THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

MISSION PHARMACAL COMPANY, Plaintiff, v. AVION PHARMACEUTICALS, LLC, Defendant.	)	Case No. 5:15-cv-510 **JURY TRIAL DEMANDED**

ORIGINAL COMPLAINT

Plaintiff Mission Pharmacal Company ("Mission Pharmacal"), for its original complaint for patent infringement, false advertising and unfair competition against defendant Avion Pharmaceuticals, LLC ("Avion"), alleges as follows:

PARTIES

1. Mission Pharmacal is a Texas corporation with its principal place of business in San Antonio, Texas.

2. Upon information and belief, Avion is a corporation organized under the laws of Delaware and having its principal place of business at 11675 Great Oaks Way, Suite 120, Alpharetta, Georgia 30022. Avion may be served with process by serving a copy of the Complaint on its Registered Agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, and for false advertising and unfair competition under the Lanham Act, Title 15 of the United States Code and/or common law unfair competition. Jurisdiction is based on 28 U.S.C. §§ 1331, 1338 and 1367, and 15 U.S.C. §§ 1116 and 1121.

4. This Court has personal jurisdiction over Avion by virtue of the fact that Avion conducts business in the State of Texas, and has availed itself of the rights and benefits of Texas law, has engaged in substantial and continuing contacts with the State, and has infringed Mission Pharmacal's patent rights through sales in Texas. Moreover, Avion markets, promotes, advertises, offers for sale, sells and/or distributes its FeRivaFA® ("FeRivaFA") and FeRiva 21/7™ ("FeRiva 21/7") iron supplementation products and its Prenate Mini® ("Prenate Mini") prenatal supplement product 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 Western District of Texas, with the expectation that its products will be purchased by consumers in the Western District of Texas.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 (b) and (c) and 1400(b).

FACTS SUPPORTING PATENT INFRINGEMENT CLAIMS

Mission Pharmacal Owns the Patent Covering Its Dual-Iron Supplements

6. Mission Pharmacal is the owner as assignee of United States Patent No. 6,521,247 ("the '247 Patent"). The '247 Patent lawfully issued on February 18, 2003. A true and correct copy of the '247 patent, along with its reexamination certificate, is attached hereto as Exhibit A.

7. The '247 Patent claims, among other things, a nutritional supplement containing both a slowly dissolving and a rapidly dissolving iron compound, a method of alleviating iron deficiency with the dual iron nutritional supplement, and a method of making the dual iron nutritional supplement. Claim 1 of the '247 Patent is directed to a nutritional supplement with folic acid, carbonyl iron, and a different pharmaceutically acceptable iron compound selected to be rapidly dissolving.

8. Mission Pharmacal sells the Ferralet® 90 ("Ferralet") iron supplement covered by the '247 Patent and used for treatment of iron deficiency anemia. Mission Pharmacal also sells

the CitraNatal® family of products ("CitraNatal") covered by the '247 Patent that are multivitamin/mineral prescription drugs indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

Avion Infringes the Dual-Iron Patent

9. Avion is a Georgia-based pharmaceutical company that develops, manufactures, markets and sells what it calls "specialty pharmaceuticals," including dietary supplement products. Avion promotes, markets, sells and distributes its products nationwide, including Texas. Avion is in no way affiliated with Mission Pharmacal or its related entities or has permission to practice under the '247 Patent.

10. Specifically, Avion manufactures, imports, sells, and/or offers to sell, and induces others to sell, offer to sell, and use, certain iron supplements including FeRivaFA and certain prenatal supplement products including Prenate Mini in this jurisdiction and elsewhere in the United States in competition with Mission Pharmacal.

11. On information and belief, the manufacture, use and sales of FeRivaFA and Prenate Mini are covered by at least claim 1 of the '247 Patent. Upon information and belief, FeRivaFA and Prenate Mini each contain folic acid and carbonyl iron. Upon information and belief, FeRivaFA contains ferrous bis-glycinate chelate, which is a pharmaceutically acceptable iron compound selected to be rapidly dissolving. Upon information and belief, Prenate Mini contains ferrous asparto glycinate, which is a pharmaceutically acceptable iron compound selected to be rapidly dissolving.

12. Mission Pharmacal marks its dual-iron products, including Ferralet and certain CitraNatal prenatal supplements with the '247 patent. Therefore, Avion was at least on constructive notice about the '247 patent at least as early as when it began making FeRivaFA and

Prenate Mini.

FACTS SUPPORTING FALSE ADVERTISING AND UNFAIR COMPETITION CLAIMS

Mission Pharmacal Produces Ferralet to Reduce the Side Effects Associated With Iron Supplementation Regimens for Treating Anemia

13. Founded in 1946 and headquartered in San Antonio Texas, Mission Pharmacal is a pharmaceutical company specializing in the development, marketing and sales of a wide range of prescription medications and over-the-counter products in four expanding therapeutic areas of focus: women's health, urology, pediatric, and dermatology. Mission Pharmacal's healthcare products are designed to meet the unique healthcare needs of women throughout all stages of life, pediatric patients, and those persons dealing with urologic and dermatologic conditions.

14. Iron deficiency anemia (IDA) is a common medical problem. It is estimated that up to 9% of women and up to 5% of men in the United States have IDA. IDA results when the body does not have enough healthy red blood cells to carry oxygen to the tissues and cells of the body. Iron is a building block of oxygen-carrying hemoglobin in red blood cells, and a person develops IDA when iron stores in the body run low.

15. The percentage of iron that is absorbed from iron-rich food (known as iron bioavailability) varies, but it can range from 1% to 50%. The portion of the small intestine called the duodenum is the chief area where iron absorption takes place. Absorption of iron from the diet is influenced by the type and quantity of iron present in the food, the presence of inhibitors and promoters of iron absorption in the diet, and the amount of iron the body already has stored. Although normal physiologic losses of iron can be replenished by diet alone, supplemental iron is almost always required to treat to IDA.

16. One of Mission Pharmacal's leading products is its prescription iron supplement, Ferralet. Ferralet is indicated for use in the treatment of all anemias that are responsive to oral iron

therapy. These include: hypochromic anemia associated with pregnancy; chronic and/or acute blood loss; metabolic disease; postsurgical convalescence; and dietary needs.

17. A distinctive feature of Ferralet is that it includes 90 mg of a patented blend of two iron ingredients, including ferrous gluconate which is ready for immediate absorption when it enters the body, and carbonyl iron which is absorbed over a prolonged period of time.

18. For many years, treatments for IDA relied almost exclusively on ferrous salts, *e.g.*, ferrous sulfate, ferrous gluconate and ferrous fumarate, which are immediately bioavailable and have twice the absorbability of most forms of iron found in the diet. However, high doses of ferrous iron have well known gastrointestinal side effects, such as constipation, nausea, vomiting, and diarrhea. Extremely high doses of ferrous iron are toxic.

19. Carbonyl iron consists of microparticles of highly purified elemental iron. It must be dissolved in the stomach's gastric secretions and converted to hydrochloride salt prior to absorption by the body. Although absorption of carbonyl iron in the small intestine is similar to that of ferrous iron, because the absorption rate is restricted by the body's rate of gastric acid production, the process occurs over a longer time interval (1 to 2 days).

20. Thus, the unique blend of iron in Ferralet counters iron depletion, but decreases the likelihood that patients will experience unpleasant gastrointestinal side effects because of the slower, more gradual way carbonyl iron is absorbed by the body and its lower toxicity.

21. The use of the patented dual-iron blend in Ferralet is used by Mission Pharmacal as a key selling point. Patients are more likely to continue taking iron supplements if the formulation is well tolerated and not accompanied by disagreeable side effects. Mission Pharmacal has invested substantial time and resources into building awareness of Ferralet and promoting the advantages it offers to patients suffering from IDA. Mission Pharmacal's representatives meet with doctors, nurses and other healthcare practitioners in primary care,

women's health and oncology settings, and provide them with information on the use and benefits of Ferralet. As a result, Ferralet has become a leading prescription iron supplementation product, and annual sales of Ferralet have grown to more than $7.4 million.

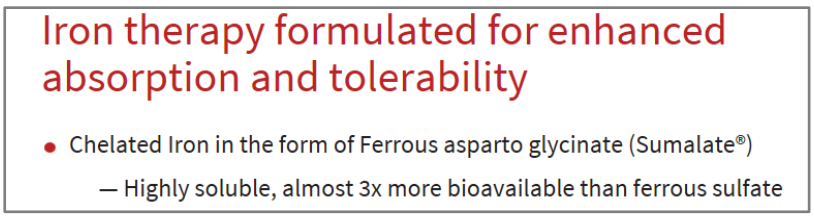
Avion Advertises FeRiva 21/7™ as Superior To Ferralet

22. In addition to FeRivaFA, Avion also markets and promotes a 28-day iron supplementation regimen it calls FeRiva 21/7. FeRiva 21/7 is a once-daily iron therapy sold by prescription. FeRiva 21/7 is comprised of 21 red tablets, each containing 75 mg of iron (as ferrous asparto glycinate, or Sumalate®) and other ingredients, and 7 purple inert tablets. Avion markets FeRiva 21/7 "for use in improving the nutritional status of patients with iron deficiency."

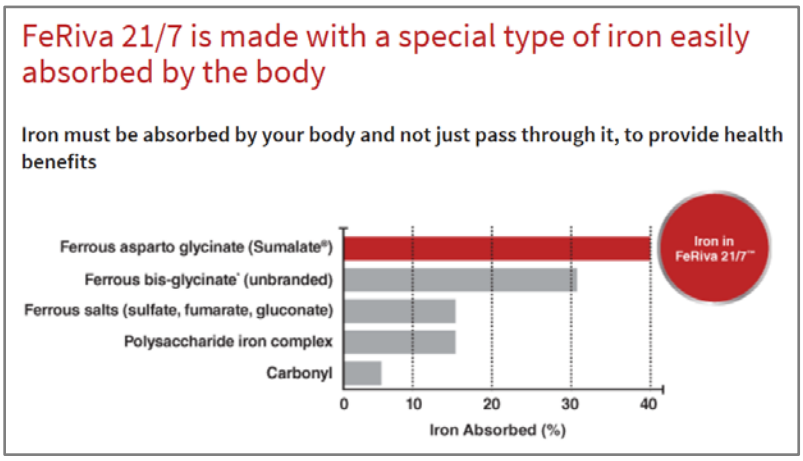
23. In its commercial advertising and promotion of FeRiva 21/7, including on its web site, in print publications, and in brochures distributed by its sales staff, Avion makes misrepresentations of fact concerning the nature, characteristics and qualities of FeRiva 21/7, both alone and in comparison, connection or association with Ferralet. These claims include, among others:

a. **Superior Iron Absorption Because of Ingredient**. In its commercial advertising, including the FeRiva 21/7 website, Avion describes the iron ingredient used in Feriva 21/7 as providing superior absorption and bioavailability by the body than iron ingredients used in other supplements, including the iron ingredients used in Ferralet. *See e.g.*, FeRiva 21/7 website, describing FeRiva 21/7 as providing "enhanced absorption," and having an ingredient "almost 3x more bioavailable than ferrous sulfate."[1]

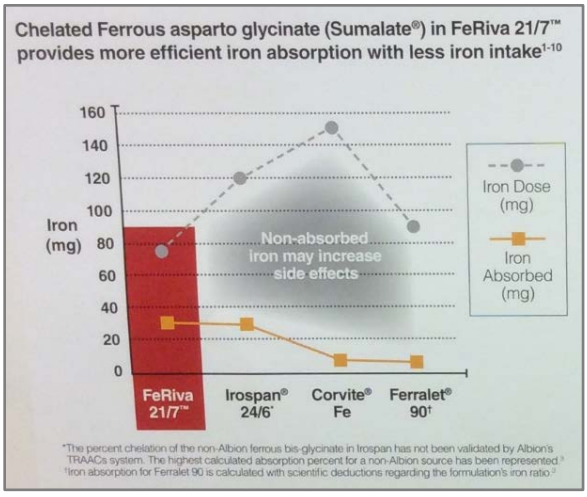
[1] The FeRiva 21/7 website is available at http://www.feriva21-7.com. A true and correct copy of same with its subpages is attached hereto as Exhibit B.



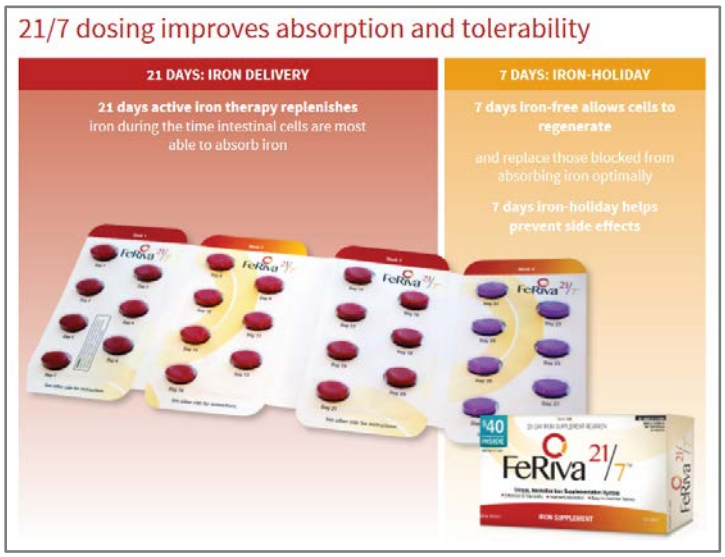
See also graph purporting to show that whereas the body absorbs 40% of the iron content of Sumalate®, the body absorbs less than 20% and 10% of the iron in ferrous gluconate and carbonyl, respectively.



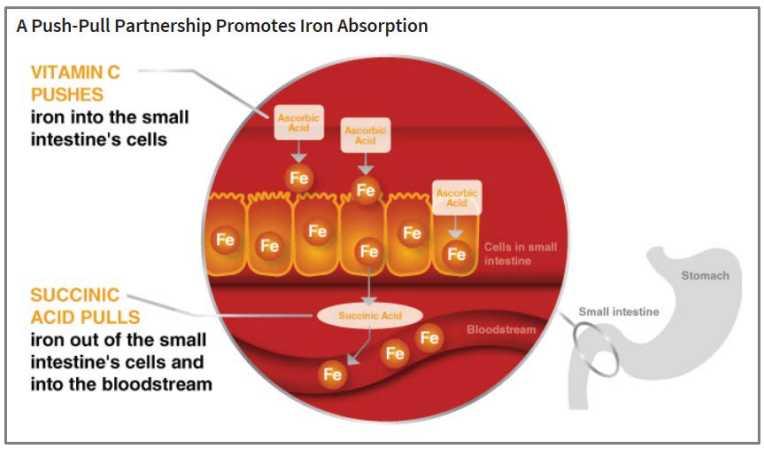
Likewise in print advertising distributed by its sales staff, Avion describes Feriva 21/7 as providing "more efficient iron absorption with less iron intake," and displays a chart purporting to compare the "iron absorbed" and the "iron dose" of Feriva 21/7 against three other iron supplements, including Ferralet:



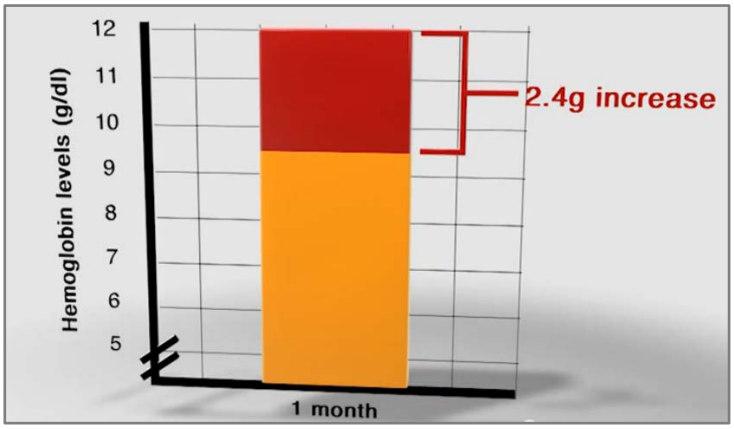
b. **Superior Iron Absorption and Tolerability Because of Scientific Dosing System**. In its commercial advertising, including the FeRiva 21/7 website, Avion claims that its "scientific dosing increases absorption and tolerability," because its "21 days of iron active iron therapy replenishes iron during the time intestinal cells are most able to absorb iron," while its 7-day "iron holiday" "allows cells to regenerate and replace those blocked from absorbing iron optimally," thereby "help[ing to] prevent side effects."



c. **Superior Iron Absorption Because of "Push-Pull Partnership."** In its commercial advertising, including the FeRiva 21/7 website, Avion claims that "two added nutrients" in FeRiva 21/7 "work together to further absorb the iron" provided by the supplement. Specifically, Avion claims that the Vitamin C (also known as ascorbic acid) in FeRiva 21/7 "pushes iron into the small intestine's cells," and that the succinic acid in FeRiva 21/7 "pulls iron out of the small intestine's cells, and into the bloodstream." Avion further contends that the amounts of Vitamin C and succinic acid in FeRiva 21/7 "were selected based on clinical studies balancing the most effective amount with the least side effects."



d. **Increased Hemoglobin Production Because Of Use of Chelated Iron Ingredient**. In its commercial advertising, including in a video on the FeRiva 21/7 website called "FeRiva 21/7: How It Works[2]," Avion claims, "[c]linical studies have demonstrated a 2.4 g increase in hemoglobin within 1 month of treatment using ferrous chelates including Sumulate."



Defendant's Advertising of FeRiva 21/7 is Literally False and/or Misleading

24. Avion's advertising and promotional claims concerning FeRiva 21/7 are false and/or misleading to its audience. FeRiva 21/7 does not have the nature, characteristics and qualities it purports to have, alone or in comparison to Ferralet.

[2] The video is available at https://www.youtube.com/watch?v=qFywYhWQb2I.

25. Avion's claim that data shows the iron in FeRiva 21/7 is better absorbed than the iron used in Ferralet is both unsubstantiated and false. Upon information and belief, no well-controlled clinical study, or other credible scientific evidence establishes that iron from the Sumalate® in FeRiva 21/7 has "enhanced absorption" or is more completely absorbed by the body relative to the iron in Ferralet, particularly when the therapies are used as directed. Likewise, upon information and belief, no well-controlled clinical study, or other credible scientific evidence establishes that 40% of the iron in FeRiva 21/7 is absorbed by the body, whereas the iron ingredients in Ferralet are less than 20% absorbed. Furthermore, upon information and belief, the iron in FeRiva 21/7 does not have superior absorption compared to the iron in Ferralet and certainly not more than twice as much absorption.

26. Avion's assertion that Feriva 21/7 provides more efficient iron absorption, *i.e.*, higher absorption with less iron intake, than Ferralet is both unsubstantiated and false. It is also misleading. Upon information and belief, no well-controlled clinical study, or other credible scientific evidence establishes that FeRiva 21/7 provides higher iron absorption with less iron intake than Ferralet. Furthermore, upon information and belief, Feriva 21/7 does not provide more "efficient" iron absorption compared to Ferralet and is certainly not two times more efficient than Ferralet. Finally, the "efficiency" of iron absorption from different supplements using different iron ingredients does not have any bearing on the "superiority" of one supplement over another. A benefit of using carbonyl iron as an ingredient in iron supplements is that patients can tolerate much higher doses without adverse effects or toxicity. Because Avion's representations imply that Feriva 21/7 is superior to other iron supplements including Ferralet because it purportedly delivers iron more "efficiently," they are misleading

27. Avion's advertising claims that Feriva 21/7's "scientific dosing" increases absorption and tolerability are both false and unsubstantiated. Avion's assertion that cells in the

intestine (enterocytes) lose their ability to absorb iron and become "blocked" from further iron absorption, necessitating an "iron holiday," is based on a 1960's "mucosal block theory" that is no longer accepted. Upon information and belief, no well-controlled clinical study, or other credible scientific evidence establishes that FeRiva 21/7's "scientific dosing" increases absorption and tolerability, or reduces a patient's experience of side effects relative to Ferralet or any other iron supplement.

28. Avion's assertions that the Vitamin C and succinic acid in FeRiva 21/7 work together in a "push-pull relationship" are false and unsubstantiated. While evidence suggests that ingestion of Vitamin C can increase the absorption of iron from plant-based foods by increasing the solubility of the iron in the intestine, Vitamin C does not physically "push" iron into the small intestine's cells, especially when the body's iron stores in the enterocytes are adequate. Likewise, while succinic acid can also enhance iron absorption, large amounts exceeding that found in FeRiva 21/7 are also required. Upon information and belief, no well-controlled clinical study, or other credible scientific evidence establishes that the Vitamin C in FeRiva 21/7 "pushes" iron into the small intestine's cells, or that the succinic acid in FeRiva 21/7 "pulls" iron out of the small intestine's cells and into the bloodstream.

29. Avion's assertion that "[c]linical studies have demonstrated a 2.4 g increase in hemoglobin within one month of treatment using ferrous chelates including Sumalate," is at a minimum, misleading to its audience. First, Avion fails to identify any "clinical study" which purports to demonstrate a 2.4 g increase in hemoglobin in any patient or group of patients within one month of treatment using Sumalate, much less to any study establishing that such an outcome will result in any or all patients using FeRiva 21/7. Second, supplementation with therapeutic doses of iron will generally increase hemoglobin levels by 0.7-1.0 g/dl per week; an increase in hemoglobin concentration of at least 2 g/dl after three weeks of therapy is generally

used as the criterion for an adequate therapeutic response to iron supplementation. Thus, supplementation with ferrous chelates generally, or Sumalate® in particular, is not required to achieve such an outcome. Because Avion's representations imply that such an outcome is a unique benefit of Sumalate® or FeRiva 21/7 that cannot be realized from other oral iron supplements including Ferralet, they are misleading.

Defendant's False and Misleading Advertising Claims Are Material

30. Efficacy, performance characteristics, mechanisms of action, quality and safety are inherent characteristics of any pharmaceutical product. They are the key factors doctors, nurses and other healthcare practitioners consider when selecting a method of treatment for their patients. Doctors, nurses and other healthcare practitioners also look for well-controlled clinical studies that support the efficacy, performance and quality of pharmaceutical products.

31. Avion's claims concerning the absorption of iron, increase in hemoglobin production and tolerability of FeRiva 21/7, and the availability of scientific data to support these features, are material in that they are likely to affect, and in fact, do affect the decision by physicians, nurses, and other healthcare providers to recommend and prescribe FeRiva 21/7.

Defendant's False and Misleading Advertising is Harming Plaintiff

32. Avion's commercial advertising and promotion have misled its audience into believing that FeRiva 21/7 is more efficacious in delivering iron to the body and increasing hemoglobin production than Ferralet, and that FeRiva 21/7 is better tolerated by patients than Ferralet.

33. The actions of Defendant as detailed above have caused and continue to cause Plaintiff harm. Defendant's false and misleading commercial advertising claims are likely to mislead and deceive physicians and other healthcare providers into prescribing FeRiva 21/7

instead of Ferralet for iron supplementation. Plaintiff has lost and continues to lose sales of Ferralet because physicians and other healthcare providers are prescribing, and patients are using FeRiva 21/7 in place of or instead of Ferralet based on the false and misleading statements of Defendant.

34. Plaintiff's valuable reputation and goodwill have been and will continue to be harmed by Defendant's false and misleading promotion of FeRiva 21/7. Based on Defendant's false and misleading promotion, physicians and other healthcare providers are being led to believe that FeRiva 21/7 is more efficacious in delivering iron to the body than Ferralet, and that FeRiva 21/7 is better tolerated by patients than Ferralet. No basis in fact exists to support such beliefs.

COUNT I

PATENT INFRINGEMENT

35. Upon information and belief, Avion has and will continue to directly infringe, and induce others to infringe, the '247 Patent through Avion's manufacture, sale and distribution without authority of certain nutritional supplements, including FeRivaFA and Prenate Mini.

36. Mission Pharmacal has been damaged by Avion's infringement of the '247 Patent, and its continued sales of FeRivaFA and Prenate Mini has caused monetary damages. The injury to Mission Pharmacal is continuing and irreparable unless enjoined by this Court.

37. Upon information and belief, Avion was aware of the '247 patent and has infringed despite an objectively high likelihood that its actions constitute infringement of a valid patent, thereby infringing willfully.

COUNT TWO

FALSE ADVERTISING – LANHAM ACT § 43(A), 15 U.S.C. § 1125(A)

38. Plaintiff refers to and incorporates herein the allegations of the preceding paragraphs.

39. Defendant Avion markets FeRiva 21/7 to doctors, nurses and other healthcare providers in interstate commerce. Defendant states and implies, and intends for potential customers to believe that FeRiva 21/7 is more efficacious in delivering iron to the body and increasing hemoglobin production than Ferralet, and that FeRiva 21/7 is better tolerated by patients than Ferralet.

40. Defendant's promotional claims about FeRiva 21/7 are literally and/or impliedly false and misleading. No research demonstrates that FeRiva 21/7 is more efficient or efficacious in delivering iron to the body or increasing hemoglobin production than Ferralet, or that FeRiva 21/7 is better tolerated by patients with fewer side effects than Ferralet. No scientific studies compare the absorption of iron in, or the experience of side effects by, patients using FeRiva 21/7 vs. Ferralet. No actual data shows that the iron in FeRiva 21/7 is absorbed at a two-to-eight times greater rate than the iron in Ferralet. Defendant's claims comparing FeRiva 21/7 and Ferralet are unsubstantiated. Moreover, upon information and belief, they are false.

41. Defendant's promotional claims violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that "any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act."

42. By reason of Defendant's conduct, Plaintiff has suffered, and will continue to suffer, damage to its business, reputations, and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiff is entitled to damages for Defendant's Lanham Act violations, an accounting of profits made by Defendant on sales of its products, and recovery of Plaintiff's costs for this action.

43. Defendant's acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiff to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

44. Unless enjoined by this Court, Defendant's acts will irreparably injure Plaintiff's goodwill and erode Plaintiff's market share. Pursuant to 15 U.S.C. § 1116, Plaintiff is entitled to preliminary and permanent injunctive relief to prevent Defendant's continuing acts.

COUNT THREE

UNFAIR COMPETITION – LANHAM ACT § 43(A), 15 U.S.C. § 1125(A)

45. Plaintiff refers to and incorporates herein the allegations of the preceding paragraphs.

46. Mission Pharmacal has become uniquely associated with Ferralet and the public identifies Mission Pharmacal as the source for Ferralet.

47. Avion has marketed and continues to market FeRiva 21/7 as more efficacious in delivering iron to the body and increasing hemoglobin production, and as better tolerated by patients than Ferralet. In doing so, Avion has deceived, misled and confused nurses, physicians and surgeons, and other healthcare providers who recommend and prescribe iron supplementation products for patients. This has enabled Defendant to trade-off of Mission Pharmacal's reputation and good will.

48. Defendant's misleading comparisons of FeRiva 21/7 to Ferralet and omission of relevant facts are likely to cause and have caused confusion, mistake or deception about the

nature, characteristics and qualities of Defendant's misleading comparisons of FeRiva 21/7 to Ferralet and omission of relevant facts are likely to cause and have caused confusion, mistake or deception about the nature, characteristics and qualities of FeRiva 21/7 in comparison, connection or association with Ferralet.

49. Defendant knows, or in the exercise of reasonable discretion should know, that its marketing program deceives physicians and surgeons, nurses, patients and others about the nature, characteristics and qualities of FeRiva 21/7 in comparison, connection or association with Ferralet.

50. Defendant's conduct amounts to deception, trickery and/or unfair methods and has damaged and jeopardized Plaintiff's business. As a result of such malicious, wanton and/or fraudulent conduct, Defendant has caused, and unless enjoined by this Court, will continue to cause, consumer confusion as to the nature, characteristics and qualities of FeRiva 21/7 in comparison, connection or association with Ferralet.

51. Therefore, by its conduct Defendant has violated Section 43(a) of the Lanham Act which provides, "Any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which … is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person " in comparison, connection or association with Ferralet.

52. By reason of Defendant's conduct, Plaintiff has suffered, and will continue to suffer, damage to its business, reputation and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiff

is entitled to damages for Defendant's Lanham Act violations, an accounting of profits made by Defendant on sales of FeRiva 21/7, and recovery of Plaintiff's costs for this action.

53. Avion's acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiff to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

54. Unless enjoined by this Court, Avion's acts will continue to cause immediate and irreparable harm to Plaintiff for which there is no adequate remedy at law. Pursuant to 15 U.S.C. § 1116, Plaintiff is entitled to preliminary and permanent injunctive relief to prevent Avion's acts.

COUNT FOUR

COMMON LAW UNFAIR COMPETITION

55. Plaintiff refers to and incorporates herein the allegations of the preceding paragraphs.

56. With full knowledge of Ferralet, Avion has made false and misleading explicit and implicit representations of fact to physicians, healthcare providers and others that that FeRiva 21/7 is more efficacious in delivering iron to the body and increasing hemoglobin production than Ferralet, and that FeRiva 21/7 is better tolerated by patients than Ferralet. In making these representations, Defendant has deceived, misled and confused physicians, healthcare providers and others. Defendant's selective and misleading comparisons of FeRiva 21/7 with Ferralet, and its omission of relevant facts, are likely to cause confusion, mistake or deception about the nature, characteristics and qualities of FeRiva 21/7 in comparison, connection or association with Ferralet.

57. Defendant knows or in the exercise of reasonable discretion should know, that its marketing program encourages the sale and use of FeRiva 21/7 in place of Ferralet, and the deception of physicians and surgeons, nurses, healthcare providers and others, about the nature,

characteristics and qualities of FeRiva 21/7 in comparison, connection or association with Ferralet.

58. Defendant's actions are willful and have been undertaken with the purpose of deceiving customers.

59. As a result of such conduct, Defendant has caused, and unless enjoined by this Court, will continue to cause, consumer confusion as to the nature, characteristics and qualities of its prescription iron supplements in comparison to Ferralet.

60. Plaintiff is entitled to damages for Defendant's unfair competition, an accounting of profits made on sales of FeRiva 21/7, and recovery of Plaintiff's costs of this action.

61. As a result of Defendant's conduct, Plaintiff has suffered, and unless such acts and practices are enjoined by this Court, will continue to suffer, damage to its business, reputation and goodwill for which it is entitled to relief.

PRAYER FOR RELIEF

Plaintiff Mission Pharmacal respectfully requests the Court enter a judgment awarding Plaintiff the following:

A. A permanent injunction against Avion and others acting in concert with it from engaging in directly, or inducing others to engage in, the commercial manufacture, distribution, use, offer to sell, or sale of supplements as claimed by the '247 patent, including FeRivaFA and Prenate Mini® and all other acts of infringement of the '247 patent, prior to the expiration of that patent;

B. A judgment and order that Avion, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from directly or indirectly falsely advertising or

promoting FeRiva 21/7, alone or in comparison to Ferralet, or inducing others to purchase, prescribe and/or use FeRiva 21/7 as an iron supplement in place of or in lieu of Ferralet;

C. A judgment and order that Avion, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of FeRiva 21/7 in such fashion as to suggest that FeRiva 21/7 is more effective in delivering iron to patients than Ferralet, or is better tolerated by patients, or produces less side effects than Ferralet;

D. A judgment and order that Avion take corrective action to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of FeRiva 21/7, including without limitation the placement of corrective advertising;

E. A judgment and order granting Plaintiff such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics or qualities of FeRiva 21/7, alone or in relationship to Ferralet;

F. A judgment and order requiring Avion to pay Plaintiff actual damages under 35 U.S.C. § 284 but not less than a reasonable royalty;

G. A judgment and order requiring Avion to pay Plaintiff treble damages based on a finding of willful infringement against Avion;

H. A judgment and order requiring Avion to pay Plaintiff damages under 15 U.S.C. § 1117(a) in the amount of Plaintiff's actual and consequential damages resulting from its false and misleading advertisements and marketing, and unfair competition pursuant to 15 U.S.C. § 1117(a), and the common law of the State of Texas;

I. A judgment and order requiring Defendant to pay the costs of this action under 15 U.S.C. § 1117(a);

J. A judgment and order finding that this is an exceptional case and requiring Avion to pay Plaintiff additional damages equal to three times the actual damages awarded Plaintiff pursuant to 15 U.S.C. § 1117(a);

K. The Court enter an order finding that Defendant acted maliciously, wantonly and/or fraudulently, requiring Defendant to pay Plaintiff punitive damages pursuant to the common law of the State of Texas;

L. An accounting be directed to determine Defendant's profits resulting from its illegal activities and such profits be paid over to Plaintiff, increased as the Court finds to be just under the circumstances of this case pursuant to 15 U.S.C. § 1117(a);

M. A judgment and order requiring Defendant to pay Plaintiff prejudgment and post-judgment interest;

N. A judgment and order requiring Defendant to pay Plaintiff's attorneys' fees including those available under 35 U.S.C. § 285, 15 U.S.C. §1117(a) and any other applicable law; and

O. All other relief as the Court may deem appropriate.

JURY DEMAND

Plaintiff Mission Pharmacal demands a trial by jury on all issues.

Dated: June 19, 2015

Respectfully submitted,

By: ***s/Charles B. Walker, Jr.***

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