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5 6 7 8 9 10	Karen I. Boyd (SBN 189808) FISH & RICHARDSON P.C. 500 Arguello Street, Suite 500 Redwood City, CA 94063 Telephone: (650) 839-5070 Facsimile: (650) 839-5071 Attorneys for Plaintiffs UNITHER PHARMA, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSIT and NEW YORK MEDICAL COLLEGE	ΓY ,	
12 13	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA		
14 15 16 17 18 19 20 21 22	UNITHER PHARMA, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, and NEW YORK MEDICAL COLLEGE, Plaintiffs and Counter-Defendants, v. THE DAILY WELLNESS COMPANY fka THE WELLNESS BEVERAGE COMPANY, Defendant and Counter-Claimant.	Case No. CV 02-05284 JW and Related Case No. CV 03-0415 JW SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL	
23 24	Plaintiffs Unither Pharma, Inc., the Board of Trustees of the Leland Stanford Jr. University and New York Medical College hereby allege as follows:		
25 26 27	THE PARTIES 1. Unither Pharma, Inc. ("Unither") is incorporated under the laws of the state of Delaware, and has a regular and established place of business at 1110 Spring Street, Silver Spring		
28	Maryland 20910. Unither is the successor in interest of Cooke Pharma, Inc. ("Cooke Pharma"),		

which was incorporated under the laws of the state of California and located at the same address as Unither.

- 2. The Board of Trustees of the Leland Stanford Jr. University ("Stanford") is a body having corporate powers under the laws of the state of California with a location in Stanford, California.
- 3. New York Medical College ("NYMC") is a body having corporate powers under the laws of the state of New York with a location in Valhalla, New York.
- 4. Upon information and belief, the Daily Wellness Company ("Daily Wellness"), formerly known as the Wellness Beverage Company, is incorporated under the laws of the State of California, and has a regular and established place of business at 271 Santa Ana Court, Sunnyvale, California 94085.

JURISIDICTION AND VENUE

- 5. This Court has subject matter jurisdiction of this action under 28 U.S.C. § 1338(a), in which the district courts have original and exclusive jurisdiction of any civil action for patent infringement.
- 6. This Court has personal jurisdiction over Defendant because Defendant Daily Wellness is located in and is doing business in this judicial district.
- 7. Venue is proper in this Court under 28 U.S.C. §§ 1391 (b), (c) and 1400 because Defendant Daily Wellness resides in this judicial district.

GENERAL ALLEGATIONS

8. Stanford is the assignee of certain patents related to the use of L-arginine in treating vascular disorders and improving vascular function and physical performance. These patents include U.S. Patent No. 5,428,070 ("the '070 patent," attached as "Exhibit A"), issued June 27, 1995, U.S. Patent No. 5,891,459 ("the '459 patent," attached as "Exhibit B"), issued April 6, 1999, U.S. Patent No. 6,117,872 ("the '872 patent," attached as "Exhibit C"), issued September 12, 2000, and U.S. Patent No. 6,646,006 ("the '006 patent," attached as "Exhibit D"), issued November 11, 2003.

- 9. NYMC is the assignee of U.S. Patent No. 5,217,997 ("the '997 patent," attached as "Exhibit E"), issued June 8, 1993, related to the use of L-arginine in treating high vascular resistance disorders.
- 10. Stanford and Cooke Pharma entered into agreements under which Stanford granted Cooke Pharma an exclusive license under the '872, '070, '459, and '006 patents for the use and sale of amino acid–based dietary supplements or pharmaceuticals to enhance the level of endogenous nitric oxide in the vascular system. Under the same agreements, Stanford provided Cooke Pharma with a right to institute actions and recover damages for infringement of the '872, '070, '459, and '006 patents and the right to join Stanford as a plaintiff in any such action. Unither is the successor in interest to all rights granted by Stanford to Cooke Pharma under the agreements.
- 11. NYMC and Cooke Pharma entered into an agreement under which NYMC granted Cooke Pharma an exclusive worldwide license under the '997 patent for the manufacture, use, and sale of amino acid–based functional foods, dietary supplements, medical foods, or pharmaceuticals. Under the same agreement, NYMC provided Cooke Pharma with a right to institute actions and recover damages for infringement of the '997 patent and the right to join NYMC as a plaintiff in any such action. Unither is the successor in interest to all rights granted to Cooke Pharma under that agreement.
- 12. Unither manufactures and sells products containing L-arginine designed to improve vascular health, improve human sexual performance, and treat erectile dysfunction, which are covered by the '872, '070, '459, '006, and '997 patents.
- 13. Upon information and belief, Defendant Daily Wellness competes with Unither and manufactures and sells at least three products, ArginMaxTM for Men, ArginMaxTM for Women, and FertilityBlendTM for Women, that contain L-arginine as the primary active ingredient.
- 14. Upon information and belief, Defendant Daily Wellness advertises, inter alia, that its L-arginine-based products improve vascular health and support healthy erectile functioning and blood pressure.

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FIRST CAUSE OF ACTION

(INFRINGEMENT OF THE '872 PATENT)

- 15. Each allegation contained in paragraphs 1-14 above is incorporated herein by reference.
- 16. Defendant Daily Wellness has had actual notice that the use of its products are covered by the claims of the '872 patent since at least May 1, 2001 (Letter to Daily Wellness attached as "Exhibit F").
- 17. Defendant Daily Wellness is currently and has been infringing, inducing and/or contributing to the infringement of the claims of the '872 patent by making, using, selling, offering to sell and/or importing its products containing L-arginine without the consent of Unither.
- 18. Defendant Daily Wellness will continue to infringe, induce and/or contribute to the infringement of the claims of the '872 patent unless enjoined by this Court.
- 19. Defendant Daily Wellness has willfully and deliberately infringed, induced and/or contributed to the infringement of the claims of the '872 patent with full knowledge and disregard of Plaintiffs' rights thereunder, rendering this an "exceptional" case within the meaning of 35 U.S.C. § 285.
 - 20. As a result of Defendant Daily Wellness's acts, Plaintiffs have suffered damages.

SECOND CAUSE OF ACTION

(INFRINGEMENT OF THE '070 PATENT)

- 21. Each allegation contained in paragraphs 1-20 above is incorporated herein by reference.
- 22. Defendant Daily Wellness has had actual notice that the use of its products are covered by the claims of the '070 patent since at least January 20, 2000 (Letter to Daily Wellness attached as "Exhibit G").
- 23. Defendant Daily Wellness is currently and has been infringing, inducing and/or contributing to the infringement of the claims of the '070 patent by making, using, selling, offering to sell and/or importing its products containing L-arginine without the consent of Unither.

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- 34. Defendant Daily Wellness has had actual notice that the use of its products are covered by the claims of the '997 patent since at least January 20, 2000 (Letter to Daily Wellness attached as "Exhibit G").
- 35. Defendant Daily Wellness is currently and has been infringing, inducing and/or contributing to the infringement of the claims of the '997 patent by making, using, selling, offering to sell and/or importing its products containing L-arginine without the consent of Unither.
- 36. Defendant Daily Wellness will continue to infringe, induce and/or contribute to the infringement of the claims of the '997 patent unless enjoined by this Court.
- 37. Defendant Daily Wellness has willfully and deliberately infringed, induced and/or contributed to the infringement of the claims of the '997 patent with full knowledge and disregard of Plaintiffs' rights thereunder, rendering this an "exceptional" case within the meaning of 35 U.S.C. § 285.
 - 38. As a result of Defendant Daily Wellness's acts, Plaintiffs have suffered damages.

FIFTH CAUSE OF ACTION (INFRINGEMENT OF THE '006 PATENT)

- 39. Each allegation contained in paragraphs 1-38 above is incorporated herein by reference.
- 40. Defendant Daily Wellness is currently and has been infringing, inducing and/or contributing to the infringement of the claims of the '006 patent by making, using, selling, offering to sell and/or importing its products containing L-arginine without the consent of Unither.
- 41. Defendant Daily Wellness will continue to infringe, induce and/or contribute to the infringement of the claims of the '006 patent unless enjoined by this Court.
- 42. Defendant Daily Wellness has willfully and deliberately infringed, induced and/or contributed to the infringement of the claims of the '006 patent with full knowledge and disregard of Plaintiffs' rights thereunder, rendering this an "exceptional" case within the meaning of 35 U.S.C. § 285.
 - 43. As a result of Defendant Daily Wellness's acts, Plaintiffs have suffered damages.

SIXTH CAUSE OF ACTION

(PROVISIONAL RIGHTS UNDER THE '006 PATENT)

- 44. Each allegation contained in paragraphs 1-43 above is incorporated herein by reference.
- 45. The United States Patent and Trademark Office published U.S. Patent Application No. 10/060,252 ("the '252 application"), now the '006 patent, pursuant to 35 U.S.C. § 122(b), 37 C.F.R. § 1.211, et seq., on October 17, 2002, Publication No. US 2002/0151592 A2 (attached as "Exhibit H").
- 46. The invention as claimed in the '006 patent is substantially identical to the invention as claimed in the published '252 application.
- 47. Defendant Daily Wellness has had actual notice of the '252 application since at least November 6, 2002 (Letter to Daily Wellness attached as "Exhibit I").
- 48. Defendant Daily Wellness violated Plaintiffs' provisional rights under the '006 patent by making, using, selling, offering to sell and/or importing its products containing L-arginine without the consent of Unither.
- 49. As a result of Defendant Daily Wellness's acts, Plaintiffs have suffered damages and are entitled to a reasonable royalty.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

- a. That this Court adjudge and declare that Defendant Daily Wellness has infringed, induced and/or contributed to the infringement of the '997, '872, '070, '459, and '006 patents;
- That this Court adjudge and declare that Defendant Daily Wellness has violated
 Plaintiffs' provisional rights under the '006 patent;
- c. That this Court preliminarily enjoin Defendant Daily Wellness, its officers, directors, employees, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or in concert with them from infringing, actively inducing

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1			infringement or contributing to infringement of the '997, '872, '070, '459, and '006
2			patents;
3		d.	That this Court permanently enjoin Defendant Daily Wellness, its officers, directors,
4			employees, agents, licensees, servants, successors and assigns, and any and all
5			persons acting in privity or in concert with them from infringing, actively inducing
6			infringement and/or contributing to infringement of the '997, '872, '070, '459, and
7			'006 patents;
8		e.	That this Court award to Plaintiffs damages adequate to compensate them for
9			Defendant Daily Wellness's acts of infringement, inducement of and/or contributions
10			to infringement of the '997, '872, '070, '459, and '006 patents, together with interest
11			thereon;
12		f.	That this Court award to Plaintiffs reasonable royalties for Defendant Daily
13			Wellness's violation of Plaintiffs' provisional rights under the '006 patent;
14		g.	That this Court award treble damages against Defendant Daily Wellness for its
15			willful infringement, inducement of and/or contribution to infringement of the '997,
16			'872, '070, '459, and '006 patents;
17		h.	That this Court order Defendant Daily Wellness to pay Plaintiffs their reasonable
18			attorneys' fees for this action;
19		i.	That this Court order Defendant Daily Wellness to pay Plaintiffs any and all costs of
20			this action; and,
21		j.	That this Court grant to Plaintiffs such other and further relief as it may deem just
22			and equitable.
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A JURY TRIAL IS DEMANDED BY PLAINTIFFS. Dated: November 17, 2003 FISH & RICHARDSON P.C. By: $/_{\rm S}/$ Karen I. Boyd Attorney for Plaintiffs UNITHER PHARMA, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, AND NEW YORK MEDICAL COLLEGE

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CERTIFICATION PURSUANT TO CIVIL L.R. 3-16 1 2 Pursuant to Civil L.R. 3-16, the undersigned certifies that the following listed persons, 3 associations of persons, firms, partnerships, corporations (including parent corporations) or other 4 entities (i) have a financial interest in the subject matter in controversy or in a party to the 5 proceeding, or (ii) have a non-financial interest in that subject matter or in a party that could be 6 substantially affected by the outcome of this proceeding: 7 United Therapeutics Corporation, which is the parent of wholly owned subsidiary Unither 8 Pharma, Inc., one of the plaintiffs in this action. 9 10 Dated: November 17, 2003 FISH & RICHARDSON P.C. 11 12 By: Karen I. Boyd 13 Attorney for Plaintiffs 14 UNITHER PHARMA, INC., THE BOARD OF TRUSTEES OF THE LELAND 15 STANFORD JUNIOR UNIVERSITY, AND 16 NEW YORK MEDICAL COLLEGE 17 50183935.doc 18 19 20 21 22 23 24 25 26

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