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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, NORTHERN DIVISION

ALBION LABORATORIES, INC., a Utah corporation; ALBION INTERNATIONAL, INC., a Nevada corporation; and BRECKENRIDGE PHARMACEUTICAL, INC., a Florida corporation, Plaintiffs, v. PRUGEN, INC., an Arizona corporation, Defendant.	Case No. 1:09-cv-00093-TC **SECOND AMENDED COMPLAINT** **Honorable Tena Campbell** **(Jury Trial Demanded)**

Plaintiffs Albion Laboratories, Inc., Albion International, Inc., and Breckenridge Pharmaceutical, Inc., (collectively, "Plaintiffs") allege and complain of defendant PruGen, Inc., as follows:

THE PARTIES

1. Plaintiff Albion Laboratories, Inc. is a Utah corporation, and plaintiff Albion International, Inc. is a Nevada corporation. Both Albion Laboratories, Inc. and Albion International, Inc. (collectively, "Albion") have their principal place of business at 101 North Main Street, Clearfield, Utah, 84015.

2. Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a Florida corporation with its principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida, 33487.

3. Defendant PruGen, Inc. ("PruGen") is an Arizona corporation with its principal place of business at 8711 East Pinnacle Peak Road, Suite C-201, Scottsdale, Arizona, 85255.

JURISDICTION AND VENUE

4. This Court has original jurisdiction over the subject matter of the First Claim for Relief stated below under 28 U.S.C. §§ 1331 and 1338(a), because it arises under the patent laws of the United States.

5. This Court has original jurisdiction over the subject matter of the Second Claim for Relief stated below under 28 U.S.C. § 1331 and 15 U.S.C. § 1121(a), because it concerns violation of section 43 of the Lanham Act, 15 U.S.C. § 1125.

6. This Court has supplemental jurisdiction over the subject matter of the Third Claim under 28 U.S.C. §§ 1332 and 1367, because the parties are of diverse citizenship, and also

because the subject matter of the state law claim therein is so related to the claims asserted under federal law as to form part of the same case or controversy.

7. This Court has personal jurisdiction over PruGen because it sells and/or offers to sell the accused products, directly or indirectly, to residents of the State of Utah, has directly or indirectly sold multiple units of at least one of the accused products in the State of Utah, has directed its activities at Utah residents, and has caused tortious injury in this state.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1400 and 1391 because PruGen is subject to personal jurisdiction in this district.

GENERAL ALLEGATIONS

Albion's Leading Position And Reputation As A Supplier Of Mineral Chelates For Human Consumption

9. Since Albion began producing and commercializing mineral chelates for human consumption over 30 years ago, it has invested very significant amounts of money, time, and effort to establish itself as the leading company for the development, scientific understanding, and production of mineral chelates.

10. Albion has invested millions of dollars over the past decades in the scientific study of mineral nutrition generally, and of the benefits of high quality chelated minerals specifically. Albion has financed and conducted hundreds of studies and/or clinical trials, with over 200 of those studies published in peer-reviewed scientific journals.

11. Albion is the preeminent leader in the mineral nutrition industry in working with the United States government and foreign governments to establish definitions of mineral chelates and other mineral organic compounds, to set safety standards and consumption levels, and to create other standards related to mineral chelates.

12. Albion invests heavily in marketing, advertising and branding activities to establish industry and public awareness of its leading role and expertise in the field of mineral nutrition and chelated minerals, and thus to establish and maintain a reputation consistent with its accomplishments in this field.

13. Based on its years of significant investment in the food, pharmaceutical and nutrition industries, producers of human nutritional products associate chelated minerals with Albion. Consumers as well are beginning to recognize and associate Albion with chelated minerals.

14. Albion has also invested millions of dollars into research leading to intellectual property. Albion has prosecuted and secured over 130 patents in multiple countries in the field of mineral nutrition, the chemistry of chelation, production processes, specific applications and methods of using chelated minerals, and the compositional identification and analysis of chelated minerals.

15. Among its intellectual property related to mineral chelates, Albion is the owner by assignment of U.S. Patent No. 6,716,814, entitled "Enhancing Solubility of Iron Amino Acid Chelates and Iron Proteinates" ("the '814 patent"), attached hereto as Exhibit A.

16. Among the mineral chelates manufactured and sold by Albion is ferrous asparto glycinate, an iron amino acid chelate marketed by Albion under the trademark Sumalate®.

Breckenridge's Well-Established Role As A Supplier Of Generic Prescription Products, Including Products Containing Iron Chelates

17. For over 25 years, Breckenridge has been in the business of developing and marketing pharmaceutical products, which it sells to retailers, wholesalers, distributors, and other purchasers of such products nationwide.

18. As is well known, pharmaceutical products are often available as a brand product and also as one or more "generic" versions that contain the same active ingredients, dosage form, and strength as the brand product.[1]

19. The market for any particular generic product typically begins with one established brand-name product, which is joined later by lower-cost, generic alternatives. Breckenridge competes in the pharmaceutical market by developing and selling such generic alternatives.

20. Before introducing any new generic pharmaceutical product into the marketplace, Breckenridge invests significant resources to ensure that the formulation, testing, and manufacture of each such product comply both with internal quality-control release standards and with all applicable U.S. Food and Drug Administration ("FDA") regulations, including current Good Manufacturing Practices ("cGMP"), and that the active ingredients are properly listed and disclosed in all labeling.

21. Breckenridge ensures that quality control measures include, without limitation, analytical testing of the raw ingredients, installation qualification and operational qualification of the equipment, process validation (which includes analytical testing of three batches of each product), validation of analytical methods, and dissolution and assay testing of the final product ("Quality Control Measures").

22. Because such Quality Control Measures are both a universal industry practice in the production of prescription pharmaceutical products, and are required by cGMP, the marketing of a pharmaceutical product as a prescription product, that is, as "Rx Only," is

[1] The term "generic" is not used herein in the narrower sense sometimes applied only to drugs listed by the FDA as therapeutically equivalent, but in the widely-used meaning of "multisource" products with the same active ingredients, dosage form, and strength as the comparable brand product.

understood in the pharmaceutical industry as a representation that such Quality Control Measures have been performed in connection with the manufacture of that product.

23. Breckenridge also ensures that for each product, stability testing has been performed and that the results thereof are sufficient to support the expiration assigned to that product.

24. Because such stability testing is both a universal industry practice and required by cGMP, the assignment of an expiration date to a prescription pharmaceutical product is understood in the pharmaceutical industry as a representation that appropriate stability testing has been performed, and that the results of such testing support that expiration date.

25. Because of the time and effort Breckenridge has expended in assuring the quality of its products, it has established a high reputation in this generic market.

26. Among the generic prescription pharmaceutical products marketed by Breckenridge are certain products containing iron for use in treating anemia ("Hematinic Products").

27. Breckenridge is the exclusive licensee of the Albion '814 patent for a particular field of use, including generic prescription Hematinic Products in the United States that contain ferrous asparto glycinate, an iron chelate, mixed with organic acids pursuant to the method claimed by the '814 patent.

28. Among the prescription Hematinic Products marketed by Breckenridge under this exclusive license are: Multigen, Multigen Folic, Multigen Plus, Ferrex 150 Forte Plus, and Ferrex 28 (collectively, the "Breckenridge Hematinic Products"). The packaging insert for one of the Breckenridge Hematinic Products, Ferrex 28, is attached hereto as Exhibit B.

29. These generic Breckenridge Hematinic Products contain the identical active ingredients, in the same dosage form and strength, as the brand products formerly marketed under the brand names of (respectively) Chromagen, Chromagen FA, Chromagen Forte, Niferex 150 Forte, and Repliva 21/7 (the "Brand Hematinic Products"), and are thus properly marketed as generic alternatives to those products. The packaging insert for one of the Brand Hematinic Products, Repliva 21/7, is attached hereto as part of Exhibit C.

30. Wholesalers, distributors, retailers (such as pharmacies), and other purchasers of generic pharmaceutical products often choose among several competing versions of a generic product to dispense at the retail level, and in so doing rely on the representations of the marketer, and the listings and "links" provided by industry databases. These databases "link" a particular generic alternative with a particular brand product, based on information supplied to them by the generic pharmaceutical company indicating that the generic alternative product contains the same active ingredients, in the same dosage form and strength, as the brand product.

31. Consistent with normal industry practice, prescriptions continue to be written for the Brand Hematinic Products, which are filled by the dispensing of generic alternatives that have been linked to the Brand Hematinic Products, including Breckenridge's Hematinic Products.

The Recent Introduction By Newcomer PruGen Of Its Sub-Potent Hematinic Products

32. Defendant PruGen only began marketing its first prescription pharmaceutical product in 2008, and now markets less than a dozen total products, all as generic equivalents to certain brand products.

33. More recently, in 2009, PruGen began marketing five of these products under the names of FerroVite, FerroVite FA, FerroVite Forte, Ferroflex-150 Forte, and PruVate 21/7 (the "PruGen Hematinic Products"). The packaging and packaging insert for one of the Brand Hematinic Products, PruVate 21/7, is attached hereto as Exhibit D.

34. PruGen has marketed, promoted, advertised, offered for sale, sold, and distributed the PruGen Hematinic Products to customers, including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others, throughout the United States, including in the State of Utah. Furthermore, prescriptions of the PruGen Hematinic Products have been dispensed in Utah.

35. PruGen has promoted and marketed the PruGen Hematinic Products as generic alternatives to, respectively, the Brand Hematinic Products of Chromagen, Chromagen FA, Chromagen Forte, Niferex 150 Forte, and Repliva 21/7.

36. The labeling for the PruGen Hematinic Products, including the product inserts, represents that they contain the identical active ingredients, in the same dosage form and strength, as the respective Brand Hematinic Products, including the elemental iron which is necessary to treat anemia.

37. PruGen has provided these product inserts and the information thereon to the pharmaceutical industry database companies, and thus has induced the databases to "link" the PruGen Hematinic Products to the Brand Hematinic Products -- the same products to which the Breckenridge Hematinic Products have also been linked.

38. However, an independent laboratory analysis of one of the PruGen Hematinic Products, PruVate 21/7, revealed that the tested product contained only 24% of the elemental

iron claimed on the label. This is an amount so far below the label claim that the ferrous asparto glycinate and the ferrous fumarate in PruVate 21/7, which are claimed on the label to provide certain amounts of elemental iron, were also necessarily both unacceptably sub-potent by industry standards.

39. Upon information and belief, PruGen has used the same manufacturer for all five of the PruGen Hematinic Products, and all five of the PruGen Hematinic Products were severely deficient and sub-potent in the amount they contained of the key active ingredient of iron.

40. Nevertheless, PruGen has represented to prospective purchasers of its Hematinic Products, directly through its labeling and indirectly through the pharmaceutical databases, that the PruGen Hematinic Products contain the same amounts of iron as the respective Brand Hematinic Products and Breckenridge Hematinic Products.

41. Additionally, PruGen has explicitly or implicitly represented, directly or indirectly, that the PruGen Hematinic Products are generic equivalents of, and/or substitutable for, and may be dispensed to fill prescriptions for, the respective Brand Hematinic Products.

42. Thus, PruGen also has explicitly or implicitly claimed that the PruGen Hematinic Products contain an iron amino acid chelate in the form of ferrous asparto glycinate, mixed with the same solubilizing organic acids present in the Brand Hematinic Products.

43. Moreover, PruGen has marketed its Hematinic Products with an expiration date stamped on the package labels, thus representing and advertising to the mutual customers of PruGen and Breckenridge that stability testing sufficient to justify these expiration dates had been performed.

44. In fact, PruGen has declined to pay for such stability testing by its manufacturer, and instead simply printed on its product labels an expiration date not supported by any stability testing or data. (*See* Exhibit D, second page.)

45. PruGen has marketed its Hematinic Products as prescription products, stating on the labeling that these products are "Rx Only" (*see* Exhibit D), thus representing and advertising to the mutual customers of PruGen and Breckenridge that these products were manufactured with the Quality Control Measures that are universal industry practice in the manufacture of prescription products, and that are also required by cGMP.

46. In fact, upon information and belief, PruGen specifically and purposefully failed to inform its contract manufacturer that its Hematinic Products were to be marketed as prescription products, in order to induce the manufacturer to produce these products without performing any of the Quality Control Measures that its own manufacturer would otherwise have insisted on performing.

47. Upon information and belief, PruGen intentionally followed this course of action, solely for the purpose of producing its Hematinic Products as quickly and cheaply as possible, in order to seize market share, increase its own profits, and undercut the prices of legitimate competitors such as Breckenridge.

48. By virtue of at least the foregoing representations, PruGen has made sales of the PruGen Hematinic Products to parties that would otherwise have purchased the Breckenridge Hematinic Products in place of the Brand Hematinic Products, and has forced Breckenridge to lower its prices in order to avoid losing additional sales to PruGen.

49. By representing that its sub-potent Hematinic Products contain ferrous asparto glycinate, an iron chelate, PruGen is causing irreparable harm to the reputation of Albion, which has invested so much time and effort to establish the benefits of mineral chelates and is now associated with mineral chelates by the industry and the public, and to the reputation of Breckenridge, which has worked for years to establish generic prescription products as acceptable and equivalent alternatives to brand prescription products.

FIRST CLAIM FOR RELIEF
(Patent Infringement)

50. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

51. PruGen manufactures, uses, sells, and offers to sell the PruGen Hematinic Products, and thereby directly infringes, contributorily infringes, and/or induces infringement of, the '814 patent.

52. Plaintiffs have been injured thereby, in an amount to be determined at trial.

53. Upon information and belief, the infringement of the '814 patent by PruGen is willful.

54. Upon information and belief, PruGen will continue its infringement of the '814 patent unless its acts of infringement are restrained and enjoined by this Court. Due to PruGen's continuing acts of infringement of the '814 patent, Plaintiffs have suffered and/or will suffer irreparable injury for which they have no adequate remedy at law.

SECOND CLAIM FOR RELIEF
(Violation Of The Lanham Act)

55. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

56. PruGen has engaged in false advertising, actionable under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), by using in commerce and in connection with its Hematinic Products, false and misleading descriptions and representations of fact, and other words, terms, and devices that misrepresent the nature, characteristics, and/or qualities of its Hematinic Products, including by way of illustration but not limitation: explicit and/or implicit representations that the PruGen Hematinic Products contain certain amounts of elemental iron; explicit and/or implicit representations that the PruGen Hematinic Products are generic equivalents of, substitutable for, and may be dispensed to fill prescriptions for, the respective Brand Hematinic Products; expiration date representations and markings; and designation of the PruGen Hematinic Products as "Rx Only."

57. Plaintiffs have been injured thereby, in an amount to be determined at trial.

58. Upon information and belief, PruGen will continue its violation of the Lanham Act unless this violation is restrained and enjoined by this Court. Due to PruGen's continuing acts of false advertising, Plaintiffs have suffered and/or will suffer irreparable injury for which they have no adequate remedy at law.

THIRD CLAIM FOR RELIEF
(Violation of the Utah Truth in Advertising Act)

59. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

60. By reason of the foregoing, PruGen has engaged in the proscribed deceptive trade practices enumerated in Utah Code § 13-11a-3(1)(e) and (g).

61. Plaintiffs have been injured thereby, and are entitled to recover damages, costs, and attorneys' fees pursuant to Utah Code § 13-11a-4, in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court:

(a) Preliminarily and permanently enjoin PruGen, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from making, using, offering to sell, or selling the PruGen Hematinic Products;

(b) Enter judgment against PruGen for compensatory damages by reason of its infringement of the '814 patent, as determined at trial, but not less than a reasonable royalty;

(c) Determine that such infringement was willful, and award treble damages to Plaintiffs by reason thereof;

(d) Declare this case to be "exceptional" within the meaning of 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys' fees, expenses and costs of this action;

(e) Preliminarily and permanently enjoin PruGen, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from falsely advertising the PruGen Hematinic Products, whether by representing that they contain the same amounts of iron as the respective Brand Hematinic Products and Breckenridge Hematinic Products, or that they are generic equivalents of, or

substitutable for, the respective Brand Hematinic Products; by placing unsubstantiated and unsupported expiration dates on the PruGen Hematinic Products or containers thereof; by designating the PruGen Hematinic Products as "Rx Only"; or otherwise;

(f) Enter judgment against PruGen for compensatory damages by reason of its violation of the Lanham Act, as determined at trial;

(g) Enter judgment against PruGen for compensatory damages by reason of its violation of the Utah Truth in Advertising Act, as determined at trial;

(h) Enter judgment against PruGen for costs and attorneys' fees by reason of its violation of the Utah Truth in Advertising Act; and

(i) Enter an Order granting Plaintiffs such other and additional relief against PruGen as may be just and proper under the circumstances.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury of all issues properly triable to a jury in this case.

DATED this 7th day of December, 2009

L. Rex Sears
Janna J. Lewis
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WORKMAN | NYDEGGER, A PROFESSIONAL CORPORATION

C. Randolph Ross
BRECKENRIDGE PHARMACEUTICAL, INC.

By /s/ L. Rex Sears

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