 3-5, 14-26.

54. Innova has infringed and is currently infringing one or more claims of the '703 Patent in violation of 35 U.S.C. § 271(a), including but not limited to Claim 1, by, among other things, making, having made, using, importing, offering to sell and/or selling in the United States products that embody the patented invention, including, the SPM Supreme product made with the Concentrate.

55. Each of the SPM Supreme product and Concentrate include (a) 18-HEPE, 17-HDHA, and 14-HDHA, (b) omega-3 fatty acids in an amount of about 20% to about 95%, by weight, of the composition, (c) 18-HEPE in an amount of 0.02% to about 1%, by weight.

56. On information and belief, Innova's infringement of the '703 Patent has been willful and intentional because Innova had prior knowledge of the '703 Patent yet continues to infringe the patent by committing the acts described above.

57. Innova's infringement of the '703 Patent has caused and will continue to cause Solutex both monetary damage and irreparable harm for which it has no adequate remedy at law.

58. Unless this Court enjoins Innova's infringing conduct, Solutex will continue to be irreparably harmed by Innova's infringement of the '703 Patent.

COUNT VI INFRINGEMENT OF THE '703 PATENT
(Against KD Pharma)

59. Solutex incorporates by reference Paragraphs 3-5, 14-17, 24-28.

60. KD Pharma has infringed and is currently infringing one or more claims of the '703 Patent in violation of 35 U.S.C. § 271(a), including but not limited to Claim 1, by, among other things, offering to sell and/or selling in the United States products that embody the patented invention, including, the Concentrate.

61. The Concentrate includes (a) 18-HEPE, 17-HDHA, and 14-HDHA, (b) omega-3 fatty acids in an amount of about 20% to about 95%, by weight, of the composition, (c) 18-HEPE in an amount of 0.02% to about 1%, by weight.

62. On information and belief, KD Pharma's infringement of the '703 Patent has been willful and intentional because KD Pharma had prior knowledge of the '703 Patent yet continues to infringe the patent by committing the acts described above.

63. KD Pharma's infringement of the '703 Patent has caused and will continue to cause Solutex both monetary damage and irreparable harm for which it has no adequate remedy at law.

64. Unless this Court enjoins KD Pharma's infringing conduct, Solutex will continue to be irreparably harmed by KD Pharma's infringement of the '703 Patent.

PRAYER FOR RELIEF

Accordingly, Plaintiff Solutex respectfully requests that this Court enter judgment against Defendants as follows:

- A. A declaration that Defendants have infringed the '858 Patent and '703 Patent;
- B. A declaration that Defendants' infringement was willful;
- C. A preliminary and permanent injunction against continuing infringement of any of the claims of the '858 Patent and '703 Patent in any manner by Defendants and their respective officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert therewith;
- D. An accounting for damages in an amount adequate to compensate Solutex for Defendants' infringement, but in no event less than a reasonable royalty, including up to treble damages for willful infringement, and together with interest thereon;
- E. A judgment in favor of Solutex that this is an exceptional case under 35 U.S.C. § 285, and an award to Solutex of its costs, including its reasonable attorney fees and other expenses incurred in connection with this action;
- F. An award of prejudgment interest under 35 U.S.C. § 284 and post-judgment interest under 35 U.S.C. § 1961 on all damages awarded; and
- G. Such other costs and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff Solutex respectfully demands a jury trial on all issues so triable.

April 30, 2021

Respectfully submitted,

By: /s/ Michael D. Crosbie

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 30, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record, and I electronically served counsel for K.D. Pharma Bexbach L.L.C. (“KD Pharma”), who is also serving as counsel of record for the other Defendants, and who has agreed to accept service for KD Pharma for the limited purpose of this litigation, as follows:

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