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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVERETT LABORATORIES, INC., Plaintiff, v. ACELLA PHARMACEUTICALS, LLC, Defendant.	Civil Action No. _____ Hon. _____ U.S.D.J. **COMPLAINT FOR PATENT INFRINGEMENT AND JURY DEMAND** (Document Filed Electronically)

Plaintiff Everett Laboratories, Inc. ("Everett"), by its undersigned attorneys, for its Complaint against Defendant Acella Pharmaceuticals, LLC ("Acella" or "Defendant"), alleges as follows:

INTRODUCTION AND SUMMARY

1. This action seeks redress for Acella's deliberate and willful infringement of U.S. Patent No. 6,814,983 (the "'983 Patent") (a copy of which is attached as **Exhibit A** hereto) and U.S. Patent No. 7,390,509 (the "'509 Patent") (a copy of which is attached as **Exhibit B** hereto) through Acella's manufacture, use, marketing, offering for sale, selling, and/or importing of its prescription-only, prenatal nutritional supplement called "PNV - OB with DHA" (hereafter also referred to as "Defendant's Product"), which is a willful exact copy of Everett's "Vitafol®-

OB+DHA" prescription-only, prenatal nutritional supplement. Both Vitafol®-OB+DHA and "PNV - OB with DHA" are sold in a two-component blister pack, with the first component being a caplet and the second component being a gelcap. The claims of the '983 Patent and '509 Patent are based on the caplet component of Vitafol®-OB+DHA.

2. According to its package insert, the caplet component of Defendant's Product contains the same vitamins and minerals, in the same amounts, as the caplet component of Everett's Vitafol®-OB+DHA. Defendant's Product hence directly infringes Claims 1-2 of the '983 Patent and Claims 1-2 of the '509 Patent. Additionally, because Acella sells and distributes the caplet component of Defendant's Product with a package insert that instructs the method of using Defendant's Product to provide nutritional supplementation to the patient, Acella is also inducing direct infringement of method Claims 3-4 of the '983 Patent and Claims 3-4 of the '509 Patent by patients.

3. Because, on information and belief, leading computerized drug databases (such as First DataBank and/or Medi-Span) have "linked" Defendant's Product to Vitafol®-OB+DHA, which causes wholesalers that utilize information from the drug databases to offer the lower-priced copy product Defendant's Product for the branded Vitafol®-OB+DHA product and causes pharmacies that utilize information from the drug databases to substitute the lower-priced copy product Defendant's Product for the branded Vitafol®-OB+DHA product when presented with a prescription for Vitafol®-OB+DHA, Everett is being and will continue to rapidly and increasingly be irreparably harmed as a result of the existence of the infringing "PNV - OB with DHA" product (Defendant's Product) in the market. It can be expected that, within less than one year of Defendant's Product being "linked" to Vitafol®-OB+DHA, Defendant's Product will have displaced 90 percent of the sales that otherwise would have been made by Everett of its Vitafol®-OB+DHA product by virtue of the "linking."

4. The presence of Defendant's Product in the market creates a huge dilemma – a "Hobson's Choice" for Everett. Either Everett stops marketing its Vitafol®-OB+DHA product or continues to spend money to market it to the advantage of its infringing competitor, Acella. Yet, if Everett stops marketing Vitafol®-OB+DHA, Everett will forfeit sales to other nutritional supplement companies which, unlike Everett, will still have an incentive to market and promote their products to doctors.

JURISDICTION AND VENUE

5. This Court has original and exclusive jurisdiction of this action, pursuant to 28 U.S.C. §§ 1331 and 1338(a), because the action arises under the Patent Laws of the United States, Title 35, United States Code. The Court also has original jurisdiction over the copyright infringement claim stated herein, pursuant to 28 U.S.C. § 1338(b), because that claim arises under Section 501(a) of the Copyright Act, 17 U.S.C. § 501(a).

6. The Court has personal jurisdiction over Defendant Acella in this action because Defendant regularly conducts business in New Jersey, has engaged in infringing acts in New Jersey, and specifically has offered to sell, offers to sell, has sold, and/or sells the product that is the subject of this Complaint in New Jersey and in this judicial district.

7. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to this Complaint occurred in this judicial district.

THE PARTIES

8. Everett is a corporation organized and existing under the laws of the State of New Jersey, having its headquarters and principal place of business at One Main Street, Suite 203, Chatham, New Jersey, 07928.

9. Upon information and belief, Acella is a Delaware limited liability company, having its principal place of business at 11675 Great Oaks Way, Suite 144, Alpharetta, GA 30022.

STATEMENT OF FACTS

Plaintiff Everett Laboratories, Inc. And Its Vitafol®-OB+DHA Product

10. Plaintiff Everett is a pharmaceutical company that has been marketing and selling and continues to market and sell various prescription-only nutritional supplement products throughout the United States. Everett's reputation has been and continues to be enviable both in the trade and to the general consuming public in the United States. Everett is well known to prescribers of prescription-only nutritional supplements and medicines as well as to retailers, wholesalers, physicians, pharmacists, patients, and distributors in the industry in the United States.

The Vitafol®-OB+DHA Product

11. Since February 2007, Everett has engaged in selling a nutritional supplement called Vitafol®-OB+DHA, which was formulated to deliver essential vitamins and minerals to the mother and her developing fetus. The caplet component of Vitafol®-OB+DHA contains specified quantities of vitamins A, D, C, E, folic acid, B_1, B_2, B_6, B_{12}, and niacin; and minerals calcium, iron, magnesium, zinc, and copper. *See* Vitafol®-OB+DHA package/product insert attached hereto as **Exhibit C**. It also contains a softgel capsule containing, *inter alia*, DHA from algae. *See* Vitafol®-OB+DHA package/product insert attached hereto as **Exhibit C**.

12. Vitafol®-OB+DHA is a "branded product." The U.S. Food and Drug Administration ("FDA") regulates "branded" drugs. Although prescription-only prenatal vitamins are not regulated like drugs are by the FDA, the parallels are similar and hence this Complaint uses the term "branded" to refer to Everett's innovator products.

13. On November 9, 2004, the U.S. Patent and Trademark Office issued the '983 Patent (**Exhibit A** hereto) for the product formulation of the caplet component of Vitafol®-OB+DHA and related methods of use.

14. Claim 1 of the '983 Patent recites the following:

> 1. A composition comprising about 2430 IU to about 2970 IU Vitamin A, about 360 IU to about 440 IU Vitamin D, about 63 mg to about 77 mg Vitamin C, about 27 IU to about 33 IU Vitamin E, about 0.9 mg to about 1.1 mg folic acid, about 1.44 mg to about 1.76 mg Vitamin B1, about 1.62 mg to about 1.98 mg Vitamin B2, about 2.25 mg to about 2.75 mg Vitamin B6, about 10.8 mcg to about 13.2 mcg Vitamin B12, about 16.2 mg to about 19.8 mg niacin, about 90 mg to about 110 mg calcium, about 58.5 mg to about 71.5 mg iron, about 22.5 mg to about 27.5 mg magnesium, about 22.5 mg to about 27.5 mg zinc, and about 1.8 mg to about 2.2 mg copper, wherein said composition is administerable to a patient, and wherein said composition is free of any other added minerals and any other added vitamins.

15. The named inventors of the '983 Patent are John A. Giordano and Charles Balzer. Everett is the owner by assignment of the '983 Patent.

16. On June 24, 2008, the U.S. Patent and Trademark Office issued the '509 Patent (**Exhibit B** hereto) for the product formulation of the caplet component of Vitafol®-OB+DHA and related methods of use.

17. Claim 1 of the '509 Patent recites the following:

> 1. A composition consisting of about 2430 IU to about 3970 IU Vitamin A, about 360 IU to about 440 IU Vitamin D, about 63 mg to about 77 mg Vitamin C, about 27 IU to about 33 IU Vitamin E, about 0.9 mg to about 1.1 mg folic acid, about 1.44 mg to about 1.76 mg Vitamin B_1, about 1.62 mg to about 1.98 mg Vitamin B_2, about 2.25 mg to about 2.75 mg Vitamin B6, about 10.8 mcg to about 13.2 mcg Vitamin B_{12}, about 16.2 mg to about 19.8 mg niacin, about 90 mg to about 110 mg calcium, about 58.5 mg to about 71.5 mg non-chelated iron, about 22.5 mg to about 27.5 mg magnesium, about 22.5 mg to about 27.5 mg zinc,

and about 1 .8 mg to about 2.2 mg copper, and one or more pharmaceutical carriers.

18. The named inventors of the '509 Patent are John A. Giordano and Charles Balzer. Everett is the owner by assignment of the '509 Patent.

19. Everett has engaged in extensive advertising and promotion of Vitafol®-OB+DHA to gain goodwill and public recognition of its product. To that end, Everett has spent substantial sums of money and resources to develop, advertise, and market Vitafol®-OB+DHA.

20. Everett has caused Vitafol®-OB+DHA to be listed in online drug databases that pharmacies use in filling prescriptions for prenatal nutritional supplements, including the leading drug database, First DataBank, as well as Medi-Span, and Gold Standard.

Defendant Acella And Its "PNV - OB with DHA" Product (Defendant's Product)

21. Acella is a Delaware limited liability company with offices in Alpharetta, Georgia. On information and belief, its business model includes formulating alternatives or substitutes for existing branded vitamin products and offering them for sale at lower prices.

22. Acella directly competes with Everett in the market for prescription-only, prenatal supplements containing DHA.

Defendant's Product

23. Upon information and belief, Acella uses, manufactures, markets, offers for sale, imports, and/or sells its "PNV - OB with DHA" product, which is a copy of, and hence competes directly with, Everett's Vitafol®-OB+DHA product. A copy of the package insert for Defendant's Product is attached as **Exhibit D** hereto. Acella sells its "PNV - OB with DHA" copy product of Everett's Vitafol®-OB+DHA product at a significantly lower price than Everett's Vitafol®-OB+DHA product. Upon information and belief, Acella offers for sale and has sold its lower-cost its "PNV - OB with DHA" copy product at pharmacies in this judicial district.

24. According to the package insert for Defendant's Product (**Exhibit D**), and as shown in the following Chart 1, Defendant's Product directly infringes Claim 1 of the '983 Patent, as its caplet component contains the same vitamins and minerals listed in Claim 1 of the '983 Patent, and it further contains them in identical amounts as the caplet component of Vitafol®-OB+DHA:

CHART 1

Ingredient	'983 Patent, Claim 1	Vitafol®-OB + DHA Product Insert	PNV-OB with DHA Package Insert
Vitamin A	about 2430 IU to about 2970 IU	2700 IU	2700 IU
Vitamin D	about 360 IU to about 440 IU	400 IU	400 IU
Vitamin C	about 63 mg to about 77 mg	70 mg	70 mg
Vitamin E	about 27 IU to about 33 IU	30 IU	30 IU
Folic Acid	about 0.9 mg to about 1.1 mg folic acid,	1 mg	1 mg
Vitamin B_1	about 1.44 mg to about 1.76 mg	1.6 mg	1.6 mg
Vitamin B_2	about 1.62 mg to about 1.98 mg	1.8 mg	1.8 mg
Vitamin B_6	about 2.25 mg to about 2.75 mg	2.5 mg	2.5 mg
Vitamin B_{12}	about 10.8 mcg to about 13.2 mcg	12 mcg	12 mcg
Niacin	about 16.2 mg to about 19.8 mg	18 mg	18 mg
Calcium	about 90 mg to about 110 mg	100 mg	100 mg
Iron	about 58.5 mg to about 71.5 mg	65 mg	65 mg
Magnesium	about 22.5 mg to about 27.5 mg	25 mg	25 mg
Zinc	about 22.5 mg to about 27.5 mg	25 mg	25 mg
Copper	about 1.8 mg to about 2.2 mg	2 mg	2 mg
Other added minerals or vitamins	None	None	None

25. Defendant's Product also directly infringes Claim 2 of the '983 Patent.

26. Additionally, because Acella sells and distributes the caplet component of Defendant's Product with a package insert that instructs the method of using the caplet component of Defendant's Product to provide nutritional supplementation to the patient, Acella is also inducing direct infringement of method Claims 3-4 of the '983 Patent by the patients.

27. According to the package insert for Defendant's Product (**Exhibit D**), and as shown in the following Chart 2, Defendant's Product directly infringes Claim 1 of the '509 Patent, as its caplet component contains the same vitamins and minerals listed in Claim 1 of the '509 Patent, and it further contains them in identical amounts as the caplet component of Vitafol®-OB+DHA:

CHART 2

Ingredient	'509 Patent, Claim 1	Vitafol®-OB + DHA Product Insert	PNV-OB with DHA Package Insert
Vitamin A	about 2430 IU to about 2970 IU	2700 IU	2700 IU
Vitamin D	about 360 IU to about 440 IU	400 IU	400 IU
Vitamin C	about 63 mg to about 77 mg	70 mg	70 mg
Vitamin E	about 27 IU to about 33 IU	30 IU	30 IU
Folic Acid	about 0.9 mg to about 1.1 mg folic acid,	1 mg	1 mg
Vitamin B_1	about 1.44 mg to about 1.76 mg	1.6 mg	1.6 mg
Vitamin B_2	about 1.62 mg to about 1.98 mg	1.8 mg	1.8 mg
Vitamin B_6	about 2.25 mg to about 2.75 mg	2.5 mg	2.5 mg
Vitamin B_{12}	about 10.8 mcg to about 13.2 mcg	12 mcg	12 mcg
Niacin	about 16.2 mg to about 19.8 mg	18 mg	18 mg
Calcium	about 90 mg to about 110 mg	100 mg	100 mg

Ingredient	'509 Patent, Claim 1	Vitafol®-OB + DHA Product Insert	PNV-OB with DHA Package Insert
Iron	about 58.5 mg to about 71.5 mg	65 mg	65 mg
Magnesium	about 22.5 mg to about 27.5 mg	25 mg	25 mg
Zinc	about 22.5 mg to about 27.5 mg	25 mg	25 mg
Copper	about 1.8 mg to about 2.2 mg	2 mg	2 mg
Pharmaceutical carriers	One or more	Microcrystalline cellulose, croscarmellose sodium, stearic acid, hydroxypropyl methylcellulose, titanium dioxide, polydextrose, magnesium stearate, colloidal silicon dioxide, hydroxypropyl cellulose, triacetin, dicalcium phosphate, FD&C Blue #1 Aluminum Lake, polyethylene glycol, FD&C Blue #2 Aluminum Lake, D&C Yellow #10 Aluminum Lake	Dicalcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, stearic acid, and silicon dioxide

28. Defendant's Product also directly infringes Claim 2 of the '509 Patent.

29. Additionally, because Acella sells and distributes the caplet component of Defendant's Product with a package insert that instructs the method of using the caplet component of Defendant's Product to provide nutritional supplementation to the patient, Acella is also inducing direct infringement of method Claims 3-4 of the '509 Patent by the patients.

Linking And Automatic Substitution By Drug And Nutritional Supplement Databases

30. Computerized drug databases (also known as compendia) – such as First DataBank, Medi-Span, and Gold Standard – link non-branded copy products to branded products

by comparing the key active ingredients of each product. If the products match in terms of type, content, and amount of the key ingredients considered by the database, the products will be linked. If products are linked, there is typically automatic substitution by the pharmacies that are asked to fill the prescription by the copy product with the lower price. Indeed, many insurance companies and other third-party payers insist that the cheaper, copy product be substituted for the branded product.

31. First DataBank and Medi-Span categorize products for purposes of determining substitutability based upon labeling provided to them by manufacturers. Their customers include retail pharmacy chains, drug wholesalers, health management organizations, insurance companies, and Medicaid state agencies. These customers purchase data from First DataBank and Medi-Span for use in their own computer database systems (such as databases utilized by pharmacists at retail pharmacies). These data support pharmacy dispensing, formulary management, drug pricing analysis, and electronic prescribing. Most major retail pharmacies and pharmacy chains rely on data provided by First DataBank or Medi-Span to assist the pharmacist in making dispensing decisions about prescription products. Specifically, First DataBank data is utilized by Rite Aid®, CVS®, CVS Caremark®, Safeway®, Publix®, and Costco® pharmacy chains, and Medi-Span data is utilized by Walgreens® and Wal-Mart® pharmacy chains.

32. First DataBank and Medi-Span obtain data about new pharmaceutical products directly from the products' manufacturers and/or distributors. Prior to the launch of a new product, manufacturers and/or distributors submit new product information to First DataBank and Medi-Span. This information includes labels, product inserts or package inserts, and other promotional materials that describe the product's ingredients, strength, dosage form, route of administration, and price.

33. Neither First DataBank nor Medi-Span performs or sponsors any independent testing of pharmaceutical products. Both databases rely strictly on information provided to them by product manufacturers and/or distributors concerning their products.

34. When First Databank first receives information about a new pharmaceutical product, it is reviewed by a research associate in the Editorial Services Department. The research associate will identify the product's key active ingredients and their strength, the dosage form, and the route of administration. If an existing product with the same key active ingredients in the same strengths, in the same dosage form, and with the same route of administration is found within the First DataBank database, the research associate will assign the new product to the same clinical formulation ID (also known as the "Generic Code Number" or "GCN code") as that assigned to the existing product in the database. The clinical formulation ID is the newly-formed identifier name for what was previously known as the Generic Code Number. Products which have the same GCN code are considered pharmaceutically equivalent to each other. Products having the same GCN code are also described as being "linked." If more than one product is assigned to the same GCN code, those products are described as "multiple source" products, *i.e.*, they are pharmaceutically equivalent products that are available from multiple sources.

35. Medi-Span has an analog to First DataBank's GCN code, which Medi-Span refers to as the "Generic Product Identifier" or "GPI code." Products assigned to the same GPI code in the Medi-Span database have the same key active ingredients in the same strengths, in the same dosage form, with the same route of administration, and are also considered pharmaceutically equivalent to each other. Products having the same GPI code are also said to be "linked."

36. When pharmacists at the retail pharmacies that utilize First DataBank and Medi-Span data process prescriptions written by doctors for Everett's Vitafol®-OB+DHA prenatal

vitamin supplement product, they will substitute defendant Acella's "PNV - OB with DHA" prenatal vitamin supplement product for Everett's Vitafol®-OB+DHA prenatal vitamin supplement product due to the linking of those products in the First DataBank and Medi-Span databases.

37. Pharmacists will make substitutions in order to capitalize upon the advantage of the lower price of Defendant Acella's "PNV - OB with DHA" generic copy product that may inure to the benefit of the patients for whom the prescriptions are being filled and/or their insurance companies (based on lower co-payment rates typically set by insurance companies for lower-priced generic copy products in order to encourage their substitution for higher-priced brand-name products), and/or the pharmacy chain from which the patient is purchasing the product and potentially the pharmacy chain's wholesaler (based on incentives created by contracts in various potential combinations between the pharmacy chain, the wholesaler, and the generic copy manufacturer such as Acella that proliferate distribution and sales of lower-priced generic copy products). Everett's sales of its Vitafol®-OB+DHA product will therefore immediately and rapidly be displaced by sales of Defendant Acella's "PNV - OB with DHA" product, respectively, due to the linking of Defendant's Product to Vitafol®-OB+DHA in the databases of First DataBank and/or Medi-Span as described hereinabove.

38. The practice of substitution is so common that displacement of sales and erosion of the market for a branded product begins to take place immediately upon a copy product being linked to it in the databases, and that sales displacement and market erosion continues to grow quickly over time, such that, in the case of Everett's innovative branded Vitafol®-OB+DHA product and Acella's "PNV - OB with DHA" generic copy product, sales of Everett's Vitafol®-OB+DHA product will be 90 percent displaced by Acella's "PNV - OB with DHA" generic copy product, respectively, within one year.

Drug Databases Are Linking Defendant's Product To Vitafol®-OB+DHA

39. On information and belief, including based on certain "screen shots" obtained by Everett, wholesalers are listing and offering Defendant's Product as a substitute for Vitafol®-OB+DHA and pharmacies are substituting Defendant's Product for Vitafol®-OB+DHA, based on the "linking" of Defendant's Product to Vitafol®-OB+DHA in one or more of the leading drug databases. In fact, based on certain additional "screen shots" obtained by Everett, First DataBank is at least one specific leading drug database that is already "linking" Defendant's Product to Vitafol®-OB+DHA in its database, which information is available to the wholesalers and pharmacies who utilize First DataBank data. Accordingly, for instance, when pharmacists at the retail pharmacies that show Defendant's Product as being linked to Vitafol®-OB+DHA based on the "linking" of Defendant's Product to Vitafol®-OB+DHA in the drug databases utilized by those pharmacies (including at least First DataBank) fill a prescription for a customer with a prescription for Vitafol®-OB+DHA, the pharmacists will substitute Defendant's Product for customers with a prescription for Vitafol®-OB+DHA. Pharmacists will make those substitutions in order to capitalize upon the advantage of the significantly lower price of the Acella copy product, "PNV - OB with DHA" (Defendant's Product). Everett's sales of its branded Vitafol®-OB+DHA product will therefore be displaced by sales of Acella's "PNV - OB with DHA" product due to the linking of the products.

Everett's Irreparable Harm From Acella's Infringing "PNV - OB with DHA" Product

40. Everett faces substantial and irreparable harm as a result of Acella's infringing sales of its "PNV - OB with DHA" product. Each time that a pharmacy substitutes Defendant's Product despite the physician's prescription having specified Vitafol®-OB+DHA, Everett directly loses that sale to Acella. Additionally, in the health care industry, there is significant (if not absolute) pressure on pharmacists (by, for example, insurance companies) to substitute the

lower-cost copy version of a prescription drug or supplement for a higher-cost brand-name version.

41. Acella is currently selling and/or distributing its "PNV - OB with DHA" product (Defendant's Product) to ultimately be sold through retail pharmacies, which, on information and belief, are selling Defendant's Product as a substitute for Vitafol®-OB+DHA. Acella will rapidly gain increasing market share with its "PNV - OB with DHA" product, which is causing and will continue to increasingly cause direct harm to Everett.

42. It can be expected that, within less than one year of Defendant's Product being "linked" to Vitafol®-OB+DHA, Defendant's Product will have displaced 90 percent of the sales that otherwise would have been made by Everett of its Vitafol®-OB+DHA product.

43. Many patients who have been prescribed prenatal nutritional supplements will not even realize that the pharmacy has substituted the lower-cost supplement for the branded product that their doctor prescribed. This has been and will continue to be the case with Defendant's Product being substituted for Vitafol®-OB+DHA. On other occasions, patients will be informed of the intended substitution and advised that if they insist on the prescribed, branded product, their "co-pay" will be significantly higher.

44. After a pharmacy has stocked up on the copy product, the pharmacy will naturally want to use up its inventory rather than see it go to waste. The critical harm to Everett in the present circumstances is evident: It is virtually impossible to "put the genie back in the bottle" once a copyist competitor (such as Acella and its infringing "PNV - OB with DHA" product) is able to get a foothold in the marketplace. The realities of the marketplace will in this manner make it impossible for Everett to overcome Acella's infringing activities.

45. Vitafol®-OB+DHA and Defendant's Product are not the only prescription-only nutritional supplements in the U.S. market. By having an innovative product and visiting

thousands of doctors and spending significant sums in marketing and promotional efforts, Everett has created a brand awareness and excellent reputation for Vitafol®-OB+DHA. However, to remain effective it is necessary that Everett continue to market and promote Vitafol®-OB+DHA to prescribing doctors, so that they do not pass over Vitafol®-OB+DHA in favor of some other nutritional supplement when writing prescriptions for their patients.

46. The presence of Acella's "PNV - OB with DHA" product in the market creates a huge dilemma – a "Hobson's Choice" for Everett. Either Everett stops marketing the Vitafol®-OB+DHA product or continues to spend money to market Vitafol®-OB+DHA to the advantage of its infringing competitor, Acella. Yet, if Everett stops marketing Vitafol®-OB+DHA Everett will forfeit sales to other nutritional supplement companies which, unlike Everett, will still have an incentive to market and promote their products to doctors. Moreover, it will not be possible to calculate how many such sales Everett will have lost to other sellers of prescription-only prenatal nutritional supplements.

47. As a result of Acella's infringement Everett will also suffer irreparable harm to its goodwill and reputation respecting its entire line of prenatal products (including Vitafol®-OB+DHA, Vitafol®-PN, Vitafol®-OB, and Select-OB®+DHA), especially as pharmacists become accustomed to using "PNV - OB with DHA" products as substitutes for Vitafol®-OB+DHA and Everett's other nutritional supplement products. Vitafol®-OB+DHA is not a retail product, but a product prescribed by doctors and dispensed by pharmacists. Over time, habits develop, and pharmacists associate Vitafol®-OB+DHA and Everett's other products with cheaper copy versions. It is critical to Everett's business that pharmacists and doctors do not associate Everett's products with cheaper copy versions, and that pharmacists do not routinely substitute Defendant's Product for Vitafol®-OB+DHA.

Copyright Registration of Everett's Vitafol®-OB+DHA Product Insert

48. Everett's Vitafol®-OB+DHA product is sold with a package/product insert authored by Everett (Everett's "Vitafol®-OB+DHA product insert"), the original version of which is attached as **Exhibit C**. Everett's Vitafol®-OB+DHA product insert has provided and continues to provide information about the vitamins and minerals of Vitafol®-OB+DHA, as well as substantial other information pertaining to the use of Vitafol®-OB+DHA. Everett has registered its copyrights in the Vitafol®-OB+DHA product insert, specifically by registering the original version (which registration, *i.e.*, United States Copyright Office Registration No. TX 6-584-656, is reflected in **Exhibit E** attached hereto).

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Infringement Of The '983 Patent)

49. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs, the same as if set forth at length.

50. Everett is the assignee and owner of the '983 Patent (which patent was duly and legally issued by the PTO on November 9, 2004).

51. Upon information and belief, Defendant has through the conduct described above, engaged in the manufacture, use, sale, offer for sale, and/or importation of products that infringed and continue to infringe, directly and/or indirectly by contributorily infringing and/or inducing to infringe, one or more of the claims of the '983 Patent, in violation of 35 U.S.C. § 271 and without Everett's authority. The infringing product embodying the claimed invention(s) is Defendant's "PNV - OB with DHA" prescription prenatal multivitamin product (Defendant's Product).

52. Defendant's willful acts of infringement are causing damages and irreparable harm to Everett and will continue to cause damages and irreparable harm unless enjoined by this Court.

SECOND CLAIM FOR RELIEF

(Infringement Of The '509 Patent)

53. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs, the same as if set forth at length.

54. Everett is the assignee and owner of the '509 Patent (which patent was duly and legally issued by the PTO on June 24, 2008).

55. Upon information and belief, Defendant has through the conduct described above, engaged in the manufacture, use, sale, offer for sale, and/or importation of products that infringed and continue to infringe, directly and/or indirectly by contributorily infringing and/or inducing to infringe, one or more of the claims of the '509 Patent, in violation of 35 U.S.C. § 271 and without Everett's authority. The infringing product embodying the claimed invention(s) is Defendant's "PNV - OB with DHA" prescription prenatal multivitamin product (Defendant's Product).

56. Defendant's willful acts of infringement are causing damages and irreparable harm to Everett and will continue to cause damages and irreparable harm unless enjoined by this Court.

THIRD CLAIM FOR RELIEF

(Copyright Infringement)

57. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs, the same as if set forth at length.

58. This cause of action arises under the federal Copyright Act, 17 U.S.C. §§ 101, *et seq.*

59. The Court has original jurisdiction over this matter pursuant to Everett's filing of, and the federal Copyright Office's subsequent issuance of, a copyright registration certificate covering Everett's Vitafol®-OB+DHA product insert specifically registering the copyrights for the original product insert for Everett's Vitafol®-OB+DHA product insert, which registration was issued as United States Copyright Office Registration No. TX 6-584-656. *See* **Exhibit E**.

60. Everett is the sole owner of all copyrights in the Vitafol®-OB+DHA product insert and all corresponding text, layout, and other elements of expression encompassed therein, including the selection and arrangement of text and other elements of expression. The Vitafol®-OB+DHA product insert is original. Further, the U.S. Copyright Office has registered Everett's copyrights identifying Everett as the copyright author and therefore owner. *See* **Exhibit E**.

61. Defendant has infringed Everett's copyrights in the Vitafol®-OB+DHA product insert. Defendant has, among other things, copied, distributed, used, sold, displayed, and distributed virtually all of the Vitafol®-OB+DHA product insert without approval or authorization from Everett.

62. Defendant had access to and copied copyright-protected elements of the Vitafol®-OB+DHA product insert to create Defendant's infringing "PNV - OB with DHA" package insert.

63. Defendant's acts as alleged herein constitute copyright infringement under the U.S. Copyright Act, 17 U.S.C. § 101, *et seq.* By its actions alleged above, Defendant has intentionally and willfully infringed, and will continue to intentionally and willfully infringe, Everett's copyrights in the Vitafol®-OB+DHA product insert.

64. As a direct and proximate result of Defendant's unlawful acts of copyright infringement as set forth above, Everett has suffered and will continue to suffer injury to its

business, goodwill, and property in an amount not presently known. Everett is entitled to recover from Defendant the damages it has sustained and will sustain as a result of Defendant's unlawful acts of copyright infringement as alleged herein, pursuant to 17 U.S.C. § 504. Everett is further entitled to recover from Defendant the gains, profits, and advantages that Defendant has obtained as a result of the wrongful conduct alleged herein, pursuant to 17 U.S.C. § 504. Everett at present is unable to ascertain the full extent of its damage, or the gains, profits and advantages that Defendant has obtained by reason of the wrongful conduct described herein.

65. Alternatively, as Everett's copyright registration was issued before the infringement occurred, Everett may elect to seek statutory damages under 17 U.S.C. § 504(c) for Defendant's unlawful and willful acts of copyright infringement as set forth above.

66. Everett is also entitled, pursuant to 17 U.S.C. § 502, to an order for injunctive relief that prevents and restrains Defendant from continuing to infringe on the Vitafol®-OB+DHA product insert and, pursuant to 17 U.S.C. § 503, to an order impounding any and all of Defendant's products that contain the infringing "PNV - OB with DHA" package insert. Everett is further entitled to an order compelling Defendant to recall and retrieve and all of Defendant's products that contain the infringing "PNV - OB with DHA" package insert that are in the marketplace. Everett has no adequate remedy at law for Defendant's wrongful and unlawful conduct because, among other things: (a) Everett's copyrights in its Vitafol®-OB+DHA product insert are unique and valuable property which have no readily determinable market value; (b) Defendant's infringement harms Everett such that Everett could not be made whole by any monetary award for such infringement; and (c) Defendant's wrongful and unlawful conduct, and the resulting damage and harm to Everett, is continuing and irreparable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Everett Laboratories, Inc. asks that this Court enter judgment against Defendant Acella Pharmaceuticals, LLC, granting the following relief:

A. Judgment that Defendant has directly infringed U.S. Patent No. 6,814,983 and U.S. Patent No. 7,390,509.

B. Judgment that Defendant has indirectly infringed U.S. Patent No. 6,814,983 by inducing the direct infringement of the '983 Patent, and that Defendant has indirectly infringed U.S. Patent No. 7,390,509 by inducing the direct infringement of the '509 Patent.

C. Judgment that Defendant has indirectly infringed U.S. Patent No. 6,814,983 by contributing to the direct infringement of the '983 Patent, and that Defendant has indirectly infringed U.S. Patent No. 7,390,509 by contributing to the direct infringement of the '509 Patent.

D. That Defendant be held to have willfully engaged in copyright infringement in violation of Section 501 of the Copyright Act, 17 U.S.C. § 501.

E. That a preliminary and permanent injunction issue prohibiting Defendant and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them, from further direct and/or indirect copyright infringement of the Vitafol®-OB+DHA product insert.

F. That Defendant be required to:

1. Deliver upon oath, to be impounded during the pendency of this action, and for destruction pursuant to judgment herein, all "PNV - OB with DHA" products;

2. Seek and obtain a full recall of all "PNV - OB with DHA" products that have been sold, consigned, or placed into inventory of a wholesaler or retailer;

3. Place all revenues generated from the sale of "PNV - OB with DHA", as well as all future payments from the sale of "PNV - OB with DHA", in a trust account during the pendency of this action;

4. Issue a recall and retrieve all "PNV - OB with DHA" products and/or any nutritional supplements or any other of Defendant's products that bear or contain the infringing "PNV - OB with DHA" package insert, or any other material that infringes on Everett's Vitafol®-OB+DHA product insert, that are being or have been used, advertised, marketed, offered, distributed, or sold in the marketplace; and

5. Deliver upon oath, to be impounded during the pendency of this action, and for destruction pursuant to judgment herein, any and all "PNV - OB with DHA" package inserts and any other of Defendant's materials that infringe on Everett's copyrights.

G. That Defendant be required to file with the Court and serve on Everett, within 30 days after service of the Court's Order as herein prayed, a report in writing under oath stating in detail the manner and form in which Defendant has complied with the Court's Order.

H. That Defendant be required to account for and pay over to Everett all profits obtained by Defendant from its violations of law complained of herein.

I. That the Court grant a preliminary and permanent injunction enjoining Acella from manufacturing, marketing or selling, importing, or offering for sale, "PNV - OB with DHA" (Defendant's Product).

J. That the Court grant a preliminary and permanent injunction enjoining Acella from making claims that would cause Defendant's Product to be listed as interchangeable with, or a substitute for, Vitafol®-OB+DHA.

K. That the Court order Acella to pay compensatory damages to Everett in an amount to be determined at trial.

L. That the Court order Defendant to pay Everett's damages and Defendant's profits pursuant to 17 U.S.C. § 504(b) for Defendant's willful infringement of Everett's copyrights or, alternatively, if Everett elects, statutory damages pursuant to 17 U.S.C. § 504(c).

M. That Defendant pay Everett additional damages for willful infringement of the '983 Patent and the '509 Patent in an amount to be determined at trial pursuant to 35 U.S.C. § 284.

N. Judgment that this is an exceptional case under 35 U.S.C. § 285 and awarding Everett its costs, expenses and reasonable attorneys' fees incurred in this action.

O. Judgment awarding Everett its full costs and reasonable attorneys' fees incurred in this action under Section 505 of the Copyright Act, 15 U.S.C. § 505.

P. That Defendant be ordered to pay prejudgment interest to Everett.

Q. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38, Fed. R. Civ. P., Plaintiff Everett Laboratories, Inc. hereby demands a jury trial on all issues triable of right by a jury.

Respectfully submitted,

RIKER DANZIG SCHERER HYLAND & PERRETTI LLP

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Dated: June 6, 2013.

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CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1(d)(2), the undersigned attorneys for Plaintiff, Everett Laboratories, Inc., certify that this action is not eligible for arbitration under Local Civil Rule 201.1 because the relief sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive relief, as well as damages believed to be in excess of $150,000.00, exclusive of interest, costs, and any claim for punitive damages, and involves complex issues of patent and copyright law.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiff, Everett Laboratories, Inc., certifies that, to the best of his knowledge, the matter in controversy is not the subject of another action pending in any court or of any arbitration or administrative proceeding.

RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP
Attorneys for Plaintiff
Everett Laboratories, Inc.

By /s/ Robert J. Schoenberg

Dated: June 6, 2013.

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